

POLICY ISSUE **(NOTATION VOTE)**

November 1, 2011

SECY-11-0155

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED CHANGES TO THE ENFORCEMENT POLICY
ASSOCIATED WITH CONSTRUCTION ACTIVITIES

PURPOSE:

This paper requests Commission approval of an approach to address construction-related topics in the next revision of the U.S. Nuclear Regulatory Commission's (NRC's) Enforcement Policy (Policy). This paper does not address any new commitments or resource implications.

BACKGROUND:

The NRC's Policy contains policy and basic procedures that the staff uses to consider potential enforcement actions in response to apparent violations of requirements. The primary purpose of the Policy is to support the NRC's overall safety mission (i.e., to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment). The NRC first published the Policy in the *Federal Register* on October 7, 1980 (46 FR 66754), as an interim policy, and the agency last published a revision to the Policy on September 30, 2010 (75 FR 60485).

The Commission directed this review in response to construction-related issues identified at the Vogtle Electric Generating Plant (Vogtle) site in April 2010. In response to the Commission's direction, the staff considered a number of approaches to address potential non-conformances during construction, and is recommending changes to the Policy. Specifically, staff is proposing revising certain sections for clarity, amending current Section 2.3, "Disposition of Violations," and changing other sections on enforcement discretion for inclusion in the next Policy revision.

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This paper describes the proposed changes to the Policy, along with background on those topics evaluated by the staff, including a discussion of potential regulatory issues associated with each topic.

In “Staff Requirements Memorandum – SECY-10-0140 – Options for Revising the Construction Reactor Oversight Process Assessment Program,” dated March 21, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML110800557), the Commission directed the staff to develop a construction assessment program for nuclear power plants that includes a regulatory framework, the use of a construction significance determination process to determine the significance of findings identified during the construction inspection program, and the use of a construction action matrix to determine the appropriate NRC response to findings. The draft process developed by the staff will be piloted for 1 year starting January 1, 2012. The staff recognizes that additional Policy changes related to construction may be required based on experience gained during this pilot.

DISCUSSION:

Public Involvement in the Policy Revision Process

The staff provided several opportunities for the public to provide input and comments on the recommended revisions to the Policy.

An FRN published on August 9, 2011 (76 FR 48919), announced that the NRC was reevaluating construction-related topics in the Policy and was soliciting comments on revisions recommended by the staff. The proposed changes would clarify sections that had not explicitly included construction activities, revise how the NRC dispositions noncited violations (NCVs), and both clarify and revise how the NRC expects to exercise enforcement discretion at construction sites. The FRN solicited comments from interested parties, including public interest groups, States, members of the public, and the regulated industry (i.e., reactor and materials licensees, vendors, and contractors). The public comment period ended on September 8, 2011.

On August 30, 2011, the NRC conducted a public meeting to discuss the proposed changes to the Policy. The meeting consisted of a detailed presentation of the changes as published in the FRN. Stakeholders and members of the public engaged in an open discussion with the NRC staff.

In response to the FRN of August 9, 2011 (76 FR 48919), and the public meeting on August 30, 2011, the staff received written comments on the proposed revisions to the Policy.

Several stakeholders offered changes to the language in the Policy to assist the staff in clarifying the intent of the proposed revisions. The NRC also received comments from regulated industry stakeholders about the Agency’s policy on the use of enforcement discretion during construction. Based in part on the comments received from external stakeholders, the staff made appropriate changes to the proposed Policy. A summary of the public comments on the Policy and the staff’s responses to those comments are available in ADAMS under Accession No. ML11286A123.

In addition to the public comment period announced in the FRN, the NRC staff held public meetings to discuss other aspects of the Policy. The proposed revisions to the Policy reflect the insights gained by the staff from these meetings on topics related to construction activities.

Enforcement Discretion During Early Phases of Construction

As noted above, the Commission directed the staff to reevaluate portions of the Policy to determine under what conditions enforcement discretion can be used in cases involving the holder of a Limited Work Authorization (LWA) or Combined Operating License (COL). This direction stems from an issue during the early phases of construction work at the Vogtle Unit 3 site. In April 2010, the licensee informed the NRC that the excavating backfill used in seismic Category 1 applications came from areas other than those described in its approved site safety analysis report. The licensee's excavating operations and subsequent use of the backfill departed from the terms and conditions of the Vogtle early site permit (ESP) as well as its LWA. Although the NRC later determined that the violation was minor, the issue prompted industry representatives to again ask the NRC to allow notices of enforcement discretion (NOED), or to develop an NOED-like process, for use during construction. The staff notes that for the specific circumstances at Vogtle, an NOED-like process would not have been able to resolve the ESP and LWA departure issues.

As background, the existing NOED process is, in essence, a preemptive request by an operating power reactor licensee with an associated preemptive determination by the NRC to permit the licensee to exceed the technical specifications (TS) limiting conditions for operation (LCOs). For power reactor facilities, the current NOED process becomes applicable after an operations finding under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.57, "Issuance of Operating License," for those licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," or after a finding under 10 CFR 52.103(g), "Operation Under a Combined License," for those licensed under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," because these key licensing milestones determine the point when TS become effective. Additionally, the NOED policy, in its current form, is predicated on the expectation that public health and safety will be preserved with the granting of an NOED. NOEDs effectively allow the licensee to continue plant operations while attempting to restore compliance with NRC requirements.

However, because TS LCOs is not applicable to new reactors under construction, the existing NOED process is also not applicable.

The staff has identified three distinct periods during the construction process of power reactors. These periods are: (1) from the issuance of a construction permit pursuant to 10 CFR 50.50, "Issuance of Licenses and Construction Permits," but before the 10 CFR 50.57 operations finding, (2) from the issuance of a COL but before the 10 CFR 52.103(g) finding, and (3) after the issuance of an LWA. Inspection findings that typically lead to enforcement action during these periods are largely those findings associated with a licensee's failure to follow the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. Examples of such findings include: (1) a failure to identify or document (or both) a nonconforming condition (i.e., a condition that does not meet the licensee's current licensing basis) in the licensee's corrective action program, (2) a failure to follow written procedures, and (3) a failure to adequately perform a required test. Additionally,

licensees are at all times subject to enforcement action for violations involving deliberate misconduct, such as in cases involving employee discrimination.

The staff considered whether the development of an analogous NOED-like process had merit as a means of maintaining safety during these construction periods and for the findings described above while avoiding unnecessary regulatory burden. The staff determined that an NOED-like process would either not apply to these types of findings or would be of limited benefit. The staff's conclusion is based, in part, on factors such as the limited use of LWAs, the fact that prior approval from the NRC is not required in the circumstances described above, and issues during construction, in most cases, are within the licensee's control to correct. In fact, the staff and regulated industry representatives, to date, have been unable to identify plausible scenarios in which an NOED or NOED-like process would be appropriate during construction activities.

For the purpose of maintaining licensing basis configuration control and in order to avoid unnecessary construction delays related to changes during construction arising after the issuance of the COL, the staff is currently developing the Changes during Construction (CdC) process so that the change can be resolved in a timely and effective manner. The CdC process is an elective precursor to the license amendment review, established via license condition. This process does not apply to construction of non-reactor facilities. The staff believes the CdC process will provide an appropriate licensing-based change control process that will address the vast majority of issues identified during construction, by allowing licensees to effect changes in parallel with the staff's review of the acceptability of the change.

In summary, although the staff does not foresee a need for one at this time, the staff will consider developing a NOED-like process at a later time, if warranted and consistent with the conditions described above.

Recommended Revisions to the Policy

In accordance with the Commission's direction in Staff Requirements Memorandum (SRM)-SECY-09-0190, the staff has evaluated the construction aspects of the Policy and is recommending certain changes to address construction issues.

1. Proposed Changes to Clarify the Current Policy

The staff identified editorial changes that would clarify the implementation of the Policy for issues relating to construction. For example, the staff intends to improve consistency between the Policy and inspection procedure terminology by adding the word "construction," and related terms, to recognize that the NRC's authority to regulate includes the application to construct and the actual construction of facilities that will eventually operate under the NRC's regulations. The staff also intends to add a new Section 2.2.6, "Construction," to address when and how the NRC will assess violations during construction under traditional enforcement.

2. Proposed Revisions to Section 2.3.2, "Noncited Violation"

The staff recommends revising Section 2.3.2, "Noncited Violation," to be consistent with the results of its Policy review that led to the issuance of Enforcement Guidance Memorandum (EGM)-11-002, "Enforcement Discretion for Licensee-Identified Violations at Power Reactor Construction Sites Pursuant to Title 10 of the *Code of Federal Regulations* [10 CFR] Part 52,"

dated June 3, 2011 (ADAMS Accession No. ML11152A065). The staff intends on incorporating the EGM's language and guidance for exercising enforcement discretion when the staff dispositions Severity Level IV violations identified by licensees and applicants as NCVs at power reactors under construction.

3. Proposed Revisions to Policy Sections on Enforcement Discretion

The current Policy permits some flexibility for exercising enforcement discretion, and the staff believes that clarifying the Policy by expanding and, thus, amplifying the discussion to include certain construction issues is more appropriate. Therefore, the staff is proposing to add new Section 3.9, "Violations Involving Certain Construction Issues." For fuel cycle facilities under construction under 10 CFR Part 40, "Domestic Licensing of Source Material," or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and reactors under construction under 10 CFR Part 50 or 10 CFR Part 52, the proposed policy states that the NRC "may choose to exercise discretion...based on the general enforcement discretion guidance," and clarifies the Policy's flexibilities in those cases. In addition, for new reactors being constructed under 10 CFR Part 52, the staff proposes to allow enforcement discretion for unplanned changes to the current licensing basis when: (1) the licensee identified the unplanned change, (2) the licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or the licensee submits information to the NRC stating that it will restore the current licensing basis, and (3) either (a) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (b) the licensee placed the cause of the unplanned change in its corrective action program to ensure the application of comprehensive corrective actions to address the cause of the change and preclude recurrence.

RECOMMENDATIONS:

The NRC staff recommends that the Commission take the following two actions:

- (1) Approve the revised Policy ([Enclosure 1](#)) for publication in the FRN.
- (2) Approve the revised Policy FRN ([Enclosure 2](#)).

COORDINATION:

The Office of the General Counsel has no legal objection to the Policy revision.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. [Revised \(Redline-Strikeout\) Enforcement Policy](#)
2. [Draft Federal Register Notice](#)
3. [Revised Policy Changes Roadmap](#)

NRC Enforcement Policy

_____, 2011

U. S. Nuclear Regulatory Commission
Office of Enforcement
Washington, DC 20555-00



Enclosure 1

NRC ENFORCEMENT POLICY

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1.0 Introduction

The mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.

The following are some of the activities the NRC performs as part of its mission:

- a. establishing requirements and guidance addressing the possession and use of source, byproduct, and special nuclear material
- b. licensing applicants to use source, byproduct, and special nuclear material, and **construct and** operate licensed facilities in accordance with NRC requirements and specific license conditions
- c. promoting the transparency and openness of the NRC's enforcement program for all stakeholders

Oversight of licensed activities ensures that licensees are complying with NRC requirements and license conditions. Enforcement is an important part of the NRC's oversight activities.

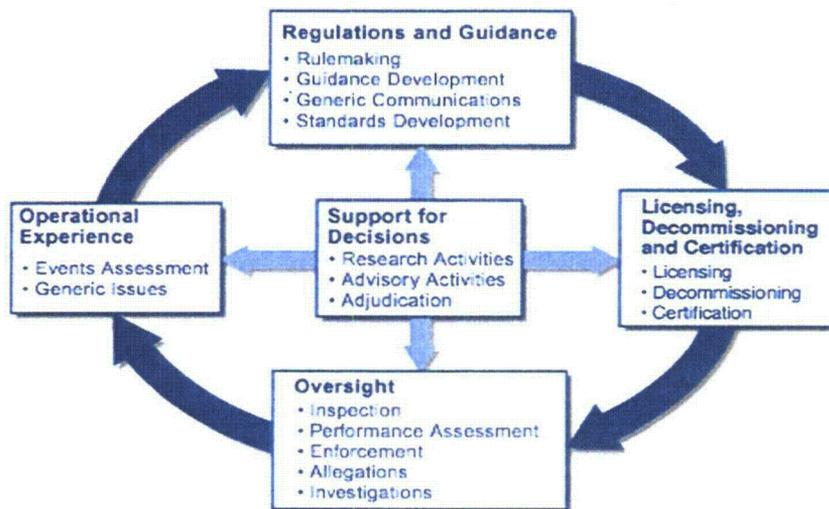


Figure 1. How the NRC Regulates

1.1 Purpose

The NRC Enforcement Policy supports the NRC's mission to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. Compliance with NRC requirements, including regulations, technical specifications, license conditions, and Orders, provides reasonable assurance to the NRC and the public that safety and security are being maintained. The application of this Policy ensures that associated enforcement actions properly reflect the safety or security significance of such violations. Consistent with this objective, the Enforcement Policy endeavors to do the following:

- a. Deter noncompliance by emphasizing the importance of compliance with NRC requirements.
- b. Encourage prompt identification and prompt comprehensive correction of violations of NRC requirements.

1.2 Applicability

The Enforcement Policy applies to all NRC licensees and applicants, to various categories of nonlicensees, and to individual employees of licensed and nonlicensed entities involved in NRC-regulated activities. These include, but are not limited to the following:

- a. organizations and individuals holding NRC licenses
- b. license applicants
- c. contractors and subcontractors to NRC licensees
- d. holders of and applicants for various NRC approvals, including, but not limited to:
 1. NRC certificates of compliance
 2. early site permits
 3. standard design certifications
 4. quality assurance (QA) program approvals
 5. certifications
 6. limited work authorizations
 7. construction authorizations
 8. other permits and forms of NRC approval
- e. vendors supplying safety-related components to NRC licensees
- f. employees of any of the above

Not all NRC requirements apply to all of the categories listed above; however, the Agency will use the Enforcement Policy, as appropriate, to address violations of NRC requirements.

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may

cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.

The NRC may use the term "licensee" in this Policy to generally refer not only to licensees, but also to certificate holders and applicants.

1.3 Statutory Authority

The NRC derives its principal authority to license and regulate the civilian use of nuclear materials from two statutes: (1) the Atomic Energy Act (AEA) of 1954, as amended, which provides broad authority to license and regulate the civilian use of nuclear materials, and (2) the Energy Reorganization Act (ERA) of 1974, as amended, which established the Agency and its major offices. The Administrative Dispute Resolution Act of 1996 (ADRA), 5 U.S.C. §§ 571-584, provides the statutory framework for the Federal Government to use alternative dispute resolution (ADR).

1.4 Regulatory Framework

The NRC's enforcement program is governed by its regulations. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," describes the formal procedures that the NRC uses to implement its enforcement authority.

1.5 Adequate Protection Standard

Adequate protection of the public health and safety and assurance of the common defense and security and protection of the environment are the fundamental regulatory objectives. Compliance with NRC requirements plays a critical role in giving the NRC confidence that safety and security are being maintained. While adequate protection is presumptively assured by compliance with NRC requirements, circumstances may arise where new information reveals that an unforeseen hazard or security issue/event exists or that a substantially greater potential exists for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety, and to ensure security of materials.

The NRC also has the authority to exercise discretion to permit continued operations—despite the existence of a noncompliance—where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When noncompliance with NRC requirements occurs, the NRC must evaluate the degree of risk posed by that noncompliance to determine whether immediate action is required. If the NRC determines that the noncompliance itself is of such safety significance that adequate protection is no longer provided, or that the noncompliance was caused by a failure of licensee controls so significant that it calls into question the licensee's ability to ensure adequate

protection, the NRC may demand immediate action, up to and including a shutdown or Identification of Violations

The enforcement process begins with the identification of violations, either through NRC inspections or investigations, or through a licensee report, or by substantiation of an allegation.

All violations are subject to consideration for civil enforcement action; some violations may also be considered for criminal prosecution by the U.S. Department of Justice. After a potential violation is identified, it is assessed in accordance with this Policy. The NRC's enforcement assessment process is fact driven, performance based, and, when appropriate and possible, risk informed. The NRC reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level appropriate to the safety significance of the particular violation.

2.2 Assessment of Violations

After a violation is identified, the NRC assesses its significance or severity. Severity levels are assigned to violations processed under traditional enforcement. The severity level assigned to the violation generally reflects the assessment of the significance of a violation, and is referred to as traditional enforcement. For most violations committed by operating power reactor licensees, the significance of a violation is assessed using the significance determination process (SDP) under the Reactor Oversight Process (ROP), as discussed below in Section 2.2.3, "Operating Reactor Assessment Program." All other violations will be assessed using traditional enforcement as described in Section 2.2.4, "Exceptions to Using Only the Operating Reactor Assessment Program." Power reactor facilities under construction, independent spent fuel storage installations (ISFSI), and nuclear materials facilities are not subject to the SDP and, thus, traditional enforcement will be used for these facilities.

2.2.1 Factors Affecting Assessment of Violations

In determining the appropriate enforcement response to a violation, the NRC considers the four specific factors discussed below. Whenever possible, the NRC uses risk information in assessing the safety significance 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.

- a. Whether the violation resulted in actual safety or security consequences. In evaluating actual consequences, the NRC considers issues such as whether the violation resulted in the onsite or offsite releases of radiation, onsite or offsite radiation exposures, **onsite or offsite chemical hazard exposures resulting from licensed or certified activities**, accidental criticality, core damage, loss of significant safety barriers, loss of control of radioactive material or radiological emergencies, or whether the security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an act of radiological sabotage occurred.
- b. Whether the violation had potential safety or security consequences. In evaluating potential consequences, the NRC considers whether the violation created a credible

2. any violation during an actual General Emergency that prevents offsite response organizations from implementing protective actions, under their emergency plans, to protect the public health or safety
 3. violations resulting in substantial releases of radioactive material
- b. violations that may impact the ability of the NRC to perform its regulatory oversight function
 - c. violations involving willfulness
 - d. violations of NRC requirements for which there are no associated SDP performance deficiencies (e.g., a violation of TS which is not a performance deficiency.) These violations are normally dispositioned using discretion, similar to that described in Section 3.2 of this Policy.

2.2.5 Export and Import of NRC-Regulated Radioactive Material and Equipment

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).

Section 2.2.6 Construction

In accordance with 10 CFR 50.10, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under 10 CFR Part 50, a combined license under 10 CFR Part 52, an early site permit authorizing the activities under 10 CFR 50.10(d), or a limited work authorization under 10 CFR 50.10(d). In an effort to preclude unnecessary regulatory burden, while maintaining safety, the Changes during Construction (CdC) Process, as developed in Interim Staff Guidance (ISG)- 025, permits the licensee to proceed with the installation and testing of structures, systems or components different from the current licensing basis while the license amendment request (LAR) is under NRC review. Any activities undertaken under the CdC process are at the risk of the licensee, and the licensee is obligated to return to the current licensing basis (CLB) if the related LAR is subsequently not approved by the NRC. Failure to timely restore the CLB may be subject to separate enforcement, such as an order, a civil penalty, or both.

In accordance with 10 CFR 70.23(a)(7) and 10 CFR 40.32(e), commencement of construction before the NRC finishes its environmental review and issues a license for processing and fuel fabrication, conversion of uranium hexafluoride, or uranium enrichment facility construction and operation is grounds for denial to possess and use licensed material in the plant or facility. Additionally, in accordance with

10 CFR 70.23(b), failure to obtain Commission approval for the construction of the principal structures, systems, and components of a plutonium processing and fuel fabrication plant before the commencement of construction may also be grounds for denial of a license to possess and use special nuclear material.

2.3 Disposition of Violations

This section describes the various ways that the NRC can disposition violations.

2.3.1 Minor Violation

Violations of minor safety or security concern generally do not warrant enforcement action or documentation in inspection reports but must be corrected. Examples of minor violations can be found in the NRC 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 the NRC 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."

2.3.2 Noncited Violation

Severity Level IV violations and violations associated with green ROP findings (**for operating reactors**) are normally dispositioned as noncited violations (NCVs). Inspection reports or inspection records document NCVs and briefly describe the corrective action the licensee has taken or plans to take, if known. Licensees are not required to provide written responses to NCVs; however, they may provide a written response if they disagree with the NRC's description of the NCV and/or dispute the validity of the NCV. Typically, all of the **criteria in either 2.3.2.a or b.**~~following criteria~~ must be met for the disposition of a violation as an NCV.:

For all SL IV violations identified by the NRC at fuel cycle facilities (under construction or in operation) in accordance with 10 CFR Part 70 or 10 CFR Part 40 and reactors under construction in accordance with 10 CFR Part 50 or 10 CFR Part 52, before the NRC determines that an adequate corrective action program has been implemented, the NRC normally issues a Notice of Violation. Until the determination that an adequate corrective action program has been implemented, NCVs may be issued for SL IV violations if the NRC has determined that the applicable criteria in 2.3.2.b. below are met. For reactor licensees, after the NRC determines that an adequate corrective action program has been implemented, the NRC will normally issue an NCV in lieu of an SL IV violation, whether that violation is identified by the licensee or the NRC.

a. Power Reactor Licensees

1. The licensee must place the violation into a corrective action program to **restore**

compliance and address recurrence.⁴

2. The licensee must restore compliance within a reasonable period of time (i.e., in a timeframe commensurate with the significance of the violation) after a violation is identified.
3. The violation must either not be repetitive² as a result of inadequate corrective action, or, if repetitive, the repetitive violation must not have been identified by the NRC. This criterion does not apply to violations associated with green ROP findings. ~~and violations associated with facility construction under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."~~
4. The violation was not willful. Notwithstanding willfulness, an NCV may still be appropriate in the following circumstances:
 - (a) The licensee identified the violation and promptly provided the information concerning the violation, if not required to be reported, to appropriate NRC personnel, such as a resident inspector or regional branch chief.
 - (b) The violation involved the acts of an individual in a low-level position within the licensee's organization (and not a licensee official as defined in Section 2.2.1, "Factors Affecting Assessment of Violations").
 - (c) The violation appears to be the isolated action of the employee without management involvement, and 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.
 - (d) The licensee took significant remedial action commensurate with the circumstances. This action demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's organization.

The approval of the Director, OE, is required for dispositioning willful violations as NCVs.

b. All Other Licensees

⁴ ~~For reactor facilities under construction in accordance with 10 CFR Part 52, the corrective action program must have been demonstrated to be adequate.~~

² 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.

entrusted to MMLs, the NRC may use discretion to increase a civil penalty by multiples of the normal base civil penalty. This increase would normally be applied in cases where a programmatic failure occurred in the MML's oversight program.

3.7 Exercise of Discretion to Issue Orders

The NRC may exercise discretion, where necessary or desirable, by issuing Orders with or in lieu of civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations.

3.8 Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants³

The NRC may choose not to enforce the applicable technical specification (TS) limiting condition for operation (LCO) or other license conditions, in circumstances where compliance would involve an unnecessary plant transient or the performance of a test, inspection, or system realignment that may not be the most prudent action to take under the specific plant conditions, or unnecessary delays in plant startup, without a corresponding health and safety benefit. Similarly, for example, for a gaseous diffusion plant, circumstances may arise where compliance with a technical safety requirement or TS 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.

The NRC will issue a notice of enforcement discretion (NOED) only if the staff is clearly satisfied that the action is consistent with protecting the public health and safety or security. The NRC 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. The staff shall inform the Commission expeditiously following the granting of a NOED in these situations.

Issuance of an 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. In each case where the NRC has chosen to issue an NOED, enforcement action will normally be taken for the root causes, to the extent violations were involved, that led to the noncompliance for which enforcement discretion was used.

Additional guidance on the process for issuing an NOED is found on the NRC's web site.

³ "NOEDs will not be used at reactors during construction before the Commission's 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy."

3.9 Violations Involving Certain Construction Issues

a. Fuel Cycle Facilities

The NRC may choose to exercise discretion for fuel cycle facilities under construction (construction is defined in 10 CFR 40.4 for source material licensees and in 10 CFR 70.4 for special nuclear material licensees) based on the general enforcement discretion guidance contained in Section 3 of this Enforcement Policy.

b. LWA Holders

The NRC may exercise discretion for LWA holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy.

c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction⁴ and that would otherwise require prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

- The licensee identifies unplanned changes implemented during construction not previously approved by the NRC that the staff would otherwise disposition as a Severity Level IV violation of NRC requirements⁵.
- The licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or submits information to the NRC stating that it will restore the current licensing basis.
- Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the cause of the unplanned change in its corrective action program to ensure comprehensive corrective actions to address the cause of the change to preclude recurrence.

For similar issues not identified by the licensee, the NRC may refrain from issuing an NOV/NCV on a case-by-case basis depending upon the circumstances of the issue, such as whether the

⁴ The NRC may issue enforcement action for the cause of these unplanned changes, such as a failure to implement appropriate work controls or quality control measures, or a failure to adhere to procedures, processes, instructions, or standards that implement NRC requirements. This enforcement may be appropriate for the actions that led to the CdC issue.

⁵ NRC-identified violations that result in a "use as built" determination or that result in an unplanned change (or both) will normally be dispositioned as a cited or noncited violation, whether or not the unplanned change issue is resolved by a subsequently approved license amendment.

requirements were clearly understood or should have been understood at the time, the cause of the issue, and why the licensee did not identify the issue.

In all such cases when a licensee determines that an unplanned change during construction associated with a violation of requirements meets the outlined criteria above and makes timely submittal of the necessary information for NRC evaluation, the licensee's continued failure to meet the current licensing basis will not be treated as a willful or continuing violation while the NRC reviews the submittal. (Note: If the NRC subsequently denies a requested license amendment change, or if the NRC requires additional measures to be taken for the change to be considered acceptable, then a separate NOV or order may be issued to ensure appropriate corrective actions are taken, including restoring the configuration to the CLB).

4.0 ENFORCEMENT ACTIONS INVOLVING INDIVIDUALS

Any individual may be subject to NRC enforcement action if the individual (1) deliberately causes or would have caused, if not detected, a licensee to be in violation of any regulation or Order, or any term, condition, or limitation of any license issued by the Commission related to NRC-licensed activities or (2) deliberately submits materially inaccurate or incomplete information to the NRC, a licensee, an applicant or a licensee, or a contractor or subcontractor of a licensee or applicant for a license (e.g., see "Deliberate Misconduct" regulations in 10 CFR 30.10, 10 CFR 50.5, 10 CFR 52.4, and 10 CFR 76.10).

The Agency will normally take enforcement actions against nonlicensed individuals only in cases involving deliberate misconduct by the nonlicensed individual, in cases involving a lack of reasonable assurance, as discussed below in Section 4.2, "Notices of Violation and Orders to Individuals," 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). However, the NRC may take enforcement action against NRC-licensed reactor operators⁶ even if the violation does not involve deliberate misconduct, since operators licensed by the NRC are subject to all applicable Commission requirements (see 10 CFR 55.53(d)).

The NRC considers enforcement actions against individuals to be significant actions that will be closely evaluated and judiciously applied. Typically, the Agency will take an enforcement action involving an individual, either licensed or nonlicensed, only when the violation has actual or potential safety or security significance. NOVs and Orders are examples of enforcement actions that may be issued to individuals. Enforcement actions issued to individuals will normally be placed on the NRC OE Web site. Generally, before taking enforcement action against an individual, the NRC will seek to gather information to determine whether an Order or other enforcement action should be issued. The Agency may gather such information by conducting a PEC, by requesting a written response from the individual, or by issuing a DFI. If the violation was deliberate, the individual may also be provided the opportunity to address the apparent violation during ADR. The exact nature of the opportunity to address the apparent violation will depend on the circumstances of the case, including the significance of the issue, the enforcement sanction the NRC is contemplating, and whether the individual has already had

⁶ As used in this Policy, the term "licensed reactor operator" includes NRC licensed reactor operators (ROs) and NRC licensed senior reactor operators (SROs).

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," enforcement actions and licensees' responses are normally made publicly available for inspection. However, some security-related information will not be made available to the public. The NRC Office of Public Affairs is responsible for making final decisions as to whether press releases will be issued; however, such releases are normally issued for Orders and civil penalties at the same time that the Order or proposed imposition of the civil penalty is issued. Press releases may also be issued when a civil penalty is withdrawn or substantially mitigated. Press releases are not normally issued for NOV's that are not accompanied by Orders or proposed civil penalties, unless the issue or licensee involved is of some particular interest.

6.0 VIOLATION EXAMPLES

The violation examples in this Policy are intentionally broad in scope so as to serve as a set of guiding examples that are neither exhaustive nor controlling for making severity level determinations. Licensed activities are placed in the most appropriate activity area in light of the particular violation involved, including activities not directly covered by one of the listed areas (e.g., import and export license activities). The violation examples are not intended to address every possible circumstance. However, when an enforcement case scenario very nearly achieves all or some of the criteria set forth in an example, the case should be considered to be at the severity level of that example. For example, when using the examples in Section 6.7, "Health Physics", if the circumstances of a case are such that one or more of the severity levels in an example were very nearly reached, and it was only fortuitous that the limit was not actually met and/or exceeded, then the severity level for the subject example would be applicable. Additionally, if the circumstances for a case do not squarely fit any particular violation example, a comparable example in the same activity area may be considered to determine the severity (e.g., the case for an industrial licensee presents a set of circumstances and considerations comparable to those for a medical example provided in Section 6.3, "Materials Operations"; hence, the severity level for the medical example can be applied).

Many examples are written to reflect the risks associated with the use of nuclear materials. However, violations during construction generally occur before the nuclear material and its associated risk are present. Therefore, the NRC will consider the lower risk significance of violations that occur during construction in the areas of emergency preparedness, reactor operator licensing, and security and may reduce the severity level for those violations from that indicated by the examples in those areas. In order to maintain consistent application, the staff must coordinate with the Office of Enforcement before applying this lower risk significance concept for violations that occur during construction.

6.1 Reactor Operations

a. *Severity Level I* violations involve, for example:

subcontractor of a licensee or applicant for a license or (2) provides materially inaccurate or incomplete information to a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license.

Demand for Information (DFI), as defined in 10 CFR 2.204, requires a licensee or other person subject to the jurisdiction of the Commission to respond with specific information for the purpose of enabling the NRC to determine whether an Order should be issued or whether other action should be taken.

Discrimination, as described in 10 CFR 10 CFR 50.7 (or similar provisions in 10 CFR Parts 30, 40, 52, 60, 61, 63, 70, 71, 72, and 76), is the taking of an adverse action against an employee because the employee engaged in certain protected activities.

Escalated Enforcement Actions include Severity Level I, II, and III NOVs; NOVs associated with an inspection finding that the SDP evaluates as having low to moderate (white) or greater safety significance; civil penalties; NOVs to individuals; Orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities; and Orders issued to impose civil penalties.

Event, as used in this Policy, means (1) an occurrence 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. For example, an equipment failure discovered through a spill of liquid, a loud noise, the failure of a system to respond properly, or an annunciator alarm would be considered an event; a system discovered to be inoperable through a document review would not. Similarly, if a licensee discovers, 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 disclose an overexposure, the issue would be considered an event.

Fuel Cycle is the series of steps involved in supplying fuel for nuclear power reactors. It can include mining, milling, isotopic enrichment, fabrication of fuel elements, use in a reactor, chemical reprocessing to recover the fissionable material remaining in the spent fuel, reenrichment of the fuel material, refabrication into new fuel elements, and waste disposal.

Impacts the NRC's Ability To Perform Its Regulatory Function refers to a situation that prevents the NRC from using appropriate regulatory tools to address a noncompliance because the Agency is unaware that the noncompliance exists (e.g., provision of inaccurate and incomplete information or failure to submit a required report).

License Applicant, as used in this statement of policy, means any person who submits an application for review.

Licensee means a person or entity authorized to conduct activities under a license issued by the Commission. **However, in most cases in the Policy the term is applied broadly to refer to any or all of entities listed in Section 1.2, "Applicability."**

NUCLEAR REGULATORY COMMISSION

[NRC-2011-XXXX]

NRC Enforcement Policy Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy revision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) is publishing revisions to its Enforcement Policy (Enforcement Policy or Policy) to address construction-related topics, including enforcement discretion.

DATES: This revision is effective on [INSERT DATE OF PUBLICATION].

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry

into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this final rule can be found at <http://www.regulations.gov> by searching on Docket ID **NRC-20XX-XXXX**. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov

FOR FURTHER INFORMATION CONTACT: Carolyn Faria, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by telephone at 301-415-4050 or by e-mail to carolyn.faria-ocasio@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

In SRM-SECY-09-0190, "Staff Requirements—SECY-09-0190—Major Revision to NRC Enforcement Policy," dated August 27, 2010 (ADAMS Accession No. ML102390327), the Commission approved a revision to its Enforcement Policy (Policy). The NRC published a notice in the *Federal Register* on September 30, 2010 (75 FR 60485), announcing a revision to the Policy. The Commission also directed the NRC staff to reevaluate the portions of the Policy associated with construction activities (e.g., reactor or uranium enrichment plants), including under what conditions enforcement discretion could be applied to cases involving the holder of a limited work authorization (LWA) or combined license (COL). In a *Federal Register* notice (FRN) published on August 9, 2011 (76 FR 48919), the NRC solicited written comments from interested parties, including public interest groups, States, members of the public, and the regulated industry (i.e., reactor and materials licensees, vendors, and contractors) on

construction-related topics that the NRC staff was evaluating for discussion in a Commission paper that would include recommended revisions to the NRC Enforcement Policy. On August 30, 2011, the NRC conducted a public meeting to discuss the proposed changes to the Policy. The meeting consisted of a detailed presentation of the changes as published in the FRN, and members of the public who attended the meeting received the opportunity to have an open discussion with the NRC staff.

In response to the FRN dated August 9, 2011 (76 FR 48919), and the public meeting on August 30, 2011, the staff received written comments on the proposed Policy revisions. Several stakeholders offered changes to the language in the Enforcement Policy to assist the staff in clarifying the intent of the proposed revisions. The NRC also received comments from regulated industry stakeholders about the agency's policy on the use of enforcement discretion during construction. Based in part on the comments received from external stakeholders, the staff has made changes to the Policy language where it deemed it appropriate to do so. A summary of the public comments on the proposed Policy and the staff's responses to those comments is available in ADAMS under Accession No. ML11286A123.

Summary of Revisions to the Enforcement Policy

The following sections describe the changes to the Enforcement Policy. These sections also provide background information on those topics evaluated by the staff.

1. Revision to Section 1.0, "Introduction"

Added the phrase "**construct and**" to Item b to recognize that the NRC's regulatory authority includes applications for, and the actual construction of, facilities that will eventually operate under NRC regulations.

2. Revision to Section 1.2, "Applicability"

Added the following two paragraphs to clarify that the Enforcement Policy applies to license holders, applicants, holders of construction authorizations, and certificate holders:

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.

The NRC may use the term “licensee” in this Policy to generally refer not only to licensees, but also to certificate holders and applicants.

3. Revision to Section 2.2.1.a, “Factors Affecting Assessment of Violations”

Added the phrase “***onsite or offsite chemical hazard exposures resulting from licensed or certified activities***” as the third criterion when evaluating actual consequences for uniformity. The inclusion of “onsite and offsite chemical hazard exposures” is consistent with the current Policy, including the examples provided in Section 6.2, “Fuel Cycle Operations.” The first example in Section 6.2 involves a high-consequence event, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, “Domestic Licensing of Special Nuclear Material.” In particular, 10 CFR 70.61, “Performance Requirements,” defines “high consequence” to include, among other things, acute chemical exposure.

4. New Section 2.2.6, “Construction”

Add a new section, as follows:

Section 2.2.6 Construction

In accordance with 10 CFR 50.10, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a

construction permit under 10 CFR Part 50, a combined license under 10 CFR Part 52, an early site permit authorizing the activities under 10 CFR 50.10(d), or a limited work authorization under 10 CFR 50.10(d). In an effort to preclude unnecessary regulatory burden, while maintaining safety, the Changes during Construction (CdC) Process, as developed in Interim Staff Guidance (ISG)- 025, permits the licensee to proceed with the installation and testing of structures, systems or components different from the current licensing basis while the license amendment request (LAR) is under NRC review. Any activities undertaken under the CdC process are at the risk of the licensee, and the licensee is obligated to return to the current licensing basis (CLB) if the related LAR is subsequently not approved by the NRC. Failure to timely restore the CLB may be subject to separate enforcement, such as an order, a civil penalty, or both.

In accordance with 10 CFR 70.23(a)(7) and 10 CFR 40.32(e), commencement of construction before the NRC finishes its environmental review and issues a license for processing and fuel fabrication, conversion of uranium hexafluoride, or uranium enrichment facility construction and operation is grounds for denial to possess and use licensed material in the plant or facility. Additionally, in accordance with 10 CFR 70.23(b), failure to obtain Commission approval for the construction of the principal structures, systems, and components of a plutonium processing and fuel fabrication plant before the commencement of construction may also be grounds for denial of a license to possess and use special nuclear material.

This language addresses when and how the assessment of violations during construction occurs; it parallels the information provided for the assessment of violations for operating reactors.

5. Revisions to Section 2.3.2, “Noncited Violation”

Added the words “**(for operating reactors)**” to the first sentence of the first paragraph to clarify the use of the Reactor Oversight Process. Modified the last sentence of the first paragraph to read: “**Typically, all of the criteria in either 2.3.2.a. or b. must be met for the disposition of a violation as an NCV.**”

Added a new second paragraph to be consistent with Enforcement Guidance Memorandum (EGM)-11-002, “Enforcement Discretion for Licensee-Identified Violations at Power Reactor Construction Sites Pursuant to Title 10 of *the Code of Federal Regulations* Part 52,” dated June 3, 2011 (ADAMS Accession No. ML11152A065):

For all SL IV violations identified by the NRC at fuel cycle facilities (under construction or in operation) in accordance with 10 CFR Part 70 or 10 CFR Part 40 and reactors under construction in accordance with 10 CFR Part 50 or 10 CFR Part 52, before the NRC determines that an adequate corrective action program has been implemented, the NRC normally issues a Notice of Violation. Until the determination that an adequate corrective action program has been implemented, NCVs may be issued for SL IV violations if the NRC has determined that the applicable criteria in 2.3.2.b. below are met. For reactor licensees, after the NRC determines that an adequate corrective action program has been implemented, the NRC will normally issue an NCV in lieu of an SL IV violation, whether that violation is identified by the licensee or the NRC.

The purpose of this EGM is to clarify the guidance for exercising enforcement discretion when the staff dispositions, as noncited violations (NCVs), Severity Level (SL) IV violations identified by licensees or applicants at power reactors that are under construction. The addition of this language also reflects current practices for dispositioning NCVs at fuel facilities (under construction or in operation).

6. Revisions to Section 2.3.2.a, “Power Reactor Licensees”

Added the phrase “**restore compliance and**” to criterion 1 to more accurately reflect NRC expectations.

Deleted the current footnote, “**For reactor facilities under construction in accordance with 10 CFR Part 52, the corrective action program must have been demonstrated to be adequate,**” from criterion 1 to consistently communicate to Policy users the Policy’s intent.

Deleted the phrase “**and violations associated with facility construction under 10 CFR Part 50, ‘Domestic Licensing of Production and Utilization Facilities,’ and 10 CFR Part 52, ‘Licenses, Certifications, and Approvals for Nuclear Power Plants’**” from criterion 3 to reflect the NRC’s expectation of crediting corrective action programs at operating reactors to address both immediate corrective actions and any actions to preclude recurrence.

7. Revisions to Section 3.8, “Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants”

Added a footnote to clarify that the notice of enforcement discretion (NOED) process is not applicable while reactor facilities are under construction:

NOEDs will not be used at reactors during construction before the Commission’s 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking

enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy.

The NRC has not identified any plausible scenarios where risk to public health and safety (or security) would be exacerbated by the failure of the NRC to grant such a licensee, or permit holder, an NOED.

8. New Section 3.9, "Violations Involving Certain Construction Issues"

Added a new section to incorporate new construction activities with traditional enforcement discretion. The new section also acknowledges that the staff is developing a CdC process that will work in conjunction with the license amendment review process. The new process is intended to permit licensees to proceed at risk with certain construction activities that differ from the licensing basis while the NRC is evaluating the related license amendment request.

3.9 Violations Involving Certain Construction Issues

a. Fuel Cycle Facilities

The NRC may choose to exercise discretion for fuel cycle facilities under construction (construction is defined in 10 CFR 40.4 for source material licensees and in 10 CFR 70.4 for special nuclear material licensees) based on the general enforcement discretion guidance contained in Section 3 of this Enforcement Policy.

b. LWA Holders

The NRC may exercise discretion for LWA holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy.

c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction and that would otherwise require prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

- The licensee identifies unplanned changes implemented during construction not previously approved by the NRC that the staff would otherwise disposition as a Severity Level IV violation of NRC requirements.***
- The licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or submits information to the NRC stating that it will restore the current licensing basis (CLB).***
- Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the cause of the unplanned change in its corrective action program to ensure comprehensive corrective actions to address the cause of the change to preclude recurrence.***

For similar issues not identified by the licensee, the NRC may refrain from issuing an NOV/NCV on a case-by-case basis depending upon the circumstances of the issue, such as whether the requirements were clearly

understood or should have been understood at the time, the cause of the issue, and why the licensee did not identify the issue.

In all such cases when a licensee determines that an unplanned change during construction associated with a violation of requirements meets the criteria outlined above and makes timely submittal of the necessary information for NRC evaluation, the licensee's continued failure to meet the current licensing basis will not be treated as a willful or continuing violation while the NRC reviews the submittal. (Note: If the NRC subsequently denies a requested license amendment change, or if the NRC requires additional measures to be taken for the change to be considered acceptable, then a separate NOV or order may be issued to ensure appropriate corrective actions are taken, including restoring the configuration to the CLB).

Added two footnotes relating to the new Section 3.9:

The NRC may issue enforcement action for the cause of these unplanned changes, such as a failure to implement appropriate work controls or quality control measures, or a failure to adhere to procedures, processes, instructions, or standards that implement NRC requirements. This enforcement may be appropriate for the actions that led to the CdC issue.

and

NRC-identified violations that result in a "use as built" determination or that result in an unplanned change (or both) will normally be dispositioned as a cited or noncited violation, whether or not the unplanned change issue is resolved by a subsequently approved license amendment.

9. Revisions to Section 6.0, “Violation Examples”

Added a second paragraph to the introduction of the section:

Many examples are written to reflect the risks associated with the use of nuclear materials. However, violations during construction generally occur before the nuclear material and its associated risk are present. Therefore, the NRC will consider the lower risk significance of violations that occur during construction in the areas of emergency preparedness, reactor operator licensing, and security and may reduce the severity level for those violations from that indicated by the examples in those areas. In order to maintain consistent application, the staff must coordinate with the Office of Enforcement before applying this lower risk significance concept for violations that occur during construction.

The staff recognizes that, although certain requirements (i.e., those for emergency preparedness, reactor operator licensing, and security) apply generally during construction activities, flexibility is needed to factor in the lower risk associated with certain violations that occur during construction.

10. Revisions to Section 7.0, “Glossary”

Revised the glossary definition of “licensee” to reflect the addition of language to Section 1.2, “Applicability”:

“Licensee” means a person or entity authorized to conduct activities under a license issued by the Commission. However, in most cases in the Policy, the term is applied broadly to refer to any or all of entities listed in Section 1.2, “Applicability.”

Procedural Requirements

Paperwork Reduction Act Statement

This policy statement contains and references new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval numbers 3150-0136.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid OMB control number.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

For the Nuclear Regulatory Commission.

Dated at Rockville, MD, this XX day of XXXX

Roy P. Zimmerman, Director,
Office of Enforcement

DESCRIPTION OF CHANGES—ENFORCEMENT POLICY

COMPARISON OF DRAFT REVISION OF ENFORCEMENT POLICY TO THE CURRENT (SEPTEMBER 2010) VERSION

ENFORCEMENT POLICY

<u>Section</u>	<u>Change Summary</u>
Contents	Added references to new Sections 2.2.6, “Construction,” and 3.9, “Violations Involving Certain Construction Issues.”
1.0	Added the phrase “ <i>construct and</i> ” to Item b to recognize that the NRC’s regulatory authority includes applications for, and the actual construction of, facilities that will eventually operate under NRC regulations.
1.2	Added the following two paragraphs to clarify that the Enforcement Policy applies to license holders, applicants, holders of construction authorizations, and certificate holders: <p style="text-align: center;"><i>It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.</i></p> <p style="text-align: center;"><i>The NRC may use the term “licensee” in this Policy to generally refer not only to licensees, but also to certificate holders and applicants.</i></p>
2.2.1.a	Added the phrase “ <i>onsite or offsite chemical hazard exposures resulting from licensed or certified activities</i> ” as the third criterion when evaluating actual consequences for uniformity. The inclusion of “onsite and offsite chemical hazard exposures” is consistent with the current Policy, including the examples provided in Section 6.2, “Fuel Cycle Operations.” The first example in Section 6.2 involves a high-consequence event, as defined in Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 70, “Domestic Licensing of Special Nuclear Material.” In particular, 10 CFR 70.61, “Performance Requirements,” defines “high consequence” to include, among other things, acute chemical exposure.

2.2.6 Added a new Section 2.2.6, "Construction:"

Section 2.2.6 Construction

In accordance with 10 CFR 50.10, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under 10 CFR Part 50, a combined license under 10 CFR Part 52, an early site permit authorizing the activities under 10 CFR 50.10(d), or a limited work authorization under 10 CFR 50.10(d). In an effort to preclude unnecessary regulatory burden, while maintaining safety, the Changes during Construction (CdC) Process, as developed in Interim Staff Guidance (ISG)- 025, permits the licensee to proceed with the installation and testing of structures, systems or components different from the current licensing basis while the license amendment request (LAR) is under NRC review. Any activities undertaken under the CdC process are at the risk of the licensee, and the licensee is obligated to return to the current licensing basis (CLB) if the related LAR is subsequently not approved by the NRC. Failure to timely restore the CLB may be subject to separate enforcement, such as an order, a civil penalty, or both.

In accordance with 10 CFR 70.23(a)(7) and 10 CFR 40.32(e), commencement of construction before the NRC finishes its environmental review and issues a license for processing and fuel fabrication, conversion of uranium hexafluoride, or uranium enrichment facility construction and operation is grounds for denial to possess and use licensed material in the plant or facility. Additionally, in accordance with 10 CFR 70.23(b), failure to obtain Commission approval for the construction of the principal structures, systems, and components of a plutonium processing and fuel fabrication plant before the commencement of construction may also be grounds for denial of a license to possess and use special nuclear material.

This language addresses when and how the assessment of violations during construction occurs; it parallels the information provided for the assessment of violations for operating reactors.

2.3.2 Added the words "(for operating reactors)" to the first sentence of the first paragraph to clarify the use of the Reactor Oversight Process. Modified the last sentence of the first paragraph to read: "Typically, all of the criteria in either 2.3.2.a or b. must be met for the disposition of a violation as an NCV."

Added a new second paragraph to be consistent with Enforcement Guidance Memorandum (EGM)-11-002, "Enforcement Discretion for Licensee-Identified

Violations at Power Reactor Construction Sites Pursuant to Title 10 of the *Code of Federal Regulations* Part 52,” dated June 3, 2011 (ADAMS Accession No. ML11152A065):

For all SL IV violations identified by the NRC at fuel cycle facilities (under construction or in operation) in accordance with 10 CFR Part 70 or 10 CFR Part 40 and reactors under construction in accordance with 10 CFR Part 50 or 10 CFR Part 52, before the NRC determines that an adequate corrective action program has been implemented, the NRC normally issues a Notice of Violation. Until the determination that an adequate corrective action program has been implemented, NCVs may be issued for SL IV violations if the NRC has determined that the applicable criteria in 2.3.2.b. below are met. For reactor licensees, after the NRC determines that an adequate corrective action program has been implemented, the NRC will normally issue an NCV in lieu of an SL IV violation, whether that violation is identified by the licensee or the NRC.

The purpose of this EGM is to clarify the guidance for exercising enforcement discretion when the staff dispositions, as noncited violations (NCVs), Severity Level (SL) IV violations identified by licensees or applicants at power reactors that are under construction. The addition of this language also reflects current practices for dispositioning NCVs at fuel facilities (under construction or in operation).

2.3.2.a Added the phrase “*restore compliance and*” to criterion 1 to more accurately reflect NRC expectations.

Deleted the current footnote, “*For reactor facilities under construction in accordance with 10 CFR Part 52, the corrective action program must have been demonstrated to be adequate,*” from criterion 1 to consistently communicate to Policy users the Policy’s intent.

Deleted the phrase “*and violations associated with facility construction under 10 CFR Part 50, ‘Domestic Licensing of Production and Utilization Facilities,’ and 10 CFR Part 52, ‘Licenses, Certifications, and Approvals for Nuclear Power Plants’*” from criterion 3 to reflect the NRC’s expectation of crediting corrective action programs at operating reactors to address both immediate corrective actions and any actions to preclude recurrence.

3.8 Added a footnote to clarify that the notice of enforcement discretion (NOED) process is not applicable while reactor facilities are under construction:

NOEDs will not be used at reactors during construction before the Commission’s 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise

discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy.

The NRC has not identified any plausible scenarios where risk to public health and safety (or security) would be exacerbated by the failure of the NRC to grant such a licensee or permit holder an NOED.

- 3.9 Added a new Section 3.9, "Violations Involving Certain Construction Issues," to incorporate new construction activities with traditional enforcement discretion. The new section also acknowledges that the staff is developing a CdC process that will work in conjunction with the license amendment review process. The new process is intended to permit licensees to proceed at risk with certain construction activities that differ from the licensing basis while the NRC is evaluating the related license amendment request.

3.9 Violations Involving Certain Construction Issues

a. Fuel Cycle Facilities

The NRC may choose to exercise discretion for fuel cycle facilities under construction (construction is defined in 10 CFR 40.4 for source material licensees and in 10 CFR 70.4 for special nuclear material licensees) based on the general enforcement discretion guidance contained in Section 3 of this Enforcement Policy.

b. LWA Holders

The NRC may exercise discretion for LWA holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy.

c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction and that would otherwise require prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

- The licensee identifies unplanned changes implemented during construction not previously approved by the NRC*

that the staff would otherwise disposition as a Severity Level IV violation of NRC requirements.

- *The licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or submits information to the NRC stating that it will restore the current licensing basis (CLB).*
- *Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the cause of the unplanned change in its corrective action program to ensure comprehensive corrective actions to address the cause of the change to preclude recurrence.*

For similar issues not identified by the licensee, the NRC may refrain from issuing an NOV/NCV on a case-by-case basis depending upon the circumstances of the issue, such as whether the requirements were clearly understood or should have been understood at the time, the cause of the issue, and why the licensee did not identify the issue.

In all such cases when a licensee determines that an unplanned change during construction associated with a violation of requirements meets the criteria outlined above and makes timely submittal of the necessary information for NRC evaluation, the licensee's continued failure to meet the current licensing basis will not be treated as a willful or continuing violation while the NRC reviews the submittal. (Note: If the NRC subsequently denies a requested license amendment change, or if the NRC requires additional measures to be taken for the change to be considered acceptable, then a separate NOV or order may be issued to ensure appropriate corrective actions are taken, including restoring the configuration to the CLB).

Added two footnotes relating to new the Section 3.9:

The NRC may issue enforcement action for the cause of these unplanned changes, such as a failure to implement appropriate work controls or quality control measures, or a failure to adhere to procedures, processes, instructions, or standards that implement NRC requirements. This enforcement may be appropriate for the actions that led to the CdC issue.

and

NRC-identified violations that result in a “use as built” determination or that result in an unplanned change (or both) will normally be dispositioned as a cited or noncited violation, whether or not the unplanned change issue is resolved by a subsequently approved license amendment.

6.0 Added a second paragraph to the introduction of the section:

Many examples are written to reflect the risks associated with the use of nuclear materials. However, violations during construction generally occur before the nuclear material and its associated risk are present. Therefore, the NRC will consider the lower risk significance of violations that occur during construction in the areas of emergency preparedness, reactor operator licensing, and security and may reduce the severity level for those violations from that indicated by the examples in those areas. In order to maintain consistent application, the staff must coordinate with the Office of Enforcement before applying this lower risk significance concept for violations that occur during construction.”

The staff recognizes that, although certain requirements (i.e., those for emergency preparedness, reactor operator licensing, and security) apply generally during construction activities, flexibility is needed to factor in the lower risk associated with certain violations that occur during construction.

7.0 Revised the glossary definition of “licensee” to reflect the addition of language to Section 1.2, “Applicability”:

*“**Licensee**” means a person or entity authorized to conduct activities under a license issued by the Commission. However, in most cases in the Policy, the term is applied broadly to refer to any or all of entities listed in Section 1.2, “Applicability.”*

Analysis of Comments Received on Proposed Changes to Enforcement Policy

The period for submitting public comments on proposed changes to the U.S. Nuclear Regulatory Commission's (NRC's) Enforcement Policy (Policy) expired on September 8, 2011 (76 FR 48919). A summary of the issues raised by the stakeholders, followed by the NRC's responses to the comments, is provided below.

1. Comment Summary: One commenter recommended adding text as a new last paragraph to Section 1.1, "Purpose," to address the current staff actions to broaden the use of the Reactor Oversight Process into other major areas such as fuel facility operations and construction activities of both power reactors and fuel and enrichment facility licensees. (For additional information, see Agencywide Documents Access and Management System (ADAMS) Accession No. ML11242A113.)

Response: The NRC disagrees with the suggested change. The suggested additional language describes certain programs under development and goes beyond discussing the overall purpose of the NRC's Enforcement Policy.

2. Comment Summary: One commenter recommended including the additional underlined text in the first paragraph being added to Section 1.2, "Applicability" (see ADAMS Accession No. ML112370041):

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees **when conducting activities under the license, certificate, or application**, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.

Response: The NRC staff disagrees that the additional language will further clarify when enforcement is appropriate for licensees, certificate holders, and applicants. The Policy currently allows for the staff to address how to disposition enforcement actions against the various entities on a case-by-case basis.

3. Comment Summary: A commenter referenced a discussion that took place during the public meeting on August 30, 2011, about the proposed changes to Section 1.2 of the Policy. Although the commenter did not propose any specific changes to the Policy, the commenter urged the NRC to consider providing additional guidance on how the staff determines whether or not a licensee, vendor, or both is cited for violations of NRC requirements. In addition, the commenter urged the NRC staff to consider whether, in a situation where the licensee has properly executed its oversight responsibilities and the contractor or vendor has acceptable programs in place, yet compliance with those programs is not met, the licensee should be subject to enforcement action since the licensee does not have direct control of compliance with contractor or vendor programs. The commenter further opined that it "seems fairer and more appropriate that the contractor or vendor—not the licensee—receive the enforcement action, assuming the licensee has fully exercised its responsibilities." (See ADAMS Accession No. ML11256A012.)

Response: The NRC discussed the need to provide additional guidance on the issuance of violations against licensees, vendors, or both. The staff concluded that the Policy, as revised, provides sufficient latitude to take action against licensees and applicants, various categories of non-licensees, and individual employees of licensed and non-licensed entities involved in NRC-

regulated activities. Going forward, the staff will consider providing additional guidance in the Enforcement Manual in coordination with the NRC program offices responsible for vendor inspection programs.

4. Comment Summary: A commenter recommended that the staff withdraw proposed changes to Section 2.2.1.a, “Factors Affecting Assessment of Violations”; specifically, the staff should delete the proposed wording “onsite and offsite chemical hazard exposures resulting from licensed or certified activities as a factor.” The commenter believes that including this wording would broaden the scope of Section 2.2.1.a without any clear rationale or supporting basis, and that the wording is unrelated to construction. The commenter suggested that the NRC consider resubmitting the wording at a later date when the technical and legal bases could be better understood. (See ADAMS Accession No. ML11256A012.)

Response: Although the NRC agrees that this language may be considered unrelated to construction, this proposed revision to the will include it. The incorporation of “onsite and offsite chemical hazard exposures” is consistent with current Policy, including the examples provided in Section 6.2, “Fuel Cycle Operations.” In fact, the first example involves a high-consequence event, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, “Domestic Licensing of Special Nuclear Material.” The regulation at 10 CFR 70.61, “Performance Requirements,” defines “high consequence” to include, among other things, acute chemical exposure. Therefore, the proposed change is not attempting to impose a new requirement or a new interpretation of an existing requirement; rather, it is intending to clarify current Policy, as written.

5. Comment Summary: One commenter recommended adding the following language at the end of the first paragraph of Section 2.2.6, “Construction”:

Failure to timely restore the CLB [current licensing basis] may be subject to separate enforcement, such as an order, a civil penalty, or both.

The commenter stated that the additional language would enhance public confidence that the NRC will take appropriate action as necessary to ensure the integrity of the licensing process. (See ADAMS Accession No. ML11242A113.)

Response: The NRC agrees with the recommendation to add language relating to the timely restoration of the CLB.

6. Comment Summary: A commenter recommended that the NRC simplify the use of noncited violations (NCVs) by minimizing the staff effort to determine, before dispositioning violations, the acceptability of licensee corrective actions for issues of very low safety or security significance, as well as by minimizing the staff effort in dispositioning willful violations of very low significance not caused by licensee officials. The commenter recommended replacing the entire guidance provided in Section 2.3.2, “Non-Cited Violation,” with the following (see ADAMS Accession No. ML11242A113):

The NRC will typically issue NCVs for all violations that are determined to be of SL [Severity Level] IV severity or associated with a finding that is of no greater than green significance. The NRC may issue a Notice of Violation for a SL IV violation if the issue also involves a willful act by a licensee official, and the resultant action is not otherwise considered for escalated enforcement for the licensee, or the individual, or both. Particularly poor licensee performance, such

as indicated by weak or ineffective corrective actions for very low severity/significance issues should be addressed through other means provided in the NRC inspection or assessment processes in lieu of issuing cited NOVs [notices of violation].

Response: Although the NRC staff agrees with the commenter's intent to simplify the guidance in the Enforcement Policy, it disagrees with the recommended changes. The NRC believes that other staff efforts initiated to address Item 1.f of SRM-SECY-09-0190, "Staff Requirements—SECY-09-0190—Major Revision to NRC Enforcement Policy," dated August 27, 2010, will generate further changes to this section of the Policy and will likely result in the intended simplification of this section of the Policy. In addition, the staff believes that this proposal would remove an incentive for licensees to identify violations early (a specific goal of the NRC's Enforcement Policy). Also, it would substantially reduce the staff's ability to provide a graded enforcement response involving issues associated with a failure to correct the violation and repetitiveness would be reduced substantially. This is a particular challenge in the case of nonreactor licensees.

7. Comment Summary: Based on discussions held during the public meeting on August 30, 2011, a regulated industry stakeholder recommended alternative language on how the NRC will normally issue an NCV in lieu of an SL IV violation identified by either the licensee or the NRC. The commenter suggested that the latter part of the proposed second paragraph of Section 2.3.2 read as follows (see ADAMS Accession No. ML11256A012):

Until the determination that an adequate corrective action program has been implemented, NCVs may be issued for licensee/applicant-identified SL IV violations if the NRC has determined that the applicable criteria in 2.3.2.b. below are met. For reactor licensees, after the NRC determines that an adequate corrective action program has been implemented, the NRC will normally issue an NCV in lieu of a SL IV violation whether that violation is identified by the licensee or NRC.

Response: The staff agrees with this comment and has made the recommended changes to the proposed revision of the Policy.

8. Comment Summary: One commenter noted that the NRC is developing a Changes during Construction (CdC) process for combined license (COL) holders and agreed that the CdC process is expected to address the vast majority of situations during construction that might have otherwise necessitated a process similar to that of notices of enforcement discretion (NOEDs). Because the effectiveness and flexibility of the CdC process have not been demonstrated, and because neither the industry nor the NRC staff can foresee all the complexities associated with building a plant while maintaining compliance with a license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," the commenter urged the NRC staff to remain open to reconsidering the need for an NOED-like process during construction based on experience from the lead 10 CFR Part 52 projects. (See ADAMS Accession No. ML11256A012.)

The commenter further suggested changes to the proposed footnote in Section 3.8, Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants, for greater clarity when reading this section in isolation:

NOEDs will not be used at reactors during construction before the Commission's 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy.

Response: The NRC acknowledges the commenter's statement that the CdC process is not yet in place, and that the effectiveness and flexibility of the process have not been demonstrated. The staff will remain open to consider the establishment of an NOED-like policy, if warranted; however, neither the staff nor the industry has identified a scenario where an NOED-like process is necessary.

The NRC staff also agrees with the suggested changes to the footnote and has incorporated them.

9. Comment Summary: One commenter expressed concerns that the proposed changes to the Policy do not appear to extend the CdC concept to the fuel cycle industry. The commenter also expressed disappointment in the progress of discussions between the NRC and the fuel cycle licensees and applicants on this subject. The commenter reiterated that the NRC's approach to CdC could raise significant policy issues and that the approach should be fully vetted with the fuel cycle industry.

Moreover, the commenter is concerned with the proposed language in new Section 2.2.6 on the failure of an applicant to obtain Commission approval for construction activities at plutonium processing and fuel fabrication plants and the possible denial of a license to possess and use special nuclear material. Specifically, the commenter is concerned that the NRC's "ultimate intent is to include other fuel cycle applicants (and licensees who are constructing while operating), such as uranium enrichment facilities, in this language." (See ADAMS Accession No. ML11256A011.)

Response: After the NRC finalizes interim staff guidance on the CdC process (ISG-25), it will consider whether similar guidance is appropriate for facilities under construction under 10 CFR Part 40, "Domestic Licensing of Source Material," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." As a result, the NRC may revise existing guidance or develop specific CdC guidance for fuel cycle facilities. In considering the applicability of the CdC, or a similar process, to fuel cycle facilities and in developing associated guidance, the NRC would appropriately engage representatives of the fuel cycle industry and other interested stakeholders.

10. Comment Summary: One commenter stated that the proposed new Section 3.9, "Violations Involving Certain Construction Issues," specifies that the NRC's general enforcement discretion guidance is applicable to fuel cycle facilities and holders of limited work authorizations (LWA) and noted that the general enforcement discretion guidance is also applicable to COL holders. The commenter recommended that the revised Policy clearly reflect the COL holder's option to restore the current licensing basis in addition to the option to request a change to the licensing basis. The commenter provided suggested changes (underlined here) to the language to clarify the proposed new Section 3.9 (see ADAMS Accession No. ML11256A012.):

c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction **without and that would otherwise require** prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

- The licensee identifies **unplanned** changes implemented during construction not previously approved by the NRC that the staff would otherwise disposition as a Severity Level IV violation of NRC requirements,
- The licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, **or submits information to the NRC stating that it will restore the current licensing basis,** and
- Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the **cause of the unplanned** change in its corrective action program to ensure comprehensive corrective actions to address **the cause of the change to prevent** recurrence.

Response: The NRC staff agrees with this comment and has made the recommended changes.

11. Comment Summary: An industry stakeholder stated that it was coordinating its response with the Nuclear Energy Institute (NEI) about the proposed changes to the Enforcement Policy and has provided input for the industry comments.

Response: The NRC understands that NEI's submittal incorporated the stakeholder's comments.