

Proposed Enforcement Policy Revisions

Executive Summary

The Office of Enforcement (OE) staff and management reviewed and selected 28 feedback topics for inclusion in this proposed revision to the U.S. Nuclear Regulatory Commission (NRC) Enforcement Policy (Policy), consistent with the goals of the Enforcement Guidance Document Feedback process. The proposed revision includes suggested improvements to increase readability and clarifications based on lessons learned from recent casework. Key topic areas include clarifying and relocating the current Policy on lost or missing sources to a new separate section; removing the significance determination process qualitative color descriptions; revising guidance on miscellaneous actions involving individuals; adding a new section for independent spent fuel storage installations; revising several severity level violation examples, including examples for import/export activities, licensed reactor operators, materials operations, and fuel cycle operations; and sunsetting Interim Enforcement Policy 9.2, "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)," for permanent implant brachytherapy medical reporting requirements.

For each topic area (i.e., item number), this document typically includes a summary of the proposed change; a discussion of the background and historical data to support the proposed revision, including Commission papers, *Federal Register* notices, and precedent case information; and a public comment section, which lists and dispositions any comments received.

The revisions proposed for each section of the Policy are as follows:

- **Section 2.0, "NRC Enforcement Process"**
 - enhancing readability in multiple subsections and adding a footnote describing the term "related violations"
- **Section 2.2.3, "Assessment of Violations Identified Under the ROP or cROP"**
 - removing the qualitative color descriptions in the Reactor Oversight Process (ROP) significance determination process from the Policy, to accommodate planned changes to the descriptions of white and yellow findings in the ROP
- **Section 2.3, "Disposition of Violations"**
 - clarifying the terms "programmatic," "repetitive," and "isolated" as used in violation examples
 - clarifying the guidance as to which civil penalty amount is to be applied (the amount at the time of assessment, not the time of violation)
 - clarifying how to identify the appropriate severity level and civil penalty in enforcement cases in which a licensee recovers missing material in a timely manner
 - clarifying the civil penalty assessment when assessing credit for identification and credit for promptness and comprehensiveness of corrective actions

- **Section 2.4, “Participation in the Enforcement Process”**
 - clarifying that in an alternative dispute resolution session, the NRC seeks corrective actions broader than those likely achieved through the traditional enforcement process
- **Section 3.0, “Use of Enforcement Discretion”**
 - revising Section 3.8, “Notices of Enforcement Discretion,” to add nonpower production and utilization facilities and to remove gaseous diffusion plants
- **Section 4.0, “Enforcement Actions Involving Individuals”**
 - clarifying guidance for when the NRC discovers potentially damaging or disqualifying information about an individual’s trustworthiness and reliability
 - clarifying the criteria for issuing an enforcement sanction to an alleged who engages in deliberate misconduct
- **Section 6.0, “Violation Examples”**
 - adding violation examples for a failure to retain quality records
 - revising fuel cycle violation examples
 - revising decommissioning violation examples
 - adding a new materials violation example for a failure to maintain control and constant surveillance of a portable gauge
 - adding a new materials violation example to cover less significant violations of 10 CFR 30.34, “Terms and conditions of licenses”
 - revising licensed operator violation examples by applying a graded, performance-based approach
 - revising a materials shipping violation example to account for the term “marking”
 - revising export and import violation examples by integrating the term “substantial potential for overexposure”
 - adding a new section for independent spent fuel storage installations
- **Section 7.0, “Glossary”**
 - clarifying the terms “programmatic,” “repetitive,” and “isolated” as used in violation examples
 - clarifying the definition of “confirmatory action letter”
 - clarifying the definition of “significance”

- adding the definition of “inspection finding”
- **Section 9.0, “Interim Enforcement Policies”**
 - sunsetting Interim Enforcement Policy 9.2
- **Miscellaneous**
 - updating website address
 - updating Paperwork Reduction Act information
 - removing references to specific inspection manual chapters

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Proposed Changes

Item #349—Miscellaneous Updates

The staff revised the instructions for navigating to the U.S. Nuclear Regulatory Commission (NRC) Enforcement Policy (Policy) on its public website in the Preface section and updated the Paperwork Reduction Act statement in Section 10, “Paperwork Reduction Act Statement and Public Protection Notification.” (Enclosure 2, pp. 4, 102)

Item #320—Enhancement and Clarification of Overarching Philosophy for Assessment of Violations

Summary

This revision intends to clarify the characterization of violations that impact the NRC’s ability to perform its regulatory oversight function, and violations that involve willfulness, by supplementing the definitions of severity level (SL) III and SL IV violations. The revision also facilitates the application of “potential consequences” by integrating the term “substantial potential for overexposure” into an expanded definition of potential consequences in Section 7.0, “Glossary.” The revision will increase the predictability and transparency of the NRC’s application of this term by acknowledging that there is a gradient associated with risk and articulating the basic characteristics of these levels. (Enclosure 2, pp. 12, 93, 94, 95)

Discussion

The existing sections 2.2.2(c) and (d) provide a scoping discussion of SL III and SL IV violations associated with actual and potential consequences, as compared to the more detailed discussion in Section 6.0, “Violation Examples.” However, violations that impact the NRC’s ability to perform its regulatory oversight function or violations that involve willfulness are not considered.

To determine the significance of a violation, assign it a severity level, and identify the appropriate enforcement response, the NRC considers four broad factors: (1) actual safety or security consequences, (2) potential safety or security consequences, (3) impact on the NRC’s ability to perform its regulatory oversight function, and (4) willfulness. The first and second factors, and their influence on a violation’s significance or severity level, are already well defined in the Policy. Accordingly, the staff is supplementing the assessment of severity level III and IV violations by explicitly considering the impact of the violation has on the NRC’s ability to perform its regulatory oversight function and of those violations which involve willfulness.

In addition, to clarify the definition and application of “potential safety or security consequences” the staff has integrated the definition of “substantial potential for exposure” into the glossary definition of “potential safety or security consequences.” The definition now encompasses a gradient, including the terms “low or relatively inappreciable” and “substantial,” to characterize the significance of potential consequences. This revision will increase the predictability and transparency of the staff’s case-by-case evaluation of the significance of violations.

The revision is intended, in part, to clarify that actual consequences (e.g., accidental criticality or core melt) are not prerequisites for a violation to be issued as escalated enforcement (e.g., SL III, II, or I).

Substantial potential consequences are shown by a realistic likelihood of exceeding a regulatory limit. The likelihood is typically demonstrated by cases exhibiting concrete, tangible outcomes that did not exceed the regulatory limit, but were definable, and in which it was only because of fortuitous circumstances that the limit was not exceeded. The concern is not whether the relevant limit was exceeded, but whether the licensee maintained adequate controls over the situation to avoid exceeding the limit. Substantial potential consequences are demonstrated by a near miss, or “close call,” such that if the as-found conditions were changed slightly, the licensee would be unlikely to avoid actual consequences. Substantial potential consequences warranting an SL I violation would include circumstances where there were no remaining barriers to actual consequences, an initiating event occurred or very nearly occurred, and only fortuitous circumstances prevented the actual consequences.

Potential consequences refer to a realistic possibility of safety or security consequences, typically demonstrated in scenarios where most or all barriers to a safety or security consequence were absent, but only a limited tangible outcome was possible.

Low or relatively inappreciable potential consequences pertain to credible scenarios where safety or security consequences could have occurred, but where at least one barrier, with a low likelihood of failure, remained to provide defense in depth.

Public Comments¹

A. The NRC received two comments related to proposed changes to section 2.2.2. The originally proposed paragraphs (c) and (d) would read as follows:

(c) SL III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event). Additionally, violations involving licensee officials that either actually impeded or influenced a specific regulatory action such as a licensing decision or inspection activity that would have likely resulted in a different regulatory decision, or violations that were committed willfully, are typically assigned at least an SL III significance.

(d) SL IV violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences). Additionally, a significance of SL IV is typically assigned to violations that impeded or influenced a specific regulatory action, such as a licensing decision or inspection activity, but that would likely not have led to a different regulatory decision.

1. Comment:

The proposed addition is vague, and it is unclear exactly what type of influence

¹ The comments shown in this document are color coded, black text refers to original text, red text refers to staff proposed changes, and green text refers to public comment proposed changes.

or impediment a licensee official would need to undertake to result in an SL III or SL IV violation.

a. Suggested revision:

The Nuclear Energy Institute (NEI) recommends the NRC keep the original language.

b. Comment disposition:

See 2.b below.

2. Comment:

This change relates to additional factors for consideration of assigning a severity level under traditional enforcement for SL III and IV violations. Specifically, the changes would now add consideration of situations where a licensee official “actually impeded or influenced” a regulatory action such that the regulatory decision would “likely” have resulted in a different decision.

The way this language is stated appears vague and is recommended to be more intentional. The common definition of impeding simply means obstructing. There could be valid reasons for obstruction, including mistake of fact. Therefore, as this language change is arguably aimed at addressing purposeful intent to cause NRC’s decision to be based on false, misleading, or incomplete information, it should include these attributes to make clear what the change is intending to address. If the change is intended for something different, it still needs to be clarified so that licensees are given adequate notice and opportunity to comment on its meaning. If the purpose of the language is as suggested above, it needs to be explained as to why the regulations addressing completeness and accuracy and/or deliberate misconduct are not currently adequate to address the purported situation.

In addition, even with clarification of the language change purpose, the use of the terminology “likely” is vague and overly broad. Enforcement actions, especially those that involve escalated enforcement like a SL III violation, should be based on easily discernible, objective criteria. The use of “likely” opens the door too widely for arbitrary conclusions.

a. Suggested revision:

There are probably several ways that such a terminology can be clarified and made more objective. Perhaps, when a technical matter is involved, some form of probability analysis should be employed. When non-technical matters are involved, perhaps tried and true concepts used in the legal context like “more probable than not” should be employed. Whatever the methodology, more clarification and objectivity is warranted.

b. Comment disposition:

As noted in the existing language of section 6.9.c.1, for violations that could impact the NRC's regulatory oversight function, an SL III determination is significantly influenced by whether accurate and complete information "would likely have caused the NRC to reconsider a regulatory position or undertake a substantial further inquiry." This portion of the Policy does not include willful aspects. Definitive, objective criterion here would not allow for consideration of the facts of each specific case, as no two cases are the same. Further, this is a high-level definition of severity level, not the objective criteria as provided in the detailed severity level examples of section 6.0. However, the additional language does highlight a threshold of licensee official involvement and deemphasizes the undertaking of "substantial further inquiry" in cases that would not result in a change in regulatory position.

Similarly, the portion involving willfulness is intended to make clear that typically, willful violations involving licensee officials will be evaluated as an SL III, consistent with section 2.2.1.d. Consequently, no change to the staff's proposed revision is necessary.

B. The NRC received one comment related to proposed changes to section 7.0. The proposed definitions relevant to this comment include the following:

Potential Safety or Security Consequences include potential outcomes based on realistic and credible scenarios (i.e., the staff considers the likelihood that safety or security could have been negatively impacted under these scenarios).

- **Substantial Potential Consequences**—a realistic likelihood of exceeding a regulatory limit, typically demonstrated by cases exhibiting concrete, tangible outcomes that did not exceed a regulatory limit, but were definable, and in which it was only because of fortuitous circumstances that the limit was not exceeded. The concern is not whether the relative limit was exceeded, but whether the licensee maintained adequate controls over the situation to prevent exceeding the limit.
- **Potential Consequences**—a realistic likelihood of safety or security consequences, typically demonstrated in scenarios where most, or all barriers to a safety or security consequence were absent, but only a limited tangible outcome was possible.
- **Low or Relatively Inappreciable Consequences**—credible scenarios where safety or security consequences could have occurred, but where at least one definable barrier, with a low likelihood of failure, remained to provide defense-in-depth.

1. Comment:

We believe the NRC will find it particularly difficult to ensure uniform application of this expanded definition of “Potential Safety or Security Consequences” to ensure consistent application across the regions. In addition, the continued use of undefined and subjective terms such as “*realistic likelihood*” and “*credible scenarios*” does little to provide clarity or promote consistent application across the regions.

a. Suggested revision:

None given by the commenter.

b. Comment disposition:

The proposed enhancements are not intended to replace the detailed examples in section 6.0, but rather to help incorporate a risk “gradient” into the philosophy of potential consequences. As noted in the narrative, the intent of the proposed revision is to acknowledge the existence of a risk gradient within the category of “potential consequences,” articulate basic characteristics at different levels, and link those levels to severity levels. The staff is not proposing any change to the Policy philosophy (i.e., to the consideration of potential consequences in determining severity level). The goal is to provide further explanation and clarify the consideration of risk in the identification of potential consequences. The staff believes that the expanded definitions will increase the consistency of Policy implementation. Consequently, no change to the staff’s proposed revision is necessary.

Item #314—Removal of Specific Inspection Manual References

Summary

The staff is removing references to specific inspection manual chapters (IMCs) from the Policy, so that future changes to IMC numbering or titles will not necessitate Policy revisions. (Enclosure 2, pp. 12, 15, 46, 62, 73, 94, 98)

Discussion

The Policy currently contains precise references to applicable IMCs, and any changes to these references require specific Commission approval. Replacing these precise references with general descriptions will (1) maintain stability and adequate clarity and (2) eliminate the need for future Policy revisions to address revisions to IMC titles or names.

Public Comments

The NRC received no comments.

Item #317—Removal of the Reactor Oversight Process Qualitative Color Descriptions

Summary

The staff is proposing to remove the Reactor Oversight Process (ROP) significance determination process (SDP) qualitative color descriptions from the Policy to accommodate planned changes to the descriptions of white and yellow findings in the ROP. (Enclosure 2, pp. 12, 46, 47, 61, 91)

Discussion

On September 19, 2018, the Nuclear Energy Institute (NEI) submitted multiple proposed ROP revisions for consideration by the Office of Nuclear Reactor Regulation (NRR) (Agencywide Documents Access and Management System Accession No. ML18262A322). Included was the recommendation to “establish labels of Green as ‘very low safety significance,’ White as ‘low safety significance,’ Yellow as ‘moderate safety significance,’ and Red as ‘high safety significance’” (see item 2B.6 in ML18262A322). Although these ROP revisions do not require specific Commission approval,² the staff did include the ROP qualitative color description changes, among other ROP changes, in SECY-19-0067, “Recommendations for Enhancing the Reactor Oversight Process,” dated June 28, 2019. This SECY was previously published for a 60-day public comment period (84 FR 38675; August 7, 2019), during which the staff did not receive any specific comments on revising these descriptions. Although SECY-19-0067 was withdrawn, the staff did communicate its intent to change the ROP color descriptions to the Commission in a Commissioner Assistants’ note dated April 2, 2019. The staff determined that the ROP revisions require corresponding revisions to the Policy; therefore, staff has added this item to this proposed Policy revision.

If the Commission approves item #317, the staff will remove from the Policy all references to qualitative descriptions of color findings and replace them with simple references to the ROP colors, to minimize the impact on the Enforcement Program across all inspection programs. The staff will also make complementary changes to the ROP qualitative descriptions for white and yellow findings in the applicable IMCs (e.g., IMC 0609, “Significance Determination Process,” and IMC 2519, “Construction Significance Determination Process”). The ROP qualitative color descriptions in the applicable IMCs would be revised as follows (with no change to red or green finding descriptions):

- red—high safety or security significance
- yellow—**moderate** [emphasis added] safety or security significance
- white—**low** [emphasis added] safety or security significance
- green—very low safety or security significance

The purpose of these qualitative descriptions is to better communicate to stakeholders the relative significance of inspection findings associated with each threshold and to help stakeholders understand how the significance of the findings logically affects the NRC’s oversight, as indicated by the ROP action matrix column. To clearly communicate the relative significance, the qualitative descriptions should use comparative terms; the term “substantial” is not comparable to the other ROP descriptions, and stakeholders’ interpretations of it may differ

² Management Directive 8.13, “Reactor Oversight Process,” dated January 16, 2018 (ML17347B670).

widely. The revised descriptions will eliminate potential confusion about the difference between findings of substantial safety significance (yellow) and high safety significance (red). They will also eliminate the existing inconsistency of defining white findings using a range of significance levels (i.e., low-to-moderate safety significance), while not using a range for any other color.

Some of the staff believes that this revision increases clarity by more closely aligning white and yellow findings with the descriptions of the ROP action matrix columns with which they are associated, as described in IMC 0305, "Operating Reactor Assessment Program." Specifically, a licensee would enter the Regulatory Response Column (Column 2) for one white finding. Column 2 is described as meeting cornerstone objectives with *minimal* degradation in safety performance, which better matches the revised white finding description of "low safety significance." Similarly, the Degraded Performance Column (Column 3), entered for a yellow finding, is described as meeting cornerstone objectives with *moderate* degradation in safety performance, which better matches the revised yellow finding description of "moderate safety significance." In addition, the revision preserves the most relevant connection between white findings and traditional enforcement SL III violations, by retaining the SDP threshold for white findings and maintaining all greater-than-green findings as escalated enforcement. In short, there will be no changes to the process used to determine the color of a finding or which findings will be considered for escalated enforcement. This change only impacts how the color of findings will be qualitatively described and the location where those descriptions are defined.

However, other staff believe that the proposed revision does not align with the clarity and reliability Principles of Good Regulation. Specifically, some of the staff believe that substituting "low" for "low-to-moderate" in the definition of a white finding will remove any connection, however tenuous, to the previous alignment with traditional enforcement SL III violations.

The enforcement program's original use of "low-to-moderate significance" when describing a white finding appears in SECY-00-0061, "Proposed Revision to the Enforcement Policy to Address the Revised Reactor Oversight Process," dated March 9, 2000, which states the following:

The new assessment process will use a Significance Determination Process (SDP) to characterize inspection findings based on their risk significance and performance impact. The SDP will assign a color band of green, white, yellow, or red to each inspection finding to reflect its risk significance.

While the staff did not adopt the direct tie between a severity level III and a white finding, the two were approximately correlated, as both corresponded to the lowest level of enforcement sanction subject to formal review through the escalated enforcement process. The staff proposed a qualitative description of "low-to-moderate safety or security significance" for white findings and stated that white findings were significant enough to warrant treatment as escalated enforcement. The Commission approved the staff's proposal in SECY-00-0061, and the Policy became effective on May 1, 2000.

Moreover, ROP development documents refer to white findings as "risk-significant." Therefore, the staff has proposed, and the Commission has approved the proposal, to define violations associated with white findings as escalated enforcement and subject to a formal legal review process ending with an NOV (rather than as noncited violations, which typically result from the less formal nonescalated enforcement process). For example, the proposed revised Policy glossary defines escalated enforcement actions as follows:

Escalated enforcement actions include SL I, II, and III NOVs; NOVs associated with an inspection finding that the SDP evaluates as red, yellow, or white safety or security significance; civil penalties; NOVs to individuals; orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities; and orders issued to impose civil penalties.³

The removal of the qualitative description is not by itself significant. However, this change could lead to more frequent questioning of enforcement process outcomes, and stakeholders, both internal and external, could reasonably consider it excessive to treat findings of “low” safety or security significance as escalated. To date, the staff has rejected this argument.

In summary, the qualitative descriptions are a tool to communicate the relative safety significance of ROP inspection findings. The staff is not proposing to change any significance thresholds or the SDP, and it is not changing the position that white findings are significant enough to be considered for escalated enforcement, consistent with SECY-00-0061. This change is intended to clarify the safety significance of ROP inspection findings and to better align the descriptions with their associated Action Matrix columns.

Public Comments

This item was added to this proposed revision after the Policy was published for public comment. However, the ROP qualitative color description changes, among other ROP changes, SECY-19-0067, “Recommendations for Enhancing the Reactor Oversight Process,” was previously published for public comment (84 FR 38675; August 7, 2019) and received a 60-day public comment period. Staff did not receive specific comments directed at the proposal to revise these descriptions. Although SECY-19-0067 was withdrawn, the NRR staff communicated to the Commission plans to make this change in a Commissioners Assistants’ note.

Item #313—Section 2.0, “NRC Enforcement Process,” and Section 7.0, “Glossary”

Summary

In section 2.0, the staff is revising multiple subsections to increase readability and adding a footnote describing the term “related violations.” In section 7.0, the staff is adding the definition of the term “inspection finding” and is incorporating the revised definition of “potential consequences” into the definition of “significance.” (Enclosure 2, pp. 8, 9, 10, 11, 13, 92)

Discussion

Upon the inception of the ROP, the Commission determined that certain violations at power reactors would continue to be dispositioned under the traditional enforcement process. This decision (64 FR 43229; August 9, 1999) stated, in part, the following:

Three categories of violations are within this group:

- 1) violations that involve willfulness, including discrimination,

³ This is the current proposed revision to escalated enforcement actions.

- 2) violations that may impact the NRC's ability for oversight of licensee activities such as those associated with reporting issues, failure to obtain NRC approvals such as for changes to the facility as required by 10 CFR 50.59, 10 CFR 50.54(a), 10 CFR 50.54(p), and failure to provide the NRC with complete and accurate information or to maintain accurate records, and
- 3) violations that involve actual consequences such as an overexposure to the public or plant personnel, failure to make the required notifications that impact the ability of federal, state, and local agencies to respond to an actual emergency preparedness or transportation event, or a substantial release of radioactive material.

The NRC later revised its approach for assessing significance (64 FR 61142; November 9, 1999) and identified four specific issues to consider:

- (1) actual safety consequences
- (2) potential safety consequences, including the consideration of risk information
- (3) potential to impact the NRC's ability to perform its regulatory function
- (4) any willful aspects of the violation

At the time of publication, this approach was listed in the Policy under Supplement IV, "Significance of Violations." This section was subsequently relabeled as section 2.2.4, and the listed approach has been modified slightly.

Section 2.2.4 currently states, in part, "In determining the severity level assigned to such [traditional enforcement] violations, the NRC will consider information in this Policy and the violation examples in section 6.0 of the Policy, as well as Significance Determination Process (SDP)-related information, when available." However, at times, available SDP-related information may be at odds with the significance level of the applicable examples; furthermore, in some cases (e.g., discrimination or willful violations) it is not appropriate to consider SDP-related information. The Policy currently does not inform readers that related violations may result in the issuance of both an ROP finding (i.e., green, white, yellow, or red) and a traditional enforcement violation (i.e., SL I, II, III, or IV). The "related violation" concept was initially mentioned in a previous Policy revision (65 FR 25370; May 1, 2000) to address the application of the SDP to assign a severity level to a 10 CFR 50.59 violation.

The revised section 2.2.4 includes a footnote to describe the term "related violation." Additionally, in section 7.0, the staff has added the term "inspection finding" and modified the definition of "significance" to incorporate the revised definition of "potential consequences."

Lastly, this revision includes editorial changes to increase the readability of multiple subsections in section 2.0.

Public Comments

- A. The NRC received two comments related to proposed changes to section 2.2.1. The originally proposed paragraphs (c) and (d) would read as follows:

...The existence of a regulatory process violation does not automatically mean that the issue is significant to safety or security. In determining the significance of a violation, the NRC will consider appropriate factors for the particular regulatory process violation. These factors may include the significance-potential or actual consequences of the underlying issue, whether the failure actually impeded or influenced regulatory action, the level of individuals involved in the failure and the reason why the failure occurred given their position and training, and whether the failure invalidates the licensing basis.

...In determining the significance of a violation involving willfulness, the NRC will consider such factors as the position, training, experience level, and responsibilities of the person involved in the violation (e.g., licensee official or nonsupervisory employee), the significance-potential or actual consequences of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation.

1. Comment:

Originally, 1(a) considered the actual consequences and 2(b) considers potential consequences, but now (1)(c) and (d) consider “actual or potential” consequences. NEI suggests using consistent language when discussing types of concerns. The NEI suggested changes to 2.2.1 (c) and (d) are to clarify the distinction between the reporting or willfulness issues and the underlying noncompliance.

a. Suggested revision:

Consistent and clear language is needed here to discuss the different concerns. Specifically, 2.2.1(c) suggested revisions: “The existence of a regulatory process ~~failure violation~~ does not automatically mean that either the regulatory process failure or the underlying issue is significant to safety or security. In determining the significance of a regulatory process violation, the NRC will consider appropriate factors for the particular regulatory process ~~violation-failure~~. These factors may include the potential or actual consequences of the underlying issue, whether the failure actually impeded or influenced regulatory action, the level of individuals involved in the failure and the reason why the failure occurred given their position and training, and whether the failure invalidates the licensing basis.”

Replace 2.2.1(d) NEI suggested revisions: “In determining ~~the significance of~~ whether to escalate a violation involving willfulness, the NRC will consider such factors as the position, training, experience level, and responsibilities of the person involved in the violation (e.g., licensee official or nonsupervisory employee), the potential or actual consequences of any underlying ~~violation-noncompliance~~, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation.”

b. Comment disposition:

The staff is adopting, in part, some of the editorial changes suggested by the commenter to increase consistency and clarity when discussing potential or actual consequences in section 2.2.1. Accordingly, the staff will revise sections 2.2.1(c) and (d), as follows:

...The existence of a regulatory process violation does not automatically mean that the underlying issue is significant to safety or security. In determining the significance of a regulatory process violation, the NRC will consider appropriate factors for the particular failure. These factors may include the potential or actual consequences of the underlying issue, whether the failure actually impeded or influenced regulatory action, the level of individuals involved in the failure, the reason the failure occurred given their position and training, and whether the failure invalidates the licensing basis.

...In determining whether to escalate the significance of a violation involving willfulness, the NRC will consider such factors as the position, training, experience level, and responsibilities of the person involved in the violation (e.g., licensee official or nonsupervisory employee); the potential or actual consequences of the underlying issue; the intent of the violator (i.e., careless disregard or deliberateness); and the economic or other advantage, if any, gained as a result of the violation.

B. The NRC received two comments related to proposed changes to section 2.2.4. The proposed paragraphs would read as follows:

Section 2.2.4: ...Related² violations may be dispositioned in parallel within both the traditional and ROP/cROP processes. The SDP will inform but may not necessarily determine the severity level, while the severity level or civil penalty amount should not influence the SDP.

Footnote 2:

In this context, the term "related" refers to violations that have a cause and effect relationship or are directly related to the same event. For example, a willful failure to adequately perform a quality related work order (dispositioned using traditional enforcement) that results in an inoperable structure, system or component (dispositioned using ROP or cROP).

1. Comment:

Section 2.2 preserves the position that violations are dispositioned under either the cROP/ROP or traditional enforcement, but the changes to 2.2.4 confuse this point. Section 2.2.4 includes the concept of a "related violation" which as

described, appears to endorse a sort of double counting when dispositioning a violation by permitting both traditional and SDP enforcement for the same event.

Further, the example provided to define the term “related” in footnote 2 does not flow from 2.2’s logic.

Specifically, a willful failure to adequately perform a quality related work order should be dispositioned entirely through traditional enforcement. Equipment that became inoperable due to that willful failure is part of the same violation and should not be considered separately.

a. Suggested revision:

Section 2.2.4 and the associated footnote 2 require clarification. Specifically, NEI suggests the NRC revise the example in footnote 2 to more clearly state the NRC’s intent on enforcing “related violations.”

At a minimum, NEI suggests adding to the end of the last parenthetical of footnote 2 “as an impact to a performance indicator.”

b. Comment disposition:

See 2.b below.

2. Comment:

When the ROP was created, there was deliberate consideration given to differentiating between whether an issue should be dispositioned through the SDP or Traditional Enforcement Process. The intent, which was a fundamental concept, was to not double count the particular issue in terms of licensee accountability and NRC oversight. The thought process was that a licensee should not be penalized with both a white or greater colored finding (which causes movement to the right in the ROP Action Matrix and the increased regulatory oversight) and a potential escalated enforcement action (i.e., severity level I, II, or III violation with a potential civil penalty).

The example provided in the footnote gives context to what constitutes a related violation; nonetheless, we believe there could be broad interpretation applied in reaching a conclusion that a violation is related to an issue that is subject to the SDP. Despite the statement in the Policy that, “The SDP will inform but may not necessarily determine the severity level, while the severity level or civil penalty amount should not influence the SDP,” we believe the Office of Enforcement (OE) through its program oversight function will be hard-pressed to ensure consistent application across the regions.

a. Suggested revision:

In keeping with the fundamental premises upon which the ROP was based, and to avoid challenges by the headquarters and regional offices in ensuring consistent and predictable outcomes, we believe an issue should not be dispositioned by applying the SDP and traditional

enforcement in parallel as contemplated. Rather, the issue should be dispositioned via one of the two processes, i.e., either the SDP or traditional enforcement.

In the example provided with respect to related violations, i.e., a willful failure to adequately perform a quality related work order that results in an inoperable structure, system or component, the most appropriate disposition would be for the NRC to issue an escalated enforcement action based on the willful aspect of the violation and its associated safety significance since the deliberate action resulted in an inoperable structure, system, or component. If the violation did not involve a willful aspect, then the violation should be dispositioned via the SDP and an appropriately colored finding issued by the NRC based on the associated significance determination result.

b. Comment disposition:

The purpose of this revision is to more clearly state the agency's Policy on the disposition of a concern that falls within both the ROP and the traditional enforcement process. This understanding is already reflected in other agency guidance and actions. For example, Section 8.13.G (Directive Handbook) of Management Directive 8.13 states the following:

When a violation satisfies the traditional enforcement criteria and there is an underlying finding, staff will use both the traditional enforcement process and the ROP. Specifically, the violation would be given a severity level and would be considered for a civil penalty. In addition, the finding would be processed under the SDP and the result would be entered into the action matrix, as appropriate.

Additionally, IMC 0612, "Issue Screening," describes following both paths (i.e., the ROP path and the traditional enforcement path).

Finally, SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," dated January 8, 1999, states the following (page 8):

Enforcement actions taken (e.g., the number of cited violations, the amount of a civil penalty) should not be an input into the assessment process. However, the issue that led to the enforcement action will continue to be considered in the assessment.

This concept, along with other proposed concepts, was approved by the Commission in SRM-SECY-99-007, dated June 18, 1999.

Consequently, no change to the staff's proposed revision is necessary.

Item #322—Section 2.3, “Disposition of Violations”

Summary

The staff is stating that the Policy inherently applies risk in determining appropriate enforcement actions and sanctions. (Enclosure 2, p. 14, 15)

Discussion

Although this is not explicitly stated, since its inception, the Policy has inherently applied risk factors in the determination of enforcement actions. In a June 1973 letter to Atomic Energy Commission (AEC) licensees (ML21126A186), the Commission incorporated three severity categories (I, II, and III) because “the significance of the violations of AEC requirements vary in their potential for affecting public health and safety of the public, the common defense and security, and the environment.” An October 7, 1980, revision (45 FR 66754) clarified how the NRC assessed CPs and introduced the CP assessment process (figure 2 in the Policy). It outlined several considerations for determining a CP: namely, the severity level, the duration of the violation, how the issue was identified, the financial impact on the licensee, the good faith of the licensee, prior enforcement history, and whether the violation was willful. It also introduced the concept of discretion, under which the CP amount could be increased if the licensee could have taken effective preventive measures and did not or decreased for “self-identification.”

In a policy statement published December 10, 1996 (61 FR 65090), the Commission addressed risk explicitly, stating, “Although there is inherent discretion in the Enforcement Policy to increase Severity Levels and sanctions based on risk, the Commission believes it is appropriate to modify the Policy to state the consideration of risk aspects more clearly.” This makes it clear that risk is appropriately considered in evaluating the technical significance of a violation (i.e., the potential and actual consequences).

Public Comments

- A. The NRC received one comment related to proposed changes to section 2.3. The proposed revision read as follows:

~~This section describes the various ways that the NRC can disposition violations. The general tenets of this Policy are used to assess the safety and security significance of a violation. Recognizing that 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 the violation and the appropriate enforcement sanction to be taken. The range of enforcement actions include a Noncited Violation (NCV), a Notice of Violation (NOV), an Order, and a civil penalty. This judgment and discretion include the decision to issue an NOV, or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of Policy and the significance of the violations, as well as the surrounding circumstances.~~

~~Whenever possible, The NRC also uses risk information to aid in this decision process. in assessing the safety or security significance of violations and assigning severity levels. A higher severity level may be~~

warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance. The severity level examples in Section 6.0 of this Policy were developed using qualitative risk insights to determine the appropriate severity level of a violation with Severity Level IV being the lowest and Severity Level I the most significant. Additionally, both the ROP and cROP utilize quantitative and qualitative tools using significance determination processes that assigns an inspection color finding. Duration of the violation is also an appropriate consideration in assessing the significance of the violation.

Cleaned up for readability, the above two paragraphs read as follows:

The general tenets of this Policy are used to assess the safety and security significance of a violation. Recognizing that 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 appropriate enforcement sanction to be taken. The range of enforcement actions include a Noncited Violation (NCV), a Notice of Violation (NOV), an order, and a civil penalty.

The NRC also uses risk information to aid in this decision process. A higher severity level may be warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance. The severity level examples in section 6.0 of this Policy were developed using qualitative risk insights to determine the appropriate severity level of a violation with Severity Level IV being the lowest and Severity Level I the most significant. Additionally, both the ROP and cROP utilize quantitative and qualitative tools using the SDP that assigns an inspection color finding.

1. Comment:

The NRC proposes to modify the language in the Enforcement Policy as to how the safety and/or security significance of a violation should be evaluated. Instead of the prior language, which is primarily aimed at “what” types of actions NRC’s discretion could be applied to (e.g., whether to issue a violation and whether to impose a civil penalty), the new language appears to address “how” the discretion should be applied. It now states that because regulation does not lend itself to “mechanistic treatment, judgement and discretion must be exercised” in assessing an enforcement sanction. While this general statement has conceptual merit, it cannot and should not be used as a default method for taking arbitrary action. Objective use of such discretion is critical. If this broad stated authority cannot be made more quantifiable and objective, then it must be paired with the responsibility and requirement to fully articulate why the discretion was applied (this includes application of discretion pro and con).

a. Suggested revision:

This paired responsibility and requirement cannot simply be implied—it must be stated in writing, and NRC management must ensure that enforcement discretion implemented under this broad authority is always examined against this standard before being issued. Anything less risks the possibility of vague and/or arbitrary enforcement discretion decision.

b. Disposition:

The staff agrees with the commenter that the proposed revision appears to emphasize the use of discretion to disposition all violations. This was not the intent of the revision. During the revision process, the staff found numerous statements referring to the disposition of violations before Section 2.3, “Disposition of Violations.” The staff moved these statements to section 2.3 to create a better flowing document. The final draft issued for public comment erroneously contained several of the deleted sentences, which created further confusion. The new proposed paragraph reads as follows:

2.3 Disposition of Violations

This section describes the various ways that the NRC can disposition violations. The general tenets of this Policy are used to assess the safety or security significance of a violation.

The NRC also uses risk information to aid in determining the appropriate enforcement outcome. A higher severity level may be warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance. The severity level examples in section 6.0 of this Policy were developed using qualitative risk insights to determine the appropriate severity level for a violation, with SL IV being the least significant and SL I the most significant. Additionally, both the ROP and the cROP use quantitative and qualitative tools based on the SDP, which assigns an inspection color finding. The duration of a violation is also an appropriate consideration in assessing its significance.

Item #333—Section 7.0, “Glossary”

Summary

This revision will clarify the terms “programmatic,” “repetitive,” and “isolated” as used in the violation examples and update the glossary accordingly. A common understanding of these terms is essential for agencywide consistency in characterizing and assessing the significance of violations. (Enclosure 2, pp. 16, 21, 22, 23, 36, 38, 51, 52, 54, 92)

Discussion

The terms “programmatic,” “isolated,” and “repetitive” are used throughout the Policy, most notably in characterizing and assessing the significance of a violation. However, neither current nor previous versions of the Policy and the Enforcement Manual have defined the terms “programmatic” and “isolated.” A common understanding of these terms is essential for agencywide consistency when characterizing and assessing the significance of a violation.

During enforcement panels and when evaluating violations, the staff has recognized various interpretations of these terms. For example, the term “programmatic” is sometimes interpreted as “associated with a particular program,” while at other times it is considered to refer to “the framework of the program necessary to ensure safety and regulatory compliance.” Similar inconsistencies have been noted in the use of the terms “isolated” and “repetitive.”

Therefore, consistent with Section 2.2, “Assessment of Violations,” the staff has:

- (1) Concluded that the existing definition of “repetitive” is appropriate and proposes to add the following definitions:
 - **Isolated** refers to a violation that was an anomaly relative to otherwise adequate licensee implementation, and where there is evidence that the licensee typically implements the regulated program correctly.
 - **Programmatic** refers to aspects of a program necessary to maintain safety and regulatory compliance. This includes the establishment of the necessary framework, procedures, and processes; verification that they are adequate to perform their functions; and the provision of appropriate training, supervision, and oversight to ensure the implementation of activities in accordance with all procedures and policies.
- (2) Reviewed each use of the terms “programmatic” and “isolated” in the Policy to determine whether the usage was consistent with the proposed definitions and then revised all passages where this was not the case. In addition, the staff has verified that each use of the term “repetitive” was clearly related to repetitive violations and has revised all instances where it was not.

Public Comments

The NRC received no comments.

Item #326—Section 2.3.4, “Civil Penalty”

Summary

In section 2.3.4, the staff is clarifying the CP amount to be applied, based on the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. (Enclosure 2, pp. 18, 19)

Discussion

In SECY-16-0081, “Notice of Intent to Publish Revision to the Enforcement Policy Table of Base Civil Penalties,” dated June 20, 2016 (ML16125A215), the staff informed the Commission of its

intent to publish a *Federal Register* notice announcing a revision to table A in Section 8.0, “Base Civil Penalties.” This revision was in response to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (ML20181A596), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, mandating that Federal agencies (1) adjust civil monetary penalties through rulemaking with an initial “catch-up” adjustment by July 1, 2016, and (2) make subsequent annual adjustments for inflation beginning in 2017. Accordingly, the NRC published a final rule (81 FR 47689; July 22, 2016) amending 10 CFR 2.205, “Civil penalties,” to reflect the new maximum civil monetary penalty. The staff then revised table A in section 8.0 of the Policy, including a footnote that states, “In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Improvements Act), the civil penalty amounts apply to any penalties assessed on and after the date that the new amounts take effect; not from the date of the violation.” However, the staff did not revise section 2.3.4, which states, “The civil penalty amounts applied should be those in effect at the time of the violation.” The proposed revision will resolve the conflict between section 2.3.4 and section 8.0, stating that the CP amount applied should be the amount in effect at the time the NRC assesses the CP, not at the time of the actual violation.

Public Comments

The NRC received no comments.

Item #336—New Section 2.3.13, “Failure to Control and Loss of NRC-Regulated Material”

Summary

The staff is clarifying how to apply the appropriate severity level and CP to enforcement cases when a licensee has taken action to recover missing material in a timely manner. This revision aligns with the current Policy’s level of deterrence, encourages licensees to take prompt action upon discovering that regulated material is lost or missing, and includes new severity level examples involving lost or missing regulated material. (Enclosure 2, pp. 18, 19, 31, 32, 37, 65, 66, 96)

Discussion

During the 1980s and 1990s, the NRC became increasingly concerned that individuals who possessed devices permitted under a general license under 10 CFR 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,” were not always aware of applicable requirements and thus might not be fully complying with these requirements. The concerns expressed at that time involved multiple incidents in which generally licensed devices (GLDs) were handled or disposed of improperly. In some cases, the mishandling of regulated material resulted in radiation exposure to members of the public and the contamination of property. Some GLDs had been accidentally melted in steel mills, causing considerable contamination of the mill, the steel product, and the wastes from the process (i.e., the slag and the baghouse dust).

To address these concerns, the NRC staff developed what became known as the GLD registration program. In the staff requirements memorandum (SRM) to SECY-00-0106, “Final Rule: 10 CFR Parts 30, 31, and 32—‘Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material’ and Related Change to the Enforcement Policy,” dated July 11, 2000, the Commission approved a final rule amending 10 CFR Parts 30, 31, and 32 to explicitly require general licensees who possessed certain devices containing byproduct

material to register their devices. The Commission also approved changes to the Policy with respect to the loss, abandonment, or improper transfer or disposal of sources and devices, to include increased CPs for both general and specific licensees. Specifically, the CP amount for lost sources was set to be approximately three times the estimated cost to properly dispose of certain quantities of regulated material. Recognizing that some sources were more expensive to dispose of than others, the Commission approved the use of three levels of CPs. In addition, the Commission made it clear at that time that a CP in the amount of at least the base CP would be appropriate in the case of loss, abandonment, or improper transfer or disposal of a sealed source or device. This change was published in the *Federal Register* (FR) (65 FR 79139; December 18, 2000) and became more widely known as the Lost Source Policy (LSP).

The LSP remained largely unchanged for the next 10 years. If a licensee had lost required control of its regulated radioactive material for any period of time, the Policy stated that “the NRC normally should impose at least a base civil penalty.” The Policy did not explicitly give the staff the latitude to consider actions taken by licensees if they discovered a source was lost and quickly recovered it with little or no risk to the public. Recognizing this apparent lack of flexibility, the Commission directed the staff to develop a proposed revision to the Policy. In SRM-SECY-09-0190, “Staff Requirements—SECY-09-0190—Major Revision to NRC Enforcement Policy,” dated August 27, 2010, the Commission stated that “language stating that violations will normally be assessed a Civil Penalty (CP) should be removed to avoid any impression that the CP will be assessed without regard to the circumstances surrounding the violation.” SRM-SECY-09-0190 also stated that “loss of control” should be added to the list of violations for which discretion should be considered in Section 3.6, “Use of Discretion in Determining the Amount of a Civil Penalty.” In response to the SRM, the staff submitted SECY-12-0047, “Revisions to the Nuclear Regulatory Commission Enforcement Policy,” to the Commission on March 28, 2012.

On January 28, 2013, the staff issued a revised Policy to remove the language implying that the NRC would assess at least a base CP in cases involving loss of control of radioactive materials. The *Federal Register* notice of the Policy change (76 FR 54986; September 6, 2011) described the Commission’s intent at that time as follows:

The intent is to maintain the existing lost source policy to issue at least a civil penalty while giving the staff the flexibility to disposition those cases where a licensee has lost NRC regulated material, but took immediate action to recover it, in a timely manner, with little or no risk to the public while the material was not in the licensee’s control. In such cases where loss of control is the issue, rather than actual lost material, the normal civil penalty assessment process, described in Section 2.3.4, would be used rather than typically issuing at least a base civil penalty as required by the current lost source policy.

Over the past 5 years, the staff has dispositioned over 20 escalated violations involving lost or missing regulated material. In doing so, the staff has identified a need to clarify the Policy’s language on “the circumstances surrounding the violation” and the application of CPs when a licensee took action to recover missing material in a timely manner. Therefore, to clarify and risk-inform the LSP, the staff is recommending that the existing LSP guidance from Section 2.3.4, “Civil Penalty,” be moved to a new standalone section, Section 2.3.13, “Failure to Control and Loss of NRC-Regulated Material.” This revision allows the agency to more fully describe how it considers the circumstances surrounding a violation and how it determines a CP. The proposed language preserves the high level of deterrence in the current Policy by keeping the CP amount for lost sources at approximately three times the estimated cost of

disposal. However, it also gives licensees a clear incentive to take prompt action upon discovering that regulated material is missing by providing the possibility for a reduced CP or no CP when circumstances warrant.

The proposed revision establishes several new severity level examples involving lost or missing regulated material in Section 6.7, "Health Physics." Examples are being proposed for less significant violations that do not warrant escalated enforcement (SL IV), as well as SL II and SL III examples for more serious violations that do warrant escalated enforcement. Two examples of less significant violations that involve little or no risk to members of the public are those involving GLDs not requiring registration and those involving limited quantities of low-activity sealed sources that can reasonably be presumed to be intact, such as radioactive "seeds" used in medical treatments. The examples use a relatively short half-life of less than 120 days to capture these or similar types and limited quantities of sources when the circumstances pose a very low risk to the public.

Under the new section 2.3.13, consultation with the Office of Enforcement (OE) will be required for all cases involving lost or missing regulated material, to ensure consistent application of the LSP. When evaluating the significance of a violation and determining a CP, the staff will continue to consider the actual or potential consequences of the licensee's loss of control of the regulated material, including any effect on occupationally exposed individuals, members of the public, or the environment. The Policy will continue to allow the staff to use discretion to mitigate or escalate a CP based on the merits of a specific case, and, when appropriate, consider actual consequences and actual costs of disposal to determine the CP amount.

In cases where the licensee either failed to recover the regulated material or did not recover it in a timely manner, and for which escalated enforcement is being considered, corrective action credit under the CP assessment process is not usually warranted, and the staff will normally apply a CP. The CP amount in such cases will normally be the higher of (1) the amount listed in section 8.0, table A, paragraph f (which is not adjusted by the multipliers in table B), or (2) the amount listed in section 8.0, table A, paragraphs a–e (adjusted by the applicable multiplier in table B).

In cases where the licensee recovered the regulated material in a timely manner with little or no risk to the public, and for which escalated enforcement is being considered, the staff may consider corrective action credit under the CP assessment process. The staff will typically apply any resulting CP using the amounts listed in section 8.0, table A, paragraphs a–e (adjusted by the applicable multiplier in table B).

In addition, the staff will normally consider using discretion in accordance with section 3.6 and assess a CP in cases where the licensee did not promptly identify or discover that its regulated material was uncontrolled or missing. This use of discretion is intended to emphasize the importance of maintaining control over, and awareness of the whereabouts of, licensed material. However, the CP amount should also reflect the decreased risk resulting from a licensee's prompt action to recover the material.

Public Comments

- A. The NRC received one comment related to proposed changes to violation example 6.7.b.7 (SL II example). The originally proposed violation example would read as follows:

A licensee (1) loses and subsequently recovers regulated material, i.e., loss of control; or (2) loses, abandons, or improperly transfers or disposes of regulated material. Such violations involve actual public or occupational exposures in excess of the applicable limits in 10 CFR Part 20, "Standards for Protection Against Radiation," or a likely potential for such exposures to occur based on the extent that the activity, form, half-life, circumstances of loss, and recovery are known.

1. Comment:

Punctuation correction.

a. Suggested revision:

We believe the correct wording and punctuation for this phrase should be ". . . , circumstances of loss and recovery, are known."

b. Comment disposition:

The staff agrees with the recommended punctuation change and has made conforming changes to the new proposed SL II and SL III violation examples, so that the examples now read "and circumstances of loss and recovery are known."

Item #336a—Recent Lessons Learned

During recent enforcement panel discussions regarding LSP cases, the staff identified remaining challenges not specifically addressed by the proposed revisions developed by the working group as described above. Consequently, the staff is recommending the following additional revisions:

- In the proposed violation example 6.7.d.7(b), add context for the term "limited quantities." The example is referenced for enforcement cases that involve lost sources, or sources that were out of the licensee's control for some time but were subsequently recovered. Recent enforcement casework has revealed that the term "limited quantities" is overly subjective and needs clarification. Therefore, the staff recommends adding "(e.g., one or two seeds of iodine-125)" to the proposed violation example 6.7.d.7(b). (Enclosure 2, pp. 67)
- Currently, the amounts listed in section 8.0, table A, for item f, are not adjusted for inflation because "these amounts are determined by the estimated or actual cost of authorized disposal."⁴ Recent inflation adjustments required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Improvements Act), have required the other civil penalty amounts in table A to be adjusted accordingly. However, this resulted in the current lost source CP amount, item f.3 (\$7,000) to be less than the lowest CP any licensee would incur through the traditional CP calculation of \$8,750 (table A, item e, with a 50 percent multiplier adjustment from table B).

⁴ See SECY-16-0081.

When a similar issue occurred in the past, the Commission approved an adjustment to item f.3 (65 FR 79139; December 18, 2000) and noted the following:

Sources and devices containing small amounts of radioactive material, such as gas chromatographs, and devices containing hydrogen-3 (tritium) can be disposed of for less than one third of the lowest base civil penalty amount under the current Enforcement Policy. It would be illogical to establish a lower base civil penalty amount specifically for loss, abandonment, or improper transfer or disposal.

Consequently, the staff recommends revising item f.3, in both current and future versions of the Policy, to be consistent with half of item e, so that the CP for losing a source is at least equal to an SL III CP (currently \$8,750). The types of licensees listed in item e are also those most likely to be using and, for the purposes of this discussion, losing sources of the sizes listed in item f.3, which further supports making a correlation between items e and f.3. (Enclosure 2, pp. 96)

- In recognition of the nondiscretionary and expedited nature of the civil monetary penalty annual adjustments required by the 2015 Improvements Act, the Commission granted explicit delegation of authority to the Executive Director for Operations (EDO) to update table A, items a–e and g.⁵ Accordingly, the staff recommends that the Commission extend the delegation of authority to the EDO to update item f.3 in table A.

Item #334—Section 2.3.4, “Civil Penalty”

Summary

The NRC is clarifying several paragraphs in section 2.3.4 to maintain consistency and increase efficiency in assessing CP credit for identification and for promptness and comprehensiveness of corrective actions. (Enclosure 2, pp. 22–26)

Discussion

In a *Federal Register* notice dated February 18, 1992 (57 FR 5791), the Commission revised multiple parts of the Policy, such as the CP adjustment factors, including those in the “Corrective Action” section. This section was revised to reflect that the factor is now based on both immediate and long-term corrective actions. The revision introduced the concept that “if immediate action was not taken to restore safety and compliance once the violation was identified, mitigation based on this factor would not normally be considered and escalation may be considered to address the licensee’s failure.” A revision dated June 30, 1995 (60 FR 34381), introduced the term “prompt corrective action.” This revision encouraged prompt identification and prompt, comprehensive correction of violations and their root causes, emphasizing compliance so as to deter future violations and focus licensees’ attention on violations of significant regulatory concern. Later revisions also incorporated this emphasis on identifying problems before events occur, and on taking prompt and comprehensive corrective actions when problems are identified.

⁵ Staff Requirements Memorandum for SECY-16-0108, “Revised Delegation of Authority to the Executive Director for Operations to Initiate and Sign Rules Amending Civil Penalties for Inflation,” dated October 19, 2016 (nonpublic).

Through recent discussions, the staff recognized that Policy sections on the assessment of CP credit for identification and for promptness and comprehensiveness of corrective actions should be clarified to enable consistent implementation throughout the agency, as well as to increase the efficiency of enforcement reviews.

The staff has revised both section 2.3.4 and other associated sections of the Policy, specifically to clarify the following:

- Replaced the term “root cause” with “underlying cause,” because of a history of controversy about materials licensees not being required to perform formal root cause analyses.
- Third-party assessments and self-assessments should be recognized as suitable means of informing a licensee of a violation.
- If a licensee took action to address an issue, even an issue that the licensee did not characterize as a violation, the licensee should be given identification credit. Materials licensees often do not have regulatory assurance groups that would provide precise regulatory characterization of an issue.
- The concept of a “missed opportunity” to identify a violation should not be applied in cases when the licensee took, or planned to take, reasonable action within a reasonable timeframe, even if another failure occurred before the corrective actions could be fully implemented.
- When assessing promptness and comprehensiveness of corrective actions, it is necessary to assess the adequacy of both immediate and long-term corrective actions.
- Information such as third-party assessments and industry/multiplier information should be considered opportunities when both assessing promptness and comprehensiveness of corrective actions and the starting point for assessing promptness of corrective actions, as well as determining appropriate identification credit.

Public Comments

- A. The NRC received one comment related to section 2.3.4.b.2.(a). The originally proposed paragraph would read as follows:

Licensee Identified—~~When The NRC should normally give the licensee identification credit if~~ a problem requiring corrective action is ~~licensee identified (i.e., identified by the licensee (including a contractor for the licensee))~~ before the problem results in an event, ~~the NRC should normally give the licensee credit for actions related to identification,~~ regardless of whether prior opportunities existed to identify the problem.

1. Comment:

We believe that similar clarification should be added to the discussions related to licensee corrective actions. For consistency the corrective

actions taken/or not taken by contractors or third parties should also be considered.

a. Suggested revision:

None given by the commenter.

b. Comment disposition:

The revision is intended to clarify that identification credit should be given for problems identified by contractors; a policy that was not being applied consistently in these types of cases. The NRC has consistently given corrective action credit for actions completed on behalf of the licensee. Furthermore, it is not the intent to give corrective action credit for actions the contractor takes on its own without representing the licensee or without the licensee committing to the actions the contractor suggested and/or implemented. Consequently, no change to the staff's proposed revision is necessary.

B. The NRC received one comment related to the proposed changes to section 2.3.4.b.2.(c). The originally proposed paragraph would read as follows:

If the NRC identified the violation but concludes that, under the circumstances, the licensee could not have reasonably identified the problem earlier, the ~~matter would be treated as~~ NRC may still give identification credit licensee identified for the purposes of assessing the civil penalty.

1. Comment:

NEI is concerned that this supposed "clarity" may actually be walking back the application of the "not reasonably identifiable" credit to licensees. There is a difference in application between "may be given consideration" and "would be treated as licensee identified."

a. Suggested revision:

NEI recommends the NRC keep the original language.

b. Comment disposition:

Based on the comment, the staff has inserted the word "normally." The revision is intended to clarify the wording, that is, to substitute "identification credit" versus "licensee identified." Also, the revision enables collegial discussion among the staff as to whether the merits of the case support the reasonableness as to whether the licensee would have identified the problem earlier (i.e., whether identification credit is warranted). The proposed language would be revised as follows:

Section 2.3.4.b.2.(c)

If the NRC identified the violation but concludes that, under the circumstances, the licensee could not reasonably have identified the problem earlier, the NRC will normally give the licensee identification credit for the purposes of assessing the civil penalty.

Item #347—Section 2.3.4, “Civil Penalty”

Summary

This revision clarifies that a CP will not be proposed for certain discrimination cases (i.e., instances when the licensee takes appropriate early action, the NRC opts not to investigate, and the licensee’s corrective actions are judged to be prompt and comprehensive). (Enclosure 2, p. 26)

Discussion

The present text, read literally, could be interpreted as stating that an NOV will be issued for all discrimination cases, and that a CP will not be assessed for any discrimination cases in which the licensee takes appropriate corrective actions.

The intent of the current (section 2.3.4) Policy wording is to state that the staff will not assess a CP for certain discrimination cases. These cases typically include those in which all of the following apply: (1) the licensee promptly informs the NRC of the issue, (2) the licensee resolves the discrimination concern before the NRC initiates an Office of Investigations (OI) investigation, and (3) the staff judges the licensee’s corrective actions to be prompt and comprehensive. The decision not to assess a CP in such cases is affirmed by Section 2.4.3, “Alternative Dispute Resolution,” which states that under certain circumstances, “...the NRC will not investigate the discrimination complaint or take enforcement action.”

Public Comments

- A. The NRC received one comment related to section 2.3.4(c). The proposed paragraph would read as follows:

~~If the corrective action is judged to be prompt and comprehensive, an NOV normally should be issued with no associated civil penalty. If the corrective action is judged to be less than prompt and comprehensive, the NOV normally should be issued with a base civil penalty. When a licensee voluntarily informs the NRC that a violation of NRC employee protection regulations has occurred for a discrimination issue in which the NRC did not perform an investigation, a civil penalty is not proposed if corrective action is judged to be prompt and comprehensive. If the corrective action is judged to be less than prompt and comprehensive, the NOV normally should be issued with a base civil penalty.~~

1. Comment:

The original language included “normally should be issued” which allowed for some discretion in the application of civil penalties for discrimination cases were deemed necessary [sic]. The revised language removes that discretion and instead, favors the issuance of civil penalties, with exception only in cases where:

1. Licensee voluntarily informs the NRC of violation (could eliminate cases of request for information prompted internal assessment findings);
2. NRC does not investigate; and
3. NRC determines the corrective action taken is prompt and comprehensive.

a. Suggested revision:

NEI recommends the NRC keep the original language.

b. Comment disposition:

The staff agrees with the commenter’s recommendation and will retain the original text. The original paragraph will be reordered slightly within section 2.3.4 to enhance clarity.

Item #303—Section 2.3.7, “Administrative Actions,” and Section 7.0, “Glossary”

Summary

The staff is improving the readability of section 2.3.7 and updating the definition of a confirmatory action letter (CAL). (Enclosure 2, pp. 27, 91)

Discussion

The definition of a CAL states, in part, “...voluntary agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.” The term “significant” is also used in Section 2.2.2, “Traditional Enforcement,” of the Policy, to define the significance of an SL II violation. However, in the context of enforcement, these terms (CAL and SL II) have entirely different meanings. A CAL is a voluntary agreement involving no enforcement action, while an SL II refers to a violation with substantial impact on safety or security.

The staff has determined that a CAL is more appropriately defined as an administrative tool used by the agency to address “specific concerns,” and this definition is better aligned with the staff’s current usage of CALs. For example, IMC 0305 (section 10.02.d.4–5) directs the usage of a CAL to document a licensee’s commitments, as discussed in its performance improvement plan. Most components of a performance improvement plan would not be deemed actions necessary to remove significant concerns about health and safety, safeguards, or the environment.

The staff also noted that in the Policy the definition of a CAL is more stringent than that of a confirmatory order, which is “an order that confirms the commitments made by a licensee or individual to take certain actions. Before issuance of the confirmatory order, the licensee or individual and the NRC mutually agree on the terms of the order.” Moreover, a confirmatory order is enforceable, while a CAL is not.

Public Comments

The NRC received no comments.

Item #324—Section 2.4.3, “Alternative Dispute Resolution”

Summary

The staff is revising section 2.4.3 to clarify the nominal expectation for the extent of licensee corrective actions agreed upon in an alternative dispute resolution (ADR) settlement action, that is, to make it clear that the NRC seeks a level of corrective actions broader than those likely achieved in traditional enforcement. (Enclosure 2, p. 33)

Discussion

Recent staff experience has revealed that it would be useful to clarify the nominal expectation for the extent of licensee corrective actions agreed upon in an ADR settlement. Since ADR is a voluntary program designed to resolve disputes less formally while meeting both parties’ interests, during ADR the staff seeks a level of corrective actions broader (or more comprehensive) than those likely achieved in traditional enforcement (which typically seeks simply to restore compliance).

Since ADR is an interest-based negotiation, and the NRC’s interests include both deterrence and prompt, comprehensive correction of violations, the corrective actions agreed to in an ADR mediation session must be more comprehensive than those expected for a potential CP case. This is because the ADR outcome will be used *in lieu of* traditional enforcement sanctions. The degree to which the actions exceed what would be acceptable in the traditional enforcement process varies with the actions the NRC may agree to take, or not take, in return.

Public Comments

- A. The NRC received one comment related to section 2.4.3. The originally proposed paragraph would read as follows:

ADR may also be used for discrimination violations based solely on a finding by the U.S. Department of Labor (DOL); however, the NRC will not negotiate the DOL finding. Individuals within the Commission’s jurisdiction may also be offered ADR. ADR complements, and works in conjunction with, the traditional NRC enforcement process. ADR may be offered (1) before a PEC, (2) after the initial enforcement action is taken (i.e., an NOV or proposed imposition of a civil penalty), or (3) with the imposition of a civil penalty and prior to a hearing request. Use of the ADR program is voluntary for all parties, including the NRC; any participant may end the process at any time. Mediation activities are kept confidential in accordance with 5 U.S.C. § 574; however, the terms of the settlement

agreement are normally formalized in a confirmatory order, which is published in the *Federal Register*. The resulting confirmatory order typically reflects more comprehensive corrective actions than typically achieved through the traditional enforcement process. Normally, there is also a press release providing information about the settlement agreement.

1. Comment:

The Policy summary states that this proposed change is “to clarify the nominal expectation for the extent of licensee corrective actions agreed upon in an ADR settlement.” However, the actual language change in the markup (section 2.3.4) is not expressed and not an expectation, but rather as a comment or observation about what “typically” happens. If the intent is an expectation, it should be stated clearly as such. Noting this administrative issue, it seems questionable that the NRC believes a licensee’s corrective actions must be broader and “more comprehensive corrective actions than typically achieved through the Traditional Enforcement Process.” This viewpoint seems to place an arbitrary limitation on the ADR process—should not the goal be to simply achieve the “best” balanced set of corrective actions for the stakeholders involved, and not just a greater quantity of and/or more severe set of actions?

a. Suggested revision:

The NRC should reconsider the implications of its proposed language.

b. Comment disposition:

The commenter suggested that the nominal scope of corrective actions in an ADR agreement would be more appropriately characterized as the best-balanced set of corrective actions. The staff believes that the notion of the “best-balanced set” is very subjective. The intent of this sentence is to recognize that if the agency agrees to reduce or eliminate a CP, or to recharacterize wrongdoing in a less definitive manner, then broader actions intended to provide greater assurance of continued compliance in the future throughout a licensee’s organization are appropriate. While each case is unique and corrective actions are determined based on the specific circumstances, one example that demonstrates the concept for power reactor licensees is some form of fleetwide corrective action. Traditional enforcement would not necessarily expect fleetwide actions in response to one site’s performance. However, if the staff refrains from citing a violation, eliminates a potential CP, or recharacterizes wrongdoing, it may be appropriate for the licensee to take corrective action that ensures that all sites within its control remain in compliance.

Such a threshold has been recognized as part of the ADR program since its inception and documented multiple times. For example, SECY-12-0161, “Status Update: Tasks Related to Alternative Dispute Resolution in the Allegation and Enforcement Programs,” dated November 28, 2012, states the following:

[The] staff maintains that it typically produces corrective actions that are more extensive than those achieved through the normal enforcement process while having similar deterrence effect. For example, through Post-investigation ADR, the staff has been able to obtain fleet wide corrective actions in some cases that it otherwise could not have achieved through traditional means.

Consequently, the goal is not to achieve “a greater quantity of and/or more severe set of actions,” but rather to characterize the best-balanced set of actions as something more than would be expected under traditional enforcement. Consequently, no change to the staff’s proposed revision is necessary.

Item #342—Section 3.8, “Notices of Enforcement Discretion for Operating Power Reactors and Non-Power Production or Utilization Facilities”

Summary

The staff is adding nonpower production and utilization facilities (NPUFs) to, and removing gaseous diffusion plants from, section 3.8, previously titled “Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants.” (Enclosure 2, p. 38)

Discussion

Based on a review of the current process for notices of enforcement discretion (NOEDs), the staff has determined that the regulatory structure (i.e., the nature of technical specifications) for NPUFs is similar to that of power reactors. Moreover, as with power reactors, in some possible but rare circumstances, the use of the NOED process for NPUF operations could provide public health and safety benefits (i.e., when noncompliance is less risky than compliance); therefore, the NOED process should include NPUFs. The staff’s review also determined the need to clarify the NOED policy to include reactor power plants that have transitioned to a decommissioning phase, up to the stage when the fuel has been permanently removed from the spent fuel pool and transferred to dry cask storage. Finally, since there are no current or anticipated gaseous diffusion plants, it is appropriate to remove the reference to them in the Policy.

Public Comments

The NRC received no comments.

Item #299—Section 4.0, “Enforcement Actions Involving Individuals”

Summary

The staff is clarifying Policy guidance regarding the NRC’s provision to licensees of potentially disqualifying information about individuals with security clearances when that information is discovered during NRC investigations into potential deliberate misconduct. (Enclosure 2, pp. 41, 43)

Discussion

The NRC requires certain licensees to establish, maintain, and implement the requirements of 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants." These requirements have been established to provide high assurance that individuals granted unescorted access and those certified for unescorted access authorization are trustworthy and reliable and do not pose unreasonable risks to public health and safety or the common defense and security, such as the potential for radiological sabotage. A revision to the Policy published January 28, 2013 (78 FR 5838), updated provisions for handling potentially damaging or disqualifying information about an individual's trustworthiness and reliability, which could affect the individual's unescorted access authorization for licensee facilities.

The staff frequently investigates individuals for potential deliberate misconduct in complying with NRC regulations. Lessons learned from previous enforcement cases identified the need for clarification about situations where the NRC discovers potentially damaging or disqualifying information about the trustworthiness and reliability of an individual who possesses a national security clearance. When the staff learns such information and loses reasonable assurance that the individual is willing and able to comply with NRC requirements, the agency may, on a case-by-case basis, notify the licensee that granted or is in the process of granting the individual unescorted access authorization. This notification may occur in the preliminary or final determination stage of the enforcement action against the individual, as appropriate, with approval of the Director, OE.

The staff believes that it is useful and prudent for the NRC to share this information to enable the licensee to meet the requirements of its access authorization program. It is the licensee's responsibility to evaluate the information provided in accordance with its access authorization program and determine the appropriate actions for the individual's access authorization. However, an entity, agency, or licensee may reasonably conclude that the information provided by the NRC is not disqualifying under the circumstances (e.g., based on additional facts, based on a different assessment of the facts, or based on the final outcome of the enforcement process).

In addition, the staff is proposing to delete legacy language reflective of orders to employers involving individuals that predates the deliberate misconduct rule and subsequently the use of ADR.

Public Comments

The NRC received no comments.

Item #321—Section 4.1, "Considerations in Determining Enforcement Actions Involving Individuals"

Summary

This revision clarifies the criteria for when an enforcement sanction would be issued to an alleged who engages in deliberate misconduct. (Enclosure 2, p. 42)

Discussion

After the last substantive Policy revision, the staff processed an enforcement case that revealed the need for additional clarity on alleged offenders found to have engaged in wrongdoing. A lessons-learned review, conducted by a staff member independent of the specific case but knowledgeable about the enforcement and allegation processes, identified that the main reason it took excessive time to complete the action was that the staff could not decide how best to handle deliberate violations committed by an alleged offender. The lessons-learned review recommended developing improved guidance for the allegation and enforcement programs, considering both programmatic goals. The staff concluded that neither the allegation nor the enforcement program has a clear, established policy or clear criteria for issuing an enforcement sanction to an alleged offender who deliberately violates NRC regulations (a rare, although not unheard-of, circumstance).

The programmatic goals of the allegation and enforcement programs conflict in situations involving alleged offender deliberate misconduct. The allegation program seeks to encourage individuals to communicate concerns candidly to the NRC. If an alleged offender receives an enforcement sanction after communicating with the NRC, both that individual and others may be less likely to communicate with the NRC again. However, if an individual engages in deliberate misconduct, then communicates such an act to the NRC, they are not protected from disciplinary action for the deliberate misconduct (e.g., Employee Protection rules, such as 10 CFR 50.7(d) and NRC Form 3, "Notice to Employees"); such protection would be contrary to the enforcement program goal of deterrence.

Consequently, the staff is proposing a revision to articulate a philosophy and criteria for when to issue an enforcement sanction to an alleged offender who engaged in deliberate misconduct. In such cases, the staff should consider the individual's sphere of influence, the significance of the underlying violation, and whether the individual was still employed within the NRC's jurisdiction. Case-specific facts, such as the involvement of more senior management, may warrant additional consideration.

Public Comments

- A. The NRC received two comments related to section 4.1. The originally proposed paragraph would read as follows:

Apparent violations involving alleged offenders who are found to have engaged in deliberate misconduct will be processed through the normal enforcement process. However, an alleged offender would typically be issued an appropriate enforcement sanction (e.g., NOV or order) only if: (1) the alleged offender is a licensee official (as defined in Section 7.0, "Glossary"); (2) escalated enforcement due to the alleged offender's actions appears to be warranted for the licensee; and (3) the alleged offender continues to be employed within the NRC's jurisdiction (either at the original or different licensee) or has the potential to be employed within the NRC's jurisdiction in the future. Clear, significant escalation and mitigation factors may be considered in determining an appropriate sanction and will be documented in the final enforcement decision. An example of an escalation factor is the alleged offender directing others to engage in deliberate misconduct. An example of a mitigation factor is the alleged offender being a lower level licensee official who was directed by a senior licensee official to engage in deliberate

misconduct. The presence of one or more significant mitigation factors may result in a reduction of the allegeder's enforcement sanction or use of discretion to not issue any enforcement sanction (e.g., if an enforcement action is taken against a more senior licensee official who directed the inappropriate action).

1. Comment:

The term "alleged" is not defined in the Policy or in the Allegation Program. The term most often used in the allegation program is "Concerned Individual." To prevent confusion and misapplication, NRC should define and use a common term in both the enforcement and allegation programs.

a. Suggested revision:

We propose that the discussion be modified to include context from the allegation program in order to continue to encourage concerned individuals to bring forward allegations of misconduct. The current added text leaves the reader with the impression that allegeders are routinely processed through the normal enforcement process, subject only to very specific limited exceptions.

b. Comment disposition:

The term "alleged" is defined in section I.A. of Directive Handbook (DH) 8.8, "Management of Allegations." To maintain consistency, the Policy should use the definition from DH 8.8; further definition would be neither helpful nor desirable.

The suggested revision states that the text implies that "allegeders are routinely processed through the normal enforcement process." However, the proposed Policy text actually refers to "allegeders *who are found to have engaged in deliberate misconduct*" (emphasis added); that is, the "pool" of allegeders who might be processed through the enforcement process is limited to those found to have engaged in deliberate misconduct. Historically there have been very few of these, roughly one or two per decade. To emphasize how rare the scenario is, the staff is adding the following sentences to the Policy:

Individuals who are employed by licensees, contractors, and subcontractors are encouraged to report violations through the allegation program. Although a rare occurrence, it is possible that the NRC could determine, as the result of an investigation based on an allegation by a person subject to NRC jurisdiction (e.g., an employee of a licensee, contractor, or subcontractor), that the allegeder has engaged in deliberate misconduct.

2. Comment:

Setting the expectation that an alleged who commits deliberate misconduct will “typically” be subject to enforcement only if the individual is a “licensee official” could be interpreted as a Policy to ignore situations where an alleged uses a discrimination claim to mask or cloud his/her conduct.

a. Suggested revision:

The NRC should clarify that this type of situation will not be ignored.

b. Comment disposition:

The proposed revision does not address employee protection issues; it is limited to deliberate misconduct. The Employee Protection regulations are clear and preclude the concern articulated by the commenter. Specifically, paragraph (a)(3) in the Employee Protection rules states the following:

This section has *no application* to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), *deliberately causes a violation* of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended [emphasis added].

Further, paragraph (d) notes that protected activities do not render immunity from discharge or discipline for legitimate reasons:

Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. *An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations* [emphasis added].

Clearly, an employee who engages in deliberate misconduct is not “protected” by alleging discrimination in an attempt to “mask or cloud” their conduct. Consequently, no change to the staff's proposed revision is necessary.

Item #281—Violation Examples, Section 6.1, “Reactor Operations”

Summary

Currently, section 6.1 lacks examples involving a failure to retain quality records as required by 10 CFR 50.71, “Maintenance of records, making of reports,” or by Criterion XVII of Appendix B,

“Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.” This revision proposes new SL III and SL IV violation examples for lost records that address the following: impact on the regulatory process; impact on the licensee’s ability to maintain operability of safety-related structures, systems, and components (SSCs); and consequences as related to the SDP. (Enclosure 2, p. 46)

Discussion

Currently, section 6.1 does not contain violation examples involving a failure to retain quality records as required by 10 CFR 50.71, 10 CFR Part 50, Appendix B, Criterion XVII, or 10 CFR 73.55(q). These violations impact the NRC’s ability to perform its regulatory oversight function. Specifically, failure to retain quality records impacts the NRC’s ability to fully assess the functionality of safety-related SSCs. Accordingly, violations involving this failure are addressed through traditional enforcement. The staff has developed proposed examples of record retention violations by considering previous violations that were assessed using current Policy examples but were not specific to 10 CFR 50.71, 10 CFR Part 50, Appendix B, Criterion XVII, or 10 CFR 73.55(q).

The proposed revision includes an example of an SL III violation that considers the consequences as related to the SDP. It also gives an example of an SL IV violation that considers how the licensee’s lack of records affects the operability of safety-related SSCs in terms of both the regulatory process and the licensee’s ability to perform subsequent actions.

Public Comments

The NRC received no comments.

Items #236 and #330—Violation Examples, Section 6.2, “Fuel Cycle Operations”

Summary

For items #236 and #330, the staff has modified the fuel cycle violation examples by removing references to gaseous diffusion plants and by clarifying the difference between an SL III and an SL IV violation for the loss of a criticality accident alarm system (CAAS). In addition, this revision aligns the emergency preparedness examples in section 6.2 “Fuel Cycle Operations” with the violation examples in Section 6.6, “Emergency Preparedness,” using the philosophy that the severity level of a violation at a fuel cycle facility should be one step lower than the severity for a similar event at a reactor site based on the lower postulated risk at the fuel cycle facility. (Enclosure 2, pp. 47, 49, 50)

Discussion

Before 2010, the Policy combined fuel cycle operations and materials operations in one supplement (Supplement IV). A September 30, 2010, revision to the Policy (75 FR 60485) created a separate violation example section for fuel cycle operations and revised the examples to adopt the integrated safety analysis methodology under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material.” This newly adopted methodology provided the baseline for future revisions of fuel cycle violation examples.

Currently, there are no gaseous diffusion plants licensed under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," and the staff does not expect there to be any in the future; therefore, the staff has eliminated all references to either gaseous diffusion plants or 10 CFR Part 76 from section 6.2.

This revision clarifies the difference between an SL III and an SL IV violation for the loss of a CAAS. These violation examples have three parts:

- (1) Duration: The endorsed version of American National Standards Institute (ANSI) / American Nuclear Society (ANS)-8.3, "Criticality Accident Alarm System," section 6.3, states, "System response to radiation shall be measured periodically to confirm continuing instrument performance. The test interval should be determined based on experience. In the absence of experience, tests should be performed at least monthly." This default test frequency would limit the duration of any failure to less than 30 days. ANSI/ANS-8.3, together with the common use of 30 days as a threshold in risk analyses, was the primary basis for the use of a 30-day threshold. In addition, assuming a 50-week work-year of 7 days per week, 24 hours per day, the 30-day threshold provides over 90 percent reliability. The Policy acknowledges that all systems, no matter how robust, have some nonzero failure frequency.
- (2) Area: The area affected by the CAAS failure, together with the duration of the failure, should be used to risk-inform the violation severity. A failure affecting a large area (such as a major process area) is more significant than a failure affecting a small area (such as a bathroom). The previous wording of the CAAS examples implicitly included this principle by considering the size of the affected area in determining what constituted a "substantial" failure duration.
- (3) Compensatory measures: The basis for this is ANSI/ANS-8.3 (endorsed by the NRC in Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Nuclear Materials outside Reactor Cores"), which allows the use of compensatory measures during routine maintenance of the CAAS (as well as during nonroutine maintenance, such as due to an equipment failure) and the use of compensatory measures to supplement an installed CAAS.

The term "emergency planning standard" used in the violation examples no longer applies to fuel cycle operations; it has been replaced with "10 CFR Part 70" to specify the implementation requirements for emergency plans at fuel cycle facilities.

Public Comments

- A. The NRC received one comment related to the current violation examples in section 6.2.(b) and (c). The originally proposed violation examples are as follows:

6.2.(b).1

Under 10 CFR Part 70, Subpart H, a high-consequence event is "not unlikely" based on a licensee's ISA;

6.2.(c).1-2

Under 10 CFR Part 70, Subpart H, a high-consequence event is “unlikely” based on a licensee’s ISA;

Under 10 CFR Part 70, Subpart H, an intermediate-consequence event is “not unlikely” based on a licensee’s ISA;

1. Comment:

The NRC staff can and have interpreted this to indicate that when a failure of an IROFS, as defined by 10 CFR 70.4, occurs, the likelihood of an IROFS failure has changed. In some cases, the likelihood of an event does indeed need to change as a result of an identified failure and increase in the failure frequency of such IROFS. However, in some instances when the failure of an IROFS does result in the failure frequency of that IROFS increasing, adequate risk was maintained in accordance with 10 CFR 70.61 as failures for less reliable controls are expected, especially in administrative controls. The failure of an IROFS is considered in ensuring adequate risk is maintained, i.e., the initiating event has not occurred or other IROFS failures did not occur simultaneously leading to an actual event.

The current language could also be interpreted that if an initiating event occurs, that event is no longer unlikely or not unlikely albeit that no instances of this occurring could be recalled.

The current language in the Policy ignores these facts.

a. Suggested revision:

Violation Example 6.2(b)1:

Under 10 CFR Part 70, Subpart H, a high consequence event is “not unlikely” based on a licensee’s ISA, i.e., the failure frequency of an IROFS or the initiating event of an accident sequence was increased and the licensee no longer meets 10 CFR 70.61 performance requirements; and

Violation Example 6.2(c)1 and 2:

Under 10 CFR Part 70, Subpart H, a high consequence event is “unlikely” based on a licensee’s ISA, i.e., the failure frequency of an IROFS or the initiating event of an accident sequence was increased and the licensee no longer meets 10 CFR 70.61 performance requirements;

Under 10 CFR Part 70, Subpart H, an intermediate consequence event is “not unlikely” based on a licensee’s ISA, i.e., the failure frequency of an IROFS or the initiating event of an accident sequence was increased and the licensee no longer meets 10 CFR 70.61 performance requirements;

b. Comment disposition:

The initiating event and a failure (complete or partial) of an item relied on for safety (IROFS) are two possibilities that could change the category of an accident sequence, causing it to no longer be highly unlikely or unlikely (i.e., causing it to be of high or intermediate consequence). Unanalyzed conditions could also lead to these severity levels. No matter how the licensee gets there, the result is a different likelihood category. Therefore, a change in the likelihood category corresponds to a change in the severity of the violation. Consequently, no change is required to the current violation examples.

Item #335—Violation Examples, Section 6.3, “Materials Operations”

Summary

This revision expands and clarifies the current violation examples for materials licensees who fail to have or to follow written procedures. It also adds violation examples for a failure to properly secure a well logging source. (Enclosure 2, pp. 51, 53–55)

Discussion

Section 6.3 provides limited violation examples for assessing the severity level of violations involving failures by materials licensees to follow written procedures. The staff is proposing to expand the violation examples to cover other materials program areas, such as 10 CFR Parts 34, 35, and 39. In preparing its revisions, the staff considered the current section 6.3 violation examples and consulted section 2.2.2 for severity level guidance.

As part of this revision, the staff has also expanded the SL III and SL IV violation examples to address procedural violations pertaining to recordkeeping, surveys, and inventories. The expanded examples enable the NRC to assess more significant cases of failures to perform required surveys and inventories or to maintain records. The existing standalone SL IV example is no longer necessary and will be deleted when the revised violation examples are incorporated.

The staff also noticed that section 6.3 did not contain violation examples for failure to secure a well logging source in accordance with 10 CFR 39.31, “Labels, security, and transportation precautions.” Although the Policy does contain examples addressing failures to maintain control and constant surveillance over licensed material that exceeds 1,000 times the quantity specified in Appendix C, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR Part 20, these examples generally do not address the unique security-related requirements of 10 CFR 39.31. Therefore, the staff is proposing new SL III and SL IV violation examples specifically addressing 10 CFR 39.31 violations.

Lastly, the staff is revising violation example 6.3.d.10 to address the repetitive aspect of the example. The example includes three conditions: (1) one level of physical control existed, (2) there was no actual loss of material, and (3) the failure is not repetitive. A previous Policy revision incorporated Enforcement Guidance Memorandum (EGM)-11-004, “Interim Guidance for Dispositioning Violations of Security Requirements for Portable Gauges,” dated April 28, 2011 (ML111170601), into the development of violation example 6.3.d.10. However, condition (3) was revised to say, “The failure is not repetitive” instead of “The failure was

isolated.” The staff will now restore the word “isolated” in the violation example, as outlined in the EGM.

Public Comments

The NRC received no comments.

Item #211—Violation Examples, Section 6.3, “Materials Operations”

Summary

This revision both modifies the existing SL III violation example and adds a new SL IV violation example for failures to meet decommissioning requirements. The revision specifies that the SL III violation example is for significant failures to meet decommissioning requirements, while the new SL IV violation example is for less significant violations of the decommissioning requirements. Both revised examples include four subexamples to illustrate their respective significance levels. (Enclosure 2, pp. 54, 55)

Discussion

On July 15, 1994 (59 FR 36026), Supplement VI (currently section 6.3, “Materials Operations”) of the Policy was modified as follows:

...to provide that violations involving a failure to notify the NRC as required by regulation or license condition, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required schedules without adequate justification may be classified as Severity Level III and may result in consideration of monetary civil penalties or other enforcement action as appropriate.

The specific violation example was described as follows:

A significant failure to meet decommissioning requirements including a failure to notify the NRC as required by regulation or license condition, substantial failure to meet decommissioning standards, failure to conduct and/or complete decommissioning activities in accordance with regulation or license condition, or failure to meet required schedules without adequate justification.

This violation example was revised on September 30, 2010 (75 FR 60485); however, the corresponding Commission paper (SECY-09-0190) did not go into detail on the revision, simply stating that several Policy violation examples had been reworded, presumably to add clarity.

The staff proposes both to (1) specify that the SL III example is for significant failures to meet decommissioning requirements and (2) add four subexamples to illustrate what may constitute a significant failure. The first subexample clarifies the scope of the example by referring to “decommissioning standards and requirements,” which the staff intends to apply to failures to meet release criteria and other failures not specifically covered in the other subexamples.

The second subexample addresses a failure to begin decommissioning when the facility involved is not required to submit a decommissioning plan (DP). In the absence of any other decommissioning violation, this example can be assessed as being of lower significance.

The third subexample specifies that for licensees that are required to submit a DP, failure to provide the required notification of decommissioning to the NRC and submit the DP is a significant failure meriting SL III consideration. For this example, the staff considered guidance in NUREG-1757, "Consolidated Decommissioning Guidance," which states that facilities required to submit a DP are typically those that were authorized for the use of unsealed radioactive material or for licensed activities that require more significant decontamination activities to meet release criteria. The DP, which requires NRC approval, describes how and when a licensee proposes to conduct and complete decommissioning activities. Since a facility for which a DP is required is more likely to be contaminated, the regulatory impact of a failure to notify the NRC that decommissioning is required is more significant for such a facility.

The fourth subexample expands on the current Policy language to clarify that a "failure to meet required schedules" means a failure to complete decommissioning without requesting NRC approval for an alternate schedule for completing decommissioning.

The staff considers the above SL III subexamples to exemplify "significant failures of decommissioning requirements," in that they describe delays in the planning or initiation of decommissioning activities for risk-significant facilities, or failures to complete decommissioning activities within the required timeframe. As described in *Federal Register* notice (59 FR 36026; July 15, 1994), these situations present an increased risk that safety practices may become lax or that bankruptcy, corporate takeover, or other unforeseen changes in the licensee's financial status may complicate and perhaps further delay decommissioning. This, in turn, could lead to the abandonment of sites and materials at sites, including contamination in areas no longer in use, potentially resulting in inadvertent exposure or in unauthorized access by members of the public. The staff also believes that the SL III subexample (a) provides sufficient flexibility to address other decommissioning violations that are not covered by the Decommissioning Timeliness Rule but that the staff determines to constitute a significant violation of decommissioning requirements. These situations can be evaluated by the staff and will, by process, be discussed at an enforcement panel to ensure that alignment is reached before the NRC dispositions the SL III violation.

The staff is also proposing to add new SL IV subexamples for decommissioning requirement violations. The first subexample addresses failures to notify the NRC that decommissioning is required but a DP submittal is not. Facilities not requiring a DP typically only possess sealed sources and/or use licensed materials in a way that precludes significant contamination of the facility or environment, so that significant decontamination activities are not required. The staff proposes that such violations can be assessed at a level commensurate with the lower safety significance of the licensed activities involved.

The second subexample is for situations in which a licensee required to submit a DP for its facility provides the decommissioning notification but fails to submit the DP or to obtain NRC approval for an alternate schedule for submitting the DP. In this scenario, because the licensee has notified the NRC that decommissioning is required, the staff is actively monitoring the licensee's activities; therefore, the risk of abandonment or improper remediation is lower than in cases where the NRC is entirely unaware of the licensee's status (as in the proposed SL III example violation).

The third subexample is for situations in which a licensee has failed to complete decommissioning activities within the required timeframe, but the licensee was only involved in licensed activities that were of very low safety significance. Specifically, this SL IV example is for licensees that only possessed sealed sources that did not leak, and the licensee has, as a corrective action for the violation, either disposed of or transferred the sources and requested license termination.

Public Comments

The NRC received no comments.

Item #315—Violation Examples, Section 6.3, “Materials Operations”

Summary

The staff is adding a new SL IV violation example to section 6.3 to address failures to maintain control and constant surveillance of a portable gauge during operational conditions in accordance with 10 CFR 20.1802, “Control of material not in storage.” (Enclosure 2, p. 56)

Discussion

On May 21, 1991, the NRC revised the requirement for control of licensed material not in storage (56 FR 23360). The regulation (10 CFR 20.1802) prevents (1) damage to the licensed device, (2) inadvertent exposure of workers and members of the public to radioactive material, and (3) the loss or theft of licensed material.

Unexpected and uncontrollable events occasionally occur at job sites (e.g., heavy construction equipment inadvertently contacts a gauge and causes damage). However, thanks to the robust design of portable gauges, these events do not necessarily cause appreciable security or safety concerns (e.g., inadvertent exposures of individuals). In addition, portable gauges are often used at remote, temporary job sites where few individuals are present. At such sites, there is little risk that an unauthorized person could remove the portable gauge without the gauge user’s knowledge, or that workers or the public could inadvertently be exposed.

Over the years, licensees have reported incidents involving the damage of portable gauges at temporary job sites. In these incidents, the portable gauge or gauge housing sustained severe mechanical damage; however, in most cases the radioactive sources remained intact, and no contamination leakage or exposure was identified, due to the robust design characteristics of portable gauges and sources. In some incidents, the sources were breached or could not be retracted, which increased the potential for external radiation exposure to members of the public and a higher dose to workers during source recovery.

Normally, for incidents in which a portable gauge user fails to maintain control and constant surveillance of a portable gauge as required by 10 CFR 20.1802 (i.e., the user leaves the gauge unattended), the NRC issues the licensee an SL III violation in accordance with Section 6.7, “Health Physics,” regardless of whether any damage occurred. However, the Policy does not contain any specific SL IV examples that address less significant violations (e.g., the user fails to maintain control for a short period while taking measurements). Because there were no SL IV violation examples for this scenario, case processing was difficult, and the staff identified inconsistencies among the regions.

On January 12, 2005 (70 FR 2001), the NRC promulgated 10 CFR 30.34(i), which requires the use of a minimum of two independent physical controls that form tangible barriers whenever portable gauges are not under the licensee's control and constant surveillance. The primary intent of this rule was to increase licensee control of portable gauges, to reduce the opportunity for unauthorized removal or theft. The rule applies to any licensee with a portable gauge, regardless of the location, situation, and activities involved. The licensee is required always to either maintain control and constant surveillance of the portable gauge or use a minimum of two independent physical controls to secure it to prevent unauthorized removal or theft.

Section 6.3 of the Policy addresses the failure to secure a portable gauge during storage and transport, as required by 10 CFR 30.34(i); the examples include both SL III and SL IV violations. Although the requirement for two tangible barriers under 10 CFR 30.34(i) is applicable to portable gauges stored in a truck, stored in their permanent storage location, or purposely left unattended for a period of time, it is not applicable during active use of the gauge, such as when taking or preparing to take measurements, or immediately after taking measurements.

The proposed SL IV violation example is suitable for instances where independent physical controls were not in place because the licensee reasonably expected to maintain control and constant surveillance (e.g., when the portable gauge was at a job site, being used to take measurements, but was out of the licensee's control for a short period). The staff believes that this example may help resolve disagreements and maintain consistency among the regions.

On August 1, 2018, the staff piloted this graded approach in EGM-18-002, "Interim Guidance for Dispositioning Violations for Failure to Control and Maintain Constant Surveillance for Portable Gauges" (ML18170A167). After 2 years of monitoring, and in accordance with the EGM's recommendation, the staff believes that an SL IV violation example should be used for certain violations of 10 CFR 20.1802 that are less serious, but are of more than minor concern, and that resulted in no or relatively inappreciable potential safety or security consequences, as long as they met certain criteria, as defined in the proposed example.

Public Comments

The NRC received no comments.

Item #343—Violation Examples, Section 6.3, "Materials Operations"

Summary

The staff is adding a new violation example to section 6.3 for less significant violations of 10 CFR 30.34, "Terms and conditions of licenses." (Enclosure 2, p. 56)

Discussion

Section 30.34(c) of 10 CFR requires, in part, that each licensee under 10 CFR Parts 30–36 and 39 confine its possession and use of byproduct material to the locations and purposes authorized in its license. The licensing process is a basic component of the NRC's regulatory structure to ensure safe use of byproduct material. Possession of byproduct material without a license, or not in accordance with a license, denies the NRC the opportunity to perform the necessary oversight to ensure the material's safe use, and calls into question whether the licensee understands its license and has sufficient controls in place to ensure that it operates within its limits.

A licensee's failure to seek required NRC approval before implementing a significant change in licensed activities that has radiological or programmatic significance (e.g., a radiologically significant increase in the quantity or change in the type of radioactive material being processed or used) is a 10 CFR 30.34(c) violation categorized as an SL III violation. This is currently the only violation example for this scenario. When the staff encounters a scenario with little to no radiological or programmatic significance, the staff must apply judgment to disposition the case as an SL IV violation.

On July 15, 2020, the staff successfully implemented this approach through EGM-20-003, "Interim Guidance for Dispositioning Violations of Licensed Material Possession and Use Limits" (ML20156A340), for cases with little to no radiological or programmatic significance. Now the staff is recommending adding a new SL IV violation example to the Policy and sunsetting the EGM.

Public Comments

The NRC received no comments.

Item #319—Violation Examples, Section 6.4, "Licensed Reactor Operators"

Summary

The staff is revising section 6.4 by both applying a graded, performance-based approach and revising the usage of the performance attribute "error" in the violation examples. (Enclosure 2, p. 57)

Discussion

According to the current Policy, the NRC considers enforcement actions against individuals to be significant actions that will be closely evaluated and judiciously applied. Typically, the NRC will take an enforcement action involving an individual, either licensed or nonlicensed, only when the violation has actual or potential safety or security significance.

The Policy also states, "...the NRC may take enforcement action against NRC-licensed reactor operators even if the violation does not involve deliberate misconduct, since operators licensed by the NRC are subject to all applicable Commission requirements (see 10 CFR 55.53(d))." Consequently, the staff will prudently assess the appropriateness of issuing an enforcement action to a licensed operator.

The current Policy assigns either an SL II or an SL III when a licensed operator is determined to be (1) in noncompliance with a condition stated on the individual's license, or (2) in violation of 10 CFR 55.53, "Conditions of licenses." Currently, there are no SL I or SL IV violation examples for this type of violation.

The staff is revising the current examples using a graded, performance-based approach to allow certain violations of this type to be assigned a significance of SL I or SL IV. The graded approach will align the Policy with the staff's current practice of assigning a significance of SL IV to issues with no or relatively inappreciable potential safety consequences. Regardless of the severity level, OE enforcement panels will continue to be conducted for all proposed individual actions.

Public Comments

- A. The NRC received one comment related to proposed violation example 6.4.c.5. The originally proposed violation example would read as follows:

A nonwillful compromise (see 10 CFR 55.49, "Integrity of Examinations and Tests") of an application, test, or examination required by 10 CFR Part 55, "Operators' Licenses," or inaccurate or incomplete information inadvertently provided to the NRC, ~~subsequently contributes to the NRC making an incorrect regulatory decision, such as the following and has any of the following effects:~~

- (a) in the case of initial operator licensing, contributes to an individual being granted an operator or senior operator license, or
- (b) in the case of operator requalification, contributes to an individual being permitted to continue to perform the functions of an operator or senior operator, or
- (c) contributes to a medically unqualified individual performing the functions of a licensed operator or senior operator.

1. Comment:

The wording of this revision will result in violations that have little to no consequence being classified as Severity Level III violations. The action of "contributing to an individual being granted an operator license" is left vague and open to interpretation.

NEI suggests adding clarity to the revision by adding the requirement that the violation has or could have had moderate safety or security consequences, consistent with the definition of a severity level III violation.

- a. Suggested revision:

Revise (a) to say:

in the case of initial operator licensing, contributes to an individual being granted an operator or senior **had the information been provided completely and accurately, the individual would not have been granted an operator license** or

Similarly, revise (b) to say:

in the case of operator requalification, contributes to an individual being **had the information been provided completely and accurately, the individual would not have been permitted to continue to perform the functions or an operator or senior operator.**

b. Comment disposition:

Generally, the commenter recommended clarification of the statement “contributing to an individual being granted an operator license.”

The staff agrees with the commenter that the violation example needed clarification. As a result, the staff has reinserted a previously deleted phrase (i.e., “...subsequently contributes to the NRC making an incorrect regulatory decision...”). Additionally, the staff has incorporated a variation of the commenter’s proposed change (i.e., “...that should not have been granted...”) in violation examples 6.4.c.5(a)–(b). Therefore, the updated violation example 6.4.c.5 is as follows:

A nonwillful compromise (see 10 CFR 55.49) of an application, test, or examination required by 10 CFR Part 55, or inaccurate or incomplete information inadvertently provided to the NRC, subsequently contributes to the NRC’s making an incorrect regulatory decision, and has any of the following effects:

- (a) In the case of initial operator licensing, it contributes to an individual’s being granted an operator or senior operator license that should not have been granted.
- (b) In the case of operator requalification, it contributes to an individual’s being permitted to continue to perform the functions of an operator or senior operator when they should not have been permitted to do so.
- (c) It contributes to a medically unqualified individual’s performing the functions of a licensed operator or senior operator.

B. The NRC received one comment related to proposed changes to violation example 6.4.d.1(d). The proposed paragraph would read as follows:

an individual operator who met ~~ANSI/ANS 3.4, Section 5, the applicable industry standard~~ as certified on NRC Form 396, required by 10 CFR 55.23, but ~~who did not perform the functions of a licensed operator~~ failed to report a condition that would have required a license restriction to establish or maintain medical qualification based on having the undisclosed medical condition.

1. Comment:

The addition of the phrase “who did not perform the functions of a licensed operator” is overly restrictive and not consistent with the definition of an SL IV violation as defined in the section 2.2.2.

Section 2.2.2(d) states that SL IV violations are those that resulted in “inappreciable potential safety or security consequences.” Section 2.2.2(c) also states that “SL III violations are those that resulted in or could have resulted in moderate safety or security consequences.” However, the condition described in (d)(1)(d) of section 6.4 is one where a licensed operator failed to report a license restriction but was found to be in compliance with that condition. Since the operator was found to be in compliance with the industry standard, it is not necessary to require an additional restriction to say that the operator “did not perform the functions of a licensed operator” during the time in question.

a. Suggested revision:

NEI recommends for consistency with section 2.2.2 and for clarity, the NRC should delete, “who did not perform the functions of a licensed operator.”

b. Comment disposition:

The commenter recommended the deletion of the phrase “who did not perform the functions of a licensed operator” to maintain consistency within section 2.2.2.

The staff agrees with the commenter’s recommendation and has revised violation example 6.4.d.1(d) accordingly. Additionally, the staff made two other changes: it relabeled violation example 6.4.d.2 as 6.4.d.1(e), and it replaced the term “individual operator” with “licensed operator.” The updated violation example 6.4.d.1 is as follows:

There is a nonwillful compromise of an application, test, or examination required by 10 CFR Part 55, such as one of the following:

- (a) Inaccurate or incomplete information is inadvertently provided to the NRC, but the NRC does not make an incorrect regulatory decision as a result of the originally submitted information.
- (b) A licensed operator does not meet the applicable industry standard as certified on NRC Form 396, “Certification of Medical Examination by Facility Licensee,” which is required by 10 CFR 55.23, “Certification,” but has not performed the functions of a licensed operator or senior operator while having a disqualifying medical condition.
- (c) A licensed operator does not meet the applicable industry standard as certified on NRC Form 396, which is required by 10 CFR 55.23, because of an incomplete medical examination, but is

subsequently found to meet the health requirements for licensing.

- (d) A licensed operator meets the applicable industry standard as certified on NRC Form 396, which is required by 10 CFR 55.23, but fails to report a medical condition that would have required a license restriction to establish or maintain medical qualification.
- (e) A licensed operator actively performs the functions covered by that position, in noncompliance with requirements based on a medical condition stated on the individual's license but does not violate the applicable industry standard or commit any error that has or could have significant safety or security consequences.

Item #345—Violation Examples, Section 6.8, “Transportation”

Summary

Violation example 6.8.c.3 will be revised to include the word “marking” in the text. This will aid in the disposition of certain transportation violations involving a licensee’s failure to ensure that appropriate markings are placed on shipping containers, in accordance with NRC and U.S. Department of Transportation (DOT) regulations. (Enclosure 2, p. 68, 69)

Discussion

The information currently in section 6.8 includes common aspects of transportation noncompliances. Such noncompliances include when a licensee either overlooks or poorly executes the preparation of radioactive material for transport. Selection of the proper package, commensurate with the activity of the radioactive material content, is the primary means of ensuring safety during transport of radioactive material. Equally important is proper communication about the shipment (i.e., marking and labeling of packages, placarding of vehicles, generating accurate shipping papers and related emergency response information, and adherence to proper training and security steps, as appropriate). The markings on a package (e.g., the proper shipping name of the radioactive material, the United Nations identification number, the address of the shipper or receiver) are important because they describe the contents of a package. Additionally, the United Nations identification number marking helps emergency responders cross-reference emergency response guides/steps to mitigate any incidents during transportation. Thus, it is important that the markings on a package be accurate and reflect DOT regulations. Inaccurate markings could lead to an incorrect or incomplete response to a transportation incident.

In 10 CFR 71.5, “Transportation of licensed material,” the NRC requires licensees to implement certain DOT regulations associated with the transport of licensed materials on public thoroughfares, including a requirement for appropriate “marking and labeling.” The staff noted that violation example 6.8.c.3 does not include the term “marking,” although the SL IV examples allude to marking. The regulations in 10 CFR 71.5 require NRC licensees to comply with 49 CFR Part 172, “Hazardous Materials Table, Special Provisions, Hazardous Materials

Communications, Emergency Response Information, Training Requirements, and Security Plans,” Subparts C–I. The addition of the term “marking” to the SL III violation example will help the staff in dispositioning transportation concerns that involve a licensee’s failure to ensure that appropriate markings are placed on shipping containers, in accordance with NRC and DOT regulations.

Public Comments

The NRC received no comments.

Item #294—Violation Examples, Section 6.15, “Export and Import Activities”

Summary

In section 6.15, the staff has added five new violation examples and revised one existing violation example to integrate lessons learned from previous enforcement casework. (Enclosure 2, pp. 86, 87)

Discussion

On January 28, 2013, the NRC revised the Policy to include new violation example section 6.15 (78 FR 5838). This new section provided several examples associated with violations of 10 CFR Part 110, “Export and Import of Nuclear Equipment and Material,” including four SL III violation examples and three SL IV violation examples.

Since 2013, the NRC has dispositioned a variety of violations of 10 CFR Part 110. Based on this experience, to promote consistent application of the Policy for the most common violations, the staff is proposing one clarification to an existing violation example, two new SL III violation examples, and three new SL IV violation examples. These revisions are as follows:

(1) Clarification to existing violation example 6.15.c.1:

This revision adds a “for example” phrase to identify two types of actions that the NRC might need to take in response to a more significant failure to provide advance notification to the NRC, as required by 10 CFR 110.50(c). If the NRC staff is not informed of the import or export of certain higher-risk sources or equipment, it could miss an opportunity to prevent a potential incident or accident (e.g., by requesting a license application, or requiring further steps to mitigate potential radiation exposure).

(2) New SL III violation examples:

- The new violation example 6.15.c.5 addresses the failure to obtain a specific license before importing nuclear material that is under NRC jurisdiction when the U.S. recipient is not authorized to possess the material. The regulation at 10 CFR 110.27(a) permits any person to import byproduct, source, or special nuclear material if the U.S. consignee is authorized to receive and possess the material under the relevant NRC or Agreement State regulations. The failure to obtain a specific import license when the provisions of 10 CFR 110.27(a) are not met has significant public health and safety implications if the recipient of the imported material is not authorized to receive or possess the material.

- The new violation example 6.15.c.6 focuses on attempted export and shipment without having a proper license in accordance with 10 CFR 110.31, “Application for a specific license.” Occasionally, U.S. Customs and Border Protection has stopped attempted unauthorized exports of nuclear material or equipment under NRC jurisdiction before they left U.S. soil. If the attempted export had been consummated without the necessary authorization, it could have resulted in significant public safety or foreign policy or diplomatic consequences for the United States.

(3) New SL IV violation examples:

- The new violation example 6.15.d.4 addresses a licensee’s failure to seek required NRC approval before making a change in ownership, when the change in ownership does not significantly affect import or export activities under NRC jurisdiction.
- The new violation example 6.15.d.5 addresses untimely advance notification (as opposed to failure to provide advance notification at all), where the lack of timely notification was less significant and did not cause the NRC to take further action or make inquiries.
- The new violation example 6.15.d.6 addresses the failure of a licensee exporting radioactive material to submit a copy of an authorization to confirm that the foreign recipient in the importing country is authorized to receive and possess the material under the law and regulations of the importing country. Without this authorization, the NRC staff cannot confirm that the foreign recipient is authorized to possess the radioactive material.

Public Comments

- A. The NRC received one comment related to violation example 6.15.d.4. The originally proposed violation example reads as follows:

A licensee fails to seek required NRC approval before the implementation of a significant change in licensed activities, such as a change in ownership of a parent company or the licensee or change in ownership of the licensee;

1. Comment:

I do not agree with this as written—it does not convey the intent of the violation example. The Policy example should address a change in ownership that does NOT have significant impact on importing or exporting activities.

- a. Suggested revision:

This violation example should be rewritten to say “...before the implementation of less significant changes in licensed activities, such as...” that does not impact importing or exporting activities;

b. Comment disposition:

The staff agrees with the recommended change and has made conforming changes to violation example 6.15.d.4 as follows:

A licensee fails to seek required NRC approval before implementing less significant changes in licensed activities, such as either a change in ownership of the parent company of a licensee or change in ownership of a licensee, that does not impact importing or exporting activities.

Item #337—Violation Examples, New Section 6.16, “Independent Spent Fuel Storage Installations”

Summary

This revision adds a new section of violation examples for independent spent fuel storage installations (ISFSIs). (Enclosure 2, pp. 72, 74, 87)

Discussion

NRC inspectors have identified a need for ISFSI violation examples. Currently, when dispositioning violations, the inspection staff considers precedents from similar violations, applicable areas in the Policy, and the overall risk significance of the violation. Specific ISFSI violation examples will enable the staff to disposition these violations efficiently and consistently.

To develop the SL III and SL IV violation examples, the staff researched previously dispositioned ISFSI violations and recent events at ISFSI facilities (e.g., the San Onofre Nuclear Generating Station (SONGS) canister misalignment event). The proposed violation examples are based on this analysis. The SL IV violation examples encompass the “more common” ISFSI violations, while all SL III violations reflect past events.

A historical review revealed that only one SL II violation and no SL I violations had been issued for ISFSIs. However, for consistency with other categories of violation examples, the staff is proposing an SL I violation example. To ensure consistency, the SL II violation example considers both a previously issued violation and other existing violation examples.

The staff is also proposing a revision to Section 6.9, “Inaccurate and Incomplete Information or Failure to Make a Required Report,” based on past enforcement case experience and recent events at SONGS. ISFSI-specific examples will help inspectors assess the significance of violations related to failures to make required reports.

Public Comments

A. The NRC received one comment related to proposed violation example 6.16.a.1–3. The proposed violation example reads as follows:

A violation that resulted in loss of fission product barriers (e.g., fuel cladding and confinement) resulting in a member of the public receiving a radiation dose in excess of regulatory limits;

A violation that resulted in significant contamination to the environment; or

A violation that resulted in an inadvertent criticality event.

1. Comment:

These examples cannot occur at an ISFSI and new examples should be written to reflect actual scenarios at an ISFSI.

a. Suggested revision:

Delete 6.16(a)(1-3)

b. Comment disposition:

The staff disagrees with the commenter and believes that while these scenarios are unlikely, there is in fact a chance of occurrence at an ISFSI. Consequently, no change to the staff's proposed revision is necessary.

B. The NRC received one comment related to proposed violation example 6.16.b.1–3. The proposed violation example reads as follows:

A violation that resulted in or could have resulted in loss of fission product barriers (e.g., fuel cladding or confinement); or

A violation that resulted in loss of a system designed to prevent or mitigate a serious safety event; or

A violation that resulted in a significant loss of criticality margin.

1. Comment:

NEI has modified example (b)(1) to more accurately reflect what occurs at an ISFSI. Specifically, the “loss of fission product barriers” is not a meaningful term with respect to cladding in dry storage. What the design is intended to do is limit “gross rupture,” which is not the same as a defect in the individual rod. We have added language to example 1 to reflect that fact.

a. Suggested 6.16.(b)(1) revision:

A violation that resulted in or could have resulted in loss of fission product barriers (e.g., fuel cladding or confinement) unable to perform their design function;

b. Comment disposition:

The staff considers a “gross rupture” to be a loss of fission product barrier and not a defect in an individual rod. Consequently, no change to the staff's proposed revision is necessary.

- C. The NRC received one comment related to proposed violation example 6.16.c.1. The proposed violation example reads as follows:

A licensee fails to obtain prior Commission approval as required by 10 CFR 72.48 for a change that caused the NRC to undertake a further inquiry such that a significant revision to either the licensee's change or evaluation was required;

1. Comment:

NEI modified example 1 as indicated in green. Revising an evaluation should not have the same consequences as having to significantly revise the actual change being evaluated. The former should be evaluated under 6.16(d).

- a. Suggested 6.16.(c).1 revision:

A licensee fails to obtain prior Commission approval as required by 10 CFR 72.48 for a change that caused the NRC to undertake a further inquiry such that a significant revision to either the licensee's change or evaluation was required;

- b. Comment disposition:

After reevaluating its draft proposal, the staff has modified both violation examples 6.16.c.1 and 6.16.d.3 and added a new violation example 6.16.d.4, as follows:

6.16.c.1

A significant failure to adequately evaluate a change to the facility or spent fuel storage cask design, as required by 10 CFR 72.48, "Changes, tests, and experiments," results in implementation of the change without a required NRC license or certificate amendment.

6.16.d.3–4

A violation of 10 CFR 72.48(d)(1) occurs, with significant revisions to the bases for the determination in the written evaluation of the change, test, or experiment that do not require a license amendment.

A less significant failure to adequately evaluate a change to facility or spent fuel storage cask design, as required by 10 CFR 72.78, results in implementation of the change without a required NRC license or certificate amendment. The failure does not lead to an SL I, II, or III violation.

Item #383—Interim Enforcement Policy 9.2, “Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)”

Summary

In 2018, rulemaking codified specific criteria for permanent implant brachytherapy in 10 CFR 35.40, “Written directives”; 10 CFR 35.41, “Procedures for administrations requiring a written directive”; and 10 CFR 35.3045, “Report and notification of a medical event.” Therefore, the staff is proposing to sunset Interim Enforcement Policy 9.2, “Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045).” (Enclosure 2, pp. 101–102)

Discussion

On July 16, 2018, the Commission approved the final rule “Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments” (83 FR 33046). This rule revised 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045 to accommodate specific requirements for permanent implant brachytherapy.

Specifically, 10 CFR 35.40(b)(6) was amended to clarify that a written directive (WD) for permanent implant brachytherapy is divided into a preimplantation and a postimplantation portion. The preimplantation portion of the WD requires documentation of the treatment site, the radionuclide, and the total source strength. The postimplantation portion requires documentation of the treatment site, the number of sources implanted, the total source strength implanted, and the date; this must be completed before the patient leaves the posttreatment recovery area.

In 10 CFR 35.41(b), the NRC addresses the requirements that the licensee must follow when developing, implementing, and maintaining written procedures to provide high confidence that each administration requiring a WD is in accordance with the WD. With respect to permanent implant brachytherapy programs, the regulation at 10 CFR 35.41(b) now requires licensee procedures for any administration requiring a WD to include procedures for determining whether a medical event occurred, as defined in 10 CFR 35.3045. It also requires licensees to have specific procedures that include the determination of postimplant source position within 60 calendar days from the date the implant was performed, or a written justification that this determination could not be made within the 60 calendar days because the patient was not available. The determination must include the total source strength administered outside of the treatment site, compared to the total source strength documented in the postimplantation portion of the WD. These determinations are used to partially assess whether a medical event occurred, as defined in 10 CFR 35.3045.

Finally, the staff added a new paragraph (10 CFR 35.3045(a)(2)) that contains separate criteria for reporting a medical event involving permanent implant brachytherapy. These criteria are as follows: (1) the total source strength administered differs by 20 percent or more from the total source strength documented in the postimplantation portion of the WD, (2) the total source strength administered outside the treatment site exceeds 20 percent of the total source strength documented in the postimplantation portion of the WD, or (3) the administration involves the wrong radionuclide; the wrong individual or human research subject; sealed source, or sources, implanted directly into a location discontinuous from the treatment site, as documented in the postimplantation portion of the WD; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

Public Comments

This item was not published for public comment.