

**Analysis of Comments Received on Proposed Changes to Enforcement Policy  
(76 FR 54986, dated September 6, 2011)**

The period for submitting comments on proposed changes to the U.S. Nuclear Regulatory Commission's (NRC's) Enforcement Policy (documented in Volume 76 of the *Federal Register*, page 54,986 (76 FR 54986), on September 6, 2011) expired on October 6, 2011. Comments were received from three external stakeholders and one internal stakeholder within the 30 day comment period. No comments were received after October 6, 2011. Summaries of the comments provided by stakeholders, followed by the NRC's responses to those comments, are provided below. The responses are based on the staff's understanding of the comments and on information available to the staff at the time the response was written. The staff may, if appropriate, reconsider its responses or its proposed changes to the policy if new or additional information becomes available.

1. Comment Summary: A commenter stated that daily civil penalties should be preserved for unique cases of special significance. Providing detailed guidance on the use of daily civil penalties may result in more application of this extraordinary tool. The NRC should be careful not to unnecessarily restrict the broad discretion that it has been given through the Atomic Energy Act of 1954, as amended. At the same time, regular use of this discretion can quickly result in large civil penalties that may cause licensees to focus their attention on litigation rather than on the identification of violations and corrective action.

Response: The staff is proposing this guidance at the direction of the Commission in Staff Requirements Memorandum (SRM)-SECY-09-0190, "Major Revision to NRC Enforcement Policy," dated August 27, 2010. Since the Enforcement Policy currently provides limited guidance on the use of daily civil penalties, the proposed revision is intended to assist the staff in its evaluations of continuing violations of at least moderate significance (i.e., Severity Level III or greater) when daily civil penalties appear to be appropriate.

2. Comment Summary: A commenter recommended that daily civil penalties be available for use in cases involving significant violations for which a strong regulatory message for deterrence is warranted, not just for cases involving deliberate wrongdoing. At a minimum, daily civil penalties should be applied to significant violations that also involve careless disregard and to cases in which the licensee could have prevented the impact of the violation since, with the exercise of reasonable diligence, the licensee should have been aware of the violation.

Response: The staff agrees that careless disregard, not just deliberateness, should be considered when evaluating the appropriateness of issuing daily civil penalties. The staff will propose replacing the word "deliberate" with the word "willful," which encompasses both "deliberate" and "careless disregard."

As the staff proposed in the revision to Section 2.3.4, "Civil Penalty," of the Enforcement Policy, a prerequisite to exercising discretion to assess a daily civil penalty is that the licensee must be aware of the violation and have had a clear opportunity to prevent, identify, and correct the violation but failed to do so. In addition, one of the evaluation factors proposed by the staff is whether the violation resulted in actual consequences to public health and safety (i.e., the impact of the violation).

3. Comment Summary: A commenter stated that given the somewhat detailed proposed policy direction on the use of daily civil penalties, the question becomes, when will a deliberate violation at Severity Level I, II, or III not result in a daily civil penalty? If the Commission does not change the direction it has given to the staff, it is important that the NRC develop for the Enforcement Manual some hypothetical examples of when daily civil penalties might and might not be used. The Commission should approve the examples before they are included in the Enforcement Manual to ensure that the Commission's expectations are met.

Response: The staff does not intend the proposed guidance on the use of daily civil penalties to be all inclusive. In fact, the proposed guidance states, "...the NRC will consider such factors as..." The staff may consider other factors on a case-by-case basis. The staff does not agree that the guidance should also include examples of when daily civil penalties are not appropriate. The staff does not intend the proposed guidance, either in the Enforcement Policy or in the Enforcement Manual, to provide a more comprehensive list of possible scenarios for either the use or nonuse of daily civil penalties.

4. Comment Summary: A commenter recommended that consultation with the Commission should be required [before issuing] a daily civil penalty.

Response: The staff agrees with the recommendation and will add the proposed wording to Section 2.3.10, "Commission Notification and Consultation on Enforcement Actions," of the Enforcement Policy to incorporate the recommendation as another action that will require advanced consultation with the Commission.

5. Comment Summary: A commenter recommended that the NRC develop guidance to differentiate between a violation that lasts one day but has an impact continuing for more than one day and a violation of requirements that continues for more than one day.

Response: The staff disagrees with the comment. Violations are cited, in part, based on the duration of the violation, not on whether the impact of the violation continues after compliance has been restored. However, the significance of the violation is one of the attributes of an enforcement decision.

6. Comment Summary: A commenter stated that allowing daily civil penalties for all violations of at least "moderate" significance is too ambiguous, given the lack of clarity on what constitutes "moderate significance." The NRC provides no definition or guidance concerning this language.

Response: Although the proposed guidance on the use of daily civil penalties does not refer specifically to a Severity Level III violation, the current definition of a Severity Level III violation in Section 2.2.2, "Severity Levels," of the Enforcement Policy uses the words "moderate safety or security consequences," in part, to define a Severity Level III violation. The staff intends to consider daily civil penalties, when appropriate, for Severity Level I, II, and III violations. The staff will revise the proposed wording to clarify this intent.

7. Comment Summary: A commenter stated that the NRC should impose daily civil penalties only in connection with violations that are considerably more egregious than those of moderate significance (i.e., considerably more egregious than a Severity Level III violation). The

commenter proposed that only Severity Level I violations warrant a daily civil penalty. The commenter asked the NRC to provide another opportunity, before finalizing any changes to the Enforcement Policy, for the public to provide input on the issue of severity levels for violations considered for daily civil penalties.

Response: On December 6, 2011, the NRC published a notice in the *Federal Register* (76 FR 76192) soliciting comments on additional proposed changes to the Enforcement Policy. The notice, in part, offered the opportunity for any interested parties to revise their previous comments submitted in response to 76 FR 48919, dated August 9, 2011, and 76 FR 54986, dated September 6, 2011. The staff discussed with the commenter the opportunity offered in the notice dated December 6, 2011, to revise previously submitted comments. The commenter agreed that the opportunity to provide revised comments on this issue when responding to the notice dated December 6 meets the intent of the request.

8. Comment Summary: With regard to the use of daily civil penalties, a commenter suggested that the NRC focus on the time period after the discovery of a violation.

Response: The staff believes that the proposed wording for Section 2.3.4 of the Enforcement Policy addresses the comment. Specifically, the staff's proposed wording states, "The NRC may exercise this discretion when a licensee was aware of a violation..." and "[the NRC will consider such factors as]...the responsiveness of the licensee once the violation and its significance were identified and understood...."

9. Comment Summary: A commenter suggested that the revised Enforcement Policy clarify that none of the daily civil penalty evaluation factors will be applied to impose a daily civil penalty unless the violation in question is a continuing violation of greater than moderate significance, typically a Severity Level I violation.

Response: The staff believes that daily civil penalties should not be limited just to Severity Level I violations but should be considered for all continuing violations of serious, significant, or moderate safety or security consequences (i.e., Severity Level I, II, or III violations).

10. Comment Summary: With regard to the criterion for a noncited violation (NCV) in Enforcement Policy item 2.3.2.a.3, a commenter noted that it is unclear why it is in the public interest that this criterion does not apply to violations associated with green Reactor Oversight Process (ROP) findings. All licensees, including those with reactors, should have every incentive to prevent violations from recurring. The commenter recommended that the agency revise the Enforcement Policy such that item 2.3.2.a.3 would apply to all Severity Level IV reactor violations.

Response: The staff disagrees with the recommendation. For reactors, the NRC does not normally issue a notice of violation for a Severity Level IV violation or green finding unless (1) the licensee fails to restore compliance within a reasonable time after the violation was identified, (2) the licensee fails to place the violation into the corrective action program (CAP) to address recurrence, (3) the violation was willful, or (4) the violation was repetitive as a result of inadequate corrective action, or, if repetitive, the repetitive violation must have been identified by the licensee. The fourth criterion does not apply to violations associated with green significance determination process findings, but it does apply to violations by reactor licensees

evaluated under traditional enforcement. In other words, under the ROP, if a finding associated with a violation is determined to be of very low safety significance, the NRC will treat the violation as an NCV, regardless of the number of times the violation is repeated. (Reference: Section 3.1, “Violations Assessed using the SDP,” of Attachment 5, “Technical Basis for Enforcement,” dated October 16, 2006, to NRC Inspection Manual Chapter 0308, “Reactor Oversight Process (ROP) Basis Document”)

11. Comment Summary: With regard to the NRC criteria in Section 2.3.2.a, “Noncited Violation, Power Reactor Licensees,” of the Enforcement Policy, the commenter recommended that the licensee should be expected to provide the NRC with a file reference showing evidence that the violation has been placed in the CAP.

Response: The NRC already provides such guidance in the Enforcement Manual in Section 2.13.2, “Documenting Non-Cited Violations (NCVs).” Section 2.13.2 provides specific guidance on documenting NCVs and also states that the inspection report should include the licensee’s CAP file reference. Such guidance is also provided in NRC Inspection Manual Chapter 0612, Power Reactor Inspection Reports.

12. Comment Summary: With regard to the NCV criterion in Enforcement Policy item 2.3.2.a.3 (i.e., repetitiveness), a commenter suggested that a notice of violation should not result if, despite the violation’s recurrence, the NRC finds the licensee’s corrective actions for the previous violation to be reasonable.

Response: The staff agrees. However, the agency already provides such guidance in the Enforcement Manual in Section 3.1, “Non-Cited Violations (NCVs)” (e.g., see the note on page 3-8 of the Enforcement Manual).

13. Comment Summary: With regard to Enforcement Policy item 2.3.2.a.3, a commenter recommended that this NCV criterion apply only to repetitive violations identified by the NRC so as to encourage licensee identification and correction of repetitive issues.

Response: The current wording in Enforcement Policy item 2.3.2.a.3 (i.e., “...the repetitive violation must not have been identified by the NRC”) already achieves what the commenter is suggesting—that is, the repetitive violation must be identified by the licensee, not the NRC, in order to meet this NCV criterion.

14. Comment Summary: With regard to credit for fuel cycle licensee CAPs, a commenter asked the NRC to clarify the applicability of these changes to the range of licensees that would be eligible to receive credit for CAPs.

Response: The staff agrees with the recommendation and will add proposed wording to Section 2.3.2, “Noncited Violations,” of the Enforcement Policy to incorporate the comment. The NRC intends to provide NCV credit to all NRC licensees, applicants, and certificate holders for having and maintaining an effective CAP.

15. Comment Summary: With regard to credit for fuel cycle licensee CAPs, a commenter suggested that the NRC should provide additional information on CAP inspection criteria for fuel cycle licensees. The NRC should explain whether these new inspection criteria will be different for the other types of licensees that would fall within the scope of the revised Enforcement Policy Section 2.3.2.a. In addition, it is not clear what entity, if any, “approves” a licensee’s CAP and what form such “approval” would take.

Response: The staff agrees with the comment that the proposed revision to the Enforcement Policy does not provide specific details about the inspection criteria to be used to determine the efficacy of a CAP, nor does it provide details on the form to be employed for documenting approval. The staff will develop this information, with adequate opportunity for input from external stakeholders, during development of the Fuel Cycle Oversight Process.

16. Comment Summary: With regard to the proposed corrective action credit for fuel cycle licensees in Section 2.3.2 of the Enforcement Policy, a commenter noted that it is not clear from the proposed change if the term “all licensees” encompasses current and future waste licensees, including those possessing special nuclear material. Typically, the term “fuel cycle licensees” applies to facilities licensed under 10 CFR Part 40, “Domestic Licensing of Source Material,” and 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.” Waste licensees would include current licensees under 10 CFR Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” and 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste,” and possible future licensees under 10 CFR Part 60, “Disposal of High-Level Radioactive Wastes in Geologic Repositories,” or 10 CFR Part 63, “Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.” NRC regulations require all of these types of waste licensees to have a CAP under their quality assurance program. The commenter suggested that the proposed changes refer to both waste and fuel cycle licensees with a CAP.

Response: The staff agrees with the recommendation and intends to add proposed wording to Section 2.3.2 of the Enforcement Policy to incorporate the comment. The NRC intends to provide credit to all NRC licensees, applicants, and certificate holders for having and maintaining an effective CAP.

17. Comment Summary: With regard to corrective action credit for fuel cycle licensees in Section 2.3.2 of the Enforcement Policy, a commenter noted that gaseous diffusion facilities regulated by the NRC under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants,” are not “licensees” but, instead, are considered “certificate holders.” They also have a CAP. Therefore, fuel cycle certificate holders should also be able to take advantage of the proposed NCV credit provisions. The commenter suggested that the proposed changes refer to “fuel cycle certificate holders with a CAP.”

Response: The staff agrees with the recommendation and will add proposed wording to Section 2.3.2 of the Enforcement Policy to incorporate the comment. The NRC intends to provide credit to all NRC licensees, applicants, and certificate holders for having and maintaining an effective CAP.

18. Comment Summary: With regard to issuing civil penalties to individuals who release Safeguards Information (SGI), a commenter recommended that the NRC consider applying civil penalties for the willful, not just deliberate, release of SGI to serve as a deterrent. Furthermore, the commenter suggested that the civil penalty should not necessarily depend on the employer's initial action.

Response: The NRC already provides such guidance in the Enforcement Policy. Section 4.0, "Enforcement Actions Involving Individuals," and Section 4.3, "Civil Penalties to Individuals," of the Enforcement Policy provide specific guidance that the NRC may impose enforcement actions, including civil penalties, on "any person" who violates any requirement directly imposed on him or her, which would include both nonwillful and willful acts. Furthermore, since it is NRC policy to hold licensees responsible for the acts of their employees and contractors, it is appropriate for NRC to consider the employer's corrective actions in evaluating whether enforcement action should be taken against the employer.

19. Comment Summary: With regard to guidance on the use of civil penalties for violations involving the release of SGI, a commenter noted that although the proposed text refers to corresponding changes to Table A in Section 8.0, "Table of Base Civil Penalties," of the Enforcement Policy, the *Federal Register* notice does not include any such changes to Table A.

Response: As indicated in the *Federal Register* notice, the staff is proposing a base civil penalty in the amount of \$3,500 for individuals who release SGI. The staff will also propose the addition to Table A of a new category (i.e., category g, "Release of Safeguards Information by Individuals"), with a base civil penalty of \$3,500.

20. Comment Summary: A commenter noted that proposed new guidance in Section 4.3.1, "Individual Civil Penalty for Release of Safeguards Information Violations," of the Enforcement Policy references examples of violations in Section 6.13, "Information Security," that the NRC may use in determining the severity level of violations involving the release of SGI, but the guidance does not explain the interplay between these sections. The commenter suggested that the NRC discuss why the existing examples of violations in Section 6.13 should be considered analogous.

Response: The staff does not believe that further explanation in the proposed text is necessary. The reference to Section 6.13 merely points out that Section 6.13 provides examples of the severity level of violations, including examples regarding SGI violations, which the staff uses in the severity level determination process. After it determines the appropriate severity level, the staff evaluates the violation in accordance with the Enforcement Policy's civil penalty assessment process to determine whether a civil penalty is appropriate.

21. Comment Summary: With regard to the guidance on use of civil penalties for violations involving the release of SGI, a commenter suggested that the staff provide more detail as to how the NRC will use the evaluation factors. Furthermore, the commenter stated that, for example, it is important for the industry to understand whether the new criteria in Section 4.3.1 of the Enforcement Policy could be applied in a manner that could change the current delineations between the severity levels of violations.

Response: Releases of SGI have varying degrees of significance or severity. Circumstances surrounding the release, the type of information released, and the vulnerability that the disclosure created in terms of public health and safety are all important factors when determining the severity level of the violation. The NRC has two processes to inform its decisions on how to appropriately categorize the significance or severity of the violation using the factors known (i.e., the ROP and traditional enforcement, which utilizes the violation examples in Section 6.0). Neither process is exhaustive or controlling for making significance or severity level determinations. The NRC evaluates all known factors before making a final enforcement determination. The staff believes that the new criteria in Section 4.3.1 would not change the current delineations between the existing severity levels but would strengthen the review process that is needed to determine the severity level.

22. Comment Summary: With regard to guidance on the use of civil penalties for violations involving the release of SGI, a commenter noted that it is unclear whether the NRC intends the proposed revision to apply to Safeguards Information—Modified Handling (SGI-M), which has less restrictive handling requirements than SGI. The commenter suggested that the NRC clarify the applicability of the guidance to violations involving SGI-M.

Response: The regulation at Title 10 of the *Code of Federal Regulations* (10 CFR) 73.21, “Protection of Safeguards Information: Performance Requirements,” specifically addresses SGI-M. Furthermore, SGI-M has essentially the same requirements as SGI, and those requirements also apply to any person. However, to ensure clarity, the staff will revise the proposed wording to include SGI-M.

23. Comment Summary: With regard to the new proposed Section 4.3.1, a commenter noted that NRC certificate holders under 10 CFR Part 72 and 10 CFR Part 76 can also possess SGI. Furthermore, applicants for a license or a certificate of compliance can also possess SGI (under various parts of 10 CFR Chapter 1). Therefore, referring to “licensees” alone is insufficient. The commenter suggested that the proposed change refer to “licensees, certificate holders, applicants for a license or a certificate of compliance, or their contractors.”

Response: The staff agrees with the comment and intends to add these entities (i.e., certificate holders and applicants) to the proposed language as stated in the applicability section of 10 CFR 73.21.

24. Comment Summary: With regard to civil penalties for individuals who disclose SGI, a commenter noted that the proposed revision to Section 6.13 of the Enforcement Policy refers only to “licensees.” The commenter recommended that Section 6.13 refer to both licenses and certificate holders.

Response: The *Federal Register* notice merely points out that Section 6.13 provides examples to assist the staff in determining the appropriate severity level of a violation involving SGI. The staff is not proposing any revisions to Section 6.13. The term “licensee” is used broadly in the context of this statement in the notice when discussing severity level and significance determination and is intended to include all entities to which the policy applies (see Section 1.2, “Applicability,” of the Enforcement Policy).

25. Comment Summary: With regard to the proposed examples of violations in Section 6.15, “Export and Import Activities,” of the Enforcement Policy, a commenter noted that several of the proposed notification requirements relating to 10 CFR Part 110, “Export and Import of Nuclear Equipment and Material,” appear to be outside of the control of the NRC licensee, and that the agency does not provide guidance on this subject. The commenter suggested that the NRC conduct a public meeting to discuss with stakeholders, including the industry, aspects of these new provisions for which implementation guidance may be needed.

Response: The staff has scheduled a public meeting for January 24, 2012, to discuss the commenter’s concerns.

26. Comment Summary: A commenter expressed concern about the proposed severity levels for proposed violation examples 6.15.b.1 and 6.15.c.1 involving the notification of imports. The commenter stated that industry experience indicates that occasions arise in which an overseas shipment of a quantity under Appendix P, “Category 1 and 2 Radioactive Material,” to 10 CFR Part 110 will occur without any prior notification, and the licensee is unaware of the shipment until the package has arrived and is awaiting clearance in customs.

Response: In 2005, the NRC amended its regulations in 10 CFR Part 110 to implement requirements consistent with the International Atomic Energy Agency’s “Code of Conduct on the Safety and Security of Radioactive Sources,” issued January 2004, and its supplement, “Guidance on the Import and Export of Radioactive Sources,” issued March 2005. This rulemaking, in part, implemented new specific import and export licensing and preshipment notification requirements for Category 1 and Category 2 quantities of radioactive materials listed in Appendix P to 10 CFR Part 110. In 2010, the NRC amended 10 CFR Part 110 to remove the specific import license requirement, authorize imports of Category 1 and 2 quantities of radioactive material under a general license, and require advance notifications of imports to be submitted 7 days in advance of shipment, instead of 24 hours as required under the 2005 rule. As explained in the proposed rule, this change gives the NRC staff adequate time to verify the information provided in the advance notification to support imports under a general license rather than under a specific import license. The NRC staff understands the licensee concerns and has noted improved timeliness in import notifications as importers have reached out to their international customers to enhance communications. The NRC enforcement process takes into consideration circumstances such as those noted in the comment that are beyond a licensee’s control.

27. Comment Summary: With regard to the proposed examples of violations for the export and import of regulated material, a commenter noted that the proposed revisions imply that for exports under the general license in 10 CFR 110.23, “General License for the Export of Byproduct Material,” licensees need to have a copy of the ultimate consignee’s license. Under 10 CFR 110.23, licensees export to distributors who then distribute to the ultimate consignee. The commenter suggested that the NRC clarify the applicability of this guidance.

Response: The staff agrees with the comment and will delete proposed violation example 6.15.d.3.

28. Comment Summary: With regard to the proposed examples of violations in Section 6.15 of the Enforcement Policy, a commenter noted that the NRC gives no clear definition of “ultimate consignee.” Licensees exporting under a specific license may ship to distributors who are considered to be the ultimate consignee, and subsequently the distributor may ship to a final end user. The commenter suggested that the NRC address this scenario in implementing guidance.

Response: The requirements to identify “intermediate and ultimate consignees” and “end use” in applying for a specific license are highlighted in 10 CFR 110.32, “Information Required in an Application for a Specific License/NRC Form 7.” Foreign distributors in certain countries are considered ultimate consignees if the final end user is not known. They could also be an intermediate consignee if the ultimate consignee is known. In either case, the licensed recipient needs to be identified on a preshipment notification, and the Category 1 or 2 items should be added to that country’s source tracking system upon their receipt. It is incumbent on U.S. exporters to determine that a distributor or the actual end user is legitimate and appropriately authorized by the regulator to receive and possess the material.

29. Comment Summary: With regard to the proposed violation examples in Section 6.15 of the Enforcement Policy, a commenter noted that the proposed examples appear to mix terminology. Specifically, violation examples 6.15.a.2 and 6.15.c.3 use the term “quantities of concern,” while examples 6.15.b.1 and 6.15.c.1 use the term “10 CFR Part 110, Appendix P.” The commenter suggested that consistent terminology be used.

Response: The NRC staff agrees with the comment as it pertains to example 6.15.c.3 and intends to modify the proposed language as follows: “6.15.c.3—Export of byproduct material identified in 10 CFR Part 110, Appendix P, to individuals/entities not authorized to receive such materials.”

The term “materials in quantities of concern” in example 6.15.a.2 is used in a more generic sense to refer to any nuclear materials of concern; the emphasis of this violation example is the “deliberate misrepresentation of facts that led to unauthorized individuals obtaining...” nuclear materials.

30. Comment Summary: With regard to the proposed violation examples in Section 6.15 of the Enforcement Policy, a commenter recommended that example 6.15.d.3 be revised to read as follows: “Export of 10 CFR part 110, Appendix P, byproduct material exceeding the possession limits authorized for the ultimate consignee, not involving a Severity Level I, II, or III violation....” The commenter further suggested that NRC either include violation examples under Severity Levels I, II, and III or remove this language. Additionally, the commenter noted that the intended distinction between examples 6.15.c.4 and 6.15.d.5 is unclear. The commenter questioned the intent of the wording “not involving a Severity Level I, II, or III violation” in example 6.15.d.5. The commenter suggested that the NRC clarify the intended distinction. The commenter also suggested that the NRC include examples of when a failure to obtain a specific license would result in a Severity Level I or II violation.

Response: The staff agrees with the comments and intends to delete violation examples 6.15.d.3 and 6.15.d.5. The staff will revise example 6.15.d.4 to read “Unauthorized export of foreign-obligated material or equipment in violation of 10 CFR 110.50(b)(3) requirements.”

31. Comment Summary: With regard to the proposed violation examples in Section 6.15, a commenter noted that the examples of violations involving incomplete or inaccurate information appear to be inconsistent with Section 6.9, “Inaccurate and Incomplete Information or Failure to Make a Required Report,” of the existing Enforcement Policy. The commenter suggested that the NRC review these sections, modify the violation examples as appropriate, and provide guidance on this point.

Response: The staff agrees with the comment and intends to modify violation example 6.15.b.3 to read as follows:

Inaccurate or incomplete information provided or maintained that led to unauthorized individuals possessing radioactive materials. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to terminate or deny a license, to issue an Order requiring suspension or cessation of licensed activity, or efforts to block an export or import, to protect the public health and safety or common defense and security.

32. Comment Summary: With regard to the proposed violation examples in Section 6.15 of the Enforcement Policy, a commenter noted that Severity Level III violation example 6.15.c.1 is excessive in that the exporting licensee may not have given the importing licensee sufficient time to make the notification in a timely manner. In some cases, the importing licensee receives no forewarning of an impending import.

Response: The staff agrees with the comment and intends to modify the example to read “Failure to submit timely notification of the import of 10 CFR Part 110, Appendix P, material, as required by 10 CFR 110.50, where, if this information had been available and provided, it would likely have caused the NRC to take further action or inquiry.”

33. Comment Summary: With regard to the proposed violation examples in Section 6.15 of the Enforcement Policy, a commenter noted that Severity Level IV violation example 6.15.d.3 should be limited to exports conducted under a specific export license. Exports conducted under the general export license provided in 10 CFR 110.23 are often sent to a distributor who then transfers the material to the ultimate consignee; the NRC or Agreement State licensee may never know the identity of the ultimate consignee. Additionally, current regulations do not require that the exporting licensee verify the ultimate consignees’ possession limit when transferring radioactive materials under the 10 CFR 110.23 general export license (refer to 10 CFR 30.42(b)(6)).

Response: The staff agrees with the comment and intends to delete violation example 6.15.d.3.

34. Comment Summary: With regard to civil penalties for loss of control of radioactive material (Section 2.3.4, “Civil Penalty,” of the Enforcement Policy), a commenter noted that it is unclear whether a temporarily missing package in the transportation cycle qualifies as loss of control. If so, it is unclear whether the shipper or the carrier is responsible. To eliminate this ambiguity, the commenter suggested that the NRC address this question in the final version of the Enforcement Policy revision.

Response: The staff believes that the lost source policy (LSP) applies to sources in transport. Determination of the responsible party may depend on the circumstances that led to the loss of control. Additional guidance is currently available in the Enforcement Manual, Section 8.2.1, “Memorandum of Understanding (MOU) Between NRC and DOT [Department of Transportation].” As described in Section 8.2.1, in situations involving transportation, the NRC coordinates with DOT in accordance with the MOU between the two agencies (<http://www.nrc.gov/reading-rm/doc-collections/memo-understanding/>). Each agency has its own inspection and enforcement programs within its jurisdiction to ensure compliance with its requirements. DOT and the NRC will consult with each other on the results of their respective inspections in the areas where the results are related to the other agency’s requirements. Each agency will take enforcement action, within the limits of its authority, as it believes appropriate. The Enforcement Policy permits the NRC to consider the merits of a specific case.

35. Comment Summary: With regard to civil penalties for loss of control of radioactive material (Section 2.3.4 of the Enforcement Policy), a commenter suggested that the reference to “regulated source material” be replaced with the phrase “regulated sealed sources or devices containing radioactive material” to more accurately reflect what the commenter believes to be the NRC’s intent. Additionally, the commenter suggested that the NRC consider changing the title of the LSP.

Response: The staff agrees with not using the phrase “regulated source material” since the LSP applies to byproduct, source, and special nuclear material, but disagrees with the suggested replacement wording since the LSP was expanded (through the Enforcement Policy revision in September 2010) to include all forms of radioactive material and no longer focus solely on sealed sources. The paragraph in the Enforcement Policy that defines LSP (Section 7.0, “Glossary”) includes the following phrase: “...regardless of the use, license type, quantity, or type of regulated material...” This wording does not limit the LSP to source material or sealed sources or devices containing radioactive material. Consequently, to keep the terminology consistent, the staff will replace the phrase “regulated source material” with “regulated material.”

36. Comment Summary: With regard to civil penalties for loss of control of radioactive material (Section 2.3.4 of the Enforcement Policy), a commenter noted that the Commission’s direction in SRM-SECY-09-0190 was for the revised policy to “avoid any impression that the CP [civil penalty] will be assessed without regard to the circumstances surrounding the violation.” In the commenter’s view, the proposed revision to the definition of LSP does not fully reflect this aspect of the Commission’s instructions. The commenter noted that the new language suggests that the NRC may impose a civil penalty “regardless of the use, license type, quantity or type of regulated material.”

Response: As noted in the response to the above comment, the NRC expanded the LSP definition in September 2010 to include all forms of regulated material. The LSP definition allows application of the policy to all regulated material. Section 2.3.4 provides more specific direction regarding the application of the policy and the factors to be considered in its application, including escalation and mitigation. The Commission’s direction was to assess the risk associated with the actual loss. The form of the material is one aspect of this risk and should be included in the staff’s assessment. The assessment should also consider other factors, such as length of time the material is missing, the accessibility of the missing material to the public, and source strength.

The revised paragraph reflects the Commission’s direction to “avoid any impression that the CP will be assessed without regard to the circumstances surrounding the violation” as follows: “However, the agency may **mitigate** or escalate a civil penalty amount based on the merits of a specific case” [emphasis added].

As described in the *Federal Register* notice, the Enforcement Policy permits the NRC to consider the merits of a specific case when determining the amount of a civil penalty. Therefore, the intent is to maintain the existing LSP to issue at least a civil penalty, while giving the staff flexibility in dispositioning those cases in which a licensee lost NRC-regulated material, but took immediate action to recover it promptly, with little or no risk to the public while the material was not in the licensee’s control. In such cases, where loss of control is the issue, rather than actual lost material, the NRC would use the normal civil penalty assessment process, described in Section 2.3.4 of the Enforcement Policy, rather than typically issuing at least a base civil penalty as required by the current LSP.

37. Comment Summary: A commenter suggested that the definition of “lost source policy” in Section 7.0 of the Enforcement Policy be revised to read as follows:

**Policy on Loss of Control of Regulated Sealed Sources or Devices (formerly Lost Source Policy)** is the policy of the NRC in which a civil penalty may be issued for violations resulting from regulated sealed sources or devices containing radioactive material being out of the control of the licensee, regardless of the use, license type, quantity, or type of regulated material (e.g., loss, abandonment, improper transfer, or improper disposal of regulated material). Alternatively, NRC may exercise its discretion and decline to issue a civil penalty or take no enforcement action in such situations.

Response: The staff disagrees. As explained in responses above, the current LSP definition allows application of the policy to all regulated material. Section 2.3.4 of the Enforcement Policy provides more specific direction regarding the application of the policy and the factors to be considered in its application, including escalation and mitigation. The staff’s proposed changes to Section 2.3.4 clarify that the LSP no longer focuses solely on sealed sources or devices and that the policy includes the use of discretion based on consideration of the specific situation.