



NUCLEAR ENERGY INSTITUTE

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USNRC

Re: Nuclear Energy Institute Comments on NRC Enforcement Policy Revision

Dear Mr. Lesar:

Please find enclosed comments of the Nuclear Energy Institute (NEI) on the NRC Enforcement Policy Revision announced at 73 Fed. Reg. 53,286 (Sept. 15, 2008). We will also file the comments by first-class mail.

Should you require more information or have questions regarding this matter, please contact me directly at 202-739-8140.

Sincerely,

Ellen C. Ginsberg
Ellen C. Ginsberg

ECG/mab
Enclosure

*SUNSI Review Complete
Template = ADM-013*

*E-R-FDS = ADM-03
Add = D. Starkey
(dps)*



ENERGY INSTITUTE COMMENTS ON PROPOSED REVISIONS TO NRC ENFORCEMENT POLICY

I. OVERVIEW

The Nuclear Energy Institute (NEI)¹ appreciates the opportunity to comment on the proposed revisions to the NRC Enforcement Policy ("Policy") announced at 73 Fed. Reg. 53,286 (Sept. 15, 2008). Since 1980, this statement of policy has supported the Commission's radiological safety and security mission by emphasizing the importance of compliance with NRC regulatory requirements and encouraging prompt, comprehensive identification and correction of violations. The purpose of this revision is to clarify the use of terms and update the Policy by removing outdated information and adding relevant new information, to better reflect "changing requirements and additional experience." It is not a major substantive revision.

As the Staff observes, NRC enforcement actions deliver "regulatory messages." To the extent the proposed Policy changes will better ensure that these regulatory messages are comprehensible, fair, consistent, and transparent to stakeholders, we support those changes. We also concur that the Policy should continue to reflect the Commission's focus on safety and appropriately address the subject areas that NRC regulates. It also should provide a framework that supports consistent rather than rigid implementation, and recognizes that the appropriateness of any enforcement action depends upon the specific underlying facts. See 73 Fed. Reg. 53,287. Further, any revisions to the current Policy should reflect the Commission's risk-informed and performance-based regulatory approach to the protection of public health and safety and the environment.

Relationship between the Enforcement Policy and the Enforcement Manual

A key purpose of the Policy revisions is to streamline the Policy to remove extraneous information: "The intent is that this revised Policy more closely reflects the Commission's statement of policy and that it not be a guidance document or procedure which discusses every specific implementation aspect of enforcement." 73 Fed. Reg. 53,287. To that end, "some of the information in the current policy, which more closely resembles procedural guidance than Commission policy, has been either reworded, deleted, or moved to a guidance document, *e.g.*, the NRC Enforcement Manual."

In general, NEI agrees that a statement of Commission policy need not and should not contain excessively detailed implementing guidance. Such a level of detail is more appropriate for NRC regulatory guidance (in this case, the NRC Enforcement Manual), provided that the guidance document is clear, comprehensive, and readily available to all stakeholders. While the question of how much detail a policy statement should include is a subjective one, we believe that, at some point, the usefulness of the Enforcement Policy could be undermined if too much information is removed.

¹ 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, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

Based on conversations with NRC enforcement staff, we understand that virtually all of the material removed from the revised Policy is already covered in the NRC Enforcement Manual ("Manual").² This suggests that little of the existing Policy will be lost, with the possible exception of text that duplicates material in the Manual. The presumption that all important sections of the Policy are retained in the Enforcement Manual is important, since the value of this revision would be significantly undercut by the total elimination of material, including explanatory text and examples, interpretations, implementing details and other "lore," on which NRC licensees and other stakeholders have historically relied to understand and participate in the enforcement process.

In connection with NRC's proposal to move various implementation details from the Enforcement Policy to the Enforcement Manual, there is some industry concern that the Manual is not a document typically made available for public comment. We also note that there does not appear to be any index or table of contents for the Manual in its entirety, which makes it less user-friendly to stakeholders. We urge the Staff to make conforming changes to the Manual through a public comment process and include an index or table of contents to make the document more accessible. This effort should be given a high priority since the Manual will become an even more important guidance document with the revision of the Policy.

Nor is there information to suggest that the NRC Staff plans to modify the Manual in the near future to conform to a revised Policy. Even a cursory review of the Manual shows that such an update is needed. Absent such coordination, such as contemporaneous Staff guidance cross-referencing deleted Policy material with Enforcement Manual sections, it is difficult for any stakeholder, including the industry, to predict how the Staff will implement a revised enforcement policy. Ideally, an updated version of the Manual would have been issued at the same time NRC issued the revised Policy for comments.

In the absence of conforming changes to the Enforcement Manual, there is not only a lack of transparency for licensees on how the policy will be implemented but also an increased risk that NRC Offices and Regions will not apply the new Enforcement Policy correctly, consistently and uniformly. This is particularly important given the breadth of NRC-licensed activities and high percentage of new and relatively new employees. To address this concern, NEI suggests that the revised Policy include a section briefly describing the purpose, scope, contents, etc. of the Enforcement Manual, and instructions on how to access it.³

Because the revised Policy is a completely new document, NEI's review has focused on the extent to which the revision (when compared to the current Policy) is clear and cogent, sufficiently but not overly detailed, and whether it accurately reflects the Commission's position. The industry also seeks to ensure that the revised Policy will re-confirm the objectives of the

² In preparing these comments, NEI has relied on the Staff's representations and has not compared the approximately 390-page Manual with the text of the current and revised Policy statements.

³ NRC Office of Inspector General Audit Report OIG-08-017 (Sept. 26, 2008) expressed a concern regarding a lack of consistent application of the Policy and made recommendations to the NRC Executive Director for Operations in this regard.

traditional enforcement process and the Reactor Oversight Process (ROP), by emphasizing an objective, realistic, and risk-informed enforcement program that disfavors subjective, qualitative or overly conservative risk assumptions. Overall, the revised Policy appears to meet this goal.

Limit Traditional Enforcement to Findings Not Suitable for Treatment under the SDP

The development of the ROP, with its more structured performance assessment process, provided an opportunity to integrate assessment and enforcement. While this approach has generally resulted in a more predictable, explicable process focused on risk and performance, we urge the NRC to keep the goals of the integrated enforcement process in mind when finalizing the Policy revisions. The Policy should maintain a unified approach for determining and responding to performance issues. That approach should: (1) maintain a focus on safety and compliance; (2) yield consistent and predictable results; (3) be more effective and efficient; (4) be easily understood by the public and licensees; and (5) decrease regulatory burden.⁴

As part of this integrated approach, NRC should continue to reserve traditional enforcement for findings that are not amenable to treatment under the Significance Determination Process (SDP); e.g., violations involving willfulness (including discrimination), actions that impact the regulatory oversight process such as failure to provide complete and accurate information, and situations involving actual safety consequences. The revised Policy meets this objective. All other performance deficiencies would continue to be addressed by the SDP under the ROP. This framework should result in enforcement that complements risk-informed assessments, maintains consistency, and promotes a predictable, unified regulatory message.

On a related point, NEI understands that the NRC is currently considering the extent to which traditional enforcement should be used in the ROP assessment process. (Currently, only Severity Level III or higher violations are considered.) At the June 17, 2008, monthly public meeting on the Reactor Oversight Process, industry was informed that an NRC working group was tasked with identifying and evaluating changes to existing guidance that would allow for more consistent use, incorporation, and/or consideration of traditional enforcement outcomes in the ROP assessment process.

On behalf of the nuclear industry, we are concerned that the NRC is apparently considering such a major change to the ROP without seeking stakeholder involvement. Traditional enforcement was purposefully excluded from the ROP assessment process unless the safety significance of the violation could be determined. The ROP was designed to use objective performance indicators and risk insights to determine the appropriate level of safety and inspection resources to deploy above the baseline. Although not addressed in the current revised Policy (to our knowledge), the potential inclusion of traditional enforcement in ROP plant assessments is an extremely important "enforcement policy" issue that needs to be addressed directly and not through an internal working group without public participation.

⁴ See NRC Inspection Manual Chapter 0308, Attach. 5, "Technical Basis for Enforcement" (2005), at 3.

II. SPECIFIC COMMENTS

Proposed Revisions to the Table of Base Civil Penalties

The Table of Base Civil Penalties in the revised Policy (p. 42) reflects several significant changes from the table in the current Policy (p. 21), as follows:

- Entry a. (\$130,000 base penalty) would apply to violations relating to the Yucca Mountain Repository as well as to power reactors and gaseous diffusion plants.
- Entry b. (\$65,000 base penalty) is unchanged.
- Entry c. (\$32,500 base penalty) is revised to include violations by fuel fabricators authorized to possess Category III quantities of SNM, industrial processors, ISFSIs and monitored retrievable storage installations, mills and uranium conversion facilities, and gas centrifuge uranium enrichment facilities.⁵ (Table Entry d. (\$13,000 base penalty) is correspondingly revised to delete the latter two categories.)
- Entry e. (\$6,500 base penalty) is unchanged.
- Entry f. is revised to address violations involving loss, abandonment, or improper transfer or disposal of *regulated material*, rather than *sealed sources or devices*.

Addition of Base Civil Penalty for U.S. Department of Energy Violations relating to the Yucca Mountain High Level Waste Repository

NRC proposes to modify Entry a. of Table A to include violations against DOE as the license applicant for the Yucca Mountain High Level Waste Repository. See 73 Fed. Reg. 53,287-89; revised Policy, p. 42. The base civil penalty for a violation relating to the repository would be \$130,000. NEI agrees with NRC's decision to provide for the application of appropriate enforcement tools with respect to the Yucca Mountain project in a manner consistent with the application of civil penalties to power reactors and gaseous diffusion plants.⁶

The safety of the federal high level waste repository is of significant importance to the nuclear industry. It is appropriate that the Yucca Mountain project meet the same high standard of accountability for compliance with NRC regulations as other NRC licensees. We also agree with the Commission's statement that during the repository construction application period, few if any violations would escalate to Severity Level I or II due to the lack of direct consequences to

⁵ Under the existing Policy, mills and uranium conversion facilities are currently listed under Table entry d. Gas centrifuge uranium enrichment facilities are not specifically mentioned.

⁶ On a related point, the Federal Register notice incorrectly states (73 Fed. Reg. 53,288, middle column, 1st full paragraph) that the high level waste inventory at Yucca Mountain is "at least 70 million metric tons." This should be corrected to read "at least 70,000 metric tons."

public health and safety. 73 Fed. Reg. 53,288. We encourage NRC to include in the Enforcement Manual language specific to the Yucca Mountain project, consistent with these statements, to ensure clarity in the implementation of this approach.

Addition of Civil Penalties for Violations relating to Gas Centrifuge Uranium Enrichment Facilities

The revised Policy would establish a new base civil penalty for enforcement actions at gas centrifuge uranium enrichment facilities, currently not included in Table A. NRC observes that appropriate guidance for this type of facility is now timely because NRC is currently considering license applications for two such enrichment facilities. 73 Fed. Reg. 53,288-89. NRC further explains that in developing its recommended base penalty, it compared the radiological, chemical and security hazards associated with gas centrifuge uranium enrichment facilities with those of the gaseous diffusion plants (GDPs) and Category III fuel fabricators.

NRC found that the radiological and chemical hazards at gas centrifuge uranium enrichment facilities "are substantially less than these hazards at GDPs based on the significantly lower quantities of liquid and gaseous uranium hexafluoride (UF₆) in the process systems and the significantly lower potential for releases of large quantities of UF₆." *Id.* at 53,288. With regard to security hazards, the NRC determined that the security measures needed to operate gas centrifuge uranium enrichment facilities are more similar to GDPs than to Category III fuel fabricators. It further concluded that the overall radiological, chemical and security implications for gas centrifuge uranium enrichment facilities "are more comparable to that of Category III fuel fabricators" than for GDPs. Accordingly, the revised Policy would establish the base civil penalty for enforcement activities involving gas centrifuge uranium enrichment facilities at \$32,500, placing these facilities in Entry c. of Table A, along with Category III fuel fabricators.

Increase in Base Civil Penalty for Violations at Uranium Conversion Facilities

The revised Policy would raise the base civil penalty for enforcement activities associated with uranium conversion facilities from \$13,000 to \$32,500 (moving these facilities from Entry d to Entry c of Table A). Currently, the only operating conversion plant in the United States is the Honeywell facility in Metropolis, Illinois. NRC states that a criticality accident is not possible at a conversion facility and that the radioactive risk is small. 73 Fed. Reg. 53,289-90. The greatest radiation exposure rates arise from processes that concentrate the radioactive decay daughter products in waste streams, and the health risk stems from the toxic nature of uranium, which is similar to other heavy metals. The NRC concludes that the chemical, radiological and security hazards associated with uranium conversion facilities "are much more significant" than those associated with test reactors, waste disposal licensees, industrial radiographers and other large material users – with which conversion facilities are classified under the current Policy – but "just somewhat less than that of gaseous diffusion plants." *Id.* at 53,290. Accordingly, NRC concludes that, given their nuclear material inventories and potential consequences to the public, violations related to uranium conversion facilities warrant a higher base civil penalty. The NRC discussion does not indicate what (if any) events led it to change its position on this matter, or otherwise justify the increase.

Section 1.0 Introduction

Although the organization and level of detail in this material differs from that in the current Policy, the only new substantive content in this section is the insertion of the concept of security in Section 1.1. ("Compliance with NRC requirements, including regulations, technical specifications, license conditions, and orders, provides confidence to the NRC and the public that safety *and security* are being maintained.")⁷ Similar conforming changes appear in other sections.

Section 2.0 NRC Enforcement Process

The introductory text (pp. 6-7) states that: "Throughout the process, an organization or individual subject to an NRC enforcement action has multiple opportunities to provide input." This may be something of an over-statement. A review of the revised Policy suggests that the licensee has the opportunity to provide input during the on-site inspection exit meeting; upon review of the Notice of Violations; and during the enforcement conference if NRC decides to conduct one (see p. 15, "Pre-decisional Enforcement Conference" and "Regulatory Conference").

The revised Policy is silent on the process NRC follows to disposition the information gathered during and considered after the enforcement conference but before the final enforcement action is taken. If the enforcement process is applied and a final enforcement decision issued without further opportunity for input, there is a lack of transparency both on the disposition of such information and NRC's process for issuing the final decision. We suggest NRC consider including a "comment/resolution" portion of the final enforcement package to indicate how licensee input was considered in taking the enforcement action. NRC uses a similar approach when addressing comments from an Agreement State whose program has been reviewed by NRC under the Integrated Materials Performance Evaluation Program, as described in NRC Management Directive 5.6. Specifically, the final NRC report to the Agreement State includes a "comment/resolution" portion to provide much needed transparency.

Section 2.2 - Assessment of Violations

The revised Policy states (p. 7) that plants under construction are not subject to the Significance Determination Process (SDP) and that traditional enforcement will be used, including the issuance of civil penalties.

Section 2.2.1 - Factors Affecting Assessment of Violations

The revised Policy expands the factors used in determining the appropriate enforcement response to violations to include the concept of "security;" for example, whether the violation "resulted in actual safety *or security* consequences" or "has potential safety *or security*

⁷ In most cases NEI has not provided specific comments on those sections of the revised Policy that are identical to, or substantially the same as, the current Policy.

consequences." Of particular interest, under the revised Policy (p. 7), consideration of whether a violation resulted in actual safety or security consequences would address whether "the security system did not function as required and, as a result of the failure, there was a significant event." This concept (a "significant event" in the context of security) is subjective and vague. No interpretation of the term is provided in the Glossary, and NRC has not, to our knowledge, provided any regulatory justification for the revision.⁸

In this regard, section 6.11.a.3. of the revised Policy includes as a severity level I violation example: "Radiological sabotage in which the security system did not function as required and, as a result of the failure, there was a significant event, such as a Safety Limit being exceeded; a system designed to prevent or mitigate a serious safety or security event was not able to perform its intended function when actually called, an accidental criticality occurred or core damage." We suggest that this fuller explanation, which incorporates the concept of radiological sabotage, be added to Section 2.2.1.

The introductory text reiterates the important concept that NRC will use risk information "whenever possible" in assessing the safety significance of violations and in assigning severity levels. (Compare current Policy, p. 9.) Perhaps in an effort to shorten the Policy, discussions of the use of risk information in other contexts have been omitted. We would propose reinserting such references, which need not be lengthy, in the final revisions to the Policy.⁹

Several statements in Section 2.2 seem to reflect a throwback to the concept of "regulatory significance." A sentence in Section 2.2.1 states: "Noncompliances may be significant because they may challenge the regulatory envelop [*sic*] upon which certain activities were licensed." It is not clear what is intended by this statement. Perhaps more importantly, Section 2.2.2.a. contains a definition of an SL I violation that includes "violations associated with a significant regulatory concern." This language comes close to re-introducing "regulatory significance" to the Policy, which is not appropriate.

The discussion in the revised Policy (pp. 7-8) of whether a violation affects NRC's ability to perform its oversight function omits the reference in the current Policy to the tenet that a

⁸ On a similar point, we suggest that NRC consider revising the language of Section 2.2.1.b (p.7) to state as follows: "Whether the violation has potential safety or security consequences. In evaluating potential consequences, the NRC considers whether the violation created a credible accident or exposure scenario that could potentially have significant actual consequences *for security, duration and exploitability.*"

⁹ For example, the discussion of the loss of NRC-regulated material (pp. 12-13) states that NRC will "treat separately" any violation involving a licensee's loss of control of any regulated material, for any period of time, regardless of the use, license, type, quantity or type of radioactive material. Such an approach is not risk-informed from a public or worker health and safety or environmental perspective, given the very broad spectrum of NRC licensees. The same concern applies to the discussion of imports and exports of NRC-regulated material on page 13. NRC's enforcement approach to such matters should be commensurate with the risk-- as the licensee's response would be when discovering a loss of control of regulated material.

licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of that condition or event. We suggest that this point be retained. Similarly, NRC should consider retaining in the revised Policy some of the current Policy's discussion (p. 10) concerning whether a violation involved willfulness. This topic also should be addressed fully in the Enforcement Manual.

Section 2.2.2 – Severity Levels

The changes in the revised Policy relating to severity levels of violations are discussed at pp. 17-29 of these comments, below.

Section 2.2.3 – Significance Determination Process

The discussion of the Significance Determination Process (SDP) on p. 9 of the revised Policy incorporates the concept of security significance (along with safety significance) into the definition of red, yellow, white and green findings. Related discussion in the current Policy (pp. 10-11) appears to have been deleted.

Section 2.2.3.1 – Exceptions to the Use of the SDP

This section of the revised Policy (pp. 9-10) roughly corresponds to the discussion in the current Policy at pp. 8-11, although a direct comparison of the factors is difficult. Under the revised Policy, the following types of violations will not be evaluated through the SDP and are instead subject to traditional enforcement, including civil penalties:

- a. Violations that resulted in or could have resulted in substantial actual safety consequences, including, but not limited to:
 1. Violations resulting in radiation exposures to the public or plant personnel above regulatory limits;
 2. Violations involving failures to make required notifications that impact the ability of Federal, State, or local agencies to respond to actual emergencies;
 3. Violations resulting in transportation events; and
 4. Violations resulting in substantial releases of radioactive material.
- b. Violations that impact the ability of the NRC to perform its regulatory oversight function; and
- c. Violations involving willfulness.

Notably, example a. appears to reflect a substantial broadening of this criterion to include not only violations that resulted in substantial actual safety consequences but also violations that *could have resulted* in substantial actual safety consequences (but did not). Allowing the Significance Determination Process to be avoided in cases with only potential consequences is inconsistent with the purpose of the SDP. In our view, this expansive new language should be narrowed in the final revised Policy.

Section 2.3 – Disposition of Violations

While there are brief discussions of "Minor Violations" in the revised Policy (pp. 9-10), the revised severity level examples (pp. 26-36) do not include any examples of minor violations. NEI believes it is essential that meaningful specific examples of minor violations be added to Section 6.0 of the revised Policy to assist those subject to it, as well as NRC personnel. For example, the current Part 70 Industry-NRC collaborative Working Group on enforcement matters identified the following specific risk-informed "minor violation" example, which NEI urges NRC to include for clarity and transparency.

Under Section 6.2, add a new item e:

Under 10 CFR Part 70, Subpart H, a failure of a safety control, whether credited as an IROFS or not, that does not result in a failure to meet the performance requirements of 10 CFR 70.61.

A failure of safety systems or controls that does not result in an adverse material impact on safety.

In Section 2.3.a. (p. 10), the criteria for dispositioning a violation as a Non-Cited Violation (NCV) have been re-phrased. While most of the criteria appear substantively the same as those in the current Policy, the discussion of situations in which a willful violation may be treated as an NCV has been deleted. See current Policy, pp. 17-18. The reason for this omission is not clear.

In Section 2.3.b., the description of a Notice of Violation (NOV) omits the point in the existing Policy that an NOV is a written notice setting forth one or more violations *of a legally binding requirement*. We suggest that this important point be re-inserted into the text of the Policy.

In Section 2.3.c., the discussion of factors considered in assessing a civil penalty includes as factor 1: "Whether the licensee has had any previous escalated enforcement action *for a non-willful violation* (regardless of the activity area) during the past two years or past two inspections, whichever is longer." By contrast, the wording of this factor in the current Policy (p. 22) is as follows: "Whether the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past two years or past two inspections, whichever is longer." The remaining factors are unchanged. In our view, the new language is somewhat confusing as to NRC's intent regarding treatment of previous willful violations in the context of assessing civil penalties. The final revised Policy should be clarified on this point.

In general, the discussion of the civil penalty assessment process at pp. 10-12 eliminates considerable detail in the current Policy (see pp. 19-29). In our view, at least some of this information, e.g., details relating to the flow chart, base civil penalties, the escalated enforcement process, and the Commission's enforcement philosophy regarding the use of graduated sanctions, is sufficiently important and nuanced to warrant inclusion in the Policy.

For example, we believe the revised Policy should provide a fuller description of the role of licensee self-identification of potential violations, and effective, comprehensive corrective action to prevent a recurrence. This concept appears to have largely been edited out of the discussion of

the NRC process for identification and assessment of violations in Sections 2.1 and 2.2. (Compare current Policy, pp. 23-27.) Industry believes that the revised Policy should more explicitly reward licensees that are proactive and effective in self-identifying compliance matters. Such an approach may result in a higher percentage of licensee compliance and fewer NRC enforcement actions.

On another point, we suggest that the revised Policy include a reference to NRC coordination with Agreement States, either individually or collectively, to address enforcement issues of mutual concern. The Enforcement Manual should provide additional detail.¹⁰ Consistent with NEI's March 26, 2007, comments on upcoming Enforcement Policy revisions, we urge NRC to consider establishing the expectation, as a matter of compatibility, that Agreement States implement an enforcement policy that is similar to and meets the intent of NRC's policy. In that regard, coordination with the Agreement States to meet this objective is imperative.

Section 2.3.5 – Commission Notification and Consultation

Section III of the current Policy (Responsibilities, pp. 6-8) explains which NRC departments and officials are responsible for overseeing and implementing the enforcement program, the circumstances in which the Staff may depart from the Policy, and when the Commission is to be notified in writing or consulted about certain enforcement actions or enforcement-related situations. Some of this text is retained in Section 2.3.5 of the revised Policy (pp. 14-15). Although the text omitted will presumably be included in the Manual, the Staff should consider re-inserting in the Policy at least some of this material concerning the agency's internal oversight process. This topic could be addressed at a level of detail that will neither unduly constrain the operation of the enforcement program nor require frequent Policy updates.

The remaining discussion in the revised Policy focuses on the circumstances that require notification of and consultation with the Commission. There appears to be some reduction in the required notifications.

Section 2.4 – Participation in the Enforcement Process

The discussion on pre-decisional enforcement conferences (PEC) and regulatory conferences on p. 15 of the revised Policy parallels the considerably longer discussion on pp. 13-16 of the current Policy. In this area, NRC should ensure that certain details omitted from the revised Policy are discussed in the Enforcement Manual, including:

- Factors NRC considers in deciding whether to give an individual an opportunity for a PEC or addressing an apparent violation in writing, and the types of information that may be

¹⁰ Agreement States regulate over 80% of NRC byproduct materials licensees. NRC and Agreement States could routinely share information regarding an enforcement action that either entity proposes to take against a company or individual that crosses jurisdictional lines (e.g., industrial radiographers) and that may be licensed by both entities. Also, other programmatic information, such as the use of effective enforcement tools that may result in increased regulatory compliance by some categories of licensees (e.g., press releases) should be shared.

presented.¹¹ (See revised Policy, p. 23, under the discussion of enforcement actions against individuals.)

- Circumstances that warrant a PEC being closed to the public. The revised Policy would narrow the circumstances in which PECs may be closed. (Alternatively, the revised Policy may reflect the Staff's decision to characterize more generally the circumstances that warrant a closed meeting, giving the Staff greater flexibility in such matters.) Knowing whether a PEC may be open to the public or not would likely be of interest to licensees and other entities potentially involved in such a conference.

Section 2.4.3 – Alternative Dispute Resolution

NRC proposes to delete the interim enforcement policy regarding the use of alternative dispute resolution (ADR) at pp. 72-80 of the current Policy and replace it with two paragraphs in the revised Policy (see pp. 15-16; see also 73 Fed. Reg. 53,291). In contrast to the treatment of other deleted material, there appears to be no discussion of ADR in the Enforcement Manual, no plan to incorporate such a discussion, and no reference to other NRC guidance documents that address the NRC's ADR program.

In our view, the omission of this substantive discussion is a mistake, particularly given the Office of Enforcement's conclusion that the pilot program on the use of ADR was successful and that the Staff "intends to continue using the ADR program for discrimination and other wrongdoing cases." At a minimum, the final revised Policy should include a specific cross-reference to the NRC guidance document(s) and/or website location where stakeholders can find specific information on NRC's ADR program.¹² To avoid confusion, the final revised Policy also should include a discussion of the use of so-called "early ADR."

In its March 2007 comments on the proposed Enforcement Policy revisions, NEI stated that formal incorporation of ADR into the Policy should bring increased visibility and acceptance of the ADR program, thereby advancing the agency's enforcement goals of encouraging prompt identification and corrective actions and deterring non-compliance. We noted that there may be some reluctance among NRC licensees to participate in the ADR process, perhaps in part because of the lack of clarity and certainty regarding the integration of ADR into the overall enforcement program. Accordingly, NEI proposed that the revised Policy should formalize the interactions between the U.S. Department of Labor (DOL) and the NRC, and the relationship between early ADR and NRC Office of Investigation (OI) investigations. Further, NEI noted, the

¹¹ Section 2.4 states that the "organization or individual subject to the enforcement action will typically be offered a conference with the NRC to present facts relevant to the assessment and disposition of the violation." It is not clear whether and, if so, how, NRC will inform licensees of its decision *not* to offer an enforcement conference. In such cases, NRC should inform the entity or individual and consider allowing an opportunity for additional informal licensee input.

¹² The revised Policy does reference the ADR program in NRC Management Directive 8.8., but that reference appears in Section 3.4, not in the discussion of ADR in Section 2.4.3.

Policy revisions should fully integrate the ADR policy in the area of whistleblowers and Severity Levels. The revised Policy does not address these recommendations.

On a related point, NEI commented that the revised Enforcement Policy should ensure that the Policy is properly calibrated to reward prompt and comprehensive licensee actions with finality, and should provide more effective incentives for licensees that engage in their own (non-NRC) efforts to settle discrimination claims to avoid litigation and/or investigations. We argued that these licensee efforts will serve the same policy as does ADR under the NRC program. While the Policy now addresses settlements in the area of discrimination cases, it should be conformed to the ADR approach whereby settlement eliminates the need to pursue the traditional investigation/enforcement paradigm. These concepts do not appear to have been adopted in the revised Policy.

The revised Policy retains the current Policy's approach concerning NRC's exercise of discretion not to take enforcement action when the licensee has addressed the overall work environment for raising safety concerns and has publicized that a complaint of discrimination for engaging in protected activity was made to the DOL. To be eligible for enforcement discretion, the licensee should also state that the matter was settled to the satisfaction of the employee, and that, if the DOL Area Office found discrimination, the licensee has taken action to positively re-emphasize that discrimination will not be tolerated. However, the list of "exceptions" to the use of discretion is littered with highly subjective terms (*e.g.*, blatant, programmatic, and egregious). As stated in our 2007 comments, we urge the NRC to revise the section on exercise of discretion in discrimination cases to provide a simpler, more predictable, and therefore more usable and effective template for settlement, consistent with the ADR policy.

Section 3.0 Use of Enforcement Discretion¹³

Section 3.6 – Use of Discretion in Determining the Amount of a Civil Penalty

The discussion of using enforcement discretion in determining the amount of a civil penalty (revised Policy, pp. 18-19) generally parallels the discussion at pp. 30-32 of the current Policy.

¹³ No comments are provided on Section 3.1 (*Violations Identified during Extended Shutdowns/Work Stoppages*). The discussion of enforcement discretion in this situation (revised Policy, pp. 16-17) parallels the text of Section VII.B.2. (p. 33) of the current Policy. No comments are provided on Section 3.2 (*Violations Involving Old Design Issues*). The discussion of enforcement discretion in this situation (revised Policy, p. 17) parallels the text of Section VII.B.3. of the current Policy (pp. 33-34), except for the omission of text relating to the treatment of cases of longstanding deviations from the Final Safety Analysis Report. No comments are provided on Section 3.3 (*Violations Identified due to Previous Enforcement Action*). The discussion of enforcement discretion in this situation (revised Policy, p. 17) parallels the text of Section VII.B.4. of the current Policy (pp. 34-35). No comments are provided on Section 3.4 (*Violations Involving Certain Discrimination Issues*). The discussion in the revised Policy (pp. 17-18) parallels that in the current Policy (p. 35). No comments are provided on Section 3.5 (*Violations Involving Special Circumstances*). The discussion in the revised Policy (p. 18) parallels that in the current Policy (p. 36). No comments are provided on Section 3.7 (*Exercise of Discretion to Issue Orders*). The discussion in the revised Policy (p. 19) parallels that in the current Policy (p. 32).

However, the list of relevant factors in the revised Policy omits several of the factors in the current Policy: see p. 31, #(d); p. 32## (g) and (h). NRC should ensure that the omitted text is available in the Enforcement Manual.

Section 3.8 – Notices of Enforcement Discretion (NOED) for Power Reactors and Gaseous Diffusion Plants

The discussion in the revised Policy (pp. 19-20) generally parallels that at pp. 36-39 of the current Policy, although many details have been omitted. Assuming the omitted text is available in the Enforcement Manual, this re-organization is unobjectionable. To the extent the seemingly broader language of the revised Policy is intended to provide (or may result in) less frequent grants of enforcement discretion to licensees under a narrower array of circumstances, we ask NRC to reconsider such proposed revisions, and we note that no basis or justification is provided for such changes.

Enforcement Discretion for Pandemic Situations

The second paragraph states that NRC may grant enforcement discretion in cases involving severe weather or other natural phenomena, and that NOED use is based on a balancing of the public health and safety or common defense and security of not operating against the potential radiological or other hazards associated with continued operation, and a determination that safety or security will not be impacted unacceptably by exercising this discretion. This discussion brings to mind the analogous question of NRC exercise of enforcement discretion during a pandemic, which is the subject of ongoing NRC and NEI discussions.

As set forth in NEI's March 2007 comments on the proposed revisions to the Enforcement Policy, the time is ripe for the NRC Enforcement Policy to address licensing and enforcement issues that may arise in connection with a pandemic.¹⁴ NRC's Pandemic Response Plan notes that some routine licensing, exercises and inspections may be deferred, delayed or cancelled depending on the availability of staff, but only if operational safety and security can be maintained. Similarly, licensee actions related to certain functions that are non-essential for safe plant operation, as well as safety functions that may be impacted by personnel shortages but that may be safely performed with existing personnel, warrant consideration for the application of enforcement discretion where those impacts would cause a violation of NRC requirements absent relief.

NEI continues to advocate the incorporation of enforcement discretion for pandemic situations into the Enforcement Policy. The Policy should recognize the potential for an influenza pandemic to reduce nuclear plant staffing below the levels necessary to maintain full compliance with all NRC regulatory requirements. It should establish discretionary criteria to

¹⁴ A pandemic is an outbreak of infectious disease, such as influenza, that spreads globally across large geographical regions and threatens potentially serious health, social, and economic impacts. An important goal of the U.S. pandemic response strategy is assuring the continued reliability of the electric grid. Continued safe operation of nuclear plants during a pandemic is an important consideration in the context of overall pandemic planning.

permit continued operation with reduced staffing levels, consistent with the protection of public health and safety, until pandemic conditions subside and staffing returns to normal levels. Regulatory relief to permit rescheduling of selected activities and deferral of some administrative and programmatic requirements, consistent with a pre-established policy, would create the flexibility to manage a range of pandemic-related situations while continuing to assure the safe operation of the plant. Other regulatory options (license amendments, exemptions, orders) could be used as needed to supplement enforcement discretion.

Section 3.9 – Enforcement Discretion for Certain Fire Protection Issues

This interim policy was moved in its entirety into the revised Policy. The following comments are based on both Section 3.9 of the revised Policy and the most recent change to the Interim Enforcement Policy Regarding Enforcement Discretion for Certain Fire Protection Issues (Interim Policy), issued September 10, 2008. See 73 Fed. Reg. 52,705. Importantly, previous versions of the Interim Policy indicated that NRC would entertain licensee requests on a case-by-case basis to extend the enforcement discretion provided in those documents, if adequate justification was provided.¹⁵

In a February 2, 2007, letter, NEI requested that NRC modify the Interim Policy to allow staggered submittal of license amendment requests (LAR), with the LARs coming in four groups over a period of 24 months after issuance of the Safety Evaluation Report (SER) for the first pilot plant. This staggered approach was proposed to address the limited resources available to develop key areas of the license amendment request. The NRC did not adopt that approach. Instead, in response to NEI's request, the NRC staff recommended an extension of the enforcement discretion window for a period ending six months after issuance of the SER approving the LAR for the second pilot plant. See COMSECY-08-0022 (July 16, 2008). The NRC staff recommended that this additional discretion be granted on a case-by-case basis to licensees that demonstrate substantial progress in transitioning to 10 CFR 50.48(c), and continue to maintain and enhance fire safety at their facilities. The Commission approved the NRC staff's proposed revision to the Interim Policy on August 19, 2008.

Notably, the revised Interim Policy published on September 10, 2008, does not state that the policy "may be extended on a case-by-case basis, by request, with adequate justification, from the licensee." Thus, the general statement on additional discretion present in earlier versions of the Interim Policy has been replaced with a statement that specifies both the duration of any additional discretion period (six months from the second pilot SER), and the showing that the licensee must make to obtain additional discretion. In essence, this change decreases the NRC staff's flexibility to grant case-by-case requests for additional enforcement discretion beyond the six month time period specified in the revision.

¹⁵ The June 14, 2004, Interim Policy stated: "This discretion policy may be extended upon a request from the licensee with adequate justification." 69 Fed. Reg. 33,685, col. I. Likewise, the April 18, 2006, Interim Policy stated: "This enforcement discretion policy may be extended on a case-by-case basis, by request, with adequate justification, from the licensee." 71 Fed. Reg. 19,906, col. III.

While the Interim Policy does not preclude a licensee from requesting additional discretion, it also does not explicitly provide NRC staff with the latitude to grant such additional discretion. As a result, Commission approval may be required. In addition, there is a substantial likelihood that some licensees will need to request additional discretion due, in part, to the fact that the revised enforcement discretion policy does not effectively resolve the industry's concern about limited technical resources. Specifically, the approach adopted in the Interim Policy will likely result in a large number of NFPA 805 LARs all being due at the same time – 6 months after the SER for the second pilot plant. Therefore, licensees will be competing for limited NRC technical resources during that same time period.

Further, with respect to the discussion on p. 21 of the revised Policy, NEI requests clarification of whether the NRC will exercise enforcement discretion with respect to existing identified non-compliances, and non-compliances identified during the 10 CFR 50.48(c) transition process, in the event that an LAR submitted pursuant to 10 CFR 50.48(c) is rejected (without an opportunity to resubmit) or denied by the NRC staff.

While the Interim Policy does not directly address this scenario, we are concerned that, going forward, the enforcement discretion period would end if an LAR is rejected (without an opportunity to resubmit), or is denied. See 73 Fed. Reg. 52,705 ("The discretion period would continue until the NRC dispositioned the LAR.") and 73 Fed. Reg. 52,706 ("The enforcement discretion will continue to be in place, without interruption, until NRC approval of the license amendment request to transition to 10 CFR 50.48(c)."). NEI believes that an approach similar to that explained in the Interim Policy for situations where a Letter of Intent is withdrawn by a licensee, would also be appropriate in the case of a rejection or denial of an LAR. 73 Fed. Reg. 52,706. In the event of a rejection or denial, NEI suggests that the NRC, as a matter of practice, refrain from taking enforcement action against (i) existing identified non-compliances, or (ii) non-compliances identified during the 10 CFR 50.48(c) transition processes that were either corrected during the transition process or where reasonable and timely corrective actions are in progress. In addition, if a licensee intends to resubmit the LAR after addressing the cause of the rejection, enforcement discretion should remain in force during that re-submittal of the revised LAR, as long as the re-submittal occurs within a timeframe acceptable to the NRC.

NEI and the nuclear industry remain committed to gaining insights through participation the ongoing NFPA-805 pilot process to ensure that high quality LARs are submitted in a stable and predictable regulatory environment. This effort should minimize the likelihood of rejection or denial of an LAR. However, it is important that licensees who decide to transition to the risk-informed approach to fire protection provided in Section 50.48(c) understand the potential consequences of a rejection or denial. Therefore, NEI requests clarification of this issue.

Section 4.0 Enforcement Actions against Individuals¹⁶

While the discussion of enforcement actions against individuals (revised Policy, pp. 23-25) generally parallels the discussion of this issue at pp. 39-42 of the current Policy, notable changes include the following.

NRC has modified the factors it will use in determining whether an enforcement action (EA) against an individual will be undertaken. The revised Policy provides (p. 23) that an EA will normally be undertaken only when NRC is satisfied that the individual (a) fully understood his or her responsibility; (b) knew the required actions were not taken; and (c) knowingly failed to take required actions that have actual or potential safety significance. By contrast, the standard in the current Policy is that NRC must be satisfied that the individual (a) fully understood *or should have understood* his or her responsibility; (b) knew *or should have known* the required actions; and (c) knowingly *or with careless disregard (i.e., with more than mere negligence)* failed to take required actions that have actual or potential safety significance.

Examples illustrating the NRC practice that enforcement action will not be taken against an individual if his or her improper action was caused by management failures (current Policy, pp. 39-40) have been eliminated, although the revision retains a general statement to this effect (p. 23). Examples of situations that could result in enforcement actions against individuals (current Policy, p. 40) have been eliminated in the revised Policy. On this point, the revised Policy states only that enforcement actions against unlicensed individuals will only be taken in cases involving "deliberate misconduct" – consistent with NRC's existing practice.

The existing list of factors NRC will consider in deciding whether to issue an EA to an unlicensed person as well as against an NRC licensee (current Policy, pp. 40-41) has been changed. New factors include: "the significance of the underlying technical issue (not considered in discrimination cases)." Factors eliminated include the identity of the entity that identified the misconduct, the individual's training and experience, and the employer's response (disciplinary action taken). The revised Policy also states (pp. 23-24) that in such situations, judgments will be made on a case-by-case basis.

Additional discussion (current Policy, pp. 41-42) regarding the types of orders that can be issued to NRC-licensed operators also has been eliminated.

Section 4.2 – 4.3 NOVs, Orders and Civil Penalties to Individuals

The discussion in sections 4.2.1 (*Licensed Individuals*), 4.2.2 (*Non-Licensed Individuals*) and 4.3 (*Civil Penalties to Individuals*) generally parallels the discussion of these topics found in various

¹⁶ We suggest that the revised Policy retain the statement that NRC may take enforcement action for reasons that would warrant refusal to issue an initial license, and, therefore, that "appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence, fitness-for-duty, or other matters that may not necessarily be a violation of specific Commission requirements." See current Policy, p. 42.

portions of the existing Policy. For clarity and to ensure that this useful detail is readily available to stakeholders, NRC should ensure that the substantive text deleted from the revised Policy is available in the Enforcement Manual.

Section 4.4 – Confirmatory Orders to Individuals

We suggest that this short section be moved and added to the discussion of Alternative Dispute Resolution in Sections 2.4.3 and 3.4.

Section 5.0 (Public Availability of Information re Enforcement Actions)

The discussion in the revised Policy (pp. 25-26) is essentially identical to that in the current Policy (Section XII, p. 45), except for updated citations and the new statement that some security-related information may not be made available to the public.

Supplements – Examples of Severity Levels (SL) of Violations

The revised Policy provides background information on this topic in Section 2.2.2 (Severity Levels). The description of severity levels (SLs) of violations in the revised Policy (pp. 8-9) is generally consistent with that in the current Policy (p. 12). Some details differ, however, making a direct comparison between the versions of the policy statement difficult. Additionally, the basis for the changes made is not readily apparent.

For example, while the current Policy describes SL I and II violations as matters of "very significant regulatory concern," the revised Policy eliminates this distinction. The examples accompanying the severity level definitions are different in that they incorporate the concept of security as well as safety violations. Furthermore, the revised definitions of severity levels I and II are identical in that they are both "violations that resulted in or could have resulted in serious safety or security consequences." The other portions of the severity level definitions, which are intended to convey distinguishing details, would arguably be more useful if some criteria were included to better differentiate a SL I from a SL II violation.

The discussion on p. 8 of the revised Policy correctly emphasizes that the NRC will use its judgment and discretion on a case-by-case basis in determining severity levels of violations and appropriate sanctions, and that comparisons of significance between activity areas are inappropriate. One important point that should be re-inserted in the revised Policy is the statement on p. 12 of the current Policy that each of the examples of severity levels "is predicated on a violation of a regulatory requirement."

The revised Policy makes clear that the violation examples in these sections are intentionally broad in scope and are "neither exhaustive nor controlling." The reader is directed to the Enforcement Manual for expanded examples. To the extent that industry disagrees with the proposed changes in this section (see comments below), our concerns stem from a lack of clarity as to whether the more broadly-worded examples given for some SL violations in the revised Policy could be used to justify the imposition of civil penalties in a broader array of situations. Although the NRC has broad discretion in the interpretation and implementation of

its enforcement process, we would urge the Staff to provide a clear, compelling justification to the public before issuing more stringent severity level criteria. To our knowledge, the current enforcement climate does not warrant such an expansion.

Supplement Section 6.1 – Reactor Operations

Section 6.1 of the revised Policy (p. 26) contains examples of violations relating to reactor operations at every severity level (compare current Policy, Supp. I, pp. 45-48). The SL I violation examples are essentially unchanged from the current Policy, except that a broader definition of "safety limit" is used. The SL II, SL III and SL IV violation examples are also the same as those in the current Policy, except that numerous examples of SL III and IV violations have been omitted (and will presumably be included in the Enforcement Manual). Examples in the current Policy relating to violations by licensed operators have been moved to Section 6.4.

Supplement Section 6.2 – Fuel Cycle Operations

Section 6.2 of the revised Policy (pp. 26-27) contains examples of violations relating to fuel cycle operations at every severity level (compare current Policy, Supp. VI, pp. 57-61). On behalf of the its fuel cycle members, NEI commends NRC's incorporation of input from the Industry-NRC working group on 10 CFR Part 70 enforcement matters into these SL examples. The revised examples are significantly more risk-informed and reflect the risk insights gained from the facility-specific, NRC-approved Integrated Safety Analysis. We encourage NRC to work with industry representatives from other categories of licensees to incorporate relevant risk insights into other Supplements. Industry is willing to assist in this effort.

Supplement Section 6.3 – Materials Operations

Section 6.3 of the revised Policy (p. 28) contains examples of violations relating to materials operations at every severity level (compare current Policy, Supp. VI, pp. 57-61). As a preliminary matter, note that in Sections 6.3, 6.7 (Health Physics) and 6.8 (Transportation), the phrases "risk-significant quantity of material" and "risk-significant quantity of material equivalent to Category 1" are used without definition. Nor are these terms included in the Glossary. The revised Policy should contain a definition of these important concepts, and/or cite the relevant pages of the Enforcement Manual where they are defined.

The SL I example differs significantly from that in the current Policy regarding the threshold level for radiation exposure and releases. In the current guidance, Severity Level I includes: "Radiation levels, contamination levels, or releases *that exceed 10 times the limits specified in the license.*" In the revised guidance, SL I includes: "radiation exposures or releases to the environment *in excess of five times the regulatory limits.*" The reduction from 10 times to 5 times appears to be arbitrary and lacks any clear regulatory justification. If this change is incorporated into the final revision, NEI requests that NRC explain and justify the much more stringent new enforcement standard, to provide clarity to stakeholders.

The SL II example also differs significantly from that in the current Policy in the threshold level for radiation exposure and releases. Currently, SL II violations include: "Radiation levels,

contamination levels, or releases that exceed 5 times the limits specified in the license." In the revised Policy, SL II violations include: "radiation exposures or releases to the environment in excess of the regulatory limits." The reduction from 5 times the limit to any exposures in excess of the limit appears to be arbitrary and lacks any clear regulatory justification. If this change is incorporated into the final revision, NEI requests that NRC explain and justify the much more stringent new enforcement standard, to provide clarity to stakeholders.

Additionally, the Severity Level II example in Section 6.3 appears to incorrectly reference transportation requirements.

Supplement Section 6.4 – Licensed Operators

Section 6.4 of the revised Policy (pp. 28-29) contains examples of violations relating to licensed operations at each severity level (compare current Policy, Supp. I, pp. 45-48, where the examples are addressed under Reactor Operations).¹⁷ The SL examples in this section have been completely re-worded to cover "very significant failures" or "significant failures" by licensed operators or senior licensed operators, in a broad array of circumstances. Existing specific examples have been omitted. In our view, the usefulness of these examples could be increased by restoring descriptions that more clearly link the RO/SRO actions to safety events and consequences.

To the extent that NRC plans to retain the current specific examples of licensed operator violations in the Enforcement Manual and continue to use them to inform decisions on severity levels, industry does not object strongly to these changes. However, to the extent that the new, broader language of the revised Policy can be read to give the NRC Staff more discretion to impose civil penalties under an expanded array of circumstances, we would object. Moreover, NRC does not provide any basis or justification for doing so.

Supplement Section 6.5 – Facility Construction (Parts 50 & 52 Licensees and Fuel Cycle Facilities)

The revised Policy (p. 29) contains examples of violations relating to facility construction, including Part 50 licensees, Part 52 licensees and fuel cycle facilities, at each severity level.¹⁸

Severity Level I:

The existing criterion is: "Violations involving structures or systems that are completed in such a manner that they would not have satisfied their intended safety related purpose."¹⁹

¹⁷ The introductory sentence in this section appears misplaced. It provides an expanded definition of "systems" but that term is not used in this section. We recommend this text be deleted or moved to the lead-in paragraph for Section 6.0.

¹⁸ Compare to Supplement II of the current Policy (p. 49), which provides examples of violations at each severity level for 10 CFR Part 50 construction activity violations.

The proposed revised criterion is: "A significant breakdown of a licensee QA program for construction resulting in multiple structures, systems or components not being able to satisfy their intended safety purpose."

The proposed revision to the SL I violation example is an improvement in that it establishes a more precise and, in our view, more appropriate standard. We agree that only a "significant breakdown" of the construction QA program (not merely "a violation") should trigger a severity level I violation. Further, we agree that for a SL I construction-related violation, such a breakdown should involve the inability of *multiple* structures or multiple systems to satisfy their intended safety purpose.

However, we do not agree that inclusion of "components" is appropriate in this context. Components are not included in the existing SL I violation example for new plant construction (current Policy, p. 49), and no rationale is offered for this change. Similarly, components are not mentioned in the SL I violation examples for operating plants in the current Policy (p. 46). Accordingly, NEI recommends that in the final revised Policy, this severity level I example be changed to read as follows:

"A significant breakdown of a licensee QA program for construction resulting in multiple structures or multiple systems not being able to satisfy their intended safety purpose."

Severity Level II.

The existing criteria are:

- "1. A breakdown in the Quality Assurance (QA) program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). These deficiencies normally involve the licensee's failures to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or
2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations."

The proposed revised criterion is:

"A significant breakdown of a licensee QA program for construction resulting in multiple deficiencies related to more [than] one work activity (e.g., structural, piping, electrical, foundations) or a single system, structure, or component not being able to satisfy its intended safety purpose."²⁰

¹⁹ NRC should clarify via a footnote or otherwise that "completed" means completion of construction including review and acceptance by the construction QA organization.

²⁰ There is a spelling error in section 6.5.b.1.: "that" should be "than."

In our view, the proposed revision to the SL II violation example appropriately requires a "significant breakdown" of the construction QA program and "multiple deficiencies related to more than one work activity." The revised Policy also replaces language relating to completion of a structure or system "in a manner that could have an adverse effect on the safety of operations," with the concept of a structure or system "not being able to satisfy its intended safety purpose." This revision also is logical, because the example relates to construction-related violations, not operating plant violations. Finally, we assume that the requirement for a significant QA program breakdown applies to the entire definition, and request NRC verify this in the final revised Policy. (See the proposed re-write below.)

As with the severity level I violation example, the inclusion of "components" in this example is inappropriate. Here again, components are not included in the existing SL II violation example for new plant construction (current Policy, p. 49) or in the SL II violation examples for operating plants in the current Policy (p. 46). Accordingly, NEI recommends that in the final revised Policy, this severity level II example be clarified and changed to read as follows:

"A significant breakdown of a licensee QA program for construction resulting in either (i) multiple deficiencies related to more than one work activity (e.g., structural, piping, electrical, foundations) or (ii) a single system or single structure not being able to satisfy its intended safety purpose."

Severity Level III:

The existing criteria are:

1. A deficiency in a licensee QA program for construction related to a single work activity (e.g., structural, piping, electrical, or foundations). This significant deficiency normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;
2. A failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or
3. A failure to make a required 10 CFR 50.55(e) report."

These examples of SL III violations in the current Policy (p. 49) have been replaced by a single SL III criterion in the revised Policy: "A breakdown of a licensee QA program for construction related to a single work activity or resulting in a single system, structure, or component being of unknown quality."

Rather than a "deficiency" in a construction QA program relating to a single work activity, the revision requires "a breakdown of the QA program;" this appears appropriate. But the proposed revision also unreasonably lowers the threshold for a SL III violation by eliminating the expectation of "multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation." We suggest that the "multiple examples" language be retained in the revised Policy. The proposed SL III example also sets the

enforcement threshold too low by providing that a single component of unknown quality could result in a SL III violation. Consistent with our comments on the SL I and SL II examples, and also consistent with the current Policy (which speaks in terms of systems and structures only), we recommend that references to "component" be removed from the example.

Accordingly, NEI recommends that in the final revised Policy, this severity level III example be clarified and changed to read as follows:

"A breakdown of a licensee QA program for construction (i) involving multiple examples of deficient construction related to a single work activity; or (ii) resulting in a single system or structure being of unknown quality."

Severity Level IV:

The language in the revised Policy is essentially unchanged.

During 2007 and 2008, the nuclear industry and other public stakeholders have interacted with NRC Staff from Office of New Reactors in a series of meetings on the new plant construction inspection process (CIP). This interaction is ongoing, and may well continue after the revised Enforcement Policy is issued. Notably, these discussions have included a focus on severity level examples for construction-related enforcement violations, and the development of examples of violations at each severity level. The SL violation examples in the revised Policy are not identical to those examples discussed during these NRC public workshops. We understand that the examples in the revised Policy are intended to be consistent with those SL examples but written at a higher level of generality. This appears to be true in some, but not all, cases. As a general comment, we request that NRC modify the final Enforcement Policy provisions to reflect the changes that we propose above.

To avoid confusion, NRC also should ensure that the severity level examples being developed and discussed by stakeholders and the Staff in the new plant construction inspection process meetings are added to the Enforcement Manual. (They appear to be too new to be included in the 2006 version of the Manual.) In this area, it is essential that the Manual be updated promptly, and that NRC provide an opportunity for stakeholder review and comment on the proposed Manual changes. We hope that active and timely coordination between the NRC Office of Enforcement and the Office of New Reactors will continue in this area. NEI, on behalf of the industry, is willing to assist in this process as needed.

Without the opportunity to review the abbreviated SL examples in the revised Policy against the additional SL examples to be included in the Manual, it is impossible to determine whether the revised Policy could be read to give the NRC Staff more discretion than it now has to impose new-plant construction related civil penalties under an expanded array of circumstances. Industry would oppose such a result absent a clear regulatory basis and justification. At this time, we merely suggest that Staff-licensee interactions continue, and seek an opportunity to comment on the update to the Manual. We will continue to monitor and support those efforts.

Supplement Section 6.6 – Emergency Preparedness

Section 6.6 of the revised Policy (pp. 29-30) contains examples of violations relating to emergency preparedness at each severity level (compare current Policy, Supp. VIII, p. 65). These examples have not been changed.

Supplement Section 6.7 – Health Physics

Section 6.7 of the revised Policy (pp. 30-31) contains examples of health physics-related violations at each severity level (compare current Policy, Supp. IV, pp. 52-56). In general, the SL examples in Sections 6.7 and 6.8. reflect consolidation of SL criteria into broader, one-sentence descriptions. This consolidation may reduce NRC Staff objectivity and consistency in applying the more general criteria. Additionally, this change will almost certainly make enforcement decisions less transparent and comprehensible. Nor has the Staff explained or justified the modifications to the severity levels. For these reasons, we suggest that the specific listing of examples be updated, clarified, and retained in the Enforcement Policy, as appropriate, without consolidation.

Moreover, the severity level criteria in Sections 6.7 and 6.8 refer broadly to "the regulatory limits." There are numerous "limits" in NRC regulations. The specific regulatory limits being referenced should be cited in the criteria or defined in the Glossary to assure clarity and consistency. Similarly, severity level criteria in both sections refer to "reportable quantity of material." There are numerous reporting criteria in NRC regulations. The specific regulatory reporting criteria should be cited in the criteria or defined in the Glossary to assure clarity and consistency.

We also note that the revised SL criteria in Sections 6.7 and 6.8 refer to "risk-significant quantity of material." In some criteria, the reference is clarified with the addition of the phrase "equivalent to category 1;" other examples lack any clarification. We suggest that NRC amend each reference to "risk-significant quantity of material," for example, by adding the phrase "equivalent to Category 2." Alternatively, a definition should be provided in the Glossary.

Finally, Sections 6.7.c and 6.8.c refer to "the potential for radiation exposures or releases to the environment in excess of the regulatory limits, or that could have resulted in the potential for loss of control of reportable quantity of material." This standard differs from that in the current Policy, which refers to "substantial potential." Notably, the new standard implies a lowering of the threshold for escalated enforcement that is not justified by inspection and enforcement experience. The concept of "substantial potential" has previously been well-defined and implemented in NRC's enforcement program and is defined in the Glossary in the proposed revised Policy. It is also used in the Significance Determination Process. Equally important, this concept has been proven to be effective in bringing heightened regulatory attention to significant failures to comply with regulations in which it was fortuitous that consequences did not occur. For these reasons, this concept should be retained and the phrase "substantial potential" should be reinstated in the affected sections of the final revised Enforcement Policy.

Additionally, we have the following specific comments:

- For clarity, references to "material" should be changed to "licensed material."
- The criteria in Section 6.7.a. refer to "radiation exposures or releases to the environment in excess of *five times* (emphasis added) the regulatory limits." This is inconsistent with criteria in the current Policy, which refer to concentrations in unrestricted areas (fifty times) and the disposal quantities and concentrations (ten times). No regulatory basis or rationale is provided for the more restrictive standards NRC is proposing. Accordingly, we suggest that the current criteria be retained in the final revised Policy.
- The SL II and III examples in Section 6.7.b. and 6.7.c. appear to have been cut and pasted from Section 6.8 without adequate editing. As written, the criteria would only include failures to meet "transportation requirements." These sections should be edited to clarify applicability to "violations."
- Section 6.7.d. should be edited for clarity. It should refer to "loss of control of reportable quantities of licensed material, or radiation exposures or releases to the environment" in excess of the regulatory limits.

Supplement Section 6.8 – Transportation

Section 6.8 of the revised Policy (p. 31) contains examples of violations relating to transportation at each severity level (compare current Policy, Supp. V, pp. 56-57). It is not clear why other sections (e.g., 6.3 and 6.7) also contain transportation-related examples.

These SL examples are generally similar to those in the current Policy in their focus on failure to meet transportation requirements that results in loss of control of radioactive material (although the revision uses the term "material") and resulting exposures or releases, or potential exposures and releases. One notable difference is that the current Policy would require a loss of control of radioactive material "with a breach in package integrity," while the revised language requires a loss of control of material *or* a breach in package integrity—seemingly a more stringent standard.

A more important difference between the current and revised SL examples is reflected in the level of detail and threshold levels. The revised Policy examples imply that any "radiation exposures or releases to the environment" above the regulatory limit would be either a Severity Level I or II violation. In contrast, the current Policy follows the established "graded approach" by identifying different levels for public exposure, external radiation levels, and contamination levels that correspond to each of the four severity levels. Public exposure, external radiation levels, and contamination levels are separately addressed in the current Policy's SL violation examples, with different thresholds applied for each item and each severity level.

A related concern is that because the revised Policy's severity level violations do not explicitly discuss external radiation levels and contamination levels, the reader cannot discern if the phrase "radiation exposures or releases to the environment" encompasses external radiation levels and contamination levels. If this change is incorporated into the final revision, additional

clarification is needed on this important point. NEI also requests that NRC explain and justify the more stringent new enforcement standard, to provide clarity to stakeholders.

Supplement Section 6.9 – Inaccurate and Incomplete Information & Reporting

This section (pp. 31-32) contains examples of violations relating to inaccurate and incomplete information and reporting at each severity level (compare current Policy, Supp. VII (Miscellaneous Matters), pp. 61-64).

SL I violation example #1 appears broader than the current example in that it covers inaccurate or incomplete information deliberately provided to the NRC *or* maintained or withheld by a licensee or contractor.²¹ (The specific reference to contractors is also new.) SL I violation example #2, "Failure to make a required report which, had it been submitted, would have resulted in an extremely significant NRC action such as the issuance of an Immediately Effective Order," generally resembles example #2 in the current Policy (p. 62).

SL II violation example #2 is new: "Inaccurate or incomplete information associated with an ITAAC Notification letter that, had it been accurate and complete, would have resulted in the NRC rejecting closure of the ITAAC." In our view, this new criterion is unjustifiably broad and lacks a clear regulatory basis. It would allow the NRC to impose a severity level II penalty for incomplete and inaccurate information without a showing of careless disregard or negligence on the part of the licensee, and without any showing that the error was material.

To the extent that NRC plans to retain the current specific examples of licensed operator violations in the Enforcement Manual and continue to use them to inform decisions on severity levels, industry does not object strongly to these changes (other than those relating to ITAAC notifications, which should be clarified as stated above). To the extent that the new, broader language of the revised Policy can be read to give the NRC Staff more discretion to impose civil penalties under an expanded array of circumstances, NRC provides no basis or justification for doing so.

Supplement Section 6.10 – Discrimination

Like Section 6.9, Section 6.10 of the revised Policy (p. 33) contains examples of SL violations relating to employee discrimination that roughly parallel examples in Supplement VII (Miscellaneous Matters) of the current Policy (pp. 61-64).

The new examples of SL I violations differ markedly from those in the existing Policy in certain respects. Where the current example of a SL I violation relating to employee discrimination is "action by senior corporate management in violation of 10 CFR 50.7 or similar regulations against an employee;" the revised Policy's SL I example is: "Employee discrimination involving significant tangible adverse action taken or approved by a senior corporate officer or manager,

²¹ This new concept is also incorporated into SL II violation example #1, SL III example #1, and SL IV violation example #1, on p. 32.

or which has widespread site or organizational impact." The new examples of SL II, SL III and SL IV violations involving employee discrimination are analogous. They retain the current Policy's reference to discriminatory actions by mid-level management or below, but add new standards relating to "tangible adverse action" and whether the adverse action has "widespread site or organizational impact."

Supplement Section 6.11 – Reactor and Fuel Facility Security

The revised Policy (pp. 33-35) contains examples of violations relating to reactor and fuel facility security at each severity level (compare current Policy, Supp. III, pp. 50-52).

Example #3 in the revised SL I violation examples states: "Radiological sabotage in which the security system²² did not function as required and, as a result of the failure, there was a significant event, such as a Safety Limit being exceeded; a system designed to prevent or mitigate a serious safety or security event was not able to perform its intended function when actually called, an accidental criticality occurred or core damage." Based on the definition of "security system" in the footnote, we recommend replacing the term "security system" with "site protective strategy."

Example #1 of the revised SL II violation examples is: "A substantial potential for an act of radiological sabotage of a significant quantity of radioactive material." The phrase "substantial potential" appears to reflect an unduly broad, open-ended standard that lacks any clear regulatory justification. The fact that NRC regulations contain a design basis threat suggests that the "potential" exists and is substantial. The same comment would apply to SL II, example 3, and to SL III, example 1, which use this same term. We suggest that this change not be adopted and that the final revised Policy revert to the previous language.

Example #6 of the revised SL II violation examples is: "Actual damage to components of a target set, i.e., safety-related components or vital equipment." In our view, adoption of this example would establish a security standard that does not exist today. Not losing a complete target set is the current threshold for high assurance that the site protective strategy will prevent radiological sabotage. The fact that one component in a target set is damaged is not a basis for a violation. Accordingly, to avoid improperly imposing a new regulatory standard (in the guise of enforcement guidance) with a significant adverse impact on licensees, this new language should be omitted and the example rephrased or deleted.

Example #4 of the revised SL III violation examples is: "A failure to conduct a search or conducting an inadequate search at any protected area access control point that resulted in the introduction of firearms, explosives, or incendiary devices or reasonable facsimiles thereof that could assist in committing radiological sabotage or theft or diversion of strategic SNM." The term "reasonable facsimile" in this security context is unfamiliar and must be clarified. It is

²² Security system, as used in this supplement, includes personnel who are, at the time of the failure, filling a function required to implement the licensee's protective strategy.

improper to introduce new regulatory terms or concepts in NRC enforcement guidance or policy statements. Such changes should be made only through the rulemaking process, which allows the public an opportunity to comment and makes clear the agency's legal and regulatory basis for changing its requirements and expectations.

Example #6 of the revised SL III violation examples is: "A failure to protect or control classified or safeguards information of licensees' protective strategies, contingency plans or documents that directly reflect the implementation of strategies." The intent of this language is unclear, in that NRC licensees are already obligated to protect and control information marked classified or safeguards information (SGI), pursuant to NRC requirements. If the Staff's intent is to expand the Policy to provide that information the Staff believes *may* be SGI – even though not marked as such – is in violation of the rules, we would object to that new interpretation. We also note that in the existing enforcement guidance, this is a Level IV (not III) violation; no justification is provided for such an increased enforcement consequence.

Example #7 of the revised SL III violation examples is: "A failure to maintain the required number of responders to respond to an event, as described in the licensee's NRC approved security plan(s) and/or the licensee's protective strategy, to provide protection to vital equipment or strategic SNM." This should be limited to the NRC approved plan.

Example #1 of the revised SL IV violation examples is: "A potential for an act of radiological sabotage of radioactive material." This standard is unduly broad and subjective, and should be changed to provide more precision and transparency.

Example #3 of the revised SL IV violation examples is: "A failure to properly secure or protect classified or safeguards information not considered to be significant inside the protected area, accessible to those not authorized to have access to such information." The difference between this criterion and that in example #6 of a SL III violation is unclear and should be clarified. NRC licensees always have the obligation to control and protect this type of information.

Supplement Section 6.12 – Materials Security

The term "risk significant quantity of material" is used in item c.1. (p. 36) but is not defined in the Glossary. We recommend that this term be defined because it is presumably not Category 1 or 2 material, which is explicitly referenced in the Supplements. Absent clarification, there could be confusion whether this is intended to refer to IAEA Category 3 material or beyond.

Supplement Section 6.13 – Information Security

Section 6.13 of the revised Policy (p. 36) contains examples of violations relating to information security at each severity level. These examples presumably derive from the Safeguards-related severity level examples in the current Policy (pp. 50-52) and Supplement 6.11 of the revised Policy,²³ but appear significantly broader than their predecessors. Adoption of these severity

²³ See discussion above of Supplement Section 6.11, Example #6 of the revised SL III violations, and Example #3 of the revised SL IV violations.

level examples as drafted would expand the Staff's enforcement authority in this area and lower the threshold for enforcement action at all severity levels, without basis or justification.

Contrary to Section 2.2 of the revised Policy, these severity level examples fail to address the significance of the information, the significance of the disclosure of the information, or the elements of willfulness that could be relevant to a violation involving an individual. For example, under the current Policy, a severity level I violation would involve (i) an act of radiological sabotage, a security system failure, and a significant event; or (ii) the theft, loss or diversion of a formula quantity of special nuclear material (SNM); or (iii) actual unauthorized production of a formula quantity of SNM. By contrast, the SL I violation example in the revised Policy is: "Failure to control secret or top secret information where the information was removed or disclosed to an unauthorized person." A comparison of the existing and revised SL examples yields a similar result for SL II, SL III, and SL IV violations in this area.

Thus, under the revised Policy, NRC could presumably impose a SL I violation for any "failure to control" secret or top secret information where the information was "removed or disclosed to an unauthorized person." It could impose a SL II violation for any "failure to control confidential or safeguards information" where the information was "removed or disclosed to an unauthorized person." It could impose a SL III violation for any "failure to control classified or safeguards information" where there was the potential, *but no actual removal or disclosure*, of the information to an unauthorized person. Notably, the revised Policy does not define key terms, such as "failure to control" or "removal or disclosure" of protected information.

Consistent with the overall objectives of the Enforcement Policy, we suggest the following changes to the severity level examples in section 6.13 of the revised Policy.

- a. SL I violation examples involving, for example: "Failure to control secret or top secret information where the information was actually removed or disclosed to an unauthorized person, and for which the disclosure of such information (i) could significantly adversely impact national security or (ii) involved willfulness."
- b. SL II violations involving, for example: "Failure to control confidential or safeguards information where the information was actually removed or disclosed to an unauthorized person, and for which the disclosure of such information (i) could adversely impact national security or significantly compromise the security of a facility or (ii) involved negligence."
- c. SL III violations involving, for example: "Failure to control classified or safeguards information where there was the substantially high potential that the information could have been removed or disclosed to an unauthorized person and disclosure of such information could adversely impact national security or facility security."
- d. SL IV violations involving, for example: "Failure to control classified or safeguards information where the information was not removed and was not disclosed to an unauthorized person and for which disclosure of such information could adversely impact national security or facility security."

Glossary

The NRC should consider adding definitions for "Fuel Cycle Operations," "Materials Operations," "Fuel Cycle Facilities," "Reactor and Fuel Facility Security," and "Materials Security" as used in the Supplement, to assist licensees in their review of the severity level examples. For example, it is not clear whether "Materials Operations" applies to byproduct materials licensees or those who possess other categories of regulated material such as special nuclear material.

Also, the terms "Category 1" and "Category 2" are used throughout the Policy but not defined in the Glossary. Presumably, this refers to the International Atomic Energy Agency's categorization of sources, which has been adopted by the U.S. and represents the two highest risk categories of sources. However, it could be confused with categories of fuel cycle facilities are described in 10 CFR Part 70.

The term "risk significant quantity of material" is used in Supplement 6.12.c.1 (Materials Security) but is not defined. We suggest that this term be added to the Glossary because it presumably does not refer to Category 1 or 2 material, which is explicitly referenced in the Supplements. In the absence of a definition, it will not be clear to licensees or NRC or an Agreement State whether this is intended to refer to IAEA Category 3 material or beyond.