Analysis of Comments Received on Proposed Changes to the NRC's Enforcement Policy
(*Federal Register* Notice 76 FR 76192, dated December 6, 2011)

The NRC solicited comments on proposed revisions to the NRC enforcement policy in a Federal Register Notice (76 FR 76192). The proposed revisions to the enforcement policy discussed in 76 FR 76192 are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML11259A100. The period for submitting comments on the changes proposed to the NRC's enforcement policy in *Federal Register* (FR) Notice 76 FR 76192 expired on January 5, 2012.

This document summarizes the stakeholders' comments and the NRC's responses to the comments. The responses are based on the NRC staff's understanding of the comments and on information available to the staff at the time the responses were written. Part I addresses the comments about proposed policy changes based on direction to the staff described in Staff Requirements Memorandum (SRM)-SECY-0190, "Staff Requirements—SECY-09-0190—Major Revision to NRC Enforcement Policy," dated August 27, 2010. Part II addresses comments on staff-initiated proposed policy changes. The staff may, if appropriate, reconsider its responses or its proposed changes to the policy if new or additional information becomes available.

On January 24, 2012, a member of the public commented on a previously issued document that proposed changes to the enforcement policy, 76 FR 54986, dated September 6, 2011. Part III of this document addresses that comment.

Part I: Comments on the Proposed Changes Based on Direction to the Staff in SRM-SECY-09-0190

1. Comment Summary: The commenter noted that, in the changes proposed to Section 2.3.4 of the policy, "Civil Penalty," the staff's proposed response to the SRM for SECY-09-0190 focused only on the option not to change the policy—maintaining the existing base civil penalty for conversion facilities at $70,000—even though the SECY directed the staff to evaluate whether the civil penalties for uranium conversion facilities could be tied to the inventory of chemicals maintained by the facility and to provide options for the Commission's consideration. The commenter acknowledged that the staff had only recently changed the base civil penalty for conversion facilities from $14,000 to $70,000, as a result of the latest policy revision. However, the commenter suggested that the staff consider a change to the base civil penalty for conversion facilities to $35,000 as a viable option to present to the Commission. The commenter stated that making the base civil penalty for uranium conversion facilities equal to that for gaseous centrifuge enrichment facilities, uranium mills, and Category III fuel fabricators would strike a better balance among the criticality-related radiological and chemical hazards across the range of NRC facilities.

Response: The staff agrees with the comment that the staff's response to SECY-09-0190 currently does not contain options for the Commission's consideration of the base civil penalty for uranium conversion facilities. Therefore, the staff will prepare options for the Commission's consideration, in addition to the option not to change the existing base civil penalty.

2. Comment Summary: A commenter recommended that the NRC remove the discussion of a proposed change to Section 2.4.1 of the policy, "Predecisional Enforcement Conference [PEC],"

that allows the NRC staff to issue an enforcement action without first obtaining the licensee's response to the documented apparent violation.

Response: The staff believes it should not remove this discussion but instead revise it to clarify that, if the NRC concludes that it has sufficient information to make an informed enforcement decision involving a licensee, the NRC will notify the licensee that a PEC does not appear to be necessary. In such a case, unless the licensee specifically requests a PEC, one will not be held. Although the NRC normally offers the licensee the opportunity to attend a PEC or respond in writing, or both, there may be instances when it is appropriate to issue an enforcement action before obtaining the licensee's response (e.g. an immediate safety or security issue).

Part II: Comments on Other Policy Changes Proposed by the Staff for Inclusion in the Next Policy Revision

1. Comment Summary: With regard to the changes proposed to Section 2.2.1 of the policy, "Factors Affecting Assessment of Violations," a commenter noted that the proposed text in Section 2.2.1.c, as drafted, refers to changes in licensed activities that a licensee would be "required" to implement. The commenter requested that the NRC clarify this point to provide appropriate context and guidance. The commenter also stated that the proposed addition, in the same paragraph, of language clarifying failures to comply with reporting requirements is helpful and appropriate.

Response: The staff agrees that the use of the word "required" should be clarified in the context in which it was proposed. Therefore, the staff proposes to revise two phrases within Section 2.2.1.c to read, "…failures to receive prior NRC approval for changes in licensed activities, when required; failures to notify the NRC of changes in licensed activities, when required…"

2. Comment Summary: A commenter noted that the proposed revisions to policy Section 2.2.4, "Exceptions to Using Only the Operating Reactor Assessment Program," delete specific examples of the types of violations dispositioned using traditional enforcement. The commenter noted that the NRC proposes to reference policy Section 2.2.1, which describes actual safety and security consequences, potential safety and security consequences, and the impact of the violation on the NRC's ability to perform its regulatory oversight functions. In the commenter's view, the proposed deletions are acceptable, because they reduce the potential for an inconsistent interpretation of Sections 2.2.4 and 2.2.1.

Response: The staff has no additional comments.

3. Comment Summary: A commenter noted that the first sentence of the proposed revision to policy Section 2.3.4, "Civil Penalty," states that civil penalties are "typically assessed" for Severity Level (SL) I and SL II violations and deliberate violations of the reporting requirements under the Energy Reorganization Act of 1974. The commenter does not believe this characterization is appropriate, given the civil penalty assessment process set forth in Section 2.3.4. Moreover, if the NRC reinserts language stating that civil penalties are "normally assessed" for certain violations, it may effectively override new language that emphasizes evaluating the appropriateness of a civil penalty for any escalated enforcement action on a case-by-case basis. The proposed NRC language further states, appropriately, that the civil penalty assessment process should be followed. The commenter suggested that the first

sentence be modified to state that civil penalties are considered for all SL I and SL II violations, some SL III violations, and deliberate violations of the referenced reporting requirements.

Response: The staff partially agrees with the comment. According to the current civil penalty assessment process, civil penalties are considered for all Severity Level I, II and III violations that meet the required criteria. The staff proposes minor clarifying edits to the last sentence of the proposed paragraph but otherwise agrees with the commenter's proposed wording. The modified paragraph reads as follows:

> Civil penalties are considered for all Severity Level (SL) I, II, and III violations. The civil penalty assessment process described in this section and depicted in Figure 2 should be followed to determine the appropriateness of a civil penalty for any escalated enforcement action. Notwithstanding the outcome of the normal civil penalty assessment process, discretion, as discussed in this section and in Section 3.6, "Use of Discretion in Determining the Amount of a Civil Penalty," may be exercised by either escalating or mitigating the amount of the civil penalty.

4. Comment Summary: A commenter stated that the proposed revisions to Section 2.3.2.b of the policy, "Noncited Violation, All Other Licensees," are intended to clarify that the NRC may also issue noncited violations (NCVs) to nonlicensees when they meet the NCV criteria in Section 2.3.2.b. The commenter had no comment on this proposed change.

Response: The staff has no additional comments.

5. Comment Summary: The commenter stated that reinserting the guidance in policy Section 2.3.11, "Inaccurate and Incomplete Information," into the enforcement policy will be helpful to stakeholders. The guidance offers useful information to both the NRC staff and its licensees about the factors the agency considers when determining whether to take enforcement action. The guidance also provides useful context on how the NRC will take various circumstances into account on a case-by-case basis. The commenter had no other comments.

Response: The staff has no additional comments.

6. Comment Summary: A commenter recommended that the NRC staff explicitly state, in policy Section 2.3.12, "Reporting of Defects and Noncompliance," that when a licensee ensures that a contractor's program meets applicable requirements, exercises appropriate oversight of the implementation of the contractor's program, and does not otherwise miss opportunities to prevent a violation by a contractor, the NRC will not issue notices of violation and civil penalties to licensees if it can (and will) take enforcement action directly against the contractor or the contractor's employees.

Response: The staff disagrees with the comment. The recommended revision, as written, could undermine the basic premise that the licensee is responsible for the activities of its contractors and subcontractors. As stated in policy Section 3.5, "the NRC may refrain from issuing enforcement action for violations resulting from matters not within a licensee's control, such as equipment failures that were not avoidable by reasonable licensee QA [quality assurance] measures and/or management controls. Generally, however, licensees are held responsible for the acts of their employees and contractors."

7. Comment Summary: A commenter stated that the proposed addition to policy Section 4.0, "Enforcement Actions Involving Individuals," which discusses the NRC informing licensees of information it developed about the trustworthiness and reliability of individuals, is misplaced. The commenter recommended inserting the language on this topic as a standalone paragraph. The commenter also recommended the NRC emphasize that the licensee is responsible for evaluating the information provided in accordance with its access authorization program to determine the appropriate actions for authorizing individual access.

Response: The staff agrees with the comment and will incorporate the commenter's suggestions.

8. Comment Summary: A commenter noted that the NRC proposes to delete four examples of SL IV violations from policy Section 6.0, "Violation Examples," that include "catchall" language (e.g., "does not amount to an SL I, II, or III violation" or "does not result in an SL I, II, or III violation"). The commenter observed that the staff's stated rationale for these changes is that the "examples do not provide useful, specific guidance regarding the condition that would result in an SL IV violation. Rather, these four examples default to an SL IV primarily because the violation does not rise to the level of an SL I, II, or III violation." The commenter disagreed with the staff, finding that these examples are useful, because they clarify that, unless the violations warrant a higher SL on the basis of specific risk or significance factors referenced in the SL I, II, or III examples, the violation or noncompliance should be treated as an SL IV. The commenter proposed a revision to violation example 6.4.d.2, as follows, "A licensed operator or senior operator has a confirmed positive test for drugs or alcohol after arriving on-site to perform scheduled work or to attend required requalification training, but was not actively performing the functions covered by that position ~~that does not result in a Severity Level I, II, or III violation~~". The commenter recommended that all four SLIV examples be retained, to include 6.8.d.4, 6.11.d.3, and 6.14.d.4.

Response: The staff disagrees with the commenter's proposed revision to example 6.4.d.2 and also disagrees with the commenter's recommendation to retain this example, whether or not it is revised. The revision proposed by the commenter implies that a licensed operator who arrives at the site to report for duty or attend requalification training, but does not perform the duties required by the position, would be in violation of the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 55, "Operators' Licenses," and subject to an SL IV violation. In past enforcement cases, the NRC determined that, because the licensed operator did not perform functions requiring a license (i.e., "licensed duties") while under the influence of alcohol, an SL IV violation of 10 CFR Part 55 by the license holder did not occur. In these types of cases, the effectiveness of the licensee's fitness-for-duty program required by 10 CFR Part 26, "Fitness for Duty Programs," to detect unfitness for duty and prevent the licensed operator from performing licensed duties will be assessed for potential enforcement actions against the plant licensee. Because Section 6.4 relates to 10 CFR Part 55 license holders, the staff proposes to delete example 6.4.d.2.

The staff acknowledges that the commenter offers sound logic for retaining SL IV violation examples 6.8.d.4, 6.11.d.3, and 6.14.d.4. However, the staff believes that these examples do not achieve the level of specificity that the policy's other violation examples exhibit (that is, other violation examples—with some limited exceptions—do not contain a "default statement"). The staff prefers to use "standalone" violation examples that do not contain catchall language like "does not amount to an SL I, II, or III violation" or "does not result in an SL I, II, or III violation." Therefore, the staff proposes to delete these three violation examples.

9. Comment Summary: A commenter recommended that the NRC modify violation example 6.3.d.9 in policy Section 6.3, "Materials Operations," for clarity.

Response: The staff agrees with the following proposed revision:

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

10. Comment Summary: A commenter stated that the new fatigue-related SL I example proposed for Section 6.4 of the policy, "Licensed Reactor Operators," is inappropriately severe. Specifically, the commenter stated that, in comparison to drug- or alcohol-related fitness-for-duty issues that are supported by objective tests, assessments of postevent fatigue are much more subjective and would be difficult to validate. Therefore, the commenter recommended that example 6.4.a.1 be removed from the SL I category and instead, be included in the SL II violation example, 6.4.b.1.

Response: The staff partially agrees with the comment. The staff believes the determination that an individual is unfit for duty means that he or she is unable to perform the duties required of a licensed operator and that the severity level should be determined based on the potential consequences of the individual being unfit. Specific, measurable criteria—such as cutoff levels for alcohol and illegal drugs—form the basis of a fitness-for-duty determination related to alcohol and illegal drug use. Making the determination that an individual is "under the influence of prescription or over-the-counter drugs" (an existing example of an SL I violation) relies on behavioral observation by trained individuals. The new example related to postevent fatigue also relies on trained and qualified individuals to make a subjective determination, as specified in 10 CFR Part 26, and is therefore consistent with the existing example of the influence of prescription or over-the-counter drugs. In addition, a "postevent" fatigue assessment is, by definition, one conducted after an event that resulted in significant illness or personnel injury, radioactive exposure or release of radioactivity in excess of regulatory limits, or substantial degradation (whether actual or potential) of the safety of the plant. The occurrence of a significant event sets an appropriate threshold for the fatigue assessments considered in the proposed example.

Because the subjectivity of the method used to determine that an individual is "unfit for duty" or "under the influence" is irrelevant in determining the severity level of the violation, the staff recommends retaining the recommended SL I violation example of unfitness for duty for reasons of postevent fatigue. The new SL I example focuses on the fact that an individual who was unfit for duty caused or exacerbated a significant event. The commenter's argument that the determination of unfitness for duty as a result of fatigue should not be added to the SL I examples is not consistent with other fitness-for-duty conditions already contained in the examples. The determination that an individual is unfit for duty is the basis for the existence of a violation, not the basis for determining the significance. The staff does, however, agree with the commenter that the fatigue example should be added to the SL II discussion and the NRC staff further determined that it also should be considered for SL III examples, as fatigue is not solely a severity level I issue. Accordingly, the staff recommends that this example be retained under examples of SL I violations and that the example also be added to examples of SL II and SL III violations.

11. Comment Summary: A commenter stated that the addition of two new violation examples related to 10 CFR Part 21, "Reporting of Defects and Noncompliance," to Section 6.5, "Facility Construction: 10 CFR Part 50 and 52 Licensees and Fuel Cycle Facilities," appears to be helpful and appropriate.

Response: The staff has no additional comments.

12. Comment Summary: A commenter stated that the gradation among the new violation examples proposed for policy Section 6.6, "Emergency Preparedness," captures the relative significance of each event classification. In the commenter's opinion, however, some of these examples seem inappropriately severe—and, in some cases, inconsistent with current NRC practice—with no justification given for imposing more stringent enforcement outcomes.

Response: The staff does not agree with the changes the commenter proposed, because they would not maintain comparability between severity levels and significance levels—the stated goal of this revision. The severity level examples proposed are consistent with the significance levels in the Reactor Oversight Process.

13. Comment Summary: A commenter noted that the NRC proposed to add three new violation examples to policy Section 6.9, "Inaccurate and Incomplete Information or Failure To Make a Required Report," and revise an existing example. The commenter stated that the first proposed example is helpful and appropriate, the second offers additional guidance for violations of 10 CFR Part 21, and the third seems appropriate. The commenter stated that the revision to the existing example is a useful clarification and, therefore, appropriate.

Response: The staff has no additional comments.

14. Comment Summary: A commenter noted that the NRC proposed to revise the following four terms in policy Section 7.0, "Glossary":

(1) The commenter agreed with the proposed clarification to the definition of "Actual Consequences."

(2) The commenter stated that proposed changes to the definition of "Apparent Violation" generally provide useful clarifications and are appropriate.

(3) The commenter had no comments on the revised definition of "Traditional Enforcement."

(4) Finally, the commenter had no comment on the proposal to change the name of the definition "Substantial Potential for Exposures or Releases in Excess of the Applicable Limits in 10 CFR Part 20" to "Substantial Potential for Overexposure" to more accurately reflect the requirements of 10 CFR Part 20.

Response: The staff has no additional comments.

15. Comment Summary: A commenter noted that the staff's proposed revision to policy Section 8.0, "Table of Base Civil Penalties," Table A, Category C, replaces the language referring to "fuel fabricators authorized to possess Category III quantities of SNM [special nuclear material]" with the phrase "all other fuel fabricators," in an effort to clarify the fact that the table also applies to fuel facilities under construction. The commenter did not believe this

proposed revision provided the intended clarification. The commenter instead suggested that Table A, Category C, be changed to "all other fuel fabricators, including facilities under construction."

Response: The staff agrees with the comment and, therefore, proposes to modify Section 8.0, "Table of Base Civil Penalties," Table A, Category C, as the commenter suggested.

Part III: Additional Comments on 76 FR 54986, Dated September 6, 2011

On September 6, 2011, the staff solicited comments (76 FR 54986) on proposed changes to the enforcement policy. The period for submitting comments on the changes proposed in 76 FR 54986 expired on October 6, 2011. However, in 76 FR 54986, the NRC stated that comments received after October 6, 2011, would be considered if it were practical to do so. On January 24, 2012, a member of the public who had commented on 76 FR 54986 before October 6, 2011, made an additional comment on one specific staff-proposed policy change discussed in 76 FR 54986. (A summary of all the comments received on 76 FR 54986 and the staff's responses is publicly available in ADAMS at Accession No. ML11299A156.)

The paragraphs below summarize the initial comment and the staff's response, followed by the same person's further comment (dated January 24, 2012) and the staff's response.

Comment Summary: In the comment period that expired on October 6, 2011, the commenter recommended that the enforcement policy make daily civil penalties available for use in cases involving significant violations for which a strong regulatory message is warranted for the sake of deterrence—not just for cases involving deliberate wrongdoing. At a minimum, the commenter argued, daily civil penalties should be applied to significant violations that involve careless disregard and to cases in which the licensee should have exercised reasonable diligence to become aware of the violation and prevent its adverse impact.

Response: In its response to the initial comment summarized above, the staff agreed that careless disregard, not just deliberate wrongdoing, should be considered when evaluating the appropriateness of issuing daily civil penalties. The staff stated its intention to propose replacing the word "deliberate" with the word "willful," which encompasses the concepts of deliberate wrongdoing and careless disregard.

The staff's proposed revision to Section 2.3.4, "Civil Penalty," of the enforcement policy states that, for the NRC to assess a daily civil penalty, it must demonstrate that the licensee was aware of the violation and had a clear opportunity to prevent, identify, and correct it but failed to do so. In addition, one of the evaluation factors the staff proposed is the extent of the violation's impact on public health and safety, if any.

Comment Summary: On January 24, 2012, the same commenter stated that the staff's previous response (above) did not address the issue of a significant violation for which the licensee "should have been aware of the violation with the exercise of reasonable diligence." The commenter stated that the NRC should not unduly limit its discretion to issue daily civil penalties for cases in which the licensee is aware of a violation. The commenter further stated that the enforcement policy's guidance on daily civil penalties should be broader than proposed, given that the use of daily civil penalties is discretionary and involves consultation with the Commission. The commenter suggested that the proposed guidance state that daily civil penalties also may be warranted for cases in which the licensee should have been aware of

significant violations through reasonable diligence and, therefore, could have prevented or mitigated the impact of the violation.

Response: As stated in 76 FR 54986, the NRC proposes to weigh the relative importance of each contributing factor, as well as any extenuating circumstances, to determine whether it is appropriate to use daily civil penalties. However, the staff believes that to attempt to determine, in each case, whether a licensee "should have been aware of the violation," as the commenter suggested, would be subjective—and, therefore, more difficult to support in any enforcement action involving the use of daily civil penalties. Furthermore, the staff believes that the threshold for the use of daily civil penalties for continuing violations should be set high and that including "should have been aware of the violation" as one of the evaluation factors would potentially lower—not raise—the threshold for the use of daily civil penalties. Therefore, the staff believes that determining whether the licensee had a clear opportunity to prevent, identify, and correct the violation, but failed to do so, is a more objective approach and sets a higher threshold for the appropriateness of issuing a daily civil penalty. For these reasons, the staff disagrees with the commenter's suggestion.