



Ellen C. Ginsberg  
VICE PRESIDENT, GENERAL COUNSEL & SECRETARY

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Ms. Cindy Bladey, Chief  
Rules, Announcements & Directives Branch (RADB)  
Office of Administration, Mail Stop TWB-05-B01M  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

12/6/2011

76FR 76192

(1)

Re: Nuclear Energy Institute Comments on Proposed Revisions to the NRC Enforcement Policy (Docket ID NRC-2011-0273)

Dear Ms. Bladey:

The Nuclear Energy Institute (NEI)<sup>1</sup> is pleased to provide the following comments in response to the U.S. Nuclear Regulatory Commission's (NRC) notice at 76 Fed. Reg. 76,192 (Dec. 6, 2011). The NRC is soliciting comments on (1) the overall effectiveness of the agency's September 2010 major revision to the Enforcement Policy, and (2) additional proposed revisions to the September 2010 version of the Policy, as set forth in the "Proposed Revisions to NRC Enforcement Policy" (ADAMS Accession #ML11259A100) ("NRC Draft"). NEI's comments are set forth in the attachment to this letter.

The proposed changes in Part 1 of the NRC Draft are intended to respond to SRM-SECY-0190. NEI's comments on these topics focus on areas where we believe Commission direction is not yet fully reflected in the Policy. See the discussion of proposed changes to Policy section 2.3.4 (relating to appropriate civil penalties for uranium conversion facilities), and clarifications needed in the Policy's discussion of predecisional enforcement conferences, in section 2.4.1.

In a number of instances, NEI's comments on Policy changes described in Part 2 of the NRC Draft support the proposed revisions with minor edits for clarity (e.g., proposed modifications to Policy Section 2.2.1 (factors affecting the assessment of violations) and Section 2.3.12 (reporting of defects and non-compliances)). Additionally, we concur with the modifications to Section 2.2.4 (exceptions to using only the operating reactor assessment program), Section 2.3.2.b (applicability of non-cited violations to non-licensees), and the re-insertion of background language in Section 2.3.11 (incomplete and inaccurate information). We disagree with some aspects of new language to be added to Section 2.3.4 (civil penalty) and suggest alternative language. NRC also proposes revisions to Section 4.0 (enforcement actions involving individuals) and our comments include several suggestions for clarification.

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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Call - D. Starkey (drs)

His Excellency Jean-David Levitte

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We also have carefully reviewed the NRC's proposed changes and additions to various enforcement violation examples relating to materials operations, licensed reactor operators, facility construction, emergency preparedness, and Part 21. In most cases we agree that the new examples should provide useful guidance. In some cases, however, we suggest that the existing violation examples be retained rather than deleted. Finally, we point out instances where the new violation examples appear inappropriately severe and/or inconsistent with current agency practice, and suggest that the Staff re-consider the proposed changes or assign them a lower severity level.

Please feel free to contact me or Anne Cottingham if you have questions relating to these comments.

Sincerely,

A handwritten signature in black ink that reads "Ellen C. Ginsberg". The signature is written in a cursive style with a large, prominent initial "E".

Ellen C. Ginsberg

Attachment

cc: Mr. Roy Zimmerman, NRC Office of Enforcement  
Mr. Stephen Burns, NRC General Counsel  
Mr. Doug Starkey, NRC Office of Enforcement



NUCLEAR ENERGY INSTITUTE

## **NUCLEAR ENERGY INSTITUTE COMMENTS ON PROPOSED ENFORCEMENT POLICY REVISIONS, NRC DOCKET ID NRC-2011-0273**

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The Nuclear Energy Institute (NEI)<sup>1</sup> is pleased to provide the following comments in response to the U.S. Nuclear Regulatory Commission's (NRC) notice at 76 Fed. Reg. 76,192 (Dec. 6, 2011). The NRC is soliciting comments on (1) the overall effectiveness of the agency's September 2010 major revision to the Enforcement Policy, and (2) additional proposed revisions to the September 2010 version of the Policy, as set forth in the "Proposed Revisions to NRC Enforcement Policy" (ADAMS Accession # ML11259A100) ("NRC Draft").

In addition to these proposed Enforcement Policy revisions, NRC has solicited public comment on other proposed Policy changes earlier this year. See 76 Fed. Reg. 48,919 (Aug. 9, 2011) and 76 Fed. Reg. 54,986 (Sept. 6, 2011). Given this piecemeal approach, we note that it may be difficult for industry stakeholders to assess the full effect of all proposed Enforcement Policy changes until they are presented in their entirety. NEI therefore intends to review the complete set of proposed Policy revisions once they become publicly available, and we may provide additional comments based on that holistic review.

Given the importance of the collective revisions to the Enforcement Policy, we urge the NRC to publish any corresponding changes to the Enforcement Manual concurrently with the promulgation of the final Policy revisions, or as soon as possible thereafter. Making those updates available to stakeholders simultaneously would improve transparency, and avoid potential confusion for both NRC Staff and NRC licensees as they implement these new and amended provisions.

### **COMMENTS ON SPECIFIC PROPOSED CHANGES**

#### ***Part 1 – Proposed Changes Based on Direction to the Staff in SRM-SECY-09-0190***

##### **1. Policy Section 2.3.4 (Civil Penalty)**

These Section 1 proposed changes are discussed at pp. 1-2 of the NRC Draft.<sup>2</sup> Notably, this section does not propose any changes to the language of Enforcement Policy Section 2.3.4. Rather, the discussion in this section is intended to respond to the Staff Requirements

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<sup>1</sup> The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

<sup>2</sup> References to "sections" 1-15 herein refer to designated portions of the NRC Draft, which contains a part 1 (with sections 1 and 2) and a part 2 (with sections 1-15).

Memorandum (SRM) for SECY-09-0190, *Major Revision to NRC Enforcement Policy* (Aug. 27, 2010). In that SRM, the Commission directed the NRC Staff to "evaluate whether the civil penalties for uranium conversion facilities could be tied to the inventory of process chemicals and other materials maintained by the facility." The SRM also directed the Staff to provide "an analysis of the civil penalties for conversion facilities" and "options for the Commission's consideration." (SRM, sec. 1.(e), p. 2.)

In our view, the discussion in this section of the NRC Draft does not fully address the Commission's request. Specifically, this discussion should include a more detailed and compelling explanation of why the NRC Staff is not proposing a threshold quantity of hydrogen fluoride (HF) above which the base civil penalty (CP) would be \$70,000. Although the NRC Staff only recently changed the base civil penalty for conversion facilities from \$14,000 to \$70,000 (a significant increase),<sup>3</sup> the Commission has nevertheless requested that the NRC Staff present a range of options for conversion facility civil penalties. As written, this section of the NRC Draft focuses only on the option NRC Staff has already selected.

Another viable option, we believe, would be to change the base civil penalty for conversion facilities to \$35,000 (in between the former \$14,000 base CP and the current \$70,000 base CP). We request that the Staff consider such an approach. In increasing the base CP for conversion facilities to \$70,000, the NRC Staff concluded that the radiological and chemical hazards at uranium conversion facilities are similar to those of gaseous diffusion plants (GDPs). The NRC Staff did not directly compare the radiological and chemical hazards to, for example, gas centrifuge enrichment facilities. However, the Staff also noted that the criticality risk present at a GDP and Category III fuel fabricators is not a major risk factor at a uranium conversion facility. NRC also found that the security and safeguards measures necessary at a uranium conversion facility are similar to or less than those of Category III fuel fabricators and GDPs. (See NRC Enforcement Policy Revision, 75 Fed. Reg. 60,485, 60,486 (Sept. 30, 2008).)

Nevertheless, the NRC Staff set the base civil penalty for violations at uranium conversion facilities at \$70,000, which is the same amount established for fuel fabricators authorized to possess Category I or II quantities of special nuclear material. Setting the base civil penalty at \$35,000 (the same as the base civil penalty for gas centrifuge enrichment facilities, uranium mills, and Category III fuel fabricators) would arguably strike a better balance among the criticality, radiological, and chemical hazards at the range of NRC facilities. Such a balancing would appear to be more consistent with the approach set forth in Policy Section 2.3.4.<sup>4</sup>

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<sup>3</sup> See July 12, 2011, NRC Enforcement Policy, Sec. 8.0 (Table of Base Civil Penalties), p. 70.

<sup>4</sup> Section 2.3.4 of the current Enforcement Policy provides (p. 14) that NRC's policy of imposing graduated civil penalties generally takes into account the gravity of the violation as the primary consideration. Thus, operations involving greater nuclear material inventories, significantly higher consequences resulting from a release/exposure to radioactive material, and consequences to the public and workers receive higher civil penalties.

## **2. Policy Section 2.4.1 (Predecisional Enforcement Conference)**

These Section 2 proposed changes are discussed at pp. 2-3 of the NRC Draft. The NRC Staff is proposing to replace in its entirety the current discussion of predecisional enforcement conferences ("PEC") in Policy Section 2.4.1. According to the NRC, the proposed change will provide clear and consistent guidance regarding when PEC will be conducted, in response to the SRM for SECY-09-0190, sec 1.(b), pp. 1-2, as well as clarify that "the NRC will, to the extent feasible, consider responses to apparent violations before taking final escalated enforcement action."

We believe that the second paragraph of the proposed revision to Section 2.4.1. is confusing and does not satisfactorily reflect Commission direction in the SRM. In particular, the Commission asked the Staff to develop "clear and consistent guidance *that allows licensees and individuals to respond to apparent violations before final escalated enforcement action is taken.*" Further, the Commission stated that appropriate changes to the Policy "should be made consistent with this principle." The SRM emphasized the need for consistent criteria for determining whether PECs will be offered, and criticized Policy text stating that a PEC will normally not be held if NRC concludes it has sufficient information to make an informed enforcement decision. (SRM, p. 1.)

As drafted, the second paragraph of the proposed revised Section 2.4.1 states that, where an escalated enforcement action appears to be warranted, the NRC will offer an opportunity to attend a PEC and/or provide a written response. This is appropriate — the choice should be the licensee's (unless, as the paragraph continues, the NRC specifically requests a PEC). However, the paragraph then states that the NRC can issue an enforcement action, without a civil penalty, without first obtaining the licensee's response. The need for this statement is not clear. Even if no civil penalty is assessed, an escalated enforcement action can be detrimental to the interests of an NRC licensee (e.g., increased inspection or increased future enforcement severity, negative public perception). No escalated action should be taken prior to the licensee's opportunity to be heard on the issues. Additionally, the proposal states that the NRC in this situation will notify the licensee that a PEC is not planned, and the licensee can then respond and request a PEC or "choose to respond in writing" before the NRC takes action. How is this different from simply issuing the choice letter described in the first sentence of the paragraph? The paragraph could be edited by deleting all but the first, second, and last sentences.

### Current Policy language:

#### 2.4.1 Predecisional Enforcement Conference

A predecisional enforcement conference (PEC) is the conference held for violations assessed using traditional enforcement. The purpose of the PEC is to obtain information from the licensee, contractor, or other persons 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 the NRC concludes that it has sufficient information to make an informed enforcement decision involving a licensee, contractor, or vendor, a PEC will not normally be held. If a PEC is not held, the licensee may be given an opportunity to respond to a documented apparent violation (including its root causes and a description of planned or implemented corrective actions) before the NRC takes enforcement action. However, if the NRC has sufficient information to conclude that a civil penalty is not warranted, it may issue an enforcement action without first obtaining the licensee's response to the documented apparent violation. A PEC is typically the final step in the NRC's fact-finding process before the Agency decides whether to take an enforcement action.

The NRC will normally provide an opportunity for an individual to address apparent violations before the Agency takes escalated enforcement action. Whether an individual will be given an opportunity for a PEC or an opportunity to address an apparent violation in writing will depend on the circumstances of the case, including the severity of the issue, the significance of the action the NRC is contemplating.

NRC Proposed Revised Policy language:

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.

NEI Markup of NRC Proposed Revised Policy language:

*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. The NRC will consider the licensee's response before taking escalated enforcement action.~~*

**Part 2 – Other Policy Changes Proposed by the Staff for Inclusion in the Next Policy Revision**

**1. Policy Section 2.2.1 (Factors Affecting Assessment of Violations)**

These Section 1 proposed changes are discussed at pp. 4-5 of the NRC Draft. The purpose of the proposed change is to clarify the discussion in Policy Section 2.2.1 regarding factors affecting assessment of violations. The remainder of Section 2.2.1 is unchanged.

In proposed 2.2.1.c, second sentence, NRC proposes to add the word "required" (twice). It is not clear what this is meant to accomplish. If the intent is to limit the example to changes

where prior NRC approval is required, the proposed text would not appear to achieve that objective. As drafted, the text refers to changes that a licensee would be required to implement. NRC should clarify this point to provide appropriate context and guidance for both the Staff and NRC licensees.

The proposed addition in the same paragraph of clarifying language for failures to comply with reporting requirements is a helpful and appropriate clarification.

NRC Proposed Revised Policy language (revisions to current Policy are underlined):

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. Policy Section 2.2.4 (Exceptions to Using Only the Operating Reactor Assessment Program)**

These Section 2 proposed changes are discussed at p. 5 of the NRC Draft. The proposed revisions to Policy Section 2.2.4 delete language that discusses the specific examples of the types of violations dispositioned using traditional enforcement. Instead, NRC proposes to 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. In our view, the proposed deletions are acceptable and reduce the potential for inconsistent interpretation of Sections 2.2.4 and 2.2.1.

Current Policy language:

2.2.4 Exceptions to Using Only the Operating Reactor Assessment Program

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

NRC Proposed Revised Policy language:

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. Policy Section 2.3.4 (Civil Penalty)**

These Section 3 proposed changes are discussed at pp. 5-6 of the NRC Draft. This proposed revision to Section 2.3.4 (as opposed to the earlier discussion of Policy Section 2.3.4 at pp. 1-2 of the NRC Draft) inserts new text into the discussion of civil penalties. NRC describes the purpose of the change as follows: "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."

Interestingly, the statement that "Civil penalties are normally assessed for Severity Level I and II violations and knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act." was included in the November 2008 Enforcement Policy but appears to have been omitted from Section 2.3.4 in the current (July 2011) version of the Policy. The NRC Draft does not explain this inconsistency or otherwise discuss the Staff's basis for concluding that Policy language so recently removed should now be re-inserted.

In any event, the first sentence of NRC's proposed revision to Section 2.3.4 states that civil penalties are "typically assessed" for Severity Level I and II violations and deliberate violations of reporting requirements of the Energy Reorganization Act. It is not clear that this characterization is appropriate, given the civil penalty process set forth in the Policy. Moreover, re-insertion of language stating that civil penalties are "normally assessed" for certain violations may effectively override new language intended to emphasize the need to evaluate the appropriateness of a civil penalty for any escalated enforcement action on a case-by-case basis. The proposed NRC language further states, appropriately, that the civil penalty assessment process should be followed. We therefore suggest that the first sentence be modified to state that civil penalties are *considered* for all Severity Level I and II violations, some SL III violations, and deliberate violations of the referenced reporting requirements.

#### NRC Proposed Revised Policy language:

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.

NEI Markup of NRC Proposed Revised Policy language:

*Civil penalties are considered for all Severity Level (SL) I and II violations, some SL III violations, and deliberate violations of the reporting requirements of Section 206 of the Energy Reorganization Act. 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. Policy Section 2.3.2.b (Non-Cited Violations, All Other Licensees)**

These Section 4 proposed changes are discussed at p. 6 of the NRC Draft. The proposed revision to Section 2.3.2.b changes the title of the section to include nonlicensees. The proposed revisions to the text are intended to clarify that noncited violations (NCVs) may also be issued to nonlicensees when they meet the NCV criteria in Section 2.3.2.b. NEI has no comment on this proposed change.

NRC Proposed Revised Policy language (changes to current Policy are underlined):

- 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. Policy Section 2.3.11 (Inaccurate and Incomplete Information)**

These Section 5 proposed changes are discussed at pp. 6-8 of the NRC Draft. This revision involves adopting "essentially verbatim" language from a prior version of the Enforcement Policy that was omitted from the current version of the Policy. No reason is given for the deletion of this section from the July 2011 Policy. In our view, re-inserting this guidance in the Enforcement Policy will be helpful to stakeholders. The guidance provides useful information to both the NRC Staff and NRC licensees regarding the factors considered by the agency in determining whether to take enforcement action. The guidance also provides useful context on how various circumstances will be taken into account on a case-by-case basis. NEI has no other comments.

### NRC Proposed Revised Policy language:

#### 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. Policy Section 2.3.12 (Reporting of Defects and Noncompliance)**

These Section 6 proposed changes are discussed at pp. 8-9 of the NRC Draft. This revision involves adopting "essentially verbatim" language from a prior version of the Enforcement Policy. In our view, re-inserting this guidance in the Enforcement Policy will be helpful to stakeholders as well as the NRC Staff. The proposed guidance provides useful information on how the NRC will treat violations in the context of NRC licensees and contractors. The guidance also clarifies the NRC's approach to issuing NOVs to individuals in contractor organizations.

While the proposed guidance is acceptable, it could be enhanced. Specifically, we note that the revision, as drafted, provides little guidance on the important issue of when an NOV should be

issued to an NRC *licensee* for a violation by a *contractor*. Licensees are always responsible for the actions of their contractors, and the language states that "NOVs and civil penalties will be issued, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements." This language does not otherwise explain the qualifier "as appropriate." The Policy should recognize explicitly that a licensee who assures that a contractor has established a program that meets applicable requirements, exercises appropriate oversight of the contractor's program implementation, and did not otherwise miss opportunities to prevent a violation by a contractor, will not be issued NOVs and civil penalties where enforcement action can and will be taken directly against the contractor or the contractor's employees. We request that the Staff incorporate this concept into this Enforcement Policy revision. (See NEI's suggested changes below.)

NRC Proposed Revised Policy language:

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.

NEI Markup of NRC Proposed Revised Policy language:

*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. However, in cases where enforcement action can be taken directly against the contractor or the contractor's employees, the NRC will not typically issue NOVs or assess civil penalties if a licensee has taken steps to assure that a contractor has established a program that meets applicable requirements, exercises appropriate oversight of the contractor's program implementation, and did not otherwise miss opportunities to prevent a violation by a contractor.*

*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. Policy Section 4.0 (Enforcement Actions Involving Individuals)**

These Section 7 proposed changes are discussed at pp. 9-10 of the NRC Draft. This proposal will insert language to address the concept that the NRC may inform licensees of information it has developed regarding an individual's trustworthiness and reliability that may impact a licensee's access authorization. NEI believes that this is an appropriate topic to be addressed. We have two comments on the proposed revision as drafted.

First, we believe the insertion of the new language into the existing paragraph as proposed is confusing. As an alternative, we suggest inserting the language on this topic as a stand-alone

paragraph, following the paragraph that the NRC proposes to amend. (See NEI proposed markup, below.)

Second, with respect to the substance of the insert, NEI concurs that it is appropriate for the NRC to inform an NRC licensee of potentially disqualifying information regarding an individual's trustworthiness and reliability. NRC licensees bear a heavy responsibility to assure the integrity of individuals with unescorted access authorization and should not remain uninformed of potential disqualifying information. In this regard, we believe an additional point should be emphasized in the language incorporated into the Policy. This can be accomplished by including in the Policy the last sentence in the NRC's "purpose of the change" statement: "It is the licensee's responsibility to evaluate the information provided in accordance with its access authorization program to determine the appropriate actions regarding individual access authorizations." Further, we request that the revised Policy recognize that, if the NRC provides potentially disqualifying information as contemplated, there will be a strong perception among licensees that the NRC believes that the information *is* disqualifying. This should not be the case, however. To counter that inaccurate perception among NRC licensees, the Policy should reflect that the licensee may reasonably reach a conclusion that the information is *not* disqualifying (*e.g.*, based on additional facts, based on a different assessment of the facts, or based upon the final resolution of the enforcement process).

NRC Proposed Revised Policy language:

The NRC considers enforcement actions against individuals to be significant actions that will be closely evaluated and judiciously applied. Typically, the ~~NRC Agency~~ will take an enforcement action involving an individual, either licensed or nonlicensed, only when the violation has actual or potential safety or security significance. 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~~ OE Web site. Generally, before taking enforcement action against an individual, the NRC will seek to gather information to determine whether an Order or other enforcement action should be issued. The ~~agency~~ Agency may gather such information by conducting a PEC, by requesting a written response from the individual, or by issuing a Demand for Information ~~DFI~~. 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.



NEI Markup of NRC Proposed Revised Policy language:

*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. 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.*

*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. If the NRC makes such a notification, it nevertheless remains the licensee's responsibility to evaluate the information provided in accordance with its access authorization program to determine the appropriate actions regarding individual access authorizations. A licensee may reasonably reach a conclusion 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 upon the final resolution of the enforcement process).*

**8. Policy Section 6.0 (Violation Examples)**

These Section 8 proposed changes are discussed at p. 10 of the NRC Draft. NRC proposes to delete four severity level (SL) IV violation examples in the current Policy that include "catchall" language, e.g., "does not amount to a SL I, II, or III violation" or "does not result in a SL I, II, or III violation."<sup>5</sup> The Staff's stated rationale for these changes is that the "examples do not provide useful, specific guidance regarding the condition that would result in a SL IV violation. 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."

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<sup>5</sup> Similar language (i.e., a violation does "not amount to a Severity Level I, II, or III violation") can be found in violation example 6.14.d.2. The NRC Staff is not proposing to delete this example, and we agree that it should be retained.

These examples were only recently added to the Policy. Rather than deleting the examples in their entirety, we suggest that the Staff revise some of the examples to eliminate the reference to SL I, II, or III violations. For example, we suggest that the Severity Level IV example in existing Policy Section 6.4.d.2 be revised as follows, rather than deleted:

*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, but was not actively performing the functions covered by that position that does not result in a Severity Level I, II, or III violation.*

While the other SL IV violation examples identified in the proposed revisions are not as specific as the one above, we do not agree that none of these examples is useful. The examples all refer to specific SL IV violations or non-compliances. The utility of retaining these examples is in making clear that, unless the violations warrant a higher severity level based on specific risk or significance factors referenced in the SL I, II, or III examples, the violation or non-compliance should be treated as a severity level IV.

For example, Enforcement Policy Section 6.8.d.4 currently references non-compliances that involve shipping papers, marking, labeling, placarding, packaging, or loading. By referencing back to SL III violations (see Policy Sec. 6.8.c.3), the examples serve to clarify that SL IV violations would not be appropriate for those non-compliances that could reasonably result in a significant failure to identify the type, quantity, or form of materials; a failure of the carrier or recipient to exercise adequate controls; or a substantial potential for either personnel exposure or contamination above regulatory limits of improper transfer of material.

Therefore, we recommend that the following Severity Level IV violation examples be retained in the Policy:

*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. Policy Section 6.3 (Materials Operations)**

These Section 9 proposed changes are discussed at p. 11 of the NRC Draft. NRC proposes to add a new example of a SL IV violation to address "less significant cases" 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. NEI supports including the new example. However, we believe that the language could be modified for clarity, as suggested below.

NRC Proposed Revised Policy Language:

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.

NEI Markup of NRC Proposed Revised Policy language:

*6.3.d.9—Failure to seek NRC approval, when required, 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. Policy Section 6.4 (Licensed Reactor Operators)**

These Section 10 proposed changes are discussed at pp. 11-14 of the NRC Draft. The revisions to Section 6.4 add one new example each for Severity Level I, II and III violations. According to the NRC, the three new examples are based on the Staff's enforcement experience with violations regarding fitness-for-duty issues involving licensed reactor operators. Additionally, NRC proposes to rewrite, for clarification, the SL IV examples relating to non-willful compromise of an application, test, or examination required by NRC regulations in 10 CFR Part 55. (The NRC proposal to delete SL IV Example 6.4.d.2 was addressed in Item 8, discussed above.)

In our view, the proposed additional examples and clarifications for SL I, II, and III violations are generally appropriate. However, NEI believes that the proposed new fatigue-related SL I example (in example a.1) is inappropriately severe. The new example of an operator who is determined, after an event, to have been unfit for duty due to fatigue is equated to events involving operators unfit for duty due to drugs or alcohol, or under the influence of prescription or over-the-counter drugs. However, unfitness for duty due to drugs or alcohol can be determined based on objective test results, and is subject to validation through confirmatory processes. In contrast, a post-event fatigue assessment is a much more subjective assessment that would be difficult to validate. Moreover, the operator involved may have felt fit and, as a result, did not self-declare fatigue – a situation subjectively less egregious than an operator unfit for duty due to drug or alcohol use. For these reasons, NEI proposes that the proposed new example be included in the SL II example b.1 rather than SL I example a.1.

The additional example of a Severity Level IV violation for non-willful compromises (see 10 CFR 55.49) of an application, test, or examination required by 10 CFR Part 55 also is useful and appropriate.

NRC Proposed Revised Policy language (revised text is underlined):

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 non-willful 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.

NEI Markup of NRC Proposed Revised Policy language:

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;*

*(d) unfit for duty as determined by a post event fatigue assessment required by 10 CFR 26.211(a)(3).*

#### **11. Policy Section 6.5 (Facility Construction: 10 CFR Part 50 and 52 Licensees and Fuel Cycle Facilities)**

These Section 11 proposed changes are discussed at p. 14 of the NRC Draft. The revisions to Policy Section 6.5 add two new examples of a SL III and a SL IV violation related to 10 CFR Part 21. The proposed new examples appear helpful and appropriate.

##### NRC Proposed Additional Examples:

###### *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. Policy Section 6.6 (Emergency Preparedness)**

These Section 12 proposed changes are discussed at pp. 14-17 of the NRC Draft. The proposed revisions to Section 6.6 revise the severity level examples for emergency preparedness (EP). According to the NRC, the proposed changes relate to modifications to the "Emergency Preparedness Significance Determination Process" used for assigning significance levels to findings under the Reactor Oversight Process ("ROP"), and are intended to maintain consistency

between enforcement outcomes for violations treated under traditional enforcement and those treated under the ROP.

With respect to proposed new violation 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, the gradations of enforcement actions reflected here do capture the relative significance among event classifications. Significantly, however, some of these examples appear inappropriately severe and, in some cases, inconsistent with current NRC practice. No justification is provided for imposing these more stringent enforcement outcomes. A better approach, in our view, would be to reduce the severity levels for proposed violation examples 6.6.b.3 and 6.6.c.3 by one level. This would better maintain consistency with the existing examples in Policy sections 6.6.c.5 and 6.6.d.1. In parallel, the Staff should eliminate proposed violation examples 6.6.d.2 and 6.6.d.4.

The logic of the new examples also is broadly consistent with the approach under the ROP as described in NRC Inspection Manual Chapter 0609, Appendix B (ADAMS Accession No. ML112220481). The proposed modifications to violation examples in Policy Sections 6.6.a.1(a), 6.6.b.1(a), and 6.6.c.1(a) are generally helpful in clarifying the NRC intent that the licensee both classify and declare the emergency event. The additional text in footnote 10 and the new footnote are also useful.

NRC Proposed Revised Policy language:

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 non-power 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.

NEI Markup of NRC Proposed Revised Policy Language:

#### 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 non-power reactor facilities.*

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

*\* \* \**

*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~~

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.

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~~

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 but not within the 15-minute requirement; 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.~~

\* \* \*

**13. Policy Section 6.9 (Inaccurate and Incomplete Information or Failure to Make a Required Report)**

These Section 13 proposed changes are discussed at pp. 14-17 of the NRC Draft. The NRC proposes several revisions to Policy Section 6.9. The first revision would add a new SL III example to provide additional enforcement guidance relating to violations of 10 CFR Part 21:

Proposed New Policy Section 6 Example:

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.

In our view, the proposed change is helpful and appropriate.

The second proposed change would revise SL IV Example 6.9.d.7 to address a failure to make a medical report. According to the NRC, if the failure to report actually impeded the NRC's regulatory response, then the violation would typically be cited at SL III. If, however, 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 would be warranted. Also according to the NRC, 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 should be SL IV violations. The proposed change provides a useful clarification and therefore is appropriate.

Current violation example Section 6.9.d.7:

6.9.d.7—A materials licensee fails to provide or make a report or notification, other than an immediate or 24-hour report or notification, to the NRC, including 15- or 30-day written reports, or fails to include all information required by regulation or license condition in a 15-day or 30-day report;

NRC Proposed Revised Example Section 6.9.d.7:

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.

The third proposed change to Section 6.9 would add a new SL IV example to provide additional guidance for violations of 10 CFR Part 21.

NRC Proposed Additional Example 6.9.d.12:

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

The last proposed change to Section 6.9 would 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 as a SL III violation example. The SL III violation example is the only example currently provided in the Policy. In adding the new example, the NRC reasons that, 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. If, however, 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. The clarification and additional example appear appropriate.

NRC Proposed Additional Example:

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. Policy Section 7.0 (Glossary)**

The Section 14 proposed changes are discussed at pp. 20-21 of the NRC Draft. The NRC is proposing four changes to the definitions in Policy Section 7.0. First, NRC plans 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." NEI agrees with the proposed clarification.

NRC Proposed Revised Policy language (revised text is underlined):

**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.

The NRC is also proposing 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). NEI agrees with the proposed clarification.

Current definition:

**Apparent Violation** is a violation of regulatory requirements that is being considered for escalated enforcement action.

NRC Proposed Revised definition:

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

Additionally, NRC proposes 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. The NRC states that the change also clarifies that "actual consequences" means "actual safety and security consequences." The proposed revision is also intended to provide a simple and more accurate description of issues with no ROP "performance deficiency." The proposed changes generally provide useful clarifications and are appropriate.

NRC Proposed Revised definition:

**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, noncolor (non-SDP) inspection findings (i.e., a violation of NRC requirements for which there is not an associated SDP performance deficiency), (6) materials regulations, and (7) deliberate violations committed by individuals.

The fourth proposed change to the Glossary section renames the definition "Substantial Potential for Exposures or Releases in Excess of the Applicable Limits in 10 CFR Part 20" as "Substantial Potential for Overexposure." According to the NRC, this will more accurately reflect the requirements of 10 CFR Part 20. The NRC also proposes to insert the words "radiation" and "dose" into the definition for consistency with 10 CFR Part 20. NEI has no comments on the proposed change.

NRC Proposed Revised definition:

**Substantial Potential for Overexposure** ~~Substantial Potential for Exposures or Releases in Excess of the Applicable Limits in 10 CFR Part 20~~ 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. Policy Section 8.0 (Table of Base Civil Penalties, Table A, Category c):**

See discussion of Section 15, NRC Draft p. 21. According to the NRC, the proposed change to the Table of Base Civil Penalties is intended to clarify the applicability of the table to fuel facilities under construction. However, the revision does not appear to fully accomplish the Staff's stated objective because there is no specific reference to construction. While we have no objection to the proposed change, it would be beneficial to specifically reference facilities under construction to better meet the stated NRC objective.

NRC Proposed Revised Policy language:

~~Fuel fabricators authorized to possess Category III quantities of SNM~~All other fuel fabricators, industrial processors, independent spent fuel and monitored retrievable storage installations, mills, and gas centrifuge and laser uranium enrichment facilities.

NEI Markup of NRC Proposed Revision:

~~Fuel fabricators authorized to possess Category III quantities of SNM~~All other fuel fabricators, including facilities under construction, industrial processors, independent spent fuel and monitored retrievable storage installations, mills, and gas centrifuge and laser uranium enrichment facilities.

# PUBLIC SUBMISSION

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## General Comment

Nuclear Energy Institute Comments on Proposed Revisions to the NRC Enforcement Policy (Docket ID NRC-2011-0273)

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## Attachments

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