Analysis of Comments Received on Proposed Changes to Enforcement Policy

The period for submitting public comments on proposed changes to the U.S. Nuclear Regulatory Commission's (NRC's) Enforcement Policy (Policy) expired on September 8, 2011 (76 FR 48919). A summary of the issues raised by the stakeholders, followed by the NRC's responses to the comments, is provided below.

1. <u>Comment Summary</u>: One commenter recommended adding text as a new last paragraph to Section 1.1, "Purpose," to address the current staff actions to broaden the use of the Reactor Oversight Process into other major areas such as fuel facility operations and construction activities of both power reactors and fuel and enrichment facility licensees. (For additional information, see Agencywide Documents Access and Management System (ADAMS) Accession No. ML11242A113.)

<u>Response</u>: The NRC disagrees with the suggested change. The suggested additional language describes certain programs under development and goes beyond discussing the overall purpose of the NRC's Enforcement Policy.

2. <u>Comment Summary</u>: One commenter recommended including the additional underlined text in the first paragraph being added to Section 1.2, "Applicability" (see ADAMS Accession No. ML112370041):

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees when conducting activities under the license, certificate, or application, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.

<u>Response</u>: The NRC staff disagrees that the additional language will further clarify when enforcement is appropriate for licensees, certificate holders, and applicants. The Policy currently allows for the staff to address how to disposition enforcement actions against the various entities on a case-by-case basis.

3. Comment Summary: A commenter referenced a discussion that took place during the public meeting on August 30, 2011, about the proposed changes to Section 1.2 of the Policy. Although the commenter did not propose any specific changes to the Policy, the commenter urged the NRC to consider providing additional guidance on how the staff determines whether or not a licensee, vendor, or both is cited for violations of NRC requirements. In addition, the commenter urged the NRC staff to consider whether, in a situation where the licensee has properly executed its oversight responsibilities and the contractor or vendor has acceptable programs in place, yet compliance with those programs is not met, the licensee should be subject to enforcement action since the licensee does not have direct control of compliance with contractor or vendor programs. The commenter further opined that it "seems fairer and more appropriate that the contractor or vendor—not the licensee—receive the enforcement action, assuming the licensee has fully exercised its responsibilities." (See ADAMS Accession No. ML11256A012.)

<u>Response</u>: The NRC discussed the need to provide additional guidance on the issuance of violations against licensees, vendors, or both. The staff concluded that the Policy, as revised, provides sufficient latitude to take action against licensees and applicants, various categories of non-licensees, and individual employees of licensed and non-licensed entities involved in NRC-

regulated activities. Going forward, the staff will consider providing additional guidance in the Enforcement Manual in coordination with the NRC program offices responsible for vendor inspection programs.

4. <u>Comment Summary</u>: A commenter recommended that the staff withdraw proposed changes to Section 2.2.1.a, "Factors Affecting Assessment of Violations"; specifically, the staff should delete the proposed wording "onsite and offsite chemical hazard exposures resulting from licensed or certified activities as a factor." The commenter believes that including this wording would broaden the scope of Section 2.2.1.a without any clear rationale or supporting basis, and that the wording is unrelated to construction. The commenter suggested that the NRC consider resubmitting the wording at a later date when the technical and legal bases could be better understood. (See ADAMS Accession No. ML11256A012.)

Response: Although the NRC agrees that this language may be considered unrelated to construction, this proposed revision to the Policy will include it. The incorporation of "onsite and offsite chemical hazard exposures" is consistent with current Policy, including the examples provided in Section 6.2, "Fuel Cycle Operations." In fact, the first example involves a high-consequence event, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material." The regulation at 10 CFR 70.61, "Performance Requirements," defines "high consequence" to include, among other things, acute chemical exposure. Therefore, the proposed change is not an attempt to impose a new requirement or a new interpretation of an existing requirement; rather, it is intended to clarify current Policy, as written.

5. <u>Comment Summary</u>: One commenter recommended adding the following language at the end of the first paragraph of Section 2.2.6, "Construction":

Failure to timely restore the CLB [current licensing basis] may be subject to separate enforcement, such as an order, a civil penalty, or both.

The commenter stated that the additional language would enhance public confidence that the NRC will take appropriate action as necessary to ensure the integrity of the licensing process. (See ADAMS Accession No. ML11242A113.)

<u>Response</u>: The NRC agrees with the recommendation to add language relating to the timely restoration of the CLB.

6. <u>Comment Summary</u>: A commenter recommended that the NRC simplify the use of noncited violations (NCVs) by minimizing the staff effort to determine, before dispositioning violations, the acceptability of licensee corrective actions for issues of very low safety or security significance, as well as by minimizing the staff effort in dispositioning willful violations of very low significance not caused by licensee officials. The commenter recommended replacing the entire guidance provided in Section 2.3.2, "Non-Cited Violation," with the following (see ADAMS Accession No. ML11242A113):

The NRC will typically issue NCVs for all violations that are determined to be of SL [Severity Level] IV severity or associated with a finding that is of no greater than green significance. The NRC may issue a Notice of Violation for a SL IV violation if the issue also involves a willful act by a licensee official, and the resultant action is not otherwise considered for escalated enforcement for the licensee, or the individual, or both. Particularly poor licensee performance, such

as indicated by weak or ineffective corrective actions for very low severity/significance issues should be addressed through other means provided in the NRC inspection or assessment processes in lieu of issuing cited NOVs [notices of violation].

Response: Although the NRC staff shares the commenter's interest in simplifying the guidance in the Enforcement Policy, it disagrees with the recommended changes. The NRC believes that other staff efforts initiated to address Item 1.f of SRM-SECY-09-0190, "Staff Requirements—SECY-09-0190—Major Revision to NRC Enforcement Policy," dated August 27, 2010, will generate further changes to this section of the Policy and will likely result in the intended simplification of this section of the Policy. In addition, the staff believes that this proposal would remove an incentive for licensees to identify violations early (a specific goal of the NRC's Enforcement Policy). Also, it would substantially reduce the staff's ability to provide a graded enforcement response involving issues associated with a failure to correct the violation and repetitiveness would be reduced substantially. This is a particular challenge in the case of nonreactor licensees.

7. <u>Comment Summary</u>: Based on discussions held during the public meeting on August 30, 2011, a regulated industry stakeholder recommended alternative language on how the NRC will normally issue an NCV in lieu of an SL IV violation identified by either the licensee or the NRC. The commenter suggested that the latter part of the proposed second paragraph of Section 2.3.2 read as follows (see ADAMS Accession No. ML11256A012):

Until the determination that an adequate corrective action program has been implemented, NCVs may be issued for licensee/applicant-identified SL IV violations if the NRC has determined that the applicable criteria in 2.3.2.b. below are met. For reactor licensees, after the NRC determines that an adequate corrective action program has been implemented, the NRC will normally issue an NCV in lieu of a SL IV violation whether that violation is identified by the licensee or NRC.

<u>Response</u>: The staff agrees with this comment and has made the recommended changes to the proposed revision of the Policy.

8. Comment Summary: One commenter noted that the NRC is developing a Changes during Construction (CdC) process for combined license (COL) holders and agreed that the CdC process is expected to address the vast majority of situations during construction that might have otherwise necessitated a process similar to that of notices of enforcement discretion (NOEDs). Because the effectiveness and flexibility of the CdC process have not been demonstrated, and because neither the industry nor the NRC staff can foresee all the complexities associated with building a plant while maintaining compliance with a license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," the commenter urged the NRC staff to remain open to reconsidering the need for an NOED-like process during construction based on experience from the lead 10 CFR Part 52 projects. (See ADAMS Accession No. ML11256A012.)

The commenter further suggested changes to the proposed footnote in Section 3.8, Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants, for greater clarity when reading this section in isolation:

NOEDs will not be used at reactors during construction before the Commission's 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy.

<u>Response</u>: The NRC acknowledges that the effectiveness and flexibility of the CdC process have not yet been demonstrated. The staff will remain open to consider the establishment of an NOED-like policy, if warranted; however, neither the staff nor the industry has identified a scenario where an NOED-like process is necessary.

The NRC staff also agrees with the suggested changes to the footnote and has incorporated them.

9. <u>Comment Summary</u>: One commenter expressed concerns that the proposed changes to the Policy do not appear to extend the CdC concept to the fuel cycle industry. The commenter also expressed disappointment in the progress of discussions between the NRC and the fuel cycle licensees and applicants on this subject. The commenter reiterated that the NRC's approach to CdC could raise significant policy issues and that the approach should be fully vetted with the fuel cycle industry.

Moreover, the commenter is concerned with the proposed language in new Section 2.2.6 on the failure of an applicant to obtain Commission approval for construction activities at plutonium processing and fuel fabrication plants and the possible denial of a license to possess and use special nuclear material. Specifically, the commenter is concerned that the NRC's "ultimate intent is to include other fuel cycle applicants (and licensees who are constructing while operating), such as uranium enrichment facilities, in this language." (See ADAMS Accession No. ML11256A011.)

Response: After the NRC finalizes interim staff guidance on the CdC process (ISG-25), it will consider whether similar guidance is appropriate for facilities under construction under 10 CFR Part 40, "Domestic Licensing of Source Material," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." As a result, the NRC may revise existing guidance or develop specific CdC guidance for fuel cycle facilities. In considering the applicability of the CdC, or a similar process, to fuel cycle facilities and in developing associated guidance, the NRC would appropriately engage representatives of the fuel cycle industry and other interested stakeholders.

- 10. <u>Comment Summary</u>: One commenter stated that the proposed new Section 3.9, "Violations Involving Certain Construction Issues," specifies that the NRC's general enforcement discretion guidance is applicable to fuel cycle facilities and holders of limited work authorizations (LWA) and noted that the general enforcement discretion guidance is also applicable to COL holders. The commenter recommended that the revised Policy clearly reflect the COL holder's option to restore the current licensing basis in addition to the option to request a change to the licensing basis. The commenter provided suggested changes (underlined here) to the language to clarify the proposed new Section 3.9 (see ADAMS Accession No. ML11256A012.):
 - c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction without and that would otherwise require prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

- The licensee identifies <u>unplanned</u> changes implemented during construction not previously approved by the NRC that the staff would otherwise disposition as a Severity Level IV violation of NRC requirements,
- The licensee submits the necessary information to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or submits information to the NRC stating that it will restore the current licensing basis, and
- Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the <u>cause of the unplanned</u> change in its corrective action program to ensure comprehensive corrective actions to address <u>the cause of the change to prevent</u> recurrence.

<u>Response</u>: The NRC staff agrees with this comment and has made the recommended changes.

11. <u>Comment Summary</u>: An industry stakeholder stated that it was coordinating its response with the Nuclear Energy Institute (NEI) about the proposed changes to the Enforcement Policy and has provided input for the industry comments.

<u>Response</u>: The NRC understands that NEI's submittal incorporated the stakeholder's comments.