NUCLEAR REGULATORY COMMISSION ENFORCEMENT MANUAL

U.S. Nuclear Regulatory Commission
Office of Enforcement
Washington, DC 20555-0001

Revision 7
October 1, 2010

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ABSTRACT

The NRC Enforcement Manual (Manual):

- is the primary source of guidance regarding agency policy and procedures for NRC staff implementing the enforcement program
- contains procedures, requirements, and background information that are essential to those who develop or review enforcement actions for the NRC
- provides guidance consistent with the Enforcement Policy

The enforcement program was developed to implement the Enforcement Policy which supports the agency's overall safety and security mission, i.e., to protect the public health and safety and provide for the common defense and security. To emphasize the importance the Commission places on this mission, two major goals of the enforcement program are (1) to emphasize the importance of compliance with regulatory requirements, and (2) to encourage prompt identification and prompt, comprehensive correction of violations.

NOTE:

The guidance provided in this manual has been written to be consistent with the Enforcement Policy. Because it is a policy statement, the Commission may deviate from the Enforcement Policy and its implementing procedures, as appropriate, under the circumstances of a particular case. In such cases, the Administrative Procedure Act (APA) requires that agency decisions have a reasonable basis, and prohibits a decision that is arbitrary or capricious. The Enforcement Policy is revised periodically to reflect current Commission direction. Before deciding on a specific enforcement action for enforcement issues which were identified prior to the effective date of a policy revision, the staff will consider the guidance from both the previous version of the Policy and the revised version, and typically will apply the more lenient of the two policy versions.

The Manual applies to the enforcement activities of the Office of Enforcement (OE), the Regional Offices, the Offices of Nuclear Reactor Regulation (NRR), New Reactors (NRO), Nuclear Material Safety and Safeguards (NMSS), Federal and State Materials and Environmental Management Programs (FSME), Nuclear Security and Incident Response (NSIR), International Programs (OIP), and all other special teams or task forces involved in enforcement activities. It also applies to the enforcement role of the Office of the General Counsel (OGC), with particular emphasis placed on the Associate General Counsel for Hearings, Enforcement, and Administration, and the Assistant General Counsel for Materials Litigation and Enforcement.

Abstract

Most enforcement actions are initiated from the Regional Offices; therefore, this Manual has been structured to reflect that the Regional Offices, for the most part, initiate, recommend, or issue enforcement actions. However, all offices that conduct inspections and determine compliance should follow the guidance in this Manual.

Program offices, such as NRR, NMSS, or NSIR, that take the lead for an enforcement action, assume the responsibilities of both the Program Office and the Regional Office for that action. In such cases, the Program Office should follow the guidance applicable to both the Program Office and the Regional Office.

The Manual is a living document and is maintained on the NRC Enforcement Web site. It can also be found on the NRC's public Web site, www.nrc.gov (Select **Electronic Reading Room**, then **Document Collections**, then "click on" **Enforcement Docs** under "Related Information" select "Enforcement Guidance"). Changes to the Manual are contained in "Change Notices" posted in the Change Notice Index on the Enforcement Web site. Enforcement Policy changes are also documented annually in the NRC Enforcement Program Annual Report.

Questions or comments about this manual should be sent to John R. Wray, Senior Enforcement Specialist, Office of Enforcement at john.wray@nrc.gov.

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Introduction and Overview

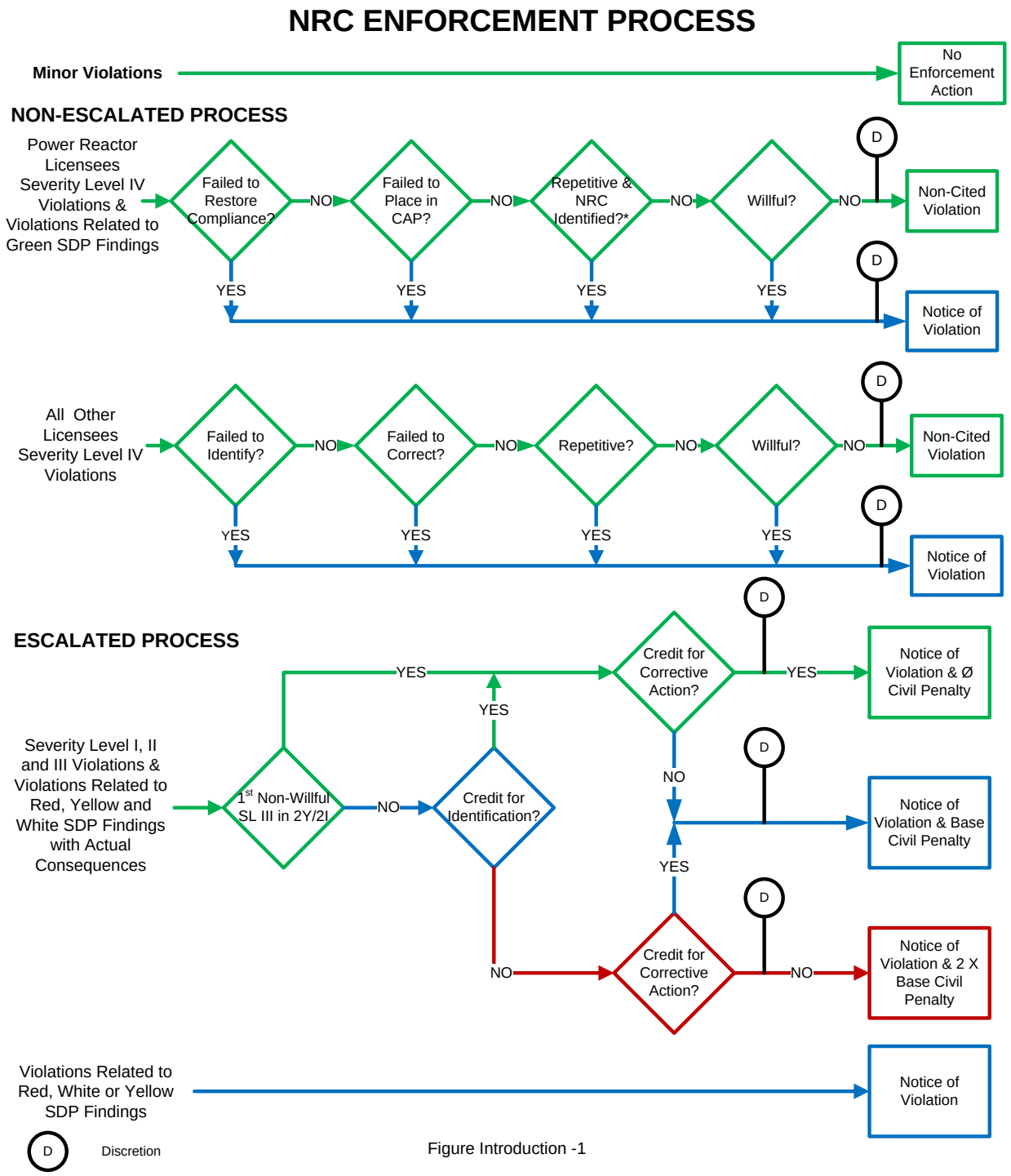

Figure Introduction-1: Represents the NRC's graded approach to dealing with violations.

The Enforcement Process

- The NRC's Enforcement Program uses a graded approach for violations, both in terms of addressing their significance and developing sanctions.

- The NRC assesses the significance of a violation by considering:

  - actual safety consequences;
  - potential safety consequences;
  - potential for impacting the NRC's ability to perform its regulatory function; and,
  - any willful aspects of the violation.

- Violations are assigned a severity level ranging from Severity Level I for the most significant violations to Severity Level IV for those of more than minor concern.

- Issues assessed through the Reactor Oversight Process's (ROP) Significance Determination Process (SDP) are assigned a color, i.e., red, yellow, white or green, based on the risk significance, red being the most significant and green being the least significant.

- Minor violations must be corrected; however, given their limited risk significance, they are not subject to enforcement action and are not normally described in inspection reports.

Overview of the Enforcement Process

Generally, violations are identified through inspections and investigations. All violations are subject to civil enforcement action and some may also be subject to criminal prosecution. When an apparent violation is identified, it is assessed using the guidance in this Manual, in accordance with the Enforcement Policy.

There are three primary enforcement sanctions available: notices of violation, civil penalties, and orders.

- A **Notice of violation** (NOV) is a written notice that concisely identifies an NRC requirement and how it was allegedly violated. The NOV may require a written explanation or statement in reply in accordance with the guidance provided in the Notice (i.e., 10 CFR 2.201 specifies that the licensee or other person submit a written explanation or statement in reply within 20 days of the date of notice or other time specified in the Notice. The staff may allow additional time to respond upon a showing of good cause).

- A **Civil Penalty** is a monetary fine that is used to emphasize compliance in a manner that deters future violations and to focus licensee's attention on significant violations. Accordingly, different levels of penalties are provided in Tables 1 and 2, "Base Civil Penalties," of the Enforcement Policy. Civil penalties are issued under the authority of Section 234 of the Atomic Energy Act (AEA) or Section 206 of the Energy Reorganization Act (ERA). Section 234 of the AEA provides for penalties up to

$100,000 per violation per day. This amount has been adjusted for inflation by the Debt Collection Improvement Act of 1996 and is currently $140,000.

- **Orders** can be used to modify, suspend, or revoke licenses or require specific actions by licensees or other persons. Orders can also be used to impose civil penalties. The Commission's order issuing authority under Section 161 of the AEA is broad and extends to any area of licensed activity that the Commission deems necessary to promote the common defense and security or to protect health or to minimize danger to life or property. In addition, as a result of a 1991 rulemaking, the Commission's regulations now provide that orders may be issued to persons who are not themselves licensed.

Enforcement

After an apparent violation is identified, the next step is to gather information about the apparent violation and, thereafter, to assess its significance. Violations are assigned a severity level that reflects their seriousness and safety significance which, in turn, determines how the violation should be dispositioned. Severity Levels range from Severity Level I, for the most significant violations, to Severity Level IV for those of more than minor concern. Minor violations are below the significance of Severity Level IV violations and are typically not the subject of enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action(s) must be taken to prevent recurrence.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section 2.3.2 of the Enforcement Policy.

For materials licensees, if violations of more than a minor concern are identified by the NRC during an inspection, such violations will be the subject of an NOV and a written response may be required pursuant to 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations can be documented on NRC Form 591 which constitutes an NOV that requires corrective action but does not require a written response.

When escalated enforcement action appears to be warranted (i.e., Severity Level I, II, or III violations, civil penalties or orders), a predecisional enforcement conference (PEC) may be conducted with a licensee before the NRC makes an enforcement decision. A PEC may also be held when the NRC concludes that it is necessary or the licensee requests it. The purpose of the PEC is to obtain information that will assist the NRC in determining the appropriate enforcement action. The decision to hold a PEC does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. If the NRC concludes that a conference is not necessary, it may provide a licensee with an opportunity to respond to the apparent violations in writing or by requesting a PEC before making an enforcement decision.

Civil penalties are normally assessed for Severity Level I and II violations and for NRC-identified violations involving knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act. Civil penalties are considered for Severity Level III violations.

If a civil penalty is to be proposed, a written NOV and proposed imposition of a civil penalty must first be issued. The NOV must advise the person charged with the violation that the civil penalty may be paid in the amount specified, or the proposed imposition of a civil penalty may be contested in whole or in part, by a written response, either denying the violation or showing extenuating circumstances. The NRC will evaluate the response and use that information to determine if the civil penalty should be mitigated, remitted, or imposed by order. Thereafter, the licensee may pay the civil penalty or request a hearing.

Orders may be used to modify, suspend, or revoke licenses. Orders may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. Persons adversely affected by orders that modify, suspend, revoke a license, or that take other action, may request a hearing.

NOTE:

The NRC may issue a press release with a proposed civil penalty, Demand for Information (DFI), or order. All orders and DFIs are published in the *Federal Register*.

In addition to the orders used to modify, suspend, or revoke licenses, the agency may issue a Demand for Information (DFI). A DFI is a significant enforcement action which can be used with other enforcement actions such as an imposition of a civil penalty. As its name implies, a DFI is a request for information from licensees and applicants for a license, vendors and contractors, in order to determine, e.g., whether a license should be granted, suspended, or revoked, or whether further enforcement action is warranted.

The Enforcement Component of the Reactor Oversight Program

The Reactor Oversight Process (ROP) utilizes the results of performance indicators (PIs) and baseline inspection findings to determine the appropriate regulatory action to be taken in response to a licensee's performance. Because there are many aspects of facility operation and maintenance, the NRC inspects utility programs and processes on a risk-informed sampling basis to obtain representative information. The objective is to monitor performance in three broad areas -- reactor safety (avoiding accidents and reducing the consequences of accidents if they occur); radiation safety for both plant workers and the public during routine operations; and protection of the plant against sabotage or other security threats. The ROP has been in effect since April 2000.

Under the ROP, the staff assesses certain inspections findings at nuclear power plants through the Significance Determination Process (SDP). The SDP is a risk-informed framework that was developed to evaluate the actual and potential safety significance of

these findings. Such findings may contribute to potential safety concerns or programmatic weaknesses that do not violate NRC regulations. The SDP provides a basis for discussing and communicating the significance of such findings with the licensee. Some findings are associated with violations of the regulations. The final disposition of the violations associated with findings that have been evaluated through the SDP is contingent on the risk significance attributed to the findings (assigned the colors of green, white, yellow, or red with increasing risk).

The Enforcement Policy has been revised to state that Regulatory Conferences will be conducted in lieu of predecisional enforcement conferences if violations are associated with risk significant findings evaluated through the SDP. The Policy notes that Regulatory Conferences are conducted to discuss the significance of findings evaluated through the SDP with or without associated violations. The focus of these meetings is on the significance of the issues and not necessarily on the correction actions associated with the issue. Because the significance assessment from the SDP determines whether or not escalated enforcement action will be issued, a subsequent predecisional enforcement conference is not normally necessary. In addition, the Enforcement Policy has been modified to clarify that the mitigation discretion addressed in Sections 3.1 - 3.5 (e.g., violations identified during shutdowns, involving past enforcement actions, old design issues, or special circumstances) does not normally apply to violations associated with issues evaluated by the SDP.

Enforcement Actions Involving Individuals

The NRC will normally take an enforcement action against an individual only if the staff is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew or should have known, the required actions; and knowingly or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance.

Actions can be taken directly against individuals either because they are individually licensed or because they violated the rules on deliberate misconduct. Generally, when enforcement action is taken against an individual, enforcement action is taken against a licensee.

Statute of Limitations

The Statute of Limitations is applicable to NRC civil penalty cases (see 28 USC §2462), and requires that the NRC initiate an action imposing a civil penalty, issuing an order to modify, suspend, or revoke a license or an order prohibiting involvement in NRC licensed activity (enforcement sanction) within the 5-year statutory period.

NOTE:

The **Statute of Limitations** is an affirmative defense which can be raised by a person against whom such a sanction is proposed.

The Statute of Limitations does not prevent the staff from issuing an NOV (without a civil penalty or other sanction) even if the underlying violation occurred more than five years earlier, or from issuing an order requiring an action needed to ensure compliance with existing requirements regarding protection of the public health and safety, promoting the common defense and security, or protecting the environment.

CHAPTER 1
RESPONSIBILITIES AND AUTHORITIES

Chapter 1 provides information regarding:

- the delegation and re-delegation of responsibilities and authorities for enforcement activities as implemented in the Enforcement Policy and in Volume 9 of the NRC Management Directives (MDs)

- information regarding the requirements for Commission notification and consultation

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1. Responsibilities and Authorities

1.1 Executive Director for Operations (EDO)

A. The Executive Director for Operations (EDO) is the chief operating and administrative officer of the Commission. Except as otherwise provided by law, regulation, Commission action, or action by the Chairman, the EDO reports to and is supervised by the Chairman as provided in MD 9.17, "Organization and Functions, Office of the Executive Director for Operations."

B. The EDO, through the Chairman, ensures that the Commission is fully and currently informed about matters within its function.

C. The EDO is responsible for the following activities which may involve the agency's enforcement program:

1. Supervising, directing, coordinating, and approving the activities of the offices reporting to the EDO and Deputy Executive Directors (DEDOs);

2. Developing and promulgating rules (as defined in the Administrative Procedures Act and subject to the limitation set out in paragraphs 038, 039, and 0310 of MD 9.17);

3. Developing and approving delegations of authority for offices reporting to the EDO and DEDOs;

4. Exercising the Commission's authority to take enforcement or other action under 10 CFR Part 2, Subpart B; and

5. Issuing subpoenas under Section 161c of the Atomic Energy Act of 1954, as amended, where necessary or appropriate for the conduct of inspections or investigations.

D. Limitations placed on the authority of the EDO require that the EDO present all significant questions of policy to the Commission for resolution, and with respect to these questions, present all major views of the affected offices to the Commission (see the discussion below regarding Commission notification).

1.2 Deputy Executive Directors for Operations (DEDOs)

1.2.1 Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs (DEDMRT)

A. The DEDMRT carries out day-to-day supervision, guidance, and direction of the Offices of Nuclear Materials, Safety, and Safeguards (NMSS), Federal and State Materials and Environmental Management Programs (FSME), Research (RES), OE, and the Office of Investigations (OI).

NOTE:

The title "Deputy Executive Director" and acronym "DEDO" refer to either the DEDR or DEDMRT, as appropriate.

B. The DEDMRT provides oversight across agency lines of authority for all NRC policies and activities related to materials and waste safety.

C. The DEDMRT is responsible to the EDO for the NRC enforcement program and is authorized to approve or issue:

1. All escalated enforcement actions including orders and civil penalties pursuant to 10 CFR Part 2, Subpart B; and

2. Actions involving individuals, including licensed operators.

D. The DEDMRT is authorized to act, when delegated, in the stead of the EDO or DEDR during the EDO's or DEDR's absence and take action as necessary to perform the EDO's or DEDR's duties.

1.2.2 Deputy Executive Directors for Reactor and Preparedness Programs (DEDR)

A. The DEDR is responsible for carrying out day-to-day supervision, guidance, and direction of the Offices of NRR, NSIR and the agency's regional offices.

B. The DEDR provides oversight across agency lines of authority for all NRC policies and activities related to reactor safety and homeland protection and preparedness and has responsibility for matters dealing with the homeland security aspects of physical and personnel security, information security, information technology security, safeguards, emergency response, and threat and vulnerability assessment.

C. The DEDR is authorized to act, when delegated, in the stead of the EDO or the Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs (DEDMRT) during the EDO's or DEDMRT's absence and take action as necessary to perform the EDO's or DEDMRT's duties.

1.3 Office of Enforcement (OE)

A. In accordance with Management Directive (MD) 9.19, "Organization and Functions, Office of Enforcement," OE has delegated authority to:

1. Exercise oversight of NRC enforcement programs, including the Enforcement ADR program as described in Chapter 6;

2. Provide programmatic and implementation direction to the offices in the regions and in OE Headquarters (headquarters) that are conducting or involved in enforcement activities; and

3. Ensure that regional enforcement programs are adequately carried out.

1.3.1 Delegation of Authority to the Director, OE

A. In accordance with MD 9.19, the Director of OE is authorized to:

1. Prepare and issue enforcement actions including notices of deviations, notices of violation (NOVs), proposed impositions of civil penalties, orders, and settlement agreements, in the DEDO's absence or under the DEDO's direction;

2. Manage major enforcement actions (civil penalties, orders, and significant NOVs);

3. Approve or direct enforcement action to be taken by offices in the regions or headquarters in the DEDO's absence or under the DEDO's direction;

4. Prepare letters requesting investigations, confirming actions, or obtaining information under sections 161(c) or 182 of the Atomic Energy Act;

5. Prepare subpoenas for alleged violations of regulatory requirements, and issue those actions in the DEDO's absence or under the DEDO's direction;

6. Take necessary or appropriate action in accordance with the decision of an Administrative Law Judge, an Atomic Safety and Licensing Board, or the Commission after enforcement hearings pursuant to 10 CFR Part 2;

7. Approve, after consultation with the DEDO as warranted, the decision to disposition a willful violation as a non-cited violation (NCV);

8. Recommend to the EDO, through the DEDO, changes to rules and policies for Commission consideration concerning enforcement matters; and

9. Provide guidance and training on implementation of the Commission's Enforcement Program.

B. In accordance with the January 17, 2008, Delegation of Authority for Enforcement Actions (ML080100183) issued by the DEDO, the Director, Office of Enforcement (OE), is delegated the authority to approve, sign, and issue all enforcement actions. This delegation supersedes all previous delegations of authority to the Director, OE, regarding enforcement actions.

1. This authority includes, but is not limited to:

a. notices of violation (including those associated with inspection findings characterized as Green, White, or Yellow pursuant to the Significance Determination Process),

b. civil penalties,

c. orders (including confirmatory orders and immediately effective orders),

d. settlement agreements, and

e. enforcement actions involving individuals.

2. The Director, OE, is also authorized to take the following actions:

a. Exercise oversight of NRC enforcement programs.

b. Provide programmatic and implementation direction to the offices in the regions and in headquarters conducting enforcement activities.

c. Ensure that regional enforcement programs are adequately carried out.

d. Prepare letters requesting investigations, confirming actions, or obtaining information under sections 161(c) or 182 of the Atomic Energy Act of 1954, as amended (AEA).

e. Prepare subpoenas to licensees, companies, individuals, or other persons to obtain information to assist the Commission in the administration and enforcement of the AEA.

f. Take necessary or appropriate action in accordance with the decision of an Administrative Law Judge, the Atomic Safety and Licensing Board, or the Commission after enforcement hearings pursuant to Title 10 of the *Code of Federal Regulations* Part 2.

g. Recommend to the Executive Director for Operations, through the DEDO, changes to rules and policies for Commission consideration concerning enforcement matters.

h. Provide guidance and training on implementation of the Commission's Enforcement Program.

i. Review proposals to mitigate penalties.

C. The authority delegated to the Director, OE is subject to the following limitations:

1. The Director, OE, may not approve, sign, or issue enforcement actions that are categorized at Severity Level I or those associated with inspection findings characterized as Red pursuant to the Significance Determination Process.

2. The authority hereby delegated to the Director, OE, does not apply to cases where the Director, OE, the Director of the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, Federal and State Materials and Environmental Management Programs, New Reactors, or a Regional Administrator is in disagreement on a proposed course of action.

3. The Director, OE, shall consult with the Deputy Executive Director for Operations (DEDO) in any case involving novel issues, or substantial legal, programmatic, or policy issues raised during the review process.

D. The Director, OE, shall notify or consult with the Commission consistent with the Enforcement Policy. Notification will typically be provided by the Enforcement Notification (EN) process. Consultation will involve additional communication prior to the EN on a case by case basis.

1.3.2 Re-delegation of Authority by the Director, OE

A. The authority delegated to the Director, OE, may be re-delegated subject to the written approval of the DEDO. Such re-delegations must be made in writing and a copy filed with the Secretary of the Commission, the General Counsel, the Director, Office of Human Resources, and the Director, Office of Administration. This authority is subject to the following limitations:

1. The Director, OE, cannot delegate the authority to approve, sign, or issue immediately effective orders.

2. The Director, OE, cannot re-delegate the authority to approve, sign, or issue civil penalties to individuals licensed pursuant to 10 CFR Part 55.

1.3.3 Deputy Director, OE

A. The Deputy Director, OE:

1. Assists the Director in overseeing, managing, and directing the development of enforcement policies and programs, and in issuing enforcement actions;

2. Notifies the Office of the Secretary (SECY) when an enforcement hearing extension request is granted; and

3. Acts for the Director, OE, in the Director's absence, in accordance with the re-delegation of authority specified in section 1.3.2 above.

1.3.4 Chief, Enforcement Branch

A. As directed by the Director of OE, the Branch Chief of OE:

1. Assists the Director, OE, in developing and implementing enforcement policies and programs, and in issuing enforcement actions;

2. Acts for the Director, OE, in the Director and Deputy Director's absence. Acts for the Deputy Director, OE, in the Deputy Director's absence, in accordance with the re-delegation of authority specified in section 1.3.2 above;

3. Supervises the OE enforcement staff in the execution of its responsibilities;

4. Is authorized by the Director, OE, to review and concur on the following enforcement actions, after consultation with the Director or Deputy Director, OE, as appropriate:

   - Rulemakings initiated by other Program Offices
   - Commission papers with enforcement considerations from other offices
   - Licensee correspondence with enforcement considerations generated by other offices
   - Generic communications
   - Technical Interface Agreements (TIAs) and Technical Assistance Requests (TARs) with enforcement considerations
   - Actions utilizing enforcement discretion involving Severity Level III violations/white SDP findings and below
   - Actions utilizing enforcement discretion involving NFPA 805
   - NOVs involving Severity Level III violations and below
   - NOVs involving Severity Level III violations with a civil penalty that is no greater than 1 times the base penalty
   - Safety Orders
   - Enforcement Notifications (ENs)
   - Office Input to the Congressional Report on the Enforcement Program
   - OE Web Summaries
   - Acknowledgment letters for civil penalties
   - Close-out letters to individuals

5. Assigns and reviews quarterly audits of the enforcement program; and
6. Reviews and approves SDP/EA Request & Strategy Forms (Strategy Forms).

1.3.5 OE Staff

A. As directed by the Director of OE, the OE staff:

1. Assists the Director, OE, in developing and implementing the enforcement program and Enforcement Policy;

2. Participates in enforcement panels and Significance Determination Process/Enforcement Review Panels (SERPs) whenever practical and as directed by the Director, OE, to provide enforcement perspectives;

3. Assigns enforcement action (EA) and individual action (IA) numbers to proposed enforcement actions as appropriate and prepares and maintains Strategy Forms. Strategy forms are submitted to the Chief, EPPO, OE, within five working days of the panel;

4. Provides periodic reports to the Commission regarding cases that may challenge the Statute of Limitations;

NOTE:

The Statute of Limitations applicable to NRC civil penalty cases and orders imposing sanctions requires that the NRC initiate these actions within five years of the date of the violation.

5. Assigns EA numbers to all findings addressed in a SERP/enforcement panel, irrespective of whether a potential violation is involved (in order to allow the agency to keep track of SDP issues);

6. Reviews the enforcement strategy for proposed escalated enforcement actions to ensure technical adequacy and conformance to established policy, guidance, and precedent;

7. Participates in predecisional enforcement conferences and regulatory conferences whenever practical and as directed by the Director, OE, to provide enforcement perspectives;

8. Participates enforcement and SERP caucuses whenever practical and as directed by the Director, OE, to provide enforcement perspectives;

9. Notifies the Offices of Public Affairs (OPA), Federal and State Materials and Environmental Management Programs (FSME), and Congressional Affairs (OCA), of enforcement actions that may impact their offices' interests;

10. Prepares Enforcement Notifications (ENs) for Severity Level I and II cases, NOVs, and other enforcement activities of particular interest, e.g., specific civil penalty actions, orders, and other enforcement actions.

11. Prepares Regulatory Notifications (RNs) for significant regulatory actions, such as a Final Significance Determination for a white, yellow, or red finding (that does not include an NOV) or an order that requires additional safety or security measures beyond the regulatory framework (versus an order based on compliance issues, e.g., 2002 security orders);

12. Reviews press releases when OPA determines that one is needed;

a). Press releases that are issued to announce predecisional enforcement or regulatory conferences that are open for public observation, should:

1). be carefully worded so as not to prejudge the outcome; and

2). include an explicit description of the nature of the conference as a predecisional opportunity for the licensee to present any additional material information before the NRC arrives at a decision.

13. Coordinates the development of and reviews press releases for significant enforcement issues, such as revisions to the Enforcement Policy;

14. Reviews substantiated OI reports and coordinates with the region, OGC, and the applicable program office to determine whether enforcement action is appropriate;

15. Responds to “3-week email” regarding unsubstantiated OI reports;

16. Assists the Director, OE, in preparing letters requesting investigations, confirming actions, or obtaining information under sections 161(c) or 182 of the Atomic Energy Act, and in preparing subpoenas with respect to alleged violations of regulatory requirements;

17. Evaluates the enforcement program as carried out by the regional offices;

18. Participates in regularly scheduled conference calls with the Regional Enforcement Coordinators and the Program Office Enforcement Coordinators to discuss enforcement issues and cases;

19. Maintains and revises the Enforcement Policy and the NRC Enforcement Manual, as directed by the Director, OE;

20. Maintains the Enforcement Action Tracking System (EATS) and Individual Action Tracking System (IATS);

21. Maintains enforcement-related information on the NRC’s internal and external Web sites;

22. Prepares an annual report for the enforcement program;

23. Develops and provides training on the enforcement program;

24. Serves as petition manager for 10 CFR 2.206 petitions assigned to OE;

25. Coordinates with the Occupational Safety and Health Administration (OSHA) on the resolution of enforcement issues involving both the NRC and OSHA at NRC facilities;

26. Reviews documents generated by other Program Offices such as rulemakings, generic communications, TIAs related to enforcement, and 2.206 Director Decisions;

27. Prepares Enforcement Guidance Memoranda (EGMs) addressing emergent enforcement issues;

28. Prepares input to the Congressional Report addressing enforcement activities associated with the regulation of nuclear power plants, as required; and

29. Prepares semi-annual audits of materials non-escalated enforcement trends.

1.4 Regional Offices

The regional offices are responsible for implementing the enforcement program subject to the overall policy, program, and implementation guidance of OE.

1.4.1 Responsibilities of Regional Offices

A. In general, the regional offices:

1. Prepare and issue non-escalated enforcement actions;

2. Schedule and conduct enforcement and SERP panels, predecisional enforcement and regulatory conferences, and enforcement and SERP caucuses;

3. Prepare and issue escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required;

NOTE:

The regional offices are normally responsible for enforcement activities associated with on-site contractors.

4. Implement the ADR program as described in Chapter 6;

5. Evaluate licensees' responses to enforcement actions and prepare appropriate responses;

6. Track the status of enforcement actions;

7. Conduct regional staff training;

8. Issue regional enforcement procedures, and

9. Audit regional enforcement actions.

1.4.2 Delegation of Authority to the Regional Administrators

A. In accordance with the responsibility for supervising and directing the enforcement functions of the region, subject to the overall policy, program, and implementation guidance of OE, Regional Administrators are authorized to:

1. Approve, sign, and issue non-escalated enforcement actions.

2. Recommend all escalated enforcement actions to headquarters either**:** (1) through consultation (usually via an enforcement or SERP panel) or (2) by submitting the actual enforcement action package for review and approval.

3. Sign and issue escalated enforcement actions after either;

   a). Consultation with OE (usually via a panel or caucus),

   b). Actual enforcement action package review and approval by the Director, OE (and the DEDO and Commission, as appropriate), or

   c). In accordance with the ADR program responsibilities described in Chapter 6.4.6.1.b.

4. Sign and issue enforcement actions or letters exercising discretion in accordance with the Enforcement Policy, after consultation with OE, (and the DEDO, when required).

5. Review licensees' responses to proposed escalated enforcement actions and recommend appropriate action to the Director, OE.

6. Conduct enforcement and SERP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SERP caucuses.

7. Contact the Director, OE, as soon as possible, and generally no later than 24 hours after receiving the Strategy Form, if the Regional Administrator disagrees with an enforcement strategy (or SDP conclusion) arrived at during a SERP or enforcement panel or caucus.

8. Notify OE when an enforcement action involves significant disagreement within the region, including disagreement by the Regional Counsel.

9. Ensure that Regional Counsel, as appropriate, reviews and provides legal advice on all regional escalated enforcement action recommendations submitted to headquarters for review and approval.

10. Review OI reports promptly and notify OE whenever an OI Field Director concludes**,** during or after an investigation**,** that willfulness is involved (even if a report has not yet been issued).

11. Make recommendations to OE for enforcement action, including immediate action, when warranted.

12. Review all OI reports to determine if OI documents violations (willful or nonwillful) that are not identified as such.

13. Ensure that appropriate training and instructions are provided to regional staff to implement the enforcement program, including the use of NRC Form 591s.

14. Ensure that region-based enforcement actions, including NRC Form 591s, are periodically audited.

15. Provide copies of regional instructions and procedures to OE.

16. Ensure, for cases in which the regional licensing staff receives notice of a licensee bankruptcy action, that the regional enforcement staff determines whether any outstanding civil penalties exist and if so, promptly notifies the Director, OE, so that an appropriate claim can be filed to preserve the NRC's interest.

17. Ensure that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE.

18. Ensure that copies of TIAs that involve potential violations are sent to the Director, OE, and transmitted electronically via email to “OEMail.Resource.”

19. Review escalated enforcement actions prior to submitting them for headquarters’ review.
20. Recommend to the Director, OE, as appropriate, changes to the Enforcement Policy or guidance within this Manual.

1.4.3 Re-delegation of Authority by the Regional Administrator

A. The Regional Administrator may re-delegate his/her authority according to the following guidelines:

1. To the Deputy Regional Administrator, the authority to issue;

   a). NOVs including Severity Level III violations that do not include civil penalties, and

   b). NOVs associated with white and yellow SDP findings.

2. To Division Directors and above, the authority to sign and issue;

   a). Confirmatory Action Letters (CALs), and

   b). Cases where discretion is exercised for matters that would otherwise be Severity Level IV violations.

Note:

Division Directors and above should consult with OE by telephone or by email to "OEMail.Resource" prior to exercising discretion for matters that would otherwise be Severity Level IV violations, and document rationale in a strategy form. These actions require EA numbers.

3. To Branch Chiefs and above, the authority to issue non-escalated enforcement actions.

4. To regional management, the authority to conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses. This authority should generally not be delegated to individuals below a Deputy Division Director.

5. To qualified inspectors, the authority to issue NRC Form 591s, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

1.4.4 Regional Counsel

A. As directed by the Regional Administrator, the Regional Counsel

1. Reviews and provides legal advice on all regional escalated enforcement action recommendations, prior to being submitted to headquarters for review and approval, as appropriate and

2. Reviews other enforcement actions, as requested.

1.4.5 Regional Enforcement Coordinators

A. As directed by the Regional Administrator, the Regional Enforcement Coordinators

1. Prepare or review all escalated enforcement actions prepared by the regional staff to ensure technical adequacy and conformance to established policy, guidance, and precedents.

2. Prepare an enforcement or SERP or Panel Worksheet (Panel Worksheet) (forms are included in Appendix D) for all proposed enforcement issues and for all operating reactor findings (even those without associated violations) that will be discussed during an enforcement or SERP panel.

3. Provide the Panel Worksheet electronically via email to "OEMail.Resource" at least 72 hours prior to the scheduled panel.

4. Compile supporting documents for issues to be addressed in enforcement and SERP panels.

5. Serve as point of contact for regional reviews, comments, and concurrence for subsequent changes or revisions made to enforcement actions and final SDP letters submitted to headquarters for review and approval.

6. Ensure that all enforcement actions issued by the region that were the subject of an enforcement or SERP panel are subsequently transmitted electronically via email to "OEMail.Resource".

7. Review all OI reports and coordinate with regional and headquarters staff to determine whether enforcement action is appropriate.

8. Prepare a "3-week email" within 60 days week of receiving an unsubstantiated OI report.

   a). Indicating that either;

      1). No enforcement action is being considered, or

      2). That although a violation appears to be present, willfulness is not involved.

   b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator.

   c). Inviting a response to the proposal that barring a different view;

      1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed, or

      2). The non-willful violation will be treated in accordance with normal enforcement processes.

9. Prepare draft Commission papers for escalated enforcement actions requiring Commission consultation, or review those prepared by the regional staff.

10. Track the progress of all escalated enforcement actions and final SDP letters being prepared in preparation in the region.

11. Provide a monthly report to OE on the number of materials non-escalated enforcement actions.

12. Provide a monthly report (by the 5th of every month to provide timely input for Congressional Report) to OE on the number of escalated and non-escalated reactor enforcement actions.

13. Strive to achieve timely actions.

14. Maintain necessary records and statistics on enforcement actions taken by the region.

15. Monitor, audit, and assist in processing non-escalated enforcement actions to ensure that they are consistent with the Enforcement Policy, other guidance, and precedents.

16. Ensure that disputed minor violations, Severity Level IV violations, or violations associated with green SDP findings (irrespective of whether they were dispositioned as NCVs or in NOVs) are coordinated with OE.

17. Attend enforcement and SERP panels, predecisional enforcement conferences, regulatory conferences, and SERP and enforcement caucuses, as appropriate.

18. Participate in regularly scheduled conference calls with OE to discuss enforcement issues and cases.

19. Train regional personnel in enforcement matters.

20. Revise regional enforcement procedures, as appropriate.

21. Inform Regional Public Affairs Officer (RPAO) at least 72 hours prior to issuance of an enforcement action involving a proposed civil penalty or an escalated NOV associated with a red, yellow, or white SDP finding.

22. Review press releases for enforcement actions and activities to ensure that they conform to the guidance in this Manual.

1.4.6 Regional Division Directors

A. Regional Division Directors are responsible to the Regional Administrator for recommending escalated enforcement actions. Recommendations should include;

1. An evaluation of the significance of the violation,

2. Whether a civil penalty or order should be proposed, and

3. Whether mitigation or escalation of the civil penalty is appropriate.

1.4.7 Resident and Region-Based Inspectors

A. As directed by regional management, resident and region-based inspectors;

1. Identify violations of regulatory requirements and recommend enforcement action,

2. Appropriately document findings and enforcement action,

3. Recommend to appropriate regional management the severity level of an apparent violation and provide information that bears on the mitigation or escalation of a civil penalty, if proposed,

4. Sign and issue NRC Form 591s for Severity Level IV violations and Non-Cited Violations (NCVs), if qualified and authorized to do so and subject to the review and approval requirements specified in the appropriate inspection manual chapter,

5. Review responses to NOVs submitted by licensees to determine whether corrective actions are adequate,

6. Prepare or provide input to evaluations of licensees' responses to proposed civil penalties and orders, as appropriate, for submission to regional management, and

7. Attend enforcement and SERP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SERP caucuses, as appropriate.

1.4.8 Senior Reactor Analysts

As directed by regional management, senior reactor analysts support NRC objectives related to improving the utilization of risk insights in the reactor inspection and enforcement programs.

1.5 Office of the General Counsel (OGC)

In accordance with NRC MD 9.7, "Organization and Functions, Office of the General Counsel," the General Counsel supervises and directs the performance of all legal and administrative functions necessary to carry out the assigned responsibilities of the Office of the General Counsel.

1.5.1 Associate General Counsel for Hearings, Enforcement, and Administration

A. In accordance with MD 9.7, the Associate General Counsel for Hearings, Enforcement, and Administration;

1. Reviews and provides legal advice on all matters to be referred to the EDO, e.g., enforcement actions involving OI findings and enforcement-related orders, and

2. Reviews and provides legal advice on all matters to be referred to the Commission, e.g., enforcement-related Commission papers.

1.5.2 Assistant General Counsel for Materials Litigation and Enforcement

A. In accordance with MD 9.7, and as directed by the Associate General Counsel for Hearings, Enforcement, and Administration, the Assistant General Counsel for Materials

Litigation and Enforcement serves as the principal OGC contact for all enforcement matters. As such, the Assistant General Counsel;

1. Provides legal advice concerning NRC inspection and enforcement activities, including;

   a). Civil penalties, and

   b). Orders.

2. Provides review and statement of no legal objection for complex and novel cases and enforcement-related OI matters, when requested by OE.

3. Provides OGC review and statement of no legal objection on all orders as well as enforcement actions included in Commission papers.

4. Represents the staff in NRC adjudicatory hearings on enforcement actions.

1.6 Office of Federal and State Materials and Environmental Management Programs (FSME)

The Office of Federal and State Materials and Environmental Management Programs develops, implements and oversees the regulatory framework for industrial, commercial, and medical uses of radioactive materials, uranium recovery activities and the decommissioning of previously operating nuclear facilities and power plants. In addition, FSME, including the Regional State Liaison Officer, work in conjunction with the regional and program offices as well as the Agreement State within which the NRC plans to take enforcement action, to ensure proper transmittal of the NRC's actions to individuals licensed by the State and enforcement actions issued to Agreement State Licensees.

1.6.1 Delegation of Authority to the Director, FSME

A. In accordance with the delegation of authority from the Director, OE, dated May 7, 2008,(ML080850267) the Director of the Office of Federal and State Materials and Environmental Management Programs (FSME), is delegated authority to approve, sign, and issue certain enforcement actions. This delegation applies to enforcement actions in all areas in which FSME evaluates, directly manages, or conducts inspections. If there is overlap between regional and FSME inspection authority, and a dispute arises regarding which office should issue the enforcement action, the Office of Enforcement (OE) should be consulted. The Director of FSME is authorized to take the following actions:

   1. Approve, sign, and issue non-escalated enforcement actions to licensees, and, after consultation with OE, sign and issue non-escalated enforcement actions or letters to non-licensees.

   2. Sign and issue Confirmatory Action Letters.

3. Sign and issue non-enforcement related Orders and non-enforcement related Demands for Information to licensees.

4. Conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

5. Review disputed enforcement actions and coordinate responses with OE.

B. The Commission's regulations, the Enforcement Policy, the NRC Enforcement Manual, Enforcement Guidance Memoranda, and other guidance from OE shall be followed in conducting enforcement activities under this delegation.

1.6.2 Re-delegation of Authority by the Director, FSME

A. The Director of FSME may re-delegate this authority subject to the following limitations:

1. The Director may re-delegate authority to sign and issue non-escalated enforcement actions to branch chiefs and above and may re-delegate the authority to issue non-escalated enforcement actions on NRC Form 591, "Safety Inspection Report and Compliance Inspection," to qualified inspectors, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

2. The Director may re-delegate the authority to conduct predecisional enforcement conferences. However, this delegation should not normally be given to individuals below the level of Deputy Division Director.

3. Any other re-delegations of authority delegated herein must be approved by the Director, OE.

1.6.3 FSME Enforcement Coordinator

A. As directed by Director of FSME, the FSME Enforcement Coordinator

1. Serves as the principal FSME contact for enforcement matters involving 10 CFR Part 30, 36 and 39-40 licensees.

2. Participates in the weekly regional enforcement panels considering all 10 CFR Part 30, 36 and 39-40 licensee cases.

3. Leads the FSME review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies the Director, FSME, especially in cases where the Enforcement Coordinator disagrees with the strategy.

4. Obtains necessary technical support from other FSME divisions to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions.

5. Participates in predecisional enforcement conferences with enforcement implications, when the issues warrant.

6. Consolidates FSME views on the enforcement strategy for proposed escalated actions and forwards FSME comments (verbally, electronically, or in writing) to the Director or Deputy Director, OE, for enforcement actions.

7. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) involving vendors are coordinated with OE.

8. When applicable, reviews all applicable OI reports to identify immediate safety issues, coordinates with appropriate FSME staff, and provides FSME's perspective in determining appropriate enforcement action.

9. When applicable, prepares a "3-week email" within 60 days of receiving an OI report:

   a). Indicating that either:

      1). No enforcement action is being considered; or

      2). That although a violation appears to be present, willfulness is not involved;

   b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator; and

   c). Inviting a response to the proposal that barring a different view:

      1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed; or

      2). The non-willful violation will be treated in accordance with normal enforcement processes.

10. Participates in regularly scheduled conference calls with OE, the regions, and the other Program Office Enforcement Coordinators to discuss enforcement issues and cases.

1.6.4 Other FSME Staff and Management Support

A. In accordance with the delegations of authority for areas in which FSME evaluates, directly manages, or conducts inspections the FSME staff.

   1. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedent,

   2. Identifies violations of regulatory requirements and recommends enforcement action,

3. Appropriately documents enforcement actions,

4. Issues non-escalated enforcement actions, including notices of nonconformance, NOVs, and NCVs,

5. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed,

6. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses,

7. Prepares a Panel Worksheet and compiles supporting information for enforcement panels,

8. Requests EA numbers for all contemplated escalated enforcement actions,

9. Submits all escalated enforcement actions to OE for review and approval,

10. Reviews vendor responses to enforcement actions to determine whether corrective actions are adequate,

11. Reviews OI reports and makes recommendations to OE for enforcement actions including immediate action, when warranted.

B. As directed by the Director, FSME, FSME staff and management personnel support enforcement activities initiated by the regions, as follows;

1. Division of Materials Safety & State Agreements provides oversight and representatives as necessary to support enforcement panels,

2. Appropriate project, technical, and management personnel should:

a). Participate in enforcement caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions

b). Participate in enforcement panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions; and

c). Attend predecisional enforcement conferences.

3. Project, technical, and management personnel will:

a). Review applicable OI reports to identify immediate safety issues and provide FSME's perspective in determining appropriate enforcement action; and

b). Coordinate with OE on TIAs that have the potential for enforcement implications.

1.7 Office of New Reactors (NRO)

The Office of New Reactors is responsible for accomplishing key components of the NRC's reactor safety mission for new reactor facilities licensed in accordance with 10 CFR Part 52. As such, NRO is responsible for regulatory activities in the primary program areas of siting, licensing and oversight for new commercial nuclear power reactors, to protect the public health, safety, and the environment and to promote the common defense and security. NRO works with the regions and other offices to accomplish the agency mission.

1.7.1 Delegation of Authority to the Director, NRO

A. In accordance with the delegation from the Director, OE, dated April 24, 2008, (ML080940176) the Director of the Office of New Reactors (NRO) is delegated authority to approve, sign, and issue certain enforcement actions. This delegation applies to enforcement actions in all areas in which NRO evaluates, directly manages, or conducts inspections. If there is overlap between regional and NRO inspection authority, and a dispute arises regarding which office should issue the enforcement action, the Office of Enforcement (OE) should be consulted. The Director of NRO is authorized to take the following actions:

1. Approve, sign, and issue non-escalated enforcement actions to licensees, applicants, and vendors, and, after consultation with OE, sign and issue enforcement actions or letters to non-licensees (other than vendors).

2. Sign and issue Confirmatory Action Letters (CAL).

3. Sign and issue Orders or Demands for Information (DFIs) to licensees and applicants, on safety and security matters not related to specific violations of NRC requirements.

4. Conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

5. Review disputed enforcement actions and coordinate responses with OE.

6. The Deputy Director of NRO is authorized to exercise the authority delegated herein during the absence of the Director.

B. The Commission's regulations, the Enforcement Policy, the NRC Enforcement Manual, Enforcement Guidance Memoranda, and other guidance from OE shall be followed in conducting enforcement activities under this delegation.

1.7.2 Re-delegation of Authority by the Director, NRO

A. The Director of NRO may re-delegate this authority subject to the following limitations:

1. The Director may re-delegate the authority to approve, sign, and issue non-escalated enforcement actions to licensees, applicants, and vendors, and, after consultation with OE, sign and issue enforcement actions or letters to non-licensees (other than vendors). However, this delegation should not normally be given to individuals below the level of Branch Chief.

2. The Director may re-delegate the authority to conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses. However, this delegation should not normally be given to individuals below the level of Deputy Division Director.

3. Any other redelegations of authority delegated herein must be approved by the Director, OE.

1.7.3 NRO Enforcement Coordinator

A. As directed by the Director of NRO, the NRO Enforcement Coordinator:

1. Serves as the principal NRO contact for enforcement matters involving 10 CFR Part 52 licensees;

2. Participates in the weekly regional enforcement panels considering all10 CFR Part 52 licensee cases;

3. Leads the NRO review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies the Deputy Director for the Division of Construction and Inspection Programs of the enforcement strategy, especially in cases where the Enforcement Coordinator disagrees with the strategy;

4. Obtains necessary technical support from other NRO divisions to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that reactor construction safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions;

5. Participates in pre-decisional enforcement conferences with enforcement implications, when the issues warrant;

6. Consolidates NRO views on the enforcement strategy for proposed escalated actions and forwards NRO comments (verbally, electronically, or in writing) to the Director or Deputy Director, OE, for enforcement actions submitted to headquarters;

7. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) involving vendors are coordinated with OE;

8. Reviews all applicable OI reports to identify immediate safety issues, coordinates with appropriate NRO staff, and provides NRO's perspective in determining appropriate enforcement action; and

9. Assists the Regional Office with any received OI report:

   a). Providing support to help determine whether:

      1). No enforcement action should be considered; or

      2). That although a violation appears to be present, willfulness does not appear involved;

   b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator; and

   c). Inviting a response to the proposal that barring a different view:

      1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed; or

      2). The non-willful violation will be treated in accordance with normal enforcement processes.

10. Participates in regularly scheduled conference calls with OE, the regions, and the other Program Office Enforcement Coordinators to discuss enforcement issues and cases.

1.7.4 NRO Staff

A. In accordance with the delegations of authority for areas in which NRO evaluates, directly manages, or conducts inspections (e.g., vendors) the NRO staff:

1. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedent;

2. Identifies violations of regulatory requirements and recommends enforcement action;

3. Appropriately documents enforcement actions;

4. Issues non-escalated enforcement actions, including notices of nonconformance, NOVs, and NCVs;

5. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed;

6. Conducts enforcement panels, pre-decisional enforcement conferences, and enforcement caucuses;

7. Prepares a Panel Worksheet and compiles supporting information for enforcement panels;

8. Requests EA numbers for all contemplated escalated enforcement actions;

9. Submits all escalated enforcement actions to the Office of Enforcement, for review and approval;

10. Reviews vendor responses to enforcement actions to determine whether corrective actions are adequate;

11. Reviews OI reports and makes recommendations to OE for enforcement actions including immediate action, when warranted; and

B. As directed by the Director, NRO, NRO staff and management personnel support enforcement activities initiated by the regions, as follows:

1. Division of Construction Inspection & Operational Programs (DCIP) provides oversight and representatives as necessary to support enforcement panels;

2. Appropriate project, technical, and management personnel should:

a). Participate in enforcement caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions;

b). Participate in enforcement panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions; and

c). Attend pre-decisional enforcement conferences and regulatory conferences.

3. Project, technical, and management personnel will:

a). Review applicable OI reports to identify immediate safety issues and provide NRO's perspective in determining appropriate enforcement action; and

b). Coordinate with OE on TIAs that have the potential for enforcement implications.

1.8 Office of Nuclear Reactor Regulation (NRR)

NRR is responsible for supporting the enforcement program in all areas where NRR evaluates, directly manages, or conducts inspections, including power reactors, vendors and non-power reactors. NRR is responsible for implementing the enforcement program and Enforcement Policy subject to the overall policy, program, and implementation guidance from OE. For cases

where NRR is responsible for the allegation or inspection activity, NRR shall assume the role of the regional office, as well, in implementing the enforcement program and Enforcement Policy.

NOTE:

NRR reviews the enforcement strategy for escalated enforcement actions for 10 CFR Part 50 and 55 licensees to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

A. When NRR assumes the role of the regional office (i.e., issuing non-SDP enforcement actions), NRR generally:

1. Prepares and issues non-escalated enforcement actions;

2. Schedules and conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

3. Prepares and issues escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required;

4. Evaluates licensees' responses to enforcement actions and prepares appropriate responses;

5. Tracks the status of enforcement actions;

6. Conducts NRR staff training; and

7. Audits NRR enforcement actions.

B. For all cases where the region evaluates, directly manages, or conducts inspections, NRR generally reviews the enforcement strategy for escalated enforcement actions recommended by the regional offices to ensure that:

1. Violations have been adequately established; and

2. The significance of the violations has been properly evaluated from an overall agency perspective.

C. For the ROP, NRR generally develops and directs the implementation of policies, programs, and procedures for regional application of the SDP in the evaluation of findings and issues associated with the ROP. The output of the SDP provides a direct input into the enforcement program in terms of how a violation will be dispositioned.

1.8.1 Delegation of Authority to the Director, NRR

A. The Director, NRR is authorized to act according to the following guidelines:

1. In accordance with MD 9.27, "Organizations and Function, Office of Nuclear Reactor Regulation," the Director, NRR has been authorized to issue orders and DFIs. However, use of this authority is expected to be confined to actions not associated with violations.

2. In accordance with the delegation from the Director, OE, dated May 20, 2008, (ML081260612) the Director of the Office of Nuclear Reactor Regulation (NRR) is delegated authority to approve, sign, and issue certain enforcement actions. This delegation applies to enforcement actions in all areas in which NRR evaluates, directly manages, or conducts inspections. If there is overlap between regional and NRR inspection authority, and a dispute arises regarding which office should issue the enforcement action, the Office of Enforcement (OE) should be consulted. The Director of NRR is authorized to take the following actions:

   a). Approve, sign, and issue non-escalated enforcement actions to licensees, applicants, and vendors, and, after consultation with OE, sign and issue non-escalated enforcement actions or letters to non-licensees (other than vendors).

   b). Sign and issue confirmatory action letters (CAL).

   c). Sign and issue orders or demands for information (DFIs) to licensees and applicants on safety and security matters not related to specific violations of NRC requirements.

   d). Conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

   e). Review disputed enforcement actions and coordinate responses with OE.

3. The Deputy Director of NRR is authorized to exercise this authority delegated during the absence of the Director.

4. The Commission’s regulations, the Enforcement Policy, the NRC Enforcement Manual, Enforcement Guidance Memoranda, and other guidance from the Office of Enforcement shall be followed in conducting enforcement activities under this delegation.

1.8.2 Re-delegation of Authority by the Director, NRR

A. The Director, NRR may re-delegate this authority according to the following guidelines:

1. The Director may re-delegate the authority to approve, sign, and issue non-escalated enforcement actions to licensees, applicants, and vendors, and, after consultation

with OE, sign and issue non-escalated enforcement actions or letters to non-licensees (other than vendors). However, this authority may not be re-delegated to individuals below the level of branch chief.

2. The Director may re-delegate the authority to conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses. However, this delegation should not normally be given to individuals below the level of deputy division director.

3. Any other re-delegations of authority delegated herein must be approved by the Director of the Office of Enforcement.

1.8.3 Associate Director for Operating Reactor Oversight and Licensing, NRR

A. As directed by the Director, NRR, the Associate Director For Operating Reactor Oversight and Licensing:

1. Serves as the principal NRR manager responsible for enforcement matters involving 10 CFR Part 50 and 55 licensees;

2. Ensures that the enforcement strategy for escalated enforcement actions and cases involving Commission papers for 10 CFR Part 50 and 55 licensees are reviewed to ensure that:

   a). Violations have been adequately established, and

   b). The significance of the violations has been properly evaluated from an overall agency perspective;

3. Ensures that comments are provided (verbally, electronically via email to “OEMail.Resource”, or in writing) based on the review in paragraph (b) of this section to the Director, OE, generally within 10 working days of receipt of the enforcement package in headquarters;

4. Ensures that the NRR Enforcement Coordinator and project, technical, and management personnel attend enforcement and SERP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SERP caucuses, as appropriate;

5. Contacts the Director, OE, as soon as possible, and generally, no later than 24 hours after receiving the Strategy Form, if he/she disagrees with an enforcement strategy arrived at during an enforcement or SERP panel or caucus;

6. Reviews applicable OI reports to identify immediate safety issues and provide NRR perspective in determining appropriate enforcement action;

7. Recommends to the Director, OE, initiation of proposed enforcement action, as appropriate;

8. Ensures that responses to TIAs are coordinated with OE, as appropriate;

9. Reviews escalated enforcement actions prior to submitting them for headquarters' review; and

10. Recommends to the Director, OE, changes to the Enforcement Policy or guidance within this Manual, as appropriate.

1.8.4 NRR Enforcement Coordinator

A. As directed by the Associate Director for Operating Reactor Oversight and Licensing Inspection, NRR, the NRR Enforcement Coordinator:

1. Serves as the principal NRR contact for enforcement matters involving 10 CFR Part 50 and 55 licensees;

2. Participates in the weekly regional enforcement and SERP panels considering all 10 CFR Part 50 and 55 licensee cases;

3. Leads the NRR review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies the Associate Director for the Division of Inspection and Regional Support of the enforcement strategy, especially in cases where the Enforcement Coordinator disagrees with the strategy;

4. Obtains necessary technical support from other NRR divisions to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that reactor safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions;

5. Participates in predecisional enforcement conferences and regulatory conferences with enforcement implications, when the issues warrant;

6. Consolidates NRR views on the enforcement strategy for proposed escalated actions and forwards NRR comments (verbally, electronically, or in writing) to the Director or Deputy Director, OE, for enforcement actions submitted to headquarters;

7. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) involving vendors and non-power reactors are coordinated with OE;

8. Reviews all applicable OI reports to identify immediate safety issues, coordinates with appropriate NRR staff, and provides NRR's perspective in determining appropriate enforcement action; and

9. Prepares a "3-week email" within 60 days of receiving an OI report:

a). Indicating that either:

1). No enforcement action is being considered; or

2). That although a violation appears to be present, willfulness is not involved.

b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator; and

c). Inviting a response to the proposal that barring a different view:

1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed; or

2). The non-willful violation will be treated in accordance with normal enforcement processes.

10. Participates in regularly scheduled conference calls with OE, the regions, and the other Program Office Enforcement Coordinators to discuss enforcement issues and cases.

1.8.5 NRR Staff

A. In accordance with the delegations of authority for areas in which NRR evaluates, directly manages, or conducts inspections (e.g., vendors and non-power reactors) the NRR staff:

1. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedent;

2. Identifies violations of regulatory requirements and recommends enforcement action;

3. Appropriately documents enforcement actions;

4. Issues non-escalated enforcement actions, including notices of nonconformance, NOVs, and NCVs;

5. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed;

6. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

7. Prepares a Panel Worksheet and compiles supporting information for enforcement and SERP panels;

8. Requests EA numbers for all contemplated escalated enforcement actions;

9. Submits all escalated enforcement actions to headquarters, for review and approval;

10. Reviews vendor responses to enforcement actions to determine whether corrective actions are adequate, and

11. Reviews OI reports and makes recommendations to OE for enforcement actions including immediate action, when warranted.

B. As directed by the Director, NRR, NRR staff and management personnel support enforcement activities initiated by the regions, as follows:

1. Division of Inspection and Regional Support (DIRS) provides oversight and representatives as necessary to support enforcement and SERP panels;

2. The Division of Risk Assessment (DRA) supports assessment of the safety significance of the event(s) on which the proposed enforcement action is based. This support will include probabilistic risk assessment (PRA) and Accident Sequence Precursor calculations, where appropriate, as part of the integrated process considering all facets surrounding the violation in support of enforcement decisions;

3. Appropriate project, technical, and management personnel should:

a). Participate in enforcement and SERP caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions;

b). Participate in enforcement and SERP panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions; and

c). Attend predecisional enforcement conferences and regulatory conferences.

4. Project, technical, and management personnel will:

a). Review applicable OI reports to identify immediate safety issues and provide NRR's perspective in determining appropriate enforcement action; and

b). Coordinate with OE on TIAs that have the potential for enforcement implications.

1.9 Office of Nuclear Material Safety and Safeguards (NMSS)

NMSS is responsible for implementing the enforcement program and Enforcement Policy subject to the overall policy, program, and implementation guidance from OE, for all areas NMSS evaluates, directly manages, or for which it conducts inspections, or issues violations involving: (1) material control and accounting (MC&A), chemical, fire protection, and criticality safety activities at fuel facilities; (2) gaseous diffusion plants;
(3) transportation shipping packages; (4) independent spent fuel storage installations;

(5) dry storage systems for spent fuel; (6) decommissioning activities; (7) low-level waste licensees; (8) medical and industrial nuclear safety; (7) uranium recovery licensees; and (8) high-level waste repository safety. For cases where NMSS is responsible for the allegation or inspection activity, NMSS shall assume the role of the regional office, as well, in implementing the enforcement program and Enforcement Policy.

A. When NMSS assumes the role of the regional office, NMSS generally:

1. Prepares and issues non-escalated enforcement actions;

2. Schedules and conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

3. Prepares and issues escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required;

4. Evaluates licensees' responses to enforcement actions and prepares appropriate responses;

5. Tracks the status of enforcement actions;

6. Providing information about certain enforcement actions for Health and Human Services (HHS) database;

7. Conducts NMSS staff training; and

8. Conducts audits of NMSS enforcement actions.

B. When NMSS is providing technical support to the regions, NMSS generally reviews enforcement strategies for escalated enforcement actions recommended by the regional offices to ensure that:

1. Violations have been adequately established; and

2. The significance of the violations has been properly evaluated from an overall agency perspective.

1.9.1 Delegation of Authority to the Director, NMSS

A. In accordance with MD 9.26, "Organization and Functions, Office of Nuclear Materials Safety and Safeguards", the Director, NMSS, is authorized to issue orders and DFIs; however, use of this authority is expected to be confined to actions not associated with violations.

B. In accordance with a delegation of authority issued by the Director, OE, May 20, 2008, (ML081260602) the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) is delegated authority to approve, sign, and issue certain enforcement actions. This delegation applies to enforcement actions in all areas in which NMSS evaluates,

directly manages, or conducts inspections. If there is overlap between regional and NMSS inspection authority, and a dispute arises regarding which office should issue the enforcement action, the Office of Enforcement (OE) should be consulted. The Director of NMSS is authorized to take the following actions:

1. Approve, sign, and issue non-escalated enforcement actions to licensees, applicants, and vendors, and, after consultation with OE, sign and issue non-escalated enforcement actions or letters to non-licensees (other than vendors).

2. Sign and issue confirmatory action letters (CAL).

3. Sign and issue orders or demands for information (DFIs) to licensees and applicants on safety and security matters not related to specific violations of NRC requirements.

4. Conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

5. Review disputed enforcement actions and coordinate responses with OE.

C. The Deputy Director of NMSS is authorized to exercise the authority delegated herein during the absence of the Director.

D. The Commission's regulations, the Enforcement Policy, the NRC Enforcement Manual, Enforcement Guidance Memoranda, and other guidance from the Office of Enforcement shall be followed in conducting enforcement activities under this delegation.

1.9.2 Re-delegation of Authority by the Director, NMSS

A. The Director of NMSS may re-delegate this authority subject to the following limitations:

1. The Director may re-delegate authority to approve, sign and issue non-escalated enforcement actions to branch chiefs and above and may re-delegate the authority to issue non-escalated enforcement actions on NRC Form 591, "Safety Inspection Report and Compliance Inspection," to qualified inspectors, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

2. The Director may re-delegate the authority to conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses. However, this delegation should not normally be given to individuals below the level of deputy division director.

3. Any other re-delegations of authority delegated herein must be approved by the Director of the Office of Enforcement.

1.9.3 NMSS Regional Coordinators

A. As directed by NMSS management, the Regional Coordinators:

1. Participate in the weekly regional enforcement panels considering all material licensee cases;

2. Provide assistance to the lead division, on request, in reviewing inspection and investigation findings to identify apparent violations that may warrant escalated enforcement action;

3. Provide assistance to the lead division, on request, in developing enforcement action worksheets, agendas for enforcement panels with OE, and issuing background information to all participants at least 72 hours in advance;

4. Schedule matters to be considered during OE enforcement panels;

5. Review and coordinate comments within NMSS, after OE review, on escalated enforcement actions for all material cases submitted by the regions or prepared by OE;

6. Ensure that all applicable OI reports are reviewed and that recommendations are made to OE for enforcement action, including immediate action, when warranted;

7. Prepare a “3-week email” within 60 days of receiving an OI report:

   a). Indicating that either:

      1). No enforcement action is being considered; or

      2). That although a violation appears to be present, willfulness is not involved;

   b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator; and

   c). Inviting a response to the proposal that barring a different view:

      1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed; or

      2). The non-willful violation will be treated in accordance with normal enforcement processes.

8. Participate in all NMSS and regional predecisional enforcement conferences, when the issues warrant;

9. Determine whether a licensee has been the subject of previous escalated enforcement action for purposes of the civil penalty assessment process;

10. Provide assistance to the lead division, upon request, in drafting escalated enforcement actions, including cover letters, orders, DFIs, proposed civil penalties,

orders imposing civil penalties, and Commission papers to ensure technical adequacy and conformance to established policy guidance and precedents, and coordinate with OE during this process;

11. Serve as point of contact for NMSS reviews, comments, and concurrence for subsequent changes or revisions made to enforcement actions;

12. Provide assistance to the lead division, upon request, in arranging and conducting predecisional enforcement conferences, including developing opening remarks on the Enforcement Policy and process;

13. Provide policy advice to NMSS Divisions including the Spent Fuel Project Office (SFPO) concerning enforcement matters, including information on enforcement actions in similar cases;

14. Provide training on enforcement matters within NMSS;

15. Track progress of all escalated enforcement actions while in preparation in NMSS and strive to achieve timely actions;

16. Ensure that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE;

17. Participate in regularly scheduled conference calls with OE, the regions, and the other Program Office Enforcement Coordinators to discuss enforcement issues and cases; and

18. Coordinate with appropriate NMSS Division concerning possible enforcement action based on OI reports.

1.9.4 NMSS Staff

A. In accordance with the delegations of authority for areas where NMSS evaluates, directly manages, or conducts inspections, the NMSS staff:

1. Identifies violations of regulatory requirements and recommends enforcement action;

2. Appropriately documents enforcement actions;

3. Issues non-escalated enforcement actions, including notices of nonconformance, NOVs, and NCVs;

4. Sign and issue NRC Form 591s for Severity Level IV violations and Non-Cited Violations (NCVs), if qualified and authorized to do so and subject to the review and approval requirements specified in the appropriate inspection manual chapter;

5. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed;

6. Prepares a Panel Worksheet and compiles supporting information for SERP and enforcement panels;

7. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

8. Requests EA numbers for all contemplated escalated enforcement actions;

9. Submits all escalated enforcement actions to OE for review and approval;

10. Reviews responses to enforcement actions to determine whether corrective actions are adequate;

11. Reviews OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted; and

12. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedent.

B. In accordance with guidance from the Director, NMSS, to support the enforcement program, appropriate project, technical, and management personnel from NMSS:

1. Participate in enforcement panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions;

2. Attend predecisional enforcement conferences;

3. Participate in enforcement caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

C. In accordance with guidance from the Director, NMSS, to support the enforcement program, the NMSS staff:

1. Reviews the enforcement strategy for regional escalated enforcement actions for material licensees to ensure that the violations have been adequately established and that the safety significance of the violations has been properly evaluated from an overall agency perspective;

2. Provides comments (verbally, electronically via email to “OEMail.Resource” or in writing) based on the review conducted under the preceding paragraph of this section to OE, generally within five working days of receipt of the enforcement package; and

3. Reviews all applicable OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted.

1.10 Office of Nuclear Security and Incident Response (NSIR)

NSIR is responsible for supporting the enforcement program where NSIR has program ownership or where NSIR evaluates, directly manages, or conducts inspections involving security at nuclear facilities or security of nuclear materials and nuclear activities. This inspection responsibility typically includes force-on-force (FOF) inspections and inspection activities associated with security-related information or security-related violations involving non-licensees and vendors. NSIR is responsible for implementing the enforcement program and Enforcement Policy subject to the overall policy, program, and implementation guidance from OE. NSIR is also responsible for reviewing the enforcement strategy for escalated enforcement actions prepared by the regions to ensure that the significance of the violations has been properly evaluated from an overall agency perspective. For cases where NSIR is responsible for the allegation or inspection activity, NSIR shall assume the role of the regional office, as well, in implementing the enforcement program and Enforcement Policy.

A. When NSIR assumes the role of the regional office, NSIR generally:

1. Prepares and issues non-escalated enforcement actions;

2. Participates in enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

3. Prepares and issues escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required;

4. Evaluates licensees' responses to enforcement actions and prepares appropriate responses;

5. Tracks the status of enforcement actions;

6. Conducts NSIR staff training, and

7. Audits NSIR enforcement actions.

B. When NSIR is providing technical support to the regions, NSIR generally reviews enforcement strategies for escalated enforcement actions recommended by the regional offices to ensure that:

1. Violation have been adequately established; and

2. The significance of the violations has been properly evaluated from an overall agency perspective.

1.10.1 Delegation of Authority to the Director, NSIR

A. In accordance with the delegation of authority issued by the Director, OE, dated May 25, 2005, (ML050260007) for all areas where NSIR evaluates, directly manages, or in which it conducts inspections, the Director, NSIR, is authorized to:

1. Approve, sign, and issue non-escalated enforcement actions;

2. Recommend all escalated enforcement actions to headquarters either: (1) through consultation (usually via an enforcement panel) or (2) by submitting the actual enforcement action package for review and approval;

3. Sign and issue escalated enforcement actions (other than orders) after either: (1) consultation with OE (usually via a panel or caucus) or (2) actual enforcement action package review and approval by the Director, OE (and the DEDO and Commission, as appropriate);

4. Sign and issue enforcement actions or letters exercising discretion in accordance with the Enforcement Policy, after consultation with OE, and the DEDO, when required (these cases require EA numbers);

5. Review licensees' responses to proposed escalated enforcement actions and recommends appropriate action to the Director, OE;

6. Conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

7. Ensure that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE; and

8. Ensure that the enforcement activities conducted under this delegation are consistent with established policy, guidance, and precedents.

B. The delegations listed above do not apply to cases where the Director, OE, the Director, NSIR, or the Regional Administrator are in disagreement on a proposed action; or the DEDO advises the Director, OE, that he/she wishes to retain approval authority.

C. In accordance with the responsibility for supervising and directing all enforcement-supporting functions of NSIR, the Director, NSIR:

1. Contacts the Director, OE, as soon as possible, and generally no later than 24 hours after receiving the Strategy Form, if they disagree with an enforcement strategy arrived at during an enforcement panel or enforcement caucus;

2. Ensures that OI reports are reviewed and that recommendations are made to OE for enforcement action, including immediate action, when warranted;

3. Ensures that NSIR staff receives appropriate training and instructions to implement the enforcement program and that NSIR-based enforcement actions are periodically audited;

4. Ensures that disputed non-escalated actions (NCVs and NOVs) are coordinated with OE;

5. Ensures that copies of TIAs that involve potential violations are sent to the Director, OE;

6. Ensures that the enforcement activities conducted under this function are consistent with established policy, guidance, and precedents;

7. Reviews escalated enforcement actions prior to submitting them for headquarters' review; and

8. Recommends to the Director, OE, as appropriate, changes to the Enforcement Policy or guidance within this Manual.

1.10.2 Re-delegation of Authority by the Director, NSIR

A. The Director, NSIR, may re-delegate his/her authority according to the following guidelines:

1. To the Deputy Director, NSIR, the authority to sign and issue, after coordination with OE, Severity Level III NOVs without civil penalties;

2. To Deputy Division Directors and above, the authority to sign and issue non-escalated enforcement actions;

3. To Deputy Division Directors and above, the authority to sign and issue actions and letters exercising discretion in accordance with the Enforcement Policy for matters that would otherwise be Severity Level IV violations; and

4. To NSIR management, the authority to conduct predecisional enforcement conferences. This authority should not generally be delegated to individuals below the level of Deputy Division Director.

B. The Director, NSIR, will forward copies of further re-delegations to OE.

1.10.3 NSIR Enforcement Coordinator

A. As directed by NSIR management, the NSIR Enforcement Coordinator:

1. Serves as the principal NSIR contact for enforcement matters involving security at nuclear facilities and security of nuclear materials and nuclear activities;

2. Participates in the weekly regional SERP and enforcement panels for all cases involving security at nuclear facilities and security of nuclear materials and nuclear activities;

3. Leads the NSIR review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies appropriate NSIR management of the enforcement strategy, especially in cases where the Enforcement Coordinator disagrees with the strategy;

4. Obtains necessary technical support from other NSIR divisions/directorates to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that reactor safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions;

5. Participates in predecisional enforcement conferences and regulatory conferences with enforcement implications, when the issues warrant;

6. Consolidates NSIR views on the enforcement strategy for proposed escalated actions and forwards NSIR's comments, i.e., verbally, electronically via "OEMail.Resource", or in writing, to the Director or Deputy Director, OE, for enforcement actions submitted to headquarters;

7. Participates in regularly scheduled conference calls with OE, the regions, and the other Program Office Enforcement Coordinators to discuss enforcement issues and cases;

8. Reviews all applicable OI reports to identify immediate safety issues, coordinates with appropriate NSIR staff, and provides NSIR perspective in determining appropriate enforcement action; and

9. Prepares a "3-week email" within 60 days of receiving an OI report.

   a). Indicating that either:

      1). No enforcement action is being considered; or

      2). That although a violation appears to be present, willfulness is not involved;

   b). Addressed to the Director, OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator; and

   c). Inviting a response to the proposal that barring a different view:

      1). There does not appear to be a violation of NRC requirements, therefore, no enforcement action is proposed; or

2). The non-willful violation will be treated in accordance with normal enforcement processes.

1.10.4 NSIR Staff

A. In accordance with the delegations of authority for areas where NSIR evaluates, directly manages, or conducts inspections, the NSIR staff:

1. Identifies violations of regulatory requirements and recommends enforcement action;

2. Appropriately documents enforcement actions;

3. Issues non-escalated enforcement actions, including notices of nonconformance, NOVs, and NCVs;

4. Sign and issue NRC Form 591s for Severity Level IV violations and Non-Cited Violations (NCVs), if qualified and authorized to do so and subject to the review and approval requirements specified in the appropriate inspection manual chapter;

5. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed;

6. Prepares a Panel Worksheet and compiles supporting information for SERP and enforcement panels;

7. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses;

8. Requests EA numbers for all contemplated escalated enforcement actions;

9. Submits all escalated enforcement actions to OE for review and approval;

10. Reviews responses to enforcement actions to determine whether corrective actions are adequate;

11. Reviews OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted; and,

12. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedent.

B. In accordance with guidance from the Director, NSIR, to support the enforcement program, appropriate project, technical, and management personnel from NSIR:

1. Participate in enforcement panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions;

2. Attend predecisional enforcement conferences;

3. Participate in enforcement caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

C. In accordance with guidance from the Director, NSIR, to support the enforcement program, the NSIR staff:

1. Reviews the enforcement strategy for regional escalated enforcement actions for material licensees to ensure that the violations have been adequately established and that the safety significance of the violations has been properly evaluated from an overall agency perspective;

2. Provides comments (verbally, electronically via email to “OEMail.Resource” or in writing) based on the review conducted under the preceding paragraph of this to OE generally within five working days of receipt of the enforcement package; and

3. Reviews applicable OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted.

1.11 Office of the Chief Financial Officer (OCFO)

OCFO has delegated authority to issue orders to licensees who violate Commission regulations by nonpayment of license and inspection fees.

1.12 Office of Public Affairs (OPA)

A. OPA, including the Regional Public Affairs Officer (RPAO):

1. May issue press releases for various enforcement-related actions or activities that the agency views as significant or newsworthy; and

2. Coordinates the issuance of press releases involving enforcement actions or activities with the regional enforcement staff, and OE, as appropriate.

NOTE:

Press releases announcing predecisional enforcement conferences and regulatory conferences that are open for public observation should be brief and carefully worded so as not to prejudge the outcome; and include an explicit description of the nature of the conference as a predecisional opportunity for the licensee to present any additional material information before the NRC arrives at a decision.

1.13 Special Task Forces

A. NRC management may establish a special task force to investigate or otherwise review circumstances surrounding activities which may result in an enforcement action.

B. Special task forces can serve a valuable purpose by bringing special expertise and insight into the investigative and enforcement processes.

C. Special task forces formed to investigate or otherwise review circumstances surrounding activities which may result in an enforcement action should have a charter or tasking memorandum that:

1. Delineates their role within the agency's existing investigative and enforcement processes;

2. Clearly defines the responsibilities of the special task force and establishes a work plan at the outset that describes how the special task force will document task force findings;

3. Addresses whether the special task force's activities and work products should be independent or integrated within the existing investigative and enforcement processes;

4. Includes a clear strategy addressing how the special task force's work will ultimately be used by the agency, e.g.;

a). Whether the special task force should prepare an independent report or should prepare input for an OI, NRR, NMSS, NSIR or region-based report.

b). Whether the special task force should participate in enforcement decision-making activities, such as enforcement panels, conferences, and caucuses.

1.14 Signature Authority for Escalated Enforcement

A. Escalated NOVs without civil penalties should be signed and issued according to the following guidelines:

1. The Regional Administrator normally signs and issues NOVs with Severity Level I, II, and III violations and NOVs associated with red, yellow, or white SDP findings, after appropriate coordination with OE (and the DEDO, if applicable).

2. The Regional Administrator may re-delegate the authority to sign and issue NOVs with Severity Level III violations and NOVs associated with yellow or white SDP findings to the Deputy Regional Administrator, after appropriate coordination with OE (and the DEDO, if applicable).

3. The Director, NRR, normally signs and issues escalated NOVs involving vendors and non-power reactors, after appropriate coordination with OE (and the DEDO, if applicable).

4. The Director, NRR, may re-delegate to Associate Directors and above, the authority to sign and issue NOVs for Severity Level I and II violations involving vendors, after appropriate coordination with OE (and the DEDO, if applicable) and may re-delegate to Division Directors and above, the authority to sign and issue NOVs with Severity Level III violations involving vendors after appropriate coordination with OE (and the DEDO, if applicable).

5. The Director, NRR, may re-delegate to the Deputy Director, the authority to sign and issue NOVs for Severity Level I and II violations involving non-power reactors, after appropriate coordination with OE (and the DEDO, if applicable) and may re-delegate to the Division Director and above, the authority to sign and issue NOVs with Severity Level III violations involving non-power reactors after appropriate coordination with OE (and the DEDO, if applicable).

6. The Director, NMSS, normally signs and issues NOVs with Severity Level I, II, or III violations involving areas that they inspect, after appropriate coordination with OE (and the DEDO, if applicable).

7. The Director, NMSS, may re-delegate to the Deputy Director, the authority to sign and issue NOVs with Severity Level III violations, after appropriate coordination with OE (and the DEDO, if applicable).

8. The Director, NSIR, normally signs and issues NOVs with Severity Level I, II, or III violations involving areas that they inspect (e.g., force-on-force exercises, security issues related to non-licensees and vendors, as well as information security), after appropriate coordination with OE (and DEDOs, if applicable).

B. NOV/Civil penalty actions should be signed and issued according to the following guidelines:

1. The DEDO may choose to sign any civil penalty action. For cases that involve multiple actions (e.g., a single overall occurrence that results in an order, and a civil penalty), each of the actions should be signed by the same individual.

2. The Regional Administrator normally signs and issues all civil penalty actions, after appropriate coordination with OE (and the DEDO and the Commission, if applicable).

3. The Director, NRR, may re-delegate to Associate Directors and above, the authority to issue civil penalty actions for violations involving vendors, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable).

4. The Director, NRR, may re-delegate to the Deputy Director, the authority to issue civil penalty actions for violations involving non-power reactors, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable).

5. The Director, NMSS, normally signs and issues civil penalty actions involving areas that NMSS inspects, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable).

C. Orders Imposing Civil Penalties should be signed and issued according to the following guidelines:

1. The DEDMRT signs:

a). All impositions for 10 CFR Part 50 and 55 licensees; and

b). Impositions involving Severity Level I violations of 10 CFR Part 30, 40, 70, and 76.

2. The Director, OE, signs impositions involving violations up to and at Severity Level II of 10 CFR Part 30, 40, 70, and 76.

D. Orders (other than those imposing civil penalties) should be signed and issued according to the following guidelines:

1. The Director of OE normally signs:

a). The following orders for 10 CFR Parts 30, 40, 70, and 76 licensees:

1). Confirmatory Orders; and

2). Orders Imposing Civil Monetary Penalties for violations up to and including Severity Level II;

b). Confirmatory Orders for 10 CFR Part 50 licensees; and

c). Confirmatory Orders for individual actions under 10 CFR Parts 30, 40, 50, 70, and 76.

2. The DEDMRT signs all other orders.

E. The Director, OE, normally signs DFIs issued to 10 CFR Part 30, 40, 50, 55, 70, and 76 licensees and to individuals.

1.15 Commission Notification and Consultation

A. To ensure that the Commission has all information relating to the performance of its enforcement duties:

1. The staff notifies the Commission of its intent to issue an escalated enforcement action by issuing an Enforcement Notification (EN).

a). A same-day EN is issued for:

1). All immediately effective orders;

2). Any case on which the Commission was previously consulted and a 3-day EN has not been issued;

3). All notices of enforcement discretion involving natural events, such as severe weather conditions. (See NOED guidance in Part 9900 of the Inspection Manual for format.)

b). A 3-day EN is issued for:

1). All escalated NOVs associated with white, yellow, or red SDP findings;

2). The following enforcement actions when they are not subject to a same-day EN:

(a). All civil penalties (Note: This does not include orders imposing a civil penalty);

(b). All Severity Level I and II enforcement actions;

NOTE:

The region or program office with the lead for the enforcement action should ALWAYS consult with OE prior to issuing the action when it requires an EN or RN, to ensure that (any) comments from the Commission are considered prior to issuance.

(c). All Severity Level III enforcement actions associated with civil penalties;

(d). Enforcement actions that have special interest and would not otherwise receive an EN (e.g., discrimination issues, unique or significant issues, escalated actions that have been withdrawn for which an EN was previously issued, issues for which a press release was published);

NOTE:

There is a standard distribution list for the distribution of ENs; however, if the subject of an EN involves an enforcement action taken by one region against the subsidiary of a company that is located in another region, the region in which the parent company resides should be advised of the action.

(e). All enforcement orders (except those associated with non-payment of fees) that are not immediately effective; and

(f). Enforcement DFIs.

c). General Information regarding ENs:

1). OE prepares or coordinates the preparation of ENs with the region or program office that is the lead for the enforcement action (e.g., issues where OE previously agreed to the enforcement strategy through a panel or caucus).

2). OE issues ENs for enforcement actions that are submitted to and reviewed by OE.

3). ENs should clearly state when an order is issued to a licensed operator or a non-licensee.

4). Normally, the region or program office that is the lead for the enforcement action is responsible for contacting the licensee or individual prior to the enforcement action being taken.

B. The staff notifies the Commission of its intent to issue a significant regulatory action, such as a Final Significance Determination for a white, yellow, or red finding (that does not include an NOV) or an order that requires additional safety measures beyond the regulatory framework (versus an order based on compliance issues), by providing the Commission with a Regulatory Notification (RN).

1. A same-day RN is issued for:

a). All immediately effective safety orders;

b). Any case on which the Commission was previously consulted and a 3-day RN was not already required;

c). All significant regulatory actions that are being modified, withdrawn or rescinded, and the Commission was previously notified of their issuance.

2. A three-day RN is issued for:

a). All Final Significance Determination letters with a white, yellow, or red finding (that does not include an NOV).

b). Issues of special interest that would not otherwise receive an RN.

3. General information regarding RNs:

a). OE prepares or coordinates the preparation of RNs with the region or program office that is the lead for the enforcement action in a manner similar to the issuance of ENs.

b). OE issues RNs for enforcement actions that are submitted to and reviewed by OE.

c). OE uses the standard format in Appendix B and assigns the RN the next sequential number from the EN system.

C. When the Commission should receive a more detailed and earlier explanation of an enforcement action than an EN or RN provides, e.g., if the action is likely to have implications for broader sanctions or involves issues that are of substantial public interest [SECY-96-222; SRM 11/26/96], the Commission is consulted via either a SECY paper or memorandum prior to taking such action (unless the urgency of the situation dictates immediate action). Such actions include, e.g.:

NOTE:

When the Commission is consulted via a SECY paper or memorandum prior to taking an enforcement action, the region or program office with the lead for the enforcement action is responsible for drafting the document. OE and the EDO should be included on concurrence.

1. Any change to the Enforcement Policy.

2. An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation.

3. Proposals to impose a civil penalty for a single violation or problem that is greater than three times the Severity Level I value shown in Table 1A of the Enforcement Policy for that class of licensee [61 FR 65128].

4. Any proposed enforcement action that involves a Severity Level I violation.

5. Any action the EDO believes warrants Commission involvement.

6. For enforcement cases involving OI reports where the NRC staff (other than the OI staff) disagrees with the conclusions of the OI report concerning willfulness, Commission consultation (via a SECY paper or memorandum) is needed unless the Director, OI, agrees that it is not warranted. The Commission paper should include a summary of the rationale upon which OI based its conclusions and a summary of the non-OI staff's basis for reaching different conclusions. If the Commission is not consulted, OE should document the disagreement in its case file.

7. Any proposed enforcement action on which the Commission asks to be consulted.

8. Any enforcement action initiated more than 18 months after a violation is initially identified (based on the completion date of the inspection), or more than 18 months after referral of a potential violation to OI where the enforcement action in the case was affected or modified as a result of the age of the action and the EDO believes that Commission consultation is warranted. The region should draft a Commission paper for headquarters' review that explains:

   a). The reasons for the delay (with input from OI, as necessary); and

   b). The rationale for the staff's proposal with a specific focus on what effect the delay has on the proposed action. This would include consideration of factors such as, but not limited to:

      1). Whether the effectiveness of the proposed enforcement action will be affected by the delay;

      2). Whether the focus of the action should be modified as a result of the delay (e.g., if the staff has observed several years of good licensee performance in the area in question, perhaps the enforcement action should focus on sending a message to individual wrongdoers rather than to the licensee;

      3). Whether the delay affects our ability to find or obtain credible evidence from organizations or individuals; and

NOTE:

In cases where a memorandum from the Director, OE, to the DEDO is appropriate, a copy of this memorandum should also be provided to the Commissioner's assistants at least five days before the action is to be taken.

      4). Whether the expected benefits to public health and safety or common defense and security are justified by using limited NRC resources to pursue this action.

   c). A Commission paper is not necessary if:

      1). The enforcement action in the case was <u>not</u> affected or modified as a result of the age of the action; or

      2). The enforcement action was affected by the age of the action but the EDO does not believe that Commission consultation is warranted. In such cases OE should issue a memorandum (using the appropriate form in Appendix B) from the Director, OE, to the DEDO that:

(a). Explains the reasons or problem that caused the delay (with input from OI and the applicable regional office, as appropriate); and

(b). Explains the rationale for the staff's proposal with a specific focus on what effect the delay has on the proposed action and brief consideration of the factors included in paragraph c.8 above.

CHAPTER 2
DISPOSITIONING NONCOMPLIANCES

Chapter 2: The initial stages of the enforcement process.

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2. Dispositioning Noncompliances

2.1 Protecting Public Health and Safety and Providing for the Common Defense and Security

When an apparent safety or security issue is identified:

A. The region should initiate immediate action to correct the condition if the public is likely to be endangered by continued operations or there is a concern involving the lack of integrity of those involved in licensed activities. Immediate corrective action can include issuing:

> **NOTE:**
>
> The first response when an apparent safety or common defense and security issue is identified should be to ensure corrective actions are initiated. Whether the issue may warrant enforcement action is a secondary consideration.

1. A Confirmatory Action Letter (CAL); or

2. An immediately effective order.

B. Based on the circumstances of the case:

1. An expedited inspection report limited in scope to the issue may be prepared; or

2. The Office of Investigation (OI) may provide preliminary information.

3. Enforcement action may be taken before an inspection report is issued or a predecisional conference is held.

2.2 Identifying Noncompliances

A. Noncompliances include:

1. **Violations:** defined as a licensee's failure to comply with a legally binding requirement, such as a regulation, rule, order, license condition, or technical specification.

2. **Deviations:** defined as a licensee's failure to:

NOTE:

Failure to comply with a Regulatory Guide or a Generic Letter is not a violation (unless information in these documents has been incorporated into a license condition) because Regulatory Guides and Generic Letters are not requirements. In addition, a licensee's failure to comply with its procedures is not a violation unless the licensee's procedures have been made a legally binding requirement, e.g., by license condition.

a) satisfy a written commitment; or

b) conform to the provisions of code, standard, guide, or accepted industry practice when the commitment, code, standard, guide, or practice involved has not been made a legally binding requirement by the Commission, but is expected to be implemented.

3. **Nonconformances:** defined as a vendor's or certificate holder's failure to meet contract requirements related to NRC activities (e.g., 10 CFR Part 50, Appendix B) where the NRC has not placed requirements directly on the vendor or certificate holder.

B. Potential noncompliances may be identified through:

- NRC inspections
- NRC investigations
- Allegations supported by an NRC inspection or investigation
- Licensee internal audits
- Licensee employee reports
- Licensee self-disclosing events

2.3 Gathering Facts

A. It is necessary to gather specific information about an apparent noncompliance so that the agency can make an informed decision on how to disposition it appropriately. When an apparent noncompliance is identified, the agency must:

1. Determine whether a noncompliance has occurred (an event with safety consequences does not necessarily constitute a noncompliance);

2. Assess the safety significance;

3. Categorize the severity level (if appropriate); and

4. Determine the appropriate enforcement action.

B. The information that is gathered is also used to document the enforcement process; therefore, it must be complete and accurate.

C. The following questions serve as a guideline for gathering the information necessary to inform the enforcement process. The list should not be considered prescriptive, or all encompassing.

1. What requirement or commitment was violated?

2. How was the requirement or commitment violated?

3. Who caused the requirement or commitment to be violated?

4. When was the requirement or commitment violated?

5. How long did the noncompliance exist?

6. How, when, and by whom (licensee or NRC) was the violation discovered?

7. What is the apparent significance of the issue, e.g., actual or potential consequences, potential for impacting regulatory process, was willfulness involved?

8. What information is necessary to complete the SDP (if applicable)?

9. What was the apparent cause?

10. What corrective actions have been taken or are planned to be taken (if known)?

11. Did the licensee place the issue in its corrective action program (if applicable)?

12. Was the licensee required to report the violation and, if so, what was the applicable reporting requirement?

13. If a report was required, when was the report made to the NRC?

2.4 Assessing Significance

After the staff has determined that the nonconformance is a violation, the staff must assess the significance of the violation before determining how the violation should be dispositioned. Whenever possible, risk information is used in assessing the safety significant of violations and assigning severity levels. A higher severity level may be warranted for violations that have greater risk significance, while a lower severity level may be appropriate for issues that have lower risk significance. Duration of the violation is also an appropriate consideration in assessing the significance of the violation. The staff considers four specific factors when assessing significance:

A. Actual Safety or Security Consequences: Actual safety or security consequences include an actual:

- Onsite or offsite release of radiation
- Onsite or offsite radiation exposure

- Accidental criticality
- Core damage
- Loss of a significant safety barrier
- Loss of control of radioactive material
- Radiological emergency
- Security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an action of radiological sabotage occurred.

B. Potential Safety or Security Consequences:

1. Potential safety, security or exposure consequences include potential outcomes based on realistic and credible scenarios, i.e., the staff consider the likelihood that safety or security could have been negatively impacted under these scenarios.

2. For facilites under construction, the NRC considers the actual or potential impact on the quality of construction and its resulting effect on the safety and security of the facility.

C. Impacting the Regulatory Process: The NRC considers the safety and security implications of noncompliances that may affect the NRC's ability to carry out it statutory mission.

1. The agency is unable to use appropriate regulatory tools to address a noncompliance because the agency is unaware that the noncompliance exists. Examples of violations that impact the regulatory process include the failure to:

   - Receive prior NRC approval for changes in licensed activities
   - Notify NRC of changes in licensed activities
   - Perform 10 CFR 50.59 analyses
   - Provide the notice required by 10 CFR 150.20
   - Meet the requirement associated with the change process provisions in 10 CFR 50.54(a) (involving quality assurance programs), 10 CFR 50.54(p) (involving safeguards plans), 10 CFR 50.54(q) (involving emergency plans)
   - Notify the NRC pursuant to the Commission's requirements
   - Comply with reporting requirements
   - Provide complete and accurate information

2. In determining the significance of a violation that impacts the NRC's regulatory process, the NRC will consider:

   a) The position and responsibilities of the person involved in the execution of licensed activities relative to those activities or the use of licensed materials, regardless of the individual's job title or whether the individual is working directly for the licensee or working for a contractor engaged in activities associated with licensed activities.

NOTE:

Reporting failures is important. Many of the surveillance, quality control, and auditing systems on which both the NRC and its licensees rely in order to monitor compliance with safety standards, are based primarily on complete, accurate, and timely recordkeeping and reporting. Therefore, the NRC may consider a licensee's failure to make a required report that impedes the NRC's ability to take regulatory action, even if that failure was inadvertent or did not result in an actual consequence, to be significant. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances.

b) The significance of the underlying violation, i.e., when an issue is being considered for enforcement action because it impacts the NRC's regulatory process, it should first be reviewed on its own merits to ensure that its severity level is characterized appropriately given the significance of the particular violation.

c) Whether the failure actually impeded or influenced regulatory action and or invalidated the licensing basis.

1) Unless otherwise categorized in the Violation Examples section in the Enforcement Policy, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance and the circumstances surrounding the matter that should have been reported.

2) The severity level of an untimely report, in contrast to no report, may or may not be reduced depending on the circumstances surrounding the matter, e.g., if the NRC had received the report in a timely manner, would the NRC actually have taken an action based on the report.

D. Willfulness. Willful violations are of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor.

1. Willful violations cannot be tolerated by either the Commission or a licensee. Therefore, a violation involving willfulness may be considered more significant than the underlying noncompliance.

NOTE:

All willful violations must be coordinated with OE.

2. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances of the violation in order to create a deterrent effect within the licensee's organization and contract support. The relative

weight given to each of the following factors in arriving at the significance assessment will be dependent on the circumstances of the violation:

a) The position and responsibilities of the person involved in the execution of licensed activities relative to those activities or the use of licensed materials.

b) Notwithstanding an individual's job title or whether the individual is working directly for the licensee or working for a contractor engaged in activities associated with licensed activities, several factors should be considered when determining the severity level of a willful violation, including:

   1) Whether the individual has the formal or informal authority to direct the actions of others;

   2) Whether the individual is, in fact, directing the actions of others; and

   3) Whether the individual used his/her position to facilitate the violation, e.g., providing incomplete or inaccurate information or suppressing audit findings.

c) The significance of any underlying violation. Each issue being considered for enforcement action that includes willfulness should first be reviewed on its own merits to ensure that its severity level is characterized appropriately given the significance of the particular violation.

d) The intent of the violator.

   1) Willfulness embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements.

   2) Willfulness does not include acts which do not rise to the level of careless disregard, e.g., negligence or inadvertent clerical errors in a document submitted to the NRC.

e) The economic or other advantage, if any, gained by the individual or for the company, as a result of the violation. The avoidance of a negative consequence can be considered a benefit.

NOTE:

The NRC will normally take enforcement action for violations of the Agency's export and import requirements in 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material," for radioactive material and equipment within the scope of the NRC's export and import licensing authority (10 CFR 110.8, 110.9, and 110.9a) for (1) completeness and accuracy of information, (2) reporting and recordkeeping requirements (10 CFR 110.23, 110.26, 110.50, and 110.54), and (3) adherence to general and specific licensing requirements (10 CFR 110.23, 110.28, and 110.29).

2.5 Assigning Severity Levels

A. Severity levels are used to:

1. Indicate the significance of a violation, except when the issue involved is assessed through the Significance Determination Process (SDP); and

2. Determine the appropriate enforcement action to be taken.

B. The Enforcement Policy establishes four severity levels, with Severity Level I being the most significant and Severity Level IV being the least significant:

1. Severity Level I

2. Severity Level II

3. Severity Level III

4. Severity Level IV

C. Severity Level I and II violations:

1. Are considered to be “escalated enforcement actions.” This designation reflects the level of regulatory concern associated with the violation. Severity Level I and II violations warrant consideration of a civil penalty.

2. Usually involve actions with actual or high potential to have serious consequences on public health and safety or the common defense and security.

D. Severity Level III violations are also considered to be “escalated enforcement actions.” While not as significant as Severity Level I and II violations, Severity Level III violations are significant enough to warrant consideration of a civil penalty.

E. Although Severity Level IV violations are not as significant based on risk, assigning this severity level does not mean that a violation has no risk significance.

F. The Commission recognizes that there are other violations of minor safety or environmental concern that are below the level of significance of Severity Level IV violations.

1. Although certain violations may be designated as minor, licensees must correct them.

2. Such violations:

a) Do not <u>generally</u> warrant documentation in inspection reports or inspection records;

b) Do not warrant enforcement action; and

c) To the extent that they are described in inspection reports or inspection records, will be noted as violations of minor significance that are not subject to enforcement action.

NOTE:

Examples of minor violations can be found in this Enforcement Manual and in IMC 0612, "Power Reactor Inspection Reports" (Appendix E, "Examples of Minor Issues"). Guidance for documenting minor violations can be found in this Enforcement Manual, IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports"; IMC 0612; IMC 0613, "Documenting 10 CFR Part 52 Construction and Test Inspections"; and IMC 0616, "Fuel Cycle Safety and Safeguards Inspection Reports."

2.6 Using Enforcement Policy Violation Examples

The Enforcement Policy, Section 6.0, Violation Examples, provides examples of violations in various activity areas subject to enforcement action.

A. The Violation Examples section of the Policy contains guidance for determining severity levels. The examples are neither exhaustive nor controlling and are not intended to address every possible circumstance. Generally, if a violation fits an example contained in the Violation Examples, it is evaluated at that severity level. Application of this guidance ensures programmatic consistency throughout the regions and program offices. The Enforcement Policy contains violation examples in 14 activity areas:

- Reactor Operations
- Fuel Cycle Operations
- Materials Operations
- Licensed Reactor Operators
- Facility Construction (10 CFR Part 50 and 52 Licensees and Fuel Cycle Facilities)
- Emergency Preparedness
- Health Physics
- Transportation
- Inaccurate and Incomplete Information or Failure to Make a Required Report
- Discrimination
- Reactor, Independent Spent Fuel Storage Installation, Fuel Facility, and Special Nuclear Material Security
- Materials Security
- Information Security
- Fitness for Duty

B. If the region believes that a different severity level categorization is warranted and the circumstances are not addressed by this Manual, the region should either:

NOTE:

Consistent with the guiding principles for assessing significance, the severity level for a violation may be increased if it includes willfulness.

1. Explain the rationale in the Panel Worksheet when the case is sent to headquarters; or

2. Consult with OE prior to issuing the enforcement action in the region.

C. If the staff chooses to categorize a violation at a severity level different from the examples in the Violation Examples, the cover letter to the licensee should address the staff's rationale for categorizing the severity level.

D. If a violation does not fit an example in the Violation Examples, it should be assigned a severity level:

1. Commensurate with its safety significance; and

2. Informed by similar violations addressed in the Violation Examples.

2.7 Using Information From the Significance Determination Process (SDP)

A. For certain types of violations at commercial nuclear power plants, the enforcement process relies on information from the reactor oversight process's (ROP) Significance Determination Process (SDP).

1. The SDP is used to evaluate the potential safety significance of inspection findings to provide a risk-informed framework for discussing and communicating the significance of such findings with licensees.

2. The final disposition of violations associated with findings that have been evaluated through the SDP is contingent on the risk significance attributed to the findings.

3. Guidance on the SDP is described in NRC Inspection Manual Chapter 0609, "Significance Determination Process."

B. Depending on their significance, inspection findings are assigned the following colors:

1. Red (high safety or security significance)

2. Yellow (substantial safety or security significance)

3. White (low to moderate safety security significance)

4. Green (very low safety security significance)

C. The ROP uses an Agency Action Matrix to determine the appropriate agency response to these findings.

D. Findings are sometimes associated with one or more violations. If the violations are more than minor (i.e., red, yellow, white, or green):

1. They will be documented and dispositioned either as non-cited violations (NCVs) or NOVs. (Note: Violations associated with green SDP findings are normally dispositioned as NCVs)

2. Instead of using civil penalties as a deterrent, the staff will use other regulatory responses based on the significance of the issue, e.g.:

a) Increased inspections

b) Demands for Information (DFIs)

c) Orders

E. For issues with actual consequences.

1. Traditional enforcement will be considered, i.e., assigning a severity level with or without a civil penalty.

2. Depending on the risk significance of the issue, civil penalties will also be considered for issues involving potential safety consequences. Examples of issues with actual consequences include, but are not limited to:

- Exposures to the public or plant personnel above regulatory limits
- Failures to make required notifications that impact the ability of Federal, State, or local agencies to respond to actual emergencies
- Transportation events
- Substantial releases of radioactive material

F. Under the ROP, traditional enforcement will also be used to address violations that are willful or that have the potential for impacting the regulatory process.

1. The use of civil penalties in these instances remains appropriate as a deterrent.

2. Risk insights can inform the significance determination of the underlying violation or issue.

3. The staff should consider the SDP in conjunction with the Enforcement Policy and the guidance included in the Enforcement Policy Violation Examples when determining the appropriate severity level.

G. Traditional enforcement is also used for violations with no associated SDP performance deficiences (e.g., a violation of TS which is not a performance deficiency). These violations are normally dispositioned using enforcement discretion.

2.8 Using Risk Significance

A. Risk is a relevant consideration in enforcement decisions concerning significance, severity levels, appropriateness of sanctions, and the exercise of enforcement discretion.

B. At each enforcement or Significance Determination Process/Enforcement Review Panel (SERP) or panel, OE will ask whether the violation involves a risk significant issue.

C. The region is expected to have a position on risk significance or be able to describe what steps should be taken to obtain a view on risk if the matter may be risk significant.

1. Regional input is normally the first step; however, this should not be considered only a regional responsibility.

2. NRR should be prepared to provide its view on the risk associated with the violation(s) at issue.

D. To the extent known, the licensee's position on risk for the violations at issue should be discussed.

E. Following the decision at the SERP or enforcement panel to pursue escalated enforcement on a particular issue where risk may be relevant to the enforcement decision, an assignment will be made to the region or headquarters, as appropriate, to obtain additional risk information as necessary. A repanel will be held as warranted.

F. Assuming the event is of sufficiently increased risk significance to warrant escalated action, generally the issue of risk significance should be addressed in the correspondence with the licensee that arranges a predecisional enforcement conference or regulatory conference or in the “choice letter,” i.e., we should note that the apparent violations appear to be risk significant and that if the licensee differs in that view, the licensee should provide a brief explanation of its position.

G. Generally conferences should be held for risk significant cases.

H. The staff recognizes the uncertainties associated with risk assessment.

1. PRA models utilized by the staff and licensees vary in quality, creating the potential for differing views on the risk significance of events. In addition, some PRA limitations do exist, particularly in the area of human reliability analysis. In utilizing the results of PRA, generally the staff should not base an enforcement decision wholly on quantitative risk numbers; rather, risk significance should be one factor to be considered in determining the final enforcement action to take.

NOTE:

Some reactor cases involve issues or events that do not lend themselves to PRA insights. For example security, health physics, and emergency preparedness issues are typically not amenable to current methods of risk assessment. In these cases, risk insights from a PRA perspective will not be needed.

2. In determining the appropriate enforcement action, the staff should continue to balance risk information against the guidance currently provided in the Enforcement Policy and the Enforcement Policy Violation Examples.

3. The staff should routinely consider the risk implication of each reactor case considered for escalated action. Depending on the circumstances of the case, this assessment may be:

   a). Qualitative, relying primarily on engineering judgment based on qualitative risk insights;

   b). Quantitative risk analysis; or

   c). A combination of the two.

4. If the staff uses specific, quantitative PRA results or qualitative risk insights to support an enforcement decision, it should be reviewed by an NRC PRA specialist prior to issuance of the action, generally the Senior Reactor Analysts (SRAs).

NOTE:

The region should, to the extent practical, use the SRAs to assist them. SRAs should be consulted for risk significance insights <u>prior</u> to each respective regional enforcement panel, in order for the panel to have some assessment of the risk significance of the events discussed. Assistance from Research should also be sought, as needed. OE is available to assist the region in obtaining headquarters assistance in this effort.

   a. The Regional SRA is the preferred point for this review, due to the plant specific design and operational information available to the regional staff.

   b. Any quantitative PRA results provided as a basis for an enforcement action should explicitly reference the source (e.g., IPE, specific analysis) so that all assumptions, conditions, and methods are retrievable for subsequent review, if needed. The basis for qualitative assessment should be briefly described.

I. Judgment must be exercised in the use of risk significance as a factor in decisions regarding the appropriateness of the sanction.

1. In order to convey the appropriate regulatory message, there may be cases where, due to increased risk significance, it is appropriate to escalate the severity level and the sanction.

2. Discretion may be warranted to reach the proper enforcement action. Based on risk information it may be warranted to treat violations normally considered a Severity Level IV violation at a higher severity level. It may also be appropriate to consider a lower severity level or enforcement action for issues that have low risk significance.

a) Low risk does not excuse noncompliance.

b) If a licensee believes an issue is of low risk and not worthy of being a requirement, the licensee may seek a change to the requirement. However, until the requirement is changed, compliance is required.

2.9 Factors That Do Not Affect Significance

A. When determining significance the following items are generally not considered unless they are part of the violation itself:

1. Whether the licensee finds and reports a problem; and

2. Whether the licensee takes prompt and extensive corrective actions.

B. The significance of a violation should not be increased simply because the violation is repetitive.

1. Even when a trend in a specific program area that has safety significance exists, the staff should not view the significance of a group of related programmatic violations as being greater than the individual violations (i.e., do not aggregate the violations to increase significance).

2. A trend in a specific program area may be considered in developing the appropriate enforcement action and agency response (increased inspections, management meetings, etc.); however, it should not be used to increase significance.

C. The following are examples of additional actions that should not be considered in determining the significance of a violation:

1. The actions of a public utility commission or other State or local regulatory agency in response to a proposed NRC enforcement action; and

2. The possible impact from the reaction of a public utility commission or other State or local regulatory agency, or nature and context of an order, e.g., not allowing recovery of the cost of a civil penalty or cost of the replacement power for an outage necessitated by the violations at issue (NOTE: If a State regulatory agency has taken

enforcement action against a licensee for a transportation issue, the NRC should consider that action before determining appropriate enforcement action).

2.10 Minor Violations

A. Minor violations are below the significance of Severity Level IV violations and violations associated with green inspection findings and are not the subject of formal enforcement action.

NOTE:

Inspectors should discuss minor violations with licensees (typically during the exit meeting) so that licensees may take appropriate corrective actions. This is especially important when a minor violation is related to an allegation because the close-out letter to the alleger informs the alleger that the minor violation has been corrected.

B. Issues that represent isolated (i.e., “isolated” in that based on a reasonable effort, the staff determines that the issue is not recurring nor is it indicative of a programmatic issue such as inadequate supervision, resources, etc.) failures to implement a requirement and insignificant safety or regulatory impact should normally be categorized as minor violations.

C. As described in NRC Inspection Manual Chapter 0610, minor violations are, by their very nature, minor issues with little or no safety consequences. While licensees must correct these minor violations, generally they do not warrant documentation in inspection reports or inspections records and do not warrant enforcement action.

D. There is no set rule as to what is minor and what is not, i.e., the determination that an issue is minor will depend on the circumstances of the particular issue. The following are some examples of different categories of minor violations:

1. Record keeping issues: Minor violations involve issues that do not preclude the licensee from being able to take appropriate action on safety-related matters; or properly assessing, auditing, or otherwise evaluating the licensee’s safety-related activities, e.g.:

   Post-maintenance testing was performed on ten glycol air handling units during an outage of a Westinghouse ice condenser facility. All the required tests were performed, based on statements from licensee workers, but there was no record that an actual air flow test was conducted on two of the units. Based on indications in the control room, both air handling units had comparable air flow to those that had documented test results, and the ice condenser technical specification required air temperatures were all well-within specifications.

The violation: Criterion XI of 10 CFR Part 50, Appendix B, requires test results to be documented and evaluated to assure that test requirements are satisfied.

Minor because: This was a record keeping issue of low significance. There was reasonable assurance that test requirements were met as evidenced by actual air flow being satisfactory and technical specification temperatures being within limits.

Not minor if: The air flow in the two units was determined to be degraded during subsequent testing.

2. Licensee administrative requirement/limit issues: Minor violations involve isolated cases where licensees exceed administrative limits, i.e., limits that licensees impose upon themselves that are more conservative than NRC's regulatory limits, e.g.:

NRC inspectors identified that a high radiation door was not locked as required by plant procedures. While the licensee's procedurally controlled administrative limit for area postings was exceeded, the door to the area was conservatively classified and did not exceed regulatory radiation levels to warrant posting as a locked high radiation area.

The violation: Plant procedures require that activities shall be accomplished in accordance with procedures.

Minor because: The requirement was a licensee administrative limit. The area was conservatively posted and no regulatory limits requiring posting were exceeded.

Not minor if: The area radiation levels exceeded the regulatory radiation levels such that the area should have been a locked high radiation area.

3. Nonsignificant dimensional, time, calculation, or drawing discrepancies: Minor violations would be characterized by minor discrepant values referred to in either a licensee's Final Safety Analysis Report (FSAR) or other design documents, e.g.:

A temporary modification was installed on one of two redundant component cooling water system surge tanks to restore seismic qualification. The supporting calculations, which did not receive a second-level review, were found to contain technical errors that did not result in the train being inoperable.

The violation: Design control measures for verifying or checking the adequacy of design were not implemented. Design changes, including field changes, are required to be subjected to design control measures commensurate with those applied to the original design.

Minor because: These are non-significant calculation errors. The calculation errors were minor and the installed modification restored seismic qualification of the tank.

No minor if: The calculation errors were significant enough that the modification required revision or rework to correctly resolve seismic concerns.

4. Isolated procedural errors: Minor violations include isolated procedural errors or inadequate procedures that have no impact on safety equipment, e.g.:

While performing a reactor protection procedure, an operator inadvertently operated the bypass switch which caused a single channel trip condition. The operator failed to follow the procedure and adequately self-check to ensure the correct switch was manipulated.

The violation: Criterion V of 10 CFR Part 50, Appendix B, requires that activities be accomplished in accordance with procedures.

Minor because: This was an isolated procedural error and there were no safety consequences.

Not minor if: The error caused a reactor trip or other transient.

5. Work in progress findings: For enforcement purposes, these minor violations include violations occurring and identified in the course of performing work or maintenance on equipment that is out of service or declared inoperable per the technical specifications and has no safety consequences, and the violation is identified and corrected prior to returning the equipment to service and/or declaring the equipment operable. Errors that occur on non-designated pieces of equipment, such as inadvertently or mistakenly operating a different train of the equipment, or errors that cause another requirement (e.g., technical specifications) to be violated, are not included as minor, e.g.:

Prior to system restoration following modification, the licensee determined that the modification package that replaced the spent fuel pool cooling system suction piping did not include the siphon hole called for by the original system design. The siphon hole was not installed. Due to the location of the piping, a siphoning event would lower spent fuel pool level several feet, but would not uncover the stored fuel, nor significantly increase radiation levels in the spent fuel pool area.

The violation: The pipe design was not correctly translated into proper work instructions and drawings.

Minor because: This was a work in progress. The error was identified and corrected during turnover of the modification prior to system restoration.

Not minor if: The system was returned to service without installation of the siphon hole or completion of an evaluation to remove the requirement for the siphon hole.

6. Minor changes to requirements: Minor violations include the failure to meet 10 CFR 50.59 requirements that involve a change to the FSAR description or procedure, or involve a test or experiment not described in the FSAR, where there was no reasonable likelihood that the change would ever require NRC approval per 10 CFR 50.59, e.g.:

   The licensee developed and approved a preventive maintenance task that should have required that a change be made to the plant technical specifications. A 10 CFR 50.59 screening was not performed. When requested to perform the task, control room operators identified that the task would violate technical specifications and did not perform it.

   The violation: A task was changed that would require a change to the technical specifications without first completing a 10 CFR 50.59 screening.

   Minor because: The licensee's established process identified the problem prior to implementation. The problem did not affect any equipment and had no safety consequences.

   Not minor if: The task had been performed.

E. Violations that involve issues that are considered significant enough to be utilized in the formal NRC assessment process are not minor.

F. Inspection Manual Chapter 0612, Appendix B, "Thresholds for Documentation," provides guidance in the form of Group 1 questions to determine whether issues are more than minor. These questions can be used with the following guidance to determine whether identified violations are minor. Where a licensee does not take corrective action for a minor violation, willfully commits a minor violation, or the NRC has indications that the minor violation has occurred repeatedly, the matter should be considered more than minor, i.e., the matter should be categorized at least at Severity Level IV or associated with a green inspection finding and dispositioned in an NOV or NCV, as appropriate.

2.11 Tracking Enforcement and SDP Issues

A. The staff tracks various enforcement and SDP issues through the use of OE's Enforcement Action Tracking System (EATS). Under this system, enforcement action (EA) numbers are assigned to a variety of issues.

   1. OE or the responsible regional OE enforcement specialist will assign an EA number to <u>each</u> enforcement issue associated with a red, yellow, or white SDP finding. This enables OE to track violation/problem assessments.

      a). If additional related escalated violations or problems or SDP issues are identified subsequent to an enforcement or SERP panel, additional EA numbers will be assigned.

      b). If violations, problems, or issues are dropped subsequent to an enforcement or SERP panel, the related EA numbers should be closed.

2.11.1 Enforcement Action (EA) Numbers

A. EA numbers are assigned to administratively track and file a variety of enforcement issues, including SDP issues that are addressed in enforcement or SERP.

B. EA numbers are assigned to program office orders imposing additional regulatory requirements.

C. EA numbers are generally assigned when cases are discussed during enforcement or SERP panels, whether or not the case ultimately results in enforcement action. During or subsequent to a SERP or enforcement panel, an enforcement specialist will assign an EA number to:

1. Each issue being considered for enforcement action; or

2. Each inspection finding being assessed by the SDP that does not have enforcement implications.

D. EA numbers are placed on the SDP/EA Request and Strategy Form and forwarded to the region that initiated the action for review and comments.

E. EA numbers are assigned sequentially according to the year of issuance (e.g., EA-00-011). Once an EA number has been assigned to a proposed violation, all subsequent documents involving the violation should include the complete five-digit EA number.

F. EA numbers are assigned to the following:

1. Any issue that is discussed during a SERP or enforcement panel, regardless of whether the issue ultimately results in an enforcement action.

2. Any case in which a predecisional enforcement conference or Regulatory Conference is scheduled.

3. Any case in which the region issues a letter giving a licensee the choice of responding to apparent violations or requesting a predecisional enforcement conference (i.e., "choice letter"), if not already issued.

4. All escalated enforcement issues. This includes those cases that require headquarters' review prior to issuance, as well as those that do not. Orders that impose civil penalties retain the same EA number as the action that proposed the civil penalty.

a) Multi-sanction cases receive individual EA numbers for each sanction, e.g., a case that includes both a proposed civil penalty and a separate (stand-alone) Demand For Information (DFI) would have one EA number for the proposed civil penalty and a separate EA number for the DFI.

5. Any case involving willfulness whether or not escalated or non-escalated enforcement action is to be issued, including willful cases where the staff proposes to exercise discretion and refrain from issuing enforcement action (e.g., NCV).

6. Severity Level IV NOVs and NOVs associated with green SDP findings involving power reactors, where an NCV is determined to be inappropriate.

7. Any issue where enforcement discretion is exercised (e.g., exercise of discretion per EGMs or the Interim Policies).

8. Non-escalated enforcement actions requiring headquarters' review, including:

   a) Any enforcement action requiring Commission approval;

   b) Any non-escalated enforcement action involving an individual;

   c) Any non-escalated enforcement action which, by the examples in the Violation Examples section of the Policy, could be categorized at Severity Level III or characterized as greater than green by the SDP;

   d) Any non-escalated enforcement action related to a current proposed escalated enforcement action, unless there has been prior approval for separate issuance by the Director, OE;

   e) Any case involving the mitigation of enforcement sanctions as addressed in the Enforcement Policy;

   f) Any case in which the staff proposes to exercise discretion and refrain from issuing an enforcement action for a transportation cask contamination violation that could be categorized at Severity Level III or above.

   g) Any case in which a Notice of Enforcement Discretion (NOED) issued and the root cause that results in the need to request the NOED was a violation in itself (regardless of whether the violation will be dispositioned as an NCV or in an NOV). The EA number should be included on the subsequent enforcement action, but should not be included on the NOED when it is issued.

   h) Any case involving an OI report where enforcement action appears warranted (i.e., whether the action is based on willfulness or not and whether the action is escalated, non-escalated, or an NCV). OE will assign an EA number to the case when it determines enforcement action is warranted or when it requests an OGC analysis of whether enforcement action is supportable.

   i) Any case in which the staff proposes to issue a DFI. The DFI should be given an individual EA number even if issued together with another enforcement action. If another enforcement action is issued after the response to the DFI which addresses the subject matter of the original DFI, a new EA number is also to be obtained.

j) Any case (during review and approval) in which the region proposes to issue any action to an individual (i.e., NOV, civil penalty, DFI, order, close out letter, or similar letter)

k) Any case (during review and approval) in which the NRC proposes to issue an enforcement action (regardless of severity level) to a licensed operator for failure to comply with a facility licensee's fitness-for-duty (FFD) program.

l) Any case in which the NRC issues a "chilling effect" letter (CEL) for discrimination for engaging in protected activities. The region should request an EA number when it is determined that a CEL should be issued. The EA will be closed upon receipt of the licensee's response to the CEL. Any subsequent enforcement action proposed will be given a new EA number.

m) Any case referred to DOJ in which the NRC is considering escalated enforcement action.

n) Any disputed minor violation, Severity Level IV violation, or violation associated with a green SDP finding (regardless of whether it was dispositioned as an NCV or in an NOV) that did not have an EA number when it was originally dispositioned. Actions (including escalated) that were originally issued with an EA number should be tracked using the existing EA number. Appropriate keywords should be used to identify the violation as disputed in EATS.

o) An order (issued by the program office) imposing additional requirements beyond the existing regulatory requirements (e.g., 2002 security orders). One EA number may be used in the event the same order is issued to multiple licensees. The program office should contact OE (normally through their office Enforcement Coordinator) as soon as they believe an order should be issued.

p) Any issue that OE, the region, or the program office believes is warranted.

2.11.2 Preparing and Maintaining SDP/EA Request & Strategy Forms

A. SDP/EA Request & Strategy Forms (Strategy Forms) are used to:

1. Summarize the agency's strategy for dispositioning SDP and enforcement issues;

2. Serve as aids during case deliberations;

3. Record the conduct of enforcement or SDP meetings and discussions about the strategy that was used; and

4. Document the basis for any change in enforcement or SDP approach.

B. To ensure that Strategy Forms fully serve their purposes, the following guidance should be implemented:

1. Every issue paneled in a SERP or enforcement panel will get an EA number whether or not the case ultimately results in enforcement action, e.g., an inspection finding

characterized as white by the SDP will be assigned an EA number even if there are no violations associated with it. If a violation is associated with the white issue, only one EA number needs to be issued to address the case.

2. The OE Enforcement Specialist assigned to the case should prepare a Strategy Form following each panel. In addition to the necessary information to support EATS, the form should briefly state:

   a) What was agreed to at the panel;

   b) If there was not agreement at the panel, a brief description of the disagreement and what actions are being taken to resolve the difference;

   c) Whether actions need to be taken to obtain the views of others (briefing of the managers in the normal decision chain need not be stated);

   d) Whether additional investigation, interviews, or inspection activities are needed;

   e) Whether there is a need to revisit the agreement after further reviews of the evidence or research is conducted;

   f) The date the violation occurred (required for tracking the Statute of Limitations); and

   g) Any other actions needed to reach an enforcement decision.

3. For cases that have not been paneled but which require an EA number, the region will submit to OE sufficient information such that the Enforcement Specialist can prepare a Strategy Form.

4. The Strategy Form should list all panel attendees.

5. Subsequent to an enforcement or SERP panel, OE will provide the Strategy Form to all panel participants.

6. The Strategy Form should, in general, be completed within five working days of the initial panel, as well as any subsequent panel, enforcement caucus, or other substantiative communication where the enforcement strategy is revisited or modified.

7. Strategy Forms are entered into ADAMS and are non-publicly available.

8. Copies of the Strategy Forms are retained by OE in the official EA case files with regional work sheets and other background documents until the file is placed in storage (usually 2 years after the case is closed), at which time the Forms may be discarded.

9. After a subsequent panel, caucus, or substantiative discussion, the Strategy Form should be updated by noting the original EA number, the date of the meeting or

discussion, the form revision number (i.e., “1", “2", “3") and the outcome of the meeting, including a brief explanation of the reason for any change in strategy. The background information need not be restated unless it has changed. The updated Strategy Form is approved, distributed, and filed like the original Strategy Form.

2.11.3 Individual Action (IA) Numbers

A. Use of Individual Action (IA) numbers enables the NRC to maintain a list of individuals who have been considered for individual enforcement action.

B. IA numbers are assigned to any case in which correspondence is addressed to an individual concerning potential enforcement action; however, the region should use an EA number for the review and approval stages and get an IA number from OE when the correspondence is ready to be issued.

C. When an IA number is assigned, all external correspondence is included in a separate system of records (NRC-3, "Enforcement Actions Against Individuals"). By the notice establishing this system of records, individual actions and correspondence with individuals may be maintained by personal identifier in NRC offices.

NOTE:

IA numbers are assigned by OE to administratively track and file **all** correspondence issued to an individual, if that individual is being considered for or has been issued an enforcement action. The EA number associated with the action should **not** appear on the correspondence issued with an IA number and should **not** appear in the ADAMS profile.

D. IA numbers should be used:

1. On all close-out letters and conference or choice letters to an individual; and

2. Throughout an individual’s case, including any subsequent actions, e.g., Non-Cited Violation (NCV), NOV, civil penalty, DFI, order, or close-out letter. This includes NOVs issued to licensed operators for FFD violations, (regardless of severity level).

E. Like the original correspondence, the region should use the EA number for the draft action through the review and approval stages and include the IA number on the final action when it is ready to be issued. The EA file should be closed upon issuing the final IA action.

F. IA numbers are **not** assigned to cases in which a DFI or order involving an individual is issued to the licensee, unless the correspondence is directed to an individual concerning his or her performance, in which case, paragraph "a." applies.

2.12 Enforcement and Significance Determination Process Enforcement Review Panel (SERP) Panels

A. Enforcement panels are meetings to discuss and reach agreement on an enforcement approach for certain violations of NRC requirements. Enforcement panels assure consistency in the process for characterizing violations and issuing enforcement actions.

B. SERPs are meetings to discuss and reach agreement on the significance of inspection findings at power reactors that appear to be more significant than green under the SDP.

1. For SDP findings that have an associated violation, the panel will discuss and reach agreement on an enforcement approach for the related violation.

2. Although SERPs are similar to enforcement panels in many respects, specific guidance for SERPs is included in NRC Inspection Manual Chapter 0609.

C. When a regional office does not believe a panel is necessary for one of the items listed in e. below:

1. The Regional Enforcement Coordinator should consult with OE.

2. The Director, OE, may make exceptions to the guidance in this Manual in cases where the proposed resolution of the issue is noncontroversial and would be consistent with recent precedent and current policy.

D. An Office Director or Regional Administrator may request a panel to discuss any issue that is not specifically included in the items listed below. Otherwise, the following types of violations and related issues should be brought to an enforcement panel unless specifically exempted by current enforcement guidance in the Manual or an EGM, i.e., when enforcement guidance gives the regions the authority to classify a potentially escalated violation at Severity Level IV based on specific criteria, and those criteria are met, the issue does not need to be brought to a panel.

E. Unless otherwise specified, a panel should be held for the following items for all types of NRC licensees:

1. Violations for which escalated enforcement action is recommended, i.e., any violation for which an order, an NOV at Severity Level I, II or III, an NOV associated with a red, yellow, or white SDP finding, or a civil penalty is being recommended.

2. Violations involving a finding of wrongdoing or discrimination by OI, a licensee or DOL, including cases that OI has referred to DOJ. These violations should be discussed regardless of the apparent severity level.

3. Violations normally classified at Severity Level I, II or III or associated with a red, yellow, or white SDP finding for which enforcement discretion in accordance with the Enforcement Policy is being recommended. OE should be consulted by telephone for Severity Level IV issues.

4. Violations normally classified at Severity Level I, II or III or associated with a red, yellow, or white SDP finding for which non-escalated action is being recommended.

5. Cases in which enforcement action is being considered against an individual, including a licensed reactor operator, regardless of the severity level of the violation.

6. Cases in which a DFI is being recommended prior to making a final enforcement decision.

7. Cases where information obtained during a predecisional enforcement conference or in response to a choice letter or DFI needs to be considered in determining enforcement action.

8. Violations at power reactors where a departure from the NCV policy is proposed, i.e., to issue an NOV when the NCV criteria are met and vice versa.

9. Licensee-disputed violations and violations of 10 CFR Part 55 that cannot be resolved via coordination between the involved offices.

2.12.1 Participating in Panels

Participation in enforcement panels should be in accordance with the following guidelines:

A. Region: The region is generally responsible for chairing the panel and presenting the pertinent facts of the case except when the program office is responsible for the allegation or inspection activity, in which case the program office assumes the role of the regional office.

1. The region should notify participants one week prior to the panel.

2. In addition to OE, the region should notify the NRR, NMSS, or NSIR Enforcement Coordinator, as appropriate. The region should also notify the Assistant General Counsel for Materials Litigation and Enforcement for cases involving civil penalties, willfulness, or other legal issues, as well as the applicable OI investigator and Regional Field Office Director for cases involving willfulness.

3. The regions may choose to conduct internal meetings prior to the scheduled enforcement panel as appropriate. These internal meetings are often useful to review the details of the incident to focus the subsequent panel discussion on the major issues and for the region to develop its position for efficient presentation during the panel call. The OE Enforcement Specialist will participate in these meetings as an observer upon request by the region.

4. It is expected that the region will be represented on the panel call by a person at the Division Director level or higher. It is important to recognize that while the regional participants provide a recommendation to the Regional Administrator, their position does not represent the final region position.

B. OE: To achieve timely decision-making, either the Director, Deputy Director, or Branch Chief, EPPO, will normally participate in panels in addition to the OE Enforcement Specialist.

1. OE should help facilitate discussions and should focus on ensuring that violations are accurate and that strategies are consist with the Enforcement Policy, EGMs, other applicable guidance, and past practice.

C. Program Office: Except when the program office is responsible for the allegation or inspection activity, the program offices should be invited to participate in panels; however, attendance is not mandatory. When the program office is not responsible for chairing the panel:

1. The NRR, NMSS, and NSIR Enforcement Coordinators are responsible for arranging for participation by the appropriate and necessary program office staff and for ensuring that those participating on the panel have briefing materials in advance of the meeting.

2. NRC Manual Chapter 0609, Attachment 0609.01 describes which organization should participate in a SERP.

3. In evaluating the appropriateness of the proposed enforcement strategy, program office participants:

a) Should focus on whether the violations are factually and technically accurate and the enforcement strategy is consistent with the program office's policy, guidance, position, or past practice.

b) Are responsible for elevating their concerns to program office management (the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, and the applicable Division Director for NMSS and NSIR cases), if they disagree with the enforcement strategy discussed during the panel.

D. OGC/OI: OGC (Assistant General Counsel for Materials Litigation and Enforcement) should be invited to panels involving civil penalties, willfulness and other cases with potential issues of legal significance. OI (applicable investigator and Regional Field Office Director) should be invited to panels involving willfulness.

2.12.2 Preparing for Panels

A. In order for enforcement panels to be effective, the regions should ensure that participants are appropriately prepared.

1. The regions should send SDP-related information to OE, the NRR Enforcement Coordinator, and the NSIR Enforcement Coordinator, as appropriate, at least 72 hours in advance of a SERP (see Inspection Manual Chapter 0609 for specific details on SDP-related information).

B. It is recognized that these meetings are conducted during the preliminary stages of the enforcement process; however:

1. Sufficient information should be gathered to support the meeting's purpose, i.e., to discuss the apparent violations, severity levels, violation groupings, escalated history, preliminary civil penalty assessment, etc.

2. If sufficient information is not available, the enforcement panel should be rescheduled.

C. Briefing materials for proposed actions should include:

NOTE:

The regions should send briefing materials to OE (e-mail “OEMail.Resource”), OGC, the NRR, NMSS, and NSIR Enforcement Coordinator, as appropriate. The EDO Regional Coordinator should also receive a copy of briefing materials. The materials should be provided at least 72 hours in advance of the meeting.

1. A draft inspection report (or draft report excerpt or other draft document that addresses the circumstances of the case);

2. Other available information, e.g., an LER;

3. A case summary (the region may use the SERP Panel Worksheet (Panel Worksheet) (included in Appendix D) or comparable summary);

4. A draft NOV, and

5. Factors for the Sanction in Actions Against Individuals (see list of factors in Appendix D), if applicable.

D. Briefing information for an imposition should include the licensee’s response to the proposed civil penalty action and the region’s assessment of it.

E. All briefing materials should be appropriately marked as predecisional information. Briefing materials sent to OE should either be faxed or sent by e-mail to "OEMail.Resource " as well as to the individual OE participants.

2.12.3 Panel Outcome

A. Depending on the discussions in the enforcement panel, the staff will determine one of several outcomes.

1. If the staff concludes that no violation occurred:

a) OE will assign an EA number and document the disposition of the issue by completing the Strategy Form (no violation or SDP finding without a violation).

b) OE will send the form to the region and make it available to the program offices, OI, and OGC, as applicable.

2. If the staff concludes that non-escalated enforcement should be proposed:

a) OE or the regional enforcement specialist will assign an EA number to the case and document the disposition of the issue by completing the Strategy Form (including why an NOV vs. an NCV was issued).

b) OE will send the form to the region and make it available to the program offices, OI, and OGC, as applicable.

c) The regions may generally issue the enforcement action without prior coordination or review with OE.

d) In special cases, OE may request that the action be coordinated or reviewed prior to issuance.

3. If the staff concludes that a predecisional enforcement conference should be conducted, the region should issue the inspection report two weeks prior to the conference. Appendix B contains a template that should be used to develop the transmittal letter.

4. If the staff concludes that a predecisional enforcement conference need not be conducted, but that additional information about the licensee's corrective action is necessary to decide on enforcement action or that a civil penalty is warranted, the region:

a) Should proceed to issue the inspection report requesting a licensee response. Appendix B contains a template that should be used to develop the choice letter.

b) Issue a choice letter, if appropriate:

1) Issuing a choice letter is appropriate where a licensee appears to understand the significance of the violation and the need for corrective action at the inspection exit, but has not informed the NRC inspector of the corrective actions the licensee has taken or plans to take subsequent to the inspection exit. This is more likely to be the case for materials licensees' inspections because inspectors are not stationed at materials facilities.

2) Issuing a choice letter may provide an incentive to the licensee to develop and implement comprehensive corrective actions in order to avoid the possibility of a civil penalty.

c) Following receipt of the licensee's response to the inspection report, the region should:

1) Arrange for OE consultation with the OE Enforcement Specialist assigned to the case; or

2) Schedule another enforcement panel, if warranted.

d) The purpose of the additional consultation or panel is to provide a forum for discussion of:

1) New information or perspectives that have been obtained that may warrant reconsideration of the preliminary enforcement strategy for the case, including whether a predecisional enforcement conference is necessary.

2) The reasonableness of the licensee's corrective action.

e) If the staff concludes that a conference is necessary, the region should arrange for a conference with the licensee as soon as possible.

f) If the staff concludes that a conference is not necessary, the meeting in essence evolves into an enforcement caucus meeting, whereby the staff determines the final enforcement strategy for the case.

5. If the staff concludes that a predecisional enforcement conference need not be conducted and that sufficient information exists to conclude that a civil penalty is not warranted, the region may choose to:

a) Issue the inspection report requesting a licensee response (see Appendix B which contains a template of the transmittal letter that should be used which includes an additional paragraph informing the licensee that a civil penalty does not appear warranted). This approach may reduce resource expenditures by the licensee if the licensee understands in advance that the agency does not plan to issue a civil penalty.

b) Following receipt of the licensee's response to the inspection report, the region should:

1) Arrange for OE consultation with the Enforcement Specialist assigned to the case; or

2) Schedule another enforcement panel, if warranted.

c) The purpose of the additional consultation or panel is to provide a forum for discussion of:

1) New information or perspectives that have been obtained that may warrant reconsideration of the preliminary enforcement strategy for the case, including whether a predecisional enforcement conference is necessary.

2) The reasonableness of the licensee's corrective action.

d) An enforcement conference may be necessary and should be scheduled as soon as possible, if staff concludes that the documented corrective action is not sufficiently prompt and comprehensive such that a civil penalty may be warranted.

1) If the staff concludes that a conference is necessary or if the licensee requests a conference, the region should arrange for a conference as soon as possible. or

2) If the staff concludes that a conference is not necessary, the meeting in essence evolves into an enforcement caucus meeting, whereby the staff determines the final enforcement strategy for the case, i.e., whether the draft NOV should be modified or withdrawn.

e) The region may choose to make a **"choice call"** to the licensee.

1) In such cases, the license will be contacted by telephone and informed that the NRC does not see a need for a predecisional enforcement conference or a written response prior to issuing the enforcement action.

2) During the telephone call, the licensee is provided the option of attending a conference or submitting a written response to the apparent violations in the inspection report (see letter template in Appendix B that should be used to transmit the Notice of Violation (NOV) that documents the telephone conversation).

3) If the licensee indicates during the choice call that it does desire to have a conference or provide a written response before the NRC issues its enforcement action, then the staff should follow the applicable guidance for issuing a choice letter and then reviewing the licensee's response afterwards.

6. If the staff concludes that an additional panel or discussion is necessary:

a) When the staff concludes that an additional panel or discussion is necessary, the original principal panel participants should attend, if possible.

NOTE:

It is not always necessary to hold a new panel to change a past agreement recorded on a Strategy Form. OE management can agree to change an agreement through a consensus decision made during discussions outside the panel process. The decision as to whether to hold an additional panel is based on the complexity of the issue, level of controversy associated with the change, and the estimated impact on resources. For these cases, all effected parties must be included.

1) The other participants, to the extent that they might have information relevant to the issues to be discussed, should also attend, if possible.

2) The original participants need not be present to conduct a subsequent panel or discussion.

b) The region shall make available new information, guidance, or precedent, as applicable that is influencing the discussion to change the enforcement strategy.

c) The region shall update the Enforcement Action Worksheet (EAW) to reflect changes in the regional recommendation.

d) After a subsequent panel, the Strategy Form will be updated noting the outcome of the meeting, including a brief explanation of the reason for any change in enforcement strategy and distributed so that the region, program offices, OI, and OGC are aware of the change and can comment, if desired.

e) Following receipt of the revised Strategy Form, it is the responsibility of the principal participants to verify that the revised strategy is acceptable to the office or region.

1) The principal participants are responsible for discussing, as warranted, changes to previously agreed upon strategy with the prior panel participants from their office or region who may not have been involved in the subsequent panel or discussion.

2) The regional principal participants should discuss, as warranted, the issues with OI.

3) Disagreements with the revised strategy should be handled as discussed in the following paragraph.

7. If, after being briefed on the enforcement panel outcome, the Regional Administrator, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, the Director, OI, the Associate General Counsel for Hearings, Enforcement, and Administration, or the applicable Division Director for NMSS or NSIR cases, disagree on enforcement strategy issues such as severity level, SDP characterization, civil penalty assessment, or whether a predecisional enforcement conference is necessary:

a. These parties should contact the Director, OE, as soon as possible, and no later than 24 hours after receiving OE's summary of the enforcement strategy documented on the Strategy Form.

b. In the case of a regional disagreement, the Regional Administrator and Director, OE should confer and either resolve their differences or promptly escalate the matter to the DEDO. (Depending on the nature of the regional disagreement, OE may include the appropriate program office in the decision making process.)

c. In the case of a program office disagreement, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, or the applicable Division Director for NMSS or NSIR cases, should confer with the Director, OE, and the Regional Administrator to resolve their differences or the Director, OE will promptly escalate the matter to the DEDO responsible for the Enforcement Program.

d. Based on the outcome of these discussions, if warranted, OE will revise the summary of the agreed upon enforcement strategy on the Strategy Form to document the decision.

8. **Re-exiting**: If, as a result of the panel discussion, a substantive change is made to the apparent violations or message given at the exit, a re-exit should be held. This may be done by the branch chief by telephone.

2.13 Documenting Noncompliances

A. Noncompliances (other than minor violations) are normally documented in inspection reports or, in certain cases involving material licensees, inspection records or by using NRC Form 591, "Safety and Compliance Inspection."

NOTE:

If an issue is described in an inspection report in sufficient detail to conclude that a noncompliance has occurred, then that observation **must be dispositioned** as a violation, an apparent violation, or an NCV. To simply document a noncompliance as a "weakness," "licensee failure," "observed discrepancy," or similar characterization without dispositioning, it is inappropriate.

B. Detailed guidance on preparation of inspection reports and use of inspection records is contained in the NRC Inspection Manual, Chapter 0610, "Nuclear Material Safety and Safeguards Inspection Reports," and Chapter 0612 “Power Reactor Inspection Reports.” Inspection Manual, Chapters 0610 and 0612, address thresholds for documentation in inspection reports.

C. The manner in which a noncompliance is documented in an inspection report or inspection records depends on how the noncompliance will be dispositioned.

1. Inspection reports or inspection records must contain a sufficiently detailed discussion of the inspection findings to substantiate the significance and support any enforcement sanction the NRC may choose to issue.

2. The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance.

D. With the exception of inspection reports associated with potential escalated enforcement action, generally inspection reports are to be issued within the timeliness goals established

in Chapters 0610 and 0612 of the Inspection Manual (i.e., 45 calendar days after the completion of an inspection for regional or resident inspector reports or after the completion of an inspection for integrated and major team inspection reports).

E. If a noncompliance has not occurred, to avoid any confusion, it may be appropriate in certain situations to include a statement such as, "this issue does not constitute a violation of NRC requirements."

2.13.1 Documenting Minor Violations

A. Although, in general, minor violations should not be documented, there are a very few exceptions when documentation is warranted.

NOTE:

Minor violations must be corrected and discussed with the licensee (normally during the inspection exit), in general, minor violations should not be documented in inspection reports.

B. Documenting a minor violation may be warranted as part of closing out a Licensee Event Report (LER), where it would be obvious to a member of the public that a violation is involved (e.g., “failure to follow procedures,” in the body of the LER or as part of the title). Documentation, in this case, helps to provide public confidence that the agency has dispositioned the violation.

C. In contrast, documenting a minor violation would not be warranted where a violation is identified because of questions raised by an inspector or because of an inspector’s training and expertise.

D. Documenting a minor violation may be warranted if the associated technical information relates directly to an issue of agency-wide concern (e.g., to document the results of an NRC temporary instruction (TI)).

E. To the extent that minor violations are described, they will be noted as violations of minor significance that are not subject to enforcement action, e.g.:

F. “Although this issue should be corrected, it constitutes a violation of minor significance that is not subject to enforcement action in accordance with Section IV of the Enforcement Policy.”

G. Minor violations are generally not discussed in inspection report cover letters; however, documentation in the inspection report and inspection record should briefly describe the circumstances surrounding the violation. A discussion of the corrective actions is not necessary.

H. If a licensee disputes that a minor violation is a violation, the region should respond by following the procedures in addressing a licensee’s denial of an NCV.

2.13.2 Documenting Non-Cited Violations (NCVs)

A. In accordance with the Enforcement Policy, the NRC may disposition certain Severity Level IV violations and violations associated with green SDP findings as NCVs.

1. NCVs should be discussed in the report details and the summary of findings sections of the report and noted in the inspection transmittal letter in accordance with the following general guidance:

a) Inspection report details should briefly describe the requirement and how the requirement was violated.

1) Even though the issue may warrant disposition as an NCV, the staff must still provide sufficient detail to substantiate the existence of a Severity Level IV violation or violation associated with a green SDP finding (see applicable guidance in Inspection Manual Chapter 0612).

2) Although the degree of detail necessary to support a violation is a function of the significance and the complexity of the noncompliance, the supporting detail for a given Severity Level IV violation or violation associated with a green SDP finding should be the same, whether it is dispositioned as an NOV or NCV.

3) NCVs should be addressed in the inspection report transmittal letter (cover letter) after any cited violations. The discussion should simply note how many NCVs were identified, and include “appeal” process language. Cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.

4) The details of specific NCVs should not normally be discussed in inspection report cover letters. However, there may be instances where a brief discussion of an NCV is warranted, such as cases where categorization at Severity Level III or association with a white issue was seriously considered and where it is important to emphasize the importance of corrective action.

5) Cover letters should not be used as a substitute for an NOV. In particular, cover letters should not generally seek additional information about an NCV.

B. The following discussion provides specific guidance for documenting NCVs:

1. Power Reactor Licensees:

a) The Enforcement Policy provides that most Severity Level IV violations and violations associated with green SDP findings involving a power reactor be dispositioned as NCVs unless they meet one of the exceptions that may warrant citation in an NOV.

b) The inspection report should also include the licensee’s corrective action program file reference.

1) In many cases, the licensee will not have yet developed the corrective actions at the time of the inspection report's issuance.

2) If the inspector is aware of the licensee's corrective actions, he/she may choose to document them in the inspection report.

3) Documentation of the licensee's corrective actions is not required for enforcement purposes. An applicable conclusion should be included that the issue will not be cited, as follows:

"This Severity Level IV violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2.a of the Enforcement Policy. This violation is in the licensee's corrective action program as [Include file reference]."

or

"This violation is associated with an inspection finding that is characterized by the Significance Determination Process as having very low risk significance (i.e., green) and is being treated as a Non-Cited Violation, consistent with Section 2.3.2.a of the Enforcement Policy. This violation is in the licensee's corrective action program as [Include file reference]."

or

"Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2.a of the Enforcement Policy. This violation is in the licensee's corrective action program as [Include file reference]."

2. All Other Licensees:

a) Licensee-identified Severity Level IV violations that satisfy the criteria in the Enforcement Policy may be dispositioned as NCVs.

b) Documentation in inspection reports and inspection records should also briefly describe the corrective actions to provide a basis for a repetitive violation if the corrective actions are inadequate or not implemented.

c) NCVs documented in inspection reports should be cited in inspection reports as NCVs, while NCVs documented in inspection records should be cited as NCVs on NRC Form 591. In both cases, a conclusion should be included that the violation will not be cited, as follows (depending on whether or not the violation was willful):

"This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2.b of the Enforcement Policy."

or

> "Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section 2.3.2.b of the Enforcement Policy."

2.13.3 Documenting Non-Escalated Enforcement Actions

A. Severity Level IV violations and violations associated with green SDP findings that are cited in an NOV may be documented in an inspection report or inspection records and should be addressed throughout the documentation as "violations" versus "apparent violations," (since an actual NOV is included).

NOTE:

For materials licensees, Severity Level IV violations may also be dispositioned through the use of NRC Form 591.

1. The violations should be addressed in the report details and summary of findings, and conclusion sections of the inspection report.

2. Inspection report details should briefly describe the requirement and how the requirement was violated.

3. The staff must provide sufficient detail to substantiate the existence of a Severity Level IV violation or violation associated with a green SDP finding (see applicable guidance in Inspection Manual Chapter 0610). The degree of detail necessary to support a violation is a function of the significance and the complexity of the noncompliance.

4. The cover letter transmitting the non-escalated NOV should be prepared in accordance with the guidance in this Manual and the appropriate cover letter template in Appendix B. The cover letter MUST address why an NOV is being issued in terms of the Enforcement Policy criteria they met.

B. Deviations and nonconformances are generally issued as part of non-escalated enforcement actions and may be documented in inspection reports or inspection records.

1. The deviations or nonconformances should be addressed in the executive summary, report details, observations and findings, and conclusion sections of the inspection report.

2. The cover letter transmitting a Notice of Deviation (NOD) should be prepared using the appropriate cover letter template in Appendix B with appropriate modifications to

reflect the NOD as the enforcement action versus an NOV. NODs involving FSAR issues require the approval of the Director, OE.

3. The cover letter transmitting a Notice of Nonconformance (NON) should also be prepared using the appropriate template in Appendix B.

2.13.4 Documenting Potential Escalated Enforcement Actions

A. Issues being considered for potential escalated enforcement action should be documented in inspection reports (inspection records should not be used) and should refer to the potential noncompliances as "apparent violations" throughout the report and should not include any specific conclusions regarding the safety significance or severity level of the apparent violations or SDP characterizations.

1. The discussion of an apparent violation in the inspection report: Should address the facts supporting the significance of the issue without making any specific conclusions about the "safety significance," e.g., in a particular case involving a procedure violation, it would be appropriate to include the following sentence in the inspection report, "Although the apparent violation of the failure to follow procedures did not result in an actual safety consequence, it could have (under the circumstances) resulted in an overexposure." However, for the same case, it would not be appropriate to say, "The apparent violation of the failure to follow procedures was not safety significant."

a) The latter conclusion does not capture the full set of circumstances of the issue (i.e., that there was a potential safety consequence); and

b) Although this sentence does not specifically include a severity level categorization, the conclusion could be construed as not meeting the threshold for escalated action.

B. The safety significance and severity level or SDP characterization of issues being considered for escalated action is not normally made until after a SERP or enforcement panel, a predecisional enforcement conference or regulatory conference, and SERP or enforcement caucus.

1. A premature conclusion of the safety significance and severity level or SDP characterization for an apparent violation in the inspection report has the potential for confusion if views change based on a subsequent review of the facts.

2. Apparent violations should be addressed in the executive summary, report details, observations and findings, and conclusion sections of the inspection report.

2.13.5 Documenting Violations That Potentially Involve Willfulness

A. The discussion in the inspection report should address the circumstances surrounding the apparent violation without making a conclusion about the intent of the violator.

1. A premature conclusion as to whether an apparent violation is deliberate, willful, or was due to careless disregard, has the potential for confusion if views change based on a subsequent review of the facts.

NOTE:

Inspection reports that include apparent violations that may involve willfulness are to be coordinated with OI. OE should be notified prior to the issuance of the report.

2. Conclusions about the willfulness of an apparent violation represent agency decisions that are normally not made until after OI has performed an investigation and a predecisional enforcement conference has been held, therefore:

   a) It is appropriate to include the following sentence in an inspection report (presuming the facts are clear):

      “Despite informing the inspector that he was aware of the need to use an alarming dosimeter when performing radiography, the radiographer failed to activate his alarming dosimeter."

   b) It is **not** appropriate to include the following sentence:

      "The radiographer deliberately failed to activate his alarming dosimeter."

   c) If during an inspection indications of willfulness are identified, regional management and OI should be promptly notified.

2.13.6 Documenting Violations That Warrant Mitigation Enforcement Discretion

A. For Severity Level I, II, III, or IV violations, the NRC may choose to exercise discretion and refrain from issuing an NOV or civil penalty in accordance with the Enforcement Policy.

B. When discretion is being considered for a violation and the agency has not yet reached a formal enforcement decision, the inspection report narrative should refer to the violation as an “apparent violation.”

C. When the agency concludes that discretion should be exercised for a violation that meets the criteria of the Enforcement Policy, these issues should:

   1. Be documented in inspection reports (inspection records should not be used) as violations.

   2. The cover letter to the licensee should include a reference to the applicable section of the Policy, the severity level of the violations, and a clear basis for exercising this discretion.

2.13.7 Documenting Multiple Examples of a Violation

A. Multiple examples of the same violation during the period covered by an inspection should be included in one citation or NCV. However, inspector judgment must be used to evaluate each example on its own merits to conclude the appropriate manner for dispositioning the issue.

B. When determining whether multiple examples should be cited in a single violation, the following should be considered:

1. Whether different root causes are involved;

2. Whether different corrective actions are necessary to prevent recurrence for the different examples; and

3. Whether the facts of the case warrant separate treatment for factors such as willfulness, actual consequences, or statute of limitations, etc.

C. If the corrective action is similar for multiple examples of violations of the same requirement(s) they:

1. Should generally be cited in a single citation; and

2. An unresolved item from a previous inspection report period that is subsequently resolved to be a violation may be included with examples in a current report period if, in the judgment of the inspector and his/her management, the similarities of the violations reasonably constitute “examples” of the same underlying violation.

D. Even though there may be multiple examples of a violation, each example must be able to stand alone as a separate Severity Level IV violation. As discussed in the following section of this chapter, multiple minor violations must not be aggregated to justify a Severity Level IV violation.

1. Generally, the "contrary to" paragraph should state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc.

2. When the examples of a particular violation are numerous, the NOV should cite representative examples of the highest safety/regulatory significance in order to convey the scope of the violation and provide a basis for assessing the effectiveness of the licensee's corrective actions.

3. Normally three to five examples should be adequate.

2.13.8 Documenting Related Violations

A. The staff should not view the significance of a group of related programmatic violations as being greater than the individual violations (i.e., aggregation). While these issues may be considered in developing the appropriate enforcement action and agency response

(increased inspections, management meetings, etc.), they **should not** be used to increase significance.

B. Violations should not be aggregated for purposes of increasing the significance.

1. In some cases, it may be appropriate to group violations as examples of a **problem**.

> **NOTE:**
>
> Although it may be appropriate to group violations as examples of a problem, violations should not be "**Aggregated**" into a violation/problem of a higher severity level, e.g., assessing several NCVs that are loosely related as a Severity Level IV violation.

a) The reason for grouping violations into a problem is to appropriately characterize the significance of the event or incident.

b) Grouping the violations informs the licensee and the public that NRC is aware that the violations are closely related and are not separate regulatory breakdowns.

c) The staff will need to use judgment in determining whether grouping the violations will convey the appropriate message.

d) When dispositioning violations as a problem, the staff should only group violations that are closely related, such as having a cause and affect relationship or directly related to the same event (e.g., failure to perform adequate testing that results in a piece of inoperable equipment, loss of material and failure to report the loss).

e) The staff can group violations that have the same or different severity levels. When doing so, the problem should be assigned the severity level of the most significant violation.

f) The staff should not assign a severity level to the problem that is higher than the most significant violation (i.e., should not aggregate lower severity level violations into a problem assigned a higher severity level).

2. The cover letter should discuss the significance of each individual violation and the NOV should include all Violation Example activity areas applicable to the violations that are grouped as a problem.

3. When determining the civil penalty for the problem, the staff should follow the civil penalty assessment process for each escalated violation and should not assess a civil penalty higher than would be assessed for the most significant violation included as an example of the problem.

C. The following guidance should be used to determine the significance of a problem and whether a civil penalty is warranted:

1. For Severity Level II violations, identification credit is always considered; however, identification credit is only considered for willful Severity Level III violations or Severity Level III violations committed by a licensee who has had a violation (regardless of the activity area) within the past two years or two inspections.

2. Regardless of other circumstances, (e.g., identification, past enforcement history), the licensee's corrective action should always be evaluated as part of the civil penalty assessment process. When the licensee's corrective action is not prompt and comprehensive, at least a base civil penalty will always be assessed.

3. The following examples illustrate this guidance:

a) Example 1: This problem is composed of a two, non-willful violations, i.e., a Severity Level II violation and a Severity Level III violation, involving a licensee-identified issue where prompt and comprehensive corrective action was taken. The licensee has no history of previous violations within the past two years or two inspections.

The significance of this problem would result in a Notice of Violation involving a Severity Level II problem; however, it would not be assessed a civil penalty because:

1) The severity level of the most significant violation was a Severity Level II;

2) The Severity Level II violation was licensee-identified; and

3) The licensee took prompt and comprehensive corrective actions to address the problem.

b) Example 2: This problem is composed of a two, non-willful violations, i.e., a Severity Level II violation and a Severity Level III violation, involving an NRC-identified issue where prompt and comprehensive corrective action was taken. The licensee has no history of previous violations within the past two years or two inspections.

In this example, the significance of this problem would result in a Notice of Violation involving a Severity Level II problem with a base civil penalty because:

1) The severity level of the most significant violation was a Severity Level II;

2) The Severity Level II violation was NRC-identified; and

3) The licensee took prompt and comprehensive corrective actions to address the problem.

c) Example 3: This problem is composed of a two, non-willful violations, i.e., a Severity Level II violation and a Severity Level III violation, involving an NRC-identified issue where prompt and comprehensive corrective action was NOT taken. The licensee has no history of previous violations within the past two years or two inspections.

In this example, the significance of this problem would result in a Notice of Violation involving a Severity Level II problem with 2 x the base civil penalty because:

1) The severity level of the most significant violation was a Severity Level II;

2) The Severity Level II violation was NRC-identified; and

3) The licensee had failed to take prompt and comprehensive corrective actions to address the problem.

d) Example 4: This problem is composed of two, non-willful Severity Level III violations. The first Severity Level III violation was NRC-identified and, in addition, the licensee had not taken prompt and comprehensive corrective actions to address the problem. The second Severity Level III violation was licensee-identified and, in addition, the licensee had taken prompt comprehensive corrective actions to address the problem. (Although irrelevant in this instance, the licensee has no history or previous violations within the past two years or two inspections.)

In this example, the significance of this problem would result in a Notice of Violation involving a Severity Level III problem with 2 x the base civil penalty because:

1) The severity level of the most significant violation was a Severity Level III;

2) Although one of the violations was licensee-identified, the other violation was NRC-identified; and

3) Although the licensee took prompt and comprehensive corrective actions for the violation it identified, it did NOT take prompt and comprehensive corrective actions for the violation that was NRC-identified.

2.13.9 Documenting Examples of Violations Previously Cited

A. Cases frequently arise in which examples of violations that have been previously cited as NOVs or dispositioned as NCVs, are identified.

B. If corrective actions from the earlier issues have not been completed at the time that the current examples of the same violation(s) become known to the inspection and no broad additional corrective actions are warranted, the current examples do not need to be cited when the current examples, had they been known at the time of the original inspection,

would not have been included in the initial citation to establish the scope and depth of the needed corrective actions.

C. Any inspection report description of the additional examples should include text similar to the following:

"This violation constitutes an additional example of violation XX-YYY/YY-ZZ-01 and is not being cited individually. No additional response to violation XX-YYY/YY-ZZ-01 is required. Further corrective actions for this additional example are expected to be taken in conjunction with corrective actions for the previously cited violation."

2.14 Proper Handling of Predecisional Enforcement Information

A. The NRC staff should discuss the identification of apparent violations with licensees or release inspection reports that document apparent violations to licensees to ensure that corrective actions are initiated to protect the public health and safety and to obtain compliance. However, the NRC staff may not discuss or release predecisional enforcement information to licensees or the public. Predecisional enforcement information includes, but is not limited to:

NOTE:

Release of information that may impact an open OI matter shall be coordinated with OI in advance of its release.

1. The potential severity level of a violation;

2. The proposed amount of a civil penalty; and

3. The nature or context of an order.

B. The release of predecisional information may unnecessarily interfere with the enforcement process and may inappropriately affect licensees or their employees.

1. The premature release of information, other than premature release by clearly inadvertent actions, is a serious matter and may be considered for referral to the Office of the Inspector General (OIG).

2. If predecisional information needs to be released to, e.g., achieve a settlement of an enforcement action or to reach agreement on a confirmatory order, the Director, OE, must be consulted prior to release of such information.

C. Predecisional documents associated with a proposed enforcement action should be clearly marked, "Official Use Only - Predecisional Enforcement Information" until the final enforcement action is issued. Additional information regarding the release of predecisional information is included in Management Directive 3.4, "Release of Information to the Public" (Management Directive 3.4 is currently under revision).

CHAPTER 3
NON-CITED VIOLATIONS AND NON-ESCALATED ACTIONS

Chapter 3 provides information regarding:

- the preparation and processing of non-cited violations (NCVs) and various non-escalated enforcement actions
- the timeliness goals (included in the general discussion for each sanction)

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3. Dispositioning Noncompliances

3.1 Non-Cited Violations (NCVs)

A. **Non-cited Violation** (NCV) is the term used to describe a method for dispositioning:

1. A Severity Level IV violation; and

2. A violation associated with an inspection finding that the Reactor Oversight Process's (ROP) Significance Determination Process (SDP) evaluates as having very low safety significance (i.e., green).

B. NCVs:

1. Are normally public records of the violation;

2. Are normally issued by the region without prior OE approval;

3. Are documented as violations in inspection reports (or inspection records for some materials licensees);

4. Do not require a written response from licensees; and

5. May be sent to the licensee as an attachment to an inspection report or, in the case where inspection records are used to document the noncompliance, as an attachment to the transmittal letter.

3.1.1 NCVs for Power Reactor Licensees

A. The NRC closes NCVs when they are entered into the licensee's Corrective Action Program (CAP) and Plant Issues Matrix (PIM).

NOTE:

Violations at a decommissioned facility that continues to have a 10 CFR Part 50 CAP as well as 10 CFR Part 72 violations that occur at a facility with a 10 CFR Part 50 CAP, should be evaluated under this NCV policy.

1. Licensee may not have completed their corrective actions, identified apparent causes, or developed actions to prevent recurrence when the NRC closes the action.

2. The NRC does not require a written response from licensees describing the actions taken to restore compliance and prevent recurrence of NCVs.

a) The NRC inspection program provides an assessment of the effectiveness of licensees' CAPs and PIMs.

b) This enforcement approach places greater NRC reliance on licensees' CAPs.

B. Licensees are expected to take actions commensurate with the established priorities and processes of their CAP.

C. Unlike other NCVs, for NCVs involving significant conditions adverse to quality (SCAQ), licensees must:

1. Determine the cause of the condition (i.e., the root cause); and

2. Place the corrective actions that will be taken to preclude repetition in their CAP.

3.1.2 Circumstances Resulting in Consideration of an NOV (vs. an NCV) for Power Reactor Licensees

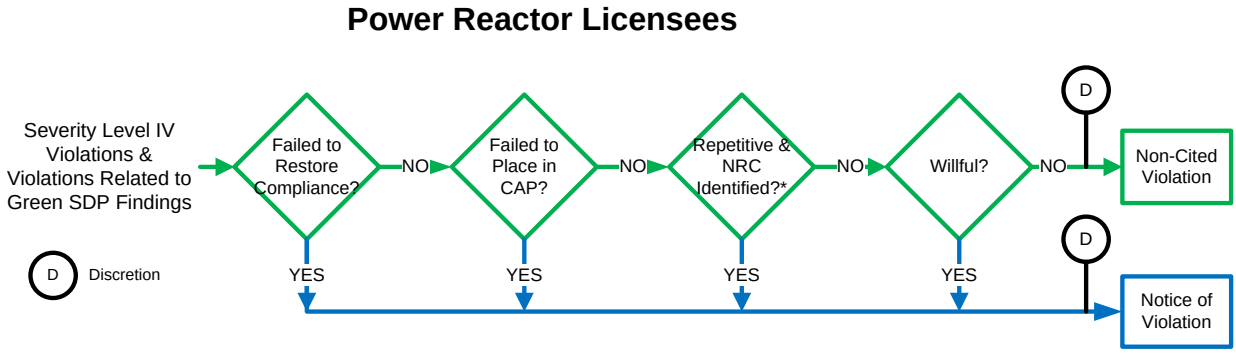

Figure 3-1

Figure 3-1: This flow chart is a graphic representation of the circumstances the staff should consider when deciding whether a violation for a power reactor licensee should be dispositioned as an NCV or in an NOV.

A. Any one of the following circumstances will result in consideration of an NOV which requires a written formal response from a licensee, instead of an NCV:

1. The licensee failed to restore compliance within a reasonable time after a violation was identified.

a) The purpose of this criterion, which applies <u>only</u> to violations that are continuing at the time of discovery (see further discussion below), is to emphasize the need to:

1) Take appropriate action to restore compliance in a reasonable period of time once a licensee becomes aware of the violation; and

2) Take compensatory measures until compliance is restored when compliance cannot be reasonably restored within a reasonable period of time.

b) For purposes of this criterion, **restoring compliance**:

1) Includes those actions taken to stop an ongoing violation from continuing; and

2) Does **not** include those actions necessary to address root causes and prevent recurrence.

c) Some violations require prompt action to restore compliance while others do not based on whether the underlying requirement is continuous or conditional; therefore, **within a reasonable time** in this criterion refers to the time needed to:

1) Stop an ongoing violation from continuing (which should be as soon as possible);

2) Take compensatory actions for a continuing violation; or

3) Be in a state where the requirement no longer applies if relief is not provided from the NRC and if compensatory action is not allowed by the requirement.

NOTE:

Absent an exemption, license amendment, or Notice of Enforcement Discretion (NOED), action must be taken to restore compliance. Until compliance can be restored, compensatory measures, as warranted, must be taken. Restoring compliance is important to prevent an ongoing violation.

2. The licensee did not place the violation into a CAP to address recurrence. (For reactor facilities under construction in accordance with 10 CFR Part 52, the corrective action program must have been demonstrated to be adequate.)

a) The purposes of this criterion are to emphasize the need to:

1) Consider actions beyond those necessary to restore compliance, including actions necessary to address root causes; and

2) Prevent recurrence.

NOTE:

While licensees should develop and place corrective actions to address recurrence in their CAP for all NCVs, licensees are required to develop and place corrective actions directed at preventing recurrence in their CAP for NCVs involving SCAQ issues.

b) Placing a violation into a CAP to address recurrence allows the NRC to close out a violation in an inspection report without detailed information regarding the licensee's corrective actions.

1) The licensee is expected to provide the NRC with a file reference indicating that the violation has been placed in its CAP.

2) The file reference indicating that the violation has been placed in a CAP would assist the NRC should it review the violation as part of an NRC inspection of the effectiveness of the licensee's CAP.

c) An NOV could be avoided for violations which do not require substantial efforts to address recurrence, e.g., an isolated implementation error with more than minor safety significance not reflecting inadequate training, procedures, resources, or oversight, if the CAP includes:

1) Corrective actions to restore compliance;

2) An evaluation of the need for additional corrective actions to address recurrence;

NOTE:

When it is determined that a repetitive violation occurred or corrective actions to address recurrence were not effective, the NOV or NCV should only use 10 CFR Part 50, Appendix B, Criterion XVI, for issues involving SCAQ. This requires additional documentation explaining the basis, usually citing requirements in the licensee's QA plan or topical report.

3) Records that have been maintained for trending so that the licensee has assurance that the matter is, in fact, isolated; and

4) Records so that the NRC can review the case as part of an inspection of the licensee's CAP.

d) While licensees should develop and place corrective actions to prevent recurrence in their CAP for all NCVs, for NCVs involving SCAQ issues, licensees

are required to develop and place corrective actions directed at preventing recurrence in their CAP.

3. The violation is repetitive as a result of inadequate corrective action, and was identified by the NRC. Note: This exception does not apply to violations associated with green SDP findings. (A violation is considered "repetitive" if it could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation. In addition, a violation is considered "repetitive" if a previous licensee finding occurred within the past 2 years of the inspection at issue, or the period between the last two inspections, whichever is longer.)

a) The purposes of this criterion are to emphasize the importance of:

1) Effective corrective action to prevent recurrence; and

2) Licensees identifying recurring issues.

b) For NRC-identified violations, reasonable reviews must be performed to ensure that the current violation is not a repetitive issue before concluding that an NCV is appropriate.

NOTE:

For determining repetitiveness, the fact that the violation has occurred before, is not the only criteria that should be considered. It does not necessarily follow that past corrective action was not reasonable or effective. The question that must be answered is: Did the licensee develop and implement reasonable corrective actions for the previous violation, commensurate with the safety significance, such that at the time the corrective actions were implemented, there was a reasonable expectation that the apparent root cause(s) of the violation would be corrected?

c) To determine whether a violation is repetitive, the staff should:

1) Review the licensee's PIM and Reactor Program System (RPS) because they provide notice to the licensee. These include:

(a) Docketed information which will have put the licensee on notice that it must take corrective action for a noncompliance or that the licensee is on record as having identified a noncompliance issue that requires corrective action (e.g., a Licensee Event Report (LER)); and

(b) Licensee CAP records, only to the extent that the inspector or regional staff had previously described the issue in an inspection report or it was described in other docketed information.

2) Perform a second review if the first review identifies a previous violation, to determine if:

(a) Corrective action for the previous violation had sufficient time to take effect and was deemed inadequate; or

(b) Adequate corrective action for the previous violation wasn't taken in a time frame commensurate with its safety significance.

3) Responses to previous NOVs, inspection reports, or the licensee's CAP should be reviewed. Note: It is acceptable to request background information from the licensee to address this review.

d) The fact that a previous procedural violation occurred does not necessarily mean that the current procedural violation is repetitive:

1) There must be a sufficient nexus between the current issue and the previous corrective action, e.g., the failure to follow a maintenance procedure would not be considered a repetitive procedural violation based on the existence of a failure to follow a radiation protection procedure that occurred one year ago, because it is not reasonable to expect that corrective action for the radiation protection procedural violation (e.g., procedure revision, enhanced training) would have prevented the maintenance procedural violation.

2) For implementation purposes, the determination of whether or not a violation is repetitive need only be made for those violations identified by the NRC.

3) A licensee-identified, non-willful repetitive violation would be cited only if the ineffectiveness of the licensee's CAP is significant enough to raise it to a Severity Level III violation.

NOTE:

The purpose of this criterion is to encourage licensees to identify and correct repetitive issues.

e) In determining whether a violation is repetitive, the fact that a violation recurs does not necessarily mean that past corrective action was not reasonable or effective, i.e., the standard for evaluating the past corrective actions is the *reasonableness* of those actions as they pertain to the nature and significance of the originally identified problem.

1) An NOV would not result if, despite the violation's recurrence, the NRC finds that the licensee's corrective actions for the previous violation were reasonable at the time.

NOTE:

As long as the corrective actions acceptably address the identified causes and no other significant credible causes exist, and the schedule for and actions necessary for implementation of the corrective actions were appropriate, the licensee's past actions should be considered acceptable and the violation should not be considered repetitive.

2) When citing a violation under this criterion, the NRC is expected to be able to address why the licensee's actions were unreasonable and why reasonable corrective action would have prevented the second violation.

f) It is not necessary for the original compliance issue to be documented or labeled a violation by the NRC, e.g., an issue can be considered under this exception if a licensee identifies a compliance issue that requires corrective action in a LER.

g) Unlike other NCVs, for repetitive NCVs involving SCAQ, whether the licensee's corrective actions for the previous violation appeared to be reasonable at the time is not applicable.

1) For NCVs involving SCAQ, licensees are required to implement corrective actions that prevent recurrence.

2) Recurring violations involving SCAQ should be cited as NOVs.

h) The NRC's level of concern about a recurring violation is unrelated to whether it can be cited. In the event a recurring violation is identified and the previous violation was not docketed:

1) The violation should be dispositioned as an NCV;

2) The documentation should note the NRC's concern about its recurrence;

3) The documentation should note that an NOV will be issued if the violation recurs.

4. The violation was willful. Notwithstanding willfulness, an NCV may still be appropriate.

a) The purposes of this criterion are to emphasize the importance of:

1) Integrity and candor in carrying out licensed activities, as expressed in the Enforcement Policy; and

2) Using this criterion only for those situations where the significance of the willfulness does not justify an increase to Severity Level III.

b) Escalated enforcement action would not be considered when:

1) The licensee identified the violation and, although not required to be reported, promptly provided the appropriate information concerning the violation to appropriate NRC personnel, such as a resident inspector or regional branch chief (who, in turn, is responsible to provide the information to the appropriate regional staff);

2) The violation appears to be the isolated action of an employee without management involvement;

3) The violation was not caused by lack of management oversight as evidenced by either a history of isolated willful violations or a lack of adequate audits or supervision of employees; and

4) Significant remedial action commensurate with the circumstances was taken by the licensee that demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's organization. While removal of the employee from licensed activities is not necessarily required, substantial disciplinary action is expected.

3.1.3 Circumstances Resulting in Consideration of an NOV (vs. an NCV) for All Other Licensees

Non-Power Reactor Licensees

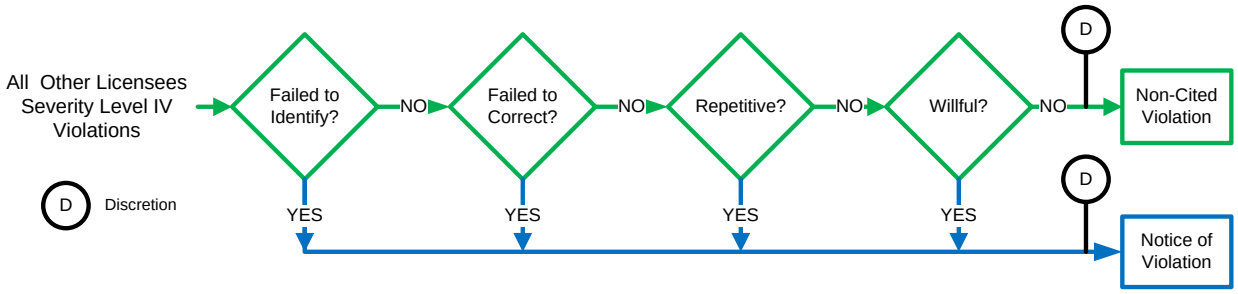

Figure 3-2

Figure 3-2: This flow chart is a graphic representation of the circumstances the staff should consider when deciding whether a violation should be dispositioned as a NCV or in an NOV for all non-power reactor licensees.

A. Any one of the following circumstances will result in consideration of an NOV requiring a formal written response from a licensee.

1. The licensee failed to identify the violation.

NOTE:

Credit for identification is warranted for Severity Level IV violations associated with events unless the staff can show credible actions that clearly should have been, and were not, taken by the licensee in identifying event causes.

a) An NOV is warranted when:

1) A licensee identifies a violation as a result of an event;

2) The root cause of the event is obvious; and

3) The licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event.

b) Disposition as an NCV may be warranted if the licensee demonstrated initiative in identifying the violation's root cause.

NOTE:

In all non-escalated cases involving events where identification credit is being denied, the Division Director must agree with the denial after consultation with the Regional or NMSS Enforcement Coordinator (as appropriate).

c) Typically, the identifiable event is the result of the underlying violation and not a violation itself.

1) Identification credit should be considered when licensee follow-up of the event demonstrates thoroughness in assessing contributing factors, as well as any obvious, direct cause.

2) The standard for the thoroughness of the licensee's actions is reasonableness based on safety significance (see the additional discussion below).

d) Cases where identification credit is denied should be limited to investigations where corrective actions or root causes default to "easy fixes" and the inspectors can demonstrate that other significant, credible causes existed that were not identified by the licensee.

1) Granting of identification credit should be considered for those cases where licensee efforts are thorough enough to rule out the potential for more subtle contributing factors.

2) There are cases where an event is caused simply by an isolated human error with minimal opportunity for prevention or without contributing causes such as

inadequate procedures, labeling errors, lack of resources or supervision, and prior opportunities, and the most obvious cause turns out to be the correct one.

2. The licensee did not correct or commit to correct the violation within a reasonable time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence.

   a) Unless the inspector, in consultation with his or her management, determines that there were other significant, credible causes that were not reasonably addressed in the corrective actions, the licensee's actions should be considered adequate.

NOTE:

If there is a dispute with the licensee on the reasonableness of its corrective actions, the Division Director must concur on any cited violation.

   b) If the licensee's corrective actions are ongoing and the licensee, after input from the inspector or other NRC staff, agrees that additional actions are necessary and states that additional actions will be taken, the licensee should be given credit for corrective action.

   c) If the licensee has previously completed its corrective action and, after input from the inspector or other NRC staff, agrees that additional corrective actions are necessary, then credit for corrective action is not appropriate.

   d) The criteria in the Enforcement Policy requires that "corrective action committed to [by the licensee, must be committed to or completed] by the end of the inspection."

NOTE:

NRC is interested in development of adequate corrective actions which reasonably may require more time after the inspection has been completed.

      1) If a licensee identifies an issue that prompts a reactive inspection, or if a licensee identifies an issue while an inspection is open, the licensee's corrective action may not be fully formulated by the end of an inspection.

      2) Cases where the licensee is implementing its corrective actions but, because of legitimate circumstances, the corrective actions are not fully formulated by the end of the inspection, can create an artificial constraint for assigning an

NCV instead of a cited Severity Level IV violation. Judgment is required in these situations to reasonably accommodate the timing of events.

(a) Denial of an NCV in favor of a cited Severity Level IV violation should not be based solely on undeveloped corrective actions due to the close proximity to the end of the inspection.

(b) If necessary, follow-up discussions via phone with licensees should be made prior to completing the inspection report (or inspection records for those inspections that do not require the issuance of an inspection report) to gain the information needed to make decisions regarding corrective action credit for licensee-identified violations.

3) If the inspection report has to be issued and there has not been a reasonable time for the licensee to develop its corrective actions (but not longer than 30 days from licensee discovery), a potential violation that otherwise meets the criteria for an NCV may be described in the inspection report as an apparent violation and still be converted to NCV status once the corrective action becomes known.

3. The violation is repetitive as a result of inadequate corrective action**.**

a) The violation could reasonably have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred:

NOTE:

Reviews must be performed to ensure that the current violation is not a repetitive issue before exercising this discretion. The expectation for these reviews would include a review of NRC inspection findings, such as inspection reports or inspection records for previous NCVs and NOVs.

1) Within the past two years of the current inspection; or

2) The period within the last two inspections, whichever is longer.

b) Use only docketed information when considering previous NRC violations or licensee findings. This information will have put the licensee on notice that it was required to take corrective action for a violation.

c) For determining repetitiveness, the use of licensee records, such as program audit records or inspection records, is appropriate only to the extent that the issue has already been described in previous inspection reports, NRC Form 591s, or other docketed information.

d) If a violation has not been previously identified in a docketed document, it should be dispositioned as an NCV so that if the licensee's corrective action fails again, an NOV would be warranted at that point.

4. The violation was willful. Notwithstanding willfulness, an NCV may still be appropriate.

a) The purposes of this criterion are to emphasize the importance of:

1) Integrity and candor in carrying out licensed activities, as expressed in the Enforcement Policy; and

2) Using this criterion only for those situations where the significance of the willfulness does not justify an increase to Severity Level III.

b) Escalated enforcement action would not be considered when:

1) The licensee identified the violation and, although not required to be reported, promptly provided the appropriate information concerning the violation to appropriate NRC personnel, such as a resident inspector or regional branch chief (who, in turn, is responsible to provide the information to the appropriate regional staff);

2) The violation appears to be the isolated action of an employee without management involvement;

3) The violation was not caused by lack of management oversight as evidenced by either a history of isolated willful violations or a lack of adequate audits or supervision of employees; and

4) Significant remedial action commensurate with the circumstances was taken by the licensee that demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's organization. While removal of the employee from licensed activities is not necessarily required, substantial disciplinary action is expected.

B. Severity Level IV violations that are dispositioned as NCVs will be described in inspection reports (or inspection records for some materials licensees) and will include a brief description of the corrective action the licensee has either taken or plans to take.

3.1.4 Issuing an NCV When Criteria in Section VI.A of the Enforcement Policy are met for Issuing an NOV

A. Notwithstanding that one of the exceptions in Section VI.A of the Enforcement Policy is met, there may be situations where a Severity Level IV violation or a violation associated with a green SDP finding does not warrant citation in an NOV. These cases:

1. Should be discussed during the regular weekly SERP or enforcement panel conference calls;

2. Require the approval of the Regional Administrator and the Director, OE, prior to issuance; and

3. Should clearly state in the cover letter transmitting the NCV, the reason(s) for not citing the issue notwithstanding the fact that it met one of the defined circumstances identified in Section VI.A of the Enforcement Policy.

3.1.5 NCV Coordination and Review

A. NCVs are normally issued by the region without prior OE approval.

> **NOTE:**
>
> The approval of the Director, OE, with consultation with the DEDO as warranted, is required for dispositioning willful violations as NCVs.

B. Enforcement Coordinators should be consulted on NCVs, as warranted.

C. The Regional Division Director should concur on an NCV prior to issuance if:

1. The Branch Chief and Enforcement Coordinator disagree on the disposition of the issue;

2. The staff is informed by the licensee during the exit interview that it disagrees that the issue is a violation or that the violation warrants Severity Level IV categorization or that the inspection finding warrants green SDP characterization; or

3. The staff wants to exercise discretion and refrain from issuing an NOV beyond the Enforcement Policy.

D. The region must schedule a SERP or enforcement panel if it proposes not to issue an NOV when one or more criteria in Section 2.3.2 of the Enforcement Policy are met for issuing an NOV.

3.1.6 NCV Signature Authority

NCVs should be signed and issued according to the following guidelines:

A. The Director, NRR, and the Director, NSIR, may re-delegate to program office Branch Chiefs and above, the authority to sign and issue NCVs.

B. The Director, NMSS, may re-delegate to program office Section Chiefs and above, the authority to sign and issue NCVs. The Director, NMSS, may re-delegate to qualified

inspectors, the authority to sign and issue NRC Form 591, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

3.1.7 Licensee Denial of NCV

A. Licensees are not required to provide written responses to NCVs; however, they may respond in order to dispute such violations.

B. When the region receives a licensee response that disputes an NCV, and the action did not have an EA number when it was issued, the region should:

1. Request an EA number from OE; and

2. Provide OE with sufficient information to document the issue on a Strategy Form.

C. Depending on whether the licensee (a) denies the violation, or (b) disagrees with the violation, the staff should use the following guidance:

NOTE:

Any errors identified in the NCV must be addressed in the region's response. If a licensee denies a violation based on incorrect information or additional information not previously disclosed, the region should prepare a more detailed response as appropriate.

1. If the licensee **disagrees that an NCV is a violation**, normally the region should:

a) Acknowledge receipt of the denial within 30 days from receipt of the licensee's denial if a response cannot be provided in that time period;

b) Send the acknowledgment letter and the final NRC response to the same person and address as the NCV;

c) Submit its prepared response to the Deputy Director, OE, and OEMail.Resource, within 80 days of receipt of the licensee's denial (or 20 days if the region plans on responding in 30 days). The region's prepared response should include all documents necessary to support the region's position. OE will review the region's response and should provide comments to the region within 10 days of the date of the region's submittal; and

d) Provide a response to the licensee that addresses the licensee's points of contention within 90 days of receipt of the licensee's denial.

D. If the licensee **disagrees with the significance,** the region should:

1. Follow the process described above when the licensee's denial addresses specific NRC guidance (i.e., Manual, Enforcement Policy, or NRC Inspection Manual Chapter (MC) 0612) that would support the violation being categorized as minor.

2. Send an acknowledgment letter when the licensee disagrees with the significance but does not provide justification for its position. The letter should state that the NRC reviewed the licensee's response and has concluded that the licensee did not provide an adequate basis to reclassify the violation; therefore, the NRC maintains that the violation occurred as stated.

NOTE:

Any errors identified in the NCV must be addressed either in a formal response or an acknowledgment letter.

E. Provide a subject line in the response to the licensee's denial as follows:

1. If the NRC maintains that the NCV remains valid, the subject line should read," RESPONSE TO DISPUTED NON-CITED VIOLATION."

2. If the region concludes that a second, revised NCV should be issued, the subject line should read, "REVISED NON-CITED VIOLATION."

3. If the region concludes that the violation should be withdrawn, the subject line should read, "WITHDRAWAL OF NON-CITED VIOLATION."

3.2 Non-Escalated Notice of Violation (NOV)

A. A **Notice of Violation** (NOV) is a formal written citation setting forth one or more violations of a legally binding requirement. Procedures for issuing an NOV are set forth in 10 CFR 2.201.

B. NRC Form 591 may also be used as an NOV for materials licensees under certain circumstances.

C. The timeliness goal for issuing routine non-escalated NOVs is the same as for issuing clear inspections (i.e. 45 calendar days after the inspection has been completed (see MC 0610 and MC 0612).

D. NOVs should be considered for Severity Level IV violations and violations associated with green SDP findings when they meet the criteria discussed in the previous section.

3.2.1 Preparing a Non-Escalated NOV Action

A. The responsible office, i.e., the region, NRR, NMSS, or NSIR, should prepare a non-escalated NOV package, including the following elements as discussed below:

1. Inspection reports should be prepared in accordance with the guidance in MC 0610, MC 0612, MC 87100, and the guidance in this Manual.

2. NOVs should be prepared by using the applicable standard formats in Appendix B and the applicable standard citations in Appendix C.

3. NOVs should be dated the same date as the cover letter transmitting the enforcement action to the licensee.

4. NOVs should include the following elements:

   a) A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (i.e., the legal citation for the violation) (see the examples of standard citations in Appendix C).

   b) A brief statement (usually no more than a few sentences) addressing the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.

   c) Each violation, including a violation with multiple examples, should contain a single "contrary to" statement.

      1) As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation.

      2) The "contrary to" paragraph should generally state the violation, followed by "...as evidenced by the following examples" and the examples delineated as 1, 2, 3, etc.

      3) When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples is adequate.

   d) The severity level proposed for the violation (i.e., Severity Level IV) and the applicable Violation Examples section of the Enforcement Policy under which the violation is categorized or, alternatively, the significance of the violation associated with a SDP finding (i.e., green SDP finding).

   e) If the staff concludes that a response is necessary, the letter should contain the elements to be included in the licensee's response, including:

      1) The reason for the violation, or if contested, the basis for disputing the violation;

2) The corrective actions that have been taken and the results achieved;

3) The corrective actions that will be taken to avoid further violations; and

4) The date when full compliance will be achieved.

f) The staff may conclude that a response is not necessary.

1) The staff may indicate that the licensee is not required to respond because the information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence are already addressed on the docket.

2) This alternative requires the licensee to respond if the description does not accurately describe the licensee's corrective actions.

B. Cover letters that transmit inspection reports and non-escalated NOVs to licensees should be prepared by the region using the appropriate form in Appendix B.

1. If an inspection report is not issued, as may be the case for certain material licensees, then all references to an inspection report should be deleted.

2. Cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.

3. NRR and NMSS should use the appropriate form for vendor and approved Quality Assurance cases, respectively.

C. Cover letters should:

1. Clearly state why a citation is being issued in terms of which criteria in Section VI.A of the Enforcement Policy has been met. The explanation may be expanded, where warranted, to convey the appropriate message to the licensee in terms of those actions that require additional attention;

2. Provide an explanation of why a citation is being issued if, using the guidance in the Enforcement Policy and this Manual, the violation could have been dispositioned as an NCV;

3. Describe the response that is necessary from the licensee (if the region concludes that a response is necessary), including any area that deserves special emphasis; or

4. Include a conclusion that a licensee response is not necessary (when the region concludes that a response is not necessary), including a provision that the licensee must respond if its understanding of the corrective action is different; and

5. Address, if applicable, any apparent violations being considered for escalated enforcement action and the scheduling of a predecisional enforcement conference.

3.2.2 Issuing a Non-Escalated NOV Beyond the Criteria in Section 2.3.2 of the Enforcement Policy

A. Although it should rarely happen, this section provides guidance for situations when, notwithstanding the outcome of the normal process for dispositioning Severity Level IV violations and violations associated with green SDP findings, the staff chooses to exercise discretion (represented in the flowchart by the letter “D” in a circle) and issue an NOV.

B. For reactor cases:

1. The Director, OE, and the EDO must approve the action;

2. The action requires an EA number; and

3. OE will coordinate the action with NRR.

C. For materials cases:

1. OE must be consulted (by telephone or email is normally sufficient) prior to issuance of the NOV; and

2. The action requires an EA number.

D. The cover letter transmitting the NOV must clearly state the reason for issuing the NOV, notwithstanding that it was not one of the defined circumstances identified in Section VI.A of the Enforcement Policy.

3.2.3 Non-Escalated NOV Coordination and Review

A. Non-escalated NOVs should be coordinated and reviewed according to the following guidelines:

1. Non-escalated NOVs for materials cases are normally issued by the regions or appropriate program office without prior consultation or review and approval by OE (see the exceptions noted below);

2. Regional Enforcement Coordinators should be available for consultation on non-escalated NOVs for materials licensees and should concur on non-escalated NOVs involving power reactors;

3. The Regional Division Director must concur on non-escalated NOVs involving power reactors;

4. The Regional Division Director must concur on non-escalated NOVs involving materials licensees if there is a dispute with the licensee on the reasonableness of its corrective actions;

5. In all Severity Level IV NOVs for materials licensees involving events where identification credit is being denied, the Division Director must agree with the denial after consultation with the Regional or NMSS Enforcement Coordinator (as appropriate);

B. Non-escalated NOVs that must be coordinated with OE (by telephone or e-mail) to support issuance of an EA number prior to issuance include:

1. Licensee-disputed violations, violations of 10 CFR 50.59, violations of 10 CFR Part 55, or violations of 10 CFR 50.65 that **can be resolved** via coordination between the involved offices;

2. Any actions resulting from an Augmented Inspection Team (AIT), Diagnostic Evaluation Team (DET), or Incident Investigation Team (IIT) inspection;

3. Any actions related to currently proposed escalated enforcement actions;

4. Any case in which a Notice of Enforcement Discretion (NOED) is issued, and the root cause that results in the need to request the NOED was a Severity Level IV violation or violation associated with a green SDP finding warranting citation in an NOV; and

5. Any actions involving the loss or failure to control or account for licensed material.

C. Non-escalated NOVs that must be coordinated with OE (through a SERP or enforcement panel) prior to issuance include:

1. Any actions based on willful violations or an OI investigation;

2. Any actions involving an individual (other than an individual licensed by 10 CFR Parts 30, 40, and 70);

3. Any non-escalated enforcement action which, by the examples in the Violation Examples section of the Policy, could be categorized at Severity Level I, II or III or characterized as red, yellow, or white by the SDP;

4. Licensee-disputed violations, violations of 10 CFR 50.59, violations of 10 CFR Part 55, or violations of 10 CFR 50.65 that **cannot be resolved** via coordination between the involved offices;

5. Any actions the regions believe warrant headquarters' review; and

6. Any actions that the Director, OE, believes warrant headquarters' review prior to issuance, such as violations that were the subject of predecisional enforcement conferences or regulatory conferences where the Director, OE, requests OE review.

D. The approval of the DEDO is required for issuing a non-escalated NOV beyond the defined exceptions in Section 2.3.2 (see the discussion below).

E. The region should send OE a copy of all non-escalated NOV packages with EA numbers after it has issued the action.

3.2.4 Non-Escalated NOV Signature Authority

A. Non-escalated NOVs should be signed and issued according to the following guidelines:

1. The Regional Administrator has the authority to sign all non-escalated NOVs issued in the region. Except as noted in the preceding section, the Regional Administrator may re-delegate to Branch Chiefs and above, the authority to sign and issue non-escalated NOVs issued in the region. In addition, the Regional Administrator may re-delegate to qualified inspectors, the authority to sign and issue NRC Form 591, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

2. The Director, NRR, and the Director, NSIR, may re-delegate to Branch Chiefs and above, the authority to sign and issue non-escalated NOVs involving vendors and non-power reactors.

3. The Director, NMSS, may re-delegate to Section Chiefs and above, the authority to sign and issue non-escalated NOVs for which NMSS evaluates, directly manages, or conducts inspections. The Director, NMSS, may re-delegate to qualified inspectors, the authority to sign and issue NRC Form 591, subject to the review and approval requirements specified in the appropriate inspection manual chapter.

4. When a predecisional enforcement conference is held and does not result in an escalated action, the non-escalated action will normally be signed at the level of the individual who conducted the conference.

3.2.5 Licensee Notification, Mailing, and Distribution for Non-Escalated NOVs

A. Licensees, States, and ADAMS (PARS) are normally sent a copy of the non-escalated NOV at the time the inspection report is issued.

1. The mailing and distribution of the inspection report NOV is controlled by regional procedures.

2. OE receives copies of all non-escalated enforcement actions through the Document Control System.

3. Copies of non-escalated NOVs issued by the program offices should be sent to the appropriate regional office. In addition, for non-escalated NOVs issued to Agreement State licensees, a copy should be sent to the Agreement State and to the appropriate Regional State Agreements Officer(s) of the appropriate region or regions.

3.2.6 Licensee Response to a Non-Escalated NOV

A. If the staff concludes that a licensee response is necessary, the provisions of 10 CFR 2.201 require that a licensee submit a written response to an NOV within 20 days of the date of the NOV or other time specified in the NOV. Normally 30 days should be used.

B. If a licensee does not respond to an NOV within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the NOV). Consideration will be given to whether additional enforcement action is warranted.

C. Licensees may be granted response extensions where good cause is shown.

1. The region may grant extensions of up to 30 days without OE approval.

2. OE should be promptly notified of any extensions the region grants.

3. OE approval is required for extensions beyond 30 days.

4. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due.

a). The confirmation may either be prepared by the NRC or the licensee.

b). A copy of this follow-up correspondence is to be sent to OE and the region.

D. Depending on whether the licensee (a) accepts the violation, (b) denies the violation, or (c) disagrees with the significance, the staff should use the following guidance:

1. If the licensee does not dispute that the violation occurred as stated in the NOV, the regional office should:

a). Review the licensee's response for the adequacy of the corrective action, including whether the licensee has properly identified the root causes;

b). Request additional information from the licensee, if necessary;

c). Acknowledge the licensee’s response within 30 days of its receipt;

d). Send the acknowledgment letter to the same person and address to which the NOV was sent, with a copy to ADAMS (PARS) and the docket file. (Note: The acknowledgment letter does not require full distribution.)

2. If the licensee denies the violation, the regional office should:

a). Acknowledge receipt of the denial within 30 days from receipt of the licensee’s denial if an NRC response cannot be provided in that time period;

b). Send the acknowledgment letter and the final NRC response to the same person and address as the NOV.

NOTE:

Any errors identified in the NOV must be addressed in the region's response. If the licensee denies the violation based on incorrect information or additional information not previously disclosed, the region should prepare a more detailed response as appropriate.

c). Submit its prepared response to the Deputy Director, OE, (and OEMail.Resource) within 80 days of receipt of the licensee's denial (or 20 days if the region plans on responding in 30 days). The region's prepared response should include all documents necessary to support the region's position. OE will review the region's response and should provide comments to the region within five days of the date of the region's submittal.

d). Provide a response that addresses the licensee's points of contention, within 90 days of receipt of the licensee's denial.

3. If the licensee disagrees with the significance, the region should:

a). Follow the process described above when the licensee's denial addresses specific NRC guidance (i.e., Manual, Enforcement Policy, or MC 0612) that would support the violation being categorized as minor.

NOTE:

Any errors identified in the NOV must be addressed either in a formal response or an acknowledgment letter.

b). When the licensee disagrees with the significance of the violation but does not provide justification for its position, send an acknowledgment letter stating that the NRC reviewed the licensee's response and concluded that the licensee did not provide an adequate basis to reclassify the violation; therefore, the NRC maintains that the violation occurred as stated.

4. The subject line in the response to the licensee's denial should appropriately describe the agency's response as follows:

a). If the NRC maintains that the NOV remains valid, the subject line should read," RESPONSE TO DISPUTED NOTICE OF VIOLATION."

b). If the region concludes that a second, revised NOV should be issued, the subject line should read, "REVISED NOTICE OF VIOLATION."

c). If the region concludes that the violation should be withdrawn, the subject line should read, “WITHDRAWAL OF NOTICE OF VIOLATION.”

3.3 Notice of Deviation (NOD)

A. A Notices of Deviation (NOD) is a written notice to a licensee describing its failure to satisfy a commitment that is not a legally binding requirement.

1. Although an NOD is considered an administrative mechanism, it is processed as a non-escalated enforcement action.

2. A NOD is normally sent to the licensee as an attachment to an inspection report.

B. The timeliness goal for issuing a routine NOD is the same as for issuing clear inspections (i.e., 21 calendar days after the inspection has been completed; 30 days for team inspections (see MC 0610 and MC 0612).

3.3.1 Preparing an NOD Action

A. The regions should prepare an NOD action package, using the applicable standard format provided in Appendix B. NODs should be dated the same date as the transmittal letter to the licensee.

1. The NOD should include the following elements:

a). Inspection reports which should be prepared in accordance with the guidance in MC 0610 and MC 87100 and the guidance provided in this Manual;

NOTE:

NODs are considered non-escalated enforcement actions, therefore, they normally do not need to be coordinated with OE prior to issuance; however, NODs involving the FSAR require the approval of the Director, OE.

b). A concise, clear statement of the applicable commitment;

c). A brief statement (usually no more than a few sentences) addressing the circumstances of the deviation, including the date(s) of the deviation and the facts necessary and sufficient to demonstrate that the commitment was not met ("contrary to" paragraph).

1). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the commitment.

2). Each deviation, including a deviation with multiple examples, should contain a single "contrary to" statement;

2. As a general rule, multiple examples of the same deviation during the period covered by an inspection should be included in one citation.

a). The "contrary to" paragraph should generally state the deviation, followed by "...as evidenced by the following examples" and the examples delineated as 1, 2, 3, etc.

b). When the examples of a particular deviation are numerous, sufficient examples should be cited to convey the scope of the deviation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples is adequate.

3. The NOD should also include:

a). A request for the licensee to provide a response which includes the reasons for the deviation;

b). The corrective actions which will be taken to avoid further deviations; and

c). The date when the corrective actions will be completed.

B. Cover letters that transmit inspection reports and NODs should be prepared by the region using the appropriate form in Appendix B modified to distinguish an NOD from an NOV.

3.3.2 Licensee Notification, Mailing, and Distribution for NODs

A. Licensees are normally sent NODs at the time an inspection report is issued. NODs are made available to the Public in accordance with agency procedures. The mailing and distribution of the inspection report and NOD are controlled by regional procedures.

B. NOVs should be used for certificate holders who fail to meet requirements directly imposed on them by the NRC and for vendors who violate 10 CFR Part 21 requirements or other requirements directly imposed on them by the NRC.

3.4 Notice of Nonconformance (NON)

A. A **Notice of Nonconformance** (NON) is a written notice to a vendor or certificate holder describing its failure to meet commitments related to NRC activities. These commitments are normally contained in contract requirements and are not directly imposed on the vendor or certificate holder by the NRC.

B. An NON is considered an administrative mechanism and is processed as a non-escalated enforcement action. An NON is normally sent to the vendor or certificate holder as an attachment to an inspection report.

C. The timeliness goal for issuing a routine NON is the same as for issuing clear inspections (i.e., 21 calendar days after the inspection has been completed; 30 days for team inspections (see MC 0610 and MC 0612).

3.4.1 Preparing a NON Action

A. NON actions should be prepared by:

1. The NRR staff responsible for vendor cases; or

2. The NMSS staff responsible for shipping package transportation cases.

B. NONs are dated the same date as the cover letter transmitting the action to the vendor or certificate holder.

C. The NON should include the following elements:

1. Inspection reports which should be prepared in accordance with the guidance in MC 0610 and MC 87100 and the guidance provided in this Manual;

2. A concise, clear statement of the applicable requirement or requirements, appropriately referenced, paraphrased, or quoted;

3. A brief statement (usually no more than a few sentences) addressing the circumstances of the nonconformance, including the dates of the nonconformance (if possible to determine) and the facts necessary to demonstrate that one or more of the requirements were not met ("contrary to" paragraph).

NOTE:

Because an NON is considered a non-escalated enforcement action, it does not need to be coordinated with OE prior to issuance.

a). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.

b). Each nonconformance, including a nonconformance with multiple examples, contains a single "contrary to" statement;

4. As a general rule, multiple examples of the same nonconformance during the period covered by an inspection should be included in one citation.

a). The "contrary to" paragraph should generally be followed by "...as evidenced by the following examples:" and examples delineated as 1, 2, 3, etc.

b). When the examples of a particular nonconformance are numerous, sufficient examples should be cited to convey the scope of the nonconformance and to provide a basis for assessing the effectiveness of the corrective actions. Normally three to five examples is adequate.

5. A request for the vendor or certificate holder to provide a response which includes a description of the actions taken or planned to correct the nonconformances, the actions taken or planned to prevent recurrence, and the date when the corrective actions were or will be completed.

D. Cover letters that transmit inspection reports and NONs should be prepared using the appropriate form in Appendix B.

3.4.2 Notification, Mailing, and Distribution of NONs

Vendors or certificate holders are normally sent NONs at the time an inspection report is issued. NONs are made available to the Public in accordance with agency procedures.

3.5 Confirmatory Action Letter (CAL)

A. **Confirmatory Action Letters** (CALs) are letters issued to licensees or vendors to emphasize and confirm a licensee's or vendor's agreement to take certain actions in response to specific issues. The NRC expects licensees and vendors to adhere to any obligations and commitments addressed in a CAL.

B. CALs should only be issued when there is a sound technical and/or regulatory basis for the desired actions discussed in the CAL.

1. CALs must meet the threshold defined in the Enforcement Policy, i.e., "to remove significant concerns about health and safety, safeguards, or the environment."

NOTE:

The level of significance of the issues addressed in a CAL should be such that if a licensee did not agree to meet the commitments in the CAL, the staff would likely proceed to issue an order.

2. CALs should be limited to those cases where the issues involved clearly meet the threshold described in the preceding paragraph.

C. Even though a CAL by definition confirms an agreement by the licensee to take some described action, it may, at times, require some negotiation with the licensee prior to issuance.

1. The licensee must agree to take the action.

2. Once a CAL is agreed upon, the licensee is expected to take the documented actions and meet the conditions of the CAL.

D. A CAL may be issued when a materials licensee is violating a particular license condition, but the license condition prescribes neither the action nor the timeliness for restoring compliance as would be prescribed by a reactor licensee's technical specification action statement.

1. A CAL would be useful in this type of situation to confirm compensatory actions which, if implemented, would ensure safety such that an immediate suspension of licensed activities might not be necessary.

2. The use of a CAL in this situation is generally reserved for materials licensees.

3. A NOED would be the appropriate tool for reactor licensees and gaseous diffusion plants if the issue is addressed by a license or certificate condition.

NOTE:

CALs are flexible and valuable tools available to the staff to resolve licensee issues in a timely and efficient manner, e.g., when an order is warranted to address a specific issue, a CAL is a suitable instrument to confirm initial, agreed upon, short-term actions covering the interval period prior to the actual issuance of the order.

E. CALs may be issued to confirm the following types of actions (note that this is not an exhaustive list):

- In-house or independent comprehensive program audit of licensed activities
- Correction of training deficiencies, e.g., radiological safety, etc.
- Procedural improvements
- Equipment maintenance
- Equipment operation and safety verification
- Voluntary, temporary suspension of licensed activities
- Licensee’s agreement to NRC approval prior to resumption of licensed activities
- Root cause failure analyses
- Improved control and security of licensed material

F. On occasion, licensees elect to submit letters to the NRC addressing actions that they intend to take in reaction to safety issues.

1. Depending on the significance of the issues involved, the staff may elect to issue a brief CAL accepting the licensee’s letter and commitments; however, this practice should not be routine.

2. CALs should be limited to those cases where the issues involved clearly meet the threshold for issuing a CAL discussed above.

G. CALs may be used to confirm that a licensee will adhere to existing provisions.

1. CALs should not be used to remove an individual from, or restrict his or her ability to perform, licensed activities. Such action normally requires an order, not only to ensure enforceability, but because individual rights are affected and the opportunity for a hearing must be given both to the licensee and the affected individual.

NOTE:

The issuance of an order, in lieu of a CAL, should be considered whenever there is a need to ensure that a legally binding requirement is in place. Orders must be coordinated between the regional office, the appropriate program office, OGC, and OE.

2. Orders should be issued instead of CALs in the following situations:

a). When it is apparent that the licensee will not agree to take certain actions that the staff believes are necessary to protect public health and safety and the common defense and security;

b). When there is an integrity issue;

c). When there is some likelihood that a licensee may not comply with a CAL commitment; or

d). When the staff has concluded that the CAL will not achieve the desired outcome.

3.5.1 Noncompliance with CALs

A. CALS do not establish legally binding commitments with the exception of the reporting provisions contained in Section 182 of the Atomic Energy Act, as amended (AEA) and its implementing regulations which require a licensee to notify the NRC when:

1. The licensee's understanding of its commitments differs from what is stated in a CAL;

2. The licensee cannot meet the corrective actions schedule; and

3. The licensee's corrective actions are completed.

B. Failure to provide the reports required by Section 182 of the AEA may be treated like any other violation of a legally binding requirement.

C. Failure to meet a commitment in a CAL can be addressed through;

1. An NOD;

2. An order where the commitments in a CAL would be made NRC requirements; and

3. A Demand For Information (DFI) where the licensee's performance, as demonstrated by the failure to meet CAL commitments, does not provide reasonable assurance that the NRC can rely on the licensee to meet the NRC's requirements and protect public health and safety or the common defense and security.

D. Issuance of a CAL does not preclude the NRC from taking enforcement action for violations of regulatory requirements that may have prompted the issuance of the CAL. Such enforcement action is intended to:

1. Emphasize safe operation in compliance with regulatory requirements; and

2. Clarify that the CAL process is not a routine substitute for compliance.

E. The NRC would not normally take additional enforcement action for those violations that continue after a CAL has been issued where compensatory actions have been accepted by the NRC and taken by the licensee in accordance with its commitments.

3.5.2 Preparing a CAL

A. CALs should be prepared using the appropriate form in Appendix B and should include the following elements:

1. A brief discussion of the specific issues with which the NRC has concern, including how and when they were identified.

2. A brief statement summarizing NRC/licensee communication on the agreed-upon actions.

a). The statement should include when the communication took place, the names and positions of the principal individuals involved in the communication, and whether the communication took place in a telephone conversation or a face-to-face meeting.

b). Face-to-face meetings should also include the location of the meeting (i.e., regional office, licensee's facility).

3. A clear description of the agreed-upon actions and where warranted and appropriate, the date(s) when actions will be completed.

4. A statement that requires the licensee to provide written notification to the NRC if its understanding of the relevant issues and commitments differ from what is stated in the CAL.

5. A statement that requires the licensee to provide written notification to the NRC if for any reason it cannot complete the actions within the specified schedule. It should also require that the licensee inform the NRC of the modified schedule.

6. A statement that requires the licensee to provide written notification to the NRC if it intends to change, deviate from, or not complete any of the documented commitments, prior to the change or deviation.

7. A statement that requires the licensee to provide the NRC with written confirmation of completed actions.

8. A statement that issuance of the CAL does not preclude issuance of an order formalizing the commitments in the CAL or requiring other actions nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of the CAL.

9. A statement that failure to meet the commitments in a CAL may result in an order if the licensee's performance, as demonstrated by the failure to meet CAL commitments, does not provide reasonable assurance that the NRC can rely on the licensee to meet the NRC's requirements and protect public health and safety or the common defense and security.

10. A statement that the letter and any licensee response will be made available to the Public.

11. Citation of the regulation implementing Section 182 of the AEA and authorizing the required responses to the CAL by the licensee.

3.5.3 CAL Coordination and Review

A. CALs should be coordinated and reviewed according to the following guidelines:

1. CALs issued by the region must be coordinated with the appropriate program office by telephone prior to issuance.

   a). Unless NMSS requests, CALs issued to materials licensees do not require NMSS concurrence.

   b). CALs issued to reactor licensees must be concurred on by the Director, NRR.

   c). Because NSIR is responsible for coordinating security assessment activities across the spectrum of NRC licensees, CALs issued to NRC licensees which include security-related provisions, must be concurred on by the Director, NSIR.

2. Regional Enforcement Coordinators should be consulted before the region issues a CAL.

3. Applicable Program Office Enforcement Coordinators should be consulted before the program office issues a CAL.

NOTE:

CALs should not be used to remove an individual from, or restrict his or her ability to perform, licensed activities. Such action normally requires an order, not only to ensure enforceability, but because individual rights are affected and the opportunity for a hearing must be given both to the licensee and the affected individual.

4. CALs issued by NRR, NMSS, or NSIR, must be coordinated with the appropriate region. This coordination will help to provide consistency between the regions and program offices in response to similar issues and provide program oversight and assistance.

5. Unless OE requests, CALs do not need to be coordinated with or concurred in by OE.

3.5.4 CAL Signature Authority

CALs should be signed and issued according to the following guidelines:

A. The Regional Administrator should sign all CALs issued by the region. Delegation of signature authority should not be below the Division Director or acting Division Director level.

B. The Director, NRR, the Director, NMSS, or the Director, NSIR, should sign all CALs issued by NRR, NMSS, or NSIR, respectively. Delegation of signature authority should not be below the Division Director or acting Division Director level.

3.5.5 Licensee Notification, Mailing, and Distribution for CALs

A. CAL distribution:

1. CALs should be sent to the licensee by either Certified Mail (Return Receipt Requested) or Express Mail.

2. Upon issuance, CALs should be distributed to:

- OE
- The appropriate Deputy EDO
- The appropriate program office (i.e., NRR, NMSS, or NSIR)
- The appropriate region
- The appropriate Regional Public Affairs Officer
- The Regional State Liaison Officer

- The State
- For material licensees, a copy should be sent to the Regional State Agreements Officer

3. CALs should, where possible, be made available to the Public.

B. The staff should be sensitive to describing agreed upon licensee corrective actions that involve safeguards matters to prevent inadvertent release of safeguards information.

3.5.6 CAL Tracking Responsibilities

A. The issuing office (i.e., region, NRR, NMSS, or NSIR) is responsible for tracking the CALs it has issued and should maintain a list summarizing the following information suitable for auditing actions associated with CALs, including:

1. How many CALs have been issued;

2. To whom the CAL has been issued;

3. Why the CAL was issued, i.e., a brief description of the issues; and

4. When all corrective actions were or will be completed.

B. CAL tracking numbers will be assigned as follows:

1. The region will assign CAL tracking numbers based on the region number, the year of issuance, and the sequential CAL number in that region for that year (e.g., 2-06-008).

2. NRR, NMSS, and NSIR will assign CAL tracking numbers in the same manner as the regions, e.g., NRR-06-006, NMSS-06-003, NSIR-06-002.

3. In cases where NSIR has the lead for the enforcement action, NSIR may, with agreement from NMSS or NRR as applicable, use the tracking system of the Office responsible for the license.

C. Addendums to CALs should retain the same CAL number followed by an alphabetical reference based on the corresponding addendum for that CAL (e.g., 2-00-008A, NRR-00-006B).

3.5.7 Closing Out CALs

A. A CAL may or may not require follow-up inspection to verify completion of the specified licensee actions. Whether the staff believes that an inspection is necessary to close a CAL will be determined on a case-by-case basis and will depend on the circumstances of the case.

B. The issuing office (i.e., region, NRR, NMSS, or NSIR) will issue documentation formally closing out the CAL.

C. Correspondence closing out a CAL should be sent to the same person/address as the CAL; however, verbal notification, in advance of written correspondence, may be sufficient to permit plant restart or resumption of affected licensee activities.

3.5.8 Press Releases for CALs

Press releases are not routinely issued to address the issuance of a CAL. If a region believes that a press release is appropriate, it should be coordinated with Public Affairs which will make that determination.

CHAPTER 4
ESCALATED ENFORCEMENT ACTIONS

Chapter 4 provides guidance regarding:

- the use of caucuses, panels, and conferences in the enforcement process
- escalated enforcement actions that can be taken
- the criteria to be used to determine whether a civil penalty should be proposed
- settlement of enforcement proceedings and actions

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4. Escalated Enforcement Actions

4.1 Predecisional Enforcement Conferences and Regulatory Conferences

A. **Predecisional Enforcement Conferences (PECs)** are normally open meetings between the NRC and a licensee, vendor, or other person when the NRC has initially determined that escalated enforcement action is being considered.

B. **Regulatory Conferences** are normally open meetings between the NRC and reactor licensees to discuss issues that the SDP assessment determines to be potentially risk significant (i.e., red, yellow, or white), whether or not violations are involved.

1. Because the significance assessment from the SDP determines whether or not escalated enforcement action will be issued (i.e., a Notice of Violation (NOV) associated with a red, yellow, or white SDP finding), a subsequent predecisional enforcement conference is not usually necessary.

2. Although regulatory conferences are similar to predecisional enforcement conferences in many respects, specific guidance for regulatory conferences is included in NRC Inspection Manual Chapter (MC) 609.

C. The decision to hold a PEC or a Regulatory Conference with enforcement implications does not mean the agency has concluded that a violation has occurred or that enforcement action will be taken.

NOTE:

The regions should send meeting notices for regulatory conferences with enforcement implications to " OEMail.Resource " and "OEWeb.Resource." The regions are responsible for ensuring that these conferences are posted on the agency's public meeting schedule Web Site.

D. The purpose of the conference is to obtain information necessary for the NRC to reach a final enforcement decision, e.g.:

1. A common understanding of the facts of the case, including whether a violation occurred, and if so, its root causes, and any missed opportunities to identify the violation sooner;

2. A common understanding of corrective actions; and

3. A common understanding of the significance of the issues and the need for lasting and effective corrective action.

NOTE:

PECs and regulatory conferences are normally categorized as Category 1 meetings in accordance with the Commission's Public Meeting Policy. The policy statement as well as additional guidance on conducting public meetings is included on the Communications and Public Meetings Web Site.

E. These conferences are not held to negotiate sanctions.

4.1.1 Applicability

A. PECs and Regulatory Conferences will normally be held:

1. When the NRC needs additional information prior to making an enforcement decision involving a potential escalated action, i.e., Severity Level I, II, and III violations; violations associated with a red, yellow or white finding, civil penalties, and orders;

2. Before issuing an order based on a violation of the Deliberate Misconduct rule;

3. Before issuing a civil penalty to an unlicensed individual;

4. To provide a licensee (or individual) an opportunity to discuss its perspective regarding the issues, prior to the NRC making enforcement decisions; and

5. When the NRC needs additional information prior to making an enforcement decision involving a significant vendor case, such as those involving recurring nonconformances.

B. The NRC may take immediate enforcement action, and hold the conference subsequently when:

1. If necessary to protect the public health and safety or provide for the common defense and security.

2. In special cases where a PEC would not serve the agency's interest, e.g., where NRC is taking its action before DOJ has completed its activities addressing escalated criminal issues.

C. A licensee, vendor, or other person may seek to waive their opportunity to participate in a conference.

1. The region should notify OE if a licensee seeks to waive a conference.

2. If a licensee waives its opportunity to participate in a conference, a DFI may be warranted if the NRC needs additional information to make an enforcement decision.

D. The region should consult with OE for those cases involving potential escalated enforcement action:

1. When the region proposes not to conduct a PEC if there has been an escalated enforcement action within the last two years or two inspections;

2. If the violation is categorized at Severity Level I or II; or

3. If the violation is willful.

E. If the NRC concludes during an enforcement panel that a PEC is not necessary, the region may either:

1. Issue the inspection report including the apparent violations and providing the licensee a choice of requesting a conference or providing a written response to the apparent violations ("**a choice letter**"); or

NOTE:

Issuing a choice letter may be appropriate where a licensee appears to understand the significance of the violation and the need for corrective action at the inspection exit, but where the inspector may not be aware of all of the corrective actions subsequent to the inspection exit. Issuing a choice letter may provide the emphasis to the licensee to develop and implement comprehensive corrective actions to avoid the potential for a civil penalty.

2. Make a telephone call to the licensee informing them that the NRC does not see the need for a conference and does not see the need for a civil penalty ("**choice call**").

F. Notwithstanding the NRC's conclusion that a PEC is not necessary, a conference will normally be held if the licensee requests it.

4.1.2 Attendance at PECs and Regulatory Conferences

This section provides specific guidance concerning attendance at PECs and Regulatory Conferences, including: NRC personnel, licensee personnel, media and members of the public, and State government personnel.

4.1.2.1 NRC Attendance at PECs and Regulatory Conferences

A. NRC personnel should attend conferences according to the following guidelines:

1. The Regional Administrator should determine regional staff attendance at conferences.

2. The region should be sensitive to the potential impact on a conference when the number of NRC attendees is significantly greater than the number of licensee attendees.

NOTE:

There should be a reason for each NRC person's attendance at PECs and Regulatory Conferences.

B. The region should discuss with the cognizant OE Enforcement Specialist or the Chief, Enforcement Policy and Program Oversight Section (EPPO), whether the issues to be discussed warrant OE attendance at the conference.

1. OE staff should attend all significant conferences, either in person or by video or telephone. (OE should generally not participate by telephone if safeguards information will be discussed.)

NOTE:

If OE plans to participate in a conference in person or by video or telephone, the region shall send to OE, along with the inspection report, any additional relevant information, at least 72 hours prior to the conference.

2. If the Regional Administrator believes that telephone or video participation would make a particular conference less effective, OE should be notified at least one week in advance so that travel arrangements can be made.

C. The NRR, NMSS, or NSIR Enforcement Coordinator should attend conferences as deemed appropriate by the program office, or as requested by the region.

D. Additional program office designees (NRR/NMSS/NSIR technical or projects staff) may attend conferences as deemed appropriate by the program office, or as requested.

E. Regional Counsel should attend PECs, unless their schedule does not permit, and in particular, should attend those conferences involving complex or novel issues or those involving a complex or significant OI investigation.

F. OGC should be requested to attend conferences involving disputes over legal issues.

G. OI should be invited to attend those conferences that involve a complex or significant OI investigation, or those that could potentially result in an OI referral for investigation.

4.1.2.2 Licensee Attendance at PECs and Regulatory Conferences

Licensee personnel should attend conferences according to the following guidelines:

A. The region should request that licensee attendance include:

1. Senior level managers and individuals prepared to address the circumstances of the apparent violations and the corrective actions, e.g., the Radiation Safety Officer; and

2. A licensee senior representative empowered to bind the licensee to commit to corrective actions on its behalf.

B. When an individual's significant personal error contributed to the violation, consideration should be given to that person's attendance at the licensee's conference because it may be beneficial for NRC management to hear first-hand the individual's explanation for the actions taken, to get a more complete understanding of the violation circumstances.

C. When an enforcement action against an individual is contemplated, the opportunity should normally be provided for a specific conference with the individual.

4.1.2.3 Public Attendance at PECs and Regulatory Conferences

A. PECs and Regulatory Conferences are generally:

1. Classified as Category 1 meetings in accordance with the Commission Public Meeting Policy;

2. Between the NRC and the licensee;

3. Normally held in the regional office; and

4. Open to public observation.

B. Conferences will not normally be open to the public if the enforcement action being contemplated:

1. Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed a wrongdoing;

2. Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

3. Is based on the findings of an NRC Office of Investigations (OI) report that has not been publicly disclosed; or

4. Involves Safeguards Information, Safeguards Information-Modified Handling (SGI-M), Privacy Act information, or information which could be considered sensitive or proprietary; and

5. Involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing personally identifying information about the individual involved, e.g., their name, employee number, etc.

C. Conferences will not normally be open to the public if the conference will be conducted at a relatively small licensee's facility.

D. Notwithstanding these criteria, a conference may still be open if:

1. The conference involves issues related to an ongoing adjudicatory proceeding with one or more interveners; or

2. The evidentiary basis for the conference is a matter of a public record, such as an adjudicatory decision by DOL.

NOTE:

Notwithstanding the criteria for opening or closing a conference to the public, with the approval of the DEDO, conferences may either be open or closed after balancing the benefit of the public observation against the potential impact on the agency's decision-making process in a particular case.

E. The Regional Administrator has the discretion to determine whether the public should be allowed to observe a video conference on a case-by-case basis.

F. The public attending an open conference may observe but not participate in the conference.

1. Members of the public may tape records (including videotape) an open conference if that activity is not disruptive.

2. It is noted that the purpose of conducting conferences in the open is not to maximize public attendance, but rather to provide the public with opportunities to be informed of NRC activities while balancing the need for the NRC staff to exercise its regulatory and safety responsibilities without an undue administrative burden.

3. Following the conference, the staff is to be available for a brief period to entertain questions and comments from members of the public concerning matters discussed at the conference.

4.1.2.4 State Government Attendance at PECs and Regulatory Conferences

A. Since most PECs and Regulatory Conferences are open to the public, state government personnel will be able to attend.

1. If the particular conference is closed, the Commission's Policy on Cooperation with States at Commercial Nuclear Power Plants and Other Nuclear Production or Utilization Facilities," dated February 15, 1989, and amended for adjacent states on February 25, 1992, permits State representatives to attend conferences if information relevant to an enforcement action is obtained by a State representative during an inspection under a State/NRC inspection agreement.

2. When other circumstances warrant, the Director, OE, may authorize the Regional Administrator to permit State personnel to attend a closed PEC or Regulatory Conference.

   a). Examples of situations where permission would be granted include where the State representative could provide helpful information or insight (e.g., the enforcement action involves a matter in which the State may also have a related regulatory interest or where the enforcement action involves a general license under 10 CFR Part 150 and an Agreement State has issued a specific license.

   b). If attendance by State personnel to a closed PEC has been deemed appropriate, the following guidelines should be met for closed conferences:

      1). State attendance should be from the appropriate State office (e.g., a person from the State office of operational or radiation protection safety and not from the State rate-setting office).

      2). The State attendee should be informed that participation during the conference is not allowed unless the State attendee was a participant in the inspection under discussion and, in that case, the State attendee may only make statements related to the areas inspected.

      3). If actual safeguards information is to be discussed, State personnel <u>shall</u> <u>be</u> <u>excluded</u> **unless** they have the necessary clearance.

      4). The State attendee must agree not to disclose the conference details with the media or the public documented in a non-disclosure arrangement between the state and NRC. Such agreement should be included in a Memorandum of Understanding (MOU) or, in its absence, a protocol agreement.

      5). This MOU or protocol agreement should be signed by the Regional Administrator, or his designee, and the State attendee or State liaison officer.

   c). The following is a sample protocol agreement:

      (State) understands, acknowledges and agrees that all enforcement action will be undertaken by the NRC. (State) attendees will not disclose any closed enforcement conference details or results with any person, the media, or the public. (State) attendees may not participate during the closed enforcement conference unless the attendee was a participant in

the inspection under discussion and, in which case, he or she may only make statements related to the areas inspected.

_____ _____
NRC Regional Administrator (or designee) Date

_____ _____
State Liaison Officer (or State Observer) Date

3. Generally, only NRC personnel may attend enforcement caucus meetings following the conference.

   a). The Director, OE, may give prior approval for someone other than NRC personnel to be present at an enforcement caucus meeting.

   b). When the Director, OE, allows a person to attend a caucus, this person should sign a non-disclosure agreement prior to attending the caucus.

4.1.3 Scheduling and Announcing PECs and Regulatory Conferences

A. Whether a PEC should be conducted is determined during an enforcement panel. The process for determining whether to conduct a regulatory conference is governed by MC 0609, Attachment 1.

   1. The region should issue the inspection report within four weeks of when the enforcement panel or SERP was conducted.

   2. OE will have already assigned an EA number to the case.

   3. Conferences should generally be held within 6 weeks after completion of an inspection. If a conference is scheduled subsequent to a licensee's response to a choice letter, the conference should generally be held within four weeks of receipt of the licensee's response.

NOTE:

See Chapter 6 for additional guidance on cases involving individuals or cases that have been referred to the Department of Justice (DOJ). These cases require coordination with DOJ and approval of the Director, OE, prior to scheduling a PEC.

B. The region should conduct a final exit briefing to inform the licensee:

   1. That the NRC would like to conduct a PEC prior to making an enforcement decision;

   2. Whether the conference will be open or closed to public observation;

3. For closed PECs, if the PEC will be transcribed;

4. The purpose of the conference and the information that the licensee is encouraged to present at the conference.

   a). This will help direct the licensee's focus and ensure that the licensee understands what is expected at the conference.

   b). This communication is especially important for material licensees because of their infrequent contact with the NRC. If time permits, a written outline or agenda of specific issues should be provided; and

5. That the licensee should begin it reviews based on the exit briefings, i.e., the licensee should not wait until the inspection report has been issued.

C. The region should inform the licensee that any information provided during the conference, including handouts or preliminary evaluations, will be made available to the Public, unless it meets the provisions of 10 CFR 2.390(a)(4) or (a)(6).

D. The region should coordinate a date to hold the PEC with the licensee, with the goal of giving the licensee at least two weeks to review the inspection report.

1. Licensees should have adequate time to perform necessary reviews or investigations, develop corrective action plans, and prepare presentations.

2. Licensees are expected to base their presentation on the inspection exit meeting.

   a). The specific findings or issues of concern may not be fully understood until the licensee has received the written report.

   b). Unless prior approval is given by the Director, OE, or unless the licensee waives receipt of the inspection report, the licensee should normally be given the inspection report at least two weeks in advance.

NOTE:

Inspection reports should be sent to OE and the appropriate program office at the same time the region sends it to the licensee.

E. In addition to the inspection report, the licensee should normally be sent a factual summary for cases involving OI reports.

F. Additional time may be needed to prepare for conferences involving complex issues.

1. The timeliness of the process is dependent on effective exit meetings.

2. If, after the exit meeting, the agency concludes that different issues should be the focus of the conference:

   a). The licensee should be put on notice.

   b). This should also be considered in scheduling the conference.

3. After the conference date and time have been set, the region should:

   a). Promptly notify OE, the appropriate program office, OI (if applicable) and the appropriate State liaison officers (unless the conference is closed); and

   b). Highlight any novel or complex cases for the attention of the Director, OE.

G. The region should prepare a meeting notice in accordance with regional procedures and include information (as applicable) in the Public Meeting Checklist Web Site. Meeting notices should also include specific enforcement-related information. Appendix D includes a checklist that consolidates the required information for conferences.

H. The meeting notice should:

1. Include the EA number.

2. Clearly identify the meeting as a "predecisional enforcement conference" or “regulatory conference.”

3. In the purpose statement, provide sufficient detail to inform the public about the general issues, including the activity area, or equipment involved.

   a). The following examples demonstrate inadequate and adequate purpose statements for meeting notices:

      1). Adequate

         (a). The purpose of the predecisional enforcement conference is to discuss the apparent willful violation involving the transfer of licensed byproduct material (EXIT signs containing tritium) without a specific license.

         (b). The purpose of the predecisional enforcement conference is to discuss the apparent procedural violation involving the motor driven emergency feedwater pump.

      2). Inadequate

         (a). The purpose of the meeting is to discuss the procedural violation identified in NRC Inspection Report No. 50-277/02-06.

(b). The purpose of the predecisional enforcement conference is to discuss the deliberate transfer of licensed byproduct material without a specific license.

4. Refer to the issues as "apparent violations" or “potential noncompliances,” to reflect the predecisional nature.

5. Indicate whether the conference is open or closed to public observation.

a). If the conference is open, include the following statement:

“This is a Category 1 Meeting: The public is invited to observe this meeting and will have one or more opportunities to communicate with the NRC after the business portion, but before the meeting is adjourned.”

NOTE:

If the case involves potential willfulness, the notice should refer to the issues generally as “apparent willful violations, instead of apparent deliberate violations.

b). If the conference is closed, include one of the following statements:

“This conference is closed to public observation because it involves the findings of an NRC Office of Investigations report that has not been publically disclosed.

or

“This conference is closed to public observation because it involves safeguards information, Privacy Act information, or information which could be considered sensitive or proprietary.

or

“This conference is closed to public observation because it involves potential wrongdoing by an individual.

or

“This conference is closed to public observation because it involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference.

or

“This conference is closed to public observation because it involves medical misadministrations or overexposures and the conference cannot be conducted

without disclosing personally identifying information about the individual(s) involved.

or

"This conference is closed to public observation because it will be conducted at a relatively small licensee's facility (or will be conducted by telephone).

6. Include the inspection report number and the ADAMS accession number, if it is available.

NOTE:

Meeting notices for Regulatory Conferences with enforcement implications should include a statement that the meeting will also address whether enforcement action is warranted.

I. The region should submit meeting notices for all conferences (open or closed) at least 10 calendar days in advance of the meeting to the Public Meeting Notice System Coordinator (e-mail PMNS).

J. To support posting a conference to the Enforcement Web Site, the region should send a copy of the meeting notice (including the EA number) at the same time it sends the notice to the Public Meeting Notice System Coordinator, to:

1. OEMail.Resource; and

2. The OE Web site Coordinator ("OEWeb.Resource).

NOTE:

It is very important in meeting the intent of the Commission's policy on public meetings to provide the meeting notice and agenda in the background information of the ADAMS package. Other related documents are normally not necessary because the inspection report and transmittal letter typically provide sufficient information. However, if a separate agenda is created, a copy of the agenda should be sent to "OEMail.Resource" and "OEWeb.Resource."

K. The region should notify OPA of all PECs and Regulatory Conferences.

1. OPA will determine whether to issue a press release announcing the conference.

2. All press releases should include language that conveys:

a). The decision to hold a predecisional enforcement conference does not mean that the agency has concluded that a violation has occurred or that enforcement action will be taken.

b). Apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action.

c). The conference is an opportunity for the licensee to present any additional material information before the NRC arrives at a decision.

L. The only exception to issuing a meeting notice may be when security-related issues are involved.

4.1.4 Conducting PECs and Regulatory Conferences

PECs and Regulatory Conferences should be conducted according to the following guidelines:

A. Conferences are normally conducted in the regional offices.

B. The region should consult with OE prior to scheduling the conference when:

1. There are special circumstances where the agency determines that it would be beneficial to the enforcement process to conduct the conference at the licensee's facility; or

2. It would be more practical for the agency to conduct the conference by telephone or video.

3. It is up to the Regional Administrator’s discretion to allow a particular conference to be conducted by telephone or video conference.

C. Members of the public will be allowed access to the NRC regional offices to attend open conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251) which provides that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" will be permitted, and that disruptive persons may be removed.

D. The Regional Administrator should determine the appropriate member of regional management to serve as the presiding official at the conference.

1. The presiding official should not normally be below a Deputy Division Director; however,

2. It may be appropriate for a Branch Chief to serve as the presiding official for certain conferences involving materials licensees.

E. For those conferences in which safeguards information is to be discussed at the conference, NRC staff should not participate by telephone, for security reasons.

1. If such participation is necessary, it should be done in accordance with Management Directive 12.4, “NRC Telecommunications System Security Program,” and 12.6, “NRC Sensitive and Unclassified Information Security Program.”

2. If security issues (not directly related to safeguards information) are the subject of the conference, NRC staff should not participate by telephone unless a compelling reason exists and safeguards information will clearly not be discussed.

NOTE:

Although some conferences may warrant transcription, conferences are not conducted under oath. However, if warranted, the staff should be clear that whether or not a statement is under oath, a false statement on a material matter may be subject to civil and criminal prosecution.

F. The presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should:

1. Announce the meeting as an open or closed predecisional enforcement conference;

2. Discuss the purpose of the conference;

3. Inform the licensee and public attendees that the decision to hold the conference does not mean that the agency has determined that violations have occurred or that enforcement action will be taken;

4. Inform the public attendees (for open conferences) that the conference is a meeting between the NRC and the licensee and that the meeting is open for public observation but not participation; and

5. Briefly explain the enforcement process, focusing on the portions of the Enforcement Policy that are applicable to the issues to be discussed.

a). When NRC staff is participating by video or telephone on a case involving security, the presiding official should also announce that safeguards information should not be discussed during the conference, for security reasons.

b). If the conference is open, the region should ensure that it has copies available of the Enforcement Policy, inspection report, and slides to be discussed.

G. The region should briefly discuss the apparent violations and explain the agency's basis for concern.

1. The level of detail to be discussed is related to the complexity and significance of the issues.

2. Most of the detailed information will have been included in the inspection report.

3. The discussion should include the root causes of the apparent violations and the corrective actions planned or taken.

   a). Corrective actions considered by the NRC to be inadequate (or only marginally acceptable) should be emphasized.

   b). It is helpful to have a slide of the apparent violations, especially in complex cases, to guide the discussion.

H. The region should address the apparent safety significance of the issues.

1. The region should not specifically discuss severity level categorizations, civil penalty amounts, or the nature or content of any orders.

2. If the region chooses to use slides or handouts for any part of its presentation, they should contain the following note: **"The apparent violations discussed in this predecisional enforcement conference are subject to further review and are subject to change prior to any resulting enforcement action."**

I. The licensee should be encouraged to:

1. Present its understanding of the facts and circumstances surrounding the apparent violations;

2. Discuss whether it agrees with the NRC's understanding of the facts, the root cause(s), the safety significance, and the immediate and long-term corrective actions taken or planned to be taken; and

3. Present other information relevant to the agency's enforcement decision, e.g.:

   a). The licensee's perspective on the severity of the issue;

   b). The factors that the NRC considers when it determines the amount of a civil penalty that may be assessed (e.g., missed opportunities to identify the violation sooner); and

   c). Any other factors that may warrant enforcement discretion.

J. The licensee should understand that the conference is a means of providing to the NRC information it believes the agency should consider in determining the appropriate enforcement action.

1. The conference is not a meeting to negotiate sanctions with the staff, nor should it be used as a forum for protracted debate.

NOTE:

PECs and regulatory conferences should normally not last longer than three hours.

2. Once the pertinent facts have been established, the presiding official must recognize differences of opinion and keep the conference productive.

K. The region should normally take a short break prior to the conclusion of the conference to meet with the staff to ensure that the staff has no outstanding questions.

L. The region should provide closing remarks. The presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should include in those remarks, a reminder for the licensee and public attendees that:

1. The apparent violations discussed are subject to further review and are subject to change prior to any resulting enforcement action; and

2. The statements of views or expressions of opinion made by NRC employees at the predecisional enforcement conference, or the lack thereof, are not final conclusions.

M. After the business portion of an open meeting has been concluded, the presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should announce that the staff is available to address comments or questions from the public. Although licensees are not obligated, they may respond to questions if they choose to do so.

4.1.5 Transcribing PECs and Regulatory Conferences

A. Under certain circumstances, the NRC may choose to transcribe a predecisional enforcement conference.

B. Absent coordination with OE, conferences should be transcribed for cases involving:

- A licensed operator
- A licensee employee who may have committed a willful violation
- A significant case in which a record is warranted
- A case involving an OI report, or a case involving discrimination
- Any other case that the region believes should be transcribed, after consultation with OE

C. Transcribed conferences should normally be closed meetings between the NRC and the licensee. As such, licensees will not be allowed to transcribe or record a conference.

D. Transcripts should not be released without the approval of the Director, OE, and only after any associated enforcement action has been issued.

1. If the licensee or any individual at the conference is subsequently provided a copy of the transcript, whether by the staff's offer or the individual's request, the individual should be informed that a copy will also be made available to the Public (subject to removal of privacy information, proprietary information, etc.).

2. Transcripts for open conferences may be made available to the Public as soon as they are available from the court reporter.

4.1.6 PEC and Regulatory Conference Summaries

A. After the PEC or Regulatory Conference has been held, the region should prepare a conference summary (see forms in Appendix D).

B. The conference summary documents the proceedings and serves as a vehicle for making the licensee's handouts and the NRC's outline or agenda available to the Public.

C. In most cases, the licensee's presentation handouts (and the NRC's handouts, if used) will provide sufficient information to summarize the conference proceedings.

D. The summary should include a brief description of the following information (if not already addressed in the licensee's handouts), including:

1. The licensee's position (i.e., if the licensee agrees with the findings in the inspection report, or if the licensee takes issue with the apparent violation(s)).

2. Any significant additions or corrections to the factual information in the inspection report.

3. Any significant additional information that affects the significance of each violation.

4. The short-term and long-term corrective actions the licensee has implemented or has committed to implement. (This description should be sufficient for the staff to judge the corrective action as part of the civil penalty assessment process.)

NOTE:

The Conference Summary should not include predecisional, safeguards, safeguards information - modified handling (SGI-M), Privacy Act information, or information which could be considered sensitive or proprietary information.

E. The conference summary should be as brief as possible.

F. The region should include the conference summary as part of the background material submitted with proposed escalated enforcement actions. The summary should be sent to the licensee either before or when the enforcement action is issued.

4.2 Enforcement and SDP Caucuses

A. **Enforcement caucuses** are meetings that are held subsequent to a predecisional enforcement conference or following receipt of a licensee's response to a choice letter, to discuss whether new information or perspectives were obtained warranting reconsideration of the enforcement approach for the case and whether, for choice letter responses, a conference should be conducted.

B. **SDP/enforcement caucuses** are meetings that are held subsequent to a regulatory conference or following receipt of a licensee's response to a choice letter, to discuss whether new information or perspectives were obtained warranting reconsideration of the significance determination for the case and whether, for choice letter responses, a conference should be conducted.

1. Because the outcome of the SDP informs the enforcement process, a secondary purpose for such meetings is to discuss and reach agreement on an enforcement approach for any violations that might be associated with the inspection findings.

2. Although these caucuses are similar to enforcement caucuses in many respects, specific guidance for SDP caucuses is included in MC 609, Attachment 0609.01, dated 06/20/03.

4.2.1 Participating in Enforcement and SDP Caucuses

A. Participation in enforcement and SDP caucuses should be in accordance with the following guidelines:

1. **Region**: The region should schedule a caucus as soon after a conference or receipt of a licensee's response to a choice letter as possible. When possible, the caucus should occur immediately following the conference.

a). The region should notify OE, and the applicable program office Enforcement Coordinator(s).

b). The region should invite the Assistant General Counsel for Materials Litigation and Enforcement and the applicable OI investigator and Regional Field Office Director for caucuses involving willfulness.

c). It is expected that the region will be represented by a person at the Division Director level or higher.

d). It is important to recognize that the regional caucus participants provide a recommendation to the Regional Administrator, i.e., their position does not represent the final region position.

2. **OE**: Enforcement Specialists should attend all caucuses.

a). If OE management did not participate in the caucus, it will provide its position to the region within one day of the meeting.

b). The decision will be documented on a Strategy Form.

c). A final decision on the enforcement action is not to be made until OE approves the enforcement strategy as documented on the Strategy Form.

3. **Program Office**: The program office should be invited to participate in caucuses; however, attendance is not mandatory except when the program office is responsible for the allegation or inspection activity (in which case the program office assumes the role of the regional office).

a). The NRR, NMSS, and NSIR Enforcement Coordinators are responsible for arranging for participation by the appropriate and necessary program office staff; and

b). For ensuring that the staff has necessary materials in advance of the meeting (e.g., conference handouts).

4. **OGC**: OGC (Assistant General Counsel for Materials Litigation and Enforcement) should participate in caucuses involving willfulness and other cases with potential issues of legal significance.

5. **OI:** OI (applicable investigator and Field Office Director) should be invited if there are questions as to OI findings.

B. In evaluating the appropriateness of the proposed enforcement strategy, program office participants should focus on whether:

1. The violations are technically accurate and factual; and

2. The enforcement strategy is consistent with the program office's policy, guidance, position, and past practice.

C. If program office participants disagree with the enforcement strategy discussed during the caucus, they are responsible for elevating their concerns to program office management (i.e., the Associate Director for Operating Reactor Oversight and Licensing for NRR cases; the applicable Division Director for NMSS cases; or the Director, Division of Security Operations, NSIR).

4.2.2 Enforcement and SDP Caucus Outcome

A. Subsequent to an enforcement or SDP caucus involving OE participation, OE will amend (as warranted) its understanding of the enforcement strategy that was agreed upon during the enforcement caucus by completing the lower portion of the Strategy Form.

1. OE will send the form to the region and provide it to the program office (through its Enforcement Coordinator).

2. The form is used to:

   a). Brief the Regional Administrator, the Director, OE (if he or she did not participate in the caucus), the Associate Director for Operating Reactor Oversight and Licensing, NRR, the applicable Division Director in NMSS, and the Director, Division of Nuclear Security, NSIR, if warranted; and

   b). Subsequently develop the enforcement action and the enforcement action transmittal letter.

B. Depending on the information gathered during the conference or provided in the licensee's response to the choice letter, and the discussions in the caucus, the staff will determine:

1. The level of headquarters' review that is necessary for the case; and

2. One of several outcomes:

   a). The staff concludes that no violation occurred.

      1). OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.

      2). OE will send the form to the region and make it available to the program office and OGC.

      3). The region should inform the licensee in writing that the NRC does not intend to issue enforcement action.

      4). The region may use the information in the Predecisional Enforcement Conference Summary to clarify why a citation was not issued.

   b). The staff concludes that non-escalated enforcement action should be proposed.

      1). OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.

      2). OE will send the Strategy Form to the region, the program offices, and OGC.

NOTE:

In special cases, OE may request that the actual enforcement action be submitted for review and approval prior to issuing a non-escalated NOV that was the subject of a predecisional enforcement conference.

3). The regions may generally issue the non-escalated enforcement action based on region/OE/program office agreement on the Strategy Form.

4). The region should include an explanation in the cover letter to the licensee of why non-escalated action was appropriate in the particular case.

5). The final action should be signed by someone at least at the level of the presiding official at the predecisional enforcement conference and should be sent to OE to close out the EA number.

c). The staff concludes that escalated enforcement action should be proposed.

1). OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.

2). OE will send the form to the region and make it available to the program office and OGC.

3). The region should prepare the appropriate escalated enforcement action.

d). Additional facts are disclosed or developed (at or after the conference) that could lead to additional violations.

1). Special efforts should be taken to substantiate these violations before they are included in the proposed enforcement action.

2). It may be appropriate to contact the cognizant licensee official, by at least a telephone conference call, to:

(a). Discuss the apparent violation before it is formalized; and

(b). Provide any additional information that may be relevant.

3). New EA numbers should be assigned to any additional Severity Level I, II, III violations or problems that are proposed with the action.

4). Strategy Forms should be prepared and updated, as appropriate.

e). The staff concludes that a conference should be conducted, or if the licensee requests a conference.

1). The region should arrange for a conference with the licensee as soon as possible.

2). A conference may be necessary if the staff concludes that the documented corrective action is not sufficiently prompt and comprehensive such that a civil penalty may be warranted.

3). The Strategy Form should be updated to reflect the information.

f). The staff concludes that an additional caucus or discussion is necessary.

1). The same principal caucus participants should attend if practicable.

2). Other participants, to the extent that they might have information relevant to the issues to be discussed, should attend if practicable.

3). All of the original participants need not be present to conduct a subsequent caucus or discussion.

4). The Enforcement Specialist should make available any previous Strategy Form(s) to support discussions regarding the case.

C. It is not always necessary to hold a new caucus to change a past agreement recorded on a Strategy Form.

1. OE management can agree to change an agreement as a result of telephone calls or meetings outside the caucus process.

2. After a subsequent caucus or substantive discussion, the Strategy Form will be:

a). Updated noting the outcome of the meeting, including a brief explanation of the reason for any change in enforcement strategy; and

b). Distributed so that the region, program office, and OGC are aware of the change and can comment, if desired.

3. Following receipt of the revised Strategy Form, it is the responsibility of the principal participants to verify that the revised strategy is acceptable to the office or region.

a). The principal participants are responsible for discussing, as warranted, changes to previously agreed upon strategy with the prior caucus participants from their office or region who may not have been involved in the subsequent caucus or discussion.

b). The regional principal participants should discuss, as warranted, the issues with OI.

D. Disagreements with the revised strategy should be handled as discussed below:

1. If the Regional Administrator, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, the applicable Division Director for NMSS cases, or the Director of the Division of Security Operations for NSIR cases disagree on enforcement strategy issues such as significance, SDP characterization, severity level, civil penalty assessment, or enforcement discretion:

   a). The Director, OE, must be informed as soon as possible, and normally no later than 24 hours, after receiving OE's summary of the enforcement strategy documented on the Strategy Form.

   b). In the case of a regional disagreement, the Regional Administrator and Director, OE, should confer and either resolve their differences or promptly escalate the matter to the DEDO. (Depending on the nature of the regional disagreement, OE may arrange for program office participation.)

   c). In the case of a program office disagreement, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, the applicable Division Director for NMSS cases, or the Director of the Division of Security Operations for NSIR cases, should:

      1). Confer with the Director, OE, and the Regional Administrator to resolve their differences; or

      2). The Director, OE, will promptly escalate the matter to the DEDO.

E. Based on the outcome of these discussions, if warranted, OE will:

1. Revise the summary of the agreed upon enforcement strategy on the Strategy Form;

2. Send it to the region; and

3. Make the revised Strategy Form available to the program office and OGC.

NOTE:

If, as discussed in this section, the Director, OE, cannot resolve an enforcement strategy issue with the Regional Administrator, the Director, OE, may request that the complete case (including the transmittal letter to the licensee) be submitted to headquarters for review and approval prior to issuance.

F. Depending on the circumstances of the case, OE will decide whether:

1. Agreement on the Strategy Form is sufficient; or

2. The actual enforcement action package needs to be submitted to headquarters for review and approval prior to issuance.

4.3 Determining Whether a Civil Penalty Should Be Proposed

A. Civil penalties are normally assessed for:

1. Severity Level I and II violations;

2. Knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act; and

3. Failure to make the required notifications that impact the ability of Federal, State and local agencies to respond to an actual emergency preparedness event (site area or general emergency).

B. Civil penalties are considered for Severity Level III violations.

C. Civil penalties are considered for violations associated with red, yellow, or white SDP inspection findings evaluated through the ROP's SDP that involve actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, or releases in excess of regulatory limits.

D. For violations that impact the regulatory process or that are willful and therefore assessed under "traditional enforcement," the SDP should be used to risk inform the significance of the underlying violation or issue to the extent possible.

NOTE:

Civil penalties **are not** normally proposed for violations associated with low to moderate or greater safety significant SDP findings absent actual consequences.

E. The staff should consider the SDP output in conjunction with the guiding principles for assessing significance and the guidance included in the Violation Examples (Section 6.0) of the Enforcement Policy to determine the appropriate severity level.

F. The following steps should be taken to determine whether a civil penalty should be proposed for the violation.

Step 1: Determine the base civil penalty appropriate for the significance of the violation and the class of licensee.

Step 2: Complete the civil penalty assessment process, which considers:

- Whether (for a non-willful Severity Level III issue) the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past two years or past two inspections, whichever is longer;
- Whether the licensee should be given credit for actions related to identification;
- Whether the licensee's corrective actions are prompt and comprehensive; and
- Whether, in view of all the circumstances, the matter in question requires the exercise of discretion.

Step 3: Compare the amount of the civil penalty resulting from the civil penalty process described above with the amount allowed by statute, to ensure that the civil penalty amount actually issued is within the statutory maximum.

Step 4: Determine whether an escalated NOV should be issued with or without a civil penalty based on the outcome of the civil penalty process.

4.3.1 Base Civil Penalty

A. The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons.

B. Violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device are treated separately, regardless of the use or the type of licensee.

C. After determining that a civil penalty should be proposed with an NOV, the next step in the civil penalty process is to determine the base civil penalty for the violation.

1. Tables 1A and 1B in the Enforcement Policy provide the base civil penalties for various reactor, fuel cycle, and materials programs, and for the loss, abandonment or improper transfer or disposal of a sealed source or device.

2. The structure of these tables takes into account both the gravity of the violation and the licensee's ability to pay, i.e., operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties.

3. Civil penalties issued to individuals are rare and are determined on a case-by-case basis.

4.3.1.1 Ability to Pay and Size of Operation

A. Although Tables 1A and 1B in the Enforcement Policy are structured to take into account as a primary consideration, the gravity of a violation, and as a secondary matter, the licensee's ability to pay, there may be circumstances that warrant an adjustment to the base civil penalty or consideration of payment of a civil penalty over time.

1. It may be appropriate to increase the size of the base penalty on the basis of the amount of nuclear materials inventoried, the potential hazards associated with them, and the size and nature of the licensee operation and program.

a). Increasing the penalty requires OE approval and may require Commission consultation.

b). Orders, rather than civil penalties, should be used when the intent is to suspend or terminate licensed activities.

c). The deterrent effect of civil penalties is best served when the amounts take into account the licensee's ability to pay.

B. If a licensee can demonstrate financial hardship, the NRC will normally consider payments over time which includes interest and administrative charges, rather than reducing the amount of the civil penalty.

1. If, after consultation with OE, payments over time or reduction of the penalty appears appropriate, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees, e.g., a DFI can be used to require the licensee to respond to such an inquiry.

NOTE:

If payment of a civil penalty could impair the licensee's ability to safely conduct licensed activity, the staff should consider whether the licensee should be allowed to maintain its license, given its questionable financial stability.

2. The licensee should be requested to provide the NRC with written evidence to demonstrate that payment of the civil penalty would substantially affect its ability to remain in business or would substantially affect its ability to safely conduct licensed activities.

a). The licensee must support its position with documentation for the past three years (such as profit and loss statements showing income and expenses including such items as gross sales and salaries, balance statements showing assets and liabilities, auditor's reports, and tax returns or other evidence) and must also provide a statement from at least one financial institution that it could not obtain a loan.

b). If the licensee's submittal does not support its claim, the responsible office should impose the civil penalty and inform the licensee that NRC evaluation of the submitted evidence does not support the licensee's claim.

c). If the licensee's submittal supports its claim, the civil penalty should be imposed over a time-frame that is consistent with NRC's evaluation of the licensee's evidence and should provide the licensee with the basis for the NRC's conclusion.

1). The regional office should prepare the terms to be included in a Promissory Note in Payment of the Civil Penalty (see the forms in Appendix B).

2). The Accounts Receivable Team, Division of Financial Management in the Office of the Chief Financial Officer (CFO/DFM/ART) will prepare all promissory notes using the terms that the regional office provides, i.e., the length of time, the minimum monthly payment, the payment schedule, etc.

3). OE will issue the note to the licensee.

4). After the licensee signs and returns the note to the NRC, the Director, OE, counter-signs the note and OE forwards a copy to the licensee.

4.3.1.2 Small Business Regulatory Enforcement Fairness Act (SBREFA)

A. The NRC is subject to the Small Business Regulatory Enforcement Fairness Act (SBREFA).

1. If a small entity claims hardship:

a). The Region may propose up to a 50% reduction to the civil penalty.

b). For proposed reductions of more than 50% and up to waiving the fine, the licensee must also demonstrate that a hardship exists by meeting the criteria for financial hardship.

c). The staff should note that payment-over-time is an option specifically tailored for small businesses.

B. Among the requirements of the SBREFA, the NRC must consider the SBREFA in taking civil penalty actions against small entities.

1. The NRC's Enforcement Policy civil penalty structure takes into account the size of the licensee by virtue of the nature of the operation, the significance of the violations, and consideration of factors such as identification, corrective action, licensee history, and willfulness or other particularly poor performance.

2. SBREFA also addresses financial hardship.

NOTE:

Not all small entities are “equal.” For the purpose of reducing licensing fees, small entities can include fairly large companies, corporations, etc.; however, when considering whether to reduce the amount of a material user’s civil penalty, the licensee must be, in fact, a small entity.

a). In reaching decisions concerning enforcement actions, the staff should keep the intent of SBREFA in mind.

b). There may be cases where, after considering the normal adjustment factors and the size of a qualified small entity to whom a civil penalty may be issued, the staff believes that the penalty should be reduced or eliminated. In those cases, it is appropriate to propose such a modification based on the intent of SBREFA.

C. Any adjustments to the proposed civil penalty under SBREFA would be applied as an exercise of discretion and the appropriate Enforcement Action Tracking System (EATS) keyword should be entered.

4.3.2 Civil Penalty Assessment Process

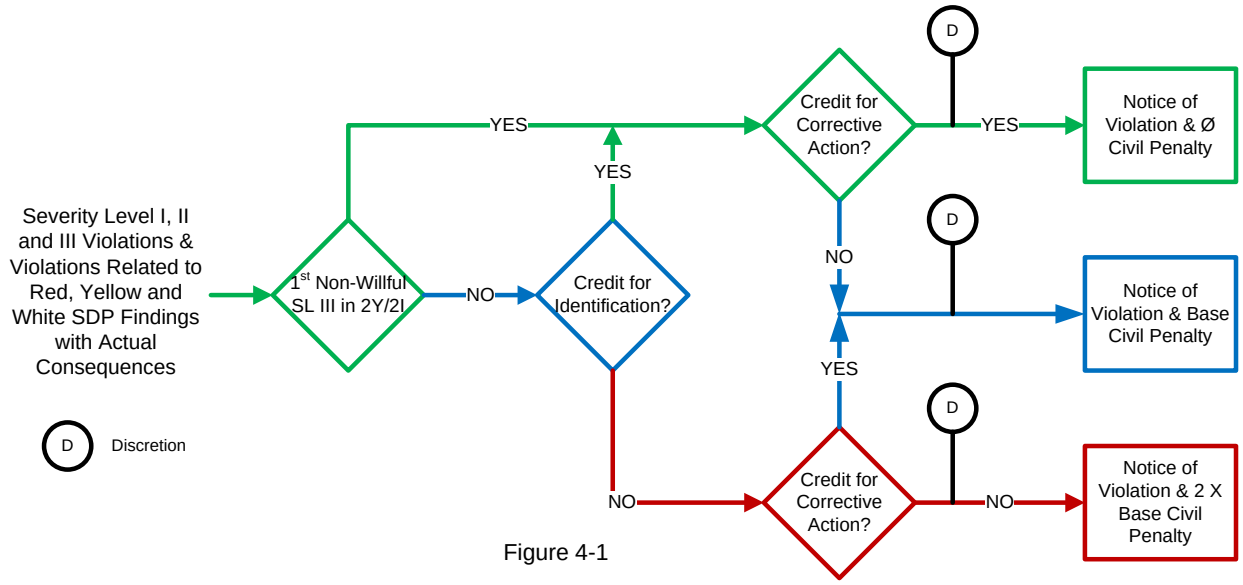

Figure 4-1: This flow chart is a graphic representation of the civil penalty assessment process.

A. The civil penalty assessment process is addressed in the Enforcement Policy.

B. In an effort to emphasize the importance of adherence to requirements and reinforce prompt self-identification of problems and root causes and prompt and comprehensive correction of violations, the NRC reviews each proposed civil penalty on its own merits.

C. The civil penalty assessment process considers these decisional points:

1. Is this the first non-willful Severity Level III enforcement action (regardless of the activity area) that the licensee has had during the past two years or past two inspections the "Standard Operating Procedures for Providing Security Support for NRC Hearings And Meetings" (whichever is longer)?

2. Should the licensee be given credit for actions related to identification? (Only consider if the answer to the previous question is no.)

3. Are the licensee's corrective actions prompt and comprehensive?

4. In view of all the circumstances, does the matter in question require the exercise of discretion, e.g., Severity Level I and II violations should normally result in a civil penalty?

D. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results:

- No civil penalty
- A base civil penalty
- Twice the base civil penalty.

4.3.2.1 Initial Escalated Action

A. The NRC will consider whether the licensee's corrective action for the present violation or problem is reasonably prompt and comprehensive when:

1. The NRC determines that a non-willful Severity Level III violation or problem has occurred; and

2. The licensee has not had <u>any</u> previous Severity Level I, II, or III escalated actions (regardless of the activity area) for this site during the past two years or two inspections, whichever is longer.

a). This includes new licensees who have not been in existence during the past two years or for two inspections (provided that they have not had previous escalated actions).

b). Because a new licensee is involved, the staff should consider whether the apparent significance of the violation requires the staff to:

1). Exercise discretion to impose a civil penalty; or

2). Take even more stringent action to address the apparent poor performance by a new licensee.

c). This criterion should also be considered for license transfers and when a licensee moves, including situations where the license is terminated and a new license is obtained.

1). This is appropriate if the facility personnel, procedures, and equipment stay the same after a license transfer or move, thereby making past enforcement history a valid issue.

2). If significant changes have been made in the above areas, consideration of enforcement history may be inappropriate.

B. This criterion considers past NRC escalated actions with severity levels, i.e., traditional enforcement.

1. It does not include previous escalated enforcement actions issued under the SDP (i.e., NOVs associated with red, yellow, or white SDP findings.)

2. It does not include previous escalated enforcement actions in an Agreement State.

a). Considering previous escalated actions in an Agreement State is not appropriate because of variations in enforcement programs in the different Agreement States.

b). If an Agreement State licensee violates a requirement while working in NRC jurisdiction under reciprocity and the staff is aware of previous escalated action in an Agreement State and the violation is directly repetitive or the enforcement history is particularly poor, the staff *may* consider an adjustment to the civil penalty assessment process by exercising enforcement discretion under the Enforcement Policy.

C. Using two years as the basis for assessment is expected to cover most situations.

1. Considering a slightly longer or shorter period might be warranted based on the circumstances of a particular case.

2. The starting point of this period is when the licensee was put on notice of the need to take corrective action.

a). For a licensee-identified violation or an event, this would be when the licensee is aware that a problem or violation exists requiring corrective action.

b). For an NRC-identified violation, the starting point would be when the NRC puts the licensee on notice, which is typically at the inspection exit meeting, or as part of post-inspection communication.

D. If the corrective action is judged to be prompt and comprehensive, an NOV normally should be issued with no associated civil penalty. If the corrective action is judged to be less than prompt and comprehensive, the NOV normally should be issued with a base civil penalty.

4.3.2.2 Credit for Actions Related to Identification

A. Identification presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed.

B. The civil penalty assessment should normally consider the factor of identification in addition to corrective action when:

1. A Severity Level I or II violation or a willful Severity Level III violation has occurred;

2. During the past two years or two inspections, whichever is longer, the licensee has been issued at least one other escalated action; or

3. A licensee has not been in existence during the past two years or for two inspections.

C. The NRC should consider whether the licensee should be given credit for actions related to identification of the problem requiring corrective action, e.g., if a licensee discovers an issue but fails to recognize that corrective actions are needed, then the licensee may not be deserving of identification credit.

1. Identification and corrective action are separate decisions.

2. The decision on identification requires considering all the circumstances of identification including:

a). Whether the problem requiring corrective action was:

- NRC-identified
- Licensee-identified
- Revealed through an event

NOTE:

An **event**, as used in this section, means (1) a situation characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, or (2) a radiological impact on personnel or the environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above NRC limits, or a loss of radioactive material, e.g., an equipment failure discovered through a spill of liquid, a loud noise, the failure to have a system respond properly, or an annunciator alarm would be considered an event. Similarly, if a licensee discovered, through quarterly dosimetry readings, that employees had been inadequately monitored for radiation, the issue would normally be considered licensee-identified; however, if the same dosimetry readings disclosed an overexposure, the issue would be considered an event.

b). Whether prior opportunities existed to identify the problem requiring corrective action, and if so, the age and number of those opportunities;

c). Whether the problem was revealed as the result of a licensee self-monitoring effort, such as conducting an audit, a test, a surveillance, a design review, or troubleshooting;

d). For NRC-identified issues, whether the licensee would likely have identified the issue in the same time-period if the NRC had not been involved:

e). For cases in which the NRC identifies the issue or identifies the overall problem (i.e., a programmatic issue requiring corrective action, consider:

1). Whether the licensee should have identified the issue (and taken action) earlier; and

NOTE:

In cases where the licensee identifies a noncompliance that has existed for an extended length of time, the ease of identification of the noncompliance should be taken into consideration.

2). The degree of licensee initiative or lack of initiative in identifying the problem or problems requiring corrective action.

f). For a problem revealed through an event, the ease of discovery, and the degree of licensee initiative in identifying the root cause of the problem and any associated violations;

D. Although some cases may consider all of the above factors, the importance of each factor will vary based on the type of case as discussed in the following general guidance:

1. **Licensee-Identified**: When a problem requiring corrective action is licensee-identified (i.e., identified before the problem has resulted in an event), the NRC should normally give the licensee credit for actions related to identification, regardless of whether prior opportunities existed to identify the problem.

2. **Identified Through an Event**: When a problem requiring corrective action is identified through an event, the decision on whether to give the licensee credit for actions related to identification normally should consider:

a). The ease of discovery;

b). Whether the event occurred as the result of a licensee self-monitoring effort (i.e., whether the licensee was "looking for the problem");

c). The degree of licensee initiative in identifying the problem or problems requiring corrective action; and

d). Whether prior opportunities existed to identify the problem.

1). Any of these considerations may be overriding if particularly noteworthy or particularly egregious, e.g., if the event occurred as the result of conducting a surveillance or similar self-monitoring effort (i.e., the licensee was looking for the problem), the licensee should normally be given credit for identification.

2). As a second instance, even if the problem was easily discovered (e.g., revealed by a large spill of liquid), the NRC may choose to give credit because noteworthy licensee effort was exerted in ferreting out the root cause and associated violations, or simply because no prior opportunities (e.g., procedural cautions, post-maintenance testing, quality control failures, readily observable parameter trends, or repeated or locked-in annunciator warnings) existed to identify the problem.

3. **NRC-Identified**: When a problem requiring corrective action is NRC-identified, the decision on whether to give the licensee credit for actions related to identification should normally be based on an additional question, i.e., should the licensee have reasonably identified the problem (and taken action) earlier?

a). In most cases, this reasoning may be based simply on the ease of the NRC inspector's discovery (e.g., conducting a walkdown, observing in the control room, performing a confirmatory NRC radiation survey, hearing a cavitating pump, or finding a valve obviously out of position). In some cases, the licensee's missed opportunities to identify the problem might include a similar previous violation, NRC or industry notices, internal audits, or readily observable trends.

b). If the NRC identifies the violation but concludes that, under the circumstances, the licensee's actions prior to identification were reasonable and may have, in fact, led to the identification, the matter can be treated as licensee-identified for purposes of assessing the civil penalty. In such cases, the question of identification credit shifts to whether the licensee should be penalized for NRC's identification of the problem.

4. **Mixed Identification**: For "mixed" identification situations (i.e., where multiple violations exist, some NRC-identified, some licensee-identified, or where the NRC prompted the licensee to take action that resulted in the identification of the violation), the NRC's evaluation should normally determine whether the licensee could reasonably have been expected to identify the violation in the NRC's absence.

a). This determination should consider, among other things:

1). The timing of the NRC's discovery;

2). The information available to the licensee that caused the NRC concern;

3). The specificity of the NRC's concern;

4). The scope of the licensee's efforts;

5). The level of licensee resources given to the investigation; and

6). Whether the NRC's path of analysis had been dismissed or was being pursued in parallel by the licensee.

b). In some cases, the licensee may have addressed the isolated symptoms of each violation (and may have identified the violations), but failed to recognize the common root cause and taken the necessary comprehensive action. Where this is true, the decision on whether to give licensee credit for actions related to identification should focus on identification of the problem requiring corrective action (e.g., the programmatic breakdown).

c). Depending on the chronology of the various violations, the earliest of the individual violations might be considered missed opportunities for the licensee to have identified the larger problem.

5. **Missed Opportunities to Identify:**

a). Missed opportunities include prior notifications or missed opportunities to identify or prevent violations through, e.g.:

1). Normal surveillances, audits, or quality assurance (QA) activities;

2). Prior notice i.e., specific NRC or industry notification; or

3). Other reasonable indications of a potential problem or violation, such as observations of employees and contractors, and failure to take effective corrective steps.

b). In assessing this factor, consideration will be given to, among other things:

1). The opportunities available to discover the violation;

2). The ease of discovery;

3). The similarity between the violation and the notification;

4). The period of time between when the violation occurred and when the notification was issued;

5). The action taken (or planned) by the licensee in response to the notification;

6). The level of management review that the notification received (or should have received).

c). Missed opportunities may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect

the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue.

d). The evaluation of missed opportunities should normally depend on whether the information available to the licensee should reasonably have caused action that would have prevented the violation.

e). Missed opportunities is normally not applied where the licensee appropriately reviewed the opportunity for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

f). In some situations the missed opportunity is a violation in itself. In these cases, unless the missed opportunity is a Severity Level III violation in itself, the missed opportunity violation may be grouped with the other violations into a single "problem."

g). If the missed opportunity is the *only* violation, then it should not normally be counted twice (i.e., both as the violation and as a missed opportunity--"double counting") unless the number of opportunities missed was particularly significant.

h). The length of time during which the licensee failed to discover the violation should also be considered. A two-year period should generally be used for consistency in implementation.

E. When the NRC determines that the licensee should receive credit for actions related to identification and the corrective action is determined to be reasonably prompt and comprehensive, the civil penalty assessment should normally result in either no civil penalty or a base civil penalty.

F. When the licensee is not given credit for actions related to identification, the civil penalty assessment should normally result in an NOV with either a base civil penalty or a base civil penalty escalated by 100%, depending on the quality of corrective action, because the licensee's performance is clearly not acceptable.

4.3.2.3 Examples Where Identification Is Considered

A. Generally, if the licensee identifies a problem before an event occurs or before the NRC identifies it, the licensee should get credit for the identification (even if missed opportunities existed, including the failure of past corrective action for similar violations).

1. If the violation is identified as the result of an event associated with normal operations, in contrast to an event associated with an assessment activity such as a surveillance test, missed opportunities should be considered.

NOTE:

Identification presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed.

2. If the NRC identifies the violation, it is appropriate to consider whether the licensee should have identified the violation.

   a). The actual application of this factor will be a function of the circumstances of the case, the issues associated with identification, and the regulatory message warranted by the facts of the case.

   b). Identification presumes recognition that corrective action is required.

B. Recognizing that application of the identification factor will require applying judgment to the particular set of facts and circumstances in each case, the following guidance should not be viewed as controlling or exhaustive:

1. Situations In Which the Licensee Should Be Given Credit:

   a). Violations identified as a result of surveillances or tests, when a parameter check is required by the procedure and limits or ranges do not meet regulatory requirements.

   b). Discovery of inoperable equipment during surveillance testing performed to determine the operability of that equipment. If as a result of the surveillance testing, an event occurs because of other equipment (i.e., equipment not being tested) failing, missed opportunities should be considered when evaluating identification for the failure of the "other" equipment.

   c). Violations identified during a surveillance test where an evolution or process that is being tested does not proceed as expected, e.g., a liquid spill due to a mispositioned valve.

   d). Disclosure of a fitness-for-duty violation during routine testing.

   e). Identification of a violation as a result of the licensee follow-up of safety concerns raised by an employee of the licensee.

   f). Violations identified in audit findings, deficiency reports, or contractor reviews, in which the condition adverse to quality was not corrected in a timely manner, but was later disclosed by a licensee review before an event occurred.

   g). Violations identified as the result of procedurally required checks of a medical treatment plan before treatment occurs, or as the result of daily checks of radiography equipment before the equipment is used.

h). Cases in which, in response to an event, a licensee investigation identifies violations that were not involved in or did not contribute to the event.

i). Violations identified as the result of a licensee's review of, e.g., generic communications, NRC Information Notices, reports generated by outside or industry groups, etc.

j). If the NRC finds a violation prior to the licensee's identification of it, but the licensee was aggressively pursuing the same issue as the result of an NRC Information Notice and likely would have found it within a reasonable time, the licensee should get credit for its identification activities.

2. Situations In Which Missed Opportunities Should Be Considered Before Giving the Licensee Credit for Identification:

a). Violations identified as the result of an event that was readily obvious by human observation or mechanical instrumentation such as a reactor trip, or leak, spills, or annunciator alarms.

b). As the result of a lost or damaged gauge, the licensee identifies a failure to maintain constant control over a gauge containing byproduct material.

c). Discovery of an overexposure documented in a dosimetry report.

d). Licensee identifying the loss of control of material after being informed by a member of the public that material has been found in the environment.

e). Receipt of records from the Federal Bureau of Investigations indicating that a person who has been granted unescorted access had a criminal history of which the licensee was not aware, although the information was available in the licensee's records.

f). As a result of an event or NRC questions, the licensee identifies violations that it should have found earlier if it had been responsive to previous audits findings, deficiency reports or contractor reviews, where conditions adverse to quality were not corrected in a timely manner.

g). Violations that caused or contributed to an event, identified as part of a follow-up to the event.

h). Violations identified as part of determining the root causes for a radiation injury to a patient.

i). Cases in which the inappropriate location of sources results in a misadministration being disclosed when the source is removed.

j). Cases in which an overexposure is identified after reading personal dosimetry or data documented in dosimetry reports following an event where, due to the event, the potential for an overexposure exists.

3. NRC-Identified Situations:

a). Cases in which a licensee does not appear to have been pursuing a matter on its own but, due to concerns raised by the NRC, identifies:

1). Violations related to equipment failures when the NRC has questioned operability of the equipment; or

2). Violations of reporting requirements found when the NRC requested information on the event.

b). Violations related to an event would be considered NRC-identified if:

1). The violation is subsequently discovered by the NRC during event follow-up where the licensee failed to initiate reviews or investigations that would have reasonably identified the violation, e.g., a misadministration may have occurred that the licensee attributes to a failure to follow procedure, and does not pursue the matter further.

2). The NRC finds that an underlying root cause violation exists (e.g., a training violation), but the licensee has not pursued it.

4.3.2.4 Credit for Prompt and Comprehensive Corrective Action

A. The purpose of corrective action is to encourage licensees to:

1. Take the actions necessary immediately upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and

2. Develop and implement (in a timely manner) the corrective actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.

B. Regardless of other circumstances (e.g., past enforcement history, identification, etc.), the licensee's corrective actions should always be evaluated as part of the civil penalty assessment process.

1. As a reflection of the importance given to this factor, an NRC judgment that the licensee's corrective action has not been prompt and comprehensive will always result in issuing at least a base civil penalty.

NOTE:

Even in cases when the NRC, at the time of the predecisional enforcement conference, identifies additional peripheral or minor corrective action still to be taken, the licensee may be given credit in this area, as long as the licensee's actions addressed the underlying root cause and are considered sufficient to prevent recurrence of the violation and similar violations.

2. In assessing this factor, consideration will be given to:

   a). The timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action);

   b). The adequacy of the licensee's root cause analysis for the violation, and,

   c). The comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern), given the significance and complexity of the issue.

C. Normally, the judgment of the adequacy of corrective actions will hinge on whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action.

1. This will normally be judged at the time of the predecisional enforcement conference (e.g., by outlining substantive additional areas where corrective action is needed).

2. Earlier informal discussions between the licensee and NRC inspectors or management may result in improved corrective action, but should not normally be a basis to deny credit for corrective action.

NOTE:

In response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee makes a prompt decision on operability, and either (1) makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as found condition; or (2) promptly initiates corrective action consistent with Criterion XVI of 10 CFR 50, Appendix B, if it intends to restore the facility or procedure to the FSAR description.

3. For cases in which the licensee does not get credit for actions related to identification because the NRC identified the problem, the assessment of the licensee's corrective action should begin from the time when the NRC put the licensee on notice of the problem.

4. Notwithstanding eventual good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, corrective action would not be considered prompt and comprehensive.

D. Corrective action for violations involving discrimination should normally only be considered comprehensive if the licensee takes prompt, comprehensive corrective action that:

1. Addresses the broader environment for raising safety concerns in the workplace; and

2. Provides a personal remedy for the particular discrimination at issue.

4.3.3 Assigning Final Civil Penalty Amounts

A. The statutory maximum civil penalty amount, as established in the 1980 revision to the AEA, is $100,000 per violation, per day; however, that amount has been periodically adjusted as required by the Debt Collection Improvement Act of 1996 and is currently $140,000 per violation, per day.

B. To calculate the statutory maximum for a given Severity Level I, II, or III problem, each associated violation should be assigned the $140,000 value, multiplied by the number of days the violation existed, and then added to the civil penalty amounts for the other violations. In other words, the statutory maximum for a given Severity Level I, II, or III problem is the cumulative result of the number of associated violations and the number of days that each violation existed.

C. Civil penalties are normally assessed using the process described in the previous section of this manual.

D. The issuance of civil penalties is intended to be remedial, i.e., to encourage prompt and effective corrective actions and to prevent recurrence.

NOTE:

The civil penalty assessment process described in this chapter is intended to be a normative standard for most Severity Level III issues. Departures from this process by the exercise of discretion (for either escalation or mitigation of the enforcement action) requires the approval of the Director, OE, and may require approval of the DEDO or EDO and/or notification or consultation with the Commission, as specified in the Enforcement Policy. However, in no instance will a civil penalty for any one violation exceed $140,000 per day.

E. The NRC reserves the imposition of daily civil penalties up to the statutory maximum for particularly significant violations, e.g., violations with actual consequences to public health

and safety or the common defense and security, repetitive significant violations, and willful violations involving senior licensee officials.

4.3.4 Civil Penalty Assessment Process Outcome

Depending on the outcome of the civil penalty assessment process, the staff will conclude that an escalated NOV should be issued without a civil penalty or that an escalated NOV should be issued with a civil penalty.

4.4 Escalated Notices of Violation without Civil Penalty

A. Notices of Violation are addressed in the Enforcement Policy.

B. The procedures for issuing NOVs are set forth in 10 CFR 2.201.

C. An NOV is a formal written citation setting forth one or more violations of a legally binding requirement. An NOV including Severity Level I, II, or III violations is considered escalated enforcement action. An NOV including violations associated with red, yellow, or white SDP findings is also considered an escalated enforcement action.

D. Escalated NOVs are normally issued subsequent to conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report. Escalated NOVs are included in the Significant Enforcement Actions collection on the Enforcement Web site.

4.4.1 Preparing an Escalated NOV Action

A. Escalated NOVs without civil penalties should be prepared by using the applicable standard format in Appendix B and the applicable standard citations in Appendix C.

B. Escalated NOVs should be dated the same date as the cover letter transmitting the enforcement action to the licensee.

C. The escalated NOV should include the following elements:

1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).

2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph).

   a). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.

   b). Each violation, including a violation with multiple examples, contains a single "contrary to" statement.

3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation.

NOTE:

To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked "**Official Use Only - Predecisional Enforcement Information**." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

a). The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc.

b). When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

4. The severity level proposed for the violation or the severity level of the problem when several violations have been grouped.

5. The applicable Violation Examples section of the Enforcement Policy under which the violation is categorized or, alternatively, the associated significance of the violation (i.e., red, yellow, or white SDP finding).

6. A request for the licensee to respond unless the region concludes that a response in not necessary, including:

a). The reason for the violation, or if contested, the basis for disputing the violation;

NOTE:

The EA number should be included for each violation or problem when there is more than one escalated issue in the action.

b). The corrective steps that have been taken and the results achieved;

c). The corrective steps that will be taken to avoid further violations; and

d). The date when full compliance will be achieved.

7. A waiver, if the region concludes that a response is not necessary based on information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence is already addressed on the docket. This alternative requires the licensee to respond if the description does not accurately describe the licensee's corrective action position.

D. Cover letters that transmit escalated NOVs without civil penalties to licensees should be prepared by the region (see forms in Appendix B).

1. The staff should refer to MC 0612 and MC 0609 for guidance related to the overall structure of the cover letter and content of introductory paragraphs for NOVs associated with SDP findings.

2. Transmittal letters with and without SDP findings should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action.

3. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.

4. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:

a). A summary of:

1). The purpose of the inspection;

2). If and how the issue was reported, e.g., 50.72, Licensee Event Report (LER), etc.; and

3). When the inspection report(s) related to this action were issued.

b). A discussion of whether a conference was conducted, a choice letter was issued, or a choice call was made, as applicable.

c). A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation.

5. For NOVs <u>without</u> SDP findings, the discussion should be sufficiently detailed to permit licensee management (and others who may review the action) to understand the safety significance of the violations, including:

a). A concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC’s ability to perform its regulatory function, or it was willful and how it relates to severity level categorization;

b). A statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable routine decisional points in the civil penalty assessment process, i.e.;

1). Whether the licensee has had any escalated actions during the past two years or two inspections (include specific reference to any prior escalated action within two years or two previous inspections);

2). Whether credit was given for identification (address only if the answer to the preceding question is “no;”

3). Whether credit was given for corrective action (include a brief description of corrective actions); and

4). If discretion was exercised, an additional explanation of this decision including a reference to the particular section of the Enforcement Policy discussing the use of discretion;

c). A statement that the NOV is considered escalated action in accordance with the Enforcement Policy because it is associated with a red, yellow, or white SDP finding;

d). A statement associated with not proposing a civil penalty, i.e., to encourage prompt (identification, if applicable) and comprehensive correction of violations, (and to recognize the absence of previous escalated enforcement action, if applicable). This section should also indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission;

6. Either:

a). A description of the response that is necessary from the licensee (if the region concludes that a response is necessary), including any area that deserves special emphasis; or

b). A conclusion that a licensee response is not necessary (if the region concludes that a response is not necessary), including a provision that the licensee respond if its understanding of the corrective action is different;

7. A statement that the NRC will determine, based on the licensee's NOV response, corrective actions, and results of future inspections, whether further enforcement action is necessary:

8. A statement that the letter and the licensee's response will be made available to the Public; and

9. Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

4.4.2 Escalated NOV Coordination and Review

A. All escalated NOVs must be coordinated with OE and headquarters prior to issuance.

1. For the purposes of this Manual, “coordination” means either that:

a). The action needs to be submitted to headquarters for actual enforcement action package review; or

b). The enforcement strategy for the action needs to be agreed upon (usually via a panel or caucus). The Strategy Form will document the level of OE review.

B. If a proposed enforcement action is required to be submitted to headquarters for formal review and approval prior to issuance, it should be electronically mailed to:

- OE ("OEMail.Resource")
- The OE Enforcement Specialist
- The Assistant General Counsel for Materials Litigation and Enforcement, and
- The applicable program office Enforcement Coordinator

C. Draft Commission papers should also be electronically mailed to the addressees listed above, as required.

D. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

1. All escalated NOVs with Severity Level I, II, and III violations and all NOVs associated with red, yellow, or white SDP findings must be submitted to headquarters for enforcement action package review and approval prior to issuance.

2. Unless OE requests, OGC will not normally provide comments for an escalated action issued without a civil penalty or order.

NOTE:

OGC review and statement of no legal objection (NLO) is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).

3. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations have been properly evaluated from an overall agency perspective.

4. Comments should be provided (verbally, electronically, or in writing) to OE and "OEMail.Resource" within 10 working days.

   a). Comments are normally provided through the program office Enforcement Coordinators.

   b). OE will consider timely program office comments and OGC comments, if proposed, and revise the enforcement action, as appropriate.

   c). The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

5. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

6. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.

7. OE will either:

   a). Approve the action (for Severity Level II materials actions); or as appropriate,

   b). Forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

E. Violations that involved interaction with OE and do not require a formal headquarters review and approval prior to issuance should be coordinated as follows:

1. Subsequent to a panel or caucus, or after additional discussions following a licensee's response to an inspection report where no conference has been conducted:

   a). OE will amend (as warranted) the Strategy Form to reflect the enforcement strategy that was agreed upon during the discussions and send it to the region and program office.

   b). The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary).

NOTE:

If there are additional discussions with the Regional Administrator and the Director, OE, the Strategy Form may need to be amended to represent the agreed upon strategy.

c). If there are disagreements on the overall enforcement strategy, OE may request that the region submit the entire action (including the transmittal letter) to OE for formal review and approval prior to issuance.

2. Regional Counsel's review and statement of no legal objection is required prior to issuance by the region. If Regional Counsel is not available to review the case and there will be a significant delay due to the Regional Counsel's unavailability, then the region should submit the action to headquarters for OE review.

3. The region should send OE the complete escalated enforcement package after it has issued the action by including OEMeb.Resource/OEMail.Resource and the Enforcement Specialist on distribution.

4.4.3 Licensee Notification & Distribution of Escalated NOVs

A. Licensee notification, mailing, and distribution should be made according to the following guidelines:

B. In most cases, Escalated NOVs are mailed to licensees and States by regular mail. NRC distribution should be made according to the distribution lists in Appendix D and regional procedures.

C. Copies of escalated NOVs issued by the program offices should be sent to OE as well as to the appropriate regional office.

NOTE:

Escalated NOVs should be e-mailed to OEMeb.Resource when they are put in ADAMS to ensure that they are posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as The licensee has received a copy of the enforcement action.

D. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

1. The Board of Trustees frequently has oversight responsibility for the legal title, management of funds, and direction of policy for the medical licensee.

2. This distribution effort will:

   a). Ensure that escalated enforcement actions and their potential implications are raised to the highest level of authority;

   b). Deter future violations; and

   c). Promote the health and safety of the public, including employees' health and safety.

E. In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available.

4.4.4 Licensee Response to Escalated NOVs

A. If the region concludes that a licensee response is necessary, the provisions of 10 CFR 2.201 require that a licensee submit a written response to an NOV within 20 days of the date of the NOV or other specified time frame; however, normally 30 days should be used.

B. If a licensee does not respond to an NOV within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the NOV) and consideration will be given to whether additional enforcement action is warranted.

C. Licensees may be granted response extensions where good cause is shown.

   1. The region may grant extensions of up to 30 days without OE approval.

   2. OE should be promptly notified of any extensions the region grants.

   3. OE approval is required for extensions beyond 30 days.

      a). Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due.

      b). The confirmation may either be prepared by the NRC or the licensee, a copy of which should be sent to OE and the region.

   4. OE is responsible for notifying the Office of the Secretary when an enforcement hearing extension extending beyond 30 days is approved.

D. A Licensee’s response to an escalated NOV may either:

1. Accept that the violation occurred as stated in the NOV. In this case, the region should:

   a). Review the licensee's response for the adequacy of the corrective action, including whether the licensee has properly identified the root causes;

> **NOTE:**
>
> Licensee denials include disputes involving NRC requirements, facts of the case, application of the Enforcement Policy, and severity levels.

   b). Send an acknowledgment letter usually within 30 days after receipt of the licensee's response to the same person and address as the escalated NOV.

2. Contest the staff's facts and/or conclusions regarding the escalated NOV. In this case, the region should:

   a). Respond within 30 days after receipt of the licensee's response to the same person and address as the escalated NOV, addressing the licensee's points of contention and the acceptability of its corrective action.

> **NOTE:**
>
> If the licensee disputes the SDP characterization of an inspection finding, the region should notify OE. While the dispute may not change the violation, it may affect how the violation should be dispositioned. In other words, if a licensee successfully argues that a white SDP finding should be green, the associated violation would likely be dispositioned as an NCV, instead of being considered escalated action. In this case, the subject line in the response to the licensee should include, "WITHDRAWAL OF ESCALATED ENFORCEMENT ACTION." OE should be notified in these cases and will take responsibility for removing any action from the Enforcement Web site.

   b). Within 21 days of the date of the licensee's denial, the region should prepare a response to the license and submit it for approval to OE, OEMail.Resource, and the OE Enforcement Specialist handling the case.

      1). If the licensee denies the violation based on additional information not previously disclosed, the region should prepare a more detailed response, as appropriate.

      2). Any errors identified in the enforcement action must be addressed in the region's response.

3. Disagree with the significance of the violation. In this case, the region should:

   a). Follow the process described above when the licensee disagrees with the specific NRC guidance (i.e., Manual, Enforcement Policy, or MC 0612) that supports the significance of the violation.

   b). When the licensee disagrees with the significance of the violation but does not provide justification for its position, send an acknowledgment stating that the NRC reviewed the licensee's response and concluded that the licensee did not provide an adequate basis to reclassify the violation; therefore, the NRC maintains that the violation occurred as stated.

4. The subject line in the response to the licensee's denial should appropriately describe the agency's response as follows:

   a). If the NRC maintains that the NOV remains valid, the subject line should read "RESPONSE TO DISPUTED NOTICE OF VIOLATION.

   b). If the region concludes that a second, revised NOV should be issued, the subject line should read, REVISED NOTICE OF VIOLATION.

   c). If the region concludes that the violation should be withdrawn, the subject line should read, WITHDRAWAL OF NOTICE OF VIOLATION.

4.5 Notice of Violation and Proposed Imposition of Civil Penalty (NOV/CP)

A. Civil penalties are addressed in the Enforcement Policy.

B. The procedures for issuing civil penalties are set forth in 10 CFR 2.205.

C. Civil penalties:

   1. Are normally proposed for Severity Level I and II violations;

   2. Are normally considered for Severity Level III violations;

   3. May be proposed for knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act; and

   4. Are considered for violations associated with red, yellow or white SDP findings that involve actual consequences.

D. Civil penalty actions are normally issued subsequent to conferences or after a licensee has had an opportunity to respond (e.g., in a PEC or in writing) to the apparent violations contained in an inspection report.

E. The purpose of a civil penalty is not retributive, but remedial, and should:

1. Encourage licensees to take effective and lasting corrective actions to avoid future problems by being in compliance; and

2. Create a deterrent that will prevent future violations, both for the individual licensee and for other, similar licensees.

F. When issuing a civil penalty, the following guidelines should be considered:

1. Separate civil penalties should normally be assessed for separate violations with different root causes.

2. Separate violations can be grouped as one violation in which case the cited violations should include both “requirement paragraphs” followed by one “contrary to” paragraph that addresses the common root cause and notes the resulting consequence.

3. A single civil penalty should normally be assessed for violations that can be grouped into one problem when they are closely related, such as cause and affect type violations, e.g., it would be appropriate to view the failure to perform adequate testing that results in a piece of inoperable equipment as one problem, warranting consideration of one civil penalty.

4. Notwithstanding a common root cause, separate civil penalties may be assessed for several violations that occurred over time, provided that each violation is addressed in its own citation (i.e., “contrary to” paragraph).

5. Civil penalties may be issued to individual directors or responsible officers of a non-licensee vendor organization who knowingly and consciously fail to notify the NRC in accordance with 10 CFR Part 21. Section 206 of the Energy Reorganization Act (ERA) authorizes the NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

6. Section 234 of the AEA gives the NRC the authority to impose civil penalties on "any person," including licensee employees. However, pursuant to the Enforcement Policy, except as noted above, the NRC will not normally impose a civil penalty on an individual.

4.5.1 Preparing an NOV/CP Action

A. The responsible office should prepare NOVs with civil penalties by using the applicable standard format in Appendix B and the applicable standard citations in Appendix C.

B. The NOV should be dated the same date as the cover letter transmitting the enforcement action.

C. The NOV should include the following elements:

1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).

2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph).

   a). The NOV should be dated the same date as the cover letter transmitting the enforcement action.

   b). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.

   c). Each violation, including a violation with multiple examples, contains a single "contrary to" statement.

3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation.

   a). The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc.

   b). When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

4. The severity level proposed for the violation or the severity level of the problem when several violations have been grouped.

5. The applicable Violation Examples section of the Enforcement Policy under which the violation is categorized.

6. The amount of the civil penalty proposed.

7. The EA number should be included for each violation or problem when there is more than one escalated issue in the action.

8. A statement requesting the licensee’s response, to include:

   a). Admission or denial of the alleged violation;

   b). The reason for the violation if admitted, and if denied, the reasons why;

   c). The corrective steps that have been taken and the results achieved;

   d). The corrective steps that will be taken to avoid further violations; and

e). The date when full compliance will be achieved.

9. Instructions to the licensee for payment of the civil penalty or for protesting the civil penalty.

NOTE:

To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked **Official Use Only - Predecisional Enforcement Information**. In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

D. Cover letters that transmits escalated NOVs with civil penalties to licensees should be prepared by the region using the appropriate form in Appendix B.

1. The letter should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action.

2. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.

3. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:

- A summary of the purpose of the inspection
- If and how the issue was reported, e.g., 50.72, LER etc.
- When the inspection report(s) related to this action were issued

4. A discussion of whether a conference was conducted, a choice letter was issued, or a choice call was made, as applicable.

5. A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation. The summary:

a). Should not be as detailed as the discussion in the inspection report; however,

b). It should be sufficiently detailed to permit licensee management and others who may review the action to understand the safety significance of the violations.

c). A concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC’s ability to perform its regulatory function, or it was willful and how it relates to severity level categorization.

d). A statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable decisional points in the civil penalty assessment process, i.e., (1) whether the licensee has had any escalated actions for the site during the past two years or two inspections (include specific reference to any prior escalated action), (2) whether credit was given for identification (address only if the answer to (1) is no), and (3) whether credit was given for corrective action (include a brief description of corrective actions). It should also include an additional explanation if discretion was exercised, including a reference to the particular section of the Enforcement Policy.

e). A conclusion of why a civil penalty is being proposed. The conclusion should:

1). State the regulatory emphasis of the case, e.g., the importance of "system operability," "procedural compliance," "attention to detail," "accurate and complete information," "control of licensed material," compliance with technical specifications," "compliance with dose limits," etc;

2). Address the licensee's shortcomings based on the civil penalty assessment process that resulted in the civil penalty, i.e., emphasize the importance of prompt identification and comprehensive correction of violations if the licensee did not get credit for these factors;

3). Recognize previous escalated enforcement actions, if applicable;

4). Indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission;

5). Indicate, as appropriate, additional concerns the NRC may have. However, care should be exercised to keep the correspondence focused on the overall regulatory concern; and

6). Discuss any violations included in the enforcement action that were not assessed a civil penalty.

f). A description of the response that is necessary from the licensee which should be expanded if a particular response is desired.

g). A statement that the NRC will determine, based on the licensee's NOV/civil penalty response, corrective actions, and results of future inspections, whether further enforcement action is necessary.

h). A statement that the letter and the licensee's response will be made available to the Public.

i). Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

4.5.2 NOV/CP Coordination and Review

A. All NOV/CP actions must be coordinated with OE and headquarters prior to issuance.

B. Prior to issuance, proposed enforcement actions should be electronically mailed to headquarters for formal review and approval to:

- OE (OEMail.Resource)
- The OE Enforcement Specialist
- The Assistant General Counsel for Materials Litigation and Enforcement
- The applicable program office Enforcement Coordinator

C. Draft Commission papers should also be electronically mailed to the addressees listed above, as required.

D. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

E. All civil penalty actions including Severity Level I, II, and III violations are sent to headquarters for formal review and approval prior to issuance.

1. OGC will review the proposed enforcement package and provide comments to OE within 10 working days of receipt of the package. OGC advises that acceptance of these comments does not necessarily constitute legal concurrence (or statement of no legal objection).

NOTE:

OGC review and statement of no legal objection (NLO) is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).

2. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations have been properly evaluated from an overall agency perspective.

3. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.

   a). Comments are normally provided through the program office Enforcement Coordinators.

   b). OE will consider timely OGC and program office comments and revise the enforcement action, as appropriate.

c). The OE Enforcement Specialist will notify the NRR, NMSS, NSIR, NRO or FSME Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

4. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

5. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.

6. As appropriate, OE will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

7. The region should send OE the complete escalated enforcement package after it has issued the action by including OEWeb.Resource/OEMail.Resource and the Enforcement Specialist on distribution.

4.5.3 Licensee Notification & Distribution of NOV/CPs

A. Licensee notification, mailing, and distribution should be made according to the following guidelines:

1. In most cases, the region will notify the licensee by telephone of an enforcement action involving a civil monetary penalty.

a). In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.

b). In all cases, the licensee will be notified of the proposed civil penalty before the information is made public.

2. Licensees are to be provided a written copy of escalated enforcement actions as expeditiously as possible.

a). Electronic transmission of escalated enforcement actions should be used to provide a written copy to licensees having facsimile equipment.

NOTE:

Escalated NOVs should NOT be made publically available in ADAMS until confirmation that the licensee has received a copy of the enforcement action (i.e., e-mail, facsimile, courier). For individual actions, contacting the individual is sometimes problematic. In such cases, every reasonable attempt should be made to contact the individual before the action is made publicly available in ADAMS.

b). Alternatively, licensees in close geographic proximity to regional offices may choose to have a written copy picked up by courier from the regional office.

c). Escalated enforcement packages are to be mailed by either Certified Mail (Return Receipt Requested) or Express Mail. If facsimile equipment is not available, escalated enforcement packages are to be mailed by Express Mail.

3. The office in which the package is signed is responsible for its distribution.

a). Escalated NOVs should be e-mailed to “OEWEB” when they are put in ADAMS to ensure that they are posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as; “the licensee has received a copy of the enforcement action.”

b). Distribution lists for NRC addressees are in Appendix D.

c). A copy should be sent to the appropriate State. (The region’s State Liaison Officer will normally handle this for program office cases, provided the Enforcement Specialist notifies the Regional Enforcement Coordinator.)

4. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman and Board of Trustees.

B. In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile.

NOTE:

In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available. For individual actions, contacting the individual is sometimes problematic. In such cases, every reasonable attempt should be made to contact the individual before the press release is issued and the action becomes publicly available.

4.5.4 Licensee Response to NOV/CPs

A. The provisions of 10 CFR 2.201 require that a licensee submit a written response addressing the violations included within a civil penalty action within 20 days of the date of the civil penalty action or other specified time frame; however, normally 30 days should be used.

B. If a licensee does not respond to a civil penalty action within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the action) and consideration will be given to whether additional enforcement action is warranted, i.e., the case should be referred to the Attorney General, an order imposing the civil penalty should be issued, or whether some other enforcement action is warranted.

C. The region may grant extensions of up to 30 days without OE approval.

1. OE should be promptly notified of any extensions the region grants.

2. OE approval is required for extensions beyond 30 days.

3. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due. The confirmation may either be prepared by the NRC or the licensee. A copy of this follow-up correspondence is to be sent to OE and the region.

D. As discussed below, licensees may:

1. Admit the violation and pay the civil penalty;

2. Deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and pay the civil penalty; or

3. Deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and not pay the civil penalty.

E. If the licensee admits that the violation occurred as stated in the NOV and pays the civil penalty, the regional office is to review the licensee's corrective action. The region should notify OE, usually within two weeks of receiving the licensee's response, of the acceptability of the licensee's response.

1. Once OE has been notified by the region of the acceptability of the licensee's response, OE will send the licensee a letter acknowledging payment of the civil penalty and stating that the corrective actions described in the licensee's response will be examined during future inspections. This acknowledgment should be sent to the licensee within one week of the region's notification.

2. If the region requires additional information from the licensee:

a). The region should notify OE; and

b). OE will send a letter acknowledging payment of the civil penalty and directing the licensee to provide the required information to the region.

3. In either case, after OE sends an acknowledgment letter, OE will normally close out the associated EA number, thereby formally closing the case.

F. If the licensee denies the violation, contests the staff's facts or conclusions, or requests mitigation of the civil penalty, but pays the civil penalty, the region is to review the licensee's points of contention.

1. If the licensee presents additional information not previously disclosed:

a). Careful consideration should be given to the appropriateness of the original proposed action.

b). The region is to prepare an evaluation of the licensee's response and submit it to OE for possible inclusion in the acknowledgment letter sent by the Director, OE.

2. If the licensee's response does not contain new information, then the region will:

a). Prepare and submit to OE a brief response addressing only those issues that are significant and appropriate along with an assessment of the licensee's corrective action.

b). OE will coordinate with the region and issue the NRC's response letter.

3. Even if the licensee's response does not present new information, an error identified in the enforcement action must be corrected.

4. Licensee responses that contest enforcement actions but pay civil penalties should usually be acknowledged within 45 days.

5. If the licensee has paid a monetary penalty and then, based on the above review of the licensee's response, it appears that the penalty was clearly paid in error, the overpayment should be promptly returned to the licensee.

a). OE will arrange to have a check issued from the Controller's Office.

b). After it is determined that the Treasury has issued a check, OE will send a letter to the licensee explaining the modification to the civil penalty.

G. If the licensee denies the violation, contests the staff's facts or conclusions, or requests mitigation of the civil penalty, and does not pay the civil penalty, the regional office should:

1. Review the licensee's response;

2. Decide whether the civil penalty should be imposed, partially mitigated, or withdrawn; and

3. Prepare a written evaluation of the licensee's response.

   a). The evaluation should:

      1). Be Submitted to OE within 45 days;

      2). Address the licensee's points of contention; and

   b). The evaluation should include:

      1). A restatement of each disputed violation;

      2). A summary of the licensee's position concerning each disputed violation;

      3). The NRC's evaluation of the licensee's position; and

      4). The NRC's conclusion.

NOTE:

Processing Time: NRC processing time is defined as that time from the date the case is opened to the issuance of an enforcement action or other appropriate disposition less: (1) anytime the NRC could not act due to the case residing with DOL, DOJ, other government entity, where additional OI field work is needed, or where the licensee requests a lengthy deferment, and (2) anytime the NRC could not act due to processing FOIA requests.

4. If the region recommends that the civil penalty should be imposed, an Order Imposing Civil Monetary Penalty should be prepared with the staff's evaluation included as an appendix to the order.

5. If the region recommends that the civil penalty should be partially mitigated, an Order Imposing Civil Monetary Penalty should be prepared to reflect partial mitigation with the staff's evaluation included as an appendix to the order.

6. If the region recommends that the civil penalty should be withdrawn, the region should prepare a cover letter, for OE issuance, to the licensee with the staff's evaluation as an appendix to the letter.

4.5.5 NOV and NOV/CP Coordination and Review Output Measures

A. Regional and OE (headquarters) timeliness on all escalated enforcement cases will be reported on a periodic basis to the Regional Administrators and Program Office Directors.

NOTE:

Start Date: The measuring period starts on the latest of the following dates: (1) inspection exit date, (2) the date the results of an agency investigation are forwarded to the staff, (3) the date that the Department of Justice (DOJ) says NRC may proceed, for cases referred to the DOJ, or (4) the date of the Department of Labor decision that is the basis for the action. The inspection exit date will be defined by the region or office performing the inspection and may be the date of the telephone re-exit. For investigation cases, the start date will typically not be the re-exit date. However, on rare occasions, when significant additional inspection effort is needed after issuance of the investigation results are forwarded to the staff, the re-exit date will be used as the start date.

B. The current timeliness output measures recognize that cases which include an OI investigation require additional time in order to review the OE report prior to determining the appropriate enforcement outcome.

1. Cases that do not include an OI investigation:

- 100% completed within 180 calendar days, and
- 100% will average 120 calendar days, reported by region and as an agency on a rolling four quarter basis.

2. Cases that include an OI investigation:

- 100% completed within 360 days of NRC processing time, and
- 100% will average 180 days of NRC processing time, reported by region and as an agency on a rolling four quarter basis.

C. Enforcement Action Timeliness Goals for processing escalated NOVs are based on the agency's enforcement action output measures.

1. **Cases that do not include an OI** investigation:

- Cases issued after OE consultation (usually via a panel or caucus) should be issued within 120 calendar days from the start date.
- Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 90 calendar days from the start date.

2. **Cases that include an OI investigation:**

- Cases issued after OE consultation (usually via a panel or caucus) should be issued within 180 days of NRC processing time.
- Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 150 days of NRC processing time.

4.6 Press Releases for NOVs and NOV/CPs

A. Regional enforcement personnel will inform the regional Public Affairs Officer (RPAO) at least 72 hours prior to the issuance of an action.

B. In the event that the RPAO decides to issue a press release, the RPAO will provide a draft press release to the regional staff for concurrence.

   1. OE may review press releases in the more significant cases.

   2. After the enforcement action has been signed, the RPAO will receive verification that the licensee has been notified of the action and has received a copy of the enforcement action.

C. If the enforcement action has not been posted on the Enforcement Web site when the press release issued, the press release should state that the action will be posted on the Enforcement Web page.

D. The regional Enforcement Coordinator should consider the following when reviewing press releases:

   1. The severity level categorization;

   2. Whether the violation reflects an actual or a potential consequence;

   3. Whether the violation impacted the NRC’s ability to perform its regulatory function;

   4. Whether the violation was willful; and

   5. Whether the licensee reported the violation or identified it.

E. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.

4.7 Order Imposing Civil Monetary Penalty (Imposition Order)

A. The procedures for issuing orders imposing civil penalties are set forth in 10 CFR 2.205 and the Enforcement Policy.

B. The NRC issues an Order Imposing Civil Monetary Penalty when a licensee refuses to pay a civil penalty unless a basis exists for withdrawal of the proposed penalty.

C. Draft Impositions, with the accompanying evaluation of the licensee's response and draft transmittal letter to the licensee, are submitted to OE within approximately 45 days of receipt of the licensee's response.

4.7.1 Preparing an Imposition Order Action

A. The responsible office should prepare the imposition package, including the following elements as discussed below:

1. An Order Imposing Civil Monetary Penalty should be prepared by using the applicable standard format in Appendix B. The Order Imposing Civil Monetary Penalty should be sent to the same person and address as the original proposed enforcement action. The order should include the following sections:

   a). The first section identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

   b). The second section briefly describes the violation(s), when the Notice of Violation and Proposed Imposition of Civil Penalty was issued, and when responses were received from the licensee.

   c). The third section is the statement of the decision to impose the civil penalty.

   d). The fourth section is the statement that orders payment of the civil penalty.

   e). The fifth section states the licensee's opportunity to request a hearing.

2. A cover letter transmitting the order to the licensee should be prepared using the applicable form in Appendix B. The letter should:

   a). Reference previous relevant correspondence between the licensee and the NRC, very briefly take into account any licensee rebuttal or reasons for mitigation or remission, impose the civil penalty.

   b). State that the order and its enclosures will be made available to the Public.

   c). Be more detailed if it is determined that an appendix will not be included (such as in certain discrimination cases).

3. An appendix may or may not be included as part of the package.

   a). OE will coordinate with OGC, the region, and the program office to determine whether an appendix should be included.

      1). Certain cases (such as discrimination) may not require an appendix.

      2). If applicable, appendices should be prepared using the applicable form in Appendix B.

   b). The appendix should include:

1). A restatement of each disputed violation;

2). A summary of the licensee's response;

3). An NRC evaluation of the response; and

4). A conclusion.

c). The appendix should discuss only violations that have been assessed a civil penalty.

1). If the licensee has contested any violations that were not assessed a civil penalty, those violations should be discussed in a separate document as an additional enclosure to the cover letter.

2). In preparing the appendix it is important to understand that it puts the involved licensee, as well as other licensees, on notice regarding the NRC position. This permits other licensees to be aware of NRC concerns.

3). The appendix may improve the NRC's litigative position by demonstrating careful consideration of the licensee's arguments.

4. The licensee's response to the proposed civil penalty action should be included in the enforcement package as background material if it has not already been provided in a panel.

4.7.2 Imposition Order Action Coordination and Review

A. All Orders Imposing Civil Monetary Penalties are sent to headquarters for review and approval prior to issuance.

B. The imposition package should be electronically mailed to:

- OE (OEMail.Resource)
- The OE Enforcement Specialist
- The Assistant General Counsel for Materials Litigation and Enforcement
- The applicable program office Enforcement Coordinator

C. Draft Commission papers, imposition packages and supporting background materials, including the licensee’s response to the proposed civil penalty, should also be electronically mailed to the addressees listed above, as required.

1. Impositions should be given priority treatment by both the region and headquarters offices.

D. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases

E. OGC review and statement of no legal objection is required on all Orders Imposing Civil Monetary Penalties. OGC will review the proposed order and provide comments to OE within 10 working days of receipt of the package.

F. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations have been properly evaluated from an overall agency perspective.

1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.

2. Comments are normally provided through the program office Enforcement Coordinators.

3. OE will consider OGC and program office comments and revise the enforcement action, as appropriate.

4. The OE Enforcement Specialist will notify the NRR, NMSS, or NSIR Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

5. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

G. The region should review the revised order and, if possible, provide concurrence on headquarters' changes by the next day.

H. OE will obtain a statement of no legal objection from OGC and issue the action, if delegated to OE or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

4.7.3 Licensee Notification & Distribution of Imposition Orders

Licensee notification, mailing, and distribution of impositions should be made according to the following guidelines:

A. In most cases, the region will notify the licensee by telephone of an Order Imposing Civil Monetary Penalty.

1. In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.

a). A copy of the action should be e-mailed to OEWeb.Resource to ensure that the action is posted to the Enforcement Web site in a timely manner.

2. In all cases, the licensee will be notified of the order before the information is made public.

B. OE is to provide licensees with a copy of the order as expeditiously as possible. Electronic transmission should be used to provide a copy to licensees having facsimile equipment. Orders should be mailed by Express Mail.

C. OE is responsible for distribution of the order.

NOTE:

In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.

1. NRC distribution lists are in Appendix D.

2. A copy should also be sent to the appropriate State.

3. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

D. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile.

E. All Orders Imposing Civil Monetary Penalties are published in the *Federal Register*. OE is responsible for this action.

4.7.4 Press Releases for Imposition Orders

A. Press releases are normally issued only for impositions where the amount of the civil penalty has been changed from the original civil penalty action.

NOTE:

To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked **Official Use Only - Predecisional Enforcement Information**. In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

B. Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when an imposition is about to be issued.

1. For impositions involving a press release:

a). The RPAO will provide the draft press release to the regional staff for concurrence.

b). Upon request, OE may also review press releases in particularly significant cases.

2. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy.

a). Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.

b). If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.

C. Press releases for impositions should indicate whether the originally proposed civil penalty is being imposed partially or in full.

4.7.5 Licensee Response to Imposition Order

A. The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame; however, normally 30 days should be used.

1. A licensee may either:

a). Pay the civil penalty; or

b). Request a hearing.

B. If a licensee does not respond to the order within the allotted time, the region should contact OE and the case will be referred to the Attorney General for collection.

C. If a licensee requests a hearing, OE will provide the request to OGC to forward to the Office of the Secretary of the Commission.

D. Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing.

1. A licensee's request for an extension must be made in writing to the Director, OE; and

2. Include a statement of good cause for the extension.

4.8 Order Modifying, Suspending, or Revoking License

A. The procedures for issuing orders are set forth in 10 CFR 2.202 and the Enforcement Policy.

> **NOTE:**
>
> The guidance included in this section is intended to primarily address orders based on compliance issues, i.e., orders that are issued based on the failure to comply with existing regulatory requirements. The program offices may issue safety orders that impose additional requirements beyond the existing regulations (e.g., 2002 security orders). In addition to program office guidance for these safety orders, the staff should follow the guidance included in this manual regarding the issuance of Enforcement Notifications (ENs), Web site postings, and the issuance of EA numbers.

B. An **order** is a written NRC directive to:

1. Modify, suspend, or revoke a license;
2. Cease and desist from a given practice or activity; or
3. Take such action as may be proper.

C. Orders may also be issued in lieu of, or in addition to civil penalties, as appropriate for Severity Level I, II, or III violations.

D. Unless a separate response is warranted, an NOV need not be issued where an order is based on violations described in the order. The violations described in the order need not be categorized by severity level.

E. The NRC may also issue orders to unlicensed persons, including vendors and contractors (and employees), when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities.

F. License Modification Orders are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.

G. Suspension Orders may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken. Suspension Orders may be used to:

1. Remove a threat to the public health and safety, common defense and security, or the environment;

NOTE:

Orders should be prepared within time-frames that are consistent with the safety and regulatory significance of the situations.

2. Stop facility construction; or

3. Revoke the license when:

   a). The licensee has not responded adequately to other enforcement action;

   b). The licensee interferes with the conduct of an inspection or investigation;

   c). Any other reason for which license revocation is legally authorized exists.

H. Revocation Orders may be used:

1. When a licensee is unable or unwilling to comply with NRC requirements;

2. When a licensee refuses to correct a violation;

3. When a licensee does not respond to an NOV where a response was required;

4. When a licensee refuses to pay an applicable fee under the Commission's regulations; or

5. Any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

I. Cease and Desist Orders may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.

4.8.1 Immediately Effective Orders

A. Orders may be effective after a licensee or individual has had an opportunity to request a hearing.

1. In such cases, the order becomes effective on the day following the deadline for requesting a hearing, if the licensee does not request a hearing.

2. If the licensee requests a hearing, the order becomes effective as determined in the hearing process.

B. Orders can be made immediately effective without prior opportunity for a hearing whenever the NRC determines that the public health and safety or common defense and security interests so require, or when the order is responding to a violation involving willfulness.

1. These orders must specify the basis for their immediate effectiveness.

a). The discussion should support the finding that the Commission no longer has reasonable assurance that activities will be conducted without undue risk to the public's health and safety.

b). Immediately effective orders should be expedited.

c). Immediately effective orders should also be supported by a draft affidavit prepared by a person who can testify as to why the public health, safety, or interest requires an immediately effective order in this case.

C. All orders are published in the *Federal Register*. The issuing office is responsible for this action.

D. If an immediately effective order is needed to eliminate an immediate hazard arising from a violation that also warrants a civil penalty, the order should be expedited, and the civil penalty issued promptly thereafter.

4.8.2 Preparing an Order Action

A. The responsible office should prepare the civil penalty package, including the following elements as discussed below:

1. The order should be prepared using the applicable standard format in Appendix B. Depending on the type of order, the order will include any of the following sections:

a). A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

b). A section that describes the relevant events, facts, violations, technical aspects or legal reasons that substantiate issuing the order.

c). A section that provides the justification for issuing the order.

d). For a confirmatory order, a section that confirms, by the order, a licensee's commitments to take certain actions.

e). A section that orders modification, suspension, or revocation of the license.

f). A section that states the licensee's obligation to respond to the order.

g). A section that states the opportunity for a licensee or any other person adversely affected by the order to request a hearing.

2. A cover letter transmitting the order to the licensee should be prepared using the applicable format in Appendix B, customized to reflect the specific order.

a). The letter should briefly state the basis for the order and describe any actions required or prohibited based on the order.

b). The letter should also state that failure to comply with the provisions of the order may result in civil and criminal sanctions and that the letter and its enclosures will be made available to the Public.

c). A contact should be provided. This is normally the Director, OE.

3. For immediately effective orders, the originating office should provide, with the draft package, a draft affidavit to support the order's immediate effectiveness.

4. Because 10 CFR 2.202(c)(2)(i) requires the staff to respond to a motion to set aside immediate effectiveness within 5 days of receipt of the motion, the originating office must be prepared to make the knowledgeable personnel available to put the affidavit in final form (see applicable form in Appendix B).

4.8.3 Order Coordination and Review

A. All orders are sent to headquarters for review and approval prior to issuance.

NOTE:

Order which are immediately effective should be expedited. Delaying issuance undermines the basis for the necessity of an immediately effective order.

B. The order package should be electronically mailed to:

- OE (OEMail.Resource)
- The OE Enforcement Specialist
- The Assistant General Counsel for Materials Litigation and Enforcement
- The applicable program office Enforcement Coordinator

C. Draft Commission papers, order packages and supporting background materials should be electronically mailed to the licensees listed above, as required.

D. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

E. Orders should be given priority treatment by both the region and headquarters offices.

F. OGC review and statement of no legal objection is required on all orders. OGC will review the proposed order and provide comments to OE within 10 working days of receipt of the package.

G. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations have been properly evaluated from an overall agency perspective.

1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.

2. Comments are normally provided through the program office Enforcement Coordinators.

3. OE will consider OGC and program office comments and revise the enforcement action, as appropriate.

4. The OE Enforcement Specialist will notify applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

H. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

I. The region should review the revised order and, if possible, provide concurrence on headquarters' changes by the next day.

J. OE will obtain a statement of no legal objection or concurrence from OGC and issue the order if delegated or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

K. For Confirmatory Orders, the consent of the recipient of the order is required.

1. OE will forward the draft order to the recipient with the text of the ordering portion of the proposed order and a cover letter requesting that the appropriate person sign and return the letter agreeing to the issuance of the order and the fact that the consent waives the right to request a hearing on the order.

2. The text of the order itself will recite the consent to the order.

4.8.4 Licensee Notification & Distribution of Orders

Licensee notification, mailing, and distribution should be made for orders according to the following guidelines:

A. In most cases, the region will notify the licensee by telephone of the issuance of an order.

1. In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.

2. In all cases, the licensee will be notified of the order before the information is made public.

B. Licensees are to be provided a written copy of the order as expeditiously as possible.

1. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment.

> **NOTE:**
>
> A copy of the action should be e-mailed to OEWeb.Resource to ensure that the action is posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, The licensee has received a copy of this action," so that the Web staff will know that it can be posted.

2. Orders should be mailed by Express Mail.

C. OE is responsible for distribution of the order.

1. Distribution lists for NRC addressees are in Appendix D.

2. Orders involving individuals where they are restricted from licensed activities in general, should be sent to the Office of State Programs for distribution to all Agreement States.

3. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

D. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.

E. All orders are published in the *Federal Register*. OE is responsible for this action.

4.8.5 Press Releases for Orders

A. Press releases are generally issued for all orders other than impositions.

B. Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when these actions are about to be issued.

1. The RPAO will provide a press release to the regional staff for concurrence.

2. OE may also review press releases in some particularly significant cases.

3. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy.

4. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.

5. If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.

4.8.6 Licensee Responses to Orders

A. The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame.

B. The licensee may:

1. Consent to the order,

2. Admit or deny each allegation and provide a basis as to why the order should not have been issued; and/or

3. Request a hearing.

C. If a licensee does not request a hearing by the deadline provided, the order becomes effective at that time (for orders not immediately effective at the time of issuance).

D. Questions concerning the effectiveness and scope of a given order should be referred to OE.

E. If the licensee has requested a hearing and subsequently calls the NRC to discuss the case, the call should be referred to OE.

1. OE will ensure that the assigned OGC hearings attorney is present in any discussions.

2. If a licensee requests a hearing, OE will provide a copy to OGC to forward to the Office of the Secretary of the Commission.

F. Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing. The request for an extension must:

1. Be made in writing to the Director, OE; and

2. Include a statement of good cause for the extension.

4.8.7 Relaxation of Orders

A. An order provides that the Regional Administrator may relax or terminate conditions of the order.

1. The purpose of this provision is to avoid the need to issue another order should the order need to be relaxed.

NOTE:

If the Director of NRR or NMSS relaxes a program office security order, a copy of the correspondence to the licensee should be sent to OEWeb.Resource to ensure prompt posting in the security order document collection.

2. The Regional Administrator is named to ensure that the licensee works directly with the region concerning the order.

3. The same offices that were involved in issuing the order are to be involved before relaxing or terminating a provision of the order.

4. If the region finds it appropriate to relax or terminate an order, OE should be contacted and OE will obtain the views (as appropriate) of NRR, NMSS, NSIR, OGC, and the DEDO.

5. In some orders, the Director, OE, is the designated official who can relax the order. In these cases, OE will obtain the views of the appropriate offices.

6. In some cases, the decision is made to withdraw an order.

a). Use of the term "withdraw" is appropriate when dropping all or part of an order.

b). The term "rescind" should be used when it is concluded that because of a basic mistake of law or fact, the action should not have been issued at all.

4.9 Demand for Information (DFI)

A. The procedures for issuing Demands for Information (DFIs) are set forth in 10 CFR 2.204 and the Enforcement Policy.

B. A **DFI** is a formal request made to a licensee or applicant to obtain information to determine whether the license should be granted, or if issued, whether it should be modified, suspended, or revoked, or other enforcement action taken.

1. DFIs may be issued to unlicensed persons, including vendors and contractors (and employees), for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued.

2. A DFI may be included within another escalated action, such as an order or proposed imposition of civil penalty.

3. A DFI is a significant action. It should be used only when it is likely that an inadequate response will result in an order or other enforcement action.

4.9.1 Preparing a DFI Action

The responsible office should prepare the DFI package, including the following elements as discussed below:

A. The DFI should be prepared using the applicable standard format in Appendix B. The Demand should include the following sections:

1. A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

2. A section that describes the relevant events, facts, alleged violations, potentially hazardous conditions, technical aspects or legal reasons that provide the substantive basis for issuing the DFI.

3. A section that requires specific information from the licensee by a certain date (determined on a case-by-case basis) to determine whether the license should be modified, suspended, or revoked.

B. A cover letter transmitting the DFI to the licensee should be prepared using the applicable form in Appendix B, customized to reflect the DFI as the applicable enforcement action. The letter should:

1. Briefly state the basis for the DFI;

2. Describe the information requested;

3. State that the failure to comply with the DFI provisions may result in enforcement action; and

4. Note whether the DFI will be made available to the Public.

C. As noted above, a DFI may also be incorporated into another action. In such cases, the DFI is normally included, in an abbreviated format, as part of the transmittal letter for the accompanying action, using language similar to the following:

"In addition, pursuant to Sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 50.54(f), in order for the Commission to determine whether your license should be modified or other actions taken, you are required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, an explanation as to:

1. why the NRC can have confidence that [request information specific to the circumstances of the case] . . . "

D. Copies of the response to the DFI should be sent to:

1. The Associate General Counsel for Hearings, Enforcement & Administration at the same address; and

2. The Regional Administrator, specifying the region and regional address.

4.9.2 DFI Coordination and Review

A. All DFIs are assigned EA numbers and are sent to headquarters for review and approval prior to issuance.

B. The DFI package should be electronically mailed to:

- OE (OEMail.Resource)
- The OE Enforcement Specialist
- The Assistant General Counsel for Materials Litigation and Enforcement
- The applicable program office Enforcement Coordinator

C. Draft Commission papers, order packages and supporting background materials should be electronically mailed to the addressees listed above, as required.

D. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

1. Orders should be given priority treatment by both the region and headquarters offices.

E. If requested, OGC will review the proposed DFI and provide comments to OE within 10 working days of receipt of the package.

F. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations have been properly evaluated from an overall agency perspective.

1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.

2. Comments are normally provided through the program office Enforcement Coordinators.

3. OE will consider timely OGC and program office comments and revise the DFI, as appropriate.

4. The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

5. The OE Enforcement Specialist will notify the program office Project Manager when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

G. OE will forward the revised DFI to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

H. The region should review the revised DFI and, if possible, provide concurrence on headquarters' changes by the next day.

I. OE will attempt to resolve any differences among the region, the program office, and OGC.

4.9.3 Licensee Notification & Distribution of DFI

Licensee notification, mailing, and distribution for DFIs should be made according to the following guidelines:

A. In most cases, the region will notify the licensee by telephone of the issuance of a DFI. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.

B. Licensees are to be provided a written copy of the Demand as expeditiously as possible. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment. Demands should be mailed by Express Mail.

C. OE is responsible for distribution of the Demand (see the distribution lists for NRC addressees are in Appendix D).

4.9.4 Licensee Response to DFI

A. The provisions of 10 CFR 2.204 require that a licensee submit a written response to a DFI under oath or affirmation within 20 days of the date of the DFI or other specified time frame (determined on a case-by-case basis).

B. If a licensee does not respond to a DFI within the required time, the NRC will consider issuing an order to modify, suspend, or revoke the licensee or consider taking such other action as necessary to compel a response.

C. After reviewing the licensee's response to the DFI, the NRC determines whether further action is necessary to ensure compliance with regulatory requirements.

4.10 Settlement of Enforcement Proceedings and Actions

A. The procedures for settlement of a proceeding to modify, suspend, or revoke a license or other action and compromise of a civil penalty are set forth in 10 CFR 2.203.

B. For those cases where a hearing has been requested:

1. Normally OGC has the lead;

2. The staff is responsible for preparing a settlement agreement;

3. The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and a hearings attorney for the NRC;

4. The stipulation or compromise is subject to approval by the designated presiding officer, or if none has been designated, by the Chief Administrative Law Judge; and

5. If approved, the Atomic Safety and Licensing Board Panel (ASLBP) will issue a decision or order settling and discontinuing the proceeding that will include the terms of the settlement or compromise.

C. For those cases that do not involve a hearing, the staff (normally OE) is responsible for preparing a settlement agreement (see the sample standard format in Appendix B).

1. The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and the Director, OE, for the NRC.
2. The settlement is subject to approval by the Director, OE after consultation, as warranted, with the DEDO.

3. If approved, the staff (normally OE) will prepare an order settling, modifying, or discontinuing the enforcement action that will include the terms of the settlement or compromise using the standard format in Appendix B.

CHAPTER 5
EXERCISE OF DISCRETION

Chapter 5: Exercising discretion to either escalate or mitigate enforcement sanctions.

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5. Exercise of Discretion

5.1 Exercising Discretion

Discretion, i.e., escalating or mitigating a civil penalty, is exercised to ensure that a proposed civil penalty reflects the significance of the circumstances.

5.1.1 Escalation of Sanctions

A. Escalation of NRC sanctions is addressed in the Enforcement Policy.

> **NOTE:**
>
> Exercise of escalation discretion requires prior approval by the Director, OE, and the DEDO and consultation with the EDO or Commission, as warranted.

B. The NRC considers the following violations to be of significant regulatory concern:

1. Violations categorized at Severity Level I, II, or III; and

2. Violations associated with Significance Determination Process (SDP) findings evaluated as having low to moderate or greater safety significance (i.e., white, yellow, or red).

C. When application of the normal guidance in the Enforcement Policy does not result in an appropriate sanction, the NRC may:

1. Exercise discretion to apply its full enforcement authority where the action is warranted. This may include:

   a). Escalating civil penalties;

   b). Issuing appropriate orders; and

   c). Assessing civil penalties for continuing violations on a per day basis, up to the current statutory limit of $140,000 per violation, per day. This amount is periodically adjusted by the Debt Collection Act of 1996.

5.1.1.1 Escalation of Civil Penalties

A. Notwithstanding the outcome of the normal civil penalty assessment process addressed in the Enforcement Policy, the NRC may either:

1. Propose a civil penalty where application of the normal process would otherwise result in a zero penalty; or

2. Propose a civil penalty greater than the amount resulting from application of the normal process (i.e., greater than the base or twice the base civil penalty).

B. The purpose of exercising this discretion to escalate the amount of the civil penalty is to ensure that the proposed civil penalty reflects the significance of the circumstances. However, in no instance will a civil penalty exceed the current statutory maximum of $140,000 per violation per day. This discretion is expected to be exercised on an infrequent basis.

C. Examples when this discretion should be considered include, but are not limited to, the following:

1. Violations or problems categorized at Severity Level I or II;

2. Over exposures or releases of radiological material in excess of NRC limits;

3. Cases involving particularly poor licensee performance;

4. Cases involving willfulness; particularly instances where the licensee made a conscious decision to be in noncompliance with NRC requirements in order to obtrain an economic benefit.

5. Cases where a licensee's previous enforcement history has been particularly poor, or where the current violation is directly repetitive of an earlier violation;

6. Cases where the violation results in a substantial increase in risk, including cases in which the duration of the violation has contributed to the substantial increase;

7. Cases where a licensee had made a conscious decision to be in noncompliance in order to obtain an economic benefit;

8. Cases involving the loss, abandonment, or improper transfer or disposal of a sealed source or device. Notwithstanding the outcome of the normal civil penalty assessment process, these cases normally should result in a civil penalty of at least the base amount; and

5.1.1.2 Orders

The NRC will, where necessary, issue orders in conjunction with civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations.

5.1.1.3 Daily Civil Penalties

A. The NRC reserves the use of daily civil penalties up to the statutory maximum for particularly significant violations, e.g., violations with actual consequences to public health and safety or the common defense and security, repetitive significant violations, and willful violations involving senior licensee officials.

B. In order to recognize the added safety significance for those cases where a very strong message is warranted for significant violations that continue for more than one day, the NRC may:

1. Exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of $140,000 for each day the violation continues; or

2. Exercise discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

5.1.2 Mitigation of Sanctions

A. Mitigation of NRC sanctions is addressed in the Enforcement Policy which provides that when a violation of NRC requirements is identified, enforcement action should normally be taken.

NOTE:

Exercise of mitigation discretion requires prior approval by the Director, OE, and DEDO consultation, as warranted.

B. There are situations when it is appropriate for the agency to either limit or forgo the normal use of its enforcement sanctions. These include, but are not limited to, the following:

1. When the NRC wants to encourage and support licensee initiative for self-identification and correction of problems. In such cases, the NRC may exercise discretion and refrain from issuing a civil penalty and/or issuing an NOV.

2. When the licensee failed to make a required report to the NRC, the NRC may exercise discretion based on the circumstances of the case while issuing a separate enforcement action for the licensee's failure to make a required report.

5.1.2.1 Violations Identified During Extended Shutdowns or Work Stoppages

A. The NRC may refrain from issuing an NOV or a proposed civil penalty for a violation that is identified after:

1. The NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee (or a work stoppage at a construction site); or

2. The licensee enters an extended shutdown or work stoppage related to generally poor performance over a long period of time, provided that the violation:

a). Is documented in an inspection report (or inspection records for some material cases); and

b). Meets all of the following criteria:

1). It was either licensee-identified as a result of a comprehensive program for problem identification and correction that was developed in response to the shutdown or identified as a result of an employee allegation to the licensee (Note: Even if the NRC identifies the violation, discretion may be appropriate if all other criteria are met);

2). The violation is based upon activities of the licensee prior to the events leading to the shutdown;

3). The violation would not be categorized at Severity Level I;

4). The violation was not willful; and

5). The licensee's decision to restart the plant requires NRC concurrence.

5.1.2.2 Violations Involving Old Design Issues

A. For operating facilities, the NRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as an engineering, design, or installation deficiency, provided that the violation:

1. Is documented in an inspection report (or inspection records for some material cases) that includes a description of the corrective action; and

2. Meets all of the following criteria:

a). It was licensee-identified as a result of the licensee’s voluntary initiative;

b). It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

NOTE:

The mitigation discretion described in the Enforcement Policy does not normally apply to violations associated with issues evaluated by the SDP. The ROP uses the Agency Action Matrix which has provisions to consider extenuating circumstances that were previously addressed through enforcement mitigation to determine the agency response to performance issues.

c). It was unlikely to be identified (after the violation occurred) by efforts such as normal surveillances or routinely scheduled quality assurance (QA) activities.

B. The NRC may refrain from issuing an NOV for cases that meet the above criteria provided the violation was caused by conduct that is not reasonably linked to present performance, e.g., violations that are at least 3 years old or violations that occurred during plant construction.

1. This discretion may not apply if the licensee should have reasonably identified the violation earlier.

NOTE:

The intent of the ROP is to encourage licensees to pursue risk significant issues. The current enforcement program gives credit to licensees for old design issues that were licensee-identified, not likely to be identified by routine licensee efforts, and where appropriate corrective actions have been or will be taken by the licensee. This exercise of enforcement discretion places a premium on licensees initiating efforts to identify and correct subtle violations that are not likely to be identified by routine efforts before degraded safety systems are called upon to work.

2. Exercising this discretion encourages licensee efforts to identify and correct subtle violations (that are not likely to be identified by routine efforts) before degraded safety systems are called upon.

C. Discretion is not generally applied to departures from the FSAR when:

1. The NRC identifies the violation unless it was likely in the staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of the licensee's initiative;

2. The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies a FSAR issue;

3. The licensee identifies the violation but had prior opportunities to do so, e.g., the

licensee was aware of the departure from the FSAR and failed to correct it earlier;

4. There is willfulness associated with the violation;

5. The licensee fails to make a report required by the identification of the departure from the FSAR; or

6. The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program with a defined scope and schedule.

5.1.2.3 Violations Identified Due to Previous Escalated Enforcement Action

In accordance with the Enforcement Policy, the NRC may refrain from issuing an NOV or a proposed civil penalty for a Severity Level II, III, or IV violation that is identified after the NRC has taken escalated enforcement action, provided that the violation:

A. Is documented in an inspection report (or inspection records for some material cases) that includes a description of the corrective action; and

B. Meets all of the following criteria:

1. It was licensee-identified as part of the corrective action for the previous escalated enforcement action;

2. It has the same or similar root cause as the violation for which escalated enforcement action was issued;

3. It does not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation;

4. It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification; and

5. It would not be characterized at Severity Level I.

5.1.3 Violations Involving Discrimination

A. The NRC may refrain from taking enforcement action for cases involving discrimination when a licensee who, without the need for government intervention:

1. Identifies an issue of discrimination; and

2. Takes prompt, comprehensive, and effective corrective action to address both the particular situation and the overall work environment, i.e., to establish a safety-conscious workplace that includes aggressive licensee follow-up providing a

message that retaliation is not acceptable within the workplace.

B. The NRC may refrain from taking enforcement action for cases where:

1. A complaint is filed with the DOL, but the licensee settles the matter before the DOL Area Office makes a finding of discrimination; or

2. A finding is made against the licensee; however, the licensee chooses to settle before the evidentiary hearing begins.

a). The NRC policy of not normally citing violations in such cases might encourage licensee settlements, thereby reducing the potential for a chilling effect.

b). Settlements normally provide a more timely remedy for the complainant and may be used to demonstrate the licensee's commitment to a retaliation-free environment.

C. The NRC may exercise its discretion not to take enforcement action:

1. When the licensee has publicized that:

NOTE:

The licensee might publicize information that discrimination will not be tolerated by posting a notice, a newsletter, a handout, or by some other means; however, the information should be conveyed in a manner designed to minimize the chilling effect on others.

a). A complaint of discrimination for engaging in protected activity was made to the DOL; and

b). The matter was settled to the satisfaction of the employee (the terms of the specific settlement agreement need not be posted); and

c). When the DOL Area Office finds discrimination, and the licensee has taken action to positively reemphasize that discrimination will not be tolerated.

d). When a person comes to the NRC without going to the DOL and the matter is promptly settled thereafter prior to the NRC conducting an investigation or, if an investigation is initiated, prior to the NRC making a substantial effort on it.

D. Even if no formal enforcement action is taken, the NRC would:

1. Issue a letter, as is normal practice in similar cases, to emphasize the need for lasting remedial action;

2. Inform the licensee that future violations may result in enforcement action; and

3. In certain cases as part of the settlement process, also consider entering into a consent order with the licensee to address remedial action.

E. Whether the exercise of discretion is appropriate depends on the circumstances of the case.

1. Enforcement discretion would not normally be appropriate for the following four types of cases, however, depending on the circumstances, mitigation for corrective actions may be appropriate:

a). Allegations of discrimination as a result of providing information directly to the NRC;

b). Allegations of discrimination caused by a manager above first-line supervisor (consistent with the current Enforcement Policy classification of Severity Level I or II violations);

c). Allegations of discrimination where a history of findings of discrimination (by the DOL or the NRC) or settlements suggest a programmatic rather than an isolated discrimination problem;

d). Allegations of discrimination which appear particularly blatant or egregious.

2. Enforcement discretion would not normally be appropriate for cases where the licensee does not appropriately address the overall work environment (e.g., by using training, postings, revised policies or procedures, any necessary disciplinary action, etc.) to communicate corporate policy against discrimination.

5.1.4 Violations Involving Special Circumstances

A. Notwithstanding the outcome of the normal civil penalty assessment process, the NRC may reduce or refrain from issuing a civil penalty or an NOV for a Severity Level II, III, or IV violation.

B. Exercise of this discretion will be based on the merits of the case after considering the guidance in the Enforcement Policy and the NRC Enforcement Manual and such factors as:

NOTE:

Discretion involving special circumstances is expected to be exercised only where application of the normal guidance in the Enforcement Policy is unwarranted.

1. The age of the violation;

2. The technical and regulatory significance of the violation;

3. The clarity of the requirement;

4. The appropriateness of the requirement;

5. The overall performance of the licensee;

6. Whether the licensee reported significant information to the NRC that was not otherwise required to be reported to the NRC; and

7. Other relevant circumstances, including any that may have changed since the violation.

C. The NRC may refrain from issuing enforcement action for violations resulting from matters not within a licensee's control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. In these cases, the staff should include a conclusion, e.g.:

"The staff has reviewed your root cause analysis of the event and has concluded that the equipment failure could not have been avoided or detected by your quality assurance program or other related control measures. Therefore, in accordance with Sections VI.A and VII.B.6 of the Enforcement Policy, the NRC has chosen to exercise enforcement discretion and not issue a violation for this issue."

D. Generally, licensees are held responsible for the acts of their employees and contractors.

1. Licensees will normally be cited at the same significance level that their employee or contractor is cited.

2. Discretion reducing the significance level of the citation issued to the licensee may be warranted in cases where, despite the thoroughness of the licensee’s oversight and auditing programs, the licensee’s employee or contractor is still cited for a violation.

E. The staff may consider exercising enforcement discretion for inaccurate or incomplete performance indicator (PI) data submitted to the NRC as part of the ROP.

1. Exercising enforcement discretion on a case-by-case basis should take into account whether the licensee has completed the initial stage of learning and recognizing ongoing PI development activities.

2. The staff may consider exercising discretion if new PIs are developed.

3. OE will work with the regional offices and NRR in determining whether enforcement discretion should be exercised for all future PI-related 10 CFR 50.9 violations.

F. In reaching decisions as to the appropriate sanction against licensees who qualify as small

entities, the staff should also consider the intent of the Small Business Regulatory Enforcement Fairness Act (SBREFA).

1. There may be cases in which, after considering the normal adjustment factors and the size of a qualified small entity to whom a civil penalty may be issued, the staff believes that the penalty should be reduced or eliminated. In those cases, it is appropriate to propose such a modification based on the intent of the SBREFA.

2. The modification of a civil penalty based on the intent of SBREFA should be treated as an exercise of enforcement discretion.

5.2 Preparation of Exercise of Enforcement Discretion (EOD)

5.2.1 The EOD Cover Letter

A. The cover letter of an exercise of enforcement discretion (EOD) letter to the licensee should include:

1. A reference to the Enforcement Policy;

2. The severity level or significance determination characterization of the violations; and

3. A clear basis for exercising this discretion.

B. While it is not necessary to include a detailed analysis of this process in a transmittal letter to a licensee, it is imperative that a sound rationale for exercising discretion is included in the letter to the licensee, lest the agency appear arbitrary and capricious in exercising its enforcement authority.

C. The subject line in the transmittal letter should either state or include, "EXERCISE OF ENFORCEMENT DISCRETION."

5.2.2 EOD Coordination and Review

A. EODs require the approval of the Director, OE, with consultation with the DEDO as warranted.

B. EOD cases require an EA number.

NOTE:

A NOED will only be exercised if the staff is clearly satisfied that the action is consistent with protecting the public health and safety.

C. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

D. OE should be consulted by telephone for Severity Level IV issues.

E. Where appropriate, based on the uniqueness or significance of the issue, e.g., the first time that discretion (as discussed in this chapter) is exercised for a nuclear power plant, the Commission should be provided prior notice through issuance of an EN. If OE determines that an EN is necessary, it should contain the same information that is included in the cover letter to the licensee.

5.2.3 EOD Signature Authority

A. The Regional Administrator should normally sign the letter transmitting the EOD if it includes an issue that could have been considered as escalated action, had it not been for the EOD.

B. The Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

5.3 Notice of Enforcement Discretion (NOED)

A. A Notice of Enforcement Discretion (NOED) is addressed in the Enforcement Policy.

B. Specific guidance and responsibilities for issuing NOEDs is provided in Part 9900 of the NRC Inspection Manual.

C. The NRC expects all of its licensees to comply with applicable requirements and license conditions.

D. In certain cases involving operating power reactor licensees, the NRC staff may choose not to enforce compliance with specific Technical Specification (TS) Limiting Conditions for Operation (LCOs) or license conditions.

1. On occasion, circumstances may arise where a licensee's compliance with a TS LCO or with other license conditions would involve an unnecessary plant transient or performance of testing, inspection, or system realignment that is inappropriate with the specific plant conditions, or unnecessary delays in plant startup without a corresponding health and safety benefit.

2. For an operating power reactor, this exercise of enforcement discretion is intended to minimize the potential safety consequences of unnecessary plant transients with the accompanying operational risks and impacts or to eliminate testing, inspection, or system realignment which is inappropriate for the particular plant conditions.

NOTE:

The Office of Nuclear Reactor Regulation (NRR) is responsible for issuing guidance for NOEDs involving operating power reactors. NMSS is responsible for issuing guidance for NOEDs involving GDPs.

3. For plants in a shutdown condition, exercising enforcement discretion is intended to reduce shutdown risk by, again, avoiding testing, inspection or system realignment which is inappropriate for the particular plant conditions, in that, it does not provide a safety benefit or may, in fact, be detrimental to safety in the particular plant condition.

4. Exercising enforcement discretion for plants attempting to startup is less likely than exercising it for an operating plant, as simply delaying startup does not usually leave the plant in a condition in which it could experience undesirable transients. In such cases, the Commission would expect that discretion would be exercised with respect to equipment or systems only when it has at least concluded that, notwithstanding the conditions of the license:

   a). The equipment or system does not perform a safety function in the mode in which operation is to occur;

   b). The safety function performed by the equipment or system is of only marginal safety benefit, provided remaining in the current mode increases the likelihood of an unnecessary plant transient; or

   c). The TS or other license condition requires a test, inspection, or system realignment that is inappropriate for the particular plant conditions, in that it does not provide a safety benefit, or may, in fact, be detrimental to safety in the particular plant condition.

E. In certain cases involving gaseous diffusion plant (GDP)s, the NRC staff may choose not to enforce compliance with a Technical Safety Requirement (TSR) or technical specification, or other certificate condition.

1. On occasion, circumstances may arise where compliance with a TSR or technical specification or other certificate condition would unnecessarily call for a total plant shutdown or, notwithstanding that a safety, safeguards or security feature was degraded or inoperable, compliance would unnecessarily place the plant in a transient or condition where those features could be required.

   a). Such regulatory flexibility is needed because a total plant shutdown is not necessarily the best response to a plant condition.

   b). GDPs are designed to operate continuously and have never been shut down. Although portions of GDPs can be shut down for maintenance, the NRC staff has been informed by the certificate holder that restart from a total plant shutdown

may not be practical and the staff agrees that the design of a GDP does not make restart practical.

1). The decision to place either GDP in plant-wide shutdown condition would be made only after determining that there is inadequate safety, safeguards, or security and considering the total impact of the shutdown on safety, the environment, safeguards, and security.

2). NOEDs would not be used for noncompliances with other than certificate requirements or for situations where the certificate holder cannot demonstrate adequate safety, safeguards, or security.

2. The staff may also grant enforcement discretion in cases involving severe weather or other natural phenomena, based upon balancing the public health and safety or common defense and security of not operating, against the potential radiological or other hazards associated with continued operation, and a determination that safety will not be impacted unacceptably by exercising this discretion.

NOTE:

OE approval is required if a violation is involved and the staff does not want to issue enforcement action (NOV or NCV).

F. A licensee or certificate holder seeking the issuance of a NOED must provide a written justification, or in circumstances where good cause is shown, oral justification followed as soon as possible by written justification, that documents the safety basis for the request and provides whatever other information necessary for the NRC staff to make a decision on whether to issue a NOED.

1. The NRC staff is expected to rarely exercise enforcement discretion in this manner.

2. Even when plant operation is impacted, the NRC staff is under no obligation to take such a step merely because it has been requested.

G. The decision to exercise enforcement discretion by issuing a NOED does not change the fact that a violation will occur nor does it imply that enforcement discretion is being exercised for any violation that may have led to the violation at issue.

1. Such enforcement action (i.e., associated with the root causes) is intended to emphasize that licensees should not rely on the NRC's exercise of enforcement discretion as a routine substitute for compliance or for requesting a license amendment.

2. If the root cause underlying a NOED request results in an escalated action, the time during which the NOED is effective will not be counted in considering the impact of the violation.

5.3.1 NOED Coordination and Review

A. NOEDs may be issued by either the Regional office, or by NRR or NMSS.

1. NOEDs should be e-mailed to “OEWeb.Resource” to ensure prompt posting to the NOED document collection.

B. When the root cause of a licensee’s need for a NOED was a violation:

1. OE must issue an EA number, regardless of the severity level or whether the violation will ultimately be dispositioned as an NOV or an NCV; however

2. The NOED should not include the EA number, i.e., the enforcement action should reference the NOED number.

5.3.2 NOED Signature Authority

A. For power reactors, the appropriate Regional Administrator, or his or her designee, may issue a NOED after consultation with the Director, NRR, or his or her designee, to determine the appropriateness of granting a NOED where:

1. The noncompliance is temporary and nonrecurring when a TS amendment is not practical,

2. The expected noncompliance will occur during the brief period of time it requires the NRC staff to process an emergency or exigent license amendment under the provisions of 10 CFR 50.91(a)(5) or (6).

B. For gaseous diffusion plants,

1. The appropriate Regional Administrator, or his or her designee, may issue and document a NOED where:

   a). The noncompliance is temporary and nonrecurring; and

   b). When an amendment is not practical.

2. The Director, NMSS, or his or her designee, may issue a NOED if the expected noncompliance will occur during the brief period of time it requires the NRC staff to process a certificate amendment under 10 CFR 76.45.

CHAPTER 6
WRONGDOING

Chapter 6 provides guidance regarding a wide range of topics related to wrongdoing, including:

- willful violations
- Office of Investigation (OI) investigations and reports
- referrals to the Department of Justice (DOJ)
- the enforcement process for discrimination cases
- discrimination for engaging in protected activities (DOL process)
- enforcement and administrative actions involving individuals
- alternative dispute resolution

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6. Wrongdoing

6.1 Willful Violations

A. A **willful violation** is one in which an NRC requirement has been breached through a voluntary and intentional action or lack of action other than a mistake or error.

1. Notwithstanding the actual safety consequence of a willful violation, the Commission has taken the position that all willful violations are of particular concern because its regulatory programs are based on licensees and their employees and contractors acting with integrity and communicating with candor.

2. OI refers cases to DOJ when willful violations are substantiated by OI.

B. Willful violations may result either from conduct which:

1. Is intentional or deliberate; or

2. Constitutes reckless or careless disregard or indifference as to whether a requirement will be violated.

C. The basic elements of a **deliberate violation** are typically:

1. A requirement exists (a regulation, license condition or technical specification, order or statute);

2. A violation of the requirement has occurred;

3. The person's actions were voluntary, as opposed to inadvertent;

4. The person committing the violation knew a requirement existed, understood the requirement, and knew the requirement was applicable at the time; and

5. The person knew that his or her actions were contrary to the requirement.

NOTE:

It is important to recognize that careless disregard is not a subset of deliberate conduct.

D. The elements of conduct which demonstrate **careless (or reckless) disregard** are typically:

1. A requirement exists (a regulation, license condition or technical specification, order or statute);

2. A violation of the requirement has occurred;

3. The person's actions were voluntary, as opposed to inadvertent, constituting or resulting in the violation;

4. The person acted with reckless disregard or indifference to:

   a). The existence of the requirement;

   b). The meaning of the requirement; or

   c). Whether the intended conduct conformed to the requirement.

6.1.1 Use of EA Numbers

A. All cases involving willful violations (including those dispositioned as NCVs or involving discretion) require:

   1. An EA number for tracking purposes; and

   2. OE and OGC concurrence on the final package.

6.1.2 Enforcement Sanctions for Willful Violations

A. Because a willful violation is normally a significant regulatory issue, enforcement sanctions:

   1. Should demonstrate the unacceptability of such actions; and

   2. Could include, in the event the agency loses reasonable assurance that licensed activities can be conducted safety, orders amending, suspending or revoking a license or preventing an individual from conducting activities involving regulated materials.

B. A violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness.

   1. In determining the significance of a violation involving willfulness, the relative weight of each of the following factors will be assessed based on the circumstances of the violation, including:

      a). The position of the person involved in the violation (e.g., a supervisory or non-supervisory employee whether working for the licensee or for a contractor);

      b). The regulatory responsibilities imposed on the person involved in the violation (e.g., a licensed operator or an unlicensed operator fulfilling a position of regulatory significance related to the public health and safety or the common defense and security;

c). The significance of any underlying violation;

d). The intent of the violator (i.e., deliberateness or careless disregard); and

e). The economic or other advantage, if any, gained as a result of the violation.

C. If a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be considered at least more than minor.

D. Licensees must take remedial action in responding to willful violations commensurate with the circumstances that demonstrate the seriousness of the violation, thereby creating a deterrent effect within the licensee's organization.

NOTE:

If the agency cannot make a conclusion as to whether an issue involves willfulness, it may issue a Demand for Information (DFI) to the licensee, requesting information on whether the NRC can have reasonable assurance that the licensee will conduct its activities in accordance with NRC requirements.

E. Every case involving a willful violation will normally be considered for escalated action. However, in an effort to encourage licensees to act responsibly in the identification and correction of such violations, the NRC may choose, in accordance with the Enforcement Policy, to disposition certain violations by issuing an NCV if the licensee identified and corrected the violation.

6.2 Office of Investigation (OI) Investigations and Reports

A. OI may conduct an investigation for alleged wrongdoing by NRC licensees, individuals or organizations who are licensed by the NRC, have applied for NRC licenses, or who are vendors or contractors of NRC licensees.

1. **Wrongdoing** involves a violation of NRC requirements resulting from discrimination, deliberate misconduct, or careless disregard.

2. The NRC staff is required to notify OI when a reasonable basis exists for believing that wrongdoing may have occurred.

3. Upon receipt of an OI report involving wrongdoing, OE, OGC, the region, and the appropriate program office perform an initial screening to determine appropriate enforcement action.

B. For **discrimination cases**, OI investigates only those cases that:

1. Meet the *prima facie* threshold discussed in (a) below.

a). To constitute a ***prima facie*** case, the complainant must establish that:

1). He/she was engaged in a protected activity (an employee participates in a protected activity when he/she raises safety-related issues or any issue within the NRC's regulatory jurisdiction, even if the context in which he or she does so is the resolution (rather than raising) of another safety issue);

2). Management had knowledge of the protected activity;

3). An adverse action was taken (or threatened); and

4). A nexus exists between the adverse action and the protected activity, i.e., the action was taken in part (contributing factor), or in close temporal proximity to, the protected activity.

2. Are potentially more significant cases from an enforcement perspective.

C. Those cases that do not constitute a *prima facie* case are not normally investigated by the NRC.

D. Complaints that do not constitute a *prima facie* case but do indicate a pattern developing at a licensee site or other circumstances which indicate a potentially degrading safety conscious work environment (SCWE) at a licensee site may warrant follow-up investigation.

1. A SCWE is an environment that encourages individuals to raise regulatory concerns to the licensee and/or directly to the NRC without fear of retaliation.

6.2.1 Delaying Enforcement Action Pending Investigation

In cases where an OI investigation is being conducted, enforcement action should generally not be taken for matters that are within the scope of the OI investigation until the investigation has been completed and the report issued.

6.2.1.1 Cases Requiring Immediate Action

A. If immediate action is required to protect the public health and safety or provide for the common defense and security, the staff will not wait for completion of the OI investigation and report. The Staff may initiate and issue enforcement action when the OI investigation discloses a significant safety issue that includes a preponderance of evidence that a person in a position of responsibility has engaged in wrongdoing, i.e., has committed a willful act that causes the NRC to lose reasonable assurance that licensed activities:

1. will be performed in accordance with the Commission's requirements, or

2. will not create an undue risk to the public health and safety or the common defense and security.

B. If during an OI investigation, the OI Field Office Director concludes that sufficient evidence of wrongdoing exists:

1. The OI Field Office Director will promptly notify the appropriate Regional Administrator (This preliminary conclusion is subject to change based on additional investigation and review);

2. The Regional Administrator will promptly consult with the Director, OE; and

3. The Director, OE, will coordinate, as appropriate, with OGC and the appropriate program office to determine whether immediate action is necessary.

C. If it appears that immediate action is appropriate, the Regional Administrator will request OI to promptly furnish the region, OE, OGC, and the program office with the evidence gathered (e.g., transcripts or document exhibits) and also provide briefings, as necessary, in order to develop an appropriate case.

D. If it is determined that enforcement action should be taken, OE will:

1. Advise the Director, OI, of the reasons why enforcement action should proceed during the pending investigation; and

2. Coordinate with DOJ (in accordance with the NRC/DOJ Memorandum of Understanding discussed below) if the Director, OI, determines that the case will likely be referred to DOJ for prosecution.

E. If the Regional Administrator and the Director, OE, determine that immediate action is not necessary:

1. The region should prepare a brief note to the regional case file, with a copy to OE and the program office, explaining the basis for the initial decision.

a). This note should: Include the caveat that the initial decision is "based on evidence to date."

b). Be labeled, "**Official Use Only - Predecisional Enforcement Information**."

2. If disagreement exists between the Regional Administrator, the Director, OE, and/or the program office, the matter will be promptly elevated for the DEDO's consideration.

3. After the complete OI investigation report is issued:

a). The region should reconsider whether regulatory action is necessary; and

b). If enforcement action is warranted but has not already been taken, such action should be taken after DOJ completes or declines the case that was referred to them.

6.2.1.2 Cases Not Requiring Immediate Action

A. If there is no immediate public health and safety or common defense and security concerns:

1. Technical issues should be addressed apart from the OI issues if this can be accomplished without compromising the pending OI investigation.

2. If addressing technical issues might involve the release of information that could compromise the OI investigation, OI must be consulted before such information is released.

B. If there are associated violations arising from an inspection that can be separated from the issues OI is investigating:

1. The region may proceed with an enforcement action for those violations before issuance of the OI report, but only after consultation with the Director, OE.

2. Review the OI report when it is issued to determine if the separated action should be reopened.

6.2.2 Department of Justice Referrals

A. Alleged or suspected criminal violations of the AEA and other relevant Federal laws are referred to DOJ.

1. All enforcement cases involving referrals to DOJ shall be coordinated with OE to ensure the statute of limitations is being tracked, as required by SRM COMSECY-05-0033, dated September 9, 2005.

B. OI refers cases to DOJ during or upon completion of an OI investigation involving willful violations.

C. OI may refer a case to DOJ involving an apparent willful violation where circumstances warrant such action.

NOTE:

OE has increased its focus on statute of limitations (see section 6.3) deadlines which will help ensure that any contemplated enforcement actions can be completed before the SOL runs out.

6.2.2.1 Policy of Withholding NRC Action

A. As a general policy, if a matter has been referred to the DOJ, unless immediate action is necessary for public health and safety or common defense and security reasons, issuance of an enforcement action should be withheld to avoid potential compromise of the DOJ case, pending DOJ determination that the enforcement action may be issued.

B. On a case-by-case basis, there may be reasons, e.g., potential resource savings or competing priorities, for delaying the review of an OI report while a case is under review at DOJ.

C. For those cases for which DOJ is likely to convene a Grand Jury, OE should coordinate its efforts with OI to ensure that OI can provide investigators who are not constrained in communicating to the NRC staff by the Federal Rules of Criminal Procedure regarding Grand Jury proceedings, and can, therefore, separately support any possible NRC enforcement action.

6.2.2.2 NRC Enforcement Action

A. Notwithstanding the policy on withholding NRC enforcement action for those cases accepted by DOJ, the staff should take certain actions to ensure timely processing of enforcement actions upon DOJ release or declination:

1. Within six weeks of receiving an OI report, or two weeks after the enforcement panel, the Director, OE, will normally contact DOJ to advise them of the NRC's intended direction in terms of any potential enforcement action. This will enable DOJ to advise OE if an NRC enforcement action will interfere with planned DOJ action.

a). If DOJ does not object to the NRC conducting alternative dispute resolution (ADR) or a PEC, then the region should do so and submit a preliminary recommended enforcement action.

b). If DOJ requests that the NRC stay the conduct of a PEC, the region should consult with OE on whether a preliminary action should be drafted pending DOJ review.

c). If DOJ determines that a referred case lacks prosecutive merit, it will normally notify the NRC (Director, OI) by a letter of declination. OI should promptly call OE upon receipt of the letter and should send copies of the letter to OE and the applicable region as soon as possible so that the enforcement process can proceed in a timely manner.

B. Following DOJ release or declination, the region should:

1. Hold a PEC, if the case is not already concluded;

2. Make any necessary adjustments to the draft enforcement action, including the Strategy Form, based on the information provided during the conference; and

3. Submit its revised recommendation to OE within a week of the conference, after which OE will process the case on an expedited basis.

6.2.2.3 Memorandum of Understanding (MOU) Between the NRC and DOJ

A. The MOU between the NRC and DOJ (published in the *Federal Register* on December 14, 1988) is included on the Enforcement Web site.

B. The MOU addresses:

1. Coordination of matters that could lead to enforcement action by the NRC as well as criminal prosecution by DOJ;

2. The exchange of information between the agencies;

3. The responsibilities of each agency, including the NRC's responsibilities to notify DOJ of suspected criminal violations;

4. Coordination with DOJ on NRC regulatory activities that run parallel to or may affect DOJ activities. Under this section, potential NRC actions are divided into three categories:

   a). Actions the NRC needs to take when it concludes that the NRC lacks reasonable assurance that activities authorized by a licensee are being conducted without endangering the health and safety of the public or the common defense and security;

   b). Immediate action the NRC must take to protect the public health, safety, or the common defense and security; and

   c). Actions the NRC must take to fix an immediate problem. This category applies when time does not allow for reasonable consultation. The NRC is to notify DOJ in advance if time permits and, if not, as soon as possible after the action is taken.

5. NRC’s responsibility to consider the views and concerns of DOJ to the fullest extent possible consistent with the regulatory action that the NRC believes is required;

6. Civil penalty actions.

   a). Before issuing a civil penalty based on a referred case or one involving "special circumstances," the NRC will notify DOJ of the contemplated action.

NOTE:

If the NRC proceeds with a case that DOJ is still processing, NRC has agreed to seek a stay in any resulting hearing, provided DOJ is prepared to support the staff with appropriate affidavits and testimony. The Director, OE, is the staff official responsible for coordinating regulatory activities with DOJ; however, the Director, OE, normally interfaces with OI and OGC also has certain coordination responsibilities.

b). NRC should defer initiation of the action until DOJ either concludes its criminal investigation or prosecution, or consents to the NRC action. One exception is provided, pertaining to matters involving the statute of limitations.

7. Exchanges of information between the NRC and DOJ; and

8. The time frames for consultation, i.e.:

a). NRC's commitment to notify the DOJ of contemplated civil enforcement action, normally within 45 days of a referral to DOJ; and

b). DOJ's commitment to notify NRC of its preliminary position on criminal prosecution or investigation, normally within 60 days of the referral.

6.2.3 Release of OI Reports and Transcripts of Interviews

A. Release of OI reports and exhibits:

1. Will not normally be provided if OI concludes that disclosure could interfere with ongoing investigation activities. If this situation arises, the Regional Administrator and Director, OE, will consult on how to proceed.

NOTE:

The Director, OE should be consulted before release of any OI report (and/or exhibits) associated with an enforcement action. In addition, in every case, exhibits will normally be provided only if requested through the FOIA process. Additional information is included in Management Directive 3.4, "Release of Information to the Public."

2. Are not generally available to the licensee or public until after the enforcement action has been issued, except in cases involving DOL hearings (discrimination cases).

3. A conference letter or choice letter (see forms in Appendix B) will normally include a factual summary which provides notice to the conference participants of the factual basis for the staff's preliminary conclusion that NRC regulatory violations occurred.

B. Transcripts of interviews conducted to support enforcement action:

1. Should **NOT** be released to licensees or the public without prior approval by the Director, OE, and the Director, OI, until after the action has been issued.

2. May be provided to individuals for review, if an individual (or individual's attorney) requests a copy of the transcript of their OI interview to prepare for a PEC (of which they are the subject), provided that the related OI investigation is complete and closed. The Director, OI, and Director, OE, should be consulted in these cases.

3. Will **NOT** be made available to the public until after the enforcement action is issued.

C. For **discrimination cases**, the SRM for SECY 02-0166, "Policy Options and Recommendations for Revising the NRC's Process for Handling Discrimination Issues," directed that the OI report, with appropriate redactions and without the supporting documentation (exhibits or other referenced information) and after OGC review of the sufficiency of the evidence, should be provided to the PEC participants prior to the conference.

NOTE:

"**PEC participants**" is a term that generally encompasses the licensee (the licensee's management and legal counsel), the complainant, and any individual who may have been offered an individual PEC.

1. To implement this direction, after an enforcement panel determines that a PEC is warranted, the responsible enforcement specialist should request, typically by electronic mail, a bracketed version of the OI report from the appropriate OI Field Office Director or OI headquarters.

2. OI will bracket, in preparation for redaction, the report using OI's second party requestor standard, including privacy and attorney-client privilege information.

3. The bracketed OI report will be forwarded from OI to the staff noting that release of the redacted report to PEC participants is acceptable. The OI report will continue to indicate that it is not for public disclosure without the approval of the originating field office director.

   a). After OI brackets the report, typically the assigned enforcement specialist, the headquarters allegation specialist, and the OGC enforcement attorney should review the report to ensure appropriate redaction has been completed.

b). OGC may complete the review as part of concurrence in the PEC letter.

c). Since the release is discretionary and not in response to a FOIA request, the staff is not bound by FOIA law when redacting the report. Additional redaction may be appropriate on a case-by-case basis, such as to protect other on-going enforcement actions.

4. The memorandum forwarding the report from OI to the staff provides approval for release to the PEC participants.

5. The redacted OI report will also be provided if a choice letter is used.

a). If a licensee provides a written response to the choice letter, determination of whether to provide the complainant a copy of the OI report will be made on a case-by-case basis.

b). Typically, if the staff is persuaded by the licensee's written presentation, the licensee's presentation and the OI report would be provided to the complainant for comment.

c). If the staff is not persuaded by the licensee's presentation, providing the OI report to the complainant will be considered on a case-by-case basis.

d). For cases involving DOL hearings, OE is to prepare a transmittal letter to send the OI report to the parties involved in the DOL action. Use the appropriate Form letter from Appendix B.

6. Consistent with all allegation material, the redacted OI report will not be placed in ADAMS because the standard for redacting documents may not adequately redact the document for general public release.

6.2.4 Processing Administratively Closed OI Cases

OI may choose to administratively close a case for several reasons including a lack of resources or because of an ongoing activity by another agency associated with the case.

A. Lack of Resources: Whenever OI closes a case for lack of resources, the region or applicable program office will review the case and make an initial determination of the action, if any, that appears warranted. This includes, where appropriate, discussing with OE the assignment of a higher priority.

1. The region or applicable program office will first review the OI priority criteria and make a determination of whether the OI priority should be changed or whether the case should be reopened.

2. If the case should be reopened, the region or applicable program office will either:

a). Issue a memorandum to the Regional Administrator/Office Director; or

b). Schedule a multi-office meeting involving the region, OE, OGC, and the applicable program office to discuss the merits of changing the priority or reopening the investigation.

3. The region or applicable program office will also review the final field notes or inspection report (not a draft) for the case to determine whether there is sufficient information to conclude that a violation exists and that enforcement action appears warranted.

4. If the region or applicable program office concludes that a non-willful violation exists, the case will be handled using the normal NOV process.

5. If the region or applicable program office concludes that a willful violation exists, the region or applicable program office will schedule a multi-office meeting with the region, OE, OGC, and the applicable program office to discuss the appropriate course of action to take.

6. If the region or applicable program office concludes that neither a violation nor wrongdoing exists, it will:

a). Issue a memorandum to the Regional Administrator, the Associate General Counsel for Hearings, Enforcement & Administration, and the appropriate Office Director, stating this conclusion and inviting the recipients of the memorandum to respond to the memorandum's proposal to take no enforcement action.

b). Close the matter if, after three weeks, no differing views have been received.

c). Subsequently, the responsible office should send a letter to the licensee or vendor (if individuals other than the alleger were interviewed during the investigation) to notify them that the matter has been resolved or closed.

1). The letter should provide the results of the investigation which can be in the form of a short summary of the OI report or a copy of the OI synopsis.

2). Release of the synopsis should be coordinated with the OI Field Office Director, unless authorization for release was previously granted.

3). The region or program office sending the close-out letter should also coordinate with OE to verify that the matter is in fact closed and that no other office has an open issue.

4). Additional information is included in Management Directive 3.4, "Release of Information to the Public."

B. Activity by Another Agency: OI may administratively close a case because another agency, such as DOL or DOJ, may be considering action associated with the case. In these cases, OE will assign an EA number to the case in an effort to:

1. Ensure that the staff revisits the case after the other agency has completed its activity; and

2. Track the issue so that the staff can determine whether to take action before the other agency has completed its activity should the statute of limitations become an issue.

6.3 Statute of Limitations

A. The **Statute of Limitations**, codified at 28 USC § 2462:

1. Establishes an affirmative defense that may be asserted by a person against whom a sanction is proposed; and

2. Is intended to prevent the prosecution of stale claims.

B. The five-year statute of limitations requires the NRC to initiate an action imposing a civil penalty, issuing an order to modify, suspend, or revoke a license, or issuing an order to prohibit involvement in NRC-licensed activities within the five-year statutory period.

NOTE:

The timeliness of initiating enforcement actions helps to ensure that the enforcement program is effective in achieving its objectives.

1. Absent special circumstances, the NRC must initiate the action imposing a sanction no more than five years from the date of the violation.

2. The statute does not prevent the staff from issuing an NOV (without a civil penalty or other sanction) even if the underlying violation occurred more than five years earlier.

3. The statute does not prevent the staff from issuing an order requiring an action needed to ensure compliance with existing requirements regarding protection of the public health and safety, promoting the common defense and security, or protecting the environment.

C. There are circumstances in which NRC's action cannot be initiated promptly, e.g., when a matter has been referred to DOJ for consideration of criminal prosecution.

1. Normally, if a matter has been referred to DOJ, issuance of an enforcement action should be withheld to avoid potential compromise of the DOJ case, pending DOJ determination that the enforcement action may be issued.

2. All enforcement cases involving referrals to DOJ should be coordinated with OE.

D. To protect the NRC's authority to impose a sanction in cases where the five-year period is nearing an end but staff review of the case is not complete:

1. The responsible office should seek a waiver from the licensee or other entity that the statute of limitations defense will not be asserted. This requires Commission approval; or

2. Issue the enforcement action before the statute of limitations date expires:

a). After appropriate consultation with DOJ, notwithstanding the pendency of the DOJ review; and

b). Without conducting discretionary agency process that are normally conducted, e.g., a PEC.

c). When the NRC issues an action prior to completing its review in order to protect its authority to impose a sanction, the action may be modified after the staff's review is complete.

NOTE:

In those very infrequent instances where the five-year limitations period is nearing an end, consult with OGC and OE.

E. There are cases in which the statute of limitations period may be suspended (i.e., tolled), e.g., where the licensee fraudulently concealed a violation or where the licensee failed to provide the NRC with a required notification of an underlying violation. In such cases, OGC should be consulted so that a legal determination can be made as to whether the statute of limitations can be tolled.

F. In accordance with the SRM COMSECY-05-0033:

1. On a quarterly basis, OE should provide a report to the Commission for information, preferably following OI's communication with DOJ, regarding the status of any cases that is under review for prosecution.

2. Once a case is within one year of the statute expiring, and no less than six months in advance of reaching the statute of limitations,

a). OE will develop a plan-of-action and inform the Commission.

b). OE should seek Commission approval prior to any agreement with DOJ that the NRC will seek a waiver of the statute of limitations from the party under investigation.

3. For cases with increased stakeholder interest, the staff should be particularly vigilant about initiating actions as soon as possible and communicating relevant information to the Commission.

6.4 Enforcement Process

A. In accordance with the Discrimination Task Force recommendation, the Commission approved centralization of the enforcement process for discrimination cases; therefore, OE has the lead for all discrimination cases.

B. For other wrongdoing cases (i.e., wrongdoing cases that do not involve discrimination), the region in which the wrongdoing occurred has the lead.

C. Alternative Dispute Resolution (ADR).

1. Used to resolve both discrimination and other wrongdoing cases after the NRC Office of Investigations has completed an investigation, i.e. post-investigation ADR, and the NRC concludes that pursuit of an enforcement action appears warranted.

   a). May be used for discrimination violations based solely on finding by the U.S. Department of Labor (DOL); however, the NRC will not negotiate the finding by DOL.

   b). Non-willful violations identified during an investigation maybe dispositioned within the scope of ADR

2. Use of ADR is voluntary by all parties, including the NRC, and may be ended by any party at any time.

   a). Individuals within the Commission's jurisdiction may be offered ADR.

   b). The only exception to offering ADR is abuse of the ADR program.

      1). There may also be circumstances where it may not be appropriate for the NRC to engage in ADR and therefore, the NRC retains the option to decline ADR as a party.

      2). If ADR is not offered for discrimination or other wrongdoing cases, the reason should be included on the strategy form.

      3). Approval from the Director, OE, is required for the NRC to decline participation in ADR.

3. Works in parallel and in conjunction with the traditional NRC enforcement program.

   a). If an agreement is not reached, the normal enforcement process is resumed.

4. Licensee's can engage in ADR to resolve discrimination complaints prior to an OI investigation, i.e. early-ADR, utilizing the NRC's program (refer to MD 8.8) or a licensee sponsored program.

6.4.1 Roles and Responsibilities

A. For discrimination cases:

1. OE has the responsibility for:

   a). Scheduling and preparing for the enforcement panel, ADR mediation session, PEC, and enforcement caucuses;

   b). Preparing enforcement actions;

   c). Reviewing responses to NOVs;

   d). Drafting and issuing any necessary press release.

   e). Communicating with licensee management, complainant, and for keeping the region informed of any actions to be taken;

   f). Assigning the EA number for the case;

   g). Filling out the Strategy Form to document the proposed enforcement strategy.

2. The region is responsible for:

   a). Participating in enforcement panels, etc., to provide specific licensee enforcement perspectives and maintain awareness of pending enforcement action;

   b). Providing notification to external stakeholders including the state liaison officer;

   c). Issuing the closeout letter for any unsubstantiated cases; and

   d). Reviewing the case for the identification and evaluation of any underlying technical issues and to provide clarification on site specific issues.

3. OGC is responsible for:

   a). Reviewing and providing legal advice on escalated enforcement actions, orders, actions involving OI findings;

   b). Representing the staff in any NRC adjudicatory hearings on enforcement actions; and

c). Determining the sufficiency of the evidence to support a violation of the discrimination regulations.

B. For wrongdoing cases:

1. The applicable region is responsible for:

a). Scheduling and preparing for the enforcement panel, ADR mediation sessions, PEC, and enforcement caucuses;

b). Preparing enforcement actions;

c). Reviewing responses to NOVs;

d). Drafting and issuing any necessary press releases;

e). Communicating with licensee management and the complainant;

f). Providing notification to external stakeholders including the state liaison officer;

g). Issuing the closeout letter for any unsubstantiated cases; and

h). Reviewing the case for the identification and evaluation of any underlying technical issues and to give clarification on site specific issues.

2. OE is responsible for:

a). Participating in enforcement panels, ADR mediation sessions, PEC, enforcement caucus, and to provide perspectives and concur on any actions taken;

b). Ensuring an EA number is assigned; and

c). Ensures the strategy form is filled out to document the proposed enforcement strategy.

C. For cases involving DOL interface, OE takes the lead once the DOL Administrative Law Judge finds for the complainant.

6.4.2 Processing OI Reports

A. The following steps (discussed in greater detail below) should be taken to process OI reports. The **responsible office** within this process refers to the region, OE, or program office responsible for the allegation(s) that are the subject of the OI investigation.

NOTE:

Coordination with OE is required for all substantiated OI reports or if the responsible office concludes that a violation in an unsubstantiated report may be willful.

1. Receipt and initial screening of the OI report by the responsible office to determine whether:

   a). There are immediate safety concerns; or

   b). Enforcement action appears warranted; or

   c). Enforcement action does not appear warranted; or

   d). Disagreement exists with OI conclusions.

      1). Conclusions should be based on the evidence in the exhibits of the OI report.

      2). The OI report should serve as an overview to guide review of the exhibits.

2. OGC completes analysis of the OI report to determine if sufficient evidence exists to support enforcement action.

3. Hold an enforcement panel to determine the general direction of any enforcement action that may be appropriate.

4. Prepare and process the resulting enforcement action.

B. Regardless of the age of issues addressed by OI reports, processing OI reports is considered an enforcement priority; therefore, timeliness goals stated within the steps of these procedures should be followed, if possible.

6.4.2.1 Receipt and Initial Screening

A. Upon receipt of the OI report, the region, OE, and the appropriate program office will determine from the OI report and exhibits whether:

   1. Safety concerns are identified; and

   2. Immediate regulatory action is warranted based on identified safety concerns.

NOTE:

Notwithstanding the stated timeliness goals, it is recognized that additional review time may be necessary for unusually complex cases or those with an unusually large number of exhibits.

B. Within one week of receiving an OI report, the responsible office will review the case and make an initial determination that:

1. If the responsible office believes an immediate safety concern exists:

   a). The responsible office will immediately notify OE.

   b). The region, program office, and OE will evaluate the need for immediate regulatory action, such as the issuance of an immediately effective order.

      1). If immediate enforcement action is warranted, OE will coordinate the action with the other offices, including OGC, and expedite the process. This should be a rare occurrence, in light of the coordination that should have occurred when the matter was first identified.

      2). If any other office or region believes that immediate action is warranted, OE should be immediately contacted.

      3). For cases which have been referred to DOJ, refer to the Memorandum of Understanding for guidance.

2. If the OI report findings indicate that no immediate safety concern exists but enforcement action appears warranted, the responsible office will:

   a). Coordinate with OE to schedule an enforcement panel with the region, the program office, and OGC to discuss the findings of the OI report and the development of possible enforcement action.

   b). Schedule a panel for approximately four weeks from the receipt date of the OI report. The responsible office should invite OI to participate.

   c). If the OI report does not indicate willfulness but there are still violations present, indicate in a three-week e-mail message (discussed below) that barring a differing view, the non-willful violations will be treated in accordance with normal enforcement processes.

3. If the responsible office determines that there does not appear to be a violation of NRC requirements and, therefore, no enforcement action appears warranted, normally the responsible Regional office enforcement coordinator will:

a). Issue an electronic mail (e-mail) message within 60 days after receiving the OI report indicating that no enforcement action is being considered. This message is commonly referred to as a "three-week e-mail" based on the allowed response time specified in the message. The e-mail message should be addressed to:

- The Director, OE
- The Assistant General Counsel for Materials Litigation and Enforcement
- The appropriate Office Director or Regional Administrator (or designee)
- Copies should be sent to OEMail.Resource, the Regional Enforcement Coordinator, and the Program Office Enforcement Coordinator

b). Invite a response to the proposal of no enforcement action;

c). Consider the matter closed if after three weeks from the date of the e-mail message, the responsible office has not received differing views; and, thereafter,

d). Send a letter to the licensee or vendor (if individuals other than the alleger were interviewed during the investigation) to notify them that the investigation is complete and that no enforcement action is being proposed. The letter should provide the results of the investigation which can be in the form of a short summary of the OI report or a copy of the OI synopsis; and

e). Send a closure letter to the alleger in accordance with Management Directive 8.8, "Management of Allegations."

NOTE:

Release of the synopsis should be coordinated with the OI Field Office Director, unless authorization for release was previously granted. (The region, in coordination with OI, will ensure that the identity of any alleger or confidential source will not be compromised through the release of the synopsis.)

C. Disagreements With OI Conclusions: If any NRC staff (other than OI) disagrees with an OI report conclusion regarding willfulness, the responsible office should:

1. Promptly inform the assigned OGC attorney;

2. Schedule an enforcement panel to discuss OI's conclusion

3. Document the decision on a Strategy Form.

a). OE will check the applicable boxes depicting the nature of the disagreement with OI's conclusion; i.e., the case does not meet:

1). The legal threshold for taking an enforcement action if OGC determines the case does not meet the threshold for prevailing at a hearing.

2). The policy threshold for taking an enforcement action regarding deliberate misconduct, careless disregard, or non-willful violations, if the staff determines that enforcement action should not be taken; e.g., for a minor violation of low safety consequence.

b). In the comment section of the Strategy Form, provide a brief (one or two sentence) statement of the reason for not taking an enforcement action.

4. OE will provide the Strategy Form to the panel participants.

a). If any of the parties disagree with the strategy, they should contact the assigned Enforcement Specialist as soon as possible, and normally not later than 24 hours after receiving the Strategy Form.

b). In rare circumstances, the issues may be significant enough to warrant direct discussion between the Directors, OI and OE.

1). If the issues cannot be resolved between the Directors, Commission consultation is necessary.

2). If the Directors determine Commission consultation is not needed, OE should document the nature of the disagreement on the Strategy Form as described above.

c). If a Commission paper is required because of disagreements concerning willfulness, the Commission paper should include a summary of the rationale upon which OI based its conclusions and a summary of the non-OI staff's basis for reaching different conclusions.

6.4.2.2 OGC Analysis of OI Report

A. Typically, within two weeks of receiving an OI report which substantiates discrimination or other willful violations, OGC should:

1. Complete its review of the OI report and exhibits;

2. Inform the responsible office enforcement coordinator; and OE Enforcement Specialist whether there is sufficient evidence to support enforcement action.

3. Discuss the apparent willful violations and the evidence which supports those violations with the assigned OE Enforcement Specialist and/or the responsible office enforcement staff to assist in preparing for the enforcement panel.

B. If OGC determines that there are significant legal concerns with the OI conclusions or that there is insufficient evidence to support them, OGC should promptly inform OE. OE will coordinate with OI and the other offices to determine the appropriate course of action during the enforcement panel.

C. If OE, the region, or the program office identifies weaknesses in the evidence, they should promptly inform the assigned OGC attorney so that their views can be considered.

6.4.3 Enforcement Panel

A. For wrongdoing cases, the responsible region or program office should prepare for an enforcement panel by preparing an enforcement panel worksheet including the responsible office's enforcement recommendation.

B. For discrimination cases, OE will prepare the enforcement panel worksheet and a written analysis of the evidence for purposes of the enforcement panel discussion.

1. It is important that participants be authorized to speak for their office.

C. Within approximately four weeks of receiving an OI report, or within two weeks following OGCs determination, OE, the region, OGC, and the applicable program office will participate in an enforcement panel to determine the general direction of any enforcement action that may be appropriate. The responsible office should invite OI to participate.

D. During the panel, the participants, among other things, may or may not:

1. Agree with the OI findings;

2. Agree on the issue of willfulness (i.e., careless disregard or deliberate intent);

3. Conclude that additional information is required; and

4. Agree on the appropriate enforcement action approach.

a). For the first two scenarios, it may be appropriate for the OI Field Office Director or the investigator to provide a briefing to the rest of the staff on the details of the case.

b). For the third scenario, potential weaknesses may be identified in the evidence. Any concern(s) should be discussed at the panel.

1). OI may be asked as to the likelihood of obtaining further information through investigation.

2). Alternatively, after consulting with OI, it may be appropriate to issue a DFI to request additional information from the licensee.

E. In discrimination cases where DOL determined discrimination occurred and OI did not substantiate:

1. It may be appropriate, depending upon the basis of the DOL decision, to schedule an enforcement panel to review the DOL documentation (e.g., Final Investigative Report, ALJ hearing transcripts, etc.).

2. If consensus cannot be reached during this panel regarding the enforcement action approach, OE will promptly arrange a meeting with the respective Office Managers.

F. If two investigative findings of discrimination by the same licensee are made within 18 months (either by OI or OSHA):

1. The region should request an EA number; and

2. The region should schedule a multi-office enforcement panel to discuss the agency's strategy for requesting the licensee to ascertain whether a cultural problem exists and to identify any particular areas within the workplace in which supervisors do not appreciate the importance of raising concerns.

a). The NRC can require the licensee's senior management to meet with the Regional Administrator to explain the employment actions in question, and to address what actions the licensee is taking to ensure that employees are not "chilled."

b). The licensee should be expected to address:

1). Whether it has confidence that remedial actions have been effective; and

2). The basis for this view.

c). The letter establishing this meeting can be in lieu of, or combined with the CEL.

G. If more than two investigative findings of discrimination occur within an 18-month period, the NRC should consider stronger action.

1. As part of that consideration, a DFI might be issued as to why the licensee should not be ordered to obtain an outside independent contractor to:

a). Review the licensee's programs for maintaining a safety-conscious work environment or safety culture;

b). Survey employees to determine whether they feel free to raise concerns without fear of retaliation; and

c). Develop recommendations, if warranted, to improve the workplace environment.

2. If an adequate response is not received to this DFI, then the NRC should consider issuing an order.

6.4.3.1 Written Summary of Case (Discrimination Only)

A. In every discrimination matter the staff considers for enforcement action, OE will prepare, prior to and for purposes of the enforcement panel discussion, a written summary of the evidence that may support each element of a discrimination case. Those elements are:

1. Did the employee engage in "protected activity" as that term is defined in Section 211 of the Energy Reorganization Act of 1974 (ERA), and the Commission's discrimination requirements, e.g., 10 CFR 50.7(a)(1), and interpreted by the Department of Labor and the courts?

2. Was the employer (an NRC licensee, applicant for an NRC license, contractor or subcontractor of a licensee or applicant) aware of the protected activity at the time of the adverse action?

3. Was an adverse action taken by the employer against the employee, which affected the employee's terms, conditions or privileges of employment?

4. Was the adverse action taken, at least in part, because of the protected activity?

B. The purpose of the written analysis is to reach a determination in each discrimination matter as to whether, based on all the available evidence, there is information sufficient to provide a reasonable expectation that a violation of the Commission's discrimination requirements, e.g., 10 CFR 50.7, can be shown by a preponderance of the evidence.

1. The analysis should include a statement of OGC's position, if available, as to whether the evidentiary standard is satisfied.

2. The staff and OGC's conclusion may be added after the panel.

3. The length of the analysis should normally be limited to one or two pages.

C. The analysis may be revised during the deliberative process, as the matter is further considered by all NRC components involved in the enforcement process.

D. Revised analyses should be distributed to the principal participants in the deliberative process.

E. The analysis should be placed in the enforcement file.

F. Appendix D includes a sample written analysis of a discrimination matter that the staff may use as a guide in preparing summaries.

6.4.3.2 Enforcement Panel Outcome

A. At the enforcement panel the staff may conclude that:

1. No violation occurred;

2. Non-escalated enforcement should be proposed;

3. Escalated enforcement action should be considered; or

4. A PEC does not need to be conducted.

B. If the staff concludes that escalated action should be considered:

1. The NRC may provide an opportunity for a PEC or ADR with the licensee, contractor, or other person before taking enforcement action; or

2. If the case has not been accepted by DOJ, the region or OE should, if applicable, schedule a PEC, or issue a choice letter to the licensee offering ADR or a PEC.

a). The conference letter or choice letter (see forms in Appendix B) will normally include a factual summary which provides notice to the conference participants of the factual basis for the staff's preliminary conclusion that NRC regulatory violations occurred.

b). If a factual summary is included, it should be a stand alone document that contains all the operative facts or the factual basis for the staff's preliminary conclusion that a NRC regulatory violation occurred. It is not intended to provide a full discussion of the evidence gathered in the course of the NRC's investigation.

c). The summary should not normally include the names of individuals involved in the potential enforcement matter, rather titles or other generic description should be utilized. Other personal or proprietary information should not be included.

1). The staff, in coordination with OI, will ensure that the identity of an alleger or confidential source will not be compromised through the release of the factual summary or synopsis.

d). While the length of the summary in each case depends on the facts, it should not ordinarily exceed two single-space pages (see sample summary in Appendix D).

e). In most cases the factual summary will provide the same information that is contained in the OI report synopsis. If this is the case, the synopsis does not need to be enclosed.

f). The conference letter or choice letter should be provided to the licensee at least two weeks in advance of the conference.

3. For discrimination cases, OE should normally schedule the PEC within 60 days from the date of issuance of the OI report.

a). A PEC may not need to be held in such cases where there is a full adjudicatory record before DOL. If a conference is held in such cases, generally the

conference will focus on the licensee's corrective action and not the facts of the case.

b). When scheduling the PEC, the NRC should establish two dates which are mutually agreeable to the NRC and the licensee. The complainant should be given the option of either of these two dates for the conference.

c). A separate letter should be sent to the individual subject to the alleged discrimination providing the individual an opportunity to attend the licensee's conference.

d). The individual should be provided with a copy of the letter to the licensee.

e). In certain cases, typically when the proposed enforcement action is based upon a decision by an Administrative Law Judge of the Department of Labor, no factual summary should be necessary, since the participants will be fully conversant with the facts to be discussed at the PEC.

f). In addition, there may be other matters in which the parties have investigated or adjudicated the issues.

1). The staff need not automatically prepare a summary when it proposes an enforcement conference.

2). The recommendation to forgo preparation of a factual summary should normally be agreed to at the enforcement panel.

6.4.3.3 Enforcement Action (EA) Number and Strategy Form

A. Enforcement Action (EA) numbers are used to administratively track a variety of enforcement issues including all findings addressed in an enforcement panel, regardless of whether a potential violation is involved.

1. Separate EA numbers should be generated for each potential violation when multiple potential violations are identified against a licensee or contractor.

2. A single EA number should be used when potential violations are identified against an individual, regardless if there is one or more potential violation identified.

B. An Enforcement Specialist fills out the Strategy Form to document the enforcement strategy agreed upon by the panel.

1. The Strategy Form should normally be completed within one working day of the panel, subsequent panel, or enforcement caucus.

2. The parties involved should contact the Enforcement Specialist as soon as possible, and normally not later than 24 hours after receiving the Strategy Form, if they

disagree with the characterization of the enforcement action as stated in the Strategy Form.

C. In rare cases where the parties involved cannot reach consensus on an enforcement strategy, the Director, OE, and the Directors of the other involved offices will meet to determine the appropriate path forward.

1. If the issues cannot be resolved between the Directors, Commission consultation is necessary.

2. If the Directors determine Commission consultation is not needed, OE should document the nature of the disagreement on the Strategy Form as described above.

6.4.4 Predecisional Enforcement Conference (PEC)

A. Predecisional enforcement conferences are addressed in the Enforcement Policy and this manual.

B. The PEC is normally closed for cases that involve:

1. Potential wrongdoing by an individual; and

2. Those that involve findings of an OI report that has not been publicly disclosed, (except if based on DOL finding).

3. Refer to NRC Form 578, “Request for court reporting services” to request transcription services.

C. Absent coordination with the Director, OE, conferences should be transcribed for cases involving a licensed operator, a licensee employee who may have committed a willful violation, a significant case in which a record is warranted, any other case involving an OI report, or a case involving discrimination.

1. Licensees will not be allowed to transcribe or record a conference.

2. Transcripts should not normally be released until after any associated enforcement action has been taken.

a). If a transcript release is being considered prior to an enforcement action being taken, the approval of the Director, OE is required.

b). If the licensee or any individual at the conference is subsequently provided a copy of the transcript, whether by the staff's offer or the individual's request, the individual should be informed that a copy will also be made available to the public (subject to removal of privacy information, proprietary information, etc.).

c). Transcripts from open conferences may be made available to the public sooner.

3. Although transcribed conferences are not conducted under oath, the staff should make it clear to the person making a statement that when a false statement is made on a material matter, the person making the statement may be subject to civil and criminal prosecution.

D. For discrimination cases where the whistleblower was not in attendance, the whistleblower is given the option of reviewing the PEC transcript and providing written comments.

1. Discrimination PECs are typically closed to public observation since they involve personnel issues and frequently personal performance issues; however,

2. If the evidentiary basis is a matter of public record, the licensee's PEC could be open to public observation.

6.4.4.1 Attendees

A. NRC Attendance: There should be a reason for each NRC person's attendance.

1. OE and the applicable region should attend all significant conferences.

2. The applicable program office enforcement coordinator should attend conferences as deemed appropriate by the program office, or as requested by the region or OE.

3. OGC or Regional Counsel should typically attend wrongdoing conferences.

B. Licensee Attendance:

1. Licensee attendance should include senior level managers and individuals prepared to address the circumstances of the apparent violations and the corrective actions.

2. When an individual's significant personal action contributed to the violation, consideration should be given to that person's attendance at the licensee's conference.

C. In addition to the above, for discrimination cases:

1. Complainant: The Enforcement Policy permits the individuals who were the subject of the alleged employment discrimination to participate in the conference.

a). The complainant is included in establishing the conference date.

b). The complainant is allowed no more than two personal representatives to attend the PEC.

c). The complainant may participate by observing the conference and, following the presentation by the licensee:

1). The complainant may, if desired, comment on the licensee's presentation and present his/her views on why he/she believes discrimination occurred;

2). The licensee is afforded an opportunity to respond; and

3). The NRC may ask clarifying questions.

6.4.4.2 Reimbursement of Complainant's Travel Expenses (Discrimination Only)

A. Management Directive 14.1 "Official Temporary Duty Travel allows for reimbursement of a complainant's travel expenses when the individual is performing a direct service to the government, generally referred to as invitational travel.

1. Because the NRC is requesting the complainant's presence at the PEC to assist the staff in determining the facts of a case, invitational travel is appropriate.

2. Because the complainant's personal representative does not provide a direct service to the government, the Federal Travel Regulation does not allow reimbursement of their expenses.

NOTE:

In the SRM for SECY-03-0172, "Reimbursement of the Travel Expenses of Individuals Requested to Attend a Predecisional Enforcement Conference," the Commission approved the reimbursement of only the complainant's travel expenses related to attending a PEC.

B. To facilitate the expense reimbursement process, OE should send the complainant a PEC confirmation letter (see forms in Appendix B) confirming the time, date, and location of the PEC.

1. When the NRC will reimburse the claimant's PEC travel expenses, the confirmation letter should also include an optional paragraph and enclosure regarding reimbursement of travel expenses. (Note: The claimant may choose to pay his or her own travel expenses or the expenses may be paid by a third party, i.e., the licensee. Under those circumstances, the optional information regarding reimbursement of travel expenses should not be used).

2. When the NRC will reimburse the claimants' travel expenses, OE should also prepare and process NRC Form 279, "Official Travel Authorization" and provide assistance to the complainant in making travel reservations and in completing travel vouchers upon completion of the travel.

6.4.4.3 Conduct of PEC

A. PECs are conducted to gain a common understanding of the facts of the case, including whether a violation occurred, and if so, its root causes, and any missed opportunities to identify the violation sooner, corrective actions taken or planned, and significance of the issues. The process for conducting a PEC is described in the Enforcement Policy and in this manual.

B. PECs generally conform to the following agenda:

1. NRC will make an opening presentation.

2. Licensee will be provided an opportunity to make a presentation.

> **NOTE:**
>
> At no time will the complainant and the licensee be allowed to question each other directly.

3. Frequently, the NRC will caucus briefly after the licensee's presentation to determine if additional questions remain.

4. Complainant (for discrimination cases) will be given an opportunity to make a statement and comment on the licensee's presentation.

   a). The complainant's personal representative does not normally participate in the conference unless they are providing comments for the complainant, such as an attorney responding to legal arguments put forward by the licensee.

5. The NRC may question the complainant regarding the complainant's statement.

6. After the complainant's presentation is complete, the licensee will have an opportunity to respond to the complainant's presentation.

7. The senior NRC official present will offer closing remarks and conclude the PEC.

C. Post Submittals (discrimination only)

1. Submittals from the licensee and complainant will not generally be accepted when the licensee and complainant have received redacted OI report prior to the conference.

2. The NRC will accept the licensee's response to a proposed NOV.

6.4.4.4 PEC Summary

A. After the PEC has been held, the staff should prepare a PEC Summary (see sample summary in Appendix D).

B. The PEC transcript should be entered into the PDR; however, transcripts should not be released until after any associated enforcement action has been issued without the approval of the Director, OE.

6.4.5 Enforcement Caucus

A. After the conclusion of the PEC, the PEC transcript is distributed to appropriate staff and an enforcement caucus is scheduled.

B. Depending on the information gathered during the PEC and the discussions in the caucus, the staff will determine one of several outcomes.

1. OE will document its understanding of the enforcement strategy that has been agreed upon during the enforcement caucus by completing a Strategy Form and will follow the normal review process.

C. For discrimination cases, OGC makes the determination, with staff input, whether:

1. By a preponderance of the evidence, the protected activity was a “contributing factor” in the unfavorable personnel action; or

2. The licensee provided “clear and convincing evidence” that a legitimate nondiscriminatory consideration was the <u>only</u> motive for the adverse action.

NOTE:

Engagement in protected activities does not immunize employees from discharge or discipline for legitimate reasons or from adverse actions dictated by non-prohibited considerations.

6.4.6 Post-Investigation Alternative Dispute Resolution

A. Alternative dispute resolution (ADR) sessions are addressed in the Enforcement Policy and this manual.

NOTE:

Licensees can utilize ADR to resolve discrimination complaints prior to the initiation of an investigation by OI (i.e., Early ADR). The Early ADR process is discussed in NUREG/BR-0313, “Early ADR Program”.

B. The Administration Dispute Resolution Act of 1996 (ADRA) authorizes and encourages the use of ADR by Federal agencies.

C. Post-investigation ADR may be used to resolve both discrimination and other wrongdoing cases apparently in violation of the NRC regulations.

1. Non-willful violations identified during an investigation maybe dispositioned within the scope of ADR.

D. Mediation is the form of ADR the NRC typically uses.

1. Mediation is an informal process in which a trained neutral (the “mediator”) works with the parties to help them reach an agreement.

2. The NRC maintains a list of organizations from which services of neutrals could be obtained.

E. Terms of the ADR settlement agreement will be confirmed by confirmatory order.

F. The use of ADR is voluntary and any participant may end the mediation at any time.

6.4.6.1 ADR Roles and Responsibilities

A. OE:

1. Director, OE, has overall ADR program responsibility.

2. Director, OE serves as the lead NRC negotiator for any ADR mediation session and in particular serves as the lead NRC negotiator for discrimination cases. This responsibility may be delegated to the Deputy Director, OE.

3. Director or Deputy Director, OE has the authority to sign settlement agreements and issue ADR confirmatory orders. This responsibility may be delegated to the Deputy Director, OE.

4. Typically take the lead to perform follow-up reviews for discrimination cases.

B. Region:

1. Regional Administrators or Deputy Regional Administrators serves as the lead NRC negotiator for ADR sessions involving wrongdoing (other than discrimination) for their region. This responsibility may be delegated to the Regional Division Directors after consultation with the Director, OE.

2. Regional Administrators or Deputy Regional Administrators have the authority to sign and issue ADR confirmatory orders involving wrongdoing cases (other than discrimination) for their region after obtaining concurrence from the Director, OE.

3. Responsibility for tracking, inspection, and follow-up of actions contained in all ADR confirmatory orders. Typically OE will take the lead to perform follow-up reviews for discrimination cases.

C. Program Offices (NRR, NMSS, FSME, NRO, NSIR):

1. Responsible for developing and maintaining procedures for follow-up and closure of ADR confirmatory orders falling within their area of responsibility.

D. Office of General Counsel :

1. Provide legal advice to the NRC ADR lead negotiator during conduct of the ADR mediation session. Regional Counsel may provide legal advice for their region.

E. Office of Investigations:

1. Available to attend ADR strategy sessions and mediation sessions, if requested.

F. Office of Public Affairs:

1. Responsible for determining whether to issue a press release (as appropriate) to announce significant agency actions, such as ADR confirmatory orders.

6.4.6.2 Confidentiality

A. All mediation activities under the ADR program are subject to the confidentiality provisions of the Administrative Dispute Resolution Act, 5 U.S.C. 574; the Federal ADR Council's guidance document entitled "Confidentiality in Federal ADR Programs;" and the explicit confidentiality terms set forth in the Agreement to Begin Voluntary Mediation signed by the parties.

1. These protections apply to communications between the neutral, who is an individual who functions to aid the parties in resolving a controversy, and the parties involved in the enforcement process.

B. A party to a dispute resolution proceeding shall not voluntarily disclose or through discovery or compulsory process be required to disclose any dispute resolution communication, with exceptions provided in the ADRA. Of particular interest to the enforcement program are the following exceptions:

1. The communication was prepared by the party seeking disclosure. In other words, if a statement is made by a party, or a document is prepared by a party, that same party is allowed to use or disclose the statement or document in any subsequent proceeding.

2. Except for dispute resolution communications generated by the neutral, dispute resolution communications provided to or available to all parties to the dispute resolution proceeding. In other words, for purposes of the enforcement program, unless the parties agree to other rules, the comments and documents shared *with each other* are not confidential. This is different than standard practice in non-Federal ADR. Typically, conversations held between the parties in ADR are confidential; however, the ADRA does not include this provision. A separate contract addressing confidentiality can be agreed to by the parties. However, that contract does not bind non-signatories, nor will it protect against disclose of documents through the Freedom of Information Act. Note that discussions and documents shared with the neutral in private discussions are confidential.

C. Nothing in the ADRA prevents the discovery or admissibility of any evidence that is otherwise discoverable, merely because the evidence was presented in the course of a dispute resolution proceeding. In other words, pre-existing documents do not become confidential solely because they were used in a dispute resolution proceeding (*e.g.,* ADR confidentiality will not prevent OI from collecting evidence that existed prior to an attempt to negotiate a settlement).

6.4.6.3 Attendees

A. Attendees shall include an ADR mediator, the NRC, and the party the NRC is considering taking escalated enforcement action against (either a licensee, contractor, or an individual)

B. NRC Attendance: There should be a reason for each NRC person's attendance.

1. Lead NRC negotiator (Director, OE, Regional Administrator, or their approved designee),

2. OGC or Regional Counsel

3. Enforcement Specialist assigned to the case

C. Licensee/Contractor Attendance:

1. Licensee/contractor attendance should include senior level managers and/or individuals who have decision making authority such that an agreement in principle can be reached.

6.4.6.4 Conduct of ADR

A. ADR is conducted to resolve issues resulting from an OI investigation. The goal is to provide a process that is less adversarial and would promote greater communication and, in turn, greater cooperation among the parties.

B. ADR can be offered at three distinct places in the enforcement process after OI has completed an investigation:

1. After an enforcement panel has initially determined that escalated enforcement action is being considered based on an OI case and prior to the conduct of a PEC;

2. After the initial enforcement action is taken, typically an NOV and potentially a proposed civil penalty; and

3. After imposition of a civil penalty and prior to a hearing request.

   a). Each case will be afforded a maximum of two attempts to reach a settlement on the same underlying issue through the use of ADR.

C. ADR generally conforms to the following agenda:

NOTE:

The purpose of ADR is not to dispute the facts of the case, but to identify ways to resolve the issue. It is designed to bring about more effective, efficient, and timely resolution of enforcement actions than normally achieved by the traditional enforcement process.

1. NRC will make an opening presentation.

2. Licensee will be provided an opportunity to make a presentation.

3. The ADR mediator will make some opening remarks.

4. Frequently, the parties will caucus briefly to allow the mediator to discuss the case privately with each party.

5. An agreement in principal is reached and signed by the parties at the conclusion of the session.

6.4.6.5 ADR Process

A. Strategy session is used to aid the NRC negotiating team in identifying the interests of the NRC staff (staff) and agreeing upon a strategy prior to conducting the ADR mediation session.

1. The strategy session should include a discussion of the staff's perception of the other party's interests, and identify general considerations for reaching an agreement. Discussions should include the types of actions that could be taken by the other party that would meet NRC's interests and therefore could warrant modification of the initial enforcement position. A strategy session is typically held approximately 10 days to 2 weeks prior to the expected mediation session.

2. The staff's negotiation strategy should be identified on a strategy sheet (see form in appendix D) and should include the agency's minimum settlement position. A general characterization of the strategy is appropriate (e.g., the staff would consider a, b, and c if the licensee agrees to x, y, z). If during the negotiation, the NRC lead negotiator believes that this minimum position is not attainable and believes a different settlement option should be pursued and is acceptable based on information obtained at the ADR mediation session, he/she should contact the Director OE to obtain headquarters' agreement.

3. Except for discrimination cases, the applicable regional office should coordinate the strategy session with the headquarters (HQ) enforcement specialist assigned to the case. Typically, the strategy sessions include the enforcement specialist, Regional Counsel, regional enforcement coordinator, lead negotiator, and the Director OE. Additional parties with knowledge of the investigation and/or site performance should be considered for participation in the strategy session (i.e. branch chief, lead inspector, OI investigator, program office, and Agency Allegation Advisor). OE is responsible for coordinating strategy sessions for discrimination cases and should follow the same guidance.

B. ADR mediation sessions may resolve: whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions for the violation(s).

1. At the ADR mediation session, typically an agreement in principle is reached and signed by the involved parties.

2. The terms and conditions of the agreement in principle are then incorporated into a confirmatory order.

C. Follow-up and Verification of ADR Confirmatory Orders

1. The applicable Regional Office will track and perform follow-up inspection on all ADR confirmatory order open actions in accordance with the guidance contained in the appropriate inspection manual chapters.

a). Follow-up inspection activity of ADR confirmatory orders should be documented in the appropriate licensee inspection report.

D. Document Control

1. ADR strategy session documents, the ADR strategy sheet, or any document the NRC generates to inform the mediator of NRC's interests, and other draft documents associated with the issuance of the confirmatory order including any Agreement in Principle reached at the ADR mediation session typically are sensitive, non-public documents with limited distribution lists and should be filed in ADAMS.

2. The choice letter, agreement to mediate, signed hearing waiver and consent form, any notice of violation, and the final confirmatory order will be placed in ADAMS as public documents unless precluded due to document classification. Distribution of these documents should include the OE ADR Program Administrator.

6.4.7 Enforcement Action and Severity Level Categorization

A. Enforcement actions for wrongdoing and discrimination should follow the guidance specified in the Enforcement Policy and this manual. Examples of sanctions that may be appropriate include NCVs, NOVs, civil penalties, orders, or DFIs.

B. Civil penalties are normally assessed for Severity Level I and II violations and are considered for Severity Level III violations.

C. With the exception of violations against the deliberate misconduct rule, NOV "contrary to" paragraphs should not include the word "willful" or "deliberate misconduct."

   1. The discussion of willfulness should be included in the cover letter as part of the significance discussion.

   2. Including "deliberate misconduct" in "contrary to" paragraphs is required when violations are based on the deliberate misconduct requirements.

D. The statute of limitations applicable to NRC civil penalty cases requires that the NRC initiate an action imposing a civil penalty, issuing an order to modify, suspend, or revoke a license or an order to prohibit involvement in NRC licensed activity (enforcement sanction) within the five-year statutory period.

6.4.7.1 Discretion

A. Notwithstanding the outcome of the normal civil penalty assessment process addressed in the Enforcement Policy, the NRC may either:

   1. Propose a civil penalty where application of the normal process would otherwise result in zero penalty; or

   2. Propose a civil penalty greater than the amount resulting from application of the normal process (i.e., greater than the base or twice the base civil penalty).

B. Exercise of this discretion:

   1. Ensures that the proposed civil penalty reflects the significance of the circumstances.

   2. Requires prior approval by the Director, OE, and the DEDO and consultation with the EDO, as warranted.

C. It is recognized that there are some cases of discrimination where enforcement action may not be warranted, e.g.:

   1. When a licensee who, without the need for government intervention, identifies an issue of discrimination and takes prompt, comprehensive, and effective corrective

action to address both the particular situation and the overall work environment is helping to establish a safety-conscious workplace; or

2. When a complaint is filed with the DOL, but the licensee settles the matter before the DOL Area Office makes a finding of discrimination.

D. Normally enforcement discretion would not be appropriate for cases that involve:

1. Allegations of discrimination as a result of providing information directly to the NRC;

2. Allegations of discrimination caused by a manager above first-line supervisor (consistent with the current Enforcement Policy classification of Severity Level I or II violations);

3. Allegations of discrimination where a history of findings of discrimination (by the DOL or the NRC) or settlements suggest a programmatic rather than an isolated discrimination problem;

4. Allegations of discrimination which appear particularly blatant or egregious; and

5. Cases where the licensee does not appropriately address the overall work environment (e.g., not using training, postings, revised policies or procedures, any necessary disciplinary action, etc., to communicate corporate policy against discrimination).

6.4.7.2 Enforcement Sanction (Discrimination Only)

A. The particular sanction to be issued for a discrimination violation should be determined on a case-by-case basis.

B. The Enforcement Policy, Section 6.10, provides examples of Severity Level I, II, III, and IV violations based on discriminatory acts by senior corporate management, plant management or mid-level management, and first-line supervision or other low-level management, respectively.

1. Notwithstanding an individual's specific job title or relationship to the person subject to discrimination, severity level categorization should consider several factors, including:

a). The position of the individual relative to the licensee's organization;

b). The individual's responsibilities relative to licensed activities; and

c). The potential chilling effect that the action could have on the licensee's organization based on the individual's position.

2. Where the level of a supervisor is concerned, e.g., first-line supervisor versus plant management, the supervisor's sphere of influence is a guide to determining the

appropriate severity level. While a vice president is the direct supervisor for only a few employees, the vice president's sphere of influence is great and the impact of his or her decision could affect the atmosphere throughout the site.

a). The examples in Section 6.10 of the Policy are provided as a guide;

b). The final severity level categorization for discrimination actions should reflect the regulatory concern the cases represent, e.g., a second-line supervisor may not necessarily be appropriately categorized at Severity Level II when there are multiple levels of management.

C. If a Commission paper is required for the enforcement action and the action is based on a decision and finding of discrimination by the DOL, the Commission paper must contain:

1. A brief but reasonably precise description of the acts of discrimination;

2. A brief summary of the DOL's (ALJ or Secretary of Labor) reasoning;

3. Copies of the DOL decisions; and

4. In cases where the staff differs with the DOL decision, the staff's reasons for differing.

D. As additional findings of discrimination are reached, the NRC's response (in addition to any enforcement action) should escalate on the premise that a pattern may be developing.

6.4.7.3 Continuing Violations (Hostile Work Environment) Involving Discrimination

A. Most violations of prohibitions on discrimination, such as a discriminatory termination or a failure to grant a promotion as the result of engaging in protected activities, are not considered "continuing."

1. An exception may apply to cases involving a hostile work environment (sometimes referred to as H&I).

a). Harassment and Intimidation (H&I) is a course of conduct directed at a specific person that causes substantial emotional distress in such person and serves no legitimate purpose or words, gestures, and actions which tend to annoy, alarm and abuse (verbally) another person.

b). Intimidation involves behavior(s) towards another person (words or actions) which causes them to be timid or fearful.

B. A hostile work environment (refer to DOL Case Number 1999ERA00025; Overall v. TVA) exists when it is permeated with discriminatory intimidation, ridicule, and insult that is sufficiently severe or pervasive to alter the conditions of employment and create an

abusive working environment. The mere utterance of an epithet which engenders offensive feelings in an employee does not sufficiently affect the conditions of employment.

1. Factors used to consider when determining whether conduct is sufficiently severe or pervasive include:

   - Frequency of the discriminatory conduct
   - Severity of the discriminatory conduct
   - Whether the discriminatory conduct is physically threatening or humiliating, or a mere offensive utterance
   - Whether the discriminatory conduct unreasonably interferes with an employee's work performance

2. Usually acts of discrimination or a pattern of activities or events would need to be identified as having produced a hostile work environment.

   a). If, following the initiating event, the hostile environment persisted, a continuing violation may exist such that daily civil penalties may be appropriate for each day that the hostile work environment continued. This is an area in which the law is evolving.

   b). OE will consult with OGC on cases involving a hostile work environment or the potential for "continuing" discrimination.

6.4.7.4 Enforcement Actions Against Licensees for Actions of Contractors

A. The Commission's long-standing policy has been and continues to be to hold its licensees responsible for compliance with NRC requirements.

   1. This is the case even if licensees use contractors for products or services related to licensed activities; therefore,

   2. Licensees are responsible for having their contractors maintain an environment in which contractor employees are free to raise concerns without fear of retaliation.

B. Nevertheless, certain NRC requirements apply directly to contractors of licensees.

   1. See, for example, the rules on deliberate misconduct, such as 10 CFR 30.10 and 50.5 and the rules on reporting of defects and noncompliances in 10 CFR Part 21.

   2. The Commission's prohibition on discriminating against employees for raising safety concerns applies to the contractors of its licensees, as well as to licensees (see, for example, 10 CFR 30.7 and 50.7).

      a). If a licensee contractor discriminates against one of its employees in violation of applicable Commission rules, the Commission intends to consider enforcement

action against both the licensee, who remains responsible for the environment maintained by its contractors, and the employer who actually discriminated against the employee.

b). In considering whether enforcement actions should be taken against licensees for contractor actions, and the nature of such actions, the NRC intends to consider, among other things:

1). The relationship of the contractor to the particular licensee and its licensed activities;

2). The reasonableness of the licensee's oversight of the contractor environment for raising concerns by methods such as licensee's reviews of contractor policies for raising and resolving concerns and audits of the effectiveness of contractor efforts in carrying out these policies, including procedures and training of employees and supervisors;

3). The licensee's involvement in or opportunity to prevent the discrimination; and

4). The licensee's efforts in responding to the particular allegation of discrimination, including whether the licensee reviewed the contractor's investigation, conducted its own investigation, or took reasonable action to achieve a remedy for any discriminatory action and to reduce potential chilling effects.

6.4.7.5 Enforcement Actions Against Contractors and Individuals

A. The staff should consider in each case application of the deliberate misconduct rule against an individual or contractor found to have committed the act of wrongdoing.

B. A demand for information, ADR, or a PEC should normally be used for each case in which wrongdoing is found, to put the burden on the licensee and the individual supervisor to explain why they believe that an individual enforcement action should not be taken.

C. Predecisional enforcement conferences, ADR, or a demand for information should normally be used with contractors and their personnel where wrongdoing is caused by contractor personnel.

6.4.7.6 Application of Corrective Action Civil Penalty Assessment Factor for Discrimination Violations

A. Application of the Corrective Action factor is discussed in the Enforcement Policy and this manual. The Enforcement Policy also provides an explanation of the Corrective Action factor as applied to discrimination cases.

B. The NRC can require broad remedial action to improve the workplace environment.

1. NRC cannot require a licensee to provide the individual with a personal remedy.

2. DOL has the authority to require a licensee to provide the individual with a personal remedy.

C. The Commission does not believe that a proposed penalty should be mitigated if a personal remedy is not provided (59 FR 60697, November 28, 1994).

1. A violation involving discrimination is not completely corrected without the personal remedy.

2. The chilling effect may continue if a personal remedy is not provided.

D. Credit for Corrective Action should normally only be considered if the licensee takes prompt, comprehensive corrective action that:

1. Addresses the broader environment for raising concerns in the workplace; and

2. Provides a remedy for the particular discrimination at issue.

E. In the determination of whether or not a remedy has been provided, the NRC considers whether a settlement has been reached or if a remedy ordered by DOL has been implemented.

1. Where a remedy has been accepted by DOL, NRC intends to defer to DOL on the adequacy of the remedy.

2. Cases where a licensee offers an employee a reasonable remedy, but the employee declines, will be handled on a case by case basis.

F. The promptness and scope of corrective action should also be considered in applying the Corrective Action factor.

1. If settlement occurs early in the administrative process, credit may be warranted based on corrective actions as the chilling effect may have been minimized by the promptness of the remedy and remedial action.

2. If settlement occurs after the evidentiary record closes before the Administrative Law Judge, credit normally would not be warranted because any existing chilling effect may have existed for a substantial time, and the complainant may have had to spend substantial resources to present his or her case.

3. If the licensee does not take broad corrective action until after a Secretary of Labor's decision, and the Secretary's decision upholds an Administrative Law Judge's finding of discrimination, corrective action may be untimely making credit unwarranted.

4. If the licensee chooses to litigate and eventually prevails on the merits of the case, then enforcement action will not be taken and, if already initiated, will be withdrawn.

5. Assuming that evidence of discrimination exists, enforcement action that emphasizes the value of promptly counteracting the potential chilling effect is warranted.

6.4.7.7 Program Fraud Involving Civil Penalties

OI investigations have occasionally uncovered that licensees have engaged in program fraud, e.g., an OI investigation of a radiography licensee regarding its willful misuse of licensed materials reveals that the licensee is not, as it has claimed (and paid the license fees for), a small entity.

A. OGC has the lead for the program fraud aspect of such cases.

B. Information about the program fraud aspect of the case should be coordinated with OE because as OE pursues the violation regarding the alleged misuse of licensed materials, the fact that the licensee has deliberately mislead the agency may provide a context in which the seriousness of the violation is assessed.

6.4.8 Processing Enforcement Actions

6.4.8.1 Concurrence Chain

A. OE has the lead for all discrimination cases; as such all correspondence regarding discrimination cases are processed in OE and provided to the region for information only.

B. For other wrongdoing cases, the applicable region has the lead and responsibility for issuance of any actions.

C. OGC reviews and provides its no legal objection on all orders as well as wrongdoing enforcement actions.

6.4.8.2 Signature Authority

The DEDO, Regional Administrator, or the Director, OE, has signature authority of the various actions depending on the severity and/or the license type.

6.4.8.3 Enforcement Notification

A. The Commission is provided a written Enforcement Notification (EN) (see forms in Appendix B) prior to issuing enforcement actions involving civil penalties, orders, and any case which the commission was previously consulted.

B. OE prepares and/or issues ENs for enforcement actions that are submitted to and reviewed by OE.

C. The Commission is consulted (SECY paper or memorandum) prior to taking action on:

1. Proposals to impose a civil penalty for a single violation or problem that is greater than three times the Severity Level I value shown in Table 1A of the Enforcement Policy for that class of licensee.
2. Any proposed enforcement action that involves a Severity Level I violation.
3. Any enforcement action initiated more than 18 months after a violation is initially identified (based on the completion date of the inspection), or more than 18 months after referral of a potential violation to OI where the enforcement action in the case was affected or modified as a result of the age of the action and the EDO believes that Commission consultation is warranted.

D. When an EN will be made publicly available in ADAMS, placement in ADAMS should be delayed seven days to ensure that the licensee has been notified of the action prior to the public availability of the action.

6.4.8.4 Press Release

A. Press releases are generally issued for civil penalties, orders, and in other enforcement cases as appropriate; however, the decision as to whether a press release will be issued rests with OPA.

1. The staff should notify the PAO at least 72 hours prior to issuance of an action with a proposed civil penalty.

B. Press releases are normally issued to announce a PEC that is open to the public.

C. Although press releases are not normally issued for escalated NOVs proposed without a civil penalty, there are two situations in which a press release will normally be issued:

1. Where, but for the five-year statute of limitations, a civil penalty would have been proposed; and
2. Where, but for the limitation of proposing a civil penalty against a vendor (i.e., could not establish that the violation was a knowing and conscious failure to notify the NRC in accordance with 10 CFR Part 21), a civil penalty would have been proposed.

D. OPA may choose to issue a press release for escalated NOVs associated with an SDP finding.

E. OPA may also choose to issue press releases for other enforcement actions that they view as newsworthy.

6.4.9 Licensee Response to Agency Action

A. Civil Penalty: The provisions of 10 CFR 2.205 require that a licensee submit a written response addressing the violations included within a civil penalty action within 20 days of the date of the civil penalty action or other specified time frame; however, normally 30 days should be used.

1. Licensees may be granted response extensions where good cause is shown.

2. The staff shall review the licensee's response and submit an acknowledgment letter or order imposing the civil penalty, as appropriate.

B. Order Imposing: The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame; however, normally 30 days should be used.

1. A licensee may either:

a). Pay the civil penalty; or

b). Request a hearing.

2. If a licensee does not respond to the order within the allotted time, the region should contact OE and the case will be referred to the Attorney General for collection. (Unless an individual receives an order, he/she is not entitled to a hearing)

3. If a licensee requests a hearing, OE will provide the request to OGC to forward to the Office of the Secretary of the Commission.

4. Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing. The request must:

a). Be made in writing to the Director, OE; and

b). Include a statement of good cause for the extension.

C. Settlement of Enforcement Proceedings Actions: For those cases where a hearing has been requested, the staff is responsible for preparing a settlement agreement:

1. Normally OGC has the lead.

2. The stipulation or compromise is subject to approval by the designated presiding officer, or if none has been designated, by the Chief Administrative Law Judge.

3. If approved, the ASLBP will issue a decision or order settling and discontinuing the proceeding that will include the terms of the settlement or compromise.

4. For those cases that do not involve a hearing, the staff (normally OE) is responsible for preparing a settlement agreement (see forms in Appendix B).

a). The settlement is subject to approval by the Director, OE after consultation, as warranted, with the DEDO.

b). If approved, the staff (normally OE) will prepare an order settling, modifying, or discontinuing the enforcement action that will include the terms of the settlement or compromise (see forms in Appendix B).

6.4.10 Closeout Letters

A. Closeout letters primarily serve to document closure of an investigation, both to individuals involved in the investigation and in the NRC's enforcement records.

B. Closeout letters are prepared and sent to individuals for whom an individual enforcement sanction had been considered but the NRC determined that an individual enforcement action was not appropriate. Individuals have been *considered* for individual enforcement if they are discussed at an enforcement panel. Closeout letters should be issued:

1. When the individual engaged in deliberate misconduct, but the NRC determined that enforcement action was not warranted in accordance with the Enforcement Policy;

2. When the individual engaged in careless disregard or when there is insufficient evidence to prove deliberate misconduct, and the NRC determined that enforcement action was not warranted in accordance with the Enforcement Policy; or

3. On a case-by-case basis, when the individual is not employed by the licensee or company that was the subject of the investigation and:

a). The individual(s) were named in an OI report conclusion; or

b). The individual(s) were part of the investigation focus, but were not named in the report conclusion.

C. Two forms of closeout letters are contained in Appendix B. The use of one or the other depends on whether the NRC concluded the individual engaged in deliberate misconduct or not, i.e., Form 45-I should be used for individuals when the NRC concludes the individual engaged in deliberate misconduct but enforcement action is not warranted. Form 45-II should be used when the NRC concludes the individual did not engage in deliberate misconduct.

D. Closeout letters are normally placed into ADAMS as sensitive, non-public documents.

1. ADAMS Document Processing Template OE-001 specifies that sensitive and non-public documents restrict viewer rights to the ADAMS group OE-RPOES and other groups determined by the originating office.

2. For closeout letters, the "other groups" are individuals who are on distribution or concur on a specific closeout letter and therefore may be included as a viewer. This ensures limited distribution and control of documents consistent with the Privacy Act.

3. A copy of the closeout letter should also be maintained in the Individual Action Tracking System files and are placed on the license docket.

6.5 Discrimination for Engaging in Protected Activities (DOL Process)

A. The NRC places a high value on nuclear industry employees being free to raise potential safety concerns, regardless of the merits of the concern, to both licensee management and the NRC.

1. Although licensees are responsible for the actions of their contractors, they are not required to specifically report to the NRC allegations that their contractors may have.

B. One of the goals of the NRC's Enforcement Policy is to ensure, through appropriate enforcement action against a licensee or licensee contractor (and when warranted, against the individual personally responsible for the act of discrimination), that employment actions taken against licensee or contractor employees for raising safety concerns do not have a chilling effect on the individual or others on the reporting of safety concerns.

C. Section 211 (formerly section 210) of the ERA provides that no employer may discharge or otherwise discriminate against any employee with respect to compensation, terms, conditions, or privileges of employment because the employee engaged in certain protected activities.

1. These protected activities include notifying an employer of an alleged violation of the AEA or ERA, refusing to engage in any practice made unlawful by those acts, testifying before Congress or in a Federal or State proceeding regarding any provision of these acts, or commencing, testifying, assisting, or participating in a proceeding under these acts.

2. The NRC regulations that are related to the protection of whistle blowers include: 10 CFR 19.20, 30.7, 40.7, 50.7, 52.5, 60.9, 63.9, 61.9, 70.7, 71.9, 72.10, and 76.7.

NOTE:

For purposes of this guidance, **discrimination** should be broadly defined and should include intimidation or harassment that could lead a person to reasonably expect that, if he or she makes allegations about what he or she believes are unsafe conditions, the compensation, terms, conditions, and privileges of employment could be affected.

3. In addition, 10 CFR Part 50, Appendix B, Criterion I provides that persons and organizations performing quality assurance functions shall have sufficient authority and freedom to identify problems and provide solutions.

D. Allegations of discrimination can be made directly to the NRC, DOL, or both.

6.5.1 Memorandum of Understanding (MOU) Between NRC and DOL

A. The MOU (published in the *Federal Register* on December 3, 1982) describes the responsibilities of the NRC and DOL in protecting the rights of employees as specified in Section 211 of the ERA.

> **NOTE:**
>
> The MOU between the NRC and DOL is included on the Enforcement Web site.

1. Section 3 of the MOU provides that the two agencies will "...cooperate with each other to the fullest extent possible in every case of alleged discrimination involving employees of Commission licensees, applicants, or contractors or subcontractors of Commission licensees or applicants."

2. If DOL receives a complaint concerning a possible violation of Section 211, it will promptly notify the NRC and inform the NRC whether DOL intends to investigate the matter.

3. DOL will notify the NRC of the results of the Occupational Safety and Health Administration's (OSHA's) Notice of Determination (the results of the DOL investigator's conciliation effort and investigation), of the Recommended Decision and Order of the Administrative Law Judge (if the Notice of Determination is appealed by either party), and of the Final Order of the Secretary of Labor, rendered by the Administrative Review Board.

4. The NRC will facilitate DOL's investigations by taking all reasonable steps to assist DOL in obtaining access to licensed facilities and any necessary security clearances.

B. The procedures for implementing the MOU to ensure prompt notification, investigation, and follow-up of complaints involving alleged discrimination against employees who have contacted or attempted to contact the NRC, are included in the MOU.

6.5.2 Processing Discrimination Complaints Filed with NRC

A. If an employee raises a concern directly to an NRC employee (rather than filing an allegation of discrimination with DOL), the NRC employee should be sensitive to his/her NRC responsibilities in this area.

B. The NRC employee should make sure that the alleger understands that the NRC is concerned about the complaint(s), following the guidance in MD 8.8, "Management of Allegations."

6.5.3 Processing Discrimination Complaints Filed with DOL

The division of responsibilities between the two agencies for processing discrimination complaints that have been filed with the DOL is detailed in the following Sections.

6.5.3.1 Department of Labor Process

A. The Department of Labor is authorized by the Energy Reorganization Act to order personal remedies for an individual found to have been discriminated against by an NRC licensee.

B. The NRC is not authorized to order personal remedies, but is responsible for regulating the nuclear industry and can take enforcement action against a licensee for discriminating against an employee for engaging in protected activities.

   1. In accordance with these different responsibilities, whereas the NRC may receive an anonymous allegation which it may decide to investigate and could later act on the findings, the DOL process starts when an individual files a complaint with the DOL seeking personal remedies.

C. In accordance with the MOU between DOL and NRC, the DOL will send copies of official correspondence and decisions to the NRC to assist the NRC in tracking complaints of discrimination at licensed facilities.

   1. The information provided by DOL to the NRC, especially the compliance officers' narrative reports, should not be publicly released without the permission of DOL other than documents NRC knows to be public.

D. The NRC tracks these complaints through NRC-6, "Discrimination Cases," a system of records that has been noticed in the *Federal Register*.

E. The following guidance describes the steps in the DOL process.

   1. OSHA: In accordance with Section 211 of the ERA, a complaint filed with DOL is first reviewed by OSHA to determine whether the complainant has established a *prima facie* case.

      a). If a *prima facie* case has been established:

         1). OSHA will acknowledge the complaint by letter and assign a compliance officer to investigate the allegation;

            (a). If additional information is needed from the DOL, it can be requested using Form 29.

         2). The compliance officer will interview individuals associated with the allegation of discrimination and compile a "narrative report" of these interviews; and

3). The compliance officer will make a recommendation as to whether discrimination occurred.

2. OSHA will issue a decision and will send copies of this decision to the complainant and his or her employer. Note that sometimes the employer of record is a licensee contractor and, in some cases, the licensee may not know at this point that a complaint was even filed against its contractor.

3. Appeal: An appeal of OSHA's decision can be filed within five days of the decision with the Office of Administrative Law Judges (ALJ). If no appeal is filed within that time, OSHA's decision is considered a final decision of the Secretary of Labor.

4. Administrative Law Judge: If there is an appeal, an "ERA" number will be assigned by DOL and the ALJ assigned to the case will schedule and conduct a hearing on the issues involved in the complaint. The ALJ will then issue a Recommended Decision and Order which can be appealed to the Secretary of Labor. If no appeal is sought by either party, the ALJ's decision becomes the final DOL decision.

5. Secretary of Labor: The Secretary of Labor will review the ALJ's Recommended Decision and Order, if one of the parties requests review. Where the Recommended Decision and Order finds discrimination and recommends relief, the Secretary is required to issue a preliminary order providing that relief, not including compensatory damages, pending the Secretary's decision on the matter. The Secretary, on May 3, 1996, delegated this authority to the Administrative Review Board of the Department of Labor.

6. Additional Appeals beyond the Secretary of Labor: The party against whom the Secretary rules may appeal the decision to U.S. Court of Appeals.

7. Settlements: The individual and the employer may settle the matter after a complaint is filed with the Department of Labor but before a final decision is reached by the DOL.

6.5.3.2 NRC Process

A. The following guidance describes the steps of the NRC enforcement process in terms of the steps of the DOL process identified in the section above.

NOTE:

If OI investigated the matter, it may not be necessary to wait until DOL completes its process.

1. OSHA

a). If the complaint is withdrawn or settled before OSHA issues a finding, or if OSHA concludes that the complaint was not timely filed, the NRC should review the complaint and any associated documents and an Allegation Review Board should be convened to determine whether an OI investigation is necessary.

1). Before initiating enforcement action, the region should request a copy of the DOL compliance officer's narrative report and should coordinate the matter with OE and OE will consult OGC to determine if a CEL or enforcement action should be issued.

b). If OSHA concludes that discrimination occurred and the licensee or contractor appeals the decision, the region should:

1). Request a copy of the DOL compliance officer's narrative report; and

2). Prepare a chilling effect letter (CEL).

c). If OSHA concludes that discrimination occurred and the licensee or contractor does not appeal the decision:

1). It is considered a final order of the Secretary of Labor and

2). Enforcement action may be appropriate.

d). If OSHA concludes that no discrimination occurred and the individual does not appeal the decision, the region should:

1). Request a copy of the DOL compliance officer's narrative report.

2). Review the report to ensure that the NRC can close the matter with no further action.

e). If OSHA concludes that no discrimination occurred and the individual appeals the decision, the staff should await the ALJ's Recommended Decision and Order.

2. Administrative Law Judge

a). After conducting a hearing, the ALJ will issue a Recommended Decision and Order. The Energy Policy Act of 1992 revised Section 211 of the ERA to, among other things, require the Secretary of Labor to issue a preliminary order providing certain relief specified by the ALJ while awaiting the final order of the Secretary.

b). If the ALJ finds that discrimination occurred and does not establish that the respondent would have taken the same action regardless of an employee’s protected activities (respondent unable to show by clear and convincing evidence):

NOTE:

If no appeal is filed (the 30 day appeal period should commence 10 business days after the ALJ's decision is rendered) the DOL decision becomes final.

1). OE should obtain an EA number and initiate the enforcement process.

2). The appropriate enforcement action should be issued following the issuance of the ALJ's Recommended Decision and Order.

3). OE should also consider whether it would be appropriate to take some action against the contractors or individual(s) found by the ALJ to be responsible for the discrimination

c). If the ALJ finds that discrimination occurred and it is appealed to the ARB, and there exists a completed and similarly factual OI investigation which does not substantiate discrimination:

1). The NRC may await a decision by the ARB before initiating the enforcement process; however, a chilling effect letter should be processed.

2). If a civil penalty is proposed, the enforcement action will require a response in accordance with the provisions of 10 CFR 2.201.

3). The licensee's response to the provisions of 10 CFR 2.205 (i.e., payment of any civil penalty) should be delayed until 30 days after the DOL decision becomes final.

d). If the ALJ finds no discrimination, the NRC should await issuance of the Secretary of Labor's decision, if an appeal is filed.

e). If the ALJ dismisses the complaint for procedural reasons (withdrawal, settlement, or untimely), the region should:

1). Review the record, including the earlier OSHA decision; and

2). Determine whether it is appropriate to initiate the enforcement process, to request additional OI investigation, or wait for the ARB's ruling, if an appeal is filed.

3. Administrative Review Board (ARB)

a). If, on a timely appeal, the ARB affirms the ALJ's finding of discrimination:

1). The licensee is expected to respond to any civil penalty already issued by the NRC.

2). Although no specific action is required by the NRC at this point, OE should ensure that the licensee has received notice of the ARB Order, especially in cases in which the Respondent is a licensee contractor, to avoid a delay in the licensee's response.

3). OE should initiate the enforcement process if not already done so.

NOTE:

The Secretary of Labor has delegated responsibility for reviewing ALJ determinations to the ARB.

b). If the ARB affirms the ALJ's finding of no discrimination, the region would normally close the case without further action.

c). If the ARB reverses the ALJ's finding that discrimination occurred and dismisses the case, the NRC normally would withdraw the enforcement action if it was based solely on the DOL process (i.e., without independent findings from an OI investigation that discrimination had occurred).

d). If the ARB reverses the ALJ's finding that no discrimination occurred, concluding instead that discrimination did occur, OE should obtain an EA number and initiate the enforcement process.

e). If the ARB dismisses the case for procedural reasons, (withdrawal, settlement, or untimely), OE should review the record, including the earlier ALJ's decision, and determine whether earlier enforcement was appropriate, whether to impose the civil penalty, or withdraw the proposed civil penalty.

4. Additional Appeals beyond the Secretary of Labor: The party against whom the Secretary rules may appeal the decision to U.S. Court of Appeals. Absent a stay issued by the Court, the NRC enforcement action is not stayed. Therefore, the region should consult with OE in such cases.

5. Settlements: The individual and the employer may settle the matter after a complaint is filed with the Department of Labor but before some final decision is reached by the DOL. In such cases, the NRC will normally need to develop the evidence to support an enforcement action if it is to prevail.

6.5.4 Chilling Effect of Actual or Potential Discrimination

In addition to concerns about the appropriate enforcement action in cases of actual discrimination, the NRC must also consider the impact of such discrimination in the workplace, i.e., whether the awareness of the discriminatory act will discourage other licensee and contractor employees from raising safety concerns.

6.5.4.1 Chilling Effect Letter (CEL)

A. In each case of a finding of discrimination, the NRC should bring the matter to the attention of the licensee. This correspondence, referred to as a chilling effect letter (CEL), serves three purposes:

1. To notify the licensee of the NRC's concern,

2. To understand the basis for the licensee's position on whether or not discrimination occurred, and

3. To obtain a description of any remedial action the licensee plans to take to address the potential chilling effect. Remedial action may be warranted, even if the licensee disagrees with the finding of discrimination, because of the potential for a chilling effect.

B. The NRC should normally issue a CEL after the OSHA investigation has been completed and a finding has been made of discrimination.

1. If the licensee settles a case soon after the OSHA finding and does not challenge the finding in adjudication, the chilling effect may be minimized and a CEL need not be issued.

2. If OSHA finds that discrimination did not occur and subsequently the ALJ reverses the OSHA finding, concluding instead that discrimination did occur, the NRC may:

a). Await the ARB final decision before taking enforcement action; and

b). While awaiting the ARB decision, a CEL is usually an appropriate response to the ALJ finding of discrimination.

C. Once a finding of discrimination is made by either the ALJ or the ARB, and neither the respondent nor the claimant appeals to the next higher level, the NRC will:

1. Evaluate whether to take enforcement action; and

2. If enforcement action is initiated based solely on a DOL finding, the NRC will normally issue a choice letter, instead of a CEL, since the choice letter, like the CEL, requires the licensee to address the violation and corrective actions.

D. The CEL requires that the licensee describe:

1. Its position regarding whether the actions affecting the individual violated 10 CFR 50.7 (or other requirement) and the basis for its position, including the results of any investigations it may have conducted to determine whether a violation occurred; and

2. The actions taken or planned to ensure that the matter is not having a chilling effect on the willingness of other employees to raise safety and compliance concerns within its organization, and as discussed in NRC Form 3, to the NRC.

E. The licensee's response to the CEL is mandatory under the provisions of the AEA, 10 CFR 2.204, “Demand for information,” and the applicable provisions of Title 10 implementing Section 182 of the AEA.

F. When a CEL is to be issued:

1. The staff should request an EA number which allows OE and the region to track CELs for each licensee.

2. Any subsequent enforcement action proposed will be given a separate EA number.

3. The EA number should be closed upon issuance of the CEL itself; therefore, the region must send a copy of the letter to OE.

4. OE should be included on concurrence of the CEL.

a). Because the CEL in this case is in response to an allegation or inspection finding versus a DOL finding, NRC OI investigation, or NRC inspection, Form 28 in Appendix B should NOT be used to draft the CEL.

G. There may be special cases involving allegations of a chilled work environment in which no DOL complaint or finding has occurred, where issuance of a CEL is appropriate.

1. The region should consult with OE to discuss the issuance of a CEL and determine the appropriate coordination with OE.

2. Because the CEL in this case is in response to an allegation or inspection finding versus a DOL finding, NRC OI investigation, or NRC inspection, the letter should not include the mandatory licensee response language in a traditional CEL (i.e., DFI).

3. The CEL should address the NRC’s concerns and request a response from the licensee.

6.5.4.2 Numerous DOL Settlements Without Findings of Discrimination

A. If a licensee has numerous cases which end in settlement agreements before DOL reaches a finding of discrimination at any level, the region should consider whether this is:

1. Indicative of true, though uninvestigated, discrimination; or

2. A chilling effect.

B. The NRC must be careful when reaching such conclusions that the agency is not perceived as discouraging settlements.

6.6 Enforcement and Administrative Actions Involving Individuals

A. The subject of enforcement actions involving individuals is addressed in the Enforcement Policy.

B. Enforcement actions involving individuals, including licensed operators, are significant actions that will be closely controlled and judiciously applied.

C. An enforcement action involving a licensed individual will normally be taken only when the NRC is satisfied that the individual:

1. Fully understood, or should have understood, his or her responsibility;

2. Knew, or should have known, the required actions; and

3. Knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance.

NOTE:

Normally, whenever action is taken against an individual, action is also taken against a licensee.

D. Action may be taken directly against individuals (licensed or un-licensed) who engage in deliberate misconduct that causes or would have caused, if not detected, a licensee to be in violation of any rule, regulation, or order related to NRC-licensed activities (e.g., 10 CFR 50.5).

E. Actions against non-licensed individuals will normally be taken only in cases involving deliberate misconduct by the non-licensed individual, in cases involving a lack of reasonable assurance, and in cases in which an individual violates any requirement directly imposed on him or her (e.g., a violation of any rule adopted under Section 147, “Safeguards Information,” of the AEA).

F. Action against NRC-licensed reactor operators may be taken even if the violation does not involve deliberate misconduct, since operators licensed by the NRC are subject to all applicable Commission requirements

G. The NRC may take enforcement action against a licensee that may impact an individual, where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted.

1. The NRC may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence,

fitness-for-duty, or other matters that may not necessarily be a violation of specific Commission requirements.

2. Enforcement actions against licensed operators for failure to meet fitness-for-duty requirements are addressed in this manual.

H. Because potential enforcement actions and administrative actions involving individuals are significant actions, the Director, OE, is to be notified as soon as the staff identifies any violation or issue that could lead to an enforcement or administrative action against an individual.

I. In those cases where the staff believes enforcement action against an individual may be warranted, the NRC will normally provide the individual with an opportunity to address the apparent violations by:

1. Responding to a choice letter; or

2. Participating in a PEC, unless the circumstances of the case warrant immediate NRC action.

J. There may also be cases in which the staff proposes to issue a demand for information (DFI) in lieu of, or in addition to, conducting ADR or a PEC.

K. When issuing an action against an individual:

1. If the individual is employed by the licensee, a copy of the action should be sent to the licensee.

2. If the individual is no longer employed by the licensee, a copy of the action is not sent to the licensee.

3. A copy of the action is placed on the Enforcement Web page.

a). NOVs should remain on the Enforcement Web page for one year from the date they are issued.

b). Orders should remain on the Enforcement Web page until all conditions of the order has been met, including, as stipulated in the order, the length of time the order is to remain in effect.

4. Enforcement Specialists should enter actions against individuals in the Action Items Tracking System (AITS) with, e.g., in the case of NOVs, a year deadline, to ensure that actions that have been placed on the Enforcement Web pages will be removed in a timely manner.

6.6.1 Individual Action (IA) Numbers

A. Individual Action (IA) numbers are assigned by OE to administratively track and file all correspondence issued to an individual, if that individual is being considered for or has been issued an enforcement action.

B. IA numbers should be used on all close-out letters and on conference or choice letters, but never on correspondence containing the corresponding EA numbers.

C. The region should use an EA number for the review and approval stages and get an IA number from OE when the correspondence is ready to be issued.

   1. The EA number should never appear on the correspondence/enforcement action issued with an IA number; nor, should it appear in the ADAMS profile.

   2. The EA file should be closed upon issuing the final IA action.

6.6.2 Predecisional Enforcement Conferences Involving Individuals

A. Once the staff determines that an individual PEC should be conducted,

   1. An EA number will be assigned if one has not previously been issued.

   2. The staff should contact OE to obtain an IA number to include on a conference or choice letter or DFI when the correspondence is ready to be issued.

   3. Although the original EA number should be used for any subsequent action or close-out letter during the review and approval stages, the IA number should be used on the final correspondence to the individual.

B. For cases where the focus of regulatory concern is the licensee but a specific individual or individuals are involved, when the staff contacts the licensee to schedule the conference, the staff should make clear to the licensee the agency's desire to have the individual or individuals attend.

C. Letters to the licensee that describe apparent violations involving the individual should avoid publicizing the individual's identity. If necessary, the apparent violation may be described in an attachment to the letter, and the letter made available to the public without the attachment.

D. Written correspondence concerning the PEC should normally not be made public (ADAMS (PARS)) in a manner that identifies the individual. The identification of the individual should be withheld from the public pending the issuance of any enforcement action, including a DFI.

E. For ADR or a PECs involving only the individual, the letter requesting the conference should have an IA number and include:

1. A clear statement of the purpose of the conference, the time and date agreed upon, and any apparent violations to be discussed.

2. A copy of the inspection report or the OI report factual summary should be enclosed if available.

3. A copy of the transcript of the individual's OI interview may be included, if the individual (or individual's attorney) requests it to prepare for the conference and the OI investigation has been completed and is closed.

   a). The Director, OI, and Director, OE, should be consulted in these cases.

   b). The transcript of the individual's OI interview will not be made available thru a FOIA requests until after the enforcement action is issued.

4. A description of the information that the individual is expected to address.

5. A description, in general terms, of the range of possible enforcement actions that the NRC is considering.

6. A statement that the individual is not required to attend the conference and that, should the individual choose not to attend, the NRC intends to proceed based on the facts already at hand.

7. A statement that the individual may choose to bring a personal representative; however, if the individual desires to bring more than one representative, the individual should contact the NRC in advance of the conference.

8. A point of contact who can answer any questions about the conference.

F. As with other PECs, a meeting notice should be issued when an individual is involved; however, care should again be taken for privacy considerations.

   1. The meeting notice should avoid using names or titles in a manner to implicate a particular individual as being the focus of the conference.

   2. For a conference in which only the individual and his/her representative(s) will be attending (i.e., no licensee representatives), the meeting notice should use a general designation (e.g., "Diablo Canyon employee") rather than the individual's name or specific title.

G. Predecisional enforcement conferences involving individuals normally will be closed and should be transcribed.

   1. Consideration should be given to having NRC counsel (regional or OGC) present.

   2. An OE staff member should also attend the more significant conferences and for all cases involving discrimination.

3. For a conference involving only the individual, the NRC may allow limited licensee attendance only if the individual who is the subject of the conference so desires. NRC attendance at these conferences should also be limited.

H. Appendix D includes opening remarks for a PEC with licensed operators. While use of the remarks is not mandated, they cover important issues that should be addressed. The presiding official should consider these remarks and adjust them as appropriate for conferences with unlicensed individuals.

I. If the individual chooses to bring a personal representative (usually an attorney, spouse, or relative), the NRC should make it clear at the outset of the conference that the purpose of the meeting is to receive information from the individual and understand the individual's perspective. As such, the NRC's questions should primarily be addressed to and answered by the individual.

J. Subsequent to the PEC, the region and/or OE should determine, whether enforcement action should be issued against the facility licensee, against the individual, or both (See guidance below).

6.6.3 Action Against the Licensee or Against the Licensee and the Individual

A. When a potential enforcement issue involves an individual, the decision must be made whether to cite solely against the licensee or cite against the individual and the facility licensee.

1. Action against an individual will not be taken if the individual's improper action was caused by management failures.

2. Most transgressions of individuals involving Severity Level III or IV violations will be handled by citing only the facility licensee.

B. Cite solely against the facility licensee.

The following examples of situations illustrate when the NRC will cite only the facility licensee:

1. Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee.

NOTE:

NOVs are issued to facility licensees to recognize their responsibility for the conduct of their employees.

2. Inadvertently missing an insignificant procedural requirement when the action is routine and fairly uncomplicated, and where no unusual circumstance exists indicating that the procedures should be referred to and followed step-by-step.

3. A case in which compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation.

4. Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

5. Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and did not attempt to have the procedure corrected.

C. Cite individual (licensed or unlicensed) & the facility licensee: Serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as against the facility licensee.

1. Listed below are examples of situations which could result in enforcement actions involving individuals, licensed or unlicensed. If the actions described in these examples are taken by a licensed operator or taken deliberately by an unlicensed individual, enforcement action may be taken directly against the individual.

2. Violations involving willful conduct not amounting to deliberate action by an unlicensed individual in these situations may result in enforcement action against a licensee that could impact an individual.

3. The situations include, but are not limited to, violations that involve:

- Willfully causing a licensee to be in violation of NRC requirements
- Willfully taking action that would have caused a licensee to be in violation of NRC requirements but did not because it was detected and corrective action was taken
- Recognizing a violation of procedural requirements and willfully not taking corrective action
- Willfully defeating alarms which have safety significance
- Unauthorized abandoning of reactor controls
- Dereliction of duty
- Falsifying records required by NRC regulations or by the facility license
- Willfully providing, or causing a licensee to provide, an NRC inspector or investigator with inaccurate or incomplete information on a matter material to the NRC
- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization
- Submitting false information designed to allow a person to gain access to a licensee facility or, as a result, allowed a person to gain unescorted access to a licensee facility

- As a contractor or other person who provides testing or other services, willfully providing false data to a licensee, when the data affects the licensee's compliance with 10 CFR Part 50, Appendix B, or other regulatory requirement
- Willfully providing false certification that components meet the requirements of their intended use, such as an ASME Code
- As vendors of equipment for transportation of radioactive material, willfully supplying casks that do not comply with their certificates of compliance
- Willfully performing unauthorized bypassing of required reactor or other facility safety systems
- Willfully taking actions that violate TS LCOs (enforcement action for a willful violation will not be taken if the operator meets the requirements of 10 CFR 50.54(x), i.e., if the operator acted reasonably considering all the relevant circumstances surrounding the emergency)

D. Cite the individual (unlicensed) & the facility licensee: In deciding whether to issue an enforcement action to an unlicensed person in addition to the facility licensee, the following factors should be considered:

1. The level of the individual within the organization;

2. Whether the violation was willful;

3. The individual's training, experience, and knowledge of the potential consequences of the wrongdoing;

4. The potential safety or common defense and security consequences of the misconduct;

5. The actual safety or common defense and security consequences of the misconduct;

6. The benefit to the wrongdoer (e.g., personal or corporate gain);

7. The degree of supervision of the individual (i.e., how closely the individual is monitored or audited, and the likelihood of detection...such as a radiographer working independently in the field as contrasted with a team activity at a power plant);

8. The employer's response, including disciplinary action taken;

9. The attitude of the wrongdoer (e.g., admission of wrongdoing, acceptance of responsibility);

10. The degree of management responsibility or culpability; and

11. Who identified the misconduct.

6.6.4 Action Against the Individual

A. The particular sanction(s) to be issued to an individual should be determined on a case-by-case basis.

B. In determining the appropriate sanction against an individual, factors to be considered are listed in Appendix D, including, e.g.:

1. The level of the individual within the organization;

2. Whether the violation was willful;

3. The actual safety or common defense and security consequences of the misconduct; and

4. The attitude of the wrongdoer.

C. All correspondence issued to an individual should include an IA number.

D. If the NRC determines that action will not be taken against an individual (for whatever reason) the staff should prepare a close-out letter using the appropriate form in Appendix B.

E. In accordance with the Enforcement Policy, an individual should normally have an opportunity to address apparent violations being considered for escalated enforcement action either in a PEC or in a choice letter.

1. In some cases, a DFI may be appropriate.

2. If the person has not had an opportunity to dispute the NRC's proposal, the action should give the individual an opportunity to dispute the action, including the underlying facts, and include an NRC contact and telephone number.

6.6.4.1 Sanctions Issued to Individuals

A. NOVs may be issued to licensed or unlicensed individuals.

1. An NOV need not require a response from the individual if the action is being issued at Severity Level IV to a low-level individual who has been terminated from employment involving licensed activities because, in such cases, there is normally not much corrective action that an individual could take; however, an opportunity for the individual to respond is to be provided.

2. With the exception of violations against the deliberate misconduct rule, NOV “contrary to” paragraphs should not include the word “willful” or “deliberate misconduct.”

a). Discussion of willfulness should be included in the cover letter as part of the significance discussion.

b). Including “deliberate misconduct” in “contrary to” paragraphs is required when violations are based on the deliberate misconduct requirements.

B. Orders.

1. In the case of NRC-licensed reactor operators, such orders may involve suspension for a specified period, modification, or revocation of their individual licenses.

2. In the case of unlicensed individuals, such orders may include provisions that prohibit involvement in NRC licensed activities for a specified period of time or until certain conditions are satisfied (e.g., completing specified training or meeting certain qualifications).

3. Once a determination is made to issue an order banning involvement in NRC licensed activities, the length of the ban must be determined.

a). Typically, bans are fixed for one, three, and five years (unless the ban is in place until certain conditions are satisfied).

b). Two factors should be considered when determining the length of a ban:

1). The position of the individual; and

2). The significance (or potential significance) of the underlying violation.

4. Orders generally require:

a). Notification to the NRC before the person resumes working in licensed activities; or

b). The person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order.

C. Civil penalties which may be assessed of an NRC-licensed operator.

1. Section 234 of the Atomic Energy Act (AEA) gives the Commission authority to impose civil penalties on "any person." Furthermore, any person, whether or not a licensee of the Commission, who violates any regulations adopted under Section 147, “Safeguards Information,” of the AEA will be subject to the full range of enforcement sanctions, including civil penalties. Section 11s of the AEA broadly defines “person” to include individuals, a variety of organizations, and their representatives or agents.

a). Such cases are rare and require Commission approval.

b). Except for individuals subject to civil penalties under Section 206 of the Energy Reorganization Act of 1974, the NRC will not normally impose a civil penalty against an individual.

D. Demands for Information (DFIs) which can be made to an individual for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued.

1. A DFI is a formal request for information that can be made to an individual for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued.

2. An individual to whom the NRC has issued a DFI may, in his or her discretion, respond to a DFI by filing a written response under oath or affirmation.

3. All DFIs should provide an opportunity for the individual to challenge the underlying facts, including any (apparent) violations.

6.6.5 Action Against the Facility Licensee

The particular sanction to be issued to a facility licensee should be determined on a case-by-case basis.

A. Most transgressions of individuals involving Severity Level III or IV violations will be handled by citing only the facility licensee.

B. In accordance with the Enforcement Policy, the NRC may disposition a licensee-identified Severity Level IV willful violation involving a low-level individual as an NCV.

C. NRC-identified willful violations involving individuals (regardless of the severity level) should always be cited in an NOV.

D. Notwithstanding the outcome of the normal civil penalty assessment process, the Enforcement Policy provides that discretion will be considered (i.e., proposing or increasing the amount of a civil penalty) for willful violations.

6.6.5.1 Sanctions Issued to Facilities

A. NOVs, with the exception of violations against the deliberate misconduct rule, should not include the word “willful” or “deliberate misconduct” in the NOV “contrary to” paragraphs. In such cases, the discussion of willfulness should be included in the cover letter as part of the significance discussion.

B. DFIs may be issued to a licensee or applicant to obtain information regarding the competence or integrity of a particular licensee employee to determine whether the license should be granted, or if issued, whether it should be modified, suspended, or revoked, or other enforcement action taken.

1. Cover letters and DFIs should include individuals' titles, but should not include individuals' names.

NOTE:

Including "deliberate misconduct" in "contrary to" paragraphs is required when violations are based on the deliberate misconduct requirements.

2. Licensees should not get copies of DFIs that may be issued to the subject individuals, because the NRC has not made final, public conclusions about the individuals.

3. Individuals who are the subject of DFIs should receive a copy of the action sent to the licensee.

C. Orders modifying the facility license may be issued in the case of an unlicensed person, whether the unlicensed person is a firm or an individual, to require:

1. The removal of the person from all licensed activities for a specified period of time or indefinitely;

NOTE:

Individuals who are the subject of orders should receive a copy of the action sent to the licensee.

2. Prior notice to the NRC before utilizing the person in licensed activities;

3. Notice of the issuance of such an order to other persons involved in licensed activities making reference inquiries; or

4. Conditions to employers which require, e.g., retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities.

D. CALs may be used instead of orders if the licensee is told that an individual may not use licensed material because the individual:

1. Is not named on the license;

2. Does not meet the Commission requirements; or

3. Where the licensee has already, on its own, removed an individual and the NRC only seeks to be informed of any decision to reinstate that individual and the basis for that decision.

   a). Such a CAL should state clearly that the agreement does not require NRC approval for reinstatement.

   b). In such cases the person, under existing license conditions or regulations, lacks authorization to be involved in the licensed activity, and the CAL is merely being used to confirm that the licensee will adhere to existing provisions (i.e., in such a situation the CAL would not affect the individual's rights).

E. When the NRC takes an enforcement action against a licensee because of an individual employee's action, and that enforcement action may affect the employment of the individual, the individual may have rights to a hearing.

   1. NRC employees may be individually liable for infringing on a person's constitutional rights.

   2. If the NRC concludes that an individual should be removed from licensed activities, an order is to be used rather than an informal action, such as a CAL, to clearly establish the opportunity for a hearing.

6.6.6 Actions Concerning Individuals Licensed by Other Authorities

A. Some enforcement actions are taken against individuals who are licensed by other authorities.

   1. The most common cases are enforcement actions taken against physicians who are licensed by individual State licensing boards.

   2. Others who may be subject to NRC action and are licensed by a State board include, e.g., nurses, medical technologists, professional engineers, and attorneys.

B. If an order is issued against an individual who is licensed (or registered) by a State, the issuing office should send a copy of the order to the licensing authority for the State.

   1. The transmittal letter to the individual should show the State on the "cc" list.

   2. In addition, a copy of the enforcement action against a physician should be sent to:

      Federation of State Medical Boards of the United States, Inc.
      400 Wiser Road, Suite 300
      Euless, Texas 76039

      a). The Federation is a central repository that maintains the Physician Disciplinary Data Bank.

b). The transmittal letter to the physician should show the Federation on the "cc" list.

C. If the region intends to forward an order issued against an individual to a State licensing authority and/or the Federation, it should highlight this intent in the Enforcement Action Worksheet included with the region's recommended proposed enforcement action to OE.

D. It is imperative that if after issuance of the action, NRC changes its position on the matter, a copy of the NRC revised position be forwarded to the same licensing authority and the Federation, as applicable.

6.6.7 Coordination and Review for Actions Involving Individuals

A. Any proposed order (other than a confirmatory order) or civil penalty to be issued to an individual requires the concurrence of the Director, OE, and the DEDO.

B. A confirmatory order, NOV without a civil penalty, NCV, or any proposed administrative action (CAL, DFI, or similar letter) directed to an individual requires appropriate coordination with OE prior to issuance.

6.6.8 Notification, Mailing, & Distribution of Actions Involving Individuals

A. Action Against the Individual:

1. In order to afford individuals the opportunity to address apparent violations before issues are made public, enforcement actions against individuals may be subject to a 45-day hold period, as discussed further below.

2. When NOVs are issued to individuals, they may be made available to the public (and posted to the Enforcement Web site (for escalated NOVs)) **ONLY** if the individual has previously had an opportunity to present his or her views on the facts of the case to the NRC.

3. When NOVs are issued to individuals the actions should **NOT** be made available to the public or the licensee, when it is sent to the individual, if the individual has not been given an opportunity to present his or her views on the facts of the case to the NRC, such as during a PEC, in response to a choice letter or a previously issued DFI, or during an OI investigation in which the individual was specifically provided an opportunity to challenge the alleged wrongdoing.

   a). In these cases, the action should provide the individual with an opportunity to respond within 30 days.

   b). The action should state that after 45 days the action will be sent to the licensee and made available to the public, unless the individual provides a sufficient basis to withdraw the action

4. A copy of the action should be distributed only to OE and those offices with a need for the document.

5. In cases where an enforcement action is being proposed for a licensee based on the actions of the individual, the enforcement action against the licensee should be withheld for at least 45 days while the individual is given the opportunity to respond.

6. If an individual provides a sufficient basis to withdraw an action, the staff should issue a close-out letter to the individual stating that the action will be withdrawn.

7. When the staff issues a close-out letter to the individual stating that an action will be withdrawn, the staff should also review the proposed action for the licensee to consider whether it remains appropriate based on the individual's response.

8. If an individual does not respond to the action or fails to provide a sufficient basis to withdraw the action, the responsible office (the region or OE) should ensure that the action (and the individual's response, if one was provided) are distributed to the licensee and made available to the public 45 days after the action was issued.

9. For an action subject to the 45-day hold, the region will forward a hard copy only to OE; and when the final enforcement decision is made, forward the electronic version to OE for posting on the Enforcement Web site (i.e., the region is responsible for tracking the 45-day hold period).

10. PEC letters, choice letters, and DFIs should only be made public if the agency concludes that enforcement action should be issued to the individual. These documents should be made public at the time the action is made public.

11. Close-out letters that are issued to individuals are not made available to the public (although they remain subject to release under FOIA). Close out letters to licensed individuals are placed on the license docket.

12. The region is responsible for mailing and distributing NOVs, civil penalties, and close-out letters to individuals for willful violations other than those cases involving discrimination.

13. OE is responsible for mailing and distributing DFIs and orders against individuals. Actions should be mailed by either Certified Mail (Return Receipt Requested) or Express Mail.

14. OE should be on distribution for all actions issued to individuals, including close-out letters. In addition, the facility licensee should be shown on the "cc" for all actions issued to individuals.

15. The issuing office should attempt to notify the individual by telephone when it is issuing an individual action. This is especially important when an order is being issued.

16. The region must ensure that the copies of actions against individuals and related documents that are made available to the public do not include individuals' home addresses.

17. Press releases that address individual actions and enforcement actions may be issued sooner than the normal five-day ADAMS hold after the staff has confirmed that the individual has received the action.

18. Exceptions to the above process will be considered on a case-by-case basis by the Director, OE.

B. Action Against the Facility Licensee:

1. Actions issued to licensees should be mailed in accordance with the normal guidance included within the applicable sections of this manual.

2. If an enforcement action is being proposed for a licensee in conjunction with an individual action, then the enforcement action against the licensee should be withheld for at least 45 days while the individual is given the opportunity to respond.

   a). If an individual subsequently provides a sufficient basis to withdraw the action, the staff should review the proposed action for the licensee to consider whether it remains appropriate based on the individual's response.

3. Individuals who are the subject of DFIs or orders that are issued against the facility licensee should receive a copy of the action that is sent to the licensee.

   a). The transmittal letter to the licensee should include language such as, "A copy of this letter and its enclosure(s) is being sent to (name or title of individual). The individual is not required to provide a response to the Demand, (order) but may do so if he or she desires within__ days under oath or affirmation."

   b). The transmittal letter to the licensee should also include the individual's name on the "cc" list.

4. Exceptions to the above process will be made on a case-by-case basis by the Director, OE.

6.6.9 Orders Restricting NRC-Licensed Activities and Requiring Notice of New Employment

A. Orders to unlicensed individuals may include provisions that prohibit involvement in NRC licensed activities:

1. For a specified period of time (normally the period of suspension would not exceed five years); or

2. Until certain conditions are satisfied (e.g., completing specified training or meeting certain qualifications).

B. Although not routinely used, under certain circumstances, orders to unlicensed individuals may include provisions that:

1. Require notification to the NRC before resuming work in licensed activities, or

2. Require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order.

C. Orders to NRC-licensed reactor operators may involve suspension for a specified period, modification, or revocation of their individual licenses.

D. In order to have current information available to those who make licensing and other decisions, OE includes orders to individuals on the Enforcement Web site within the collection of significant enforcement actions to individuals.

E. OE includes any subsequent actions, such as modifications by the official authorized in the order to relax its requirements and settlements.

F. A list of individuals who are currently subject to restrictions is included in the System of Records, NRC-3 Enforcement Actions Against Individuals, and the list can be made available to the public.

1. Distribution of the list is consistent with the Commission's direction when the Deliberate Misconduct Rule took effect in 1991 that a list be made available. The list is distributed to assist:

a). Those persons who are involved in licensing activities in making decisions as to whether an individual may be engaged in licensed activities; and

b). NRC staff members in responding to inquiries concerning individual actions.

G. Employment Restrictions

1. Generally, before relying on information from the Enforcement Web site to deny a licensing action or to initiate any contact with or to respond to an inquiry from an employer concerning a prior wrongdoer, the staff should contact OE by telephone or e-mail to verify the information.

2. For licensing actions, license reviewers should check the Enforcement Web site before recommending issuance of a license that lists individuals by name, such as RSO, authorized user, etc.

NOTE:

If it appears that a restricted individual is seeking to be involved in licensed activities, a compliance issue is raised and OE should be consulted.

a). If any name on the proposed license or amendment matches a restricted individual, the branch chief should be consulted immediately and then OE should be advised.

b). Since several people may have the same name, staff should review the order to see if the work history confirms or excludes a match of the individual.

H. Notice to NRC of New Employment

1. Many orders issued to individuals also require the individual to notify the NRC when that individual accepts a new position that involves work in NRC-licensed activities.

a). This notification requirement may apply to the first employment in NRC-licensed activities or may apply for a specified period of time. The purpose of the NRC notification requirement is to:

1). Let wrongdoers know and appreciate that their future activities may be subject to inspection; and

2). Provide the NRC with an opportunity to inspect the functional area in which a former wrongdoer is working.

b). When such a notification is received in a regional office, OE should be consulted to ensure that OE also is aware of the new employment; if OE becomes aware of the information, OE will advise the appropriate region of receipt of that information.

2. For materials licensees, the region (or program office) administering the license of the new employer should insert a notation in the employer's license docket file that notice has been received that a prior wrongdoer is now employed by that licensee.

a). This notation should not identify the individual by name.

b). The Regional Enforcement Coordinator will maintain a record of notifications.

c). The note should remain in the file for as long as the order requires notice to the NRC (Notice Period).

d). If the notice requirement applies only to the first employment, the note should remain in the file until the next inspection and then be deleted.

e). If the docket file is made available for public review, the note should be withheld.

3. For reactor licensees:

a). OE will notify the NRR Enforcement Coordinator.

b). The NRR Enforcement Coordinator will notify the operator licensing staff in NRR and the plant Project Manager and Senior Resident Inspector (SRI) of the wrongdoer's employment.

c). The NRC should not volunteer or advise the licensee that the prior wrongdoer is employed at its facility. (This is because the order allows the person to be re-employed, and if the NRC notifies the licensee, that information could have the possible effect of suggesting to the licensee that the individual should not be employed.)

4. For reactor and materials licensees, the region administering the license of the new employer, or program office for those licenses administered by headquarters, should acknowledge the notification in writing.

a). The letter to the individual will advise that the agency expects the individual to fully understand the requirements of the license and pertinent regulations, that the NRC expects full compliance with those requirements, and will routinely inspect that facility in the future.

b). This letter would be prepared by the Regional Enforcement Coordinator, with OE concurring.

c). This letter would be made available to the public in the same fashion as the letter issuing the initial action, e.g., under the IA number and without the new employer's docket number.

I. Materials licensees (without resident inspectors):

1. After learning that a prior wrongdoer has been employed by a licensee in its region:

a). The regional office should consider whether the circumstances warrant increasing the inspection frequency or advancing the next scheduled inspection.

b). If the licensee is to be inspected during the notice period for that individual, the region should plan to inspect the functional area in which the subject individual is working.

1). After seeing the note in the docket file, the inspector should check with the Enforcement Coordinator to learn the name of the prior wrongdoer.

2). To ascertain in what functional area the individual is working, the inspector and the supervisor should discuss ways to identify unobtrusively the functional area in which the subject individual is working, e.g., an inspector could look at an organization chart, staff list, film badge list, or internal telephone directory.

(a). Inspection of the functional area in which the prior wrongdoer works, is a goal, not a requirement.

3). The inspector should not do anything that is likely to alert the licensee that a prior wrongdoer is working at the facility and the inspector should not go out of the way to speak with the individual or treat him or her in an unusual manner.

4). It is acceptable for the inspector to examine the functional area in which the individual works, if that can be identified; however, the inspector should err on the conservative side, and not jeopardize the individual's right to employment if locating the individual is difficult.

c). The Inspection Report or field notes should not indicate that the inspection focused on the performance of a prior wrongdoer.

1). Any violations or potential wrongdoing identified during the course of the inspection should be handled in the normal manner, unless it appears that the prior wrongdoer was involved in the violation.

2). If the prior wrongdoer was involved in the violation, contact OE.

J. Reactors and other licensees with resident inspectors:

1. A SRI who has been notified by NRR that a previous wrongdoer is now employed at that facility can often identify unobtrusively the functional area in which the subject individual is working, using sources such as the licensee's telephone directory.

2. During routine inspection activities, the resident should inspect the functional area in which the subject wrongdoer is working. The functional area should be periodically reviewed during the notice period.

3. The Inspection Report should not indicate that inspection activity focused on the performance of a prior wrongdoer.

a). Any violations or potential wrongdoing identified during the course of the inspection should be handled in the normal manner, unless it appears that the prior wrongdoer was involved in the violation.

b). If the prior wrongdoer was involved in the violation, contact OE

CHAPTER 7
REACTOR OPERATIONS

Chapter 7 provides specific guidance regarding various reactor operations issues, including:

- enforcement activities involving reactor operations and facility construction
- safeguards
- emergency preparedness
- enforcement actions involving fitness-for-duty (ffd)

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7. Reactor Operations

7.1 Actions Involving Inoperable Equipment

A. Whether to take enforcement action for equipment inoperability:

1. Equipment operability is an important factor in establishing the safety significance of a violation.

   a). Judgment should be exercised in expending resources to determine operability.

   b). Analyses may be required to frame the safety significance of the deficiency and discover all relevant aspects of the discrepant condition.

NOTE:

The significance of findings associated with operating power reactors is normally determined by the Significance Determination Process (SDP) of the Reactor Oversight Process (ROP). To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the guidance in this section of this manual.

2. For cases where it is obvious that the system, subsystem, train, or component is inoperable, e.g., where the valves are closed or circuit breakers are open such that no flow or power is available and the complete function is lost:

   a). It is appropriate to cite directly against the Technical Specification (TS) requirement for operability.

   b). In accordance with example b.1, Section 6.1, of the Enforcement Policy:

      1). Consideration should be given to issuing a Severity Level II violation when a system designed to prevent or mitigate a serious safety event could not perform its intended function.

NOTE:

From an enforcement perspective, the NRC has the burden of proof to demonstrate inoperability in an enforcement hearing.

      2). Consideration should be given to issuing a Severity Level III violation, when a redundant safety train or subsystem (or for BWRs, a diverse system), is available.

3. For cases where it is not obvious that a degraded system is inoperable, extensive resources may be needed to determine operability:

   a). If the region believes that there is a significant operability issue, but does not believe that they can justify an operability citation, OE should be consulted:

      1). Before escalated action is ruled out; and,

      2). If, in order to make an operability judgment, excessive resources must be expended.

   b). In some cases, the message inherent in a Severity Level II enforcement action may be worth the resources to develop and prove an operability issue.

   c). The escalated enforcement package should not be delayed beyond established timeliness goals pending the results of operability evaluations without prior consultation with OE.

4. If the region believes that there is a significant operability issue, but does not believe that they can justify an operability citation without expending significant resources, a more appropriate and timely enforcement action (and more effective in achieving lasting corrective action) may be available by citing against the root cause of the violation (e.g., inadequate corrective action, procedures, reviews, design, or tests) rather than against the operability requirement for the system.

B. How to cite for equipment inoperability:

1. Technical Specifications include a section specifying Limiting Conditions for Operation (LCOs). LCOs are the lowest functional capability or performance levels of equipment required for safe operation of the facility. Each individual LCO includes both an applicability and action statement.

   a). The applicability statement specifies when the LCO is applicable (e.g., Modes 1, 2, and 3).

   b). The action statement prescribes remedial measures required under designated conditions in a narrative paragraph format.

      1). Many action statements first identify the time necessary to restore the piece of inoperable equipment (commonly referred to as the allowed outage time (AOT)), and then identify the time necessary to take other action, such as compensatory measures or shutdown, in the event that compliance with the LCO is not restored.

         (a). A violation does not necessarily exist based solely on the failure to restore equipment to operable status within the AOT.

         (b). A violation would exist when an LCO is not met and all necessary

actions have not been completed within all applicable completion times.

2). An action statement remains in effect until the condition no longer exists or the unit is not in a MODE within the LCO APPLICABILITY. While the term "AOT" is not used in improved Standard Technical Specifications (STS), the term and concept of "AOT" is being used for the purposes of this guidance.

3). For improved STS (i.e., NUREG-1430 through NUREG-1434), action statements are written in a matrix format and are separated into three discreet parts, i.e., Conditions, Required Action(s), and Completion Time(s).

2. AOT Examples: The following examples illustrate the use of completion times with different types of conditions and changing conditions.

Example 1:

When a pump is declared inoperable, Condition A is entered. If the pump is not restored to operable status within seven days (the AOT), a violation does not exist. Instead, Condition B is entered and the Completion Time clocks for Required Actions B.1 and B.2 start. A total of 12 hours is allowed for reaching Mode 3 and a total of 36 (not 48 hours) is allowed for reaching Mode 4 from the time that Condition B was entered. If Mode 3 is reached within six hours, the time allowed for reaching Mode 4 is the next 30 hours because the total time allowed for reaching Mode 4 is 36 hours. A violation exists if the pump cannot be restored to operable status after seven days and the unit is not placed in Mode 3 within the next 12 hours or a violation exists if the pump cannot be restored to operable status after seven days and the unit is not placed in Mode 4 within the next 36 hours.

Example 2:

A pump in a two train system is declared inoperable and Condition A is entered. Before Condition A expires, a second pump is declared inoperable. In this case, Condition A is not re-entered for the second pump. Instead, LCO 3.0.3 is entered, since the actions do not include a Condition for more than one inoperable pump. The Completion Time clock for Condition A does not stop after LCO 3.0.3 is entered, but continues to be tracked from the time Condition A was initially entered. While in LCO 3.0.3, if either one of the inoperable pumps is restored to OPERABLE status and the Completion Time for Condition A has not expired, LCO 3.0.3 may be exited and operation continued in accordance with Condition A with the original completion time applicable.

3. Potential enforcement should be considered based on the total duration that a condition may have existed. i.e., when the time of occurrence and the extent to which the licensee should have identified the condition earlier, is readily determined.

a). In order to address the issue of potential enforcement for a pre-existing condition, it is necessary to clearly distinguish between:

NOTE:

This guidance emphasizes the importance of licensees taking appropriate actions upon discovery of inoperable equipment, rather than focusing resources to attempt to determine when the condition occurred, e.g., choosing to shutdown the plant in a less than orderly fashion solely to comply with the TS.

1). Compliance with the TS ACTION statements; and

2). Compliance with the TS LCOs.

b). The distinction between the TS ACTION statement and the TS LCOs is evident in the general TS usage rules in the improved STS, i.e.:

- LCO 3.0.1 - LCOs shall be met during the modes or other specified conditions in the applicability, except as provided in LCO 3.0.2.
- LCO 3.0.2 - Upon discovery of a failure to meet an LCO, the Required Actions of the associated conditions shall be met, except as provided in LCO 3.0.5 and LCO 3.0.6. If the LCO is met or is no longer applicable prior to expiration of the specified completion time(s), completion of the Required Action(s) is not required unless otherwise stated.

c). The determination of whether an action statement (LCO 3.0.2) is met is based on when the condition is discovered.

1). Once discovered, the question is whether the actions to be completed are completed on time.

2). While a licensee may be in compliance with the action statement of a TS based upon the discovery of the violation, a licensee may not be in compliance with the TS LCO (3.0.1) based on when the violation occurred.

d). The following guidelines should be used for cases where the time of occurrence can be established and the licensee should have discovered the condition sooner:

1). If the time between the occurrence of the condition and the discovery of the condition is greater than the AOT for that condition, then the licensee should be cited for a failure to satisfy the TS LCO. If the licensee otherwise satisfied the TS Required Action(s) from the time of discovery of the condition, the citation and enforcement correspondence should acknowledge this.

2). If the time between the occurrence of the condition and the discovery of the condition is less than the AOT for that condition, and upon discovery the Required Actions are completed within the AOT or the shutdown track is satisfied, there is not an LCO violation. This would be true even if the time

between the occurrence of the condition and the completion of Required Actions is greater than the AOT. However, there may be a root cause issue outside of the TS issue warranting appropriate enforcement action.

3). If the time between the occurrence of the condition and the completion of Required Actions is less than the AOT, then there is no violation.

e). In determining whether to cite a violation against the LCO, consideration should also be given to other violations, such as root causes that may focus the corrective action. If there is a clear root cause violation, the LCO violation and the root cause violation should normally be combined into one escalated issue or problem.

f). Depending on the regulatory and technical significance (i.e., actual and potential consequences, including risk considerations), there may also be cases where the significance dictates more than one escalated action, one for the LCO violation and one (or more) for the root causes, e.g.:

1). Depending on the total time the equipment was inoperable and other factors determined by the root cause evaluation, enforcement discretion may be warranted to increase the amount of the civil penalty based on a substantial increase in risk due to the excessive duration of the inoperability and/or increase the severity level above Severity Level III.

2). LCO Examples: The following examples illustrate these guidelines. (Use TABLE 1 for TS examples.)

TABLE 1

CONDITION	REQUIRED ACTION	COMPLETION TIME
A. One pump inoperable.	A.1 Restore pump to OPERABLE status.	7 days
B. Required Action and associated Completion Time not met.	B.1 Be in MODE 3. AND B.2 Be in MODE 4.	12 hours 36 hours

Example 1:

Upon discovery of an inoperable pump, Condition A is entered. The licensee is able to restore the pump in seven days and three hours. Therefore, the licensee was able to comply with the TS action statement. During the root cause analysis, the licensee was able to determine that the violation occurred seven days and nine hours prior to discovery because of not following a procedure required by 10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings." It is further determined that the licensee should have identified this condition at that time. In this case, the time between the occurrence of the violation and the time of discovery of

the violation was seven days and nine hours... a time greater than the AOT of seven days. Therefore, a violation of the TS LCO would be warranted. Citations against 10 CFR Part 50, Appendix B, Criterion V and Criterion XVI, "Corrective Action" should also be considered.

Example 2:

Upon discovery of an inoperable pump, Condition A is entered. The licensee is able to restore the pump in seven days and three hours. Therefore, the licensee was able to comply with the TS ACTION statement. During the root cause analysis, the licensee was able to determine that the violation occurred six days prior to discovery because a procedure was not properly followed. It is further determined that the licensee should have identified this condition. In this case, the time between the occurrence of the violation and the time of discovery of the violation was six days. a time less than the AOT of seven days. Therefore, a violation of the TS LCO for the pre-existing condition would not be warranted. However, enforcement action for the root cause (i.e., Criterion V) and the failure to identify (i.e., Criterion XVI) should be considered.

g). When an inoperable condition is discovered, the TSs should be reviewed to determine if a violation of the TS action statement has occurred based on the time of discovery.

1). The next step would be to determine if the time of occurrence can be established and to determine if the licensee should have discovered the condition sooner.

2). The time between discovery and occurrence should be compared to the AOT to determine if a violation of the TS LCO has occurred.

4. Proper citations against equipment operability should include a paragraph describing the requirement and a paragraph describing how the requirement was not met.

a). The requirement paragraph should identify and establish:

1). What the applicable TS is;

2). When the LCO is applicable;

3). What the LCO requires; and

4). What the action statement requires.

b). The citation should establish how the requirement was not met. The "contrary to" paragraph should establish:

1). When the equipment was inoperable;

2). That the LCO was applicable;

3). How the specified equipment was rendered inoperable, and

4). That action was not taken within the specified time to restore operability.

c). Refer to the following example:

Technical Specification (TS) 3.6.6.1 requires that while the plant is in Modes 1, 2, 3, or 4, two independent Supplemental Leak Collection Release Systems shall be operable. The TS ACTION statement requires that, "with one Supplemental Leak Collection and Release System inoperable, restore the inoperable system to operable status within seven days or be in at least hot standby within the next six hours and in cold shutdown within the following 36 hours."

Contrary to the above, between June 9, 2006 and June 27, 2006, while the plant was in Mode 1, the "A" train of the SLCRS was inoperable, in that the fire damper in the train was closed, thereby stopping the flow of air in the system, and action was not taken to either restore the system to operable status within seven days or place the unit in cold shutdown within the following 36 hours.

5. When a situation exists that exceeds the designated conditions of a specific TS ACTION statement, then it may be necessary to include the generic LCO, traditionally TS 3.0.3, as part of the citation. The following example illustrates this point, i.e., the TS ACTION statement prescribes remedial measures to be taken when one of the subsystems is inoperable, but does not address when both subsystems are inoperable:

Technical Specification (TS) 3.5.2 requires, in part, that in MODES 1, 2, and 3, two independent Emergency Core Cooling System (ECCS) subsystems shall be operable with each subsystem comprised of, in part, an operable flow path capable of taking suction from the refueling water storage tank on a Safety Injection signal and automatically transferring suction to the containment sump during the recirculation phase of operation.

TS 3.0.3 requires, in part, that when a Limiting Condition for Operation is not met, except as provided in the associated ACTION requirements, within one hour action shall be initiated to place the unit in a MODE in which the specification does not apply by placing it, as applicable, in at least HOT STANDBY within the next six hours, at least in HOT SHUTDOWN within the following six hours, and at least COLD SHUTDOWN within the subsequent 24 hours.

Contrary to the above, between July 15, 2006 and August 13, 2006, while in MODE 1, both independent ECCS subsystems were inoperable in that both flow paths were incapable of supplying water from the refueling storage tank to the reactor core on a Safety Injection signal because normally open valves in each flow path were closed. With both flow paths inoperable, the licensee failed to take action within one hour to place the unit in a MODE in which TS 3.5.2 does not apply.

6. There may be cases when it is not clear exactly when a piece of equipment became inoperable. In such cases, the burden is on the agency to establish realistic time-frames for when it is most likely that the piece of equipment was rendered inoperable.

NOTE:

When it is not clear exactly when a piece of equipment became inoperable, the burden is on the agency to establish realistic time-frames for when the piece of equipment likely became inoperable.

a). In establishing realistic time-frames, consideration should be given to issues such as:

1). When the equipment was last tested as operable;

2). Whether other activities were conducted that could have impacted equipment operability;

3). Whether prior indication of inoperability existed; and

4). When the inoperable piece of equipment was discovered.

b). As long as time-frames can be established to substantiate a TS violation, the cited time-frames should be as conservative as possible. The following example illustrates this scenario.

TS 3.5.2 requires that two independent emergency core cooling system (ECCS) subsystems be operable in Modes 1, 2, and 3 with each subsystem comprised, in part, of one operable safety injection (SI) pump.

TS 3.0.3 requires that when a Limiting Condition for Operation is not met, that action be initiated within one hour to place the unit in at least HOT STANDBY within six hours, at least HOT SHUTDOWN within the following six hours, and at least COLD SHUTDOWN within the subsequent 24 hours.

Contrary to the above, on December 23, 2005 between at least 12:07 a.m. and 12:30 p.m., the reactor was operated in Mode 1 with both SI pumps inoperable, in that they could not have performed their intended function for a limited range of loss of coolant accidents, due to a freeze protection system failure that caused ice to block the common recirculation line between the SI pumps and the refueling water storage tank. With both SI pumps inoperable during this period, the licensee failed to place the unit in at least hot standby within six hours.

1). In this example, 12:07 a.m. represents the time at which there was an

indication that the equipment was inoperable. Specifically, at this time, the licensee attempted to add water to the Refueling Water Storage Tank (RWST) unsuccessfully via the recirculation line. Therefore, from at least this time, one can conclude that the recirculation line was frozen, rendering the SI pumps inoperable. 12:30 p.m. represents the time at which the licensee declared both SI pumps inoperable.

2). Although it is highly likely that the recirculation line was frozen before 12:07 a.m., proving that this was the case is not necessary to support the TS violation.

7.2 Actions Involving Degraded Equipment

A. Additional guidance on inoperable and degraded equipment is included in Generic Letter 91-18, “Degraded Conditions and Operability.”

B. It may be better to focus the enforcement action on the root cause of the problem rather than on the issue of operability for those cases where:

1. Inoperability is difficult to establish, such as cases that involve significant differences in system performance capabilities as compared to Final Safety Analysis Report (FSAR) assumptions (e.g., where margins explicitly stated or implied in the FSAR are under dispute, or the original design basis is no longer available); or

2. Complicated or complex analyses are required to determine the safety significance.

NOTE:

In many cases, resources would be better spent in focusing on identifying and correcting root cause issues that, corrected, will prevent future failures, than in determining whether or not a piece of equipment or a system was, in hindsight, operable.

C. In cases involving degraded (but not clearly inoperable) equipment:

1. The enforcement action should not cite the TS for the piece of equipment (since being degraded is not of itself a violation).

2. The enforcement action should cite the requirement that addresses the root cause of the problem that ultimately caused the piece of equipment to be significantly degraded, e.g.:

- The licensee's failure to take corrective action (i.e., 10 CFR Part 50 Appendix B, Criterion XVI)
- The failure to follow procedures (administrative TS requirement Appendix B, Criterion V)

- The failure to control design (Appendix B, Criterion III)
- The failure to control tests (Appendix B, Criterion XI)
- The failure to perform a safety analysis (10 CFR 50.59)

D. The cover letter for enforcement actions involving degraded equipment should focus on the licensee's root cause failure as the basis for the action, emphasizing that it represents a regulatory concern (rather than focusing on whether the equipment was or was not inoperable).

7.3 Enforcement of 10 CFR 50.59 and Related FSAR

A. One of the requirements of 10 CFR 50.34 is that each application for a license to operate a facility shall include a FSAR.

1. The **FSAR** contains design bases, operational limits and analyses of facility structures, systems and components. In essence, it is a statement by the applicant of how it intends to comply with many of the NRC's requirements.

B. A licensee who fails to meet an FSAR commitment that describes how it intends to meet a regulatory requirement may have, depending on the circumstances, violated that requirement.

1. Enforcement action may be taken directly against the underlying requirement (e.g., the TS or the regulation).

2. A departure from an FSAR commitment that directly involves a specific legally binding NRC requirement can cite that specific requirement.

a). When the departure from the FSAR does not directly involve a specific requirement, the NOV may cite the particular criterion of 10 CFR Part 50, Appendix B (e.g., Criterion III, Design Control) as the basis for the violation.

C. If the departure from the FSAR does not directly involve a specific requirement, the failure to implement the FSAR commitment involving safety-related matters may constitute a violation of the licensee’s quality assurance requirements.

D. The failure to update the FSAR that does not have a material impact on safety or licensed activities is considered a minor violation of 10 CFR 50.71(e).

E. Changes to the facility or procedures as described in the safety analysis report, or performance of tests or experiments not described in the FSAR may also be a violation of 10 CFR 50.59. This regulation was changed on October 4, 1999 (64 FR 53582), as amended on December 21, 2001 (66FR 64738).

NOTE:

Note that the fundamental difference in the revised rule is the criteria under which prior NRC review and approval is required. The old rule uses the concept of an unreviewed safety question exists when changes make any increase in probabilities of accidents or malfunctions, or consequences, or any decreases in margin of safety. The revised rule deletes the concept of the unreviewed safety question and allows for minimal increases or decreases in related parameters. The fundamental difference in the revised rule is the criteria under which prior NRC review and approval is required. The old rule uses the concept of an unreviewed safety question exists when changes make any increase in probabilities of accidents or malfunctions, or consequences, or any decreases in margin of safety. The revised rule deletes the concept of the unreviewed safety question and allows for minimal increases or decreases in related parameters.

1. Under either the revised or current 10 CFR 50.59, the Commission can take enforcement action concerning departures from FSAR provisions if a licensee:

   a). Incorrectly concludes that a change from the FSAR does not involve a change in the technical specifications incorporated in the license or does not require prior NRC review and approval prior to implementation;

   b). Fails to conduct a safety evaluation for a change; or

   c). Fails to report the change to the NRC or to keep a record of the change as required by the regulations.

2. Citations against 10 CFR 50.59 are appropriate when the licensee makes changes not allowed by 10 CFR 50.59 and/or when a 10 CFR 50.59 evaluation is not performed when required.

3. Citations against 10 CFR 50.59 are not generally appropriate when the facility never matched its description in the FSAR.

   a). This type of citation, known as a “defacto 50.59 violation” had been used in the past to avoid statute of limitation concerns.

   b). Latent design defects should be treated as degraded, nonconforming conditions consistent with Generic Letter 91-18, Revision 1.

      1). Sections 4.7 and 4.8 of the Attachment to Generic Letter (GL) 91-18 correctly describe how 10 CFR 50.59 is to be applied to degraded, nonconforming conditions.

      2). Latent nonconformances with FSAR specifications should be dispositioned as Appendix B violations (normally Criterion III or Criterion V), when applicable.

4. A citation against 10 CFR 50.59 should:

   a). Set out the specific FSAR language at issue and describe how it was not met;

   b). Establish that an evaluation was not performed; and/or

   c). Establish that the change constituted an unreviewed safety question (old rule) or otherwise required prior NRC review and approval prior to implementation (new rule) or a change to a TS.

5. There may be issues concerning compliance with 10 CFR 50.59 that will be complicated by whether the new rule or old rule is applicable. The following guidance is provided:

   a). For situations that violate the “old” requirements, but that would not be violations had the evaluation been performed under the revised rule:

      1). The NRC will exercise discretion pursuant to VII.B. 6 of the Enforcement Policy and not issue citations or document non-cited violations against the “old” rule.

      2). The staff will document in inspection reports that the issue was identified, but that no enforcement action is being taken because the revised rule requirements are met. Approval by the Director, OE, is required for use of Section VII.B.6 discretion.

   b). For situations identified prior to the effective date of the revised rule that involve a violation of the existing rule requirements but that would not be violations under the revised rule:

      1). By definition, if it is not a violation under the revised rule, then the significance of the violation is low; and

      2). Corrective actions are required to be taken in a time frame commensurate with the significance of the violation.

6. Because violations of 10 CFR 50.59 are violations that potentially impede or impact the regulatory process, they are:

   a). Not processed through the ROP’s SDP; and

   b). Are processed through the examples of Section 6.1 of the Enforcement Policy.

      1). Although the SDP is not designed to assess significance of violations that potentially impact or impede the regulatory process, the staff has determined that the significance of a 10 CFR 50.59 violation can be assessed through the SDP.

2). To ensure a consistent approach for significance determinations, The Section 6.1 10 CFR 50.59 violation severity level examples have been established to base the significance of 10 CFR 50.59 violations on the resulting physical, procedural, or analytical change to the facility as evaluated through the SDP.

(a). Violations will be categorized at Severity Level III if the resulting changes were evaluated by the SDP as having low to moderate, or greater safety significance (i.e., white, yellow, or red finding).

(b). Violations will be categorized at Severity Level IV if the resulting changes were evaluated by the SDP as having very low safety significance (i.e., green finding).

(c). Violations will be considered minor if there was not a reasonable likelihood that the change requiring 10 CFR 50.59 evaluation would ever require Commission review and approval prior to implementation.

7. In addition to the guidance provided regarding citations against 10 CFR 50.59, in cases where a licensee has never implemented a commitment made under oath in the FSAR or amended FSAR, a material failure to have the facility conform to the FSAR may also constitute a violation of 10 CFR 50.9 if it occurred after 10 CFR 50.9 became effective (December 31, 1987), or may constitute a material false statement.

F. In determining which enforcement action to recommend for a failure to implement an FSAR commitment (i.e., NOV against a specific requirement, Appendix B, 10 CFR 50.59, 10 CFR 50.9; or Notice of Deviation against the FSAR), the region should consider which enforcement action will convey the appropriate message to the licensee and which enforcement action will constitute the most defendable citation.

7.3.1 Application of the Corrective Action Civil Penalty Assessment Factor for 10 CFR 50.59 Violations

A. In the event a violation of 10 CFR 50.59 results in an SDP finding of red, yellow or white, it may be necessary to assess corrective actions under the traditional enforcement approach.

B. Corrective actions should normally be considered prompt and comprehensive only if the licensee makes a prompt decision on operability, and either:

1. Makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the “as found” condition; or

NOTE:

It is important for licensees to recognize the need for prompt and comprehensive corrective actions because until such actions are taken the violation continues unabated.

2. Promptly initiates corrective action consistent with criterion XVI of 10 CFR 50, Appendix B if it intends to restore the facility or procedure to the FSAR description.

7.3.2 Exercise of Enforcement Discretion for FSAR Issues

A. To encourage licensees to promptly undertake voluntary initiatives to identify and correct FSAR noncompliances, the staff may exercise enforcement discretion to either mitigate or escalate the enforcement sanction.

1. Mitigation: Old Design Issues. The staff may refrain from issuing civil penalties and in some instances, citations, for a two year period where a licensee undertakes voluntary initiative to identify and correct FSAR noncompliances that will be completed within that two year period.

2. This discretion would not normally be applied if:

a). The NRC identifies the violation unless it was likely in the staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of the licensee's initiative;

b). The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies the FSAR issue;

c). The licensee identifies the violation but had prior opportunities to do so (was aware of the departure from the FSAR) and failed to correct it earlier;

d). There is willfulness associated with the violation;

e). The licensee fails to make a report required by the identification of the departure from the FSAR; or

f). The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program. The corrective action should be broad with a defined scope and schedule.

3. Escalation: Civil Penalties the staff may escalate the amount of the civil penalties for FSAR/50.59 noncompliances identified by the NRC subsequent to the two year voluntary initiative period.

a). The staff should use this discretion to increase the fine and consider assessing

civil penalties for each violation or problem of $130,000 which may be further escalated after considering the number and nature of the violations, the severity of the violations, whether the violations were continuing, and who identified the violations (and if the licensee identified the violation, whether to exercise discretion in accordance with the Enforcement Policy), rather than the normal assessment factors.

b). This approach is intended to increase the incentive for licensees to take timely action to ensure that their facilities match the FSAR, e.g.:

1). If a single Severity Level III violation is identified by the NRC and it lasted for more than 1 day, a civil penalty of $260,000 could be assessed.

2). If the licensee identified the same violation and application of enforcement discretion under Section VII.B.3 was not warranted, a civil penalty of $130,000 ($65,000 x 2 days) could be assessed for the example cited above, providing some recognition of the licensee's efforts.

7.4 Citations Against 10 CFR Part 50, Appendix A, General Design Criteria (GDC)

A. When the Commission developed and adopted Appendix A, the GDC were intended to provide a basis for judging the adequacy of:

1. The preliminary design of the facility at the construction permit stage; and

2. The detailed design and construction at the operating license stage.

B. The **GDC** function as criteria for assessing the design criteria for the plant; therefore:

1. The GDC carry over into the requirements for the FSAR (50.34(b)) for analyses of safety-significant structures, systems, and components (SSCs) with emphasis upon performance requirements, the bases upon which such performance requirements have been established; and

NOTE:

Citations against the GDC are expected to be rare and require OE approval prior to issuance.

2. Technical specifications (TSs) are required to be derived from the analyses in the FSAR (50.36(b)).

C. The GDC are not directly applicable to operating requirements.

1. The GDC were not intended, in and of themselves, to constitute the controlling

parameters for operation of nuclear power plants.

2. TSs provide the controlling parameters on operation of a nuclear power plant, as is contemplated by Section 182.a of the AEA.

7.5 Citations Against 10 CFR Part 50, Appendix B

A. Citations for Quality Assurance (QA) issues that are violations of 10 CFR Part 50, Appendix B, should be constructed with a clear statement of the applicable Appendix B criterion, followed by a statement of how that requirement was not met.

B. Normally, for citations for QA issues, it is not necessary to:

1. Include a reference to 10 CFR 50.54(a) or 50.55(f) as the underlying regulation when citing Appendix B; or

NOTE:

10 CFR Part 50, Appendix B applies to safety-related structures, systems, and components (SSCs).

2. Reference that portion of the licensee's approved QA program which implements Appendix B, unless the licensee's approved QA program significantly differs from that of Appendix B.

a). In most circumstances, the licensee's QA program is consistent with and amplifies the provisions of Appendix B; therefore a reference to the licensee's QA program is not normally necessary.

b). If there is a conflict between an approved QA plan and Appendix B, the matter should be discussed with OE and NRR before issuing a violation.

C. In the case of operating reactors where the TS administrative requirements may encompass certain Appendix B requirements such as procedures, the TS, if more specific, should be cited.

1. It may be appropriate in a particular case to utilize Appendix B for the citation if broader corrective action is appropriate.

2. It is essential for Appendix B, Criterion XVI citations, that the “contrary to” paragraph indicates that the licensee failed to take corrective action for a condition adverse to quality.

3. The following is an example of a citation against 10 CFR Part 50 Appendix B for failure to take corrective action.

10 CFR Part 50 Appendix B, Criterion XVI, "Corrective Action," requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, deficiencies, and deviations, are promptly identified and corrected.

Contrary to the above, from June 10, 2006 to August 3, 2006, the licensee failed to take prompt and adequate corrective action for a condition adverse to quality. Specifically, on June 10, 2006, a quality assurance auditor identified that a longitudinal pipe weld on the low head safety injection system was not included in the licensee's In-Service Inspection program and the licensee failed to conduct sufficient additional reviews to identify and resolve similar problems with longitudinal pipe welds that were present in other safety-related piping.

D. The provisions of Appendix B do not generally apply to the radiation protection and safeguards areas.

1. Appendix B applies to safety-related SSCs.

2. There may be cases where procedures relating to security and radiation protection might be subject to Appendix B quality assurance criteria under certain circumstances, e.g., where "quality assurance" as defined in Appendix B comprises all those **planned and systematic actions** necessary to provide adequate confidence that an SSC will perform satisfactorily in service.

7.6 Enforcement Actions in Conjunction with Plant Shutdowns

A. Enforcement actions based on findings at plants with major shutdowns:

1. Should be processed substantially before restart is contemplated; and

2. Should normally be submitted to OE at least two months before scheduled startup, if possible, to permit:

a). The case to be issued; and

b). The licensee's corrective action to be assessed prior to startup in order to avoid issuing sanctions at the same time or after startup is authorized.

B. The logic in the preceding paragraph should be followed for plants that are to be licensed.

7.7 Actions Involving Fire Protection

A. Fire protection requirements are established by:

- 10 CFR Part 50, Appendix A
- GDC 3
- 10 CFR 50.48
- 10 CFR Part 50, Appendix R

- Facility license conditions
- Facility TSs
- Other legally binding requirements, as applicable

B. Fire protection violations may involve:

- Inoperable or inadequate fire barriers
- Separation, suppression, or detection systems
- Repair parts
- Procedures
- Other conditions or items required to prevent fires, protect shutdown equipment during a fire, or restore safe shutdown equipment to service following an actual fire

C. Failures to meet regulatory requirements for protecting trains of equipment required for achieving and maintaining safe shutdown constitute serious violations.

D. The significance of fire protection violations is normally determined by the SDP.

E. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be:

1. Assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy; and

2. Assigned a severity level commensurate with the significance.

F. The following guidance provides examples of violations at various severity levels and should be used as a guide to determine the appropriate enforcement action. (For purposes of this guidance, required SSCs are those that are necessary to achieve and maintain safe shutdown and that require the application of fire protection features as described in the licensee's fire hazards analysis report and NRC's safety evaluation report.)

1. **Severity Level I**: Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which an actual fire damages that equipment to such a degree that safe shutdown could not be achieved or maintained.

2. **Severity Level II**: Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which a postulated fire in the area would so damage that equipment that safe shutdown would not be achieved and maintained.

3. **Severity Level III**: Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which a postulated fire in the area, in the absence of additional evaluation, could so damage that equipment that shutdown could not be achieved and maintained using the applicable equipment identified in the fire hazards analysis in accordance with applicable requirements.

a). Failure to have an adequate written evaluation available for an area in which Appendix R compliance is not apparent will be taken as an indication that the area does not comply with NRC requirements, and may result in enforcement action at this severity level.

b). Licensees may exercise engineering judgment as to the threshold for documenting detailed analysis for spurious equipment actuations following a fire. Thus, potential spurious actuations judged by the licensee to not involve substantial risk to safe shutdown capability may not be covered by documented evaluations.

c). The NRC may judge differently the potential impact on safe shutdown capability, and may request the licensee to provide additional analysis. A Severity Level III violation is probably not warranted unless this additional analysis confirms a significant problem.

4. **Severity Level IV**: Failures to meet one or more fire protection requirements that do not result in a Severity Level I, II, or III violation and which have more than minor safety or environmental significance.

7.8 Actions Involving Loss of Decay Heat Removal (DHR)

A. The significance of decay heat removal violations is normally determined by the SDP.

B. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and in this section.

C. Because of the NRC staff's reassessment of the potential consequences of DHR events, actions in this area must be critically assessed to apply the appropriate severity level.

1. In some scenarios, the precursors to core damage (such as boiling in the core) may occur much sooner after a loss of DHR than previously thought, and the implications of such a loss may be more serious.

2. To ensure that these cases are handled uniformly and to better determine whether escalated action is appropriate, all actions (cited or non-cited) that result in a loss of DHR or shutdown cooling, require prior OE notification.

D. A citation against a TS Limiting Condition for Operation may not always be available since TSs may not be specific about the amount of time allowed to restore DHR after an interruption.

1. An exception is where the licensee took little or no action to immediately correct the problem. Such rare cases would clearly warrant consideration of escalated enforcement no matter what caused the DHR loss.

2. The majority of DHR problems do not involve prolonged losses or losses for which the licensee does not take at least some corrective action.

E. Under current NRC requirements, enforcement actions related to DHR events will generally consist of 10 CFR Part 50 Appendix B violations for lack of adequate procedures or not following procedures.

1. The NRC has reassessed the significance of this issue and has provided extensive prior notice to the industry on this subject (particularly events occurring during reduced reactor coolant system inventory operations) in the form of Generic Letters (GL 87-12 and GL 88-17), Information Notices, meetings with various industry groups, and letters to licensed operators.

a). Much of the NRC guidance focuses on losses of DHR during reduced reactor coolant system (RCS) inventory operation; however,

b). Other types of losses of DHR, such as one caused by an improper design change, can also be evaluated using some or all of the guidelines as appropriate.

2. Given the potential for core damage and the guidance provided by the NRC, failure of licensees to take aggressive action to assure appropriate procedures, procedure implementation, and training may be appropriately categorized at Severity Level III.

F. The following guidelines, which have been coordinated with NRR, should be used to evaluate whether a particular loss of DHR should be considered a Severity Level III matter. The factors to consider are:

1. How similar was the root cause of the loss of DHR to the deficiencies addressed in NRC generic guidance such as GL 87-12 and GL 88-17?

2. Given that a deficiency similar to that in NRC guidance occurred, how sensitive were the operators to the problem?

3. How quickly did the operators respond? (Core decay heat level may not call for instantaneous response; however, the failure to correct such a situation quickly simply because the operator does not view it as particularly pressing may indicate a lack of sensitivity to this type of problem.)

4. Did they respond using detailed procedural guidance, and if they did not, was their training sufficient in and of itself?

5. Given that the operators procedurally treated the "symptoms," did they recognize the problem as a loss of DHR?

6. Did the operators have other available indications not specified in the procedures that could have been consulted, and did they use them?

7. Does the plant have a history of interruptions of DHR? (This may indicate a continuing lack of sensitivity to this issue.)

8. Were procedures in place to provide operator guidance for alternative DHR options not normally employed? (In a number of instances licensees have made after-the-fact arguments about alternative sources of circulation and cooling. Because such sources were not defined by procedures, it was unclear if the operator in such cases could have aligned such sources quickly enough and whether the availability of such sources was only fortuitous.)

NOTE:

There is no exact formula for arriving at a severity level and the factors discussed below may be weighted differently or may not be applicable in any given case.

G. The scenarios provided in the two examples that follow illustrate certain key actions or inactions that, when considered under the guidance provided earlier, would result in the recommended severity level classifications. It should be noted that in neither instance was DHR flow lost for an extended period, if it was ever fully lost.

Example 1: For maintenance work on a reactor coolant pump seal, reactor vessel water level needs to be lowered to mid-loop. In preparation for the draindown, an auxiliary operator performs a full inspection of the tygon tube level-indication system and then reports to the control room that he is standing by to monitor level during the draindown. Shortly before level reaches the mid-loop area, the control room secures the draindown to allow the level indicators to stabilize before draining the last few inches of water. Simultaneously, maintenance personnel arrive in the containment in preparation for the seal work and inadvertently place a large box on the tygon hose. Upon resuming the draindown, the control room operator notes a growing discrepancy between the level being reported from the containment and the control room indication. Just as the control room operator terminates the draindown to investigate the discrepancy, the operating DHR pump begins to cavitate. The operator quickly secures the pump, restores RCS inventory, and starts the standby pump. The auxiliary operator again performs a walk-on of the tygon hose, discovers the blockage, and removes it before resuming draindown.

Recommendation: The licensee should be assessed either an NCV or NOV for a Severity Level IV violation for inadequate work control. Although pump cavitation occurred after a loss of adequate level, due to erroneous level indication, proper preparation for the draindown was accomplished and the operators responded quickly and correctly to the event.

Example 2: Before the draindown to mid-loop, an auxiliary operator is stationed to monitor level without first having anyone walk down the tygon hose. Earlier, maintenance personnel had entered the containment and inadvertently placed a large box on the tygon hose. After the draindown begins, the control room operator notes a growing difference between control room level indication and that being reported from the containment. He secures the draindown and then asks the auxiliary operator

about the condition of his indicating hose. The auxiliary operator replies that the level seems to be decreasing more slowly than he anticipated but the decrease has been smooth and he doesn't see any air bubbles. With that information, the control room operator decides to continue the draindown relying solely on the tygon hose rather than on the relatively new control room indicator with which there have been problems. The control room operator makes this decision despite the fact that, at the time, the control room indicator is providing a level reading significantly lower than that of the tygon hose. After recommencing the draindown, the operating DHR pump begins to cavitate. The control room operator gets a report from the containment that the level is still indicated to be well above mid-loop and, therefore, he starts the standby pump and secures the cavitating pump. Almost immediately, the standby pump also begins to cavitate. The operator, realizing that level must be too low, finally takes action to restore level and directs the auxiliary operator to walk down the tygon hose.

NOTE:

The more a case appears similar to the circumstances of the generic guidance and the less responsive the operators are, the more likely the case should be considered at Severity Level III.

Recommendation: The licensee should be assessed a Severity Level III violation. Proper preparations were not made, the operator made a nonconservative judgment in choosing which level indicator to use, and when given an opportunity to recognize the mistake, chose to start a second pump rather than to learn why the first pump was cavitating.

7.9 Actions Involving Service Water Systems

A. The significance of service water system violations is normally determined by the SDP.

B. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the guidance in this section.

C. Although the specific title of the system(s) may vary, as used in the context of this guidance, the term "service water system" (SWS) refers to the cooling water system that provides the ultimate heat sink for the plant's safety-related systems.

D. Determining the appropriate enforcement action for cases involving the SWS may be challenging because of the potential difficulty in determining whether or not the SWS can adequately perform its design function. Deficiencies that can affect the operability of the SWS include problems such as:

- Inadequate heat removal capability as a result of bio-fouling
- Silting
- Erosion and corrosion

- Single failure concerns
- Inadequate original design margin

E. The first decision in SWS cases is whether the agency should cite against SWS operability.

1. Licensee expenditures of time and resources to perform after-the-fact analyses supporting SWS operability do not obligate similar NRC expenditures to review the analysis to support enforcement action.

2. It may be preferable to cite against the root cause of the deficiency rather than to expend resources to perform complex operability analyses.

F. In some cases, it may not be prudent to cite against the SWS being unable to perform its intended function (e.g., one train of the SWS is not available).

1. In such cases, an enforcement action citing the requirement that best reflects the root cause failure may be used to establish a Severity Level III violation, e.g., the licensee has a degraded system.

2. The following example illustrates this point:

10 CFR Part 50, Appendix B, Criterion XVI (Corrective Action), requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, deficiencies and deviations, are promptly identified and corrected.

Contrary to the above, between June 15, 2006 and August 31, 2006, a condition adverse to quality at the ABC Nuclear Station was not promptly identified or corrected. Specifically, mussel clusters of enough volume to cause significant reductions in service water flow to vital components had accumulated along an 80 foot section of service water system piping. On at least nine occasions during that time period, actions taken by licensee personnel in reaction to indications of degraded service water flow were ineffective in identifying and correcting the full extent of the problem. These ineffective corrective actions resulted in significantly reduced service water flow to the "B" Diesel Generator heat exchanger which in turn resulted in a reduction in the diesel generator's electrical load carrying capability.

G. Additional examples of requirements that could be cited for the root cause failure include:

- Failure to perform a design change safety analysis (10 CFR 50.59)
- Failure to follow procedures (administrative TS requirement)
- Failure to control design (Appendix B, Criterion III)
- Failure to control tests (Appendix B, Criterion XI)

H. For those enforcement actions that do not cite against operability, the cover letter should focus on the licensee's root cause failure as the basis for the action, rather than focusing

on whether the SWS was or was not operable.

I. Additional information on SWSs is addressed in Generic Letter (GL) 89-13, “Service Water System Problems Affecting Safety Related Equipment.”

1. Failure to comply with a Generic Letter is not a violation unless the commitment is addressed by a legal requirement or has been incorporated into the licensee's license.

2. GL 89-13 may be cited to establish prior notice in assessing a civil penalty for a particular action.

7.10 Actions Involving Emergency Core Cooling Systems

A. The significance of emergency core cooling violations is normally determined by the SDP.

B. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the following guidance.

C. 10 CFR 50.46 enumerates specific steps that must be implemented by a licensee following the discovery of an error in an approved LOCA code.

1. The effect of the error on predicted peak clad temperature (PCT) must be estimated.

2. The error must be reported to the NRC on a schedule determined by the magnitude of the change in PCT.

3. If the impact of correcting the error causes the predicted PCT to exceed the acceptance criterion of 2200 °F, the licensee is required to take immediate action to return to compliance with the regulation.

D. Enforcement action could be taken against a licensee, related to non-compliance with 10 CFR 50.46 acceptance criteria, in, e.g., the following circumstances:

1. A licensee discovers an error in an approved ECCS model and does not follow the requirements for assessing and reporting the error.

2. A licensee discovers an error and assesses its impact, but does not report it or take other action mandated by the regulation as a result of the assessment (e.g., limiting power to stay under 2200 °F; replacing Dougall-Rohsenow correlation per Appendix K requirements).

3. An error is discovered in an ECCS model by the NRC staff that a licensee (or vendor) could reasonably have been expected to discover had the code been validated properly, in which case enforcement action could be taken against the licensee per the requirements of 10 CFR Part 50, Appendix B, for failure to provide adequate QA.

E. Although enforcement action might be warranted for violations of 10 CFR Part 50,Appendix B, the staff does not believe that it is normally appropriate to take enforcement action for 10 CFR 50.46 against a licensee who:

1. Discovers an error in an approved LOCA code; and

2. Follows the requirements of 10 CFR 50.46 for assessing, reporting, correcting the error, including whatever steps are needed to stay in compliance with the PCT acceptance criterion.

F. Enforcement action is generally not taken when errors in the code are not preventable by reasonable QA measures as analogous to failure of a plant component (hardware) resulting from a latent (hidden) flaw that the licensee could not reasonably have been expected to discover prior to the component failure.

1. The NRC would generally require that the failure be evaluated, once identified, to determine if the latent flaw could be generic and, therefore, requires reporting under10 CFR Part 21.

2. The equipment would also require repair and testing to demonstrate it could meet its functional requirements.

3. Evaluation (including a Part 21 evaluation), repair and testing, are types of actions that are consistent with licensee requirements under 10 CFR 50.46. Accordingly, the staff does not believe that there is a fundamental inconsistency in the way in which enforcement action is taken for software and hardware faults.

G. Enforcement policy with respect to LOCA codes and 10 CFR 50.46 requirements must be considered in the context of the fundamental differences between “hardware,” i.e., plant equipment, and “software,” i.e., computer codes and analytical results.

1. Determination of whether hardware can accomplish a specific function is, in many cases, a relatively straightforward process.

a). The equipment is operated, its output (e.g., flow from a pump) is measured, and the measured value is compared to a required value, such as that in Technical Specifications, to determine if the equipment meets its functional requirements. (Due consideration must be given to concerns such as instrument uncertainty.)

b). Functionality can be assessed retrospectively, to some extent; if equipment is shown to be out of compliance with its functional requirements, and that it met those requirements during a previous surveillance test. In that case, the assumption is often made that it would not have met its functional requirements for some period prior to the most recent assessment.

2. Computer code assessments are different from hardware assessments. Errors can be extremely subtle, and may not become apparent until a specific part of the analysis package is exercised in a certain way.

a). 10 CFR 50.46 recognizes this aspect of code development and usage, and anticipates that circumstances might arise in which a mathematical model considered to be adequate could be shown, in the light of new information, to be deficient.

b). 10 CFR 50.46 is essentially unique among the NRC's Part 50 requirements, in that it provides specific steps to be taken by a licensee if a LOCA analysis is found not to meet the peak clad temperature (PCT) acceptance criterion by virtue of correction of a newly-discovered error.

1). In such cases, enforcement action against 10 CFR 50.46 or Appendix B would not be taken.

2). However, as noted above, if the errors were preventable by reasonable QA measures, a violation of Appendix B might be warranted.

H. It must be recognized that there is not a unique, "correct" result for any given plant's LOCA analysis.

1. If a licensee's analytical model conforms to the requirements of Appendix K of 10 CFR Part 50:

a). The predicted PCT is understood to be substantially higher than that which would be occur in an actual event that followed the licensing basis accident scenario.

1). Appendix K-mandated phenomenological models are known to intentionally over- or under predict specific parameters to bias the PCT result in a conservative direction.

2). A "best-estimate" (or "realistic") calculation of plant response, using identical initial and boundary conditions, would give a much lower PCT.

b). There is no "standard" ECCS analytical model. Beyond Appendix K requirements, each vendor's codes contain different, sometimes proprietary, phenomenological models and modeling approaches (e.g., nodalization, time step), and consequently each would give a somewhat different answer for PCT.

7.11 Actions Involving the Maintenance Rule

A. Because of the non-prescriptive nature of the rule language, enforcement of the maintenance rule represents a continuing challenge to inspectors.

1. Since implementation of the maintenance rule in July 1996, enforcement of the rule has evolved as lessons were learned.

2. This guidance addresses issues typical of those which are more frequently raised by inspectors; however, it cannot possibly address every conceivable maintenance rule

compliance issue.

NOTE:

When a question regarding the application of the Maintenance Rule comes up, the regions can request that such question is paneled. OE will ensure that appropriate NRR staff attends the panel. Others, including the regional inspector, resident inspector, project manager, etc., may be asked to attend the meeting or provide input to the discussions.

B. General Enforcement Guidance for Potential Violations of the Maintenance Rule

1. A maintenance rule violation can only be cited against the specific language of 10 CFR 50.65. The most straightforward method to determine whether a violation of the maintenance rule (or any other requirement) exists is to construct a “contrary to” statement that uses parallel language of the rule or requirement in a description of what the licensee did or did not do.

2. Regulatory Guide (RG) 1.160, Monitoring the Effectiveness of Maintenance at Nuclear Power Plants (ML003761662), endorses NUMARC 93-01, Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.

   a). NUMARC 93-01 guidance is non-binding and thus, does not represent requirements and can neither be used as the basis for, nor cited in, a maintenance rule violation. NUMARC 93-01 provides methods that are acceptable to the NRC for complying with the provisions of 10 CFR 50.65.

   b). RG 1.160 and NUMARC 93-01 can be useful to inspectors in understanding how licensees typically implement their maintenance rule programs and in defining terms as they are commonly used with respect to the implementing guidance.

C. The Maintenance Rule does not require licensees to establish program procedures.

1. There cannot be a procedure violation of 10 CFR Part 50, Appendix B, Criterion V, Instructions, Procedures, and Drawings, for failing to establish, implement or to maintain Maintenance Rule process implementing procedures.

2. There cannot be a violation of the administrative section of technical specifications which invokes RG 1.33, “Quality Assurance Program Requirements.”

   a). RG 1.33 does not cover the maintenance rule process.

   b). The failure to follow a licensee’s maintenance rule implementing procedure(s) cannot be cited as part of a maintenance rule violation, although the implementing procedure may be useful in providing insights when evaluating whether a direct violation of 10 CFR 50.65 may have occurred.

D. There cannot be a violation of Appendix B, Criterion XVI for failure to identify or correct conditions adverse to quality, for failure to identify or correct deficiencies with a licensee's maintenance rule implementation because the maintenance rule process is not safety-related.

1. This reasoning also applies to violations of Criterion V.

2. As in the past, a maintenance procedure used for the performance of a maintenance activity on an SSC can be referenced in a technical specification (TS)/RG 1.33 or Appendix B, Criterion V violation, when that maintenance procedure is not adequate, is not maintained, or is not followed and, for use of Appendix B, Criterion V, when the activity was on a safety-related SSC.

E. Except in 10 CFR 50.65 (a)(4), there is no distinction in the Maintenance Rule for varying degrees of SSC risk significance.

1. The scope of Paragraph (a)(4) assessments may be limited to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.

2. The scope reduction does not apply to any other section of the Maintenance Rule.

F. Acronyms and terms have been used which are consistent with those used by licensees to describe maintenance rule-related activities. Acronyms and terms associated with the maintenance rule are described in RG 1.160 and NUMARC 93-01.

G. The SDP will be used to determine the significance of a violation or maintenance rule finding.

7.11.1 Issues That Are Violations of 10 CFR 50.65 and Issues That Are Not Violations of 10 CFR 50.65

A. Paragraph (a)(1)

1. <u>Issues that are violations of 10 CFR 50.65 (a)(1):</u>

a). Failure to establish goals for SSCs in (a)(1). Goals must be:

1). Justifiable and defensible.

2). Supported by either an adequate Expert Panel determination, adequate use of PRA), or some other reasonable basis and be commensurate with safety.

b). Failure to monitor performance or condition against established goals.

1). The monitoring program must be sufficient in scope and frequency to adequately support a determination as to whether SSCs are meeting their assigned goals.

2). Performance monitoring must include tracking of both availability and reliability, where goals of this nature are appropriate, since that provides the maximum assurance that SSCs are capable of fulfilling their intended functions.

c). Failure to take appropriate corrective action when performance or condition goals are not met.

1). Corrective actions should sufficiently address actions to achieve goals, be commensurate with the goals being monitored, and be timely and reasonable. The corrective actions of concern are those necessary to meet goals - not necessarily corrective actions to correct individual SSC failures.

2). The standard for adequacy of corrective actions is reasonableness. Unless there are significant, credible, differing causes that are not reasonably addressed in the corrective actions, the licensee's actions should be considered adequate.

d). Failure to consider industry operating experience, where practical, which should include, e.g.:

- Specific vendor recommendations
- Generic communications issued by the NRC or vendors
- Information communicated via industry working groups or owners groups

2. <u>Issues that are not violations of 10 CFR 50.65 (a)(1)</u>:

a). Failure to meet a goal. If a goal is not met, appropriate corrective action shall be taken.

b). Failure to establish goals based on industry-wide operating experience.

1). The words of the rule, "where practical, take into account industry-wide operating experience," were not intended to force compliance with industry goals, but rather were intended to require licensees to consider industry experience as an information source for setting reasonable goals.

2). A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.

c). Failure to subdivide SSCs into high safety significant (HSS) SSCs, low safety significant (LSS) SSCs, and low safety significant (LSS) standby SSCs. (The rule does not require this).

d). Failure to link goals to the licensee's PRA. (The rule does not require this.)

e). Failure to take corrective action as a result of condition monitoring which

indicates that an SSC is degrading, but is still capable of performing its intended function. When established goals are not met, either:

1). Appropriate corrective action shall be taken to achieve the goals; or

2). The goals must be changed with adequate justification.

f). Failure to perform a cause determination when a performance criterion or goal is exceeded.

1). Unlike Criterion XVI of Appendix B for significant conditions adverse to quality, (a)(1) does not require determination of causes, only that corrective actions be taken when goals are not met; however, if a licensee takes ineffective corrective actions due to fixing the incorrect cause, a corrective action violation could be considered.

2). For corrective action issues involving safety-related SSCs, Appendix B, Criterion XVI, may be more easily used for enforcement purposes.

B. Paragraph (a)(2)

1. Issues that are violations of 10 CFR 50.65 (a)(2):

a). Failure to move an SSC to (a)(1) when performance indicates that the SSC is not being effectively controlled through appropriate preventive maintenance.

NOTE:

The focus of (a)(2) is on the results achieved through maintenance. For a violation to exist there must first exist an equipment performance problem which could indicate that preventive maintenance is not being effective. If a performance problem is determined to exist, then the following two questions are relevant to a determination of whether there is a violation: (1) Does that performance problem invalidate the demonstration that the performance of the SSC is being effectively controlled through appropriate preventive maintenance; and (2) If the performance demonstration is invalid, did the licensee move the SSC to (a)(1)?

1). The performance demonstration must be technically justifiable and reasonable.

NOTE:

For enforcement purposes, the (a)(2) "demonstration" is not a one time or periodic evaluation of past SSC performance, but is a continuing requirement. Hence, if the *performance* or condition of an SSC decreases due to, e.g., failures or increased *unavailability*, the demonstration of effective preventive maintenance can be questioned.

2). When the performance demonstration is no longer technically justifiable, the demonstration ceases to be valid and the SSC is required to be moved to (a)(1) where the performance of the SSC is monitored against established goals, e.g.:

A repetitive preventive maintenance preventable functional failure would indicate that the licensee has failed to demonstrate the effectiveness of preventive maintenance and consequently that SSC must be moved to (a)(1). For such failures, the time between occurrences and the type of failure should be taken into consideration, e.g., human errors of omission or commission need not be considered repetitive after a reasonable time period. Other component specific preventable failures may be considered repeat despite lengthy periods between failures.

b). Failure to consider both reliability and availability when evaluating whether an SSC's performance or condition has been demonstrated to be effectively controlled.

1). In order for an SSC to remain capable of performing its intended function, it must be both reliable and available.

2). If the degree of reliability and availability are not technically justifiable and reasonable, a violation may exist.

2. <u>Issues that are not violations of 10 CFR 50.65 (a)(2):</u>

a). Failure to establish performance criteria, establish appropriate performance criteria, link performance criteria to the licensee's PRA, or to meet established performance criteria.

NOTE:

10 CFR 50.65 does not dictate by what method the performance is to be demonstrated. However, the licensee must be able to demonstrate, through some reasonable means, that performance is being effectively controlled through appropriate preventive maintenance. RG 1.160 endorses an acceptable method for demonstrating performance. Whatever method the licensee uses to demonstrate performance must be reasonable, technically justifiable, and take into account availability and reliability.

b). Failure to move an (a)(2) SSC to (a)(1) solely because its performance criteria are not met. (Conversely, just because performance criteria are met does not necessarily mean that an (a)(2) demonstration is valid.)

c). Failure to correctly characterize a failure as a functional failure (FF) or maintenance preventable functional failure (MPFF).

d). Failure to correctly consider a failure or unavailability period as potentially impacting the (a)(2) demonstration, but when considered, the demonstration remains valid.

e). Failure to document the demonstration. The rule has no explicit requirements to document the demonstration.

f). Failure to consider SSC failures caused by activities other than preventive maintenance.

1). Paragraph (a)(2) specifically applies to preventive maintenance.

2). Random failures or failures due to errors of design, manufacturing, modifications, or corrective maintenance do not apply in determining whether preventive maintenance is being effective.

C. Paragraph (a)(3)

1. <u>Issues that are violations of 10 CFR 50.65 (a)(3)</u>:

a). Failure to perform the required periodic evaluation at least every refueling cycle, and in any case, not to exceed 24 months.

b). Failure to evaluate (a)(1) activities (performance and condition monitoring activities and associated goals) and (a)(2) activities (preventive maintenance activities).

c). Failure to make adjustments, where necessary, to goals and monitoring to ensure that unavailability and reliability are balanced.

1). The licensee's evaluation process must be reasonable and technically justifiable and should include a reasonable basis for making or not making adjustments.

2). The intent of the evaluation is to provide an opportunity to feedback lessons learned into the process.

NOTE:

As stated previously, the focus of the rule is on the results achieved through maintenance. Consequently, there must first exist an SSC performance problem before the validity of the SSC performance demonstration comes into question. If there is a performance problem which invalidates the licensee's demonstration that the performance of the SSC is being effectively controlled through appropriate preventive maintenance, the SSC must be moved to (a)(1).

2. Issues that are not violations of 10 CFR 50.65 (a)(3):

a). Failure to document the evaluation.

1). The rule has no explicit requirements to document the evaluation.

2). Licensees should use documentation to the extent necessary to assure themselves that the requirement for an evaluation has been acknowledged and performed adequately.

b). Failure to complete the evaluation in accordance with the licensee's administrative procedure. The licensee's administrative procedure for implementation of 10 CFR 50.65 or for performing evaluations cannot be cited as part of a maintenance rule violation.

c). Failure to apply industry-wide operating experience.

1). The words of the rule, "where practical, take into account industry-wide operating experience," were not intended to force compliance with industry practices, but rather were intended to require licensees to consider industry experience as an information source for conducting evaluations.

2). A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.

D. Paragraph (a)(4)

1. Issues that are violations of 10 CFR 50.65 (a)(4):

a). Failure to perform a risk assessment prior to performing maintenance activities. Required assessments:

1). May be limited to those SSCs which, singularly or in combination, can be shown (by a risk-informed evaluation process) to have a significant effect on the performance of key plant safety functions.

2). Are significant to public health and safety.

b). Failure to perform an adequate assessment.

NOTE:

The Maintenance Rule does not give guidance on what constitutes an adequate assessment.

1). To support a violation, there should be a technically justifiable reason as to why the assessment is determined to be inadequate.

2). The sophistication of the assessment should be commensurate with the complexity of the configuration and should meet the test of reasonableness.

3). If the assessment is sufficient in complexity, technically justifiable, and reasonable, it would be difficult to conclude that the assessment was inadequate.

4). The information considered should be complete and accurate (e.g., congruence of the assessed configuration to the existing plant configuration and activities) and the assessment tool or process should be used appropriately (e.g., within its capabilities and limitations).

c). Failure to update a prior assessment due to emergent work or changing plant conditions that could have an impact on the existing assessment.

1). Included in this violation would be the identification of external factors including changed environmental conditions.

2). Reasonableness applies when evaluating whether emergent work or changing external factors become impacting. A licensee should not be expected to react at too low a threshold, e.g.:

A typical summer weather forecast for afternoon thunder storms may be too low a threshold for deferring work on an emergency diesel generator, whereas the issuance of a tornado watch due to severe storms in the area may be an appropriate level for a more rigorous reassessment and additional risk management actions.

d). Failure to manage the increase in risk that may result from the proposed maintenance activity.

1). The process for managing risk involves using the result of the assessment in plant decision making to control the overall risk impact.

2). The licensee is not bound to keeping risk below some threshold or for taking particular actions when risk exceeds some threshold.

3). The licensee is responsible for making conscious decisions as to how the increase in risk will be handled, then by following their own action plan for handling the increased risk.

2. Issues that are not violations of 10 CFR 50.65 (a)(4):

a). Failure to document the assessment.

1). The rule has no explicit requirements that the assessment be documented.

2). Licensees should use documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately.

b). Failure to use probabilistic analyses to perform a risk assessment.

1). See the Statements of Consideration (SOC) in section 7.11.3 of this chapter.

2). Depending on the complexity of the SSCs out of service, a probabilistic assessment may be the most defensible, but is not explicitly required. A violation may exist, however, if a probabilistic assessment of a deterministic risk assessment reaches a significantly different conclusion and indicates that a probabilistic assessment reasonably should have been performed in place of the deterministic assessment.

c). Failing to perform an adequate assessment that is questioned and corrected prior to commencement of maintenance activities.

1). This includes occasions when an NRC inspector questions an assessment prior to the maintenance activity commencing.

2). “Commencement” of maintenance activities is considered the point when the SSCs of concern are disabled or prevented from performing their safety function.

E. Paragraph (b)(1)

1. Issues that are violations of 10 CFR 60.65 (b)(1):

- Failure to include a safety-related SSC in scope.

2. Issues that are not violations of 10 CFR 60.65 (b)(1):

   - Failure to properly classify an SSC as either HSS or LSS. The failure to place within the scope those safety related and non-safety related SSCs as described in (b)(1) and (b)(2) is the violation, not improper classification as HSS or LSS.

F. Paragraph (b)(2)

1. Issues that are violations of 10 CFR 50.65 (b)(2):

   - Failure to include in the scope those types of non-safety related SSCs described in (b)(2).

2. Issues that are not violations of 10 CFR 50.65 (b)(2):

   - No specific guidance is provided.

7.11.2 Examples of Violations

A. **Paragraph (a)(1)**

1. Failure to set goals and monitor:

   10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions. Such goals shall be established commensurate with safety.

   Contrary to the above, between (dates), the licensee failed to perform monitoring and failed to established goals for the residual heat removal system although the system was classified as being within the scope of the monitoring program on (dates) after the preventive maintenance program was shown to be ineffective due to repeat preventive maintenance preventable functional failures.

2. Failure to take corrective actions:

   10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such structures, systems, and components (SSCs) are capable of fulfilling their intended functions. Such goals shall be established commensurate with safety. When the performance or condition of a SSC does not meet established goals, appropriate

corrective action shall be taken.

Contrary to the above, from (date), the time that the Leakage Detection System (LDS) was placed into the scope of the monitoring program, the licensee did not take corrective actions when the performance of LDS did not meet licensee established goals in that the LDS functions were determined not to have met the established goal for reliability on (date) and no changes were made to the preventive maintenance on the LDS system.

B. Paragraph (a)(2)

1. Failure to demonstrate effective preventive maintenance nor set goals and monitor:

Example 1:

10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions.

10 CFR 50.65 (a)(2) states, in part, that monitoring as specified in 10 CFR 50.65 (a)(1) is not required where it has been demonstrated that the performance or condition of an SSC is being effectively controlled through the performance of appropriate preventive maintenance, such that the SSC remains capable of performing its intended function.

Contrary to the above, as of (date), the licensee failed to demonstrate that the performance or condition of five primary containment isolation valves and the containment hydrogen analyzers had been effectively controlled through the performance of appropriate preventive maintenance and did not monitor against licensee-established goals. Specifically, the licensee failed to identify, and properly account for five preventive maintenance preventable functional failures of primary containment isolation valves and nine preventive maintenance preventable functional failures of the containment hydrogen analyzers occurring from (date) to (date) which demonstrate that the performance or condition of these SSCs was not being effectively controlled through the performance of appropriate preventive maintenance and, as a result, that goal setting and monitoring was required.

Example 2:

10 CFR 50.65(a)(1) requires, in part, that holders of an operating license shall monitor the performance or condition of structures, systems, and components (SSCs) within the scope of the monitoring program as defined in 10 CFR 50.65(b) against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions.

10 CFR 50.65 (a)(2) states, in part, that monitoring as specified in 10 CFR 50.65 (a)(1) is not required where it has been demonstrated that the performance or

condition of an SSC is being effectively controlled through the performance of appropriate preventive maintenance, such that the SSC remains capable of performing its intended function.

Contrary to the above, the licensee failed to demonstrate that performance of the 480-volt ac electrical distribution system was being effectively controlled through the performance of appropriate preventive maintenance in that a repetitive preventive maintenance preventable failure of a 480-volt ac electrical breaker occurred on (date). Following the failure, the licensee failed to consider placing the 480-volt ac electrical distribution system under 10 CFR 50.65(a)(1) for establishing goals and monitoring against the goals.

C. Paragraph (a)(3)

Example 1:

10 CFR 50.65 (a)(3) requires, in part, that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle. Adjustments shall be made where necessary to ensure that the objective of preventing failures of structures, systems, and components (SSCs) through maintenance (reliability) is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

Contrary to the above, the periodic evaluation conducted for the period (dates) did not adequately evaluate the maintenance activities to ensure that reliability was appropriately balanced against unavailability for two emergency diesel generators (EDGs). Specifically, unavailability monitoring of the EDGs during the refueling cycle completed (date) did not consider individual EDG maintenance periods for emergent work on (date) for EDG 1-1 and on (date) for EDG 2-1. As a result, total unavailability was not properly considered and assessed for the EDGs. Without considering this unevaluated unavailability, the balancing of unavailability and reliability was not adequate.

Example 2:

10 CFR 50.65(a)(3) states, in part, that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle provided the interval between evaluations does not exceed 24 months.

Contrary to the above, as of (date), the licensee had failed to complete the periodic evaluation for the refueling cycle which ended (date).

Example 3:

10 CFR 50.65 (a)(3) requires, in part, that preventive maintenance activities shall be evaluated at least every refueling cycle and these evaluations shall take into account, where practical, industry-wide operating experience.

Contrary to the above, industry-wide operating experience was not taken into account

during the evaluation conducted between (dates) for the 22 CVC pump. Specifically, industry-wide operating experience documented previous failures of the CVC pump speed increaser due to wear induced failures of the lubricating oil pump drive pins that could be prevented through performance of vendor recommended preventive maintenance. The PM developed for this activity had never been performed and was indefinitely deferred resulting in failure of the 22 CVC pump on (date).

D. Paragraph (a)(4)

Example 1:

10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and mange the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to perform an assessment prior to conducting maintenance activities between (dates) on the control rod drive (CRD) pump train B and the reactor core isolation cooling (RCIC) system. The failure to perform an assessment occurred during a Division 1 outage in which the residual heat removal (RHR) train A, the low pressure core spray system (LPCS), emergency closed cooling (ECC) train A, emergency service water (ESW) train A, and Division 1 emergency diesel generator (EDG) had already been assessed for risk and removed from service.

Example 2:

10 CFR 50.65(a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to perform an adequate risk assessment in that the overall maintenance risk assessment performed by the licensee for all plant maintenance to be performed during the week of (date(s)) was inadequate because it failed to account for certain high safety significant structures, systems, and components (HSS SSCs) or others within the licensee-established risk assessment scope) that was/were concurrently out of service.

Example 3:

10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to manage the risk associated with the repair of the pipe leak on A train of the essential service water system (ESW), in that, although a risk assessment had been performed for the A train emergent work leak repair, including a provision that isolation and draining of the affected pipe segment not commence until all

repair materials and procedures were staged to immediately commence work, isolation was accomplished prior to the correct welding procedure being completed. This resulted in an unnecessary unavailability of A train ESW for 23 hours while the weld procedure was being approved.

E. Paragraph (b)(1)

10 CFR 50.65 (b)(1) requires, in part, that the holders of an operating license shall include within the scope of the monitoring program specified in 10 CFR 50.65 (a)(1) safety-related structures, systems, or components (SSCs)that are relied upon to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, and the capability to prevent or mitigate the consequences of accident that could result in potential offsite exposure comparable to the 10 CFR, Part 100 guidelines.

Contrary to the above, as of (date), the licensee failed to include within the scope of the monitoring program specified in 10 CFR 50.65 (a)(1), the safety-related SSCs that provide the pressurizer level, reactor pressure vessel level, and residual heat removal suction relief valve over-pressure protection functions as applicable for non-Mode 1 conditions. These SSCs are relied upon during and after design basis events to maintain the reactor in a safe shutdown condition.

F. Paragraph (b)(2)

Example 1:

10 CFR 50.65 (b)(2) requires, in part, that the scope of the monitoring program specified in paragraph (a)(1) include non-safety related structures, systems, and components (SSCs) whose failure can prevent safety-related SSCs from fulfilling their safety-related function.

Contrary to the above, from (date) to (date), the Unit 2 turbine building sump system was not included in the scope of the monitoring program specified in 10 CFR 50.65 (a)(1). The inclusion of the turbine building sump in the scope of the monitoring program was necessary because the failure of that system could prevent the emergency feedwater system, a safety-related system, from fulfilling its safety-related function.

Example 2:

10 CFR 50.65 (b)(2) requires, in part, that the scope of the monitoring program specified in paragraph (a)(1) include non-safety related structures, systems, and components (SSCs) that are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (EOPs).

Contrary to the above, as of (date), the licensee failed to include the area radiation monitoring system within the scope of the monitoring program specified in10 CFR 50.65 (a)(1). The area radiation monitoring system is a non-safety related system used in the plant EOPs. As a result, the preventive maintenance on the system was not assessed following three maintenance preventable functional failures occurring between (dates).

7.11.3 Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants

A. Paragraph 50.65(a)(1)

1. Requires each holder of an operating license under 50.21(b) or 50.22 to monitor the performance or condition of SSCs against licensee-established goals in a manner sufficient to provide reasonable assurance that such SSCs, as defined in paragraph (b), are capable of fulfilling their intended functions.

   a). Such goals shall be established commensurate with safety and, where practical, take into account industry-wide operating experience.

   b). When the performance or condition of an SSC does not meet established goals, appropriate corrective action shall be taken.

   c). For a nuclear power plant for which the licensee has submitted the certifications specified in 50.82(a)(1), this paragraph only shall apply to the extent that the licensee shall monitor the performance or condition of all SSCs associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that such structures, systems, and components are capable of fulfilling their intended functions.

2. The SOC for paragraph (a)(1) indicates that the licensee establish a monitoring regime which is sufficient in scope to provide reasonable assurance that (1) intended safety, accident mitigation and transient mitigation functions of the structures, systems, and components (SSCs) described in paragraph (b)(1) and (b)(2)(i) can be performed; and (2) for the SSCs described in subparagraphs (b)(2)(ii) and (b)(2)(iii), failures will not occur which prevent the fulfillment of safety-related functions, and failures resulting in scrams and unnecessary actuations of safety-related systems are minimized.

   a). Where failures are likely to cause loss of an intended function, monitoring should be predictive in nature, providing early warning of degradation.

   b). Monitoring activities for specific SSCs can be performance oriented (such as the monitoring of reliability and availability), condition-oriented (parameter trending), or both.

   c). The results of monitoring are required to be evaluated against the licensee-established goals. Goals should be established commensurate with an SSC's safety significance.

   d). Where available, the assumptions in and results of probabilistic risk assessments (PRAs) or individual plant examinations (IPEs) should be considered when establishing goals.

3. SSCs which are treated under paragraph (a)(1) may have formally established reliability and availability goals against which they are explicitly monitored, where goals of this nature are appropriate. In addition, and regardless of the nature of the monitoring and goals established to satisfy paragraph (a)(1), reliability and availability over the longer term must be assessed periodically pursuant to the requirements of paragraph (a)(3), as part of the evaluation of goals, monitoring requirements, and preventive maintenance requirements.

B. Paragraph (a)(2)

1. States that monitoring as specified in paragraph (a)(1) of this paragraph is not required where it has been demonstrated that the performance or condition of a structure, system, or component is being effectively controlled through the performance of appropriate preventive maintenance, such that the structure, system, or component remains capable of performing its intended function.

2. The SOC for this paragraph indicates that the purpose of paragraph (a)(2) is to provide an alternate approach (a preventive maintenance program) for those SSCs where it is not necessary to establish the monitoring regime required by (a)(1).

   a). Under the terms of paragraph (a)(2), preventive maintenance must be demonstrated to be effective in controlling the performance or condition of an SSC such that the SSC remains capable of performing its intended function.

   b). It is expected that, where one or more maintenance-preventable failures occur on SSCs treated under this paragraph, the effectiveness of preventive maintenance is no longer demonstrated. As a result, the SSCs would be required to be treated under the requirements of paragraph (a)(1) until such time as a performance history is established to demonstrate that reliability and availability are once again effectively controlled by an established preventive maintenance regimen.

   c). Once such a demonstration has been made, it would be acceptable to return to treating the SSCs under paragraph (a)(2).

C. Paragraph (a)(3)

1. Requires that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle provided the interval between evaluations does not exceed 24 months. The evaluations shall be conducted taking into account, where practical, industry-wide operating experience. Adjustments shall be made where necessary to ensure that the objective of preventing failures of structures, systems, and components through maintenance is appropriately balanced against the objective of minimizing unavailability of structures, systems, and components due to monitoring or preventive maintenance.

2. The SOC for this paragraph indicates that this provision requires that SSCs performance or condition goals, performance or condition monitoring, and preventive

maintenance activities implemented pursuant to paragraphs (a)(1) and (a)(2) be evaluated in light of SSCs' reliabilities and availabilities.

a). In the case of SSCs treated under paragraph (a)(1), adjustments are to be made to goals, monitoring, or preventive maintenance requirements where equipment performance or condition have not met established goals.

b). Conversely, at any time the licensee may eliminate monitoring activities initiated in response to problematic equipment performance or industry experience once the root cause of the problem has been corrected or the adequacy of equipment performance has been confirmed.

c). In the case of SSCs treated under paragraph (a)(2), adjustment of preventive maintenance requirements may be warranted where SSCs availability is judged to be unacceptable.

d). SSCs which are treated under paragraph (a)(1) may have formally established reliability and availability goals against which they are explicitly monitored, where goals of this nature are appropriate. In addition, and regardless of the nature of the monitoring and goals established to satisfy paragraph (a)(1), reliability and availability over the longer term must be assessed periodically pursuant to the requirements of paragraph (a)(3), as part of the evaluation of goals, monitoring requirements, and preventive maintenance requirements.

D. Paragraph (a)(4)

1. Requires that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.

2. The SOC for this paragraph indicates that the intent of this requirement is to have licensees appropriately assess the risks related to proposed maintenance activities that will directly, or may inadvertently, result in equipment being taken out of service and then, using insights from the assessment, suitably minimize the out-of-service time resulting from the proposed maintenance activities while also controlling the configuration of the total plant to maintain and support the key plant safety functions.

a). In general, a risk assessment is necessary before all planned maintenance activities. Assessments should also be performed when an unexpected SSC's failure initiates required maintenance activities or when changes to plant conditions affect a previously performed assessment. However, the reevaluation of a previous assessment should not interfere with, or delay, the plant staff's taking timely actions to restore the appropriate SSCs to service or taking compensatory actions necessary to ensure that plant safety is maintained. If the SSC is restored to service before performing the assessment, the assessment need not be conducted.

b). Assessments may vary from simple and straightforward to highly complex. However, the degree of sophistication required for the assessment notwithstanding, the NRC intends that the assessment process will examine the plant condition existing before the commencement of the maintenance activity, examine the changes expected by the proposed maintenance activity, and identify the increase in risk that may result from the maintenance activity. The assessments are expected to provide insights for identifying and limiting risk-significant maintenance activities and their durations.

c). The level of complexity necessary in the assessment would be expected to differ from plant to plant, as well as from configuration to configuration, within a given plant. When a licensee proposes to remove a single SSC from service for maintenance while no other SSC is out of service, a simple deterministic assessment may suffice. If the SSC is covered by TS, then the assessment could be as simple as an expert judgment, along with confirming the relevant requirements of TS. When one SSC is out of service and the licensee proposes to remove a second SSC from service for maintenance, the assessment could be simplified through the use of a table of results for pre-analyzed combinations, typically high-safety-significant SSCs paired against each other. However, more detailed assessments are required if a licensee proposes to remove multiple SSCs from service during power operations or to remove from service systems necessary to maintain safe shutdown during shutdown or startup operations. These more detailed assessments are expected to involve probabilistic analyses where possible, and to also include considerations of key plant safety functions to be maintained and defense in depth.

d). In general, the NRC expectation regarding managing the risk is a scrutable process for controlling or limiting the risk increase of the proposed maintenance activities. This process should include an understanding of the nature (i.e., affecting the core damage, or large early release frequency) and significance of the risk implications of a maintenance configuration on the overall plant baseline risk level. For example, risk-significant plant configurations should generally be avoided, as should conditions where a key plant safety function would be significantly degraded while conducting maintenance activities. The effective control of potentially significant risk increase due to an unexpected failure of another risk-important SSC can be reasonably assured by planning for contingencies, or coordinating, scheduling, monitoring, and modifying the duration of planned maintenance activities.

e). The second sentence in the new (a)(4) paragraph states: “The scope of the assessments may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.” In response to public comments on the proposed rule, this second sentence has been added so that licensees may reduce the scope of SSCs subject to the pre-maintenance assessment to those SSCs which, singularly or in combination, can be shown to have a significant effect on the performance of key plant safety functions. The focus of the assessments should be on the SSCs modeled in the licensee’s *PRA*, in addition to all SSCs evaluated as risk

significant (high safety-significant) by the licensee's maintenance rule expert panel. Typically, these SSCs have been analyzed as causing potential initiating events, if failed, and as accident mitigators, or as high safety-significant SSCs with their support systems. Such SSCs may be identified by operating experience or by deterministic or probabilistic analyses.

f). The rule has no explicit documentation requirements. Instead, the rule emphasizes performance. A licensee's assessment process is expected to identify the impact on safety that is caused by the performance of maintenance. Licensees should use documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately.

E. Paragraph (b)(1)

1. Requires SSCs that are relied upon, to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, and the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 50.34(a)(1) or 100.11 of this chapter, as applicable.

2. The SOC indicates that the scope of SSCs subject to the final maintenance rule includes safety-related SSCs, and certain "non-safety" SSCs in the balance of plant (*BOP*) which meet one or more of four specific criteria, that include one general safety-related criterion described in (b)(1), and three non-safety related criteria described in (b)(2).

F. Paragraph (b)(2)

1. Requires the inclusion of non-safety related SSCs: (i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (*EOP*s); or (ii) Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or (iii) Whose failure could cause a reactor scram or actuation of a safety- related system.

2. The SOC indicates that the scope of SSCs subject to the final maintenance rule includes safety-related SSCs, and certain "non-safety" SSCs in the BOP which meet one or more of four specific criteria, that include one general safety-related criterion described in (b)(1), and three non-safety related criteria described in (b)(2).

G. Paragraph (c)

1. Requires that the requirements of this section be implemented by each licensee no later than July 10, 1996.

7.12 Safeguards

This section provides specific guidance concerning enforcement practices for safeguards issues. Sections 6.11, 6.12, 6.13 of the Enforcement Policy provide examples of violations in each of the four severity levels as guidance in this activity area.

7.12.1 Compliance With the Security Plan Versus 10 CFR Part 73

A. Licensees subject to the requirements of 10 CFR Part 73.25, 73.26, 73.40, 73.45, 73.46, and 73.55 must submit security plans to the NRC for approval.

1. Once these plans are approved, they are incorporated into the license by amendment and the licensee is required to meet the approved plans.

2. While citations for violations of these plan requirements must be made against the applicable section of the NRC-approved Security Plan and not against Part 73, citations may indicate the connection between the Security Plan and Part 73.

   a). This limitation does not apply to orders while they remain in effect.

   b). If changes to the Security Plan result in additional issues, these can be assessed and assigned a color using the SDP process.

   c). Violations of the requirements in an order may always be cited against the specific requirements contained in the respective order.

3. Changes to the Security Plan that reduce the effectiveness of the plan (that are made without NRC's permission), should be assigned a severity level.

B. If there is a conflict between the requirement(s) in a plan, a regulation, or an order, NSIR, NRR or NMSS (as appropriate) should be consulted.

C. Citations against the general performance criteria of 10 CFR 73.55(a) may be viable. Any such violations should be coordinated with OE and NRR prior to issuance.

D. Other general sections of Part 73 (e.g., those governing the reporting of safeguards events and the protection of safeguards information) remain in force even when licensees insert references to these requirements in their security plans.

7.12.2 Access Control

A. Access control is not only limited to protected and vital area barriers, but also includes all security measures employed to ensure that unauthorized persons, vehicles, and materials are excluded from entry into the protected and vital areas.

B. The severity level of an access control violation may be determined by considering the following factors:

1. The ease of exploitation of the vulnerability created by the violation, compounded by its predictability.

   a). In determining the vulnerability of a protected or vital area barrier, one must consider whether it could be seen by a potential adversary as being vulnerable based on, e.g., the height of fencing, delay barriers, security force separation from the objective, ease and opportunity to achieve a hostile objective, time and/or opportunity available to execute an assault, etc.

   b). Predictability refers to the ease with which an adversary can anticipate an opportunity, e.g.: Since the operational status of an alarm system is not usually apparent to a potential adversary, the fact that a particular alarm zone would not have detected an unauthorized intrusion for a short period of time will probably not be obvious, and therefore, the vulnerability is less significant. The absence of a search of particular types of containers by security staff would create predictability that could be exploited by an adversary, and therefore, the vulnerability is more significant.

   c). Ease of passage of a vulnerability refers to the type of opening and the environment in or surrounding a pathway, e.g.: If the pathway is an underground tunnel that has many twists and turns, or one that has sudden vertical drops or climbs, a simple 96-square-inch standard may not be appropriate, since the diameter of such a tunnel would be inadequate to allow an adversary to maneuver along the inside of it. Ease of passage may also refer to whether the opening is under water.

C. When considering ease of exploitation, the following elements of barrier, monitoring, and response should be weighed:

   1. Barrier Integrity:

      a). The integrity of the barrier may be compromised by breaches in that barrier, but it may also be compromised by procedural errors or improper design or installation.

      b). Lost keys and/or lost keycards have the potential to allow unauthorized and undetected access to controlled areas of a plant. The significance of such violations is a function of:

         1). Whether the keys/keycards were truly lost;

         2). Whether the keys/keycards were marked to indicate the areas to which they allowed access;

         3). Whether and when the keys/keycards were recovered; and

         4). Whether there is any evidence that the keys/keycards have been used before they were recovered.

      c). The significance of underground pathways allowing access to controlled areas is

discussed in Information Notice 86-83 (September 19, 1986).

2. Compensatory Measures for Unlocked/Unalarmed Portals:

a). The significance of security personnel being inattentive while posted as compensatory measures is determined by what functions such personnel are intended to provide.

1). If a security force member is posted at a door that is normally alarmed and locked as compensation for the alarm annunciation function, if the security force member is inattentive, only one element of access control is inadequate.

2). If a security force member is posted at a door for the controlled access logging function as well as compensation for the alarm annunciation function, if the security force member is inattentive, two elements of access control are inadequate.

7.12.3 Access Authorization Program

A. A licensee's ability to implement its safeguards security program is based, in significant part, on its access authorization program.

1. The successful completion of the elements of the access authorization program is critical to ensuring that the safeguards security program can be implemented as required.

2. Violations or licensee requirements implementing 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants," should be assessed using the Physical Protection Significance Determination Process (PPSDP), unless these violations are willful or deliberate, in which case they should be assessed as discussed in Chapter 6 of this manual.

B. Authorization versus Clearance for Access:

1. Individuals are considered cleared for access as soon as all required background investigations, evaluations, and fitness-for-duty actions have been successfully completed. At that point, however:

a). Individuals do not have authorized unescorted access and do not have such access until they are added to the licensee's authorized access list and are issued a proper badge; and

b). Actual entry of a cleared but as-yet unauthorized individual is a violation. Note, however, that this violation is not as significant as actual entry of an uncleared, unauthorized individual.

C. Improper Access by Authorized or Other Persons:

1. Employees who have been properly cleared and authorized for access to the site must still enter the protected area and vital/material access areas properly.

   a). Failing to properly log in to a vital aria by tailgating, i.e., following another employee into the area without properly logging in, is a violation although it is usually assessed as a Severity Level IV violation.

   b). It is more significant if a person is improperly allowed access to an area where the need for access to that area has not been determined.

   c). It is very significant if a person uses another person's identification to gain access to an unauthorized area, or if a person has been terminated for cause and still gains access to a protected or vital area following that termination.

D. Vital Areas Within Vital Areas:

1. Two barriers are required at power reactors, while three barriers are required at Category I fuel facilities, i.e., a parameter barrier and one or two vital area barriers.

2. As a general rule, when vital areas are contained within other vital areas, the barrier and access control requirements are not required at the inner-most barrier.

NOTE:

If an inner vital area barrier remains intact while the outer vital area barrier is discovered to have vulnerabilities, there is no violation unless the failed outer barrier allows access to vital equipment.

   a). The licensee is only required to have one vital area barrier to protect all vital areas.

   b). The inner barrier and access control functions must be fully operative at only the necessary vital area barrier.

7.12.4 Searches

A. Searches of individuals, vehicles, and packages are considered inadequate if they are not able to detect the items for which they are conducted, e.g.: a vehicle search must include an examination of the inside of the glove compartment and the undercarriage, motor area, storage areas and the area under the seats.

NOTE:

It is not sufficient to conclude that an item is not contraband or is not otherwise prohibited merely because it cannot be identified through the normal electronic or video search process.

B. Searches of hand carried items or shipping packages are considered inadequate if they are not able to identify items to the extent that such items can be excluded as contraband or as items that are otherwise prohibited.

C. When a vehicle that has entered the site is later found to have contained contraband (i.e., weapons, drugs, or explosives of any kind) in an accessible area, the presumption is that the search was inadequate.

7.12.5 Protection of Safeguards Information

A. When safeguards information is not properly protected from compromise, the severity level of the violation is a function of:

1. The location of the material during the time it was not controlled;

2. The significance of the material;

3. The amount of time left uncontrolled; and

4. The opportunity for compromise of the material while it was uncontrolled.

B. The following examples illustrate the significance of a violation involving safeguards information that is not properly controlled:

1. If safeguards information had been left in an unlocked container within the locked and continuously-staffed primary access control point, this violation is less significant than if the safeguards information had been left in an uncontrolled area inside the protected area.

2. If safeguards information had been left uncontrolled and outside of a protected area, this violation is more significant than if the safeguards information had been left uncontrolled and inside a protected area.

3. A violation involving safeguards information that has been left uncontrolled is more significant when it is:

a). Sufficiently extensive; or descriptive of the security system as to significantly assist an adversary in an act of radiological sabotage or theft of strategic special nuclear material (SSNM), this violation is more significant that if the safeguards information would not have significantly assisted the adversary.

7.12.6 Protection Against Vehicle Bomb Threats

The NRC has issued orders modifying license conditions addressing land vehicle assaults as well as waterborne assaults. These orders should be consulted prior to issuing any enforcement action involving these license conditions.

A. 10 CFR 73.55(c)(7) requires licensees to establish vehicle control measures, including vehicle barrier systems, to protect against land vehicle intrusion.

B. 10 CFR 73.55(c)(8)(I) requires licensees to confirm to the Commission that vehicle control measures established to protect against land vehicle intrusion meet the design goals and criteria specified for protection against a land vehicle bomb.

C. Under 10 CFR 73.55(c)(8)(ii), licensees may propose alternative measures for protection against a vehicle bomb that would then be subject to review and approval by the NRC.

   1. This is common in the area of physical security and 10 CFR 73.55 already provides for such alternative measures.

   2. By allowing licensees to propose alternative measures for protection against a vehicle bomb, the Commission is allowing them to change the focus of compliance from the rule to the approved plans submitted by licensees.

D. 10 CFR 73.55(c)(9) requires that licensees submit a summary description of the proposed vehicle control measures within 180 days of the effective date of the rule and fully implement the measures by within 18 months of the effective date.

E. Violations of 10 CFR 73.55(c)(8)(I) and (9)(I) should be treated in the same manner as any other incomplete and/or inaccurate statement, i.e., under 10 CFR 50.9 and Section 6.9 of the Policy.

F. Violations of 10 CFR 73.55(c)(8)(ii) should also be treated as incomplete and/or inaccurate statements, to the extent that they do not accurately "describe the level of protection that these measures would provide."

7.12.7 Citations Against 10 CFR Part 50, Appendix B

A. Appendix B of 10 CFR Part 50 addresses quality assurance criteria for nuclear power plants and fuel reprocessing plants.

   1. Any citations against 10 CFR Part 50, Appendix B in the safeguards area should be coordinated with OE prior to issuance.

   2. Appendix B applies to SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

   3. The provisions of Appendix B do not generally apply to the safeguards area.

B. If the region desires to use the Appendix B criteria as the basis for a citation in the safeguards area, it will have to include in the citation sufficient facts and discussion to support the position that the procedure in question is necessary to assure, in the event of an accident, "adequate confidence that a structure, system, or component will perform satisfactorily in service."

7.13 Emergency Preparedness

This section provides specific guidance concerning enforcement practices for emergency preparedness issues.

A. Normally emergency preparedness findings are evaluated through the SDP and enforcement actions are taken based on the SDP outcome.

B. If findings are not addressed through the SDP, Section 6.6 of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

7.14 10 CFR 50.54 Deficiency Grace Period

A. The significant provision of the regulations in this area is 10 CFR 50.54(s)(2)(ii) which provides a four-month grace period for correction of deficiencies that rise to such a level that the Commission may make a finding that the state of emergency preparedness no longer provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

   1. The grace period represents a recognition by the Commission that many elements of emergency planning involve complex arrangements and interactions with local, State, and Federal entities, much of which is beyond a licensee's direct control.

   2. The grace period reflects an acknowledgment that the licensee's degree of control in the emergency planning area is significantly less than that in the areas of reactor health and safety.

   3. Even where there are significant deficiencies in emergency plans and a formal finding to that effect is made, a grace period should be allowed for corrective action. See County of Rockland v. U.S. Nuclear Regulatory Commission, 709 F.2d 766, 770-771 (2nd Cir. 1983).

B. The policy underlying the grace period strongly suggests that it was intended to apply to emergency planning deficiencies which can be remedied only in cooperation with State and local officials.

   1. If plans are adequate, in place, and capable of implementation, but the licensee failed to implement the plans either during a drill or an actual emergency, no grace period should be necessary to remedy the deficiency.

2. In the Statements of Consideration (SOC) supporting the initial rule (45 FR 55402, August 19, 1980), the Commission discussed how it would apply the grace period, and, in considering plan deficiencies, indicated that it would consider local, State, and licensee plans to see if the features in one plan could compensate for deficiencies in another plan.

   a). If an emergency planning deficiency can be remedied only in cooperation with State and local officials, enforcement action should await the expiration of the grace period.

   b). The EDO is to be notified before establishing the grace period and should concur on the enforcement action.

   c). If the deficiency is of such a nature that cooperation with State and local officials is not necessary to remedy the deficiency, then the grace period does not apply and the matter may be pursued.

7.15 Enforcement Actions Involving Fitness-For-Duty (FFD)

A. The requirements in 10 CFR Part 26 addressing fitness-for-duty (FFD) programs apply to licensees authorized to:

   1. Operate a nuclear power reactor;

   2. Possess or use formula quantities of SSNM; or

   3. Transport formula quantities of SSNM.

B. The requirements in 10 CFR Part 55 require that licensed operators follow FFD programs.

   1. Each FFD issue must be evaluated to determine whether enforcement action should be issued against:

      a). The facility licensee for failure to adequately implement a program; or

      b). Against the individual licensed operator for failure to follow the program.

7.15.1 Action Against the Facility Licensee for FFD Violations

A. Licensees subject to 10 CFR Part 26 must establish and implement a FFD program.

   1. The program must provide, among other things, that there is reasonable assurance that nuclear power plant personnel, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM:

      a). Will perform their tasks in a reliable and trustworthy manner;

      b). Are not under the influence of any substance, legal or illegal; or

c). Mentally or physically impaired from any cause which in any way adversely affects their ability to safely and competently perform their duties.

NOTE:

If the licensee has effectively implemented its FFD program meeting NRC requirements and, based on behavior observation, identifies and removes a person not fit for duty, there may not be a regulatory violation.

B. In citing the facility licensee, it is important to note that it is not the unfit person that establishes the violation but rather the licensee's failures to implement the FFD program, including those of its contractors and vendors, which creates the violation.

C. Enforcement actions against facility licensees should be prepared and processed in accordance with the standard guidance for escalated and non-escalated actions.

1. The significance of a FFD finding at an operating power reactor should be assessed by the ROP's SDP.

2. The significance of a FFD violation for all other licensees should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the examples in Section 6.14 of the Enforcement Policy .

D. The Enforcement Policy provides examples of violations where the facility licensee failed to meet the requirements of 10 CFR Part 26.

1. The failure of a licensee to have a FFD program in place is an example of a Severity Level I violation. This violation would be of very significant concern to the NRC because it represents the failure to implement a FFD program.

2. The failure to take action when there is the potential to have a direct impact on safety-related activities is the basis of the examples for Severity Level II. These are also of very significant concern to the NRC.

3. Because of failures in an established FFD program that were directly within the licensee's control, an individual who should have been denied access to an area was able to gain access. This is an example of a Severity Level III violation.

a). Typically, these failures would be more significant if the individual improperly granted access is later confirmed to test positive for illegal drug use.

b). A failure to ensure that specimens collected in accordance with 10 CFR Part 26 are not used for purposes other than those provided by the rule without the permission of the tested individual may also be considered a significant violation.

4. Violations which, while requiring corrective action, are less significant to the overall FFD program, are normally assessed as Severity Level IV violations.

7.15.2 Action Against the Licensed Operator for FFD Violations

A. 10 CFR Part 55 sets forth the requirements for issuance of licenses to individuals to operate nuclear power plants, including the conditions and cutoff levels established pursuant to the Commission's FFD programs, or the licensee's program if the cutoff levels are lower, that are applicable to licensed operators as conditions of their licenses. Therefore, citing the individual operator would be appropriate if the determination is made by either the established testing protocols or the Medical Review Officer (MRO), that the individual is unfit for duty.

1. Prior to issuance of an order to the licensed operator, the region should inform him/her of the impending order, and provide an opportunity (typically 10 days) to respond in writing why the order should not be issued.

B. The Enforcement Policy, Section 6.4, addresses appropriate enforcement actions against individual licensed operators who fail to meet FFD requirements.

1. Licensed operator's confirmed positive test for drugs or alcohol:

a). There may be cases where the NRC chooses to exercise discretion and issue a Severity Level IV violation, e.g., where a licensed operator self-reports his or her regulatory noncompliance.

b). The second time the licensed operator fails a drug test, an order suspending the 10 CFR Part 55 license for up to three years will normally be issued. If the license has less than three years left before it must be renewed, consideration should be given as to whether the license should be renewed.

c). Second and subsequent violations of the licensee's FFD policy involving alcohol should be reviewed to determine if an order should be issued suspending the individual operator's 10 CFR Part 55 license.

2. An order would normally be issued revoking the Part 55 license whenever a licensed operator refuses to participate in the facility licensee's FFD program or is involved in the sale, use, or possession of illegal drugs.

C. All enforcement actions issued to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level):

1. Are required to be paneled;

2. Require EA numbers during the review and approval stages; and

3. Require IA numbers when the actions are issued.

7.15.2.1 Preparing FFD Actions

A. Fitness-for-duty actions against licensed operators are not processed like other escalated actions.

1. Licensed operators' failures to meet FFD requirements are typically reported to the NRC by facility licensees.

2. The NRC will normally take enforcement action based on this notification without conducting an inspection.

3. Despite the normal policy of holding a PEC prior to issuing action against an individual, a PEC is not normally held for FFD issues against a licensed operator.

4. A PEC is not normally held prior to issuing escalated action against a licensee for a FFD issue.

   a). This is, in part, due to the NRC basing its enforcement action on notification from the licensee.

   b). Licensed operators are provided an opportunity to contest the action after it has been issued.

5. The regions should prepare the enforcement package consisting of both the enforcement action transmittal letter and NOV or the combination transmittal letter and NOV (see the forms in Appendix B). The second option would be used when the facility licensee causes the licensed operator's license to expire.

B. In drafting the citation, it is important to note that the licensed operator may be in violation of Part 55 license conditions, including, e.g., the licensee’s:

1. Failure to observe an applicable rule, regulation or order of the Commission (10 CFR 55.53(d));

2. Use, sale, or possession of illegal drugs or use of alcohol (10 CFR 55.53(j)); or

3. Refusal to participate in the facility licensee's FFD program (10 CFR 55.53(k)).

C. For violations of 10 CFR 55.53(j), i.e., use, sale, or possession of illegal drugs or use of alcohol, two separate situations are possible:

1. The licensed operator uses, possesses, or sells illegal drugs, or consumes alcohol within the protected area; or

2. The licensed operator performs licensed duties while under the influence of any substance that could adversely affect an operator's ability to safely and competently perform licensed duties.

NOTE:

Section 55.53(j) states that "under the influence" includes a licensed operator exceeding, "as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A . . . or as established by the facility licensee;" therefore, performing duties immediately before or after submitting a urine sample that later tests positive would be considered performing duties "under the influence."

D. To have submitted a urine sample that will test positive and then to perform licensed activities are two separate actions; however, given the close relationship between action and result, it is sufficient to cite both requirements and include both violations in the "Contrary to" paragraph as examples of the same Severity Level III violation, e.g.:

10 CFR 55.53(j) prohibits the use of (illegal drug used in this case) and prohibits the licensee from performing activities authorized by a license issued under 10 CFR Part 55 while under the influence of (illegal drug used in this case). "Under the influence" is defined in 10 CFR 55.53(j) to mean that the "licensee exceeded, as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A, of this chapter, or as established by the facility licensee."

Contrary to the above, the licensee violated 10 CFR 55.53(j), as evidenced by the following examples:

a). The licensee used (substance) as evidenced by a confirmed positive test for that drug resulting from a urine sample submitted on (date); and

b). The licensee performed licensed duties on (date) immediately before (after) the submission of a urine sample which indicated that the licensee was under the influence of alcohol (name of drug).

This is a Severity Level III violation. (Section 6.1)

E. For violations of 10 CFR 55.53(k)), i.e., refusing to participate in the facility licensee's FFD program, the citation should use the following format:

10 CFR 55.53(k) requires that licensed operators participate in the drug and alcohol testing programs established by the Part 50 licensee pursuant to 10 CFR Part 26.

Contrary to the above, on (date), the licensee did not participate in (cooperate with) the Part 50 drug (alcohol) program on (date) in that [describe what happened].

This is a Severity Level III violation. (Section 6.1)

7.15.2.2 Coordination and Review for FFD Actions

A. Fitness-for-duty actions should be coordinated and reviewed according to the following guidelines:

1. OE, the operator licensing staff in NRR, and NSIR should be consulted early in the process when the region has determined that a reactor operator may have violated the facility licensee's FFD program, refused to participate, or violated other conditions of his or her license with regard to FFD concerns.

2. All cases when enforcement action is being considered to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level), require:

   a). A panel which OE, the operator licensing staff in NRR, and NSIR should participate in;

   b). An EA number during the review and approval stages; and

   c). An IA number when the action is issued.

B. Routine cases (i.e., cases where there is no evidence of long-term drug use or alcohol abuse and where the facts do not warrant referral for investigation) that are not required to be sent to headquarters for formal review and approval prior to issuance should be coordinated as follows:

1. Subsequent to an enforcement panel, OE will complete the Strategy Form and send it to the region and the NRR and NSIR Enforcement Coordinators.

2. The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary).

3. If there are additional discussions with the Regional Administrator and the Director, OE, the Strategy Form may need to be amended to represent the agreed upon strategy.

4. If there are disagreements on the overall enforcement strategy, OE may request that the region submit the entire action (including the transmittal letter) to OE for formal review and approval prior to issuance.

5. Regional Counsel review and statement of no legal objection is required prior to issuance by the region.

6. The region should send OE the complete enforcement package after it has issued the action.

C. Non-routine cases (including cases involving an exercise of discretion, requiring DEDO approval or Commission consultation, or involving the misuse of prescription and over-the-

counter drugs), are sent to headquarters for full enforcement action package review and approval prior to issuance.

D. OE may also request that a case be submitted to headquarters for full enforcement action package review and approval prior to issuance subsequent to an enforcement panel.

E. OGC will not normally provide comments for Severity Level III NOVs without a civil penalty or order.

1. OGC review and statement of no legal objection is required on all orders.

   a). OGC will review the proposed order and provide comments to OE within 5 working days of receipt of the package.

   b). Immediately effective orders should be expedited.

2. The NRR Enforcement Coordinator should ensure that the operator licensing staff in NRR reviews the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety have been properly evaluated from an overall agency perspective.

   a). Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within five working days. The NRR Enforcement Coordinators normally provide comments for FFD cases.

   b). Comments on immediately effective orders should be expedited.

3. The NSIR Enforcement Coordinator should ensure that the staff in NSIR reviews the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety have been properly evaluated from an overall agency perspective.

   a). Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days. The NSIR Enforcement Coordinator normally provides comments for FFD cases.

   b). Comments on immediately effective orders should be expedited.

4. OE will consider timely OGC and program office comments and revise the enforcement action, as appropriate.

5. OE will forward the revised action to the region indicating where and why the action was revised.

6. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.

7. OE will attempt to resolve any differences among the region, the program office, and OGC (if applicable) and will advise the DEDO during final review and approval.

7.15.2.3 Signature Authority for FFD Actions

FFD actions should be signed and issued according to the following guidelines:

A. The Regional Administrator (or designee) normally signs and issues NOVs for Severity Level I violations, after review and approval by the Director, OE, the DEDO, and the Commission.

B. The Regional Administrator (or designee) normally signs and issues NOVs for Severity Level II and III violations after either:

   1. Consultation with OE (usually via an enforcement panel or caucus--note that the Director, or Deputy Director, OE must concur on the Strategy Form); or

   2. Actual enforcement action package review and approval by the Director, OE.

C. The DEDO normally signs all orders.

7.15.2.4 Licensee Notification, Mailing, & Distribution of FFD Actions

A. Licensee notification, mailing, and distribution should be made according to the following guidelines:

   1. Enforcement actions against licensed operators should be mailed to individuals by either Certified Mail (Return Receipt Requested) or Express Mail.

   2. Enforcement actions against licensed operators (including any enclosures) should not be made available to the Public (ADAMS (PARS)) when they are originally issued.

   3. Copies of all FFD actions against licensed operators should be sent both to OE and the operator licensing staff in NRR.

NOTE:

Due to the personal and medical aspects of FFD violations, it is appropriate to delay making the action available to the Public until the individual has had an opportunity to rebut the conclusion.

7.15.2.5 Licensed Operator Response to FFD Action

A. Licensed operators are generally required to respond to NOVs within 30 days.

B. Licensed operators are not required to respond to NOVs where the operator's license has expired, unless the licensed operator contests the action.

C. A licensed operator's responses to NOVs can either (a) accept the violation or (b) contest the staff's facts and conclusions regarding the NOV.

1. If the licensed operator does not dispute that the violation occurred as stated in the NOV:

a). The regional office is to review the licensed operator's response for the adequacy of the corrective action and should request additional information from the licensed operator if necessary.

b). Licensed operator's responses should normally be acknowledged by the region within 30 days after their receipt.

1). The acknowledgment letter should be sent to the licensed operator.

2). A copy of the NOV, the operator's response, and the acknowledgment letter should be made available to the Public with the home address deleted.

2. If the licensed operator denies the violation:

a). The region should coordinate the agency's response to the licensed operator with OE.

b). The licensed operator's response should be carefully reviewed to ensure that the staff's initial action was appropriate.

c). The region should prepare a response to the licensed operator addressing the licensed operator's points of contention and the acceptability of the corrective action.

1). The licensed operator’s home address should be deleted from all documents made available to the Public.

2). If the licensed operator's response does not present additional information, then the region will prepare a brief response addressing the licensed operator’s points of contention.

3). Even if the licensed operator's response does not present new information, if an error in the enforcement action is identified, it must be corrected.

4). If the licensed operator provides a sufficient basis to withdraw the violation, then the violation should be withdrawn and not made available to the Public.

5). The region should normally respond to the licensed operator's responses within 30 days.

D. If the staff review of the licensed operator's response concludes that the licensed operator did not provide a sufficient basis to withdraw the violation, or if the licensed operator has

not replied within 30 days, the letter and NOV (without enclosures), and the operator's response, should then be made available to the Public.

CHAPTER 8
MISCELLANEOUS MATERIALS ENFORCEMENT ACTIVITIES

Chapter 8 provides specific guidance regarding various enforcement activities, including:

- dispositioning of violations involving sealed sources and devices containing NRC-licensed material
- transportation
- fuel cycle and materials operations
- use of material in areas under exclusive federal jurisdiction within an Agreement State
- actions involving written directive requirements
- reporting requirements for the Healthcare Integrity and Protection Data Bank

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8. Miscellaneous Materials Enforcement Activities

8.1 Loss, Abandonment, or Improper Transfer or Disposal of Licensed Material

A. The guidance in this section applies to violations that involve loss, abandonment, or improper transfer or disposal of sealed source and devices (SSDs). It does not apply to violations that involve security and control of licensed material unless the failure to secure or control results in loss, abandonment, improper transfer or disposal, or other unauthorized release of SSDs containing NRC-licensed material.

B. Violations of NRC requirements involving loss, abandonment, or improper transfer or disposal of SSDs containing NRC-licensed material will be considered for escalated enforcement action as follows:

1. Such violations, in accordance with the Enforcement Policy, "are treated separately, regardless of the use or the type of licensee."

2. The staff should assign a severity level to the violation that appropriately reflects the normal factors for considering significance, including:

a). A consideration of the chemical and physical characteristics of the radioactive material;

b). Safety and environmental significance;

c). Whether the circumstances surrounding the violation, represents an isolated, rather than programmatic, weakness; and

NOTE:

If the licensee exercises adequate security and control but the source/device is still lost (e.g., stolen), there is no violation and, therefore, no enforcement issues.

d). Whether the staff should increase the significance when a violation is willful.

C. Consultation with OE is required for all cases involving loss, abandonment, or improper transfer or disposal of licensed material.

D. The following are examples of Severity Level III violations involving the loss, abandonment, or improper transfer or disposal of SSDs:

<u>Example 1</u>:

A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 and 40 mCi of Am-241 resulting in the loss of the gauge. The gauge

was recovered eight hours later at the same time that the licensee was reporting the loss to the NRC. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

Example 2:

A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 resulting in the gauge being stolen. The amount of the radioactive material was less than 1000 times the 10 CFR Part 20, Appendix C value and the licensee had a functional program to detect and deter security violations that included training, staff awareness, detection, and corrective action; however, the violation was significant since the gauge contained more than a nominal amount of material. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

Example 3:

A licensee failed to maintain control of brachy-therapy sources containing 7.7 mCi of Ir-192 resulting in the loss of the material. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

E. The following are examples of Severity Level IV Violations.

1. All cases being considered for disposition at Severity Level IV should be coordinated with OE (normally by phone or e-mail) and should receive an EA number.

Example 1:

A licensee lost a static eliminator containing 10 mCi of Po-210. Due to the low actual safety significance associated with the isotope and small amount of material and the difficulty in gaining access to material, the NRC issued a Severity Level IV violation.

Example 2:

A licensee lost a sealed source containing 0.7 mCi of I-125. Due to the low actual safety significance associated with the small amount of material, the fact that the quantity was less than 1000 times the 10 CFR Part 20, Appendix C value, and the licensee had a functional program, the NRC issued a Severity Level IV violation.

NOTE:

The December 18, 2000, (65 FR 79139) change to the base civil penalty structure considers both the cost of proper disposal and the relative risk to the public from sources that are lost, abandoned, or improperly transferred or disposed of. The Commission believes that a base civil penalty equivalent to three times the cost of proper disposal will provide for sufficient deterrence and an economic incentive for licensees to expend the necessary resources to ensure compliance.

8.1.1 Base Civil Penalties for Violations Involving Loss, Abandonment of Improper Transfer or Disposal of a SSD

A. Civil penalties for violations that involve loss, abandonment, or improper transfer or disposal of a SSD are assessed:

1. Under Table 1A.f, of the Enforcement Policy; or

2. By considering the actual cost of proper disposal, regardless of the type of licensee or the use of the SSD.

B. The three levels of civil penalties listed in Table 1A.f are intended to correlate the civil penalty amount to the costs of properly disposing of the SSD.

1. SSDs containing small amounts of radioactive material, such as gas chromatographs, and devices containing hydrogen-3 (tritium) have a base civil penalty in the amount of $6,500 for a severity level I violation, $5,200 for a severity level II violation, and $3,250 for a severity level III violation.

2. SSDs containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, and 37 MBq (1mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)) are considered to present a higher risk for potential exposure to the public and for loss of property (due to contamination) if the device is lost, abandoned, or improperly transferred or disposed of. Based on the higher risk, violations involving loss, abandonment, or improper transfer or disposal of SSDs in this category have been assigned a base civil penalty amount of $16,500 for a Severity Level I violation, $13,200 for a Severity Level II violation, and $8,250 for a Severity Level III violation.

3. With the exception of SSDs containing hydrogen-3 (tritium), the highest activity SSDs (i.e., those with activities greater than 3.7×10^4 MBq (1 Curie)) have been assigned a base civil penalty amount of $50,000 for a Severity Level I violation, $40,000 for a Severity Level II violation, and $25,000 for a Severity Level III violation.

C. Adjustment of Civil Penalty Amounts Based on Disposal Costs:

1. In assessing the amount of a civil penalty, the NRC may consider information concerning the actual expected cost of authorized disposal instead of using the civil penalty amounts in Tables 1.A.f and 1B of the Enforcement Policy.

   a). The actual expected cost of authorized disposal would be the expected cost for an individual or organization that found and took possession of the SSD.

   b). Normally, the burden of determining the actual expected cost of authorized disposal rests with the licensee.

      1). If a licensee requests that the civil penalty amount be reduced based on the actual expected cost of disposal, the licensee should provide a copy of a written estimate from a waste disposal site, waste broker, or the SSD manufacturer.

NOTE:

NRC will typically adjust the civil penalty amount to correlate to one of the base civil penalty amounts for violations involving loss, abandonment, or improper transfer or disposal. For example, if the base civil penalty amount is $22,500, based on the violation being at Severity Level III and involving material described in Table 1Af.1., and a licensee provides adequate information demonstrating that three times the cost of authorized disposal is $6,000, the NRC would likely assess a $7,500 civil penalty (the amount a Severity Level III violation for material described in Table 1A.f.2.). In cases that the NRC decides to mitigate a civil penalty, the NRC will only mitigate the civil penalty down to the lowest base civil penalty in Tables 1A.f and 1B, currently $3000.

      2). The licensee may provide the information in (1) above, in its response to a choice letter, a proposed action, or at a pre-decisional enforcement conference (PEC).

      3). NRC may increase or decrease the value of the civil penalty if it has reliable specific information on the expected cost of disposal (e.g., assessment of a civil penalty amount for a similar case).

      4). Based on current information and recent cases, the NRC has determined that the expected authorized costs of disposal of portable moisture density gauges containing approximately 10 mCi of Cs-137 and 40 mCi of Am-241 is less than $1000. Therefore, rather than have licensees provide disposal information for such cases, the NRC will typically propose imposition of civil penalties in the amount $3000 for Severity Level III violations involving the loss, abandonment, or improper transfer or disposal of these types of devices.

2. The NRC will evaluate the merits of each specific case and may reduce or increase the amount of a civil penalty based on other information, such as the actual consequences of the loss, abandonment, or improper transfer or disposal.

   a). While NRC may adjust the civil penalty based on actual consequences (e.g., cost of recovery, decontamination, etc.). NRC will not normally reduce the amount of the civil penalty because there was a quick recovery or some other fortuitous event.

   b). NRC would typically only consider reducing the amount of a civil penalty for identification or corrective action if such actions were extraordinary.

D. Choice Letters: In some cases, NRC may have sufficient information to make an enforcement decision and does not need to hold a PEC. In such cases, NRC may send a choice letter to the licensee.

1. If the staff is considering a civil penalty, the choice letter should explicitly state that NRC is considering the use of discretion in accordance with the Enforcement Policy to issue a civil penalty.

2. The standard choice letter may include an optional paragraph that informs the licensee that the licensee may submit information regarding the expected costs of authorized disposal.

E. Conference Letters: If the staff chooses to invite the licensee for a conference, the licensee should be informed that the NRC:

1. Should normally proposes imposition of a civil penalty of at least the base amount for violations involving the loss, abandonment, or improper transfer or disposal of a SSD; and

2. May consider adjusting the civil penalty amount to a more appropriate base amount if a licensee can demonstrate that three times the actual cost of disposal would be significantly less than the base amount.

NOTE:

The license may provide information regarding the actual expected costs of authorized disposal in its response to a choice letter, a proposed action, or as part of a PEC.

F. Cover letters for NOVs with civil penalties typically discuss the complete civil penalty assessment process, including:

1. How NRC considered credit for identification and corrective action; and

2. If applicable, the use of discretion in consideration of the actual costs of disposal in determining the civil penalty.

8.2 Transportation

A. 10 CFR Part 71 establishes the requirements for:

1. Packaging;

2. Preparation for shipment;

3. Transportation of licensed material; and

4. The standards for NRC approval of packaging and shipping procedures for fissile material and for quantities of other licensed material in excess of Type A quantity.

NOTE:

Section 6.8 of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

B. The packaging and transport of licensed material is also subject to:

1. Other parts of Title 10 (e.g., Parts 20, 21, 30, 39, 40, 70, and 73);

2. The regulations of other agencies (e.g., U.S. Department of Transportation (DOT) and the U.S. Postal Service (USPS)) or Agreement States having jurisdiction over means of transport; and

3. The jurisdiction of individual states which may take enforcement action for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements.

C. Reactor transportation cases are normally addressed under the Significance Determination Process (SDP).

8.2.1 Memorandum of Understanding (MOU) Between NRC and DOT

A. The MOU between the NRC and DOT, is included on the Enforcement Web site, at http://www.nrc.gov/reading-rm/doc-collections/memo-understanding/.

B. In accordance with the MOU:

1. DOT is required to regulate safety in the transportation of hazardous materials, including radioactive materials;

2. NRC is authorized to license and regulate the receipt, possession, use, and transfer of "byproduct material," "source material," and "special nuclear material."

3. Each agency has its own inspection and enforcement programs within its jurisdiction to assure compliance with its requirements.

   a). The NRC will assist DOT, as appropriate, in inspecting shippers of fissile materials and other radioactive materials exceeding Type A limits.

   b). The DOT and the NRC will consult with each other on the results of their respective inspections in the areas where the results are related to the other agency's requirements.

   c). Each agency will take enforcement action, within the limits of its authority, as it believes appropriate.

4. In accordance with Section IV of the MOU regarding formalized working arrangements:

   a). The NRC normally carries out enforcement actions for violations of the requirements of 10 CFR 71 and 49 CFR (except 49 CFR Parts 390 through 397) by NRC licensees.

   b). DOT normally carries out enforcement actions for violations of 49 CFR (including Parts 390 through 397) by carriers of radioactive materials and shippers of radioactive materials from Agreement States, or any other shippers otherwise not subject to NRC requirements (shippers of radium, for example).

8.2.2 NRC Action in Conjunction With State Action

A. When a State takes an enforcement action (e.g., the imposition of a civil penalty or suspension or revocation of the licensee's burial permit or both) against a licensee for activities that also represent violations of NRC requirements, the following guidance should be used:

   1. Individual States may take enforcement action against shippers for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements.

   2. Notwithstanding the severity level of a violation, the NRC will not normally propose a civil penalty in cases where a State issues a civil penalty.

      a). Even if a State has taken enforcement action for the violation, the NRC may consider enforcement action beyond an NOV, such as the issuance of a civil penalty or order, if the violation is repetitive.

      b). If the region believes that a civil penalty should be assessed in a particular case, the region should submit a recommendation to the Director, OE.

3. The region should submit NOVs with Severity Level I, II, or III violations to OE for review and approval prior to issuance.

4. The region may issue NOVs with Severity Level IV violations without prior review and approval by the Director, OE, or the DEDOs.

5. Regardless of the severity level, all NOVs and accompanying documents should require the licensee to submit to the office issuing the NOV a description of the corrective action taken or planned to prevent similar future violations.

   a). This corrective action will be reviewed by the region.

   b). If the region determines that the corrective action is unsatisfactory, the region should consider further enforcement action to ensure compliance with NRC regulations.

   c). A PEC does not need to be held if:

      1). The licensee understands the significance of the violation; and

      2). The region is satisfied with the corrective action.

   d). NOVs including Severity Level III violations should:

      1). Be coordinated with OE;

      2). Have an EA number;

      3). Be signed by the Regional Administrator; and

      4). Be sent subsequently to OE for information.

B. Violations that are discovered by the NRC at the licensee's facility, or in other cases where the State has not taken action, will continue to be processed in accordance with normal NRC policy and practice.

8.2.3 Inaccessible Areas With Excessive Radiation Levels

When the area of a transport vehicle with excessive radiation levels is not easily accessible, consideration may be given to categorizing the violation at a lower severity level.

8.2.4 Exercise of Enforcement Discretion Involving Transportation Casks

A. Enforcement may not be warranted for certain cask contamination issues.

1. The Enforcement Policy provides that "...licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or

management controls."

B. Enforcement of the removable contamination limits in 10 CFR 71.87(i)(2) may not be appropriate where the licensee had taken comprehensive steps to ensure compliance, i.e., the licensee had decontaminated the cask several times before providing it for transportation and the staff is not aware of any further reasonable actions that the licensee could have taken to prevent the violation (see EA-93-306).

C. Exercise of this discretion:

1. Requires an EA number; and

2. Should be coordinated with OE.

8.3 Fuel Cycle and Materials Operations

This section provides specific guidance concerning enforcement practices for fuel cycle and materials operations.

NOTE:

Section 6.2 and 6.3 of the Enforcement Policy provide examples of violations in each of the four severity levels as guidance in the area of fuel cycle and materials operations activity area.

8.3.1 Activities of Unqualified Persons

A. When taking escalated enforcement action for violations involving unauthorized and potentially unqualified persons using material or performing licensed activities, consideration should be given as to whether the individual in question is, in fact, unqualified to use the materials or perform the activities.

B. An inspector may ask the materials licensee to explain whether or not the current unauthorized user is technically qualified.

NOTE:

An individual may be technically qualified to perform the activities in question but does not have, e.g., the appropriate certification to perform these activities. In that case, the violation may be categorized as a Severity Level IV. This stands in marked contrast to the individual who has either the appropriate training or certification to perform the activities in question. In that case, the violation may be categorized as a Severity Level III.

1. If the user is not qualified, a Severity Level III violation should be cited and the user

should be precluded from further licensed activity without appropriate supervision.

2. If the user is qualified, the violation may be categorized at a Severity Level IV.

   a). OE concurrence is not required.

   b). The licensee should take corrective action to preclude further unsupervised activity by the unauthorized user of licensed material until the license has been amended.

3. If the only user of licensed material is not qualified:

   a). In cases involving more hazardous materials, e.g., materials used in medical programs, an order suspending the license until an authorized, qualified user is obtained may be appropriate.

> **NOTE:**
>
> In accordance with 10 CFR 150.20, a licensee must submit an NRC Form-241 at least 3 days before engaging in the activities permitted under the general license. The NRC considers failure to submit this form to be significant because without this information, the NRC is not aware of the licensed activities being conducted in NRC jurisdiction and, therefore, cannot inspect these activities. This impedes the agency's ability carry out its mission to protect the public health and safety and ensure the common defense and security.

   b). If radiation hazards are minimal, e.g., materials used in stationary liquid-level-measuring gauges or stationary thickness-measuring gauges, a Confirmatory Action Letter (CAL) suspending the user or preventing the user from using licensed material until becoming qualified may be appropriate.

      1). The CAL could also state, at the licensee's option, that the licensee will suspend further activities until it finds another qualified user and amends its license to reflect this change.

      2). If the CAL is ineffective, an order suspending the license should be considered.

8.3.2 NRC Action Against Agreement State Licensee

A. An **Agreement State** is defined as any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (AEA), by which those States have assumed regulatory responsibility over byproduct and source materials and small quantities of special nuclear material.

1. Regulations addressing the activities of Agreement State licensees in areas of NRC jurisdiction are located in 10 CFR Part 150.

B. A **non-Agreement State** is defined as any other State. The materials programs in such states are subject to NRC jurisdiction.

C. Under **reciprocity**, the provisions of CFR 150.20 establish a general license authorizing any person who holds a specific license from an Agreement State to conduct the same activity in areas under NRC jurisdiction provided that the specific license does not limit the activity authorized by the general license to specified installations or locations.

D. Areas under NRC jurisdiction are:

- Areas within non-Agreement States
- Areas under exclusive Federal jurisdiction within Agreement States
- Offshore waters

E. The NRC can take enforcement action against an Agreement State licensee if:

1. It is improperly conducting activities in areas under NRC jurisdiction in conjunction with the general license in 10 CFR 150.20;

2. It is improperly conducting activities in areas under NRC jurisdiction in conjunction with an NRC specific license; or

3. It failed to submit an NRC Form-241 in accordance with 10 CFR 150.20.

F. For those cases where the NRC identifies issues involving or concerning the Agreement State licensee that may have an immediate impact on the public health and safety or the common defense and security, the office that identified the issue should provide immediate notification of the concern to the Agreement State that issued the license.

1. For proposed escalated enforcement actions, the office issuing the enforcement action should discuss the enforcement action with the Agreement State <u>before</u> the enforcement action is issued.

G. For those cases where the NRC proposes enforcement action against an Agreement State licensee:

1. For proposed escalated enforcement actions, the office issuing the enforcement action should discuss the enforcement action with the Agreement State before the enforcement action is issued to ensure that the Agreement State understands the NRC's rationale for issuing the action.

2. The office proposing enforcement action should ensure that the Agreement State that issued the specific license receives copies of any enforcement correspondence.

3. If the staff proposes to conduct a PEC, the office proposing the conference should

notify the Agreement State and forward a copy of the meeting notice for the conference.

8.3.2.1 Use of Byproduct Material in Areas Under Exclusive Federal Jurisdiction Within Agreement State

A. The AEA and NRC regulations require that, in order to use byproduct material, a person must obtain a license either from:

1. The NRC, for those areas under NRC jurisdiction; or

2. An Agreement State, for those areas under Agreement State jurisdiction.

B. In order for an Agreement State licensee to use material in areas of exclusive Federal jurisdiction within the Agreement State, the Agreement State licensee must either:

1. Obtain a license from the NRC as required by 10 CFR 30.3; or

2. File an NRC Form-241 pursuant to 10 CFR 150.20 at least 3 days before engaging in the activities permitted under the general license, as long as the Agreement State license does not limit the activity it authorizes to specified installations or locations.

NOTE:

Information indicating that the Agreement State licensee was given erroneous information concerning the status of the Federal property may be contained in a written statement from the Federal agency or a written statement signed and dated by the licensee documenting the name and title of the person at the Federal agency who provided the determination that the work site was not in an area of "Exclusive Federal Jurisdiction" and the date the determination was provided.

C. Notwithstanding its location within an Agreement State, there are areas that are under exclusive federal jurisdiction, including:

1. Areas under NRC jurisdiction, e.g., Federal facilities; and

2. Areas not under the jurisdiction of the Agreement State, e.g., Tribal lands.

D. Each case involving the failure to file an NRC Form-241 or obtain an NRC license prior to using materials in areas of exclusive Federal jurisdiction will need to be reviewed on a case-by-case basis to determine the appropriate enforcement action.

NOTE:

In February 27, 1997, an amendment to 10 CFR 150.20 (62 FR 1662) was implemented which requires licensees to file NRC Form-241 prior to using byproduct material in areas under exclusive Federal jurisdiction within Agreement States. Special consideration should be given for violations that occurred prior to this date.

E. Enforcement discretion in accordance with the Enforcement Policy may be appropriate:

1. If the Agreement State licensee was not aware that it was operating within NRC jurisdiction; or

2. If the Agreement State licensee was given erroneous information concerning the status of the Federal property.

   a). When enforcement discretion is exercised in this case, an enforcement panel with OE is not required, however:

      1). The region needs to obtain an EA number for tracking purposes; and

      2). Coordination with OE staff is warranted given the exercise of discretion.

3. If other violations of NRC requirements exist, the region should issue an NOV for these failures and the "contrary to" paragraph and cover letter should indicate that the location was an area under exclusive Federal jurisdiction.

   a). Enforcement action for other violations should only be taken in accordance with the provisions in 10 CFR 150.20.

   b). The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION." The cover letter to the licensee should include the following:

      “If, in the future, you operate at a temporary job site that is a Federally controlled site in an Agreement State and which may be subject to exclusive Federal jurisdiction (e.g., a military facility, or VA hospital) you should obtain a written jurisdictional determination from the Federal agency which controls the facility or land in question. If possible, obtain this determination in writing. If that is not available, you should keep a written record, signed and dated, that reflects the name and title of the person at the Federal agency who provided the information that the work site was not in an area of exclusive Federal jurisdiction and the date that the determination was provided. Absent this documentation, the NRC would expect to take enforcement action for future violations of this nature.”

F. Any proposed enforcement action should be prepared using the standard citation in Appendix C for failure to comply with 10 CFR 30.3, "Activities requiring license." The

violation should normally be categorized at Severity Level III.

1. The cover letter transmitting the enforcement action should specifically state that the licensee conducted NRC-licensed activities in an area under exclusive Federal jurisdiction.

2. If additional violations of NRC requirements exist, the "contrary to" paragraph should also indicate that the location was an area under exclusive Federal jurisdiction.

3. In addition to the action against the Agreement State licensee, the head of the Federal facility should be informed in writing (see forms in Appendix B).

8.3.3 Information Copies to Outside Organizations

The following office is to be sent a copy of every inspection report, CAL, NOV, or order that is issued concerning an individual radiographer:

ATTN: Technical Services Manager
American Society for Nondestructive Testing, Inc.
1711 Arlingate Lane
P.O. Box 28518
Columbus, OH 43228-0518

8.3.4 Actions Involving Written Directive Requirements

A. On April 24, 2002, Supplement VI (i.e., Section 6.3 in the current Policy) of the Enforcement Policy was modified (67 FR 20187) to revise the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material.

   1. For any administration that requires a written directive to be prepared in accordance with 10 CFR 35.40, licensees must develop, implement, and maintain written procedures in accordance with 10 CFR 35.41.

   2. The written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.

B. The Enforcement Policy places greater emphasis, and attaches greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature.

NOTE:

Substantial programmatic weaknesses apply in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. Programmatic weakness indicates that the failure is more widespread than simple occasional human error, e.g., a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions resulted in a medical event.

1. Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events that is more widespread than simple occasional human error. Examples include, but are not limited to:

   - Failure to develop and implement adequate written procedures for administrations that require a written directive
   - Failure to train personnel on the procedures
   - Failure to follow procedures

2. Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.

3. A decision on whether to categorize a violation resulting in a medical event at Severity Level I, II, III or IV must consider both the consequences and the isolated or programmatic nature of the violation.

   a). If the medical event was caused by an isolated failure and there were only limited medical consequences based on a medical consultant's report, then the violation would be categorized at Severity Level IV, e.g., the administration of a dosage of greater than 30 microcuries of sodium iodine I-131, that was not within 20% of the dosage prescribed by the authorized user, would meet the criteria for a medical event.

   b). If the medical event was caused by a one-time failure to determine the activity of the dosage prior to the administration, and the medical consultant expected limited consequences, the violation would be categorized at severity level IV.

   c). If the medical consultant found that the consequences were not limited, or if the violation appeared to result from a substantial programmatic failure or a programmatic weakness, then the violation would be categorized at Severity Level III or greater.

8.3.5 Actions Involving Radiation Safety Officers (RSOs)

A. The following examples provide additional clarification on when it may be appropriate to consider the lack of an RSO or replacement of an RSO with an unqualified individual as a Severity Level III violation.

1. If the RSO leaves the facility and no RSO is appointed, a Severity Level III violation is appropriate.

2. If the RSO leaves the facility and the individual assigned as a replacement RSO is not qualified under applicable NRC criteria, a Severity Level III violation is appropriate.

B. If, on the other hand, the RSO leaves the facility and the individual assigned as a replacement RSO is qualified under the applicable NRC criteria, but the license has not been amended to name the new RSO, a Severity Level IV violation is appropriate.

C. For some small materials licensees, there are no special qualification requirements or duties for the RSO position because of the limited types and quantities of material authorized on the license. For this type of licensee, a violation involving a change of RSO without receiving required NRC approval, or an absent RSO, is more appropriately categorized at Severity Level IV, unless other concurrent violations indicate the existence of a programmatic breakdown.

8.3.6 Severity Level For Failure To Report A Medical Event

A. 10 CFR 35.3045 requires that medical events be reported to the NRC. When there is a failure to report a medical event to the NRC, the following considerations apply:

1. Failure to report a medical event is normally categorized at Severity Level III.

2. If no report has been made to NRC at the time that NRC becomes aware of the medical event, the violation normally should be categorized at Severity Level III.

3. If the report to NRC is late or incomplete, but is nonetheless the vehicle by which NRC becomes aware of the medical event, the violation may be categorized at Severity Level IV provided that the late or incomplete nature of the report did not substantially diminish the NRC's ability to determine the significant facts of the medical event once the NRC became aware of it.

B. 10 CFR 35.3045 requires that medical events be reported to:

1. The referring physician; and

2. Either the patient, or the patient's responsible relative or guardian.

C. An exception in 10 CFR 35.3045(e) provides that the patient need not be notified if the referring physician informs the licensee that, based on medical judgment, telling the patient would be harmful.

D. When there is a failure to report a medical event to the referring physician or the patient or the patient's responsible relative or guardian, the following considerations apply:

1. If no report has been made to the referring physician, the violation normally should be categorized at Severity Level III. (The regulation does not specify that the report to the referring physician needs to be in writing; therefore, an oral report to the referring physician is sufficient.)

2. If neither an oral nor a written report has been made to the patient or the patient's responsible relative or guardian, and the referring physician did not invoke the exception in 10 CFR 35.3045(e) as it applies to the patient, the violation normally should be categorized at Severity Level III.

3. If the licensee made an oral report to the patient or the patient's responsible relative or guardian, but failed to make a written report as required by 10 CFR 35.3045(d), the violation may be categorized at Severity Level IV provided that the licensee promptly provides the written report once the matter is brought to the licensee's attention.

8.4 Guidance for Dispositioning Violations of the Clarification of Decommissioning Funding Assurance Rule

A. On July 26, 1995, the NRC issued a rulemaking on "Clarification of Decommissioning Funding Requirements" for materials licenses, (Clarification Rule) (60 FR 38235).

1. The Clarification Rule requires licensees to have:

a). Adequate financial assurance for decommissioning during licensed operations; and

b). Updated financial assurance for decommissioning when the licensee decides to cease operations and begin decommissioning.

NOTE:

Licensees were required to provide adequate financial assurance for decommissioning by November 24, 1995, the effective date of the Clarification Rule.

2. The Clarification Rule was intended to address those licensees who have been in timely renewal since the promulgation of an earlier Decommissioning Rule, or who have ceased operations without having adequate decommissioning funding arrangements in place.

3. Licensees were required to provide adequate financial assurance for decommissioning by November 24, 1995, when the Clarification Rule became

effective.

B. Violations of the Clarification Rule are normally identified during records reviews conducted to determine compliance with the rule, and enforcement action should be taken if the licensee is currently not in compliance with the requirements of the rule.

1. The staff will provide the licensee with a letter indicating that an apparent violation has been identified as a result of a records review (see forms in Appendix B).

2. The licensee can request a PEC within 7 days or can provide a written response within 30 days.

3. Since an inspection report is not issued for a violation identified during a records review, the letter needs to clearly identify and document the specific apparent violation.

a). The language used in the letter to identify and document the apparent violation may be adapted from the standard citations for 10 CFR 30.35 and 30.36.

b). Although the text of these standard citations focuses on violations of 10 CFR Part 30, the text can be adapted for violations of the identical regulation in 10 CFR Parts 40, 70, or 72.

4. In addition to sending the letter, the region should contact the licensee's management by telephone to assure that the licensee has an opportunity to ask questions in order to fully understand the apparent violation.

C. The Enforcement Policy provides that violations involving significant failure to meet decommissioning requirements should be categorized at Severity Level III.

D. Violations involving significant failure to meet decommissioning requirements may be treated by issuing a Severity Level IV violation if the licensee:

1. Responds to the apparent violation within 30 days;

2. Provides an acceptable plan for meeting the decommissioning financial assurance requirements; and

3. Fully implements the plan according to an agreed-upon schedule.

E. Where the NOV is not issued until the corrective action is completed, a response to the NOV normally would not be required.

F. Escalated enforcement action in the form of an NOV, civil penalty and/or Order is appropriate, if the licensee:

1. Is not responsive;

2. Does not provide an acceptable plan for meeting the decommissioning financial

requirements; or

3. Is not implementing the plan according to an agreed-upon schedule.

NOTE:

Corrective action is not considered in determining the severity level of a violation; however, the significance of a violation is increased if the licensee has notice of the violation but is either unwilling or unable to achieve compliance.

G. Enforcement decisions will be made on a case-by-case basis.

H. In processing cases involving significant failure to meet decommissioning requirements:

1. An enforcement action (EA) number is required to track the action.

2. Following the licensee's response, the determination of the severity level and sanction, if appropriate, is to be discussed during the weekly OE panel for the respective region.

3. Appropriate regional and Division of Waste Management and Environmental Protection staff will participate in weekly OE panels involving escalated enforcement action in response to Clarification Rule violations.

I. In the event an application for renewal of a license is outstanding under these circumstances, the staff may deny the license renewal application and require the licensee to begin decontamination and decommissioning activities.

J. As the staff considers escalated enforcement action, it should also consider matters, on a case-by-case basis, such as:

- The licensee's financial status
- The types and levels of contamination at the site
- The steps needed to ensure protection of the public health and safety if the licensee should declare bankruptcy, abandon the site, or both

8.5 Guidance for Dispositioning Violations of the Timeliness in Decommissioning of Material Facilities Rule

A. On July 15, 1994, the NRC issued a rulemaking entitled "Timeliness in Decommissioning of Material Facilities" for materials licensees (Timeliness Rule, 59 FR 36026-36040).

B. The Timeliness Rule amended 10 CFR Parts 30, 40, 70, and 72, and established definitive criteria for timely decommissioning upon termination of operations.

1. The rule establishes requirements for notifying the NRC of pending decommissioning

actions and cessation in licensee operations, establishes requirements for when decommissioning plans need to be submitted, and establishes requirements for completing decommissioning activities.

2. The rule allows licensees to request relief from the timing of requirements where justified.

C. Violations of the Timeliness Rule are normally identified during inspections of records or records reviews conducted to determine compliance with the regulation.

8.5.1 Failure to Notify NRC pursuant to 10 CFR 30.36(d)

Licensees are not required to notify NRC when a decision is made to permanently cease principal activities in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

A. If the failure is not willful and there are no other decommissioning violations for which escalated enforcement action may be taken, the violation should be dispositioned as a Severity Level IV violation.

1. Use standard citation 30.36a.

2. If the licensee is not responsive to the NOV, the issue should be paneled with OE to determine a further course of action.

B. If the failure to notify may be willful or if there are additional decommissioning violations for which escalated enforcement action may be taken, refer to the following section.

8.5.2 Processing Other Violations

A. Violations of the Timeliness Rule are dispositioned similarly to the manner in which violations of the Clarification Rule are dispositioned

1. For violations of the Timeliness Rule that may involve escalated enforcement action, the guidance for the Clarification Rule for contacting the licensee, providing notice of the apparent violation(s) in a letter to the licensee, and paneling the enforcement sanction with OE should be followed.

2. Appropriate regional and NMSS Division of Waste Management and Environmental Protection staff should participate during the panel.

B. If the violation was identified as a result of an inspection, as opposed to a records review, the cover letter should be modified accordingly.

C. The Timeliness Rule should be consulted to determine compliance requirements for certain specific situations.

8.5.3 Storage Only Licenses

A. There are two types of licenses that authorize “storage only.” The Timeliness Rule applies differently depending on the type of “storage only” license, as follows:

1. For the first type of license, storage historically was not a principal activity authorized by the license; however, the license has been amended to authorize “storage only” because as a result of some difficulty regarding the transfer or disposal of the material, the material remains on the licensee’s site.

   a). Storage under these circumstances is not a "principal activity" as defined in CFR 30.4.

   b). The requirements to notify NRC and undertake decommissioning in CFR 30.36(d)(2)-(4) are not triggered, because there is no principal activity to cease.

   c). For these licensees, decommissioning issues should be addressed when the license comes up for renewal.

   d). Concerns about such licensees also may be addressed through Demands for Information, CALs, Orders, etc.

   e). Concerns, which may involve insolvency, lack of security and control, etc., should be discussed on the weekly OE panel for the respective region which should be attended by the NMSS Division of Waste Management and Environmental Protection staff.

2. For the second type of license, storage of material historically has been the principal activity conducted by the licensee, who did not engage in an activity that produced or used the material in storage.

   a). In such cases, storage should be treated as the principal activity under the license, and the notification and decommissioning requirements in CFR 30.36(d)(2)-(4) are applicable.

   b). The requirements to notify NRC and undertake decommissioning in 10 CFR 30.36(d)(2)-(4) are triggered when the licensee ceases to store the material (i.e., the material is transferred).

B. Questions concerning an NRC position on the Timeliness Rule should be referred to the NMSS Division of Waste Management and Environmental Protection staff.

8.6 Severity Levels of Violations at Fuel Facilities

A. The severity levels in the examples in Section 6.2, Fuel Cycle Operations, of the Policy that are applicable to fuel facilities are based on the relationship of the loss of criticality safety control(s) to the availability (or likely availability) of a sufficient amount of fissile material for a nuclear criticality accident.

Also, the examples in Section 6.3, Materials Operations,address events that involve chemical processes integral to licensed activities, whether or not radioactive material is released. The following examples from Section 6.3 are illustrative:

1. Example 6.3.a.1, concerning significant injury or loss of life to site personnel, addresses a very significant regulatory concern because, in addition to the radiation, contamination and releases, the NRC is concerned about the actual impact of any occurrence from a portion of a licensed activity, including chemical processes, that has been reviewed and approved as part of the NRC licensing process.

2. Example 6.3.b.1 indicates that the loss of control over licensed or certified activities is a very significant safety concern when there is the substantial potential for a significant injury or loss of life, whether or not radioactive material is released.

3. Example 6.3.c.5, qualified person to conduct licensed activities" highlights the importance that the NRC places on having qualified persons to conduct licensed activities.

8.7 Material False Statements and Completeness and Accuracy of Information

A. Section 6.9 of the Enforcement Policy provides examples of violations involving inaccurate or incomplete information or the failure to provide significant information.

B. Submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions.

   1. The decision to view a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations.

C. The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review; however, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as:

   1. The degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;

   2. The opportunity and time available prior to the communication to ensure the accuracy or completeness of the information;

   3. The degree of intent or negligence, if any, involved;

   4. The formality of the communication;

5. The reasonableness of NRC reliance on the information;

6. The importance of the information that was wrong or not provided; and

7. The reasonableness of the explanation for not providing complete and accurate information.

D. Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official.

1. Enforcement action may be taken, e.g., for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, or if a record of the oral information such as a transcript of the communication or meeting summary containing the error was provided to the licensee, thereby giving an opportunity to correct the oral information, and was not subsequently corrected in a timely manner.

2. When a licensee has corrected inaccurate or incomplete information, the decision to issue an NOV will consider:

   a). The ease of detecting the error;

   b). The timeliness of the correction;

   c). Whether the NRC or the licensee identified the communication problem; and

   d). Whether the NRC relied on the information prior to the correction.

3. If the matter was promptly identified and corrected by the licensee prior to reliance by the NRC, or before the NRC raised a question about the information, normally no enforcement action will be taken for the inaccurate or incomplete information.

4. If the misinformation is identified after the NRC relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken.

5. If the initial submittal was thought to be accurate when made but later turned out to be erroneous because of newly discovered information or an advance in technology, a citation would not normally be appropriate (if, when the new information became available, the initial submittal was corrected).

NOTE:

10 CFR 150.20 provides that when an Agreement State licensee is operating within the NRC's jurisdiction under the general license granted by Section 150.20, the licensee is also subject to the completeness and accuracy requirements.

E. The circumstances surrounding the failure to correct may be relevant to determining enforcement action for the initial inaccurate or incomplete statement.

1. The failure to correct inaccurate or incomplete information which the licensee knew of, but did not regard as significant, normally will not constitute a separate violation.

2. An unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error.

3. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information.

4. In serious cases where the licensee's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

F. If enforcement action appears warranted for incomplete and inaccurate information, the region should prepare the appropriate enforcement action cited against the applicable regulation (e.g., 10 CFR 30.9, 40.9, 50.9, 55.9, 60.10, 61.9a, 70.9, 71.6a, 72.11, and 110.7a).

NOTE:

The provisions in 10 CFR Part 55 contains the first element only, i.e., that all information provided to the Commission by an applicant or licensee or required by the Commission to be maintained by the applicant or licensee shall be complete and accurate in all material respects.

G. The provisions of the applicable regulation address two elements:

1. A general provision that requires that all information provided to the Commission by an applicant or licensee or required by the Commission to be maintained by the applicant or licensee shall be complete and accurate in all material respects (violations are most commonly cited against this element); and

2. A reporting requirement that requires applicants and licensees to report to the NRC information identified by the applicant or licensee as having a significant implication for the public health and safety or common defense and security.

NOTE:

It is important to note that information provided to the NRC relating to a licensee's commitment to perform or complete an activity in the future is normally not a violation of 10 CFR 50.9 if it turns out that the licensee subsequently did not perform or complete the activity. This is because at the time the commitment was made, the licensee intended to perform or complete the activity; therefore, the information was accurate at the time.

H. If the inaccurate or incomplete information was provided to the NRC, after citing the requirement paragraph, the "contrary to" paragraph should establish:

1. When the information was provided to the NRC;

2. How the information was provided and to whom in the NRC, (e.g., oral presentation to the NRC staff in the NRC Region IV office; letter to the Director, NRR);

3. What the specific information was that the licensee provided (use direct quote if possible);

4. How the information was either inaccurate or incomplete; and

5. How the inaccuracy or incompleteness was material (e.g., the inaccuracy was material in that the NRC relied on the information in granting a license amendment, the incompleteness was material in that the NRC subsequently requested the licensee to make a submittal clarifying the information).

I. If the inaccurate information was required by the Commission to be maintained, the requirement section should include the requirement for maintaining the information and the "contrary to" paragraph should establish:

1. When the inaccurate or incomplete information was identified;

2. That the information was required to be maintained by the Commission;

3. How the information was either inaccurate or incomplete; and

4. How the inaccuracy or incompleteness was material.

8.8 Violations of Reporting Requirements

A. A licensee may be cited for violating reporting requirements if the licensee:

1. Did not file a required report;

   a). Ignorance of a reporting requirement is not an excuse.

2. Filed an incomplete or incorrect report; or

3. Filed a report late.

B. A licensee normally will not be cited for failing to report an issue if the licensee was not aware of the information that was reportable; however, a licensee should be cited for failure to report an issue if the licensee knew of the information to be reported, but did not recognize that a report was required.

C. The severity level assigned to the licensee's failure to submit a required, acceptable, and timely report on a violation that occurred at the licensee's facility is normally the same as would be assigned to the violation that should have been reported; however, the severity level for submitting a late report may be reduced, depending on the individual circumstances.

8.9 Violations of Record-Keeping Requirements

A. When a licensee is required to perform a task and to keep a record of having performed it, but cannot produce that record:

1. An NOV may be issued for failing to keep the record.

2. The citation may be considered supporting evidence that a licensee did not perform a required task.

NOTE:

Collaborating information, such as interviews or other evidence, should be used to determine whether the licensee failed to perform the task or merely failed to record that the task was performed.

B. Without additional evidence that the task was, indeed, not performed, the absence of the record is normally insufficient to support an NOV for "failure to perform" the task.

8.10 Meetings with Licensees on NRC Enforcement Action

A. In a few escalated enforcement cases, licensees have requested that a meeting be held after an enforcement action has been issued but before the enforcement process has been completed.

1. From the time an enforcement action is issued through the hearing process, the NRC

is considered to be in the enforcement process.

2. Throughout the enforcement process, the licensee is given numerous opportunities to discuss in detail the inspection findings, i.e., during the inspection, at the inspection exit interview, after receipt of the inspection report, during the PEC, in the formal response to the NOV, in the reply to the Order Imposing Civil Monetary Penalty, and in a hearing, if requested.

3. Unless new information has been discovered which has a significant effect on the outcome of the NRC enforcement action, additional discussion beyond those described in the preceding paragraph normally would not be useful.

B. If the licensee insists on holding a meeting with the NRC, the following guidelines should normally apply. The licensee is to be informed that:

1. An official transcript of the meeting will be made in order to have a complete record of the meeting should the staff desire to rely on it in the event that the licensee provides information that had not been provided previously in a written submittal; and

2. The transcript (absent exempt information) will be made a public record and will be made available to the Public, except when:

a). The meeting occurs after a hearing request has been made, in which case, the decision to have a transcript should be made in consultation with OGC; and

b). When a meeting will need to be closed because the new information involves privacy, safeguards, or proprietary information, in which case, the transcript will not be made available to the Public.

C. If, after consultation with the Regional Administrator, the Director, OE, concludes that such a meeting should be held, it is to be conducted with the Director or Deputy Director, OE, present.

8.11 Deliberate Misuse of Licensed Material

A. This section provides guidance as to the extent to which an NRC licensee should be held liable for deliberate, frivolous or malicious misuse of NRC-licensed material at its facility.

B. NRC licensees are required to control and limit their use of byproduct material to that authorized by the license or by regulation.

1. In general, licensees are accountable for the use of their licensed material by their employees and should normally receive at least a citation for violations involving deliberate misuse of their licensed material by their employees or agents.

2. Since the underlying issue of misuse normally would be categorized at Severity Level IV or higher, and since the Enforcement Policy states that the severity level of a willful violation may be increased, these violations normally would be categorized at Severity Level III or above and an NOV should be issued at Severity Level III or

above.

C. Although there may be cases where the ownership of the material and/or the identity of the perpetrator cannot be established definitively, in the absence of reasonable evidence to the contrary, normally the NRC will presume that:

1. The NRC-licensed material used in the incident belonged to the licensee, assuming that the licensee has possessed the type, quantity and form of the material involved;

2. The individual who perpetrated the act was an employee or agent of the licensee; and

3. The individual obtained the material while acting in the capacity of employee or agent.

D. Enforcement discretion should be considered for each case involving deliberate misuse of licensed material by licensee employees; however, it is not necessarily appropriate to seek a civil penalty against the licensee in every case.

1. NRC should encourage licensees to prevent, investigate, report, and correct violations involving deliberate misuse of licensed material.

a). If civil penalties were automatic imposed for deliberate misuse, licensees would have a disincentive to conclude that the misuse was a result of a deliberate action.

b). Where there is a need to convey a specific message about some particular facet of the case, a civil penalty may be assessed based on enforcement discretion, notwithstanding the normal application of the civil penalty factors.

2. The following are examples where it may be appropriate to use discretion to highlight a concern such as:

- Inadequate actions to prevent deliberate misuse
- The effort put forth by the licensee in investigating the deliberate misuse
- Whether deliberate misuse has occurred previously
- Whether the licensee had some basis to suspect that deliberate misuse might occur
- The corrective actions taken by the licensee
- The past performance of the licensee in controlling the use of licensed material, including training, labeling, posting, surveys, and security
- The actual and potential consequences of the deliberate misuse

E. In accordance with the Enforcement Policy, if the individual responsible for the deliberate misuse of licensed material is identified, enforcement action also may be taken directly against that individual.

8.12 Enforcement Actions involving Master Materials Licenses

A. A Master Materials License (MML) is a materials license (byproduct, source, and/or special nuclear material), issued to a Federal organization, authorizing use of radioactive material at multiple sites.

1. The MML remains an NRC licensee, and is required to meet NRC regulatory requirements.

2. The MML authorizes the licensee to issue permits to multiple user sites (permittees) for the possession and use of licensed material under the master license.

3. The MML obligates the licensee to have a centralized program that provides oversight and internal licensee inspection of the MML permittees.

B. Where responsibilities are divided between the MML management and NRC, the division of responsibilities and requirements for coordination are clearly defined and documented in a Letter of Understanding (LOU) between NRC and the MML.

1. Responsibility for allegations and enforcement are activities that are divided between the NRC and the MML.

2. Inspection activities, including reactive inspections and/or inspection frequencies are not within the purview of the Office of Enforcement (OE), and will not be addressed here.

C. The MML must have an enforcement program that commits to following NRC's Enforcement Policy to ensure that enforcement actions are consistent with the Policy and regulations, and are uniformly applied between the MML and its permittees.

8.12.1 Process for Dispositioning Violations

A. The MML

1. Based on the Enforcement Policy, when the MML identifies permittee violations of NRC or license requirements that could result in escalated enforcement (SL III, SLII, or SL I), the facts related to the case are provided to the appropriate NRC Regional MML Project Manager (PM).

2. An MML is an NRC licensee. Reports and notifications, as described in the regulations, must be made to NRC within the time frames specified in the regulation (e.g., 20.2201 Reports of theft or loss of material). Reports and notifications from permittees to the MML do not fulfill the responsibility of reporting to NRC.

3. The outcome of any NRC enforcement action against the MML depends, among other things, on appropriate corrective actions implemented at the permittee level; therefore, the MML is expected to ensure that permittees provide corrective actions appropriate to their violations.

4. The MML may take whatever enforcement action it deems appropriate against its permittee for violations of NRC regulations, license conditions, or conditions of the permit. However, the MML may not issue a civil penalty to its permittee.

B. The NRC Project Manager (PM)

1. The PM coordinates any needed Regional Office follow-up of events or incidents using the appropriate inspection guidance for MML licenses (at whatever frequency the region and Program Office believes is appropriate).

   a). Once the information has been gather and reviewed, and potential violations that may result in escalated action are identified, the region should disposition potential escalated violations through the normal enforcement process.

   b). An Enforcement Action Worksheet is prepared and an enforcement panel is scheduled. The worksheet should include the MML and/or the permittees short and long term corrective actions appropriate to the violation(s).

2. Enforcement actions taken by NRC against the MML do not preclude the MML from taking any action it deems necessary against its permittee for those violations. NRC may issue a CP to the MML, but will normally not take action against a MML permittee.

C. NRC Enforcement Discretion

1. Exercise of Discretion to either escalate or mitigate enforcement sanctions is addressed in Chapter VII of the Enforcement Policy.

2. Discretion to mitigate an escalated enforcement action regarding an MML may be considered when:

   - The violation was not willful
   - The MML has done a thorough investigation, and has reported their findings to the MML PM
   - A source is lost

3. Although these cases normally should result in a civil penalty of at least the base amount, for MMLs, discretion to mitigate the enforcement sanction may be considered when:

   - Based on the source activity/dose rate the violation would normally be dispositioned as Severity Level III or Severity Level IV
   - During the period of time that the location of the source was not known, workers or members of the public were not likely to exceed the radiation dose described in 10 CFR 20.1201 or 20.1301
   - The final location of the source is believed to be in an area where it would be unlikely for workers or members of the public to exceed the radiation dose described in 10 CFR 20.1201 or 20.1301

4. NRC discretion to either mitigate or escalate an enforcement sanction would be considered on a case-by-case basis when:

   - A source is lost, and the underlying violation was willful
   - There was an over-exposure of a worker or a member of the public; or
   - Based on the source activity/dose rate, the violation would normally be dispositioned as SL I or SL II

8.13 Liability of Former and Successor Licensees

A. The termination of an NRC license does not invalidate the former licensee's liability for actions taken under the license.

   1. Depending on the circumstances of a particular case (i.e., former licensees not in bankruptcy or out of business), escalated action may be taken against a former licensee for actions occurring during the time it held its license.

      a). The NRC's philosophy is that civil penalties should deter future violations not only for the involved licensee but also for other licensees conducting similar activities.

      b). For a particularly significant violation, it may be appropriate to issue a civil penalty to a licensee who is terminating licensed activities, to deter future violations by other licensees.

B. OE should be notified before a license is terminated for cases where:

   1. An OI investigation or inspection is ongoing, since, in such cases, enforcement action could still be taken based on the results of that investigation or inspection; and

   2. Enforcement action is pending and the licensee has not been responsive.

C. The transfer of control of a license to a new individual or business is a matter requiring NRC consent.

   1. Enforcement action should be taken if a person is found to have obtained a business or commenced operations under these conditions without obtaining NRC approval.

   2. The NRC considers the successor licensee to have assumed responsibility for violations occurring under the previous license, if these violations are not resolved when transfer of control occurs.

8.14 Enforcement Action Against Non-Licensees

A. The Enforcement Policy is also applicable to non-licensees, including:

   1. Contractors and subcontractors;

   2. Holders of NRC approvals, e.g., certificates of compliance (CoCs), early site permits,

standard design certificates, quality assurance program approvals, or applicants for any of them; and

3. Employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation.

B. Prohibitions and sanctions for any of the persons included in the preceding paragraph, who engage in deliberate misconduct or knowing submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct, e.g., 10 CFR 30.10 and 50.5.

C. Contractors who supply products or services provided for use in nuclear activities are subject to certain requirements designed to ensure that the products or services supplied that could affect safety are of high quality.

1. Contractors supplying certain products or services to licensees are subject to 10 CFR Part 21 requirements regarding the reporting of defects in basic components.

a). NOVs will be issued for contractors who violate 10 CFR Part 21.

b). Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(d)(1).

2. Through procurement contracts with licensees, suppliers may be required to have quality assurance programs that meet applicable requirements, e.g., 10 CFR Part 50, Appendix B, and 10 CFR Part 71, Subpart H.

D. When inspections determine that violations of NRC requirements have occurred, or that contractors have failed to fulfill contractual commitments (e.g., 10 CFR Part 50, Appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken.

1. NOVs and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements.

2. NOVs and civil penalties will be used against non-licensees who are subject to the specific requirements of 10 CFR Part 72.

3. Notices of nonconformance or orders will be used against non-licensees who are subject to the specific requirements of 10 CFR Part 72 (see additional discussion in the FRN for the Policy revision in 1999).

E. Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.

8.15 Reopening Closed Enforcement Actions

A. Under special circumstances, i.e., where significant new information is received or obtained by NRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, on a case-by-case basis, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record.

> **NOTE:**
>
> Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the DEDO.

1. Special circumstances include, e.g., a situation in which individuals lied to the NRC about information that would have been considered material to the NRC's disposition of the case.

2. Special circumstances do not include the discovery of additional information that was reasonably available at the time the agency made its initial decision.

B. In cases where the severity of an original enforcement sanction was inappropriately low, consideration may be given to issuing a separate sanction against a different applicable requirement, categorized at the appropriate severity level to reflect the level of NRC concern and convey the appropriate message to the licensee.

C. Even where special circumstances exist, the passage of time must be considered as well for very old violations.

8.16 Reporting Final Adverse Actions Against Healthcare Practitioners, Providers or Suppliers to the Healthcare Integrity and Protection Data Bank

A. "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners (HIPDB)," found in 45 CFR Part 61, requires federal agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the HIPDB.

1. The regulations in 45 CFR 61 define the types of <u>final</u> adverse actions that are reportable to the HIPDB.

2. The reportable actions must be formal or official actions such as the revocation or suspension of a license, reprimands, censure, probation, other negative actions or findings that limit the scope of practice, and other adjudicated actions or decisions.

B. The following final adverse actions taken by the NRC must be reported to the HIPDB:

- Orders suspending or revoking a license, excluding Orders suspending a license due

to non-payment of fees
- Orders modifying a license that limit the scope of practice of the licensee
- NOVs with associated civil monetary penalties
- CALs that limit the scope of practice of the licensee
- Orders to individuals prohibiting involvement in NRC-licensed activities
- Termination of a license by a licensee for the purpose of avoiding enforcement actions

NOTE:

The scope of actions that must be reported to the HIPDB, is defined in very broad terms.

C. The following actions do not need to be reported to the HIPDB:

- NOVs with no associated civil penalty
- Licensee corrective action plans
- Non-publically available final adverse actions

D. For those actions where the reportability of the action is questionable, the action and the associated background information should be provided to OGC for the final determination of reportability.

8.16.1 Entities that are Considered Healthcare Practitioners, Providers, or Suppliers

A. The reportability of the actions described in the previous section is limited to those actions taken against NRC licensees, and individuals employed or contracted by licensees, that satisfy the definition of a healthcare practitioner, provider, or supplier as prescribed in 45 CFR 61.

B. NRC licensees and individuals that satisfy the definitions prescribed in 45 CFR Part 61 are categorized as follows:

1. Healthcare practitioners:

- Physicians
- Technologists/technicians
- Pharmacists
- Nurses
- Medical Physicists
- Health Physicists

2. Healthcare providers:

- Hospitals

- Clinics
- Mobile Medical Units

3. Healthcare suppliers:

- Radiopharmaceutical Manufacturers
- Radiopharmacies
- Medical Source Replacement Contractors
- Source Providers (E.g. Seeds)

8.16.2 Information to be Reported

A. 45 CFR 61 specifies the information that must be reported.

1. This information is dependent on the entity involved and the type of action reported.

2. Optional information will be reported only if readily available.

B. HIPDB requires the NRC to provide certain information, such as birth date, gender, Social Security number, school attendance with dates, State license numbers, and medical specialties that the NRC may not normally collect.

1. For final adverse actions resulting from enforcement actions, OE will collect the additional information that is required as part of the final enforcement action.

2. The proposed action, e.g., NOV/CP or Order, will contain a paragraph requesting the information to be provided as part of the response to the action.

a). The action will not be closed until the required information is received.

b). NMSS and/or the Regional Office will be responsible for collecting the data for other reportable final adverse actions <u>that did not result from an enforcement action</u>, and providing it to OE for entry into the database.

c). The required information must be forwarded to the OE Office Director within 10 calendar days of those actions being final.

8.16.3 Information that must be reported

A. Mandatory information that must be reported for an Individual includes:

- Name, sex, date of birth
- Social Security Number, Home address or address of record
- Organization name and type
- Occupation and specialty, if applicable
- National Provider Identifier (NPI), when issued by the Health Care Financing Administration (HCFA)
- Name of each professional school attended and years of graduation

- NRC license number, including field of licensure
- With respect to the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held

B. Mandatory information that must be reported for an organization includes:

- Name and business address of the organization
- Federal Employer Identification Number (FEIN), or Social Security Number when it is used by the subject as a Taxpayer Identification Number (TIN)
- The NPI, when issued by HCFA
- Type of organization
- With respect to the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held

C. Mandatory information that must be reported for both an individual and an organization includes:

- A narrative description of the acts or omissions and injuries upon which the reported action is based
- Classification of the acts or omissions in accordance with reporting codes provided in the database
- Classification of the action taken in accordance with the reporting code in the database, and the amount of any monetary penalty resulting from the reported action
- The date the action was taken, its effective date and duration
- If the action is on appeal
- Name, title, address, and telephone number of the responsible official submitting the report

8.16.4 Information Collection

A. To request the information that the HIPDB requires but that the NRC does not normally collect, one of the following paragraphs should be inserted in the proposed final adverse action document after the paragraph that requires the licensee to submit a response:

1. For an individual, include:

   "In addition, 45 CFR Part 61, "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners," requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services' Healthcare Integrity and Protection Data Bank. Since the HHS Databank requires information that the NRC does not normally collect, you are required to submit the following information with your response: your date of birth; Social Security Number; sex; employment organization name and type; Occupation and/or specialty; National Provider Identifier (NPI), when the NPI is issued by the Health

Care Financing Administration (HCFA); name of each professional school attended and years of graduation; professional certification and/or registration; your State license number; your field of licensure; and the name of the State or territory in which your license is held. This information should be provided on a separate sheet of paper since it will not be publically released. This enforcement action will not be closed until this information is received."

2. For an organization, i.e., a licensee, include:

   "In addition, 45 CFR Part 61, "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners," requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services' Healthcare Integrity and Protection Data Bank. Since the HHS Databank requires information that the NRC does not normally collect, you are required to submit the following information with your response: Federal Employer Identification Number (FEIN), or Social Security Number (when it is used as a Taxpayer Identification Number (TIN)); the National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); the type of organization; and the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held. This information should be provided on a separate sheet of paper since it will not be publically released. This enforcement action will not be closed until this information is received."

B. When the NRC receives the response containing the information that the HIPDB requires but that the NRC does not normally collect, the information should be scanned into ADAMS; however, this information must be profiled as <u>not</u> publically available.

C. A copy of the response containing the information that the HIPDB requires but that the NRC does not normally collect, must be provided to the Office Director, OE, for entry into the databank.