

Proposed Revisions to NRC Enforcement Policy

The following proposed changes to the September 30, 2010, version of the Enforcement Policy (the Policy) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML093480037) are those discussed in *Federal Register*, Notice of Availability, 76 FR 76192, dated December 6, 2011. (Note: Other proposed Enforcement Policy changes were provided for public comment in 76 FR 48919, dated August 9, 2011, and 76 FR 54986, dated September 6, 2011.)

Part 1 below of these proposed revisions to the Policy discusses proposed changes based on direction given to the staff in Staff Requirements Memorandum (SRM)-SECY-09-0190, "Major Revision to NRC Enforcement Policy," dated August 27, 2010. Part 2 discusses staff-initiated proposed Policy changes.

Parts 1 and 2 are organized as follows:

- (1) Policy sections containing proposed changes are listed in section order.
- (2) The purpose of each change is given.
- (3) The proposed changes are shown in **bold** type.

Part 1

Proposed Policy Changes Based on Direction to the Staff in SRM-SECY-09-0190

1. 2.3.4 Civil Penalty

Purpose of change:

To evaluate whether civil penalties for uranium conversion facilities could be tied to the inventory of process chemicals and other materials maintained by the facility. In addition, the Commission directed the staff to present options for the Commission's consideration in this regard.

The staff has evaluated options for revisions to the base civil penalties for uranium conversion facilities and the corresponding civil penalty assessment process and is recommending that no changes be made to the Enforcement Policy. In coming to this conclusion, the staff considered that the U.S. Nuclear Regulatory Commission (NRC) is restricted to issuing Notices of Violation (NOVs) and proposing civil penalties for violations associated with chemicals at an NRC-licensed facility when these chemicals are part of, or otherwise adversely impact, NRC-licensed activities or processes. A recent NRC effort (76 FR 28336) to amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, "Domestic Licensing of Source Material," included a reevaluation of the 1988 memorandum of understanding (MOU) between the NRC and the U.S. Occupational Safety and Health Administration. That reevaluation resulted in each organization confirming its respective role and responsibility regarding the oversight of hazardous chemicals at NRC-licensed facilities. In accordance with the MOU, the presence of chemicals at any NRC-licensed facility does not, in itself, constitute grounds

for NRC enforcement activity. However, in accordance with the MOU, the staff determined that the base civil penalty proposed for uranium conversion facilities listed in Table 1A of the Enforcement Policy dated November 28, 2008 (ADAMS Accession No. ML092440278), was not commensurate with the risk associated with such facilities because of the presence at such facilities of large amounts of uranium hexafluoride (UF₆) and hydrogen fluoride (HF). As a result, the latest version of the Enforcement Policy published on September 30, 2010, increased the base civil penalty for uranium conversion facilities from \$14,000 to \$70,000.

Further, the staff has determined that a detailed analysis of the risk posed to NRC-licensed activities at a uranium conversion facility from process chemicals would necessitate the expenditure of resources beyond the expected relative benefit to the enforcement process. In coming to this conclusion, the staff considered that adequate flexibility exists in Section 2.3.4 of the current Enforcement Policy, whereby the NRC may mitigate or escalate the amount of a civil penalty based on the merits of a specific case. If the Commission directs the staff to conduct such a risk analysis, the staff would propose, for the sake of overall resource efficiency, that the analysis include all hazardous chemicals at all NRC-licensed facilities.

The staff considered that conversion and deconversion facilities may have on site between 45,000 and 450,000 kilograms (approximately 100,000 and 1,000,000 pounds) of HF, while fuel fabricators, gas centrifuge facilities, and enrichment facilities will normally have significantly less. Also, conversion and deconversion facilities may have liquid UF₆, while fuel fabricators, gas centrifuge facilities, and enrichment facilities will not. These differences in amounts of process chemicals have been factored into the base civil penalty amounts proposed in Table 1A of the current Enforcement Policy.

In addition, the staff is currently engaged in amending the regulations in 10 CFR Part 40 to add requirements for source material licensees that possess greater than 2,000 kilograms (approximately 4,400 pounds) of UF₆. The staff will reevaluate the need for any revisions to the civil penalty assessment process and the Enforcement Policy when this rule change becomes effective (expected mid-2012).

Proposed change:

The staff is not proposing to revise the Enforcement Policy or the Table of Base Civil Penalties at this time, but rather the staff is soliciting comments on the proposed approach to addressing the SRM item discussed in the Purpose of Change above.

2. 2.4.1 Predecisional Enforcement Conference

Purpose of change:

To provide clear and consistent guidance regarding when a predecisional enforcement conference (PEC) will be conducted. To add language that the NRC will, to the extent feasible, consider responses to apparent violations before taking final escalated enforcement action.

The proposed change would replace the text of the current Section 2.4.1 in its entirety.

Proposed change:

2.4.1 Predecisional Enforcement Conference

A predecisional enforcement conference (PEC) is a conference held with a licensee for violations assessed using traditional enforcement. (The term “licensee,” as used in this section, is applied broadly and includes NRC licensees, licensed and nonlicensed individuals, contractors, vendors, and other persons.) The purpose of the PEC is to obtain information from the licensee to assist the NRC in determining whether an enforcement action is necessary and, if so, what the appropriate enforcement action is. The PEC focuses on areas such as (1) a common understanding of the facts, root causes, and missed opportunities associated with the apparent violation or nonconformance and (2) a common understanding of the corrective actions taken or planned. If held, a PEC is normally the final step in the NRC’s fact-finding process before making an enforcement decision.

When the NRC determines that there is a violation for which escalated enforcement action appears warranted, the agency offers the licensee the opportunity to attend a PEC and/or provide a written response to the apparent violation before the NRC makes an enforcement decision. The NRC may specifically request a PEC if it needs additional information before making a final enforcement decision. However, if the NRC concludes that it has sufficient information to make an informed decision that an enforcement action, without a civil penalty, is warranted, it may issue the enforcement action without first obtaining the licensee’s response to the documented apparent violation. The NRC will notify the licensee that a PEC is not planned, and unless the licensee specifically requests a PEC, one will not be held. If the licensee does not request a PEC or does not accept the NRC’s offer to attend a PEC, the licensee may choose to respond in writing to a documented apparent violation (including its root causes and a description of planned or implemented corrective actions) before the NRC takes enforcement action. To the extent practicable, the NRC will consider the licensee’s response before taking enforcement action.

Part 2

Other Policy Changes Proposed by the Staff for Inclusion in the Next Policy Revision

1. 2.2.1 Factors Affecting Assessment of Violations

Purpose of change:

To clarify Sections 2.2.1.a, b, and c regarding factors affecting assessment of violations. The remainder of Section 2.2.1 is unchanged.

Proposed change:

2.2.1 Factors Affecting Assessment of Violations

- a. Whether the violation resulted in actual safety or security consequences. In evaluating actual consequences, the NRC considers issues such as whether the violation resulted in onsite or offsite radiation exposures **exceeding 10 CFR Part 20, “Standards for Protection against Radiation,” regulatory limits**, accidental criticality, core damage, loss of significant safety barriers, loss of control of radioactive material or radiological emergencies, or whether the security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an act of radiological sabotage occurred.
- b. Whether the violation had potential safety or security consequences. In evaluating potential consequences, the NRC considers whether the violation created a credible accident, security failure, or exposure scenario that could potentially have significant actual consequences. For facilities under construction, the NRC considers the actual or potential impact on the quality of construction and its resulting effect on the safety and security of the facility.
- c. Whether the violation impacted the ability of the NRC to perform its regulatory oversight function. The NRC considers the safety and security implications of noncompliances that may affect the NRC’s ability to carry out its statutory mission. These types of violations include failures to provide complete and accurate information; failures to receive prior NRC approval for **required** changes in licensed activities; failures to notify the NRC of **required** changes in licensed activities; failures to perform 10 CFR 50.59, “Changes, Tests and Experiments,” and similar analyses; and failures to comply with reporting requirements **that directly affect the NRC’s ability to assess significant issues**, etc. Even inadvertent reporting failures are important because many of the surveillance, quality control, and auditing systems on which both the NRC and its licensees rely in order to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting. 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 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.

2. 2.2.4 Exceptions to Using Only the Operating Reactor Assessment Program

Purpose of change:

To delete portions of Sections 2.2.4.a, b, and c that discuss the specific examples of the types of violations dispositioned using traditional enforcement. Instead, the proposed revisions reference Policy Section 2.2.1, which describes actual safety and security consequences, potential safety and security consequences, and impacts to the ability of the NRC to perform its regulatory oversight functions. The remainder of Section 2.2.4 is unchanged.

Proposed change:

2.2.4 Exceptions to Using Only the Operating Reactor Assessment Program

- a. violations that resulted in actual safety or security consequences **(as described in Section 2.2.1.a)**
- b. violations that may impact the ability of the NRC to perform its regulatory oversight function **(as described in Section 2.2.1.c)**
- c. violations involving willfulness **(as described in Section 2.2.1.d)**

3. 2.3.4 Civil Penalty

Purpose of change:

To incorporate a description of civil penalties from the November 28, 2008, version of the Policy, Section VI.C, "Civil Penalty," which emphasized that civil penalties are typically assessed for Severity Level (SL) I and II violations and are considered for SL III violations. However, the incorporated wording was modified to stress that the civil penalty process described in Section 2.3.4 should be followed to determine the appropriateness of any civil penalty. The remainder of Section 2.3.4 is unchanged.

Proposed change:

Civil penalties are typically assessed for Severity Level (SL) I and II violations and deliberate violations of the reporting requirements of Section 206 of the Energy Reorganization Act. Civil penalties are considered for SL III violations. However, the civil penalty assessment process described in this section and depicted in Figure 2 should be followed to determine the appropriateness of a civil penalty for any escalated enforcement action. Notwithstanding the outcome of the normal civil penalty assessment process, discretion, as discussed in Section 3.6, "Use of

Discretion in Determining the Amount of a Civil Penalty,” may be used to determine the amount of the civil penalty.

4. 2.3.2.b Noncited Violation, All Other Licensees

Purpose of change:

To change the title of Section 2.3.2.b to include nonlicensees. To clarify that noncited violations (NCVs) may also be issued to nonlicensees when they meet the NCV criteria stated in Section 2.3.2.b. To edit Sections 2.3.2.b.1, 2.3.2.b.2, and Footnote 4 to include nonlicensees. Correct typographical error in current Policy in Section 2.3.2.b.4.

Proposed change:

b. All Other Licensees **and Nonlicensees**

1. The licensee/**nonlicensee** identified the violation.
2. The licensee/**nonlicensee** corrected or committed to **correcting** the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence.
3. The violation is not repetitive as a result of inadequate corrective action.
4. The violation was not willful. Notwithstanding willfulness, an NCV may still be appropriate if it meets the criteria in Section **2.3.2.a.4** above.

The approval of the Director, **Office of Enforcement**, is required to disposition willful violations as NCVs.

Footnote 4: An NOV is warranted when a licensee/**nonlicensee** identifies a violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. Disposition as an NCV may be warranted if the licensee/**nonlicensee** demonstrated initiative in identifying the violation’s root cause.

5. 2.3.11 Inaccurate and Incomplete Information (new section)

Purpose of change:

To add a new section to provide guidance to the staff for issues involving inaccurate and incomplete information. The wording for this proposed new section is taken essentially verbatim from the November 28, 2008, version of the Policy, Section IX, “Inaccurate and Incomplete Information,” and was not included in the September 30, 2010, version of the Policy.

Proposed change:

2.3.11 Inaccurate and Incomplete Information

A violation of the regulations involving the submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee normally will be categorized based on the guidance herein, in Section 2.2, “Assessment of Violations,” and in Section 6.9, “Inaccurate and Incomplete Information or Failure To Make a Required Report.”

The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, the Commission may consider factors such as (1) the degree of knowledge that the communicator should have had regarding the matter, in view of his or her position, training, and experience, (2) the opportunity and time available before the communication to ensure the accuracy or completeness of the information, (3) the degree of intent or negligence, if any, involved, (4) the formality of the communication, (5) the reasonableness of NRC reliance on the information, (6) the importance of the information that was inaccurate or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

In the absence of at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee, thereby permitting an opportunity to correct the oral information. An example of such a situation would be a case in which the licensee had available a transcript of the communication or meeting summary containing the error and did not subsequently correct the error in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue an NOV for the initial inaccurate or incomplete information normally will depend on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the NRC or the licensee identified the problem with the communication, and whether the NRC relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee before the NRC relies on the information, or before the NRC raises a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after the NRC relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action

normally will be taken even if the information is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or an advance in technology, a citation normally would not be appropriate if, when the new information became available or the advance in technology was made, the initial submittal was corrected. The failure to correct inaccurate or incomplete information that the licensee does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee later determines that the initial submittal was in error and does not correct it, or if there were clear opportunities to identify the error. If a licensee recognizes that information not corrected is significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions in not correcting or providing information raise questions about the licensee's commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

6. 2.3.12 Reporting of Defects and Noncompliance (new section)

Purpose of change:

To add a new section to provide guidance to the staff for issues involving contractors that supply products or services for use in nuclear activities. The wording for this proposed new section is taken essentially verbatim from the November 28, 2008, version of Policy, Section X, "Enforcement Action Against Non-Licensees," and was not included in the September 30, 2010, revision to the Policy.

Proposed change:

2.3.12 Reporting of Defects and Noncompliance

Contractors that supply products or services for use in nuclear activities are subject to certain requirements designed to ensure that products or services that could affect safety are of high quality. Through procurement contracts with licensees, suppliers may be required to have quality assurance programs that meet applicable requirements (e.g., 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," Subpart H, "Quality Assurance"). Contractors supplying certain products or services to licensees are subject to the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliances," for reporting defects in basic components.

When inspections determine that violations of NRC requirements have occurred (e.g., 10 CFR Part 50, Appendix B) that could adversely affect the quality of a safety-significant product or service, the NRC will typically take enforcement

action. NOVs and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements. The NRC will issue NOVs to contractors who violate 10 CFR Part 21. Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(d)(1). The NRC will use NOVs or orders against nonlicensees who are subject to the specific requirements of 10 CFR Part 71 and 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste.” Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.

7. 4.0 Enforcement Actions Involving Individuals

Purpose of change:

To provide guidance for dealing with potentially damaging or disqualifying information involving an individual’s trustworthiness and reliability which may affect an individual’s unescorted access. The NRC requires selected 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 constitute an unreasonable risk to public health and safety or the common defense and security, including the potential to commit radiological sabotage. Occasionally, the NRC investigates individuals for potential deliberate misconduct of NRC regulations. When the NRC develops, maintains, or is informed of information regarding an individual’s trustworthiness and reliability and loses reasonable assurance that an individual is willing or able to comply with NRC requirements, the agency may give this information to the licensee who granted, or is in the process of granting, unescorted access authorization. The NRC believes that sharing this information is prudent and may be useful to a licensee in meeting 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 to determine the appropriate actions regarding individual access authorizations.

Therefore, the staff proposes revising the third paragraph of Section 4.0. The remainder of Section 4.0 is unchanged.

Proposed change:

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. **If the NRC discovers (through inspections or investigation-related material) potentially damaging or disqualifying information regarding an individual’s trustworthiness and reliability, and the individual currently possesses Unescorted Access (UA) or is in the process of obtaining Unescorted Access Authorization (UAA), the NRC will consider, on a case-by-case basis, informing the licensee that has granted, or**

is processing the UA/UAA of the developed information. This notification may occur in the preliminary or final determination stage of the enforcement process, as appropriate. NOVs and Orders are examples of enforcement actions that may be issued to individuals. Enforcement actions issued to individuals will normally be placed on the NRC **Office of Enforcement** Web site. Generally, before taking enforcement action against an individual, the NRC will seek to gather information to determine whether an Order or other enforcement action should be issued. The **agency** may gather such information by conducting a PEC, by requesting a written response from the individual, or by issuing a **Demand for Information**. If the violation was deliberate, the individual may also be provided the opportunity to address the apparent violation during **Alternative Dispute Resolution (ADR)**. The exact nature of the opportunity to address the apparent violation will depend on the circumstances of the case, including the significance of the issue, the enforcement sanction **that** the NRC is contemplating, and whether the individual has already had an opportunity to respond to the apparent violation.

8. 6.0 Violation Examples

Purpose of change:

To delete four SL IV violation examples each of which contains one or the other of the following phrases: "...does not amount to a SL I, II, or III violation" or "...does not result in a SL I, II, or III violation." The staff believes that these four SL IV examples do not provide useful, specific guidance regarding the condition that would result in an SL IV. Rather, these four examples default to an SL IV primarily because the violation does not rise to the level of an SL I, II, or III violation.

Proposed change:

Delete the following four SL IV violation examples:

6.4.d.2—A licensed operator or senior operator has a confirmed positive test for drugs or alcohol after arriving on-site to perform scheduled work or to attend required requalification training that does not result in a Severity Level I, II, or III violation.

6.8.d.4—A noncompliance occurs that involves shipping papers, marking, labeling, placarding, packaging, or loading, but the noncompliance does not amount to a Severity Level I, II, or III violation.

6.11.d.3—Violations occurred in meeting requirements contained in the licensee security plan and implementing procedures, but the violations did not amount to a Severity Level I, II, or III violation.

6.14.d.3—A licensee violates the requirements of 10 CFR Part 26, but the violation is unrelated to the behavior observation program and does not amount to a Severity Level I, II, or III violation.

9. 6.3 Materials Operations

Purpose of change:

To add a new example of an SL IV violation to address less significant cases (i.e., those violations that do not rise to the level of SL III Example 6.3.c.11(b)) in which a licensee fails to seek required NRC approval before changing the location where licensed activities are being conducted or where licensed material is being stored.

Proposed change:

6.3.d.9—A licensee fails to seek required NRC approval before changing the location where licensed activities are being conducted or where licensed material is being stored that has little or no radiological or programmatic significance, and all other safety and security requirements have been met.

10. 6.4 Licensed Reactor Operators

Purpose of change:

To add one new violation example each for SL I, II and III. The three new examples are based on the staff's enforcement experience with violations regarding fitness-for-duty issues involving licensed reactor operators. To rewrite, for clarification, the SL IV examples regarding non-willful compromise of an application, test, or examination required by 10 CFR Part 55. To delete SL IV Example 6.4.d.2 (see explanation of deletion in item 8 above).

Proposed change:

6.4 Licensed Reactor Operators

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

1. A licensed operator, or a senior operator actively performing the functions covered by that position, is involved in procedural errors that result in, or exacerbate the consequences of, an Alert or higher level emergency and, at the time the procedural errors occurred, was determined to be **any** of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the licensee, or
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j), **or**
 - (c) **unfit for duty as determined by a post event fatigue assessment required by 10 CFR 26.211(a)(3).**

b. *Severity Level II* violations involve, for example:

1. A licensed operator, or a senior operator actively performing the functions covered by that position, is involved in procedural errors and, at the time the procedural error occurred, was determined to be any of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the facility licensee, **or**
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j), or
 - (c) in noncompliance with a condition stated on the individual's license;

2. A deliberate compromise (see 10 CFR 55.49, "Integrity of Examinations and Tests") occurs of an application, test, or examination required by 10 CFR Part 55, "Operators' Licenses," or inaccurate or incomplete information is deliberately provided to the NRC and has any of the following results:
 - (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;**

3. A licensed operator or senior operator, while within the protected area, is involved in the use, sale, or possession of illegal drugs or the consumption of alcoholic beverages.

c. *Severity Level III* violations involve, for example:

1. A licensed operator, or a senior operator actively performing the functions covered by that position, is determined to be any of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the licensee, **or**
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j), or
 - (c) in noncompliance with a condition stated on the individual's license;

2. A licensed operator, or a senior operator actively performing the functions covered by that position, is inattentive to duty;

3. A licensed operator or senior operator is involved in the use, sale, or possession of illegal drugs;
 4. 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 making an incorrect regulatory decision, such as the following:
 - (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.**
- d. *Severity Level IV* violations involve, for example:
1. **A non-willful compromise (see 10 CFR 55.49) of an application, test, or examination required by 10 CFR Part 55. For example,**
 - (a) **cases of inaccurate or incomplete information inadvertently provided to the NRC that do not contribute to the NRC making an incorrect regulatory decision as a result of the originally submitted information; or**
 - (b) **an individual operator who did not meet the American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," Section 5, "Health Requirements and Disqualifying Conditions," as certified on NRC Form 396, "Certification of Medical Examination by Facility Licensee," required by 10 CFR 55.23, Certification, but who did not perform the functions of a licensed operator or senior operator while having a disqualifying medical condition; or**
 - (c) **an individual operator who did not meet ANSI/ANS 3.4, Section 5, as certified on NRC Form 396, "Certification of Medical Examination by Facility Licensee," required by 10 CFR 55.23, due to an incomplete medical examination, but was subsequently found to meet the health requirements for licensing; or**

- (d) **an individual operator who met ANSI/ANS 3.4, Section 5, as certified on NRC Form 396, required by 10 CFR 55.23, but 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.**

11. 6.5 Facility Construction (10 CFR Part 50 and 52 Licensees and Fuel Cycle Facilities)

Purpose of change:

To add an example of a SL III and of a SL IV violation of 10 CFR Part 21. Only the two new examples are shown here. The remainder of Section 6.5 is unchanged.

Proposed changes:

Severity Level III

6.5.c.4—An inadequate review or failure to review such that, if an appropriate review had been made as required, a 10 CFR Part 21 report would have been required.

Severity Level IV

6.6.d.5—A licensee fails to implement adequate 10 CFR Part 21 processes or procedures that have more than minor safety or security significance.

12. 6.6 Emergency Preparedness

Purpose of change:

To revise the severity level examples for emergency preparedness in Section 6.6. These proposed changes are related to changes being made to the “Emergency Preparedness Significance Determination Process” (NRC Inspection Manual Chapter 0609, Appendix B; see ADAMS Accession No. ML112220481) used for assigning significance levels to findings under the Reactor Oversight Process (ROP). These changes are being proposed to maintain consistency between enforcement outcomes for violations treated under traditional enforcement and those treated under the ROP.

Affected severity level examples include proposed new Examples 6.6.b.3, 6.6.c.3, 6.6.c.4, 6.6.d.2, 6.6.d.3, and 6.6.d.4; renumbering current Examples 6.6.c.3 to 6.6.c.5; and modifying current Examples 6.6.b.2 and 6.6.c.2. In addition, the NRC is proposing to modify Examples 6.6.a.1(a), 6.6.b.1(a), and 6.6.c.1(a) to clarify the NRC intent that the licensee both classify and declare the emergency event. A new footnote and modifications to the current Footnote 10 are proposed.

Proposed change:

6.6 Emergency Preparedness

These examples are appropriate for violations at operating power reactor facilities for those violations that are dispositioned under traditional enforcement rather than under the ROP. For operating power reactors, the NRC treats participant performance deficiencies identified in emergency exercises under the ROP. This section also provides examples of violations in the area of emergency preparedness at nonpower reactor facilities.

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

1. During an actual General Emergency, a licensee fails to promptly do any of the following:
 - (a) correctly classify **and declare** the event, **or**
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, "**Immediate Notification Requirements for Operating Nuclear Power Reactors,**" or 10 CFR Part 50, Appendix E, "**Emergency Planning and Preparedness for Production and Utilization Facilities**") to responsible Federal, State, and local agencies, **or**
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

b. *Severity Level II* violations involve, for example:

1. During an actual Site Area Emergency, a licensee fails to promptly do any of the following:
 - (a) correctly classify **and declare** the event, **or**
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, or 10 CFR Part 50, Appendix E) to responsible Federal, State, and local agencies, **or**
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); **or**
2. A licensee loses its ability to meet or implement any regulatory requirement related to assessment (**other than emergency classification**) or notification such that the required function would not be implemented during the response to an actual emergency; **or**
3. **An emergency action level (EAL) initiating condition (IC) has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event.**

c. *Severity Level III* violations involve, for example:

1. During an actual Alert emergency, a licensee fails to promptly do any of the following:
 - (a) correctly classify **and declare** the event,
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, or 10 CFR **Part 50**, Appendix E) to responsible Federal, State, and local agencies, or
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or
 2. A licensee's ability to meet or implement any regulatory requirement related to assessment (**other than emergency classification**) or notification is degraded such that the effectiveness of the emergency plan decreases. Although the regulatory requirement could be implemented during the response to an actual emergency, the implementation would be degraded (e.g., not fully effective, inappropriately delayed); or
 3. **An EAL IC has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event, but because of redundant EALs, an appropriate declaration could be made but not within the 15-minute requirement; or**
 4. **An EAL IC has been rendered ineffective such that any Site Area Emergency would not be declared for a particular off-normal event; or**
 5. A licensee's ability to meet or implement any regulatory requirement *not* related to assessment or notification is lost such that the required function would not be implemented during the response to an actual emergency.
- d. *Severity Level IV* violations involve, for example:
1. **The licensee's** ability to meet or implement any regulatory requirement *not* related to assessment or notification **is** such that the effectiveness of the emergency plan decreases. Although the regulatory requirement could be implemented during the response to an actual emergency, the implementation would be degraded (e.g., not fully effective, inappropriately delayed); or
 2. **An EAL IC has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event, but because of redundant EALs, an appropriate declaration could be made in an accurate and timely manner; or**
 3. **An EAL IC has been rendered ineffective such that any Site Area Emergency would not be declared for a particular off-normal event, but because of redundant EALs, an appropriate declaration could be made but not within the 15-minute requirement; or**

4. An EAL IC has been rendered ineffective such that any Alert Emergency or Notice of Unusual Event would not be declared for a particular off-normal event.

Footnote 10: As used in this example, “assessment” includes assessment of the impact of a release of radioactivity, and the making of protective action recommendations; “notification” includes only initial notifications to offsite response organizations. For power reactors, this includes the risk-significant planning standards in 10 CFR 50.47(b)(5), (b)(9), and (b)(10). **See Inspection Manual Chapter 0609, Appendix B, Section 5.0, for examples of conditions that may cause a required function not to be implemented or to be implemented in a degraded manner.**

Add a new footnote, applicable to Example 6.6.b.3: **An IC/EAL may be rendered ineffective by changes to facility procedures, systems, or equipment; errors in numeric thresholds; or any other cause that could result in an IC that should be declared not being declared in a timely and accurate manner following the change.**

13. 6.9 Inaccurate and Incomplete Information or Failure To Make a Required Report

(Note: Changes affecting four violation examples are proposed for Section 6.9. Only the four proposed changes are shown here. The remainder of Section 6.9 is unchanged.)

Purpose of change (1):

To add a new SL III example to provide additional guidance for violations of 10 CFR Part 21.

Proposed change (1):

6.9.c.5—A withholding of information or a failure to make a required interim report by 10 CFR 21.21, “Notification of Failure To Comply or Existence of a Defect and Its Evaluation,” occurs with careless disregard.

Purpose of change (2):

To revise SL IV Example 6.9.d.7 to address a failure to make a medical report. The current SL III example (i.e., 6.9.c.2.(e)) in the Policy regarding the failure to make an immediate or 24-hour report (which also addresses the next-calendar-day notification required for medical events) is based largely on the nominal response time necessary for an apparent significant medical event.

When assessing the significance of a violation involving the failure to report a medical event, the NRC considers whether the violation likely impacted the ability of the NRC to perform its regulatory function. If the failure to report actually impeded the NRC’s regulatory response (e.g., prevented a reactive inspection within the timeframe specified in NRC Management Directive 8.10, “NRC Medical Event Assessment Program,” or caused significant effort to be expended to meet the specified timeframe), then the

violation would typically be cited at SL III. Conversely, if a report was late and did not affect the NRC's ability to conduct a reactive inspection or require significant effort to be expended to meet the specified timeframe, then a SL IV violation may be warranted. This philosophy could be viewed as slightly different from the corresponding reactor reporting philosophy; specifically, the reactor philosophy is more directly risk informed, and the response norms of the two programs differ in that reactors have near continuous inspection coverage while materials licensees (including medical) frequently have multiyear inspection frequencies.

Although the licensee notification to the NRC allowing an NRC response in a timely manner may be more significant in the materials program because of the nature of the inspection programs, medical event reports that are late by a short period of time (e.g., by a few hours, or in some circumstances, a day or two), typically would not significantly impact the NRC's ability to respond, and therefore the staff believes they warrant an SL IV designation. This proposed change also improves the consistency with Section 2.2.1.c (i.e., whether the violation impacted the ability of the NRC to perform its regulatory oversight function) regarding reducing the severity level of an untimely report depending on the circumstances. Therefore, the staff is proposing to revise violation Example 6.9.d.7.

Proposed change (2):

6.9.d.7—A materials licensee fails to provide or make a 15-day or 30-day written report or notification; fails to include all information required by regulation or license condition in a 15-day or 30-day report or notification; or is late making a report to the NRC required by 10 CFR 35.3045, “Report and Notification of a Medical Event,” or 10 CFR 35.3047, “Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child,” that does not impact the regulatory response by the NRC.

Purpose of change (3):

To add a new SL IV example to provide additional guidance for violations of 10 CFR Part 21.

Proposed change (3):

6.9.d.12—A licensee fails to make an interim report required by 10 CFR 21.21.

Purpose of change (4):

To add a new SL IV example to address an Agreement State licensee's failure to submit NRC Form 241, “Report of Proposed Activities in Non-Agreement States.” The Enforcement Policy currently addresses the failure of Agreement State licensees to file for reciprocity in Section 6.9, “Inaccurate and Incomplete Information or Failure to Make a Required Report.” Specifically, paragraph 6.9.c.2(d), a SL III example, states, “failure to submit an initial NRC Form 241, ‘Report of Proposed Activities in Non-Agreement States,’ as required by 10 CFR 150.20, ‘Recognition of Agreement State licenses.’” The SL III significance is based largely on the need to allow the NRC an opportunity to inspect while licensed activities are being performed within the NRC's jurisdiction. A

SL III violation example is the only example currently provided in the Policy.

When assessing the significance of a violation involving the failure to file for reciprocity, the NRC considers whether the violation likely impacted the ability of the NRC to perform its regulatory function. If the failure to file Form 241 impeded the NRC's regulatory response (e.g., prevented an inspection that likely would have otherwise occurred), then the violation should typically be cited at SL III. Conversely, if the failure to file a Form 241 did not affect the NRC's ability to conduct an inspection, typically because the agency would not have inspected the activity anyhow, then an SL IV violation may be warranted.

Circumstances where the failure to file a Form 241 typically would not significantly impact the NRC's ability to inspect include failure to file an amended Form 241 if the NRC had previously inspected during the year and did not identify any performance issues or in cases of very limited scope or duration and of limited radiological significance, such as a single occurrence of work with a portable radiological gauge within NRC jurisdiction. Therefore, the staff believes that certain failures to file a Form 241 warrant an SL IV designation and is proposing the addition of a new SL IV example.

Proposed change (4):

6.9.d.13—A materials licensee fails to provide the NRC with a Form 241, where:

- (a) the licensed activity is not of a type designated as NRC Priority 1, 2, or 3 inspection (as identified in Enclosure 1 of NRC Manual Chapter 2800); and**
- (b) the licensee has not previously violated the requirement; and**
- (c) the facts of the specific case would not have otherwise resulted in the NRC conducting an onsite inspection; and**
- (d) the circumstances of the case generally include either the failure to file an amended Form 241 for additional work locations of limited scope, or the failure to provide an initial Form 241 for work of very limited scope and single occurrence of a few days within NRC jurisdiction (e.g., portable radiological gauge use).**

14. 7.0 Glossary

(Note: Four changes are proposed for Section 7.0. Only the proposed changes are shown here. The remainder of Section 7.0 is unchanged.)

Purpose of change (1):

To revise the definition of “Actual Consequences” to clarify that the effects of actual consequences related to onsite or offsite radiation exposures are those exposures exceeding 10 CFR 20.1201, “Occupational Dose Limits for Adults,” or 10 CFR 20.1301, “Dose Limits for Individual Members of the Public.”

Proposed change (1):

Actual Consequences include such effects as actual onsite or offsite radiation exposures **exceeding 10 CFR 20.1201, “Occupational Dose Limits for Adults,” or 10 CFR 20.1301, “Dose Limits for Individual Members of the Public,”** accidental criticality, core damage, loss of significant safety barriers, and loss of control of radioactive material.

Purpose of change (2):

To revise the definition of “Apparent Violation” to clarify that an apparent violation is an issue for which a final enforcement determination has not been made (i.e., an apparent violation does not necessarily result in an escalated enforcement action as the current Policy definition states).

Proposed change (2):

Apparent Violation is an issue that does not appear to meet NRC regulatory requirements and for which no final enforcement determination has been made.

Purpose of change (3):

To revise the definition of “Traditional Enforcement” to clarify that, although traditional enforcement is typically used under the circumstances listed in the current definition, use of traditional enforcement may not be limited to just those circumstances. To clarify that “actual consequences” means “actual safety and security consequences.” To provide a simple and more accurate description of issues with no ROP “performance deficiency.”

Proposed change (3):

Traditional Enforcement, as used in this Policy, refers to the process for the disposition of violations of NRC **requirements, including those that cannot be addressed only through the Operating Reactor Assessment Program. Traditional enforcement violations are assigned severity levels and typically include, but may not be limited to, those violations** involving (1) actual **safety and security** consequences, (2) willfulness, (3) impeding the regulatory process, (4) discrimination, (5) **issues for which no ROP performance deficiency can be identified**, (6) materials regulations, and (7) deliberate violations committed by individuals.

Purpose of change (4):

To rename the definition “Substantial Potential for Exposures or Releases in Excess of the Applicable Limits in 10 CFR Part 20” as “**Substantial Potential for Overexposure**” to more accurately reflect the requirements of 10 CFR Part 20. To insert the words “radiation” and “dose” for consistency with 10 CFR Part 20.

Proposed change (4):

Substantial Potential for Overexposure describes a situation where it was fortuitous that the resulting **radiation** exposure did not exceed the **dose** limits of 10 CFR Part 20. The concern is not the significance of the resulting or potential exposure, but whether the licensee provided adequate controls over the situation, as required, to prevent exceedance of the 10 CFR Part 20 limits.

15. 8.0 Table of Base Civil Penalties, Table A, Category c:

Purpose of change:

To revise the title of Category c, Table A, “Table of Base Civil Penalties.” The proposed title revision to Category c replaces the wording “Fuel fabricators authorized to possess Category III quantities of SNM...” with the wording “All other fuel fabricators...” to ensure that the table addresses fuel facilities under construction. The remainder of the title of Category c is unchanged.

Proposed change:

All other fuel fabricators, industrial processors, independent spent fuel and monitored retrievable storage installations, mills, and gas centrifuge and laser uranium enrichment facilities.