

## Analysis of Comments Received on Revised Enforcement Policy

The period for submitting public comments on the proposed revised Enforcement Policy expired on November 14, 2008 ([73 FR 53286](#) and [73 FR 61442](#)). Subsequent to the November 2008 comment period, the NRC staff, based, in part, on comments received from external stakeholders, proposed further revisions to the Supplements (i.e., the violation examples) in the revised Policy. The comment period for the revised proposed Supplements ended on July 8, 2009 ([74 FR 27191](#)). The NRC staff is currently evaluating the comments received on the revised supplements. Once that evaluation is completed, the staff expects to make its responses publicly available. Therefore, this Comment Analysis only addresses those comments received on the content of body of the revised Policy.

A summary of the issues raised by the commenters, followed by the NRC's responses to the comments, is provided below.

**Comment summary.** One commenter stated that 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.

**Response.** The revision to the Policy was guided by the principle that the enforcement assessment process is fact-driven, performance based, and, when possible, risk-informed. A clarifying statement was also added to this effect.

**Comment summary.** Commenters questioned whether all the important material not retained in the revised Policy would be addressed in the NRC Enforcement Manual.

**Response.** The staff has verified that all important material not retained in the revised Policy is currently addressed in the Enforcement Manual.

**Comment summary.** One commenter suggested that the revised Policy include a section briefly describing the purpose, scope, and contents of the Enforcement Manual, and instructions on how to access it.

**Response:** The Preface to the revised Policy was revised to incorporate this suggestion. The Enforcement Manual continues to be available on the NRC's public web site.

**Comment summary.** A commenter stated that it is appropriate that the Yucca Mountain project meet the same high standard of accountability for compliance with NRC regulations as other NRC licensees. The commenter agreed with the Commission's statement that during the repository construction application period, few if any violations would escalate to SL I or SL II due to the lack of direct consequences to public health and safety. The commenter recommended that NRC include in the Enforcement Manual language specific to the Yucca Mountain project, consistent with these statements, to ensure clarity in the implementation of NRC's approach.

**Response.** The NRC agrees with the recommendation to include in the Enforcement Manual language specific to the Yucca Mountain project.

**Comment summary.** One commenter stated that the discussion regarding the increase in base civil penalty for violations at Uranium Conversion Facilities (see [73 FR 53289](#)) does not

indicate what events led NRC to change its position on the base civil penalty for those facilities or otherwise justify the increase.

Response: The staff believes the discussion in the *Federal Register* Notice clearly provided the NRC's rationale and conclusions regarding increasing the base civil penalty for Uranium Conversion Facilities. As stated in the discussion, the NRC analyzed the associated radiological, chemical, and security hazards of Uranium Conversion Facilities and concluded that an increase in the based civil penalty was justified.

Comment summary. One commenter suggested that the revised Policy discussion provide for a "comment/resolution" portion in a final enforcement package to indicate how licensee input at a predecisional enforcement conference was considered by NRC in taking a final enforcement action.

Response. The NRC disagrees with the comment. Such a change would unnecessarily add burden and delay to the disposition of enforcement actions. The purpose of the opportunity for early licensee input is to insure that the NRC has all the correct and relevant facts before it makes its enforcement decision.

Comment summary. One commenter stated that the concept of a "significant event" in the context of security is subjective and vague, that interpretation of the term is not provided in the glossary, and that NRC has not provided any regulatory justification for the revision.

Response. Not all terms used in the Enforcement Policy are defined in NRC documents. The term "significant event" as related to security can be interpreted by using the definitions in the revised Policy of the four severity levels assigned to violations. In addition, the term "significance" is defined in the revised Policy Glossary.

Comment summary. One commenter suggested that a fuller explanation, which incorporates the concept of "radiological sabotage" be added to the discussion on assessing violations.

Response. NRC agrees with the comment and has expanded the discussion on assessing violations to include "radiological sabotage." The term "radiological sabotage" is also defined in 10 CFR 73.2.

Comment summary. One commenter suggested reinserting a brief discussion on the use of risk information in the revised Policy.

Response. The NRC agrees with the comment and has reinsert wording from the current Policy into the discussion on assessment of violations.

Comment summary. One commenter stated that the term "significant regulatory concern" as used in the discussion of severity levels comes close to re-introducing "regulatory significance" to the Enforcement Policy, which is not appropriate.

Response. The NRC disagrees with the comment. The words "significant regulatory concern" are also used in the current Policy. To clarify the meaning of the term in the revised Policy, the NRC has inserted a footnote from the current Policy which states, "Regulatory concern pertains to primary NRC regulatory responsibilities, i.e., safety, safeguards, and the environment."

Comment summary. A commenter noted that the discussion 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 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. The commenter suggested that this point be retained. Similarly, the commenter suggested that the NRC consider retaining some of the current Policy's discussion concerning whether a violation involved willfulness.

Response. The NRC agrees with the comments. Clarification has been added to the discussion of factors affecting assessment of violations to address failure to report a condition and to address willfulness.

Comment summary. The discussion on assessing violations appears to reflect a substantial broadening of the criteria to include not only violations that resulted in substantial actual safety consequences but also violations that could have resulted in substantial actual safety consequences.

Response. The NRC disagrees with the comment. The wording in the revised Policy is consistent with the intent and wording in the current Policy (i.e., both the actual and potential safety consequences are considered as part of the NRC's significance assessment process.)

Comment summary. The commenter suggested that the revised severity level examples should contain examples of minor violations.

Response. The NRC disagrees with the comment. Since violations of minor safety or security concerns generally do not warrant enforcement action or documentation in inspection reports, the NRC made a decision not to discuss in detail nor give examples of minor violations in the revised Policy. Instead, the revised Policy refers the reader to the NRC Enforcement Manual, Inspection Manual Chapter (IMC) 0610, IMC 0612 (Appendix E), IMC 0613, and IMC 2517 (Appendix C) where examples of minor violations can be found.

Comment summary. The commenter stated that that while most of the criteria for dispositioning a violation as a Non-Cited Violation (NCV) have been re-phrased, the discussion of situations in which a willful violation may be treated as an NCV has been deleted and that the reason for the omission is not clear.

Response. The NRC agrees with the commenter's observation and has inserted wording from the current Policy which discusses situations in which a willful violation may be treated as an NCV.

Comment summary. The commenter stated that 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 and suggested that his important point be re-inserted into the text of the Policy.

Response. The NRC agrees with the suggestion and has re-inserted that important point into the revised Policy.

Comment summary. Commenters stated that too much detail regarding the civil penalty assessment process had been removed from the revised Policy.

Response. The NRC agrees with the comment. Details of the civil penalty assessment process contained in the current Policy have been added to the revised Policy.

Comment summary. A commenter stated that the revised Policy should more explicitly reward licensees that are proactive and effective in self-identifying compliance matters.

Response. The NRC's violation and civil penalty assessment processes discussed in the revised Policy provide an appropriate level of mitigation of enforcement actions against licensees that promptly identify and correct noncompliances. The NRC does not believe that further expansion of those mitigation provisions are needed.

Comment summary: Commenters stated that the revised Policy should include a reference to NRC coordination with Agreement States to address enforcement issues of mutual concern. The commenters urged 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.

Response: Agreement States need to be able to implement policies that reflect their States' statutes and regulations as provided for by the *Final Policy Statement on Adequacy and Compatibility of Agreement State Programs* (Policy Statement), dated September 3, 1997 (62 FR 46517). Requiring the NRC Enforcement Policy to be a matter of compatibility would hinder the Agreement States in this process since NRC's Enforcement Policy does not reflect all of the differences unique to each Agreement State's statutes and regulations. Therefore, in order to allow the Agreement States the flexibility to be able to protect public health and safety, the NRC's Enforcement Policy will remain an element of adequacy and will not become a matter of compatibility.

Comment summary. A commenter suggested that the section on Responsibilities of NRC offices and officials responsible for overseeing and implementing the enforcement program be reinserted into the revised Policy.

Response. The NRC agrees with the comment and has inserted a new section in the revised Policy which discusses Responsibilities. A more detailed discussion on Responsibilities and Delegation of Authority is found in the Enforcement Manual.

Comment summary. Commenters expressed concern that the revised Policy lacked detail regarding the predecisional enforcement conference (PEC) process. A commenter recommended that licensees always be provided the opportunity to have a predecisional enforcement conference in addition to the opportunity to initially respond in writing to the apparent violation. A commenter stated that, with few exceptions, PECs should not be open to the public.

Response. The NRC has inserted wording into the revised Policy from the current Policy which more clearly describes the PEC process. In general, the decision to conduct a PEC is dependent upon whether or not the NRC has sufficient information to make an informed enforcement decision involving a licensee, contractor, or vendor. PECs are normally public meetings except when the proposed enforcement action involves discussions of classified or safeguards information, privacy information, proprietary information, or other sensitive, non-public information.

Comment summary. A commenter stated that the omission of substantive discussion on Alternative Dispute Resolution (ADR) is a mistake. 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. To avoid confusion, the final revised Policy also should include a discussion of the use of "early ADR."

Response. In response to the comment, the NRC added to the ADR section of the Revised Policy a reference to Chapter 6 of the Enforcement Manual and the NRC web location. Early ADR is part of the allegation program and is discussed in the section in the revised Policy on violations involving certain discrimination issues which references NRC Management Directive 8.8, "Management of Allegations."

Comment summary. A commenter proposed that the revised Policy formalize the interactions between the U.S. Department of Labor (DOL) and the NRC, and the relationship between early ADR and NRC Office of Investigations (OI) investigations.

Response. The revised Policy clearly states that ADR can be used after an OI investigation for discrimination and other wrongdoing cases, and also for discrimination violations based solely on a finding by the U.S. DOL. However, a reference to the Enforcement Manual has been included for further guidance and clarification on the use of ADR.

Comment summary. A commenter stated that the revised Policy should fully integrate the ADR policy in the area of whistleblowers and Severity Levels.

Response. The NRC does not believe that further change to the revised Policy is necessary. Although the NRC normally offers ADR when the NRC issues escalated enforcement actions when discrimination or other wrongdoing is involved, the Policy does not prohibit the use of ADR for SL IV violations. The Policy was revised and references the use of ADR between whistleblowers and the licensee (i.e., early-ADR).

Comment summary. A commenter stated that 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.

Response. The revised Policy has been clarified to state that if parties settle using early-ADR prior to the initiation of an OI investigation, then traditional enforcement will not be utilized for the specific claim of discrimination of the individual. For those issues that are not addressed through ADR, the revised Policy is clear that discretion can be granted if the licensee takes corrective action that addresses both the particular situation and the overall work environment for raising safety concerns.

Comment summary. A commenter stated that to the extent the seemingly broader language of the revised Policy concerning Notices of Enforcement Discretion (NOEDs) may result in less frequent grants of enforcement discretion to licensees under a narrower array of circumstances, the NRC was asked to reconsider such proposed revisions. The commenter noted that no basis or justification is provided for such changes.

Response. The wording and intent of the revised Policy regarding NOEDs is consistent with that in the current Policy. Specifically, an NOED will only be exercised if the NRC staff is clearly satisfied that the action is consistent with protecting the public health and safety.

Comment summary. A commenter advocates the incorporation of enforcement discretion for pandemic situations into the Enforcement Policy.

Response. A decision has not yet been made as to whether NRC will address, in advance, the need for enforcement discretion for pandemic situations for the many types of NRC licensees.

Comment summary. A commenter suggested 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."

Response. The NRC agrees with the comment and has added a clarifying paragraph from the current Policy.

Comment summary. A commenter suggested that that the brief short section on Confirmatory Orders to Individuals be moved and added to the discussion of Alternative Dispute Resolution in Sections 2.4.3 and 3.4.

Response. The purpose of section 4.0 in the revised Policy is to discuss the broader topic of Enforcement Actions Against Individuals. A Confirmatory Order is one such enforcement action and, therefore, is appropriate for discussion in section 4.0.

Comment summary. A commenter stated that severity level definitions, which are intended to convey distinguishing details, would be more useful if some criteria were included to better differentiate a Severity Level I from a Severity Level II violation.

Response. The NRC disagrees with the comment. The revised Policy defines the characteristics of the various severity levels. The NRC believes that these definitions are sufficient and are also consistent with the wording and intent of the current Policy.

Comment summary. A commenter noted that the revised Policy does not define key terms used in the Policy.

Response. The NRC added a clarifying statement to the introduction paragraph to the Glossary which states that the Glossary is not all inclusive and not all terms used in the Policy are defined in Glossary.

Comment summary. A commenter expressed concerned about the level of detail provided in the revised policy and recommended that a less detailed approach be taken by abbreviating the policy to cover key expectations while deferring to the Enforcement Manual for additional detail and guidance.

Response. The NRC has the position that the revised Policy should contain sufficient detail to put forth the Commission's position regarding enforcement of its regulations. The NRC has attempted to remove from the Policy verbiage that could reasonably be considered to be guidance rather than policy. Policy implementing guidance is provided in the Enforcement Manual.

Comment summary. A commenter stated that NRC should not cite a Notice of Violation for any non-reportable compliance problems self-identified and promptly and effectively corrected by the licensee. It would be reasonable for NRC to expect the finding, identification of root cause, and corrective action to be documented by the licensee for future reference. Alternatively, NRC could disposition these as Non-Cited Violations.

Response. The use of Non-Cited Violations as proposed in this comment is already provided for in the Enforcement Policy.

Comment summary. A commenter stated that the Policy needs to provide a process to allow for discussion in advance of the formal issuance of notices of violation. Citation of violations must be based on fact and licensees must be provided the opportunity to provide any additional facts surrounding potential compliance issues during an informal conference at the conclusion of the inspection and/or prior to issuance of a notice of violation. In addition, NRC inspectors must be granted authority to withdraw a notice of violation if the licensee provides adequate information to demonstrate compliance at the time of the informal conference.

Response. The issues raised in this comment are already provided for in the Enforcement Policy (i.e., exit meetings are typically held with the licensee following an NRC inspection and Predecisional Enforcement Conferences are held, prior to issuing a final escalated enforcement action, when additional information is needed by NRC to make an enforcement decision.)

Comment summary. A commenter suggested that NRC consider a voluntary protection type program with accompanying enforcement benefits. For example, after demonstration of a healthy compliant program, such a program would have a reduced frequency of inspections and would have a more liberal enforcement policy for violations.

Response. The NRC does not believe that a change is needed. The level of inspection suggested is outside the scope of the Enforcement Policy. The current policy already provides a more liberal enforcement policy for those licensees that have a fully functioning self-identification and corrective action program.

Comment summary. Commenters noted that the revised policy states the NRC will not take enforcement action against an individual if management's failures are responsible for the individual's improper actions. Commenters suggested that NRC should reconsider this example since it may not be possible to determine whether the individual received adequate training or whether the individual chose not to comply. Commenters also suggested that NRC consider the position and responsibilities of the individual in determining whether or not escalated enforcement is appropriate.

Response. The licensee is ultimately responsible for actions taken by its employees and as such the NRC typically will cite the licensee for all violations at its facilities. The NRC also has discretion to take action directly against an individual and therefore may also issue a violation against an individual for deliberate misconduct. The Revised Policy, in determining whether an action will be taken against an individual, also considers the individual's position within the organization, which is consistent with the guidance in the current Policy.

Comment summary. A commenter stated that Section 2.2.1. (c) refers to licensee failures to notify NRC or receive prior approval for changes in licensed activities as grounds for

a violation. The commenter recommended that the revised Policy provide more objective guidance on what changes are to be considered "significant" and those that are not.

Response. The NRC agrees with this comment. This section has been revised to address this comment.

Comment summary. Commenters requested that NRC provide clarification to exclude material in distribution from consideration as "lost" material and that risk significance should be taken into account when considering the amount of any civil penalty related to lost regulated material.

Response. The details of all cases of lost regulated material are reviewed and considered on a case by case basis. NRC believes that the responsibility for control of material by distributors is clear (i.e., a licensee must maintain control of its material at all times) and no further guidance is needed. Regarding risk significance, the table of civil penalties takes into account the types of and amounts of radioactive material licensed for each group of licensees. In addition, if the licensee can provide documented information of the disposal cost for the material, that documentation could impact the amount of the civil penalty. The Enforcement Manual also discusses the NRC's implementation of the "lost source" Policy and the factors to be considered.

Comment summary. A commenter stated that, in certain instances, a licensee may settle a discrimination complaint which is without merit and or for which it is not necessary or appropriate to address the overall work environment. The commenter suggested that the Policy should clarify that addressing the overall work environment as a predicate to exercise of discretion is not always required.

Response. Section 3.4 of the revised Policy was clarified to state that for the NRC to exercise discretion, the licensee must take corrective actions that address both the particular situation and, if required, the overall work environment.

Comment summary. A commenter noted that in Section 6.7, with respect to Part 70 licensees, the ISAs for the facility should be the criteria referenced.

Response. The NRC disagrees with the comment. Section 6.7, Health Physics, is agency-wide. ISA references are in Section 6.2, Fuel Cycle Operations.

Comment summary. A commenter stated that the revised policy provides an overview but not the detail that would be expected for the Commission to provide the staff in order to have a consistent national policy. The commenter further stated that the revised policy leaves many details to the discretion of the NRC staff to include in the Enforcement Manual which is a staff controlled document.

Response. The NRC agrees with the comment and, as explained in responses to several other comments, has inserted into the revised Policy guidance from the current Policy to add clarity to the revised Policy.

Comment summary. A commenter stated that it would be helpful to understand why the NRC is removing guidance concerning action against individuals, inaccurate and complete information, and the escalated enforcement process from the revised Policy.

Response. The revised Policy condenses and removes some examples of enforcement actions against individuals. It does not remove the overall guidance on individual actions. Section 6.9, Inaccurate and Incomplete Information and Reporting, was added to the revised Policy to provide example violations of incomplete and inaccurate information. For clarity and to better explain the NRC's escalated enforcement policy on certain enforcement issues, language previously not included in the revised Policy from the current Policy has been reinserted in the revised Policy.

Comment summary. A commenter stated that the elimination of the Interim Enforcement Policy for Generally Licensed Devices Containing Byproduct Material is problematic and that it should continue to apply to general licensees who are not subject to the NRC registration program that covers certain generally licensed devices.

Response. The NRC discussed the need to retain the guidance for future cases and concluded that the Enforcement Policy already provides discretion for cases that meet the interim guidance criteria to be handled appropriately on a case by case basis. Since there have been few, if any, cases that would have been influenced by the interim Policy for Generally Licensed Devices Containing Byproduct Material, the NRC does not believe there is a need to retain the Interim Policy for Generally Licensed Devices.

Comment summary. A commenter stated that the term "reporting failures" as used in section 2.2.1 is confusing and recommend the term be changed to "failures to comply with reporting requirements."

Response. The NRC agrees with the comment and has made the recommended change.

Comment summary. A commenter stated that the term "careless disregard of violation of requirements" is too subjective and recommended that violations involving willfulness be limited to deliberate violations.

Response. The NRC disagrees with this recommendation. "Careless disregard" of NRC requirements cannot be tolerated by the NRC. "Careless disregard" is a component of willfulness and is a term that the NRC believes should remain in the Enforcement Policy.

Comment summary. A commenter recommended that the revised Policy be clear on how regulations are enforced when traditional enforcement alone is used and when the SDP is used.

Response. The NRC agrees with the comment and has added clarifying wording to Section 2.2.3.1 and added to the Glossary the definition of "traditional enforcement" as used in the revised Policy.

Comment summary. A commenter noted there is a sentence in Section 2.3.2 regarding non-cited violations(NCVs) which provides examples of when a licensee's written response to an NCV is appropriate. The commenter recommended that the sentence in Section 2.3.2 be revised to include licensee disagreement with the cross cutting aspects that were assigned to the NCV.

Response. The resolution of this comment is outside the scope of the Enforcement Policy. However, the NRC notes that cross-cutting aspects are not assigned to NCV's; rather,

they are assigned to ROP inspection findings in accordance with NRC Inspection Manual Chapter 0305 (IMC 0305). Furthermore, the April 9, 2009, revision to IMC 0305 included a revision to section 13.01 which stated that transmittal letters for inspection reports that contain findings with associated cross-cutting aspects, should request licensees who disagree with the assigned cross-cutting aspect to respond in writing within 30 days of the date of the inspection report and provide the basis for their disagreement to the regional office.

Comment summary. A commenter recommend clarifying cases in which a non-repetitive NRC identified violation can be dispositioned as an NCV.

Response. The NRC agrees with the comment and has revised the section on NCVs to incorporate clarifying wording from the current Policy.

Comment summary. A commenter stated there needs to be some reasonable boundaries on what NRC considers a licensee's "opportunity to identify and correct a violation" and recommend that the word "reasonable" be inserted in the text.

Response. NRC agrees and has inserted the word "reasonable" into Section 2.3.2.3 as recommended.

Comment summary. Regarding the guidance on Immediately Effective Orders issued without prior opportunity for a hearing "whenever the NRC determines that the public health, safety, interest, or common defense and security so requires", a commenter suggested replacing the words "so requires" with "are at risk." The sentence with the suggested change would then read, "Orders are made immediately effective, without prior opportunity for a hearing, whenever the NRC determines that the public health, safety, interest, or common defense and security are at risk."

Response. The NRC disagrees with the comment. The words "so requires" are taken from 10 CFR 2.202(a)(5) which states, in part, that if the Commission finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

Comment summary. A commenter stated that the content of Section 3.9, Enforcement Discretion for Certain Fire Protection Issues (10 CFR 50.48), belongs in guidance, such as an Enforcement Guidance Memorandum (EGM) or an equivalent document.

Response. The NRC has determined that enforcement discretion related to National Fire Protection Association (NFPA) Standard 805 (NFPA 805) is a Policy issue and should be handled as such, rather than as guidance contained in an EGM.

Comment Summary. A commenter noted that there appears to be some reduction in the required notifications by the staff to the Commission for certain enforcement actions or enforcement related situations.

Response. The staff has added to the revised Policy two situations requiring written notification to the Commission listed in the current Policy but which had been inadvertently omitted from the original draft revised Policy.

Comment Summary. A commenter stated that the Policy should address issues involving licensee disclosure of findings [licensee identified violations] and other information [licensee corrective actions] as a result of audits conducted independent of NRC inspections.

Response. The NRC places a premium on licensees identifying and correcting their own violations and believes that the Enforcement Policy already provides appropriate credit for licensees identifying and correcting violations.