Office of Enforcement U.S. Nuclear Regulatory Commission

Abstract

On June 30, 1995, the Nuclear Regulatory Commission (NRC) issued a complete revision of its General Statement of Policy and Procedure for Enforcement Actions (Enforcement Policy) (60 FR 34381). In approving the 1995 revision to the Enforcement Policy, the Commission directed the staff to perform a review of its implementation of the Policy after approximately 2 years of experience and to consider public comments. This report represents the results of that review.

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I. Background

The Commission, in approving the 1995 revision to the Enforcement Policy, directed the staff to perform a review of its implementation of the Policy after approximately 2 years of experience. This report represents the results of that review.

Part I of the report provides an overview of: (1) the 1995 Enforcement Program reassessment, (2) the subsequent 1995 Enforcement Policy revision, and the Commission's request for the staff to review the Enforcement Policy and consider public comments after it had been in effect for approximately 2 years, (3) the Office of Enforcement's methods for performing the Commission-requested review, and (4) the revisions to the Enforcement Policy since June 30, 1995,

A. 1995 ASSESSMENT OF THE NRC ENFORCEMENT PROGRAM

On May 13, 1994, the Executive Director for Operations (EDO) established a Review Team composed of senior NRC managers to reexamine the NRC enforcement program. The Review Team evaluated the existing Enforcement Policy, other Federal agency enforcement policies, and solicited comments from various NRC offices, other Federal agencies, members of industry and the public. The report of this comprehensive review was published in April 1995, as NUREG-1525, "Assessment of the NRC Enforcement Program." The Review Team subsequently made recommendations to the Commission for revisions to the Enforcement Policy in SECY-95-084.

B. JUNE 30, 1995 REVISED ENFORCEMENT POLICY

In a Staff Requirements Memorandum (SRM) dated June 16, 1995, the Commission approved publication of a major revision to the NRC Enforcement Policy based on many of the recommendations made in SECY-95-084. The revised Enforcement Policy was effective upon its publication in the *Federal Register* on June 30, 1995 (60 FR 34381). The Enforcement Policy was subsequently issued as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions."

The more significant changes adopted by the Commission (as they appear in the Enforcement Policy) include: (1) clarification of the purpose statement, (2) elimination of Severity Level V categorization, (3) revision of the threshold and criteria for predecisional enforcement conferences, (4) elimination of responses to certain Notices of violation, (5) revision of the base civil penalty tables, (6) elimination of civil penalties for Severity Level IV violations, (7) streamlining the civil penalty assessment process, and (8) preservation of the ability to exercise discretion. These changes are described in further detail in Appendix A of this report.

The Commission did not approve the staff's recommendations regarding provisions for Commission consultation and open predecisional enforcement conferences. Instead, the Commission directed the staff to continue the trial program for conducting certain conferences open to public observation. The Commission also directed the staff to return to the Commission with a recommendation regarding these two issues after 1 year of experience with the Policy. (1)

In the June SRM, the Commission also directed the staff to evaluate the revised Enforcement Policy after it had been in use for approximately 2 years and to consider comments from the public based on the revised Policy.

C. METHODOLOGY

The focus of this review is the revisions that were made to the Enforcement Policy as it was published in the *Federal Register* on June 30, 1995, (60 FR 34381) and subsequently published as NUREG-1600.

The Office of Enforcement (OE) issued a *Federal Register* notice on February 5, 1997, to solicit public comments on the 1995 revisions to the Enforcement Policy. A copy of this notice is included as Appendix C. The agency received three responses, including: (1) a response from the Nuclear Energy Institute (NEI), (2) a response from members of the Region IV Utility Group (RUG IV), and (3) a response on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR).

Subsequent to the comment period, the agency received a letter from the Union of Concerned Scientists (UCS) on September 9, 1997, recommending that the agency perform a review of the Enforcement Policy aimed at (1) curtailing its subjectivity (i.e., improving consistency), and (2) improving the timeliness for enforcement actions. Although the UCS request was made beyond the comment period, the staff believes that it is appropriate to consider UCS's comments within its review of the Enforcement Policy.

In addition, a public meeting was conducted at the NRC's offices at Two White Flint North in Rockville, Maryland on December 5, 1997, to discuss the NRC's Enforcement Policy and enforcement program. The meeting was arranged at the request of UCS in response to a letter from the Director of OE, dated October 14, 1997, that responded to the September 9, 1997 UCS letter. NEI was also a scheduled participant at this meeting. Although the public meeting was conducted beyond the comment period, the staff has considered UCS's and NEI's comments made during the meeting in this review. A copy of the meeting summary was placed in the NRC Public Document Room.

OE also solicited comments from the regions and program offices on a variety of issues associated with the objectives of the revised Enforcement Policy. The staff also considered insights from industry and public comments informally communicated to the staff during the 2-year period.

D. CHANGES TO THE ENFORCEMENT POLICY SINCE JUNE 30, 1995

Subsequent to June 30, 1995, the Enforcement Policy has been revised 10 times. These revisions (listed chronologically) included the following issues: (1) adjustment of civil monetary penalties; (2) departures from the FSAR; (3) Commission consultation, open predecisional enforcement conferences, risk, and NCVs; (4) Part 20, exceedance of dose constraints; (5) correction to exercise of discretion; (6) gaseous diffusion plants, NRC organizational changes, and Commission consultation; (7) participation in enforcement conferences involving discrimination; (8) Part 34, radiography, and examples of potential violations; (9) editorial corrections; and (10) clarification on release of Office of Investigations (OI) reports associated with predecisional enforcement conferences involving discrimination and the role of the complainant. These revisions are described in further detail in Appendix B.

II. Discussion of Comments and Issues

Part II of this report provides a summary of the major comments, a discussion of the issues, and conclusions and recommendations.

A. PUBLIC INVOLVEMENT

Comments

NEI, RUG IV, and CORAR all commented that they appreciated the NRC's institution of a trial period during which the agency, industry, and members of the public have had an opportunity to evaluate whether the revisions to and the implementation of the revised Policy provide a sound regulatory framework. However, RUG IV commented that the Commission is best served when public comments are solicited and considered when important changes to existing NRC staff positions are issued. In particular, RUG IV recommended that future Enforcement Guidance Memorandums (EGMs) (2) be noticed, that public comments be considered, and that they be issued with the date of their effectiveness specifically established.

• Discussion

Because the Enforcement Policy is a policy statement and not a regulation or proposed rule, (3) changes are effective upon publication without a preliminary comment period. However, the Commission has routinely published notices to provide the public an opportunity to provide comments for the Commission's consideration. (4) EGMs, on the other hand, are not, in and of themselves statements of policy. Instead, they are internal staff documents providing guidance on how to implement the Enforcement Policy. In many cases, an issue arises that necessitates issuance of prompt guidance to the staff. To institute a notice and comment process for staff guidance would delay necessary implementation guidance and adversely affect the need for flexibility. EGMs are placed in the NRC Public Document Room, included in the NRC Enforcement Manual, NUREG/BR-0195, and recently are included on OE's home page on the Internet at www.nrc.gov/OE/. Interested parties may always provide comments for OE's consideration.

• Conclusion

EGMs should continue to be issued to the staff as necessary, and should be available to the public after issuance.

B. ALTERNATIVE ENFORCEMENT PRACTICES

Comments

Although NEI commented that the revised Enforcement Policy was an improvement from the previous version, it recommended that the NRC give serious consideration to making fundamental changes, including changes that would: (1) avoid the current disproportionate emphasis on deterrence, (2) seek to more closely focus the enforcement process on safety, (3) provide clear and positive incentives to licensees to identify and correct noncompliances, and (4) eliminate the use of enforcement as a substitute for other regulatory mechanisms. The following discussion will address NEI's view that the Enforcement Policy disproportionately emphasizes deterrence. (5) In particular, NEI stated that the purpose of the inspection and enforcement program should be to identify and promote correction of noncompliances...not to take punitive action after the licensee has addressed the problem. NEI contended that the threat of an enforcement action has little to do with licensee compliance in any given circumstance (other than a willful violation) and that licensees comply because they take their responsibility to operate safely as a paramount objective.

CORAR recommended that the NRC consider applying enforcement practices compatible with other Federal agencies. CORAR specifically recommended consideration of an approach (which they attributed to the Federal Aviation Administration (FAA)) where minor violations are brought to the attention of the licensee, but not publicly noticed unless the licensee has not corrected them after two repeat notices.

• Discussion

As part of the 1995 enforcement program reassessment, the Review Team considered the issue of deterrence as an enforcement objective (NUREG-1525, Section II.A.1.c). The NRC recognizes that in activities as complex as most nuclear operations, with hundreds and even thousands of requirements, some violations will inevitably occur. Based on this recognition, the enforcement program seeks to not only emphasize the importance of compliance, but also to emphasize the need to identify and correct violations before there is impact on the public health and safety. In the staff's view, the current Enforcement Policy appropriately provides deterrence value to both the involved licensee and other licensees who could be subject to enforcement action for similar violations. By providing incentives to promptly identify and promptly establish lasting corrective action, the Enforcement Policy provides for an appropriate balancing of the circumstances of each case to provide an additional motivation for compliance. The staff does not believe that the deterrence focus of the Enforcement Policy to provide this motivation should be changed.

The 1995 Review Team also evaluated and reviewed enforcement policies and practices of other Federal agencies, including the EPA, DOE, and FAA, and met with senior representatives from the FAA and the EPA. The staff believes that the current Enforcement Policy is better suited to regulation of nuclear activities than the other Federal agencies' programs. Using CORAR's example, NRC treatment of minor violations is similar to the description of the FAA's approach, in that they are frequently brought to the attention of the licensee, but not publicly noticed. Specifically, minor violations are not normally documented in inspection reports, and to the extent that they are, they are treated as Non-Cited Violations. (6) However, failure to take corrective action for a known violation (regardless of the severity level) is unacceptable in any nuclear program. (7) It may even represent a willful disregard for regulatory requirements. Consequently, refraining from issuing enforcement action until a licensee has been given notice to correct a violation for the third time is inconsistent with the agency's expectations for licensee performance. In addition, the NRC has a public approach to regulation. All inspection reports, except those that include safeguards information, are made public.

Finally, the staff notes that the NRC's Enforcement Policy complies with the Small Business Regulatory Enforcement Fairness Act (Act), that became effective in March 1996. Specifically: (1) under the current system, smaller licensees generally pay smaller civil penalties, because the agency's graduated civil penalty structure takes into account differences in the size of the licensee, the licensee's ability to pay, and the safety risk of the violation involved; (2) civil penalties are normally proposed only for significant violations; (3) civil penalties are normally waived for licensees who identify their own violations and take prompt and comprehensive corrective action; and (4) civil penalties are normally assessed for willful violations, particularly poor performance, overexposures, loss of radioactive material, and very significant violations.

Further, the Policy makes clear that in determining the amount of the civil penalty, financial hardship can be considered. It is not the NRC's intent that the economic impact of a civil penalty be so severe that it puts a licensee out of business or adversely affects the licensee's ability to conduct licensed activities safely. (8) In such cases, penalties may be reduced or the licensee may be permitted to pay the penalty over time.

Conclusion

The staff believes that the current Enforcement Policy is appropriately geared toward creating deterrence (i.e., taking action in a manner that will provide incentives to identify and correct violations that have occurred and discourage future violations) and is properly structured for nuclear regulation.

C. NEED FOR IMPROVED DEFINITIONS

• Comments

RUG IV commented that the current criteria in the Enforcement Manual for a violation to be classified as a minor violation have led to inconsistent application, that the current definitions in the Enforcement Manual for actual and potential safety consequence/significance lack specificity that has lead to inconsistent application, and that the current definition in the Enforcement Policy and Enforcement Manual for regulatory concern is inconsistent. RUG IV proposed definitions for actual safety significance and safety consequence and for regulatory concern. (9) RUG IV supported the position that a violation's potential safety significance or consequence be evaluated using a consistent, documented methodology and recommended that the established terms and definitions in NUREG-1022, "Event Reporting Guidelines 10 CFR 50.72 and 50.73," be used for evaluating and assessing potential safety significance.

Both NEI and UCS recommended that the NRC limit the agency's evaluation of a violation's safety significance, as used in enforcement, to include consideration of actual and potential consequence and to exclude consideration of regulatory significance. NEI and UCS based this recommendation on concerns that regulatory significance is not well defined, is inconsistently applied, and is a vehicle to base enforcement on a licensee's "regulatory standing," versus the real safety significance. NEI and UCS were particularly concerned about the agency's use of programmatic issues as an example of regulatory significance.

Discussion

The issue of minor violations will be addressed in Section II.H.4 of this report. The current Enforcement Policy does not specifically "define" actual safety significance, potential safety significance, regulatory concern, or regulatory significance. Instead, the Enforcement Policy states that the first step of the enforcement process is to evaluate the relative importance of each violation, including both the *technical and regulatory significance*. The Enforcement Policy was revised on December 10, 1996, (10) to clarify that technical significance includes both actual and potential consequences and that risk is an appropriate consideration in evaluating the technical significance of a violation. The Statements of Consideration stated:

In analyzing risk, the NRC recognizes the uncertainties associated with risk assessment. Generally, qualitative rather than quantitative risk assessments are made given the number of variables associated with risk assessment. Risk should be a consideration in proposing enforcement actions, but not necessarily determinatative. In developing higher civil penalties, the Commission intends to consider, where appropriate, assessing separate civil penalties for each violation that is aggregated into a Severity Level II problem.

The staff issued additional guidance on risk considerations in enforcement actions in EGM 97-011, dated June 6, 1997. The guidance states that risk is a relevant consideration in enforcement decisions concerning severity levels, appropriateness of sanctions, and the exercising of enforcement discretion. It also stated that the staff should continue to balance risk information against the guidance currently provided in the Enforcement Policy and the Enforcement Policy Supplements. Judgment must be exercised in the use of risk significance as a factor in decisions regarding the appropriateness of the sanction. There may be cases where, due to increased risk significance, it is appropriate to both escalate the severity level and the sanction in order to

convey the correct regulatory message to the licensee and the use of enforcement discretion may be warranted to reach the proper enforcement action. For example, based on risk information it may be warranted to treat violations normally considered a Severity Level IV violation at a higher severity level

While a higher severity level and sanction are warranted for violations that have greater risk significance, lower risk does not mean that severity levels should necessarily be reduced from those provided in the Supplements. As stated before, risk is only one component in the consideration of the appropriate severity level. Severity level considers actual consequence, potential consequence (risk), and regulatory significance. Therefore, a violation with little or no actual safety consequence and lower risk significance may still pose a significant regulatory concern and warrant a higher severity level and/or sanction. In deciding whether a violation should be categorized at Severity Level III or IV, risk significance is considered. Low risk does not excuse noncompliance. If a licensee believes an issue is of low risk and not worthy of being a requirement, the licensee may seek a change to the requirement. However, compliance is required until the requirement is changed.

The Enforcement Manual provides additional guidance to the staff and states in Section 3.5.a that safety significance involves the consideration of three factors: (1) the actual safety consequence (e.g., overexposure, offsite release, loss of a safety system), (2) the regulatory significance, and (3) potential safety consequence and provides examples to illustrate the concepts. While not specifically defined in either the Enforcement Policy or the Enforcement Manual, regulatory concern or regulatory significance has traditionally been understood to involve issues such as, but not limited to, programmatic breakdowns, repetitive violations, willfulness, reporting failures, licensees' refusal to comply, and management involvement.

The staff does not agree with RUG IV's limiting definitions provided in footnote 9 for actual safety consequence and regulatory significance. As emphasized in the preceding paragraph, the staff's guidance provides a starting point for the concepts of actual and potential safety consequence and regulatory significance. Supplements I through VIII of the Enforcement Policy provide examples of violations in eight different activity areas and serve as additional guidance in determining severity levels. Many of these examples include the level of specificity suggested in RUG IV's definition for actual safety significance. However, it should be noted that the examples in the supplements are neither exhaustive nor controlling.

NUREG-1022 clarifies the immediate notification requirements of 10 CFR 50.72 and the 30-day written licensee event report (LER) requirements of 10 CFR 50.73. While the information in NUREG-1022 has provided helpful guidance to the industry and to the staff, it was not developed with enforcement in mind. (11) Nevertheless, there may be information within NUREG-1022 that can be helpful in the enforcement program. The staff will consider this as it completes its review of the Enforcement Policy supplements. (12)

In addition, the staff does not agree with NEI and UCS that regulatory significance should be eliminated from the evaluation of a violation's significance. There may be cases where the actual and potential safety consequences are negligible or non-existent, yet circumstances exist that represent a significant concern. For example, the failure of an auxiliary operator to perform a required surveillance for a piece of equipment may not result in an actual consequence and may not pose a significant potential consequence. However, if the operator's failure represents a repetitive occurrence, the repetitive nature of the failure could represent a significant regulatory concern that could elevate the overall safety significance of the violation. The staff believes that it should assess whether a violation is part of a pattern of noncompliance (i.e., the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. NEI and UCS both raised specific concerns regarding the staff's use of programmatic issues and conclusions. For example, what factors should be considered when a single event discloses a programmatic issue in comparison to a programmatic issue based on time. The supplements to the Enforcement Policy address programmatic issues in the context of "breakdown in the control of licensed activities," (see e.g., Supplement I.C.7). The staff believes that this is an area that deserves more focus. The staff notes that the enforcement program is dependent on the inspection program's ability to identify programmatic issues in a consistent manner. This requires not only additional guidance for determining when a programmatic or breakdown in control issue is evident, but also requires strong management oversight of the inspection program to ensure that the inspection program does not inadvertently skew the enforcement program by inconsistent inspection views. The staff will consider programmatic issues as the staff

The staff recognizes the need to develop additional guidance, provide additional training, and perform audits to ensure consistency in the enforcement program. Consistency has especially been a challenge in the area of non-escalated enforcement actions because of the limited oversight by OE. In the past, OE's primary focus has been on escalated actions. OE intends to provide additional oversight and training in an effort to improve consistency. The degree of effort associated with this task will be a function of the available resources. In addition, in an effort to improve the clarity of enforcement communications, OE intends to provide additional enforcement guidance directing that correspondence transmitting escalated enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of these issues). (See the corresponding discussion in Section II.E.) As a final note, it should be emphasized that the agency's approach to enforcement involves considerable judgment and discretion rather than a mechanical treatment. In light of the considerable judgment that is exercised in determining whether an issue represents a significant regulatory concern (including programmatic issues), it may be appropriate to consider greater management oversight.

Conclusion

The staff does not believe that the Enforcement Policy should be modified to include limiting definitions for actual and potential safety consequence and regulatory significance or regulatory concern, nor should it eliminate regulatory significance as a consideration of the relative importance of a violation. The staff should provide additional guidance to the staff in establishing severity levels, including the use of terms, actual consequence, potential consequence, and regulatory significance. The staff should continue its efforts to complete the review of the Enforcement Policy supplements. Greater management oversight should be considered in cases based on regulatory significance, especially those involving programmatic issues. These actions should help improve the consistency of enforcement actions.

D. NEW RULEMAKING AND THE ENFORCEMENT POLICY

Comments

RUG IV recommended that EGMs or similar clarification of how the NRC staff will apply the Enforcement Policy to new rules be issued and evaluated concurrently with the new proposed rulemaking.

• Discussion

The staff has, in some instances, included Enforcement Policy changes as part of rulemaking, e.g., Part 20, Part 34. However, this has not always been done. Further, as RUG IV points out, the Maintenance Rule was implemented on July 10, 1996, and EGM 96-002 was issued on August 21, 1996. Development of inspection and enforcement guidance can help identify and understand implementation issues associated with the rulemaking and may identify issues with the rulemaking. The staff should develop draft guidance at the proposed stage so that the Commission can be satisfied that the staff's inspection and enforcement guidance is consistent with the Commission's intentions. In SECY-97-168, "Issuance For Public Comment of Proposed Rulemaking Package For Shutdown and Fuel Storage Pool Operation," dated July 30, 1997, the staff stated it would provide such guidance as part of the final rulemaking.

• Conclusion

The staff should consider inspection and enforcement guidance when new rules are developed and implemented.

E. MAINTAINING SAFETY FOCUS

Comments

NEI commented that enforcement can and should be more effectively linked to safety. NEI stated that for violations with little or no safety consequence, where timely and corrective action has been implemented, subsequent enforcement action only diverts licensee resources from other, more potentially safety significant activities. NEI recommended that the NRC adopt an approach that does not dictate that enforcement action be taken simply because a noncompliance is found. If the noncompliance doesn't represent a valid risk to public health and safety (such as a violation of documentation or reporting requirements), NEI recommended that no enforcement action be taken. Instead, NEI recommended that the NRC impose enforcement sanctions (presumably escalated actions) in those relatively rare cases where a licensee was or should have been aware of a potential safety problem and did not timely identify, report and/or correct it, or for noncompliances of obvious safety significance or if there is an intentional violation. By reserving escalated enforcement for those kinds of cases, NEI suggested that the NRC would send a clear signal to the licensee -- a violation then would mean an important issue exists, a message that now is diluted when violations are given routinely for matters of no real safety significance.

Discussion

The staff agrees that the enforcement program must maintain a clear focus on safety. Violations vary in their degree of safety, safeguards, or environmental significance; for that reason, the Enforcement Policy provides a graduated system of sanctions, varied according to the technical significance (i.e., actual and potential consequences) and the regulatory significance. This graduated system appears both in the range of severity levels assigned to different violations, and in the availability of different enforcement actions (e.g., NCVs, NOVs, civil penalties, and orders). Maintaining a safety focus was addressed in the 1995 enforcement program reassessment, as described in Section II.A.1.b of NUREG-1525.

Modifications were made to the Enforcement Policy to assist the staff and industry in maintaining a safety focus. For example, Section IV of the Enforcement Policy provides that minor violations not be the subject of formal enforcement action and not normally be documented in inspection reports. When sufficient information regarding a licensee's corrective actions exists on the docket, the NRC may waive a licensee's response to an NOV. Civil penalties are no longer proposed for repetitive Severity Level IV violations, unless the repetitive violation is such that it warrants classifying the matter as a Severity Level III violation. The Policy continues to provide that Licensee-identified and corrected Severity Level IV violations be dispositioned as NCVs, provided they meet the remaining criteria for discretion in Section VII.B.1.

In an SRM dated August 25, 1997, the Commission outlined a general approach to safety and compliance. The discussion stated:

As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The Atomic Energy Act of 1954, as amended, establishes "adequate protection" as the standard of safety on which NRC regulation is based. In the context of NRC regulation, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials.

While there is agreement on the need to maintain a safety focus, as discussed in Section II.C, disagreements may occur as to the *safety significance* of any particular violation. In the view of the NRC, a violation need not result in an *actual* impact to the public or to an employee (e.g., a release of radioactive material to the public or an employee overexposure to radiation) before it is considered significant. In resolving differing views on safety significance, considerations should include *all* aspects of safety significance as applied to enforcement, including the *actual safety consequence*, the *potential safety consequence*, and the *regulatory significance*. While NEI appears to recognize the safety significance of willful violations, NEI does not appear to recognize the safety significance of violations involving potential consequences, or other types of regulatory significance, such as programmatic breakdowns, repetitive violations, reporting failures, licensees' refusal to comply, and management involvement. As previously discussed in Section II.C of this report, the Enforcement Policy was modified on December 10, 1996, to clarify that technical significance includes both actual and potential

consequences and that risk is an appropriate consideration in evaluating the technical significance of a violation.

The staff is concerned that when systems fail, margins of safety are reduced, and redundancy is lost, even when events do not occur. The enforcement program seeks compliance, actual consequences do not need to occur before there is a significant regulatory concern. If a valve is in an incorrect position, but the dependent system was not called upon to work, the issue is significant, although not as significant as if the system were called upon to work. The current guidance on severity levels reflects this. It is expected that licensed facilities operate by design within the regulatory envelope.

As noted in NUREG-1525, even with the emphasis on performance-based inspections, so-called "administrative" or "paper-work" violations are not necessarily minor in safety or regulatory significance. Many of the surveillance, quality control, and auditing systems on which both the NRC and the licensees rely (in order to monitor compliance with safety standards) are based primarily on complete, accurate, and timely recordkeeping and reporting. These requirements are necessary to provide evidence that systems will work when called upon.

As noted in the Commission-approved discussion on safety and compliance in the August 1997 SRM:

Safety is the fundamental regulatory objective, and compliance with NRC requirements plays a fundamental role in giving the NRC confidence that safety is being maintained. NRC requirements, including technical specifications, other license conditions, orders, and regulations, have been designed to ensure adequate protection--which corresponds to "no undue risk to public health and safety"--through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.

Given the common misperception that safety significance is synonymous with actual consequence, the staff recommends that it provide additional enforcement guidance directing that correspondence transmitting escalated enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of these issues). Expressing safety significance in this context should help to improve the clarity of enforcement communications.

• Conclusion

The staff believes that the Enforcement Policy is appropriately structured to maintain a focus on safety. The staff recognizes, however, that there may be differing views on what constitutes "safety" and the nexus between safety and compliance. Therefore, in accordance with the Commission's direction in the August 25, 1997 SRM, the staff recommends that Section I of the Enforcement Policy be modified to include additional discussion (as appropriate) on the nexus between safety and compliance. The staff also recommends that additional enforcement guidance be issued that requires that correspondence transmitting escalated enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of these issues).

F. ENSURING ENFORCEMENT ACTIONS ARE CONSISTENT WITH REGULATORY REQUIREMENTS

Comments

NEI commented that in some cases, NRC enforcement actions seem to be based upon new interpretations of regulatory requirements, not communicated to the licensee. NEI cited recent enforcement actions on FSAR design-basis issues, 10 CFR 50.59 implementation, and the maintenance rule, and suggested a need for improvement in NRC management reviews of cited violations to ensure that the NRC does not create new regulatory requirements through the enforcement process nor penalize licensees for violations based on previously unannounced interpretations.

Discussion

The staff does not agree that enforcement actions are based on new interpretations. Licensees have the opportunity to challenge enforcement actions if they believe that new or inappropriate interpretations are being made without adequate notice. Considerable effort is made to ensure escalated enforcement actions are appropriate. This includes frequent contact with the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Materials Safety and Safeguards (NMSS) to ensure that enforcement actions reflect agency positions. In addition, to this end, NMSS has recently established the position of an NMSS Regional Program Coordinator whose duties include participation in and advise on materials enforcement activities in the regions and within NMSS. Further, more effort should be made to achieve better oversight of non-escalated enforcement actions. In this regard, all potential maintenance rule violations (regardless of potential severity level) are currently the subject of a multi-office review panel to ensure the appropriateness and consistency of enforcement actions in this area.

The staff recognizes the concerns in the area of 10 CFR 50.59 and is working on improving guidance in this area. All potential escalated actions based on 10 CFR 50.59 are subject to review by OE. The staff is establishing an OE and Office of Nuclear Reactor Regulation (NRR) review panel (like the maintenance rule panel) to ensure the appropriateness and consistency of all enforcement actions in this area.

Also, OE intends to establish a clearer process for challenging non-escalated enforcement actions (see the discussion in Section II.I.2 of this report).

Conclusion

The staff does not believe that enforcement actions are being used to create new regulatory requirements. However, the staff is establishing a multi-office review panel for potential violations involving 10 CFR 50.59 and will provide a clearer path for headquarters review of challenges to enforcement

actions.

G. ENFORCEMENT CORRESPONDENCE

Comments

CORAR stated that any federal agency publication of licensee issues should be treated with high significance and care should be taken to ensure that the public has an accurate understanding of the severity of the issue. CORAR recommended that inspection reports include an explanation of the significance of each finding.

Discussion

The significance of violations is reflected in the severity level categorizations that are given to violations, and these levels are defined and addressed in the Enforcement Policy (i.e., Section IV and severity examples in the supplements, respectively). Notices of Violation include the severity level categorization after each violation included in the citation. Standard language for NCVs distinguishes minor violations from Severity Level IV violations by referencing the applicable section in the Enforcement Policy (i.e., Section IV for minor violations and Section VII.B.1 for Severity Level IV violations) to avoid confusion. Care is taken to ensure that the licensee and other audiences reading the correspondence understand the significance of issues. Correspondence will generally address the significance in terms of actual or potential consequence or regulatory significance.

However, as noted in Section II.E of this report, given the common misperception that safety significance is synonymous with actual consequence, the staff is recommending that it provide additional enforcement guidance directing that correspondence transmitting enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of these issues). Expressing safety significance in this context should help to improve the clarity of enforcement communications.

Because of the predecisional nature, inspection reports that include apparent violations (i.e., violations that may warrant escalated enforcement action) do not include safety significance conclusions. Instead, the report includes a discussion of the circumstances, such as whether or not an actual consequence occurred or a potential consequence existed. The conclusion on safety significance is reflected in the resulting enforcement action or in a close-out letter, in the absence of enforcement action.

The staff notes that "findings" that are not identified as violations or apparent violations are not subject to enforcement action. Enforcement guidance directs the staff to properly address and disposition noncompliances as noncompliances, not "findings." Noncompliances, as previously stated, include a discussion of significance.

Manual Chapter 0610, "Inspection Reports," in the NRC Inspection Manual provides additional guidance to the staff in addressing "findings" and providing context for significance (Sections 05.01.b and 05.02).

Conclusion

While the current guidance for inspection and enforcement correspondence provides for addressing the safety significance and severity level of noncompliances, the staff recommends that enforcement guidance be expanded to require that the safety significance discussion for escalated enforcement actions address whether the issue represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of the issues).

H. LICENSEE RESPONSES TO NOTICES OF VIOLATION

Comments

RUG IV suggested that the NRC encourage prompt licensee corrective actions through increased use of "no response required."

Discussion

The Enforcement Policy was modified in 1995 to clarify that the NRC may waive all or portions of a licensee's written response to a Notice of Violation to the extent relevant information has already been provided to the NRC and is on the docket. This initiative allows the staff and licensees to channel resources to other, potentially significant issues. The staff has been implementing this option where appropriate.

Conclusion

The staff supports the continuation of the practice of waiving a licensee's response to an NOV, where appropriate.

I. NON-ESCALATED ENFORCEMENT ACTIONS

This topic includes comments and discussion related to non-escalated enforcement actions, including, the need for increased oversight, the development of a formal appeals process, the opportunity to comment on non-escalated violations before they are issued, the "test" for minor violations, and Non-Cited Violations.

1. INCREASED OVERSIGHT

Comments

To ensure uniform application of the Enforcement Policy between the NRC regional offices, RUG IV recommended increased oversight by OE and the Office for the Analysis and Evaluation of Operational Data (AEOD) of non-escalated enforcement actions.

Discussion

The staff recognizes that there have been some inconsistencies in the application of the Enforcement Policy in the area of non-escalated enforcement. The staff should focus more attention on oversight, guidance, and training in an effort to improve the consistency of non-escalated enforcement actions. The degree of effort for this task will be a function of the available resources. This is consistent with the agency's effort to increase the NRC's effectiveness.

AEOD currently assists OE in matters within its area of expertise, such as reporting requirements. From time to time, AEOD also provides enforcement-related insights to OE, such as in the development of additional guidance on severity levels. OE will continue to accept and request assistance from AEOD, when appropriate. In addition, with OE and AEOD reporting to the Deputy Executive Director for Regulatory Effectiveness, there is a greater opportunity for coordination and OE's ability to utilize AEOD's assistance.

• Conclusion

The staff should develop additional guidance, provide additional training, and perform audits to help improve the consistency in addressing non-escalated enforcement actions.

2. DEVELOPMENT OF FORMAL APPEALS PROCESS

Comments

RUG IV noted that the existing Enforcement Policy does not establish a formal process by which licensees may appeal non-escalated enforcement actions beyond the initial denial in the Reply to the Notice of Violation. RUG IV recommended that the Commission develop a formal non-escalated enforcement action appeals process.

Discussion

The provisions of 10 CFR 2.201 (Notice of Violation) and the existing Enforcement Policy do not establish a formal process by which licensees may "appeal" either non-escalated or escalated enforcement actions that are proposed without civil penalties beyond the initial denial in the Reply to the Notice of Violation (NOV). The staff does, however, have guidance in the Enforcement Manual that provides for varying degrees of independent review for disputed NOVs.

With respect to non-escalated NOVs (i.e., including Severity Level IV violations), Section 4.2.5 of the Enforcement Manual provides that the region address licensees' responses to NOVs, including denials. OE is not routinely involved in evaluating licensees' responses. OE is normally notified if a licensee contests the violation on the basis of inconsistent application of the Enforcement Policy, if the response takes longer than 60 days to prepare, if there are significant differences within the regional staff or between the region and program office staffs, or if program office views are necessary to resolve a licensee's contention. OE does, however, evaluate a licensee's response in the event it makes a subsequent denial in reply to the region's response.

With respect to escalated NOVs (i.e., including Severity Level I, II, or III violations), guidance in Section 5.6.6 of the Enforcement Manual provides that the region coordinate its response to licensee disputes with OE.

While the staff does not believe that it would be appropriate to develop a formal appeals process for NOVs similar to the appeals process for civil penalties in 10 CFR 2.205, it may be appropriate for licensee denials to be subject to more independent review. The staff intends to provide additional agency review by having the evaluation of and response to *all* NOV disputes coordinated with OE.

As a final note, additional oversight in the non-escalated area should not only improve quality and consistency, but may reduce the number of disputes.

Conclusion

The staff does not recommend that a formal appeals process for non-escalated enforcement actions be developed. Instead, processes should be established to provide for coordination of all NRC responses to disputes in cases involving NOVs proposed without civil penalties. Specifically, OE will modify the formats for NOVs to direct licensees to forward a copy of denials to the Director, OE and OE will modify the staff guidance in the Enforcement Manual to require all licensee denials to be coordinated with OE. The degree of OE review will be based on the circumstances of the case.

3. OPPORTUNITY TO RESPOND TO APPARENT VIOLATIONS AND DRAFT INSPECTION REPORTS

• Comments

CORAR recommended that licensees be provided the opportunity to review and respond to draft non-escalated enforcement actions and draft inspection reports (like potential escalated actions) before they are issued and placed in the Public Document Room. CORAR based this recommendation on the concern that non-escalated NOVs and inspection reports may include erroneous information that subsequently subjects licensees to unfair publicity. CORAR stated that the negativity is compounded because of the time delay to correct the inspection report and because of the public confusion when a second NOV is issued (i.e., the public may view it as an additional enforcement action versus a correction to a previous action).

• Discussion

Contrary to CORAR's understanding, the NRC does not issue inspection reports in draft form. Normally apparent violations that may warrant escalated enforcement action are addressed in inspection reports and issued to licensees. These inspection reports are public and are placed in the PDR when they are issued to the licensee. Licensees always have the opportunity to notify the agency when they believe that information in an inspection report is

incorrect or inaccurate. In addition, all inspection reports are reviewed by a member of NRC management familiar with the NRC requirements in the area inspected before issuance.

The staff notes that not all inspections results are documented in inspection reports. In certain cases involving materials licensees, inspection field notes and NRC Form 591, "Safety Inspection" may be used. Form 591 summarizes the findings of the inspection related to radiation safety and may be used to document Severity Level IV violations and serve as the official Notice of Violation. Some NRC inspectors are qualified to issue a Form 591 to a licensee at the time of the inspection exit without management review. However, Form 591s and accompanying field notes are reviewed by NRC management after an inspection is completed.

While the staff can appreciate CORAR's concern regarding the issuance of non-escalated enforcement actions that are subsequently revised, given the small percentage of times that this occurs, CORAR's concern does not outweigh the resource and timeliness considerations associated with CORAR's recommendation.

However, the staff agrees that issuance of an untimely inspection report correction or revised NOV can potentially mislead the public as a new issue. Therefore, OE intends to issue staff guidance in the Enforcement Manual that will require that revised NOVs clearly be identified in the subject line of the transmittal letter as such, i.e., "REVISED NOTICE OF VIOLATION."

Conclusion

The staff does not believe that providing licensees an opportunity to respond to apparent violations for non-escalated enforcement actions is warranted. It will delay resolution of issues and increase the cost of enforcement with little benefit. Moreover, as noted in Section II.J of this report, the staff is reconsidering the recent practice of providing licensees the opportunity to respond to apparent violations in lieu of predecisional enforcement conferences. Finally, OE intends to issue guidance to help reduce the possible confusion when revised NOVs are issued.

4. MINOR VIOLATIONS

• Comments

CORAR recommended that minor violations not be published. CORAR based its recommendation on its view that the public does not distinguish between levels of violations and, by publishing minor violations, the NRC inadvertently fosters a public perception of unsafe facilities.

RUG IV recommended that the Commission amend the Enforcement Policy to allow minor violations to be discussed in inspection reports without escalation to an NCV. In addition, while RUG IV did not have a concern with the definition of a minor violation in the Enforcement Policy, RUG IV commented that the "test" in the Enforcement Manual for determining whether a violation was minor was overly subjective and that any violation could fail the test, i.e., every violation could be considered more than minor.

Discussion

As previously addressed, Section IV of the Enforcement Policy provides that minor violations are **not usually documented in inspection reports**. However, there may be circumstances where it may be appropriate to document a minor violation for completeness or as part of the resolution of an allegation. If a minor violation warrants documentation, it should be recognized as a minor violation (as opposed to a "weakness," "licensee failure," or similar informal characterization). In these atypical cases, the existing policy is to note it as an NCV in accordance with *Section IV* of the Enforcement Policy (to ensure that readers understand that the violation is minor and not Severity Level IV). However, based on confusion between minor violations and NCVs, the staff, as noted below, is recommending a change to that policy.

The term "Non-Cited Violation" is defined in Section IV of the Enforcement Policy as "a violation that has not been formalized into a 10 CFR 2.201 Notice of Violation." The definition does not specify or qualify that the violation be any particular severity level. While the majority of NCVs that are issued are for Severity Level IV violations that meet the criteria for exercising discretion in accordance with Section VII.A.1 of the Enforcement Policy, NCVs may be used, as noted above, to disposition minor violations that warrant documentation. Therefore, contrary to RUG IV's view, minor violations that warrant documentation are not escalated to NCVs. Notwithstanding the appropriateness of dispositioning minor violations that warrant documentation as NCVs, the staff is proposing modifications to the Enforcement Policy to avoid possible confusion. Specifically, Section IV would be modified by deleting the footnote that includes the definition of an NCV (footnote 6) and by deleting the requirement that documented minor violations be noted as NCVs. Instead, the staff will use standard language such as, "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."

Section 6.3.1.1 of the Enforcement Manual (13) provides guidance to the staff to help determine whether an issue is a minor violation. The determination of whether the violation is minor should consider the following questions:

- Does the violation have any actual impact (or any realistic potential for impact) on safety?
- Does the violation suggest a programmatic problem that could have a realistic potential safety or regulatory impact?
- Could the violation be viewed as the possible precursor to a significant event?
- If the violation recurred, would its recurrence be a more significant concern?
- If inadvertently left uncorrected, would this violation become a more significant safety and regulatory concern?
- Are there associated circumstances that add regulatory concern to this violation (e.g., apparent willfulness, licensee refusal to comply, management involvement, etc.)?

If the answer to all of these questions is "no," the violation should be considered a minor violation. If, on the other hand, the answer to any one of these

questions is "yes," the violation should <u>not</u> be considered a minor violation.

The staff recognizes that there is considerable judgment in addressing these questions. However, elimination of these questions will not eliminate the differences in judgment on whether a violation is minor. These questions are a helpful tool and a starting point to aid the staff in determining whether a violation is minor. OE intends to develop additional guidance, conduct training, and perform audits to help improve the consistency in addressing these questions.

Conclusion

The staff recommends that the existing policy of not normally documenting minor violations be continued and that the Enforcement Policy be modified such that minor violations no longer be dispositioned as NCVs. The staff also recommends that the existing questions in the Enforcement Manual be maintained as an aid for the staff in determining whether a violation is minor. OE intends to develop additional guidance, provide additional training, and perform audits to help improve the consistency in addressing minor violations.

5. NON-CITED VIOLATIONS

Comments

Based on experience with the Enforcement Policy, modification on the use and guidance on the application of NCVs may be warranted. In addition, the current criteria for exercising the NCV discretion in Section VII.B.1, "Licensee-Identified Severity Level IV Violations" may warrant clarification.

Discussion

As discussed in Section II.1.4 of this report, RUG IV mistakenly held the belief that minor violations that were documented in inspection reports were escalated to NCVs. Therefore, the staff is proposing modifications to the Enforcement Policy to avoid this confusion. In addition, OE has developed additional guidance for the staff to use to determine whether a Severity Level IV violation can be dispositioned as an NCV (Enforcement Guidance Memorandum (EGM) 97-012). An addendum to this EGM was issued that included a flowchart, similar to the civil penalty assessment flowchart. As stated before, the staff also intends to provide greater oversight of non-escalated actions, including use of NCVs.

Based on experience with the Enforcement Policy, the criterion in Section VII.B.1.a may warrant clarification to address licensee-identified Severity Level IV violations that are identified as a result of an event. On December 10, 1996, the Commission issued a revision to the Enforcement Policy (61 FR 65088) that included a modification to the criterion in Section VII.B.1.a. Specifically, the phrase "including identification through an event" was deleted from the criterion that now simply reads, "It was identified by the licensee." The modification was intended to make it clear that use of discretion is not automatic if the violation is identified through an event. As stated in the previous paragraph, the staff issued additional guidance on dispositioning Severity Level IV violations as NCVs in EGM 97-012. This EGM states that credit for identification is not warranted when a licensee identifies a violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. The EGM also stated that credit may be warranted if the licensee demonstrated initiative in identifying the violation's root cause. Therefore, consistent with the intent of the previous policy change and consistent with staff guidance and current practice, the criterion in Section VII.B.1.a should be modified to address that credit for identification is not warranted when a licensee identifies a violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event and that credit may be warranted if the licensee demonstrated initiative in identifying the violation's root cause.

• Conclusion

The staff recommends that the Enforcement Policy be modified so that minor violations will no longer be dispositioned as NCVs. The staff also recommends that the criterion in Section VII.B.1.a be modified to address identification through an event. Specifically, a footnote should be added stating, "Discretion is not warranted when a licensee identifies a Severity Level IV violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. Discretion may be warranted if the licensee demonstrated initiative in identifying the violation's root cause."

J. ENFORCEMENT OPTIONS IN LIEU OF PREDECISIONAL ENFORCEMENT CONFERENCES

• Comment

Based on experience with the Enforcement Policy, the provision in the Enforcement Policy that provides a licensee an opportunity to respond to an apparent violation described in an inspection report in lieu of a predecisional enforcement conference (Section V) may warrant modification. Specifically, the Policy may warrant revision to include an additional option in those situations where the staff concludes that it has sufficient information to make an enforcement decision without the need for a predecisional enforcement conference.

Discussion

Prior to the 1995 Policy revision, the standard practice was to normally provide licensees an opportunity to discuss potential escalated violations (i.e., Severity Level I, II, or III violations) prior to the agency issuing an action by conducting an enforcement conference with the licensee. Given the expense of this practice (both for the NRC and licensees), the Policy was modified in 1995 to specify that conferences *only* be conducted if the agency requires additional information or the licensee requests one. However, the Policy provided that licensees would normally be provided an opportunity to address the inspection report *prior* to issuance of escalated action, in those cases where the staff concluded that a conference was not necessary. The staff uses what it refers to as "choice letters" to provide licensees the choice of responding to apparent violations in inspection reports or requesting a conference before the NRC makes a final enforcement decision. Unfortunately, in many cases, this practice has decreased the efficiency of the enforcement process

by increasing the cost and timeliness of issuing escalated actions without necessarily yielding a benefit.

For example, there have been many situations where the staff has had sufficient information (including the licensee's proposed corrective actions) to make an enforcement decision (such as issuing a Severity Level III violation without a civil penalty). Because of the predecisional nature of the correspondence transmitting the apparent violations, licensees do not appreciate that, with the given information of the case, the staff is not considering a civil penalty. Because of this lack of information, the staff believes that licensees have requested conferences solely in an effort to mitigate or eliminate civil penalties that the staff is not planning on issuing. In these situations, the staff honors the licensee's request and conducts a conference, only to subsequently issue an NOV that the licensees accepts. This type of situation represents an additional expenditure to both the NRC and licensee and delays the enforcement outcome without a clear benefit.

In cases where the licensee responds to the apparent violations and does not request a conference, the staff reviews the licensee's response and, provided its corrective actions appear appropriate, subsequently issues another letter to the licensee formalizing the apparent violations in an official NOV. Again, in this type of case, the staff basically duplicates its efforts and delays the enforcement outcome without a clear benefit.

In an effort to make the enforcement process more efficient (by reducing the number of conferences and reducing the workload of both the NRC and licensees), the staff recommends that when certain circumstances exist, an NOV should be issued for the licensee to respond to rather than responding to an apparent violation. This option might be appropriate in those escalated cases in which the staff: (1) has sufficient corrective action information from the licensee to decide on enforcement action, (2) sees no need for a predecisional enforcement conference to obtain further information prior to reaching an enforcement decision, and (3) has concluded that a civil penalty will not be proposed in the case unless the licensee fails to confirm the previously described corrective actions.

This approach would still: (1) provide licensees an opportunity to request a conference to dispute the action (although the staff believes that most licensees will not request a conference), (2) provide licensees an opportunity to dispute the action in writing through the provisions of 10 CFR 2.201 (like non-escalated violations), (3) allow the staff to conduct a conference where matters are disputed or where the licensee's documented corrective actions are not sufficiently prompt and comprehensive, and (4) provide for modification or recision of the NOV, if appropriate.

Notwithstanding the previous discussion, the staff still recommends that the option of issuing "choice letters" be maintained. The staff believes that this option is still appropriate in certain circumstances. In particular, because of the differences in materials licensees' inspection frequencies and because NRC inspectors are not stationed at materials facilities (except for certain fuel cycle facilities), materials inspectors may not be aware of a materials licensee's corrective actions subsequent to the inspection exit. (This is in contrast to a reactor inspection where inspectors are more likely to be aware of corrective action information subsequent to the inspection exit because of the presence of resident inspectors.) Issuing a choice letter may be appropriate in cases like this where a materials licensee appears to understand the significance of the violation and the need for corrective action at the inspection exit. In these cases, the choice letter may provide the emphasis to the licensee to develop and implement comprehensive corrective actions to avoid the potential for a civil penalty. In fact, recognizing the importance of corrective action, the NRC staff prepared guidance that could be used to assist materials licensees in developing and implementing corrective action in response to violations. This guidance was issued in Information Notice is included as an enclosure to choice letters.

Conclusion

The staff recommends that Section V of the Enforcement Policy be revised to address two enforcement options if a predecisional enforcement conference is not held. The staff recommends that the existing Policy discussion stating that, "...the licensee will normally be requested to provide a written response to an inspection report..." be modified to state, "...the licensee may be requested..." to indicate this approach as one enforcement option. The staff recommends that Section V be further modified to address another enforcement option by stating, "However, if the NRC has sufficient information to conclude that a civil penalty is not warranted, it may proceed to issue an enforcement action without first obtaining the licensee's response to the inspection report."

K. CIVIL PENALTY ASSESSMENT PROCESS

1. ADJUSTMENT TO BASE CIVIL PENALTY TABLE 1A

Comments

Based on experience with the Policy, modifications to the base civil penalties in Table 1A may be warranted. First, the table should be modified to address large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material. Second, the table should be modified to include additional guidance to address how other large and small materials users should be categorized. Finally, the base civil penalty for certain fuel cycle facilities should be increased based on the relative safety and safeguards risks among the different types of fuel facilities.

Discussion

As to the first issue, the staff has identified what appears to be an administrative oversight in publication of the 1995 Enforcement Policy revision. Specifically, prior to the revision, Table 1A included a footnote that indicated that large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material were considered as industrial processors. This footnote was not included in Table 1A in the *Federal Register* notice for the 1995 Enforcement Policy revision. This footnote (footnote 1) was included in the table in Section II.D.7.c of NUREG-1525 (page II.D-39). This footnote (which included an additional sentence indicating that safeguards violations for this category would be at a base penalty of \$100,000) was also included in the table in the draft *Federal Register* notice that the Commission approved for publication based on SECY-95-084. The SRM did not direct the staff to modify or delete the footnote. However, subsequent to the Commission's approval, the staff recognized that the second sentence of the footnote was included in error. Namely, it was inconsistent with the staff's position addressed in Section II.D.7.c of NUREG-1525 (page II.D-39) and in

SECY-95-084 (page 3) that the base civil penalty amount for safeguards violations should be the same as for other violations at these facilities, i.e., \$25,000. It appears that when the second sentence was deleted, that footnote 1 was inadvertently deleted in its entirety.

Second, the table should be modified to provide more guidance in determining which category other large and small material users should be considered under. The staff recognizes that each category in Table 1A contains a range of licensees, differing individually by size, scope of licensed activities, quantity and type of licensed material, number of employees, number of work locations, and financial assets. As noted in NUREG-1525, the staff believes that no simple classification system will individually account for each of these variables. As with current policy and practice, the NRC should take into account the gravity of the violation and the licensee's ability to pay. If, for a given licensee, Table 1A does not appropriately reflect these factors, the NRC should consider increasing or decreasing the amount as necessary. Consistent with this approach, the staff recommends that "other large material users" should be included in category "c" and "other small material users" should be added to category "d."

With respect to the third issue, the staff believes that the base civil penalty for certain fuel cycle facilities should be increased, commensurate with the relative safety and safeguards risks among the different type of fuel cycle facilities. The staff is currently developing this issue in a separate Commission paper. In addition, this issue was briefly addressed in the staff's recommendations regarding civil penalty assessments for gaseous diffusion plants in SECY-96-258, dated December 19, 1996.

Conclusion

The staff recommends that Table 1A be modified to include the footnote that recognizes large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material as industrial processors and to include "other large material users" in category "c" and "other small material users" in category "d." Table 1A may also warrant revision in the future depending on the Commission's decision on the staff's recommendation to increase the base civil penalty amounts for certain fuel cycle facilities.

2. INITIAL ESCALATED ACTION

· Comments

NEI recommended that the first decisional point in the civil penalty assessment process be modified to exempt only prior, non-willful escalated actions *in the same functional area*. NEI based this recommendation on its view that the effect of setting the scope of past violations so wide, together with the complexity of nuclear plant operations and the voluminous and detailed regulatory requirements, make it a near certainty that credit will be withheld because of a past violation. Despite the overall sustained good performance of most licensees, NEI stated that the plant-wide reach of this factor prevents the enforcement process from recognizing that good performance.

Discussion

The first decisional point in the civil penalty assessment process currently states that when the NRC determines that a non-willful Severity Level III violation or problem has occurred, and the licensee has not had any previous escalated actions (regardless of the activity area) during the past 2 years or two inspections, whichever is longer, the NRC will consider whether the licensee's corrective action for the present violation is reasonably prompt and comprehensive. In designing this strategy, the objectives were to simplify the previous process, give more weight to current performance than past performance, and, at the same time, maintain the flexibility to consider particularly poor or particularly good performance.

In the past, the Enforcement Policy allowed escalation or mitigation up to 100% of the base civil penalty based on the licensee's overall performance and performance specifically related to the area of the violation. Because of the broad scope and range of the "Licensee Performance" factor, including the range (100%) for discretion, consistent implementation was difficult, such as when a violation involved overlapping functional areas.

With regard to the second objective, even if a licensee's past performance has been poor, as characterized by having previous escalated enforcement action, if the licensee's *current* performance is characterized by self-identifying and promptly, comprehensively correcting the violation, a civil penalty would not normally be proposed. In other words, if a licensee is truly a good performer, even if it has had an enforcement action in a different activity area, it would not be subject to a civil penalty because it would have identified and corrected the current violation.

It is noted that there are many different types of activities at a given licensed facility. For example, at a reactor facility, these include activities associated with (but not limited to), operations, design, maintenance, health physics, chemistry, safeguards, fitness-for-duty, quality assurance, and discrimination issues. Under NEI's approach, escalated action could be taken in each area before the factor of identification is considered.

Nevertheless, the staff recognizes that there may be some situations where there is little relationship between cases, such as a discrimination case and an old design issue. The Enforcement Policy provides the staff with the flexibility to exercise discretion in special circumstances to ensure that the resulting enforcement action is appropriate for the circumstances of the particular case.

Finally, the staff notes that Section VII.B.6 specifically recognizes that mitigation may be appropriate where the overall sustained performance of the licensee has been particularly good. In addition, Section VII.A.1 of the Enforcement Policy specifically recognizes that escalation may be appropriate where the licensee's previous enforcement history has been particularly poor, or when the current violation is directly repetitive of an earlier violation.

Conclusion

The staff believes that the first decisional block in the civil penalty assessment process is appropriately structured in considering past enforcement actions, regardless of activity area.

3. INCENTIVES FOR IDENTIFICATION AND CORRECTIVE ACTION

Comments

NEI recommended that the NRC reduce civil penalty outcomes in the revised civil penalty assessment formula so that meaningful credit is awarded for self-identification or corrective action -- rather than simply withholding escalated penalties. NEI recognized that under the current process, if a licensee self-identifies and corrects a violation, a civil penalty would not normally be issued. However, NEI stated that the current civil penalty assessment process fails to provide positive incentives for achievement of either objective individually. NEI recommended that if the licensee achieves either objective (self-identification or corrective action), it should receive a 50% reduction in the civil penalty. If both results are achieved, no civil penalty should issue. But, if the licensee fails to achieve both objectives, it receives the full base penalty -- 100%.

Discussion

The current civil penalty assessment process is not limited to the consideration of two factors, identification and corrective action. Instead, the assessment process (graphically represented in Section 7 of Appendix A) considers *four* decisional points, involving past performance, identification, corrective action, and those issues that may warrant exercising enforcement discretion.

In making its recommendation, NEI overlooks the importance of the first decisional point in the assessment process. The first decisional point addresses whether the violation is the first escalated enforcement action that the licensee has had during the past 2 years or past two inspections. If the licensee has not had any past escalated actions, the assessment process then addresses the promptness and comprehensiveness of the licensee's corrective actions and then whether there are special circumstances that may warrant discretion. In this scenario, the issue of identification is not considered. In other words, even if the NRC identified the violation, this strategy is designed to provide flexibility for licensees who have traditionally been good performers. This strategy also places a premium on corrective action.

On the other hand, if a licensee has had past escalated actions, the process addresses whether the licensee should be given credit for actions related to identification and corrective actions and then whether there are special circumstances that may warrant discretion. In this scenario, the staff believes a base civil penalty is appropriate if the licensee only warrants credit for either self-identification or corrective action because the process reflects that the licensee has had a history of escalated action. However, even if a licensee has had a history of past actions, under the assessment process, a licensee would not normally be subject to a civil penalty if it identified and corrected the current violation. As stated before, this strategy gives more weight to the licensee's current performance.

Conclusion

The staff believes the current civil penalty assessment process is appropriately structured to reflect issues the agency believes are appropriate to consider in assessing whether a civil penalty should be proposed, i.e., past performance, identification, corrective action, and those that may warrant exercising enforcement discretion (i.e., VII.A.1 and VII.B.6).

4. STANDARDS FOR CORRECTIVE ACTION

Comments

NEI recommended that the NRC clarify the standard for corrective action credit in the civil penalty assessment process. NEI claimed that what constitutes "prompt and comprehensive" corrective action in the current policy is ill-defined, subjective, and detracts from predictable implementation of the process. NEI also claimed that credit for corrective action is often not given because of this lack of clarity. NEI recommended that credit be given for corrective actions, that, when implemented, restore regulatory compliance.

Discussion

Given the complexity and variety of nuclear activities subject to nuclear regulation, it would be implausible to establish standards for corrective action for each type of noncompliance. Instead, Section VI.B.2.c of the current Enforcement Policy establishes a goal for corrective action; namely that the corrective actions will promptly restore compliance and will be appropriately comprehensive to prevent occurrence of violations with similar root causes.

The Policy also provides considerable guidance in assessing the factor, such as consideration of the timeliness of the corrective action, the adequacy of the root cause analysis, the comprehensiveness of the corrective action (given the significance and the complexity of the violation), and whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive action. Recognizing the importance of corrective action, the NRC staff prepared guidance that could be used to assist materials licensees in developing and implementing corrective action in response to violations. This guidance was issued in Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," on May 1, 1996.

The staff disagrees with NEI's view that credit should be given for corrective actions that merely restore compliance with requirements. Obviously a valve must be returned to the correct position. However, it is necessary to determine *why* the valve was in the incorrect position so that lasting corrective actions can be developed and achieved. A general tenet of the Enforcement Policy is that it be used as a deterrent to prevent future violations. This requires a root cause analysis. Therefore, the staff believes it is appropriate to expect corrective actions to be sufficiently comprehensive, given the significance and complexity of the violations, to prevent occurrence of violations with similar causes. Finally, the staff notes that credit is given in the majority of cases subjected to the civil penalty assessment process⁽¹⁴⁾. In addition, in those cases when credit is not provided, the enforcement correspondence generally explains the basis for not providing credit, such as addressing other actions that could have been taken, or that the NRC had to take action to focus the licensee's actions.

Conclusion

The staff believes the current discussion in the Enforcement Policy for providing corrective action credit in the civil penalty assessment process is sufficient and that credit for corrective action should continue to be dependent on both actions to restore compliance and actions to prevent recurrence.

5. MANDATORY CIVIL PENALTIES

Comments

UCS commented that the Enforcement Policy should produce consistent enforcement actions, and to that end, recommended that the Enforcement Policy be modified to eliminate what it viewed as subjective enforcement based on performance issues. In particular, UCS recommended that the staff consistently impose a civil penalty every time a licensee fails to meet a requirement, regardless of a licensee's performance or ability to meet requirements in other areas. (The staff assumed that UCS was directing this recommendation at those violations that would currently be subjected to civil penalties, i.e., Severity Level I, II, or III violations.) UCS took the position that civil penalties are necessary to remedy deficiencies. Without a civil penalty, UCS stated that the deficiency may remain uncorrected or resources withheld or deferred.

Discussion

The staff agrees that consistency is an important element in maintaining a credible and effective enforcement program. Automatically issuing a civil penalty for every Severity Level I, II, or III violation would certainly make the Enforcement Policy consistent. However, the staff believes that an enforcement approach that strikes the proper balance between deterrence and incentives is consistent with the overarching goals of the program, namely that enforcement be used as a deterrent to emphasize the importance of compliance with requirements and to encourage prompt identification and prompt, comprehensive correction of violations. (15) Safety is furthered when licensees have incentives to identify and correct violations. If every violation resulted in the same sanction, regardless of the circumstances and the licensee's response to it, the civil penalty merely becomes a penalty and looses its remedial focus. The staff believes that the revisions made to simplify the Enforcement Policy, especially those associated with the civil penalty assessment process, have helped to produce more consistent and predictable enforcement actions.

Notwithstanding the importance of consistency, the staff does not believe that the Enforcement Policy should be reduced to a formula for rigid application. Few cases are entirely straightforward, and the NRC must always apply judgment in determining whether to give credit for the licensee's actions. Despite years of industry experience, new types of cases frequently arise, and in some cases, strict application of the Policy could result in delivering an inappropriate regulatory message. As stated in Section III of the Enforcement Policy, "...the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion must be exercised in determining the severity levels of violations and the appropriate sanctions,..."

In addition, the staff does not agree that civil penalties are necessary to remedy deficiencies. Once a licensee has been put on notice that a violation exists that requires corrective action, the agency *requires* that corrective actions be taken to restore compliance. Failure to take necessary corrective actions to restore safety and compliance could result in the agency taking more significant enforcement action, such as issuing larger civil penalties or issuing an order that could modify, suspend, or revoke a license. Further, an intentional failure to take corrective actions consistent with those described in the licensee's response to the violation (i.e., pursuant to the provisions of 10 CFR 2.201) could subject the licensee to more significant civil enforcement action, and possible criminal sanctions.

Not only does the staff disagree that civil penalties are necessary to remedy deficiencies, the staff believes that the provisions in the Enforcement Policy for allowing mitigation for corrective actions provides incentives for developing and implementing better corrective actions.

Conclusion

The staff believes that the changes to the Enforcement Policy in 1995 helped to improve the predictability and consistency of enforcement actions, while maintaining the agency's desire to use enforcement sanctions for providing appropriate incentives and deterrence to further the public health and safety. The staff will continue to improve its efforts at consistency, but does not believe that more rigidity in the civil penalty assessment process is warranted.

L. EXERCISE OF ENFORCEMENT DISCRETION

Comments

Although the revised civil penalty assessment process has improved the predictability of civil penalty outcomes, NEI commented that the process does not always reflect the safety significance of the violation and that consequently, the staff has resorted to exercising discretion more often in accordance with Section VII of the Enforcement Policy to send an appropriate regulatory message.

NEI also recommended that the NRC reexamine and refine the current examples in Section VII.B of the Policy addressing mitigation of enforcement sanctions. NEI based this recommendation on its view that the current civil penalty assessment process lacks an effective mechanism to sharpen the regulatory message and that the examples in Section VII.B were crafted well before the revision to the civil penalty assessment process. NEI suggested that mitigation be considered if a licensee is able to meet the majority of the criteria for exercising the particular discretion in Section VII.B. NEI also recommended that the criteria for exercising discretion be re-evaluated for consistency with the objectives of the Enforcement Policy. NEI took the position that the requirement for NRC concurrence for plant restart in Section VII.B.2 (Violations Identified During Extended Shutdowns or Work Stoppages) furthers no legitimate objective of the Enforcement Policy.

As discussed in Section II.L.5 of this report, UCS also recommended that the Policy be modified by eliminating the flexibility to exercise enforcement discretion based on performance issues.

Finally, based on experience with the Enforcement Policy, the applicability of Section VII.B may warrant modification to include Severity Level IV

violations.

Discussion

Prior to 1995, the civil penalty assessment process in the Enforcement Policy included the consideration of six separate factors that could collectively allow a total range of reductions up to 200% subtracted from the base civil penalty amount or increases up to 500% above the base civil penalty. The complexity of the previous process sometimes resulted in trying to send multiple messages within the issuance of a single sanction. The 1995 Review Team believed that this could at times result in each part of the regulatory message being diluted, or could send a mixed message as to what the NRC finds to be most important. Therefore, in considering changes to the civil penalty assessment strategy, the Review Team gave particular attention to simplifying the process in a manner that would increase clarity, minimizing the number and complexity of decision points while preserving the desired emphases of the existing Policy.

The staff believes that the revised civil penalty assessment process has resulted in a more predictable, understandable process. However, the staff recognizes that in simplifying the assessment process, there will be situations in which the outcome does not reflect the appropriate regulatory message. Therefore, NEI is correct to a certain extent, that the NRC has exercised discretion in the adjustment of civil penalties more in the current civil penalty assessment process than in the past. The staff believes that this is acceptable, in that issues that are important to the agency are being considered. However, instead of these issues automatically being considered as part of the process (similar to the past Policy), these issues may be considered after application of the normal process. The staff notes that it has exercised this type of discretion (i.e., increasing or decreasing the civil penalty amount) in approximately 16% of the cases issued during Fiscal Year 1996. (16)

The staff believes that the current civil penalty assessment process is appropriately structured to take mitigating factors into consideration, such as a licensee's good past performance (reflected in the first decisional block), and a licensee's initiative in identifying and comprehensively correcting violations. However, the staff recognizes that there may be additional circumstances of a case that warrant exercising discretion. Therefore, the Enforcement Policy provides flexibility through VII.B.6 (Violations Involving Special Circumstances). Unlike the other examples in Section VII.B, this example does not include specific or limiting criteria for its application, other than the stated expectation that it only be exercised where application of the normal guidance in the Policy is unwarranted. Therefore, the staff believes that Section VII.B.6 provides the staff with sufficient flexibility to ensure that the resulting enforcement decision is appropriate for the circumstances of the case and reflects the appropriate regulatory message. However, the staff does believe that the discussion in VII.B.6 should be modified to include additional factors for the staff to consider, such as whether the regulatory requirement that was violated was clear, or given the staff's current information, appropriate.

The staff also believes that the existing criteria in the remaining examples in Section VII.B are appropriate. The staff does not agree that mitigation should be routinely considered, notwithstanding the licensee's inability to meet all of the criteria. In circumstances where a case does not warrant discretion under Sections VII.B.2, VII.B.3, VII.B.4, or VII.B.5, the staff may still consider discretion appropriate under Section VII.B.6. Again, as noted elsewhere in this report, enforcement by its nature requires the exercise of discretion and judgment.

The staff does not agree with NEI's view that the requirement for NRC concurrence for plant restart in Section VII.B.2 (Violations Identified During Extended Shutdowns or Work Stoppages) furthers no legitimate objective of the Enforcement Policy. The purpose of the NRC enforcement program is to support the NRC's overall safety mission in protecting the public and the environment. The applicability criteria for Section VII.B.2 include situations in which (1) the NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee, or (2) the licensee enters an extended shutdown or work stoppage related to generally poor performance over a long period of time. Either of these situations represent a significant regulatory concern based on performance issues. As the federal agency tasked with ensuring that civilian uses of nuclear materials and facilities are conducted in a manner consistent with public health and safety, the NRC has a responsibility to ensure that it is satisfied that a licensee's corrective actions are acceptable before restart. This provision is not only acceptable, but necessary, because in these situations, the agency is not receiving the normal documentation of corrective actions that it would receive if the agency were issuing an enforcement action.

Finally, in reviewing Section VII.B, it may be appropriate to modify some of the examples to include Severity Level IV violations. The examples in Section VII.B address Severity Level II or III violations. (17) However, if the staff believes that the circumstances of a particular case may warrant discretion at Severity Level II, or III, then it would be logical to believe that discretion may be appropriate at Severity Level IV. Therefore, Sections VII.B.3, VII.B.4, and VII.B.6 should be modified to reflect that these examples of discretion are applicable for Severity Level IV violations. For example, discretion is warranted when a licensee identifies a violation as part of corrective action form a previous violation, or for an old design issue, or for an unclear requirement.

Conclusions

The staff believes that the current civil penalty assessment process takes appropriate mitigating circumstances into account. The staff believes that the provisions of Section VII.B provide the staff with the necessary flexibility to ensure that resulting enforcement decisions are consistent with the overall goals of the enforcement program. The staff believes that Section VII.B.6 should be modified to include additional factors for consideration, including whether the regulatory requirement that was violated was clear, or given the staff's current information, appropriate. The staff also believes that Sections VII.B.3, VII.B.4, and VII.B.6 should be modified to make the provisions for discretion applicable to Severity Level IV violations.

M. PUBLIC COMMUNICATIONS INVOLVING ENFORCEMENT

Comment

NEI recommended that the NRC issue press releases in connection with enforcement actions only after the agency has made a final enforcement action

decision. NEI took the position that multiple press releases in the course of the enforcement process (such as announcing a conference, and then subsequently announcing the issuance of a civil penalty) do not further the objectives of the Enforcement Policy and erode public confidence in the regulatory process.

NEI also recommended that press releases issued at the end of the enforcement process carefully put the matter into context with respect to the safety significance of the violation and that press releases should indicate whether licensees had reported the issue that was the subject of the enforcement action. (18)

RUG IV recommended that to improve overall safety, the NRC develop a process where potentially generic non-escalated enforcement issues are promptly identified and disseminated (including a discussion of the NRC's assessment of safety/regulatory consequence or concern). RUG IV suggested that NRC Bulletin, Information Notice, and Administrative Letter Processes appear to be an appropriate communication vehicle to promptly inform all licensees of enforcement actions (escalated and non-escalated) that may have generic applicability.

Discussion

The effect of publicity was discussed at length during the 1995 enforcement program reassessment. The Review Team recommended to the Commission that the NRC maintain its current practice of conducting enforcement in the public eye, including issuing press releases for proposed impositions of civil penalties. However, the Review Team recommended that the practice of routinely issuing press releases to announce open conferences be discontinued to be consistent with other agency practices. In particular, the Review Team noted that press releases are normally issued (and appropriate) for issuance of significant agency actions. However, the Review Team's view was that conferences are not in and of themselves significant agency actions, but rather predecisional to what may later result in a significant agency action. Further, the Review Team noted that press releases are not routinely issued for other open meetings. Instead, the Review Team recommended that press releases be issued only when specific issues exist that the agency believes are of sufficient interest to the public.

The Commission did not approve the Review Team's recommendation. The Commission believed that it was important to continue the practice of conducting the agency's business in an open manner and providing the public with the fullest information practicable on its activities. However, the Commission was sensitive to the concern that conferences were not being viewed in a predecisional nature. Therefore, in the June 16, 1995 SRM, the Commission directed the staff to ensure that press releases for open conferences include standard language that acknowledges and emphasizes the predecisional nature of the meeting, and note that the apparent violations being discussed are subject to review and may change prior to any resulting enforcement action.

The use of press releases to announce open conferences was again considered as part of the decisional process for the trial program for conducting open predecisional enforcement conferences. In SECY-96-222, dated October 22, 1996, the staff recommended that: (1) the Enforcement Policy be modified to provide that most conferences be open to public observation and (2) the Office of Public Affairs exercise discretion and issue press releases based on whether it believed open predecisional conferences were of sufficient interest to the public. The staff stated that given the experience in issuing press releases (19) and the continued emphasis of the agency in the area of openness, it no longer objected to the use of brief press releases to announce open conferences. NEI has not provided sufficient basis to change the staff's position.

The staff agrees that press releases issued at the end of the enforcement process should attempt to put the matter into context with respect to the safety significance of the violation. As a first step, the staff believes that public communications should include the severity level categorization in terms of the Enforcement Policy's definitions. Second, as previously discussed in Section II.E of this report, the staff will provide additional enforcement guidance directing that correspondence transmitting escalated enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern. Addressing safety significance in this context in public communications is appropriate to help inform without unnecessarily alarming the public (since many significant enforcement actions do not involve an actual consequence, such as a safety system failing to operate when actually called upon to work). The staff also agrees that press releases should indicate whether a licensee reported the issue that is the subject of the enforcement action and is modifying internal guidance to reflect this.

With regard to RUG IV's recommendation involving dissemination of potentially generic non-escalated enforcement information, the staff appreciates the value of assessing lessons learned in the enforcement program, including lessons from non-escalated enforcement actions. This is an area the staff should consider. However, the staff notes that the underlying issues associated with many non-escalated violations are frequently addressed in Information Notices, even though the violations are not escalated.

As a final note on this issue, OE announces all predecisional enforcement conferences on OE's home page on the Internet. OE also includes escalated enforcement actions on the Internet, as well as enforcement information, such as the Enforcement Policy and the NRC Enforcement Manual.

• Conclusion

The staff believes that the use of press releases to announce open predecisional enforcement conferences is appropriate (provided that press releases are brief and carefully worded to reflect the predecisional nature of the conference). The staff recommends that press releases for escalated enforcement actions put safety significance into context by discussing the severity level categorization and by addressing whether the issue reflects an actual or potential consequence, or a regulatory concern. The staff agrees that press releases for enforcement actions should indicate whether the licensee reported the issue that was the subject of the violation. Finally, the staff notes that the underlying issues associated with many non-escalated enforcement actions are already be addressed through NRC generic communications. However, the staff should consider additional methods for communicating enforcement-related information, including non-escalated enforcement actions.

N. VIOLATIONS INVOLVING TRANSPORTATION

Comments

In reviewing the Policy, the examples for violations based on radiation exposures included in Supplement V (Transportation) and Supplement IV (Health Physics) appear inconsistent.

Discussion

With respect to safety significance of individual violations, the staff notes that the Supplements to the Enforcement Policy, that provide examples in eight activity areas to assist in categorizing the significance of violations, are based on different thresholds. Section IV of the Policy, (Severity of Violations), provides that comparison of significance between activities areas are inappropriate. As an example, the Policy states that Severity I examples in Reactor Operations (Supplement I) are not directly comparable to Severity I examples in Reactor Construction (Supplement II). The same can be said for the examples in Transportation (Supplement V) and Health Physics (Supplement IV), though both of these supplements categorize violations that involve exposure to members of the public. For example, under Supplement IV, a violation involving an exposure to a member of the public of 150 millirems would be categorized at Severity Level II. However, under Supplement V, the violation could be categorized at Severity Level I.

The differences in categorization between activity areas reflects the varying degrees of significance of the particular violations based on either actual or potential consequences or regulatory significance. Significance is discussed in Sections II.C and II.E above. One reason for differences in treatment of violations in the Transportation and Health Physics supplements, is the concern that transportation failures, particularly for Type B packages, may result in unshielded and uncontrolled material being released into the public domain. (20) However, a violation not associated with transportation could have a similar result, in which case, the Policy would suggest a different level of significance.

Conclusion

The staff should consider whether changes to the severity levels in Supplements IV and V for violations of similar consequence are warranted as it completes its review of the Enforcement Policy Supplements.

O. VIOLATIONS INVOLVING DISCRIMINATION

• Comments

In reviewing the Policy, modifications to certain examples of violations involving discrimination included in Supplement VII (Miscellaneous Matters), may be warranted.

Discussion

The examples in Supplement VII used to help categorize the severity levels of violations associated with discrimination are generally based on management levels. By the Policy, management is viewed at three levels. It is recognized that there are many different types of management structures and the individual job titles a particular company may use is not necessarily controlling in determining the appropriate severity level categorization. In practice, Severity Level I is senior management, generally at the corporate level; Severity Level II is middle-management, generally at the plant management level; and Severity Level III has been low-level management and first-line supervisors. The Severity Level II example (B.4), specifically addresses plant management above first-line supervisors. However, consistent with the focus on three basic levels as described above, the staff has interpreted this example over the years to apply to middle to upper management, not simply any level above first-line supervision. This is consistent with the description in NUREG-1499, "Reassessment of the NRC's Program for Protecting Allegers Against Retaliation," January 1994, that stated that Severity Level I and II violations are "important because higher level supervisors clearly set the attitude towards safety and compliance; presumably, the higher the position, the greater the sphere of influence, with the resulting increased potential for a chilling effect if discrimination is practiced at this level."(21) In the staff's view, discrimination caused by supervisors above first-line supervision, but still relatively low in the management chain, are appropriately classified at Severity Level III. Clearly, such discrimination is of significant concern, but is not as significant as discrimination by higher level management. Thus, the staff would modify example B.4 to be action by plant management or other mid-level management. This would be consistent with the change to NRC Management Directive 8.8, "Management of Allegations," for a high priority discrimination investigation proposed in SECY 97-147 (July 14, 1997), that the Commission approved in an SRM dated September 10, 1997. Similarly, example C.4 should be modified to address actions of first-line supervisors and other low-level management.

Conclusion

Examples B.4 and C.4 of Supplement VII (Miscellaneous Matters) should be modified to reflect current practice. Specifically, example B.4 should state, "An action by plant management or mid-level management in violation of 10 CFR 50.7 or similar regulations against an employee." Example C.4 should state, "An action by first-line supervision or other low-level management in violation of 10 CFR 50.7 or similar regulations against an employee."

P. TIMELINESS OF ENFORCEMENT ACTIONS

Comments

UCS recommended that the Enforcement Policy be reviewed with a goal of improving the timeliness for enforcement actions. UCS stated that it believed that untimely enforcement actions unfairly subject licensees to unfavorable attention long after the causal event when the licensee may be far along its recovery paths.

• Discussion

The NRC recognizes the concerns expressed about timeliness of enforcement actions. The agency continues to work to make improvements in this area. The majority of enforcement cases are dispositioned in less than 90 days. However, enforcement cases involving team inspections (e.g., Augmented Inspection Teams, Incident Inspection Teams, design inspections, maintenance inspections, etc.,), Office of Investigations (OI) reports, and cases involving complex, novel, or generic issues often take longer to process. It should be noted that significant cases, especially those requiring exercise of enforcement discretion and/or Commission consultation, take time to process properly. In addition, many of the concerns about timeliness are related to cases involving wrongdoing. OI is making progress in improving the timeliness of its investigations. In some cases, delay of NRC enforcement actions is caused by the necessary time for the Department of Justice (DOJ) to reach decisions on whether to prosecute cases as provided for in the Memorandum of Understanding between the NRC and DOJ.

The staff is also mindful that a failure to take the necessary time to properly develop and coordinate an enforcement action may result in a greater impact if inappropriate decisions are made.

Finally, in light of competing priorities and resource considerations within the agency, this area will always require management attention and emphasis.

Conclusion

While the agency must continue emphasis on timeliness of significant enforcement actions, the staff does not believe that timeliness should be improved at the expense of weakening the quality of fact-finding, evaluation, and decision-making.

III. Conclusions and Recommendations

Conclusions

The staff concludes that the changes to the Enforcement Policy in 1995 (especially in the civil penalty assessment process) have helped to improve the predictability and consistency of enforcement actions, while maintaining the agency's desire to use enforcement sanctions for providing appropriate emphasis and deterrence in a way that helps to support the agency's overall safety mission. This conclusion is reflected in several aspects of the Enforcement Policy and the enforcement program:

- The current Enforcement Policy is appropriately geared toward creating deterrence (i.e., taking action in a manner that provides incentives to identify and correct violations that have occurred and discourage future violations) and is properly structured for nuclear regulation.
- The Enforcement Policy recognizes that violations have varying degrees of safety significance, and that in considering the significance of a violation, it is appropriate to consider the technical significance (i.e., actual and potential consequences) and the regulatory significance. In addition, risk is an appropriate consideration in evaluating the technical significance of a violation.
- The Enforcement Policy is appropriately structured to maintain a focus on safety.
- The current civil penalty assessment process is appropriately structured to reflect issues the agency believes are appropriate to consider in assessing whether a civil penalty should be proposed, i.e., past performance, identification, corrective action, and those warranting discretion.
- The use of discretion and judgment throughout the deliberative process recognizes that enforcement of NRC requirements does not lend itself to mechanistic treatment.
- The strides to improve the timeliness of significant enforcement actions should not be made at the expense of weakening the quality of fact-finding, evaluation, and decision-making.

Recommendations

The staff recommends:

- 1. That additional guidance and training be provided to the staff to help determine the safety significance and severity levels of violations. In particular, OE should continue its efforts to complete the review of the Enforcement Policy supplements. In addition, greater management oversight should be considered in cases based on regulatory significance, especially those involving programmatic issues. (II.C)⁽²²⁾
- 2. That inspection and enforcement guidance should be considered when new rules are developed and implemented. (II.D)
- 3. That Section I of the Enforcement Policy be modified (consistent with the Commission's direction in the August 25, 1997 SRM) to include additional discussion on the nexus between safety and compliance. (II.E)
- 4. That additional enforcement guidance be developed that directs that correspondence transmitting escalated enforcement actions indicate whether the issue was safety significant because it represented an actual consequence, a potential consequence, or a regulatory concern (or a combination of these issues).

(II.E)

- 5. That OE develop additional guidance, provide additional training, and perform audits to help improve the consistency in addressing non-escalated enforcement actions. (II.I.1)
- 6. That all non-escalated NOVs that are disputed by licensees be subject to more independent review. Specifically, OE should modify the formats for NOVs to direct licensees to forward a copy of disputes to the Director, OE, and OE should modify the staff guidance in the Enforcement Manual to require licensee denials to be coordinated with OE. The degree of OE review will be based on the circumstances of the case. (II.I.2)
- 7. That OE issue guidance to clarify correspondence when revised NOVs are issued. (II.I.3)
- 8. That the existing policy and practice of not normally documenting minor violations be continued. (II.I.4)
- 9. That the Enforcement Policy be modified such that minor violations are no longer dispositioned as NCVs. Instead, standard language should be used, such as, "This failure constitutes a violation of minor significance and is not subject to formal enforcement action." Consistent with this recommendation, Section IV of the Enforcement Policy be modified by deleting the footnote that includes the definition of an NCV (footnote 6). (II.I.4)
- 10. That OE develop additional guidance, provide additional training, and perform audits to help improve the consistency in addressing minor violations. (II.I.4)
- 11. That the criterion in Section VII.B.1.a of the Enforcement Policy be modified to address identification through an event. Specifically, a footnote should be added stating, "Discretion is not warranted when a licensee identifies a Severity Level IV violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. Discretion may be warranted if the licensee demonstrated initiative in identifying the violation's root cause." (II.I.5)
- 12. That Section V of the Enforcement Policy be revised to address two enforcement options if a predecisional enforcement conference is not held. The existing Policy discussion stating that, "...the licensee will normally be requested to provide a written response to an inspection report..." should be modified to state, "...the licensee may be requested..." to indicate this approach as one enforcement option. Section V should be further modified to address another enforcement option by stating, "However, if the NRC has sufficient information to conclude that a civil penalty is not warranted, it may proceed to issue an enforcement action without first obtaining the licensee's response to the inspection report." (II.J)
- 13. That Table 1A of the Enforcement Policy be modified to include the footnote that recognizes large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material as industrial processors and include "other large material users" in category "c" and "other small materials users" in category "d." (II.K.1)
- 14. That Table 1A of the Enforcement Policy be modified to include "other large material users" in category "c " and "other small material users" in category "d." (II.K.1)
- 15. That Sections VII.B.3, VII.B.4, and VII.B.6 of the Enforcement Policy be modified to make the provisions for discretion applicable to Severity Level IV violations. (II.L)
- 16. That Section VII.B.6 of the Enforcement Policy be modified to include additional factors for consideration, including whether the regulatory requirement that was violated was clear, or given the staff's current information, appropriate. (II.L)
- 17. That press releases for escalated enforcement actions put safety significance into context by discussing the severity level categorization and by addressing whether the issue reflects an actual or potential consequence, or a regulatory concern. (II.M)
- 18. That press releases for enforcement actions should indicate whether the licensee reported the issue that was the subject of the violation. (II.M)
- 19. That the staff consider whether changes to the severity levels in Supplements IV and V for violations of similar consequence are warranted as it completes its review of the Enforcement Policy supplements.

(II.N)

20. That example B.4 in Supplement VII of the Enforcement Policy be revised to state, "An action by plant management or mid-level management in violation of 10 CFR 50.7 or similar regulations against an employee," and that example C.4 be revised to state, "An action by first-line supervision or other low-level management in violation of 10 CFR 50.7 or similar regulations against an employee." (II.0)

APPENDIX A

SUMMARY OF ENFORCEMENT POLICY REVISION

This Appendix provides a summary description of the more significant changes adopted by the Commission (as they appear in the June 30, 1995 Enforcement Policy).

1. CLARIFIED PURPOSE

The purpose statement was revised to clarify that enforcement be used (1) as a deterrent to emphasize the importance of compliance with requirements, and (2) to encourage prompt identification and prompt, comprehensive correction of violations.

2. ELIMINATION OF SEVERITY LEVEL V CATEGORIZATION

Severity Level V violations were eliminated. The examples at that level were withdrawn from the supplements. Formal enforcement actions will now only be taken for violations categorized at Severity Level I to IV to better focus the inspection and enforcement process on safety. To the extent that minor violations are described in an inspection report, they will be labeled as Non-Cited Violations (NCVs). When a licensee does not take corrective action or repeatedly or willfully commits a minor violation such that a formal response would be needed, the violation should be categorized at least at a Severity Level IV.

3. THRESHOLD AND CRITERIA FOR PREDECISIONAL ENFORCEMENT CONFERENCES

Enforcement conferences were renamed "predecisional enforcement conferences," to emphasize their predecisional nature. These conferences should be held for the purpose of obtaining information to assist the NRC in making enforcement decisions when the agency reasonably expects that escalated enforcement actions will result. They should also normally be held if requested by a licensee. In addition, they should normally be held before issuing an order or a civil penalty to an unlicensed individual.

4. RESPONSES TO NOTICES OF VIOLATION

The Enforcement Policy was modified to clarify that the NRC may waive all or portions of a licensee's written response to a Notice of Violation to the extent relevant information has already been provided to the NRC in writing or documented in an NRC inspection report and is on the applicable docket in the NRC Public Document Room.

5. REVISION OF BASE CIVIL PENALTY TABLES

Tables 1A and 1B were revised.

Table 1A was simplified to combine categories of licensees with the same base penalty amounts. The base penalty amounts have generally remained unchanged. The revised Policy notes that the base penalties may be adjusted on a case-by-case basis to reflect the ability to pay and the gravity of the violation. 10 CFR Part 35 licensees (doctors, nuclear pharmacies, and other medical related licensees) are combined into an overall medical category, based on the similarity of hazards. Because transportation violations for all licensees are primarily concerned with the potential for personnel exposure to radiation, the violations in this area will be treated the same as those in the health physics area.

The \$100,000 base civil penalty amount for safeguards violations, which applies to only two categories of licensees, fuel fabricators and independent fuel and monitored retrievable storage installations, has been deleted. The penalty amount for safeguards should be the same as for other violations at these facilities. The NRC has not had significant safeguards violations at these facilities. If the penalty that would normally be assessed for operational violations is not adequate to address the circumstances of the violation, then discretion would be used to determine the appropriate penalty amount.

The base civil penalty for "other" materials licensees, previously set at \$1000, was increased to \$5000. The primary concerns for these licensed activities are individual radiation exposure and loss of control of material to the environment, both of which warrant a more financially meaningful penalty. A \$500 civil penalty for a Severity Level III violation (at 50% of the Severity Level I base amount) does not reflect the seriousness of this type of violation for this category of licensee. It is noted that with the revised assessment approach, these licensees will not normally receive a civil penalty if prompt and comprehensive corrective action is taken for isolated non-willful Severity level III violations.

In Table 1B, the percentage for Severity Level IV violations was deleted since such violations will not be subject to civil penalties. If a violation that would otherwise be categorized at a Severity Level IV violation merits a civil penalty because of its significance, the violation would normally be categorized at a Severity Level III.

6. ELIMINATION OF CIVIL PENALTIES FOR SEVERITY LEVEL IV VIOLATIONS

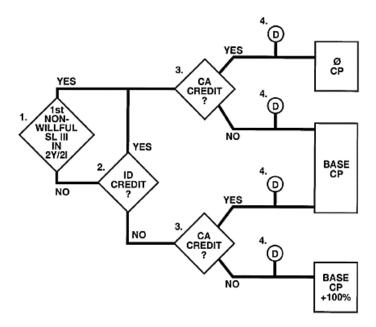
The practice of considering civil penalties for certain Severity Level IV violations was discontinued. If repetiveness or other justification exists for a civil penalty, then the Severity Level IV violation may legitimately be raised to Severity Level III.

7. STREAMLINED CIVIL PENALTY ASSESSMENT PROCESS

The revised process is intended to:

- Continue to emphasize compliance in a manner that deters future violations;
- · Encourage prompt identification and prompt, comprehensive correction of violations and their root causes;
- Apply the recognition of good past performance to give credit to a licensee committing a non-willful SL III violation who has had no previous significant violations during the past 2 years or 2 inspections (whichever is longer);
- Place greater attention on situations of greater concern (i.e., where a licensee has had more than one significant violation in a 2-year or two-inspection period, where corrective action is less than prompt and comprehensive, or where egregious circumstances, such as where it is clear that repetitiveness or willfulness, are involved);
- Streamline the NRC decisional process in a manner that will preserve judgment and discretion, but will provide a clear normative standard and produce relatively predictable results for routine cases; and
- · Provide clear guidance on applying fewer adjustment factors in various types of cases, in order to increase consistency and predictability.

The flow chart presented on the next page is a graphic representation of the civil penalty assessment process.



Once a violation has been categorized at a Severity Level III or above, the assessment process considers these decisional points:

- 1. Is this the first non-willful Severity Level III enforcement action (regardless of the activity area) for this site that the licensee has had during the past 2 years or past 2 inspections (whichever is longer)?
- 2. Should the licensee be given credit for actions related to identification? (Only consider if the answer to question 1 is no.)
- 3. Are the licensee's corrective actions prompt and comprehensive?
- 4. In view of all the circumstances, does the matter in question require the exercise of discretion?

As described in the Enforcement Policy, each of these decisional points may have several associated considerations for any given case. However, the outcome of a case, absent the exercise of discretion, is limited to three results: no civil penalty, a base civil penalty, or a base civil penalty escalated by

8. PRESERVATION OF THE ABILITY TO EXERCISE DISCRETION

The ability to exercise discretion was preserved with the revised Policy. Discretion is provided to deviate from the normal approach to either increase or decrease sanctions where necessary to ensure that the sanction reflects the significance of the circumstances and conveys the appropriate regulatory message. The Enforcement Policy was modified to provide examples where it is appropriate to consider civil penalties or escalate civil penalties notwithstanding the normal assessment process in Section VI of the Enforcement Policy. One significant example to note involves the loss of a source. This example was added to emphasize the importance of licensees being aware of the location of their sources and to recognize that there should not be an economic advantage for inappropriate disposal or transfer. Finally, Table 2, "Examples of Progressions of Escalated Enforcement Actions for Similar Violations in the Same Activity Area Under the Same License," was withdrawn from the Enforcement Policy. The guidance in that table was no longer needed because the policy is clear that each case should be judged on its own merits, especially those repetitive violation cases to which the table applied.

APPENDIX B

SUMMARY OF CHANGES TO THE ENFORCEMENT POLICY SINCE JUNE 30, 1995

This Appendix provides a summary description of the changes that have been made to the Enforcement Policy subsequent to June 30, 1995.

1. OCTOBER 11, 1996: ADJUSTMENT OF CIVIL MONETARY PENALTIES (61 FR 53557)

On September 27, 1996, the Commission approved amending the regulations to adjust the maximum amounts of civil penalties under statutes within the jurisdiction of the NRC. The changes were mandated by Congress in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996. The Commission also approved conforming changes to the Enforcement Policy such that the maximum penalty amount was increased to \$110,000 per violation per day and the civil penalty amounts in Table 1A were increased by 10%. These changes were subsequently published in the *Federal Register* on October 11, 1996, and were effective on November 12, 1996.

2. OCTOBER 18, 1996: DEPARTURES FROM THE FSAR (61 FR 54461)

On October 18, 1996, the Commission published revisions to the Enforcement Policy to address departures from the FSAR in violation of 10 CFR 50.59 and for failures to update the FSAR in violation of 10 CFR 50.71(e). The revision provides more guidance in categorizing violations by severity level and more guidance concerning the effect of corrective action, reporting requirements, and old design issues. The changes are intended to encourage licensees to voluntarily take the initiative to identify and correct FSAR discrepancies that might be identified through current surveillance and quality assurance activities.

3. DECEMBER 10, 1996: COMMISSION CONSULTATION; OPEN PREDECISIONAL ENFORCEMENT CONFERENCES; NCVS; RISK (61 FR 65088)

On December 10, 1996, the Commission published revisions to the Enforcement Policy that addressed four issues. The first modification revised the list of enforcement matters on which the NRC staff must consult with the Commission. Based on the staff's experience in implementing the Policy and the rarity of occasions when the Commission deviated from staff recommendations, Section III of the Policy was modified to reduce the number of situations on which the staff must consult with the Commission prior to taking action. The second modification revised the Policy to provide that most predecisional enforcement conferences will be open to public observation. The decision to modify Section V of the Policy came at the end of a trial program that began on July 10, 1992, that provided for conducting approximately 25 percent of all conferences open for public observation. The third modification clarified the circumstances in which a licensee-identified violation will be treated as a Non-Cited Violation. The criterion in Section VII.B.1(a) was modified by deleting the reference to licensee-identification through an event to make it clear that use of discretion is not automatic if the violation is identified through an event. The forth modification included additional guidance that stated that risk was an appropriate consideration in developing enforcement sanctions. Section IV was modified to state that in considering the significance of a violation, that risk is an appropriate consideration. Section VII.A.1(e) was also modified to state that exercise of discretion should be considered in situations where the violation has resulted in substantial increase in risk, including cases in which the duration of the violation has contributed to the substantial increase.

4. DECEMBER 10, 1996: PART 20, EXCEEDANCE OF DOSE CONSTRAINTS (61 FR 65128)

On December 10, 1996, the Commission published a revision to the Enforcement Policy that reflected the Commission's final rule amending 10 CFR Part 20 to add 20.1101(d), that establishes the requirements for reporting and taking corrective action. Supplement IV of the Policy was modified to add an example of a violation categorized at Severity Level IV involving the failure to report an exceedance of the dose constraint established in 20.1101(d), or failure to take corrective action for an exceedance.

5. DECEMBER 26, 1996: CORRECTION TO EXERCISE OF DISCRETION (61 FR 68070)

On December 26, 1996, the Commission published a correction to the revision of the Enforcement Policy that was published on December 10, 1996, involving Commission consultation. This correction modified Section VII to reflect the appropriate policy as to notification to the Commission when the

6. FEBRUARY 12, 1997: GASEOUS DIFFUSION PLANTS; NRC ORGANIZATIONAL CHANGES; COMMISSION CONSULTATION (62 FR 06677)

On February 12, 1997, the Commission published revisions to the Enforcement Policy that were consistent with the Commission's final rule amending regulations governing Gaseous Diffusion Plants (GDPs). Table 1A was modified to add GDPs to category "a," such that the base civil penalty for a Severity Level I violation at a GDP would be \$110,000 and Supplement VI was modified to provide additional examples for categorizing severity levels of violations. In addition, the Policy was amended to reflect recent NRC organizational changes. The changes redesignate which NRC officials are delegated the responsibility for performing certain enforcement functions. Section III was modified to clarify that Commission consultation was appropriate if the staff proposed to impose a civil penalty for a single violation or problem that is greater than 3 times the Severity Level I value shown in Table 1A for that class of licensee.

7. MARCH 24, 1997: PARTICIPATION IN PREDECISIONAL ENFORCEMENT CONFERENCES INVOLVING DISCRIMINATION (62 FR 13906)

On March 24, 1997, the Commission published revisions to the Enforcement Policy regarding predecisional enforcement conferences that are based on findings of discrimination. For appropriate cases, the revision allows some degree of participation by the complainant in the predecisional enforcement conference.

8. MAY 28, 1997: PART 34, RADIOGRAPHY, EXAMPLES OF POTENTIAL VIOLATIONS (62 FR 28974)

On May 28, 1997, the Commission published revisions to the Enforcement Policy that were consistent with the Commission's final rule amending 10 CFR Part 34. Supplement VI of the Policy was revised to add examples for categorizing the significance of violations of 10 CFR Part 34, Licensees for Radiography and Radiation Safety Requirements for Radiographic Operations.

9. JUNE 19, 1997: EDITORIAL CORRECTIONS (62 FR 33447)

On June 19, 1997, the Commission published a correction to the revision of the Enforcement Policy that was published on May 28, 1997, involving examples of violations of 10 CFR Part 34. The correction was necessary to correct paragraph numbering and removing unnecessary language.

10. OCTOBER 8, 1997: CLARIFICATION ON RELEASE OF OI REPORTS ASSOCIATED WITH CONFERENCES INVOLVING DISCRIMINATION AND ROLE OF THE COMPLAINANT (62 FR 52577)

On October 8, 1997, the Commission published a revision to the Enforcement Policy that clarified the procedures associated with predecisional enforcement conferences based on reports of the NRC Office of Investigations (OI) associated with discrimination. On March 24, 1997, the Commission published changes to the Enforcement Policy concerning predecisional conferences based on discrimination. Consistent with the Statement of Consideration for those changes, Section V of the Policy was modified to reflect that the OI report *may* be made public. Also, additional language was added to clarify that the purpose of the complainant's participation in a conference is to provide information to the NRC to assist the staff in its deliberations.

APPENDIX C

The following notice can also be found at the Federal Register **EXIT** web site.

FEBRUARY 5, 1997 FEDERAL REGISTER NOTICE (62 FR 5494) [Federal Register: February 5, 1997 (Volume 62, Number 24)] [Notices] [Page 5494-5495] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr05fe97-105] NUCLEAR REGULATORY COMMISSION NRC Enforcement Policy AGENCY: Nuclear Regulatory Commission.

ACTION: Opportunity for public comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is providing the public an opportunity to provide comments on the agency's Enforcement Policy

(NUREG-1600, ``General Statement of Policy and Procedure for NRC Enforcement Actions"). This invitation is open to interested public interest groups, the regulated industry, states, and concerned citizens.

DATES: The comment period expires April 7, 1997. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to: David Meyer, Chief, Rules Review and Directives Branch, Office of Administration, Mail Stop: T6D59, U. S. Nuclear Regulatory Commission, Washington, DC 20555. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC. Copies of NUREG-1600 and NUREG-1525 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Copies are also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC 20555-0001.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 415-2741.

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SUPPLEMENTARY INFORMATION: On June 30, 1995, (60 FR 34381) the Commission published a complete revision of the NRC's Enforcement Policy in the Federal Register. The changes to the Enforcement Policy resulted from the efforts of a review team established in 1994 to assess the NRC's enforcement program. The review team published its recommendations in NUREG-1525, ``Assessment of the NRC Enforcement Program," and the Commission made revisions to the Enforcement Policy after considering those recommendations. The revisions to the Enforcement Policy were intended to, among other things:

<bul><bul><bul><bul>Direct agency attention at licensees with multiple enforcement actions in a relatively short period; and

<bul><bullet> Focus on current performance of licensees.

The revisions to the Enforcement Policy were also intended to better focus the inspection and enforcement process on safety, provide greater incentives for strong self-monitoring and corrective action programs in the civil penalty assessment process, provide more predictability and consistency in the civil penalty assessment process, and to better convey clear regulatory messages.

When the Commission published the revised Enforcement Policy in the Federal Register on June 30, 1995, it stated that it would provide the public an opportunity to comment on the revised Enforcement Policy after it had been in effect for about 18 months. This opportunity for public comment is being made in accordance with this commitment.

Dated at Rockville, MD, this 30th day of January, 1997.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

[FR Doc. 97-2805 Filed 2-4-97; 8:45 am]

BILLING CODE 7590-01-P

- 1. After further consultation, the Commission subsequently approved changes to the Enforcement Policy in December 1996 to address Commission consultation and open conferences. (See Appendix B, item 3 for additional information.)
- 2. EGMs are the normal method for the Director, OE, to issue additional enforcement guidance to the staff. EGMs may add guidance for Enforcement Policy application, revise existing guidance on processing enforcement actions, or transmit temporary guidance.
- 3. See Section II.G.4 of NUREG-1525.
- 4. Unlike rulemaking, the notice and comment process is not required for Commission policy statements. However, comments received after publication are considered during implementation and for future changes.
- 5. NEI's comment regarding the need to more closely focus the enforcement process on safety is addressed in Section II.E of this report, NEI's comment regarding the elimination of the use of enforcement as a substitute for other regulatory mechanisms is addressed in Section II.F, and NEI's comment regarding the need to provide clear and positive incentives to licensee to identify and correct noncompliances is addressed in Section II.K.3.
- 6. From Section IV of the NRC Enforcement Policy.

- 7. Once a licensee identifies a violation requiring corrective action, the NRC expects that a licensee will take *some* action to correct the problem (it may be as simple as documenting a proposed action plan to correct a procedure). This is reflected, for example in Section VI.B.2.b of the Enforcement Policy, that provides that "the concept of Identification presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed." Therefore, evidence of *some* action is necessary to warrant credit for Identification. The degree of promptness and comprehensiveness is considered under the Corrective Action factor.
- 8. Orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed or certified activities.
- 9. RUG IV proposed the following definition for actual safety significance and safety consequence: "The event must cause an actual overexposure in excess of NRC regulatory limits (10 CFR 20), offsite release of radioactivity in excess of NRC regulatory limits (10 CFR 20), or result in the actual loss of the safety function of a safety train or system (inability of the safety train or system to perform its safety function as described in the UFSAR, as credited in the Chapter 15 Accident Analysis)." RUG IV proposed the following definition for regulatory concern: "The event involves any of the following circumstances: aggregation, repetition, willfulness, and/or reporting."
- 10. 61 FR 65088.
- 11. From the executive summary of NUREG-1022, "The information reported under 10 CFR 50.72 and 50.73 is used by the NRC staff in responding to emergencies, monitoring ongoing events, confirming licensing bases, studying potentially generic safety problems, assessing trends and patterns of operational experience, monitoring performance, identifying precursors of more significant events, and providing operational experience to the industry."
- 12. Recommendation II.B-3 of NUREG-1525 stated that OE should work with the program offices and regions to review the severity level examples in the supplements to ensure that the examples are appropriately focused on safety significance. OE notes that it has been unable to complete the review of the Enforcement Policy Supplements (that include examples of violations at the four severity levels) because of resource constraints. Subject to available resources, OE intends to complete the severity level review.
- 13. Consistent guidance exists in Manual Chapter 0610 of the Inspection Manual .
- 14. The Office of Enforcement Annual Report for Fiscal Year 1996 indicated that licensees were given credit for corrective actions in approximately 85% of cases subjected to the civil penalty assessment process. (See page 33 of the report.)
- 15. From Section I of the Enforcement Policy, NUREG-1600.
- 16. From the Office of Enforcement's Annual Report for Fiscal Year 1996, page 33.
- 17. The staff has applied enforcement discretion in accordance with Section VII.B.6 to Severity Level IV violations.
- 18. NEI informally communicated its recommendation involving reporting during a public meeting with the NRC.
- 19. The staff found that most press releases issued subsequent to the June 1995 SRM were brief in announcing the public conference and were carefully worded to ensure that they did not prejudge the outcome and become a penalty in themselves.
- 20. In 1992 (57 FR 5791), the Commission modified the Transportation supplement to emphasize the significance of transportation violations by providing examples at Severity Level I and II where there is a clear potential for members of the public to receive exposures in excess of .1 rems, the limit for an exposure to a member of the public. As noted by the Commission in explaining these changes, "[T]he purpose of transportation requirements is to prevent unshielded radioactive material from getting into the public domain. When that happens, there is a clear potential for a very significant exposure, and, therefore it is considered a violation of very significant regulatory concern." These violations are of concern because they generally require not only packaging errors, but also loading and handling failures resulting in actual or potential unnecessary exposure to the public. The actual exposure level under these circumstances is a function of time and distance from the source.
- 21. NUREG-1499, page II.C-12.
- 22. This refers to the section of the report where the recommendation was made.