Done in Washington, DC, this 14th day of June 2000.

Richard L. Dunkle,

Acting Administrator, Animal and Plant Health Inspection Service.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AG22

Elimination of the Requirement for Noncombustible Fire Barrier Penetration Seal Materials and Other Minor Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its fire protection regulations to remove the requirement that fire barrier penetration seal materials be noncombustible, and to make other minor changes. The final rule removes a requirement that has a negligible contribution to safety and includes editorial changes designed to meet the intent of the Presidential memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing.''

EFFECTIVE DATE: July 20, 2000.

FOR FURTHER INFORMATION CONTACT: Daniele Oudinot, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–3731; e-mail DHO@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC conducted a technical assessment of fire barrier penetration seals. The NRC documented the results of its assessment in SECY–96–146, ''Technical Assessment of Fire Barrier Penetration Seals in Nuclear Power Plants,'' July 1, 1996; in NUREG–1552, ''Fire Barrier Penetration Seals in Nuclear Power Plants,'' July 1996; and in NUREG–1552, Supplement 1, January 1999. On the basis of its findings, the NRC concluded that the noncombustibility criterion for penetration seal materials that is specified in the NRC fire protection regulation and review guidance had a negligible contribution to safety, and recommended that this noncombustibility criterion be deleted. Copies of NUREG–1552 and NUREG–1552, Supplement 1, may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy of each document is also available for inspection and/or copying at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. NUREG–1552, Supplement 1, is also available through the Technical Reports area of the NRC Reference Library accessed through the NRC Website: http://www.nrc.gov/NRC/NUREGS/index.html.

II. Analysis of Public Comments and Staff Response

The proposed rule was published for public comment in the **Federal Register** on August 18, 1999 (64 FR 44860). The comment period ended on November 1, 1999. The NRC received eight comment letters. Six commenters supported the proposed amendment; two commenters objected to the changes. This section discusses the comments received, how the NRC staff was able to incorporate some comments into the final rule and, if not, why a comment was not accepted. This section addresses all comments, but specific commenters are not identified.

A commenter suggested that footnote 1 to Section I, ''Introduction and Scope,'' of Appendix R to 10 CFR Part 50, be deleted because its wording is identical to footnote 4 to § 50. 48(b). This commenter stated that the basis for deleting footnote 4 to § 50.48 also applies to footnote 1 to Section I of Appendix R. The NRC agrees with this comment and footnote 1 to Section I of Appendix R is deleted.

One of the commenters who endorsed the proposed rule stated that, in particular, (1) There are no reports of fire that have challenged the ability of fire-rated penetration seals to confine a fire; (2) numerous fire endurance tests have confirmed the fire-resistive capabilities of the penetration seal materials, designs, and configurations installed in nuclear power plants; and (3) if penetration seals are properly designed, installed, and maintained, there is reasonable assurance that they will provide the fire-resistive integrity of the fire barriers in which they are installed, and confine a fire to its area of origin.

A commenter objected to the rule change, but did not identify any specific technical or safety information for NRC staff consideration. Therefore, the comment did not result in changes to the rule.

One commenter provided multiple comments in opposition to the proposed rule. Each of these comments are discussed below. None of the comments resulted in any changes from the proposed rule.

1. *Comment.* The non-combustibility requirement for fire seals is key in providing a high level of confidence in the operability determination for a fire seal.

Response. The Commission disagrees. 10 CFR Part 50, Appendix A, General Design Criteria (GDC), Criterion 3—Fire Protection states: ''Noncombustible and heat resistant materials shall be used wherever practical throughout the unit. * * *'' Thus, the Commission's most fundamental requirements with respect to fire protection do not mandate the exclusive use of noncombustible materials. The Commission's implementing requirements on fire protection in 10 CFR 50.48 and 10 CFR Part 50, Appendix R, require the use of fire barriers that meet 1-hour or 3-hour fire ratings; while the current regulation requires the use of noncombustible materials it is also clear that the 1-hour and 3-hour ratings can be achieved with the use of properly tested, rated and qualified material that is ''combustible.'' Penetration seals used as a part of the rated fire barrier assembly are required to meet the acceptance criteria of Nationally Recognized Testing Standards that are specifically designed to test these components. Examples of these standards include American Society for Testing and Materials (ASTM) E–814, ''Standard Test Method for Fire Tests of Through-Penetration Fire Stops,'' and Institute of Electrical and Electronics Engineers (IEEE) 634, ''Standard Cable Penetration Fire Stop Qualification Test.'' These nationally recognized testing standards do not require the penetration seal material to be noncombustible, but rather focus on the penetration seals ability to prevent flame travel through the opening and limit the heat transfer through the penetration seal assembly by measuring the cold-side temperature. As such, ''noncombustibility,'' as defined in ASTM–136, ''Standard Test Method for Behavior of Materials in a Vertical Tube Furnace at 750 °C,'' is not a necessary requirement for an adequate fire barrier or a penetration seal that is part of this barrier. Penetration seal assemblies, when properly tested, qualified, and installed, meet this requirement as a fire (heat) resistant material. In fire protection engineering design, this can be thought of as analogous to the National Fire Protection Association (NFPA) Life Safety Code, NFPA 101,

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which allows certain wooden doors to be used as 20-minute fire protection-rated doors. (See NFPA 101, Section 6–2.3.2.3.2.) The NFPA Code recognizes that even though the wooden door assembly is unquestionably combustible, as long as that fire door assembly can provide the required level of protection (20 minutes in this example) the wooden door assembly is acceptable. In sum, the current Appendix R requirement for noncombustible fire barrier penetration seals is not an inherent part of the NRC's overall regulatory approach on fire protection, and is not necessary to provide reasonable assurance of adequate protection against fire spread in nuclear power plants.

2. *Comment.* The NRC has not analyzed the risk associated with the use of combustible fire seal material as it provides a fuel supported pathway or "wick" for flame and hot gas to burn through wall penetrations into adjacent fire zones that contain vital safety systems, structures or components.

Response. As discussed in NUREG–1552 and its supplement, the NRC has evaluated fire barrier penetration seals and concluded that properly tested, configured, installed, and maintained penetration seal assemblies will not provide a fuel supported pathway or "wick" for flame and hot gas to burn through wall penetrations. Hundreds of fire endurance qualification tests have been performed by materials manufacturers, installation contractors, test laboratories, research organizations, licensees, and others. These qualification tests involved a wide variety of penetration seal designs and materials, in configurations which are found at nuclear power plants, including the actual cables that run through the fire barrier penetration seal. These tests also maximize the fire severity by subjecting the penetration seals to a rapidly rising temperature in a relatively small and confined space. Note that with few exceptions, nuclear power plant fire loads are not great enough to produce a fire approaching the severity of the Standard Time/Temperature test curve. In the unlikely event that a large fire exposes a qualified combustible or noncombustible penetration seal to high temperatures for an extended period of time, the seal will perform as rated. For the case of a silicone-based material, the silicone will ablate by design and be replaced with char or ash. The silicone foam material is sacrificial by design in preserving the integrity of the fire barrier. This sacrificial behavior and charing has been observed during full-scale qualification fire endurance tests of a wide variety of silicone-based penetration seal configurations. Other combustible penetration seal materials have also been qualified. For example, Minnesota Mining and Manufacturing Company (3M) has over 25 years of experience with combustible penetration seal designs using their intumescent materials (caulks, putty, wrap strips, and composite sheets). The intumescent material swells when heated, which causes the seal to expand and protect the penetration. Underwriters Laboratories, Inc. (UL), has qualified dozens of combustible penetration seal designs and lists and classifies these designs in a full volume of their Fire Resistance Directory (Volume 2). The NRC concludes that these tests have demonstrated that combustible, limited combustible or noncombustible penetration seals can provide the necessary fire resistance and provide reasonable assurance that a fire will not spread from one side of the fire barrier to the other side of the barrier within the 1- or 3-hour time period required by the NRC.

3. *Comment.* The NRC's technical assessment does not offer any evaluation or analysis regarding the contribution to severe accident risk evolving from a quick burn-through of fire seals resulting from the use of combustible penetration sealant material and other generic problems widely experienced with the Dow Corning product.

Response. As stated above, a large body of fire test results have proven the capabilities and effectiveness of penetration seals in maintaining the fire-resistive integrity of the barriers in which they are installed, typically for 1 or 3 hours, which precludes a quick burn-through scenario, *i.e.,* if the penetration seal assembly has passed the testing criteria to be rated, it could not experience a "quick burn-through". Further, the nature of combustible penetration seal materials and the limited air supply in penetration seals preclude a "quick burn-through," and an analysis of the contribution to severe accident risk evolving from a quick burn-through of fire seals resulting from the use of combustible penetration sealant material is not relevant. For instance, silicone-based penetration seal materials are relatively difficult to ignite and ablate slowly at a rate of about 3 inches per hour when exposed to the Standard Time/Temperature fire curve of ASTM E–119.

Fire barrier penetration seals are not considered in the assessment of postulated fire scenarios that are the major contributors to core damage for most plants, because the major contributors are those in which the redundant divisions of post-fire safe-shutdown components and systems are located in the fire affected area. Scenarios involving the spread of fire from one area of a plant to another and evolving to core damage (scenarios that could potentially involve penetration seals) are also of low frequency. It is the NRC's judgment that considering the probability of failure of a plant's passive fire barrier penetration seals would not significantly alter the overall contribution of fire risk to the plant's total calculated core damage frequency.

4. *Comment.* Given the combustibility of the silicone material, the industry has also widely documented improperly installed seals (less than sufficient sealant material, varying size voids created by problematic installation procedures and cracks). By providing for the acceptance of combustible penetration seals, the NRC is reducing the level of defense-in-depth without fully analyzing the risks associated with accelerated burn-through of seals from the combination of these widely documented factors.

Response. The NRC disagrees with the commenter's implication that there are widespread and numerous instances of improperly-installed silicone fire barrier seals. First, while plant-specific deficiencies of fire barrier penetration seals have been and will likely continue to be found, they have been isolated and not tied to any installation problems generic to this material. Installation deficiencies that have been identified to date have been or are in the process of being corrected by licensees.

Second, the NRC disagrees with the commenter's apparent argument that combustible fire seals that meet the NRC's 1- and 3-hour fire rating significantly decreases the safety of a nuclear power plant as compared to fire seals which are "noncombustible" as defined by ASTM E–136. Fire seals are one passive sub-component of fire protection provided by the defense-in-depth concept, the others being fire prevention, detection, suppression and plant-design features. As discussed in the response to Comment 2, the NRC also believes that it is highly unlikely that fire barriers in a nuclear power plant would be exposed to fires of sufficient temperature and duration such that the silicone fire seals that fail before their rated 1- or 3-hours. Thus, consideration of the probability of failure of properly-qualified penetration seals that meet the NRC's requirements for 1- or 3-hour protection would not significantly alter the overall contribution of fire risk to the plant's total calculated core damage frequency.

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Finally, the practical benefits of the silicone-based penetration seal materials (*e.g.,* easy installation, compatibility around safety-related cables, and reasonable cost) far outweigh concerns regarding material combustibility. Thus, the NRC concludes that properly qualified fire barriers will provide reasonable assurance of adequate protection to public health and safety.

5. *Comment.* The NRC does not offer any analysis and evaluation of how a combustible penetration sealant could also harbor a fire as it moves through a penetration seal. The fire could leave a protective barrier of insulating ash in its trail making it difficult to identify, locate and extinguish. Accordingly, it is inappropriate to move forward with this rule change without analysis on the quick burn-through of seals under the above stated conditions.

Response. A properly designed, tested, and installed penetration seal will maintain the fire resistive integrity of the wall/ceiling/floor assembly in which it is installed. During this time, automatic and/or manual fire suppression activities will be used to control and extinguish the fire. After the fire is extinguished, standard fire fighting procedures would require that the fire brigade perform the ''overhaul'' firefighting function of ensuring all combustibles have been extinguished. During this firefighting, if the fire brigade were to identify ash or swelled material in a penetration seal, procedures would require that the fire brigade take appropriate action either to identify whether the seal is continuing to combust (by removal), or to promptly implement extinguishing activities. This is a standard firefighting operation to check for any possible fire extension. Therefore, the NRC concludes that it is not inordinately difficult to identify and extinguish fires in combustible fire barrier penetration seals.

6. *Comment.* The basic premise of the NRC rule change fails to address industry experience in properly bounding fire tests for the myriad of fire seal configurations deployed throughout nuclear power stations. In one case, the licensee improperly used a single test to bound 2000 fire barrier penetration seals in many different fire seal configurations. This omission does not lend to the credibility of the agency's argument. Such evidence documents improperly tested seal configurations.

Response. The Browns Ferry fire of March 22, 1975, demonstrated the weakness in penetration seals to the nuclear and general building industry. After the fire, specific testing methods were developed by nationally recognized testing organizations to test and qualify penetration seals. The American Society for Testing and Materials (ASTM) first issued their standard E–814, ''Standard Test Method for Fire Tests of Through-Penetration Fire Stops,'' in 1981. The Institute of Electrical and Electronics Engineers (IEEE) first issued their standard IEEE 634, ''Standard Cable Penetration Fire Stop Qualification Test,'' in 1978. In regard to the commenter's assertions regarding ''a single test to bound 2000 fire barrier penetration seals * * *,'' the first penetration seal fire tests were often used to bound numerous configurations. This issue of bounding fire tests was addressed in Information Notice (IN) 88–04, ''Inadequate qualification and documentation of fire barrier penetration seals,'' dated February 5, 1988. Since that time, decades of experience with the test standards by the nuclear and general building industries have provided adequate assurance that such standards are appropriate for qualifying fire barrier penetration seals. Hundreds of qualification-type fire endurance tests of a wide variety of penetration seal designs and materials have been performed by material manufacturers, installation contractors, test laboratories, research organizations, licensee, and others. Underwriters Laboratories, Inc. (UL) alone publishes a complete volume of Listed and Classified rated through-penetration fire stop systems. Additionally, the NRC staff has observed fire endurance tests of fire barrier penetration seals, and reviewed fire test reports during licensing reviews and inspections. On the basis of these eyewitness accounts and reviews, the NRC staff has concluded that fire endurance tests have established the fire-resistive capabilities of numerous penetration seal materials, designs, and configurations as installed in the nuclear power plants. The NRC staff provided guidance on the bounding of plant-installed configurations with tested configurations in Generic Letter 86–10, ''Implementation of Fire Protection Requirements,'' dated April 24, 1986. Subsequently, the industry used this guidance in inspecting plant designs. As licensees identified potential penetration seal issues, the staff informed the industry through numerous INs, including: (1) IN 88–04, and Supplement 1, dated August 9, 1988; (2) IN 88–56, ''Potential Problems with Silicone Foam Fire Barrier Penetration Seals,'' dated August 4, 1988; (3) IN 94–28, ''Potential Problems with Fire-Barrier Penetration Seals,'' dated April 5, 1994; and (4) IN 97–70, ''Potential Problems with Fire Barrier Penetration Seals,'' dated September 19, 1997. These potential problems were brought forward by licensee inspections and NRC staff observed weaknesses discovered during some of its inspections.

7. *Comment.* The basic premise of the NRC rule change fails to take into account ongoing industry-wide discovery of insufficient material fill, large voids and cracking in seals as the result of the problematic installation of the silicone foam penetration seal material in the field. In numerous cases, licensees have reported universal fire seal installation problems involving the silicone foam material. Such evidence documents improperly installed silicone-based penetration seals. The NRC also fails to take into account that licensees are using the same problematic material to replace inoperable fire seals. Given these recurring and what appears to be ongoing failures, the NRC does not offer any method for determining how it is achieving properly tested, configured, installed and maintained silicone-based penetration seals. Given the apparent lack of reasonable assurance that fire barrier seals are adequately inspected to determine that they have been properly tested, configured, installed and maintained, it is inappropriate to reduce the fire protection standard by removing the non-combustibility standard. Similarly, it is inappropriate to maintain a policy of enforcement discretion for the same noncombustibility standard.

Response. The NRC disagrees with the commenter's implicit argument that historical problems with installation of silicone fire barrier penetration seals have not been rectified, and, as a result, the Appendix R non-combustibility requirement should be retained.

The NRC disagrees with the commenter's assertion that improper installation and maintenance of fire barrier penetration seals is a reasonable basis for retaining the current noncombustibility requirement. First, proper installation of fire barrier penetration seals is necessary in order for the seals to perform their intended safety function, regardless of whether the seals are made of combustible or noncombustible materials. Licensees must have appropriate procedures for installation of Appendix R-required fire barrier penetration seals and implement corrective action if improperly installed seals are discovered, regardless of the combustibility of the fire barrier penetration seal material. Thus, while improperly installed fire barrier penetration seals raise valid concerns with respect to their functionality, these concerns are not relevant to the issue of

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the need for a noncombustibility requirement.

Second, the NRC disagrees with the commenter's implicit argument that there are widespread problems with the installation, inspection, and maintenance of fire barrier penetration seals that remain uncorrected. While there have been historical problems with the installation of silicone fire barrier penetration seals, the NRC has taken a series of regulatory actions in response to instances of improper fire barrier penetration seal installation. These actions include the issuance of the information notices discussed above to alert nuclear power plant licensees of potential problems with silicone fire barrier penetration seal installation and inspection, changes to the NRC resident inspector inspection program to include fire barrier penetration seals as part of the NRC's inspection program, and continued NRC review and oversight of licensees' corrective actions. The NRC has confirmed that licensees have taken appropriate action to identify and correct improperly installed silicone-based fire barrier penetration's seals, as discussed in NUREG–1522 and its supplement. Based upon NRC inspections and audits, the NRC believes that licensees and vendors understand the fire-resistive capabilities and limitations of the penetration seal materials, and that existing licensee and vendor seal installation programs are adequate to prevent potential penetration seal installation problems. Potential penetration seal problems are understood; industry standards are available and licensees are complying with them. In regard to installation, maintenance, and in-service inspection, the NRC's comprehensive reassessment of fire barrier penetration seals included the review of procedures, specifications, and training programs for installation, surveillance, maintenance, and repair of penetration seals at both nuclear power plants and the facilities where seals are manufactured. Overall, the NRC concluded that licensees and vendors are aware of the importance of proper design, installation, surveillance, maintenance, and repair of penetration seals, including training of installers and inspectors. Therefore, based on inspections and review of the licensees' corrective action programs, the NRC concludes that historical problems with the installation of silicone-based fire barrier penetration seals have been corrected. Many plants include fire barrier penetration seals that are required by Appendix R in their Maintenance Rule's requirements program (10 CFR 50.65). This requires monitoring of the performance or condition of relevant structures, systems and components (SSCs) unless there is a continuing basis for concluding that the performance or condition of the SSCs is being effectively controlled. This provides additional regulatory assurance that fire barrier penetration seals are being properly installed, inspected, and maintained. For these reasons, the NRC concludes that historical problems with fire barrier penetration seal installation and inspection does not provide an appropriate basis for retaining the current noncombustibility requirement in Appendix R.

8. *Comment.* Visual industry reliance upon walk-downs of fire barrier penetration seals installed in walls, ceilings and floors, in many cases behind a series of obstacles, is not sufficient in determining the reliability and operability of a silicone foam fire barrier penetration seal. Non-destructive examination of installed seals (*e.g.,* ultrasound techniques) can provide a greater measure of confidence in determining if a seal has been properly installed.

Response. The NRC believes that existing inspection techniques developed by the manufacturers of silicone fire barrier penetration seals for evaluating the adequacy of installation of seals are adequate. The vendor requirements for physical parameters for the installation of seals include attributes such as density of the mixed material, cell structure, texture, and color. These are the same parameters used in the construction of the penetration seals for testing and, as such, ensure that the seals installed in the plant are representative of those qualified during testing. The installed penetration seals are passive fire barriers and remain unchanged after proper installation. The commenter did not provide any credible information showing that the manufacturer-developed installation inspection methodology (which may include visual examinations) is inadequate to detect improper installation. In the absence of such information, the NRC does not believe that any consideration should be given to requiring non-destructive examination, which is outside of the scope of the rule change. When the NRC discovers a problem with penetration seals, such as can occur in the area of surveillances, the NRC alerts licensees and advises them to evaluate whether the potential problem exists at their plants. Licensees typically evaluate this information for applicability to their plants as a part of their Nuclear Experience Review Program and take corrective actions when necessary. For example, fire penetration seal surveillance problems were discussed in IN 88–56 which examines in detail visual inspection information regarding voids, gaps, and splits in the material.

9. *Comment.* Because of the evidence of recurring non-compliance with testing, configuration, installation and maintenance, retaining and enforcing the non-combustibility standard is an essential component in establishing confidence in fire barrier penetration seal operability at nuclear power stations.

Response. As discussed above, the NRC does not agree that there are recurring, generic problems with fire barrier penetration seal qualification, configuration and installation throughout the nuclear power plant industry. The NRC believes that the proper amount of attention is being provided by licensees and will be provided for in the future. Additionally, to prevent any possible deficiencies in the penetration seal program, the NRC will continue to provide regulatory oversight.

10. *Comment.* In making the claim that combustible materials are already used in nuclear power stations, NRC attempts to circumlocate (sic.) the significant safety issue on how combustible cable jacketing installed through a penetration surrounded in a combustible fire barrier material with additional documented problems can contribute to an accelerated burn through thus failing as a rated fire barrier.

Response. As discussed in the response to Comment 2, the fire endurance tests for qualifying fire barrier penetration seals were conducted using the cable which would be used in the actual plant configurations. Thus, the contribution of the cable jacketing to combustion of the fire barrier penetration seal was an inherent part of the fire endurance qualification tests.

11. *Comment.* NRC provides no reference to what degree staff and Commission went to arrive at the determination that no technical argument exists for the fire barrier penetration seals non-combustible materials requirement.

Response. The primary documents reviewed by the NRC in attempting to identify the basis for the current noncombustibility requirement were the statements of consideration for the proposed and final Fire Protection rules, May 29, 1980; 45 FR 36082, and November 19, 1980; 45 FR 76608 and the Commission papers that led to these proposed and final rules. The primary

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technical documents and rationales for the Commission's determination that no technical basis exists for the noncombustibility requirement are contained in NUREG–1552 and Supplement 1 to that document.

III. Summary of Changes

This final rule amends Section III.M in Appendix R to 10 CFR Part 50 (Appendix R), removes footnotes 3 and 4 from § 50.48, removes footnote 1 from Section I in Appendix R, removes § 50.48 (c), (d), and (e), corrects a grammatical error in footnote 2 to Section III.G. 3 in Appendix R, and makes editorial changes.

1. In Appendix R, Section III.M, the words "shall utilize only noncombustible materials and * * *" are removed.

The technical basis for removing the noncombustibility requirement for fire barrier penetration seal materials is documented in NUREG–1552 and NUREG–1552, Supplement 1. A summary of the technical basis for this action follows.

NRC requirements and guidelines for penetration seals appear in a number of documents. In 1971, the NRC promulgated General Design Criterion (GDC) 3, "Fire protection," and subsequently developed specific guidance for implementing GDC 3; Branch Technical Position (BTP) Auxiliary Power Conversion Systems Branch (APCSB) 9.5–1, "Guidelines for Fire Protection for Nuclear Power Plants," May 1, 1976; and Appendix A to BTP APCSB 9.5–1, "Guidelines for Fire Protection for Nuclear Power Plants Docketed Prior to July 1, 1976," February 24, 1977. Most licensees complied with most of the implementing guidance. To resolve the contested issues, the NRC published the final fire protection rule (10 CFR 50.48) and Appendix R to 10 CFR Part 50 on November 10, 1980 (45 FR 76602). It is important to note that Appendix R is not a set of generically applicable fire protection requirements and applies only to plants that were operating before January 1, 1979.

The record for Appendix R does not disclose the technical basis for including the noncombustibility criterion in Appendix R. The noncombustibility criterion is not included in BTP APCSB 9.5–1, Appendix A to BTP APCSB 9.5–1, or in the industry fire endurance test standards. Section 50.48 does not address the use of combustible materials. Although GDC 3 states that noncombustible and heat-resistant materials must be used wherever practical, GDC 3 does not preclude the use of combustible materials. In general, when these materials are incorporated as integral components of the plant fire protection program, including the fire hazard analysis, they are acceptable.

Fire barrier penetration seals are one element of the defense-in-depth concept at nuclear power plants. The objectives of the defense-in-depth concept as applied to fire protection are to:

(1) Prevent fires from starting;

(2) Promptly detect, control, and extinguish those fires that do occur; and

c. Protect structures, systems, and components important to safety so that a fire that is not extinguished promptly will not prevent the safe shutdown of the plant.

To achieve defense in depth, each operating reactor maintains an NRC-approved fire protection program. Nuclear power plants are divided into separate areas by structural fire barriers, such as walls and floor-ceiling assemblies whose fire-resistance rating, typically 1, 2, or 3 hours, is determined by testing. The function of these structural barriers is to prevent a fire that starts in one area from spreading to another area. Penetration seals are used to close openings through the structural fire barriers. The intended design function of the penetration seal is to confine a fire to the area in which it started and to protect important equipment within an area from a fire outside the area. As for other fire barriers, the fire-resistance rating of the penetration seals is determined by testing.

The ability of a particular penetration seal to achieve its intended design function (*i.e.,* to contain a fire), as determined by a fire endurance test conducted in accordance with an industry standard, is the foremost design consideration. In NUREG–1552 and NUREG–1552, Supplement 1, the NRC concluded:

(1) There are no reports of fires where fire-rated penetration seals failed to confine a fire at a nuclear power plant;

(2) A large body of fire endurance tests has confirmed the fire-resistive capabilities of the penetration seal materials, designs, and configurations installed in nuclear power plants; and

(3) If penetration seals are properly designed, tested, installed, inspected, and maintained, there is reasonable assurance that they will provide the fire resistance of the tested design, maintain the fire-resistive integrity of the fire barriers in which they are installed, and confine a fire to its area of origin.

The NRC evaluated silicone-based penetration seal materials that are combustible and are the most widely used materials for penetration seals throughout the commercial nuclear power industry. In presenting the results of its evaluation in NUREG–1552 and in NUREG–1552, Supplement 1, the NRC concluded:

(1) Properly designed, tested, installed, and maintained silicone-based penetration seals are not credible fire hazards;

(2) Despite the fact that a silicone-based penetration seal could contribute some fuel to a fire, its relative contribution to overall fire severity would be negligible;

(3) Qualified silicone-based fire barrier penetration seals can accomplish their intended design function; and

(4) The benefits of combustible or limited combustible penetration seal materials outweigh any potential concerns regarding material combustibility. For example, the penetration seal material must be compatible with the penetrating item material. In the case of electrical cables, the 3M intumescent material or the Dow Corning Silicone will not damage the cable jacket and flows between the individual cables during installation. Likewise, the flexible combustible seal materials allow for normal pipe movement due to heating and cooling of the pipe. The combustible seal materials are economical to install and remove/replace during plant modifications. In short, silicone foam and silicone elastomer can fill complex irregular openings and adhere to the penetration and the penetrants; cure rapidly; have high-temperature stability; are flexible; and resist the effects of radiation exposure and aging.

2. In § 50.48, footnotes 3 and 4 are removed.

Footnote 3 to § 50.48(a) stated that basic fire protection guidance for nuclear power plants is contained in two NRC documents: Branch Technical Position (BTP) Auxiliary Power Conversion System Branch (APCSB) 9.5–1, "Guidelines for Fire Protection for Nuclear Power Plants" (for new plants docketed after July 1, 1976), dated May 1976, and Appendix A to BTP APCSB 9,5–1, "Guidelines for Fire Protection for Nuclear Power Plants Docketed Prior to July 1, 1976" (for plants that were operating or in various stages of design or construction before July 1, 1976), dated August 23, 1976. Footnote 3 also referred to footnote 4 to § 50.48(b), that lists four additional documents related to permissible alternatives to satisfy Appendix A to BTP APCSB 9.5–1. The documents listed in footnote 4 were: "Supplementary Guidance on Information Needed for Fire Protection Evaluation," dated October 21, 1976;

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"Sample Technical Specification," dated May 12, 1977; "Nuclear Plant Fire Protection Functional Responsibilities, Administrative Control and Quality Assurance," dated June 14, 1997; and "Manpower Requirements for Operating Reactors," dated May 11, 1978. The six documents that were referred to in footnotes 3 and 4 no longer reflect accurately the current NRC guidance.

Footnotes 3 and 4 were not intended to be rulemaking requirements but rather statements of fact. The footnotes reflected the Commission's approval of the NRC staff's practice, as reflected in Branch Technical Position (BTP) APCSB 9.5–1 and in its Appendix A, that the date of the docketing of the construction permit would determine the NRC staff's review criteria for verifying compliance with General Design Criterion (GDC) 3, and that compliance with the guidance of BTP APCSB 9.5–1 or its Appendix A and the other listed guidance documents would establish compliance with GDC 3. The NRC has completed its review of the fire protection programs at all operating reactors and has issued license conditions that establish the licensing bases for each reactor. The licensing bases may include the documents listed in footnotes 3 and 4, but typically include a number of other guidance documents that the NRC issued after it promulgated § 50.48. In addition, the licensees included the fire protection licensing basis for each reactor in the Updated Final Safety Analysis Report for the facility. Footnotes 3 and 4 have served their purpose and are not needed by the NRC or the licensees to maintain the fire protection licensing bases for the reactors.

The change does not affect or change the licensing basis for any plant. However, it makes 10 CFR 50.48 consistent with other reactor regulations that do not identify guidance documents. It also eliminates the need to update the footnotes to include the large number of guidance documents that the NRC has issued since it promulgated § 50.48 and to conduct future rulemakings to add new guidance documents as they are issued. The change also resolves an inconsistency between the information in footnote 3 to § 50.48 and the regulatory requirements of § 50.34(g)(1)(ii). Specifically § 50.34(g)(1)(ii) states, in part, that "Applications for light water cooled nuclear power plant construction permits, manufacturing licenses, and preliminary or final design approvals for standard plants docketed after May 17, 1982, shall include an evaluation of the facility against the SRP * * *," whereas, footnote 3 indicated that the fire protection portions of these applications would be reviewed against BTP APCSB 9.5–1.

3. In Section I of Appendix R, footnote 1 is removed.

Footnote 1 to Section I in Appendix R is identical to footnote 4 to § 50.48(b). The reasons given above for the removal of footnote 4 to § 50.48(b) also apply to footnote 1 to Section I in Appendix R.

4. In § 50.48, paragraphs (c), (d), and (e) are removed.

Paragraphs (c) and (d) of § 50.48 contained schedule requirements that were added to the Code of Federal Regulations when Appendix R became effective on February 17, 1981. These requirements applied to nuclear power plants licensed before January 1, 1979, and involved fire protection installation modifications, revisions of administrative controls, manpower changes, and training. These requirements were to be completed on a schedule determined by the provisions specified in § 50.48 (c) and (d). All scheduler requirements of § 50.48 (c) and (d) have been implemented and need not be retained.[1]

Paragraph (e) of § 50.48 specified that nuclear power plants licensed after January 1, 1979, were to complete all fire protection modifications needed to satisfy GDC 3 of Appendix A to 10 CFR Part 50 in accordance with the provisions of their licenses. License

[1] The removed paragraphs read as follows:

(c) All fire protection modifications required to satisfy the provisions of appendix R to this part or directly affected by such requirements shall be completed on the following schedule:

(1) Those fire protection features that involve revisions of administrative controls, manpower changes, and training, shall be implemented within 30 days after the effective date of this section and appendix R to this part.

(2) Those fire protection features that involve installation of modifications that do not require prior NRC approval or plant shutdown shall be implemented within 9 months after the effective date of this section and appendix R to this part.

(3) Those fire protection features, except for those requiring prior NRC approval by paragraph (c)(5) of this section, that involve installation of modifications that do require plant shutdown, the need for which is justified in the plans and schedules required by the provisions of paragraph (c)(5) of this section, shall be implemented before startup after the earliest of the following events commencing 180 days or more after the effective date of this section and appendix R to this part:

(i) The first refueling outage;

(ii) Another planned outage that lasts for at least 60 days; or

(iii) An unplanned outage that lasts for at least 120 days.

(4) Those fire protection features that require prior NRC approval by paragraph (c)(5) of this section, shall be implemented within the following schedule: Dedicated shutdown systems — 30 months after NRC approval; modifications requiring plant shutdown—before startup after the earliest of the events given in paragraph (c)(3) commencing 180 days after NRC approval; modifications not requiring plant shutdown—6 months after NRC approval.

(5) Licensees shall make any modifications necessary to comply with these requirements in accordance with the above schedule without prior review and approval by NRC except for modifications required by section III.G.3 of appendix R to this part. Licensees shall submit plans and schedules for meeting the provisions of paragraphs (c)(2), (c)(3), and (c)(4) within 30 days after the effective date of this section and appendix R to this part. Licensees shall submit design descriptions of modifications needed to satisfy section III.G.3 of appendix R to this part within 30 days after the effective date of this section and appendix R to this part.

(6) In the event that a request for exemption from a requirement to comply with one or more of the provisions of Appendix R filed within 30 days of the effective date of this rule is based on an assertion by the licensee that such required modifications would not enhance fire protection safety in the facility or that such modifications may be detrimental to overall facility safety, the schedule requirements of paragraph (c) shall be tolled until final Commission action on the exemption request upon a determination by the Director of Nuclear Reactor Regulation that the licensee has provided a sound technical basis for such assertion that warrants further staff review of the request.

(d) Fire protection features accepted by the NRC staff in Fire Protection Safety Evaluation Reports referred to in paragraph (b) of this section and supplements to such reports, other than features covered by paragraph (c), shall be completed as soon as practicable but no later than the completion date currently specified in license conditions or technical specifications for such facility, or the date determined by paragraphs (d)(1) through (d)(4) of this section, whichever is sooner, unless the Director of Nuclear Reactor Regulation determines, upon a showing by the licensee, that there is good cause for extending such date and that the public health and safety is not adversely affected by such extension. Extensions of such date shall not exceed the dates determined by paragraphs (c)(1) through (c)(4) of this section.

(1) Those fire protection features that involve revisions of administrative controls, manpower changes, and training shall be implemented within 4 months after the date of the NRC staff Fire Protection Evaluation Report accepting or requiring such features.

(2) Those fire protection features involving installation of modifications not requiring prior approval or plant shutdown shall be implemented within 12 months after the date of the NRC staff Fire Protection Safety Evaluation Report accepting or requiring such features.

(3) Those fire protection features, including alternative shutdown capability, involving installation of modifications requiring plant shutdown shall be implemented before the startup after the earliest of the following events commencing 9 months or more after the date of the NRC staff Fire Protection Safety Evaluation Report accepting or requiring such features:

(i) The first refueling outage;

(ii) Another planned outage that lasts for at least 60 days; or

(iii) An unplanned outage that lasts for at least 120 days.

(4) Those fire protection features involving dedicated shutdown capability requiring new buildings and systems shall be implemented within 30 months of NRC approval. Other modifications requiring NRC approval prior to installation shall be implemented within 6 months after NRC approval.

(e) Nuclear power plants licensed to operate after January 17, 1979, shall complete all fire protection modifications needed to satisfy Criterion 3 of appendix A to this part in accordance with the provisions of their licensees.

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conditions pertaining to fire protection have been implemented at all plants. Therefore, § 50.48(e) has been implemented and need not be retained.

5. In Section III.G.3 of Appendix R, a grammatical error is corrected.

Footnote 2 to Section III.G.3 of Appendix R read, ''Alternative shutdown capability is provided by rerouting, relocating, or modificating of existing systems; dedicated shutdown capability is provided by installing new structures and systems for the function of post-fire shutdown.'' This final rule replaces the words ''modificating of'' with ''modifying.''

IV. Plain Language

The Presidential memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing,'' directed that the Federal Government's writing be in plain language (63 FR 31883, June 10, 1998). In compliance with this directive, editorial changes have been made in these amendments to improve the readability of the existing language of the provisions being revised. These types of changes are not discussed further in this document.

V. Compatibility of Agreement State Regulations

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** September 3, 1997 (62 FR 46517), Part 50 is classified as compatibility Category ''NRC.'' The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or provisions of Title 10 of the Code of Federal Regulations.

VI. Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. The NRC is deleting the Government-unique standard in 10 CFR Part 50, Appendix R, Section III.M, which requires that fire barrier penetration seals utilize only noncombustible materials. The NRC is not aware that deletion of this requirement is inconsistent with any voluntary consensus standard.

VII. Finding of No Significant Environmental Impact

Environmental Assessment

The NRC has determined, in accordance with the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments are not a major Federal action significantly affecting the quality of the human environment; therefore, an environmental impact statement is not required.

1. The Action

The NRC is amending its regulations that require fire barrier penetration seal materials to be noncombustible and making minor changes to § 50.48 and to Appendix R to Part 50.

These minor changes are to remove footnote 3 from § 50.48(a), footnote 4 from § 50.48(b), and footnote 1 from Section I in Appendix R; remove paragraphs (c), (d), and (e) from § 50.48; correct a grammatical error in footnote 2 to Section III.G.3 of Appendix R; and make editorial changes.

2. Need for the Rulemaking Action

The technical basis for removing the noncombustibility requirement for fire barrier penetration seal materials is documented in NUREG–1552, ''Fire Barrier Penetration Seals in Nuclear Power Plants,'' July 1996; and in NUREG–1552, Supplement 1, January 1999. In these reports, the NRC staff documented the results of a technical assessment of fire barrier penetration seals. On the basis of its findings, the NRC concluded that the noncombustibility criterion for penetration seal materials specified in the NRC fire protection regulations and review guidance has a negligible contribution to safety and recommended that this noncombustibility criterion be deleted. In a staff requirements memorandum dated June 30, 1998, the Commission directed the NRC staff to amend Section III.M of Appendix R to 10 CFR Part 50 (Appendix R) to eliminate the noncombustibility requirement for penetration seal material and to make other minor changes to the fire protection regulations. These minor changes include the deletion of references that no longer reflect accurately the guidance documents published by the NRC in footnotes 3 and 4 of § 50.48 and in footnote 1 to Section I of Appendix R, the deletion of schedular requirements that have been implemented in § 50.48(c) and (d), and a grammatical correction in footnote 2 to Section III.G.3 of Appendix R. The NRC also took advantage of this rulemaking to make editorial changes to comply with the Presidential memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing.'' The deletion of the noncombustibility criterion removes a requirement that has a negligible contribution to safety. It constitutes a burden reduction for the NRC and for the licensees.

3. ''No Regulatory Action'' Alternative

No regulatory action would have continued the regulatory burden on licensees and on the NRC. Silicone-based material is currently the material of choice for fire barrier penetration seals and is combustible. The NRC has performed an assessment of silicone-based penetration seal materials and concluded that the benefits of the silicone-based materials in penetration seals, such as high-temperature stability, flexibility, and resistance to the effects of radiation exposure and aging, outweigh any potential concerns regarding material combustibility. In the past, licensees using silicone-based penetration seal materials have requested and been granted exemptions from the requirement of Section III.M of Appendix R to Part 50, regarding the use of noncombustible materials, provided the seals are qualified by fire endurance tests conducted in accordance with an industry standard. Under the previous rule, a licensee that chose penetration seals made of silicone-based materials to replace existing seals or to install new seals would have had to request an exemption from the requirement of Section III.M of Appendix R to the extent that the silicone-based material is combustible. This request for an exemption would have increased the regulatory burden on both the NRC and the licensees, and would have presented no safety benefit. No regulatory action regarding the removal of footnote 3 to § 50.48(a), footnote 4 to § 50.48 (b), footnote 1 to Section I of Appendix R, and § 50.48 (c), (d), and (e) would have had a negative regulatory impact for the following reasons. Footnotes 3 and 4 in § 50.48 and footnote 1 to Section I of Appendix R were inaccurate and incomplete. In addition, the information in footnote 3 was inconsistent with the regulatory requirements contained in § 50.34(g)(1)(ii). The requirements in § 50.48 (c), (d), and (e) had been implemented and need not be retained. No regulatory action regarding the correction of a grammatical error in footnote 2 to Section III.G.3 of Appendix R to Part 50, which was administrative in nature, would not have had any regulatory impact.

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4. Environmental Impacts of the Proposed Amendment and the Alternative

The environmental impacts of this amendment, as well as the alternative, are considered negligible by the NRC. The NRC has determined that the ability of a particular penetration seal to achieve its intended design function (*i.e.,* to contain a fire), as determined by a fire endurance test conducted in accordance with an industry standard, is the foremost design consideration. The amendment will not impact the ability to shut down the plant safely in the event of a fire and will provide a level of safety equivalent to that attained by compliance with Section III.M of Appendix R to 10 CFR Part 50. There is no environmental impact associated with the other changes which are administrative in nature. On this basis, the NRC concludes that there are no radiological environmental impacts associated with this amendment. If no regulatory action had been taken in regard to the noncombustibility requirement of Section III.M of Appendix R there would have been no radiological environmental impact, the same as the action. No regulatory action regarding the changes in § 50.48 and in Appendix R (and the correction of an error in footnote 2 to Section III.G.3 of Appendix R, which is administrative in nature) would have had no radiological impact on the environment.

With regard to potential nonradiological impacts, the amendment does not affect nonradiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant nonradiological environmental impacts associated with the amendment.

5. List of Agencies and Persons Consulted

Much of the technical information required for this rulemaking was obtained directly from technical experts within the NRC. No other agencies were consulted in preparing this environmental assessment.

VIII. Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0011.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

IX. Regulatory Analysis

The NRC has prepared the following regulatory analysis for the rule.

1. Statement of the Problem

The NRC is amending its regulations regarding the requirement for fire barrier penetration seal materials to be noncombustible and is also making minor changes to § 50.48 and to Appendix R to 10 CFR Part 50. The changes remove footnote 3 from § 50.48(a), footnote 4 from § 50.48(b), and footnote 1 from Sect. I. of Appendix R; remove paragraphs (c), (d), and (e) from § 50.48; correct a grammatical error in footnote 2 to Section III.G.3 of Appendix R; and make editorial changes to comply with the Presidential memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing.''

2. Objectives of the Rulemaking

The main objective of the rule is to remove the requirement of Section III.M of Appendix R to 10 CFR Part 50 that fire barrier penetration seal materials be noncombustible. In addition, this rule removes certain parts of § 50.48 and of Appendix R, corrects a grammatical error in Appendix R, and makes editorial changes.

3. Alternative

The alternative of no regulatory action would have continued the unnecessary regulatory burden on licensees and on the NRC.

4. Consequences

Removing the requirement that fire barrier penetration seal materials be noncombustible from Section III.M of Appendix R to Part 50 lessens the unnecessary regulatory burden on licensees and on the NRC staff. It allows licensees to use combustible materials in penetration seals without requesting an exemption from the requirement in Section III.M of Appendix R regarding the noncombustibility of penetration seal materials, provided the seals are qualified by fire endurance tests comparable to those used to rate fire barriers and conducted in accordance with an industry standard. The other minor changes are administrative and do not affect the regulatory burden on licensees.

5. Value Impact Analysis.

The value (benefit) and impact (cost) of the changes are estimated below. Section III.M of Appendix R to 10 CFR Part 50 applies to the plants that were operating before January 1, 1979, and had open items when Appendix R was published. As detailed in NUREG–1552, Supplement 1, Section III.M of Appendix R applies to 5 operating reactors. In order to estimate the benefit of the change, the NRC assumes that the licensees for these plants may want to replace some of their penetration seals with penetration seals made of silicone-based combustible material and that these licensees would request an exemption from the technical requirements of Section III.M of Appendix R. Labor cost is $145/hr for a power reactor licensee and $75/hr for NRC. The change to Section III.M of Appendix R would save licensees the cost of preparing an exemption request and would save the NRC the cost of preparing a safety evaluation and processing the request. Assuming a cost saving of approximately $7500 for licensees and approximately $2500 for NRC for each exemption request, the total cost saving from the change to Section III.M would be approximately $50,000. There would be no benefit or cost associated with the other proposed changes.

6. Decision Rationale

The NRC reviewed the requirement of Section III.M of Appendix R during its reassessment of fire barrier penetration seals and determined that this requirement has a negligible contribution to safety. The removal of the requirement of Section III.M reduces the regulatory burden on the licensee without reducing safety. In addition, the rule makes the following minor changes: removes footnote 3 from § 50.48(a), footnote 4 from § 50.48(b), and footnote 1 from Section I of Appendix R; removes paragraphs (c), (d), and (e) from § 50.48; corrects an error in footnote 2 to Section III.G.3 of Appendix R; and makes editorial changes to comply with the Presidential memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing.'' The other changes as discussed above do not change the regulatory burden on the licensees and do not affect safety.

X. Regulatory Flexibility Act Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant impact on a substantial number of small entities.

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Nuclear power plant licensees do not fall within the definition of small businesses as defined in Sect. 3 of the Small Business Act (15 U.S.C. 632) or the Commission's size standards at 10 CFR 2.810 (60 FR 18344; April 11, 1995).

XI. Backfit Analysis

The NRC has determined that these amendments do not involve any provisions that impose backfits because it does not meet the definition of backfit contained in § 50.109(a)(1) for the following reasons. The removal of the requirement that fire barrier penetration seals be noncombustible is a permissive relaxation of an existing requirement and does not constitute imposition of a new requirement. The removal of footnotes 3 and 4 from § 50.48 and of footnote 1 from Section I of Appendix R does not affect the licensing basis for existing plants, does not constitute a change in design requirements for existing plants, and is not applicable to future plants. The schedular requirements contained in paragraphs (c) and (d) of § 50.48 apply to plants licensed before February 17, 1981, and have been implemented at these plants. The requirements contained in paragraph (e) of § 50.48 apply to existing plants and have been implemented at all applicable plants. Therefore, the removal of paragraphs (c), (d), and (e) from § 50.48 does not affect the licensing basis and does not constitute a change in design or optional requirements for these plants. The correction of a grammatical error in footnote 2 to Section III.G.3 of Appendix R and the changes in the language of § 50.48 in accordance with the Presidential memorandum entitled "Plain Language in Government Writing," are administrative changes that do not change any requirement and need not be considered in this backfit determination. For the reasons stated above, a backfit analysis has not been prepared for this rulemaking.

XII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness 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.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons given in the preamble and under the authority for the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended, (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Section 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.Q. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.Q. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.Q. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.Q. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.Q. 2234). Appendix F also issued under sec. 187, 68 Stat. 954 (42 U.S.Q. 2237).

2. Section 50.48 is revised to read as follows:

§ 50.48 Fire protection.

(a)(1) Each operating nuclear power plant must have a fire protection plan that satisfies Criterion 3 of appendix A to this part. This fire protection plan must:

(i) Describe the overall fire protection program for the facility;

(ii) Identify the various positions within the licensee's organization that are responsible for the program;

(iii) State the authorities that are delegated to each of these positions to implement those responsibilities; and

(iv) Outline the plans for fire protection, fire detection and suppression capability, and limitation of fire damage.

(2) The plan must also describe specific features necessary to implement the program described in paragraph (a)(1) of this section such as—

(i) Administrative controls and personnel requirements for fire prevention and manual fire suppression activities;

(ii) Automatic and manually operated fire detection and suppression systems; and

(iii) The means to limit fire damage to structures, systems, or components important to safety so that the capability to shut down the plant safely is ensured.

(3) The licensee shall retain the fire protection plan and each change to the plan as a record until the Commission terminates the reactor license. The licensee shall retain each superseded revision of the procedures for 3 years from the date it was superseded.

(b) Appendix R to this part establishes fire protection features required to satisfy Criterion 3 of appendix A to this part with respect to certain generic issues for nuclear power plants licensed to operate before January 1, 1979.

(1) Except for the requirements of Sections III.G, III.J, and III.O, the provisions of Appendix R to this part do not apply to nuclear power plants licensed to operate before January 1, 1979, to the extent that—

(i) Fire protection features proposed or implemented by the licensee have been accepted by the NRC staff as satisfying the provisions of Appendix A to Branch Technical Position (BTP) APCSB 9.5–1 reflected in NRC fire protection safety evaluation reports issued before the effective date of February 19, 1981; or

(ii) Fire protection features were accepted by the NRC staff in comprehensive fire protection safety evaluation reports issued before Appendix A to Branch Technical Position (BTP) APCSB 9.5–1 was published in August 1976.

(2) With respect to all other fire protection features covered by Appendix R, all nuclear power plants licensed to operate before January 1, 1979, must satisfy the applicable requirements of Appendix R to this part, including specifically the requirements of Sections III.G, III.J, and III.O.

(c) [Reserved].

(d) [Reserved].

(e) [Reserved].

(f) Licensees that have submitted the certifications required under § 50.82(a)(1) shall maintain a fire protection program to address the potential for fires that could cause the release or spread of radioactive materials (i.e., that could result in a radiological hazard).

(1) The objectives of the fire protection program are to—

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(i) Reasonably prevent these fires from occurring;

(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and

(iii) Ensure that the risk of fire-induced radiological hazards to the public, environment and plant personnel is minimized.

(2) The licensee shall assess the fire protection program on a regular basis. The licensee shall revise the plan as appropriate throughout the various stages of facility decommissioning.

(3) The licensee may make changes to the fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for facilities, systems, and equipment that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.

3. In Appendix R, Section I, footnote 1 is removed and footnotes 2 through 5 are redesignated as footnotes 1 through 4, respectively. New footnote 1 to Section III.G.3, and Section III.M are revised to read as follows:

Appendix R to Part 50—Fire Protection Program for Nuclear Power Facilities Operating Before January 1, 1979

* * * * *

III. Specific Requirements * * *

G. * * *

3. Alternative of dedicated shutdown capability and its associated circuits,[1] independent of cables, systems or components in the area, room, zone under consideration should be provided: * * *

* * * * *

M. Fire barrier cable penetration seal qualification. Penetration seal designs must be qualified by tests that are comparable to tests used to rate fire barriers. The acceptance criteria for the test must include the following:

1. The cable fire barrier penetration seal has withstood the fire endurance test without passage of flame or ignition of cables on the unexposed side for a period of time equivalent to the fire resistance rating required of the barrier;

2. The temperature levels recorded for the unexposed side are analyzed and demonstrate that the maximum temperature is sufficiently below the cable insulation ignition temperature; and

3. The fire barrier penetration seal remains intact and does not allow projection of water beyond the unexposed surface during the hose stream test.

* * * * *

[1] Alternative shutdown capability is provided by rerouting, relocating, or modifying existing systems; dedicated shutdown capability is provided by installing new structures and systems for the function of post-fire shutdown.

Dated at Rockville, Maryland, this 14th day of June, 2000.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 00–15544 Filed 6–19–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-the-Counter Human Drugs; Labeling Requirements; Partial Extension of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial extension of compliance dates.

SUMMARY: The Food and Drug Administration (FDA) is providing a partial extension of the compliance dates for its final rule that appeared in the **Federal Register** of March 17, 1999. The final rule established a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. That final rule requires all OTC drug products to have the new, easy-to-read format and the revised labeling requirements within prescribed implementation periods. This partial extension provides 1 additional year for implementation for specific types of OTC drug products to be in compliance with the final rule.

DATES:

Effective Date: This rule is effective July 20, 2000.

Compliance Dates: For compliance dates, see section III of the **SUPPLEMENTARY INFORMATION** section of this document. Submit written comments by September 18, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and standardized content requirements for the labeling of OTC drug products. Those requirements are codified in § 201.66 (21 CFR 201.66).

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. This includes products marketed under a final OTC drug monograph, an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), and OTC drug products for which there is no final OTC drug monograph or approved drug application.

The agency provided different implementation dates by which OTC drug products had to be in compliance with the new requirements. These dates varied according to the regulatory status of the products (64 FR 13254 at 13273 and 13274).

A. Products in the OTC Drug Review

Products marketed under final OTC drug monographs had to comply with the final rule by April 16, 2001. Products for which a final monograph became effective on or after April 16, 1999, had to comply as of: (1) The applicable implementation date for that final monograph; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever occurs first.

Combination drug products in which all of the active ingredients are the subject of a final monograph or monographs had to comply with the final rule as of April 16, 2001. Combination products in which one or more active ingredients are the subject of a final monograph, and one or more ingredients are still under review as of the effective date of the final rule, had to comply as of the implementation date for the last applicable final monograph for the combination, or as of April 16, 2001, whichever is earlier. Combination products in which none of the active ingredients is the subject of a final monograph or monographs as of the effective date of the final rule had to comply as of: (1) The implementation date of the last applicable final monograph for the combination; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever comes first.

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