

**Response to Public Comments on Draft Regulatory Guide (DG)-3044
“Corrective Action Programs for Fuel Cycle Facilities”
Proposed Revision 0 of Regulatory Guide (RG) 3.75**

On February 12, 2014, the NRC published a notice in the *Federal Register* (79 FR 8511) that Draft Regulatory Guide, DG-3044 (Proposed Revision 0 of RG 3.75), was available for public comment. The public comment period ended on March 14, 2014. The NRC received only one comment submission, from the Nuclear Energy Institute (NEI). The following table presents the NEI comments and the NRC staff responses.

Comments were received from the following:

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General	During the April 2013 meeting, industry offered an alternative to the resource- and time-intensive license amendment process described in the earlier version of this guidance, i.e., Draft NUREG-2154. We are pleased that NRC considered the alternative and modified the guidance to streamline the process whereby a licensee may submit a license amendment committing to the RG, and stating its readiness for an NRC review of its CAP without submitting extensive, detailed information to NRC in advance of an NRC program review. The revised process represents a more efficient means to meet the intended goal.	No response necessary
General	Last April, we also suggested that NRC convert the Draft NUREG into a RG since a RG is typically the primary source of comprehensive information for licensees and	No response necessary

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	<p>applicants filing for an NRC license or requesting a licensing action. We are pleased that NRC agreed with this suggestion and converted the document to RG. This will allow licensees and applicants to commit to the RG via a license amendment thus reducing the time and resources for both NRC and industry.</p>	
C	<p>NRC states that when a licensee commits to this section of the RG, the licensee is committing to treat all “should” statements as “shall.” Industry disagrees with this prescriptive, non-performance based approach. Rather, as stated in Section D of this document and by NRC staff on numerous occasions, a RG provides <u>one</u> method by which a licensee may demonstrate compliance and alternative methods to demonstrate compliance may be deemed acceptable by NRC. Therefore, this statement should be deleted from the RG.</p>	<p>The NRC staff did not agree with this comment and did not delete this statement because it emphasizes the meaning of the commitment to this RG and provides clarity and regulatory stability to ensure the consistent implementation of the RG provisions for licensees who choose to commit to the RG. If this statement were deleted and the commitment to this RG is added as a license condition, the interpretation may be that even though the commitment to the RG is a license condition (i.e., an obligation), the RG describes the commitment as "should" statements. Therefore, licensees may treat the commitment as guidance/recommendation. As provided in Sections B and D of this RG, licensees can describe an alternate CAP in a license amendment request that meets the guidance in this RG for the purpose of applying Section 2.3.2 of the NRC Enforcement Policy. If a licensee chooses an alternative to the RG (i.e., providing an amendment request describing its CAP for NRC review), the NRC staff will verify that the submittal describes an adequate CAP and does so through use of definitive license commitments that use terms such as “will” and “shall” rather than “may” or “should”. No changes were made to the RG due to this comment.</p>
C Item 1.a	<p>Industry commented on Draft NUREG-2154 that the term “independence” or “independent” needed to be clarified. Specifically, we suggested that a performance-based approach be taken when defining this term so that</p>	<p>The NRC staff acknowledges that it did not specifically respond to industry's comment on draft NUREG-2154, but agreed with the comment. Both draft NUREG-2154 and DG-3044 identified that the independent reviewing</p>

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	<p>regardless of what group, person, organization, or consultant etc., performs the necessary review of the CAP, the person(s) has the experience and expertise to conduct such comprehensive reviews and, in some cases, make technical judgments on the information at hand and the adequacy of the CAP processes used. No modifications to the text were made in DG-3044 and this comment is not contained in the Draft NUREG-2154 comment resolution summary table dated August 2013. Therefore, it is not clear whether the staff considered this comment. If not, we respectfully request that the staff do so.</p>	<p>organization needs to be auditable and independent of the licensee’s production organization. Thus, “independent” is used to indicate independence, or separation, from cost and schedule concerns that may be associated with the production function. The language in the draft NUREG and DG further clarified the terms "independence" and "independent" by stating that the independent review duties may be assigned to an existing part of the licensee's organization provided that the designation is described in the CAP and the organization or individuals are sufficiently independent, trained, and able to meet the guidance in the RG. The description of the term "independent" is further clarified by the language in the draft NUREG and DG that states that the independent reviewing organization needs to be afforded sufficient authority, access to work areas, and organizational independence to perform its responsibilities. Thus, these are all attributes of the terms "independence" and "independent". This language has been maintained in RG 3.75.</p> <p>To provide further clarification in response to the comment, the RG was revised to identify that even though the RG states that the independent review duties may be assigned to an existing licensee organization, that existing organization can have a consultant perform the duties provided that the overall responsibility for the CAP resides with the existing licensee organization. Language was added to item 1.a to reflect the use of consultants in this capacity.</p> <p>The staff believes that the combination of the existing guidance and the added text provides a clear representation of the requirements for independence in</p>

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		CAP functions.
C, item 2.b.ii (first)	<p>The regulatory basis for the statement that a nonconformance is a failure to meet a <u>contract</u> requirement is not clear. A contract has many requirements that have no relation to the item's safety or security attributes. To call out this as a nonconformance in the context of a CAP process is not warranted.</p>	<p>The NRC staff agreed with the comment in that a failure to meet a contractual requirement may or may not affect the availability or reliability of an item relied on for safety since contractual requirements may go beyond those attributes required for proper function and performance of an item. As such, the staff revised the definition of nonconformance to be consistent with industry practice on corrective action programs and to identify that a nonconformance can render the safety and security attributes of an item or activity unacceptable or indeterminate. This provides the appropriate clarification to the term nonconformance and provides a clear correlation that a nonconformance is a condition adverse to safety and security which is warranted to be included in the CAP.</p>
C, item 2.b.ii (second)	<p>The current wording regarding adverse conditions is much broader and more prescriptive than either the current language in 10 CFR Part 50, Appendix B or 10 CFR Part 71, section 71.133. Specifically, both 10 CFR Parts read, "conditions adverse to quality (safety or security), such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected." Further, in an August 2011 document on attributes of an effective CAP, the following language was proposed to address this issue:</p> <p>The CAP policies, programs and/or procedures ensure that:</p> <ol style="list-style-type: none"> 1. Employees are informed and aware of the requirement to identify and report safety and security issues, including regulatory compliance issues, related to a variety topics 	<p>The NRC staff agreed in part with the comment, and modified the language to be consistent with Appendix B to 10 CFR Part 50. Specifically, the staff agreed that the definition could be refined to align the prescriptiveness and scope with existing regulatory requirements related to quality assurance and corrective action programs. As such, the staff deleted the term "proceses that are outside their control parameters" from the definition to better align it with cited references and to prevent the definition from being overly prescriptive or difficult to understand and implement. The staff added "deviations" to the definition to align it with the cited references.</p> <p>The staff did not use industry's proposed language because it focusd on "regulatory compliance issues" and the some portions of the proposed language (i.e., "and similar activities or conditions...") are vague and would</p>

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	<p>and areas including human performance, facility and equipment conditions, programs and procedures, administrative and regulatory limit exceedances, and similar activities or conditions that have potential or actual safety and security consequences.</p> <p>Industry suggests that, for additional clarity, NRC either rely on the 2011 proposed language (preferred) or existing Parts 50 and 71 language to address this issue.</p>	not lead to consistent implementation.
C, item 2.b.ii (third)	<p>The terms “causal analysis,” “in writing,” and “out of control process” were deleted. However, the phrase “processes outside their control parameters” was added in Section C.2(b)(ii). It should be noted that product or quality specifications usually dictate “control parameters,” and exceeding one of them is less significant than having an out of control process and most likely would not be related to a safety or security issue. Therefore, industry suggests that NRC either use comparable language found in Part 50, Appendix B or Part 71, section 71.133 or, alternatively, delete this newly introduced phrase in its entirety to avoid confusion.</p>	The NRC staff agreed with the comment, as described in the response to the above comment, and deleted the phrase “processes outside their control paramaters” as part of making the language in Section C, item 2.b.ii consistent with the language with Appendix B to 10 CFR Part 50.
C, item 2.b.ii (fourth)	<p>Industry suggested that the terms “prompt” and “nonconformance” be defined. NRC offers the following definitions and industry suggests edits as indicated below:</p> <p>Nonconformance - A failure to meet a contract requirement related to NRC activities <u>safety and security attributes to meet an NRC commitment</u> (e.g., a failure to meet the specifications included in a procurement document). The word “activities” is too broad in this context. The example in the parenthetical should be deleted since it is too prescriptive and adds no value to the definition. It should be recognized that: 1) based on the</p>	The staff agreed in part with the comment. In response to a comment described above, the staff redefined the term “nonconformance” to be consistent with industry practices on corrective action programs. The revised definition identifies that a nonconformance is a deficiency in characteristic, documentation, or procedure that renders the safety and security attributes of an item or activity unacceptable or indeterminate. This incorporates industry’s comment, in part, but retains mention of items and activities because both items and activities may be designated as items relied on for safety in accordance with 10 CFR Part 70.

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	licensee’s determination, non-conformances may or may not be significant in terms of safety or security; and 2) licensees must meet many other requirements that are outside NRC’s jurisdiction.	Resolution of NEI comments regarding the term “promptly” is described below.
C, item 2.d	We are pleased that DG-3044 addresses several of industry’s comments such as: The guide was modified to acknowledge that, when documenting security-related events in the CAP database, the CAP might need to simply reference where the information is stored and available for review.	No response necessary
C, item 3.a	<p>Industry suggested that the terms “prompt” and “nonconformance” be defined. NRC offers the following definitions and industry suggests edits as indicated below:</p> <p>Prompt - performed or executed without delay, in a turnaround commensurate with an issue’s significance, and in as brief a time period as is reasonably achievable. Industry suggests that “without delay” be deleted since it could be subject to interpretation during inspection and NRC’s intent appears to be stated in the last phrase of the definition.</p>	The NRC staff agreed with the industry’s comment because “without delay” could be subject to interpretation and is not needed in order to ensure timely response due to the other language provided in the statement related to performing actions in a turnaround commensurate with the issue’s significance and in as brief a time period as reasonably achievable. The NRC staff made the suggested change as recommended.
C, item 3.d	The language implies that the CAP include a process for reporting issues to NRC when required and, potentially, any issue which is reportable to NRC must be administered by the CAP. Industry disagrees with this premise since the CAP can be a source of input to a reporting procedure or protocol but the CAP does not assure required reporting.	The NRC staff agreed with the comment in part. The CAP is the process for identifying, documenting, and correcting conditions adverse to safety and security. As stated in the comment, the CAP can be a source of input to a reporting procedure or protocol for situations in which reporting to the NRC is warranted. The identifying and documenting parts of the CAP should include screening of issues. One of the screening questions should include whether the issue is reportable to the NRC. If an issue is reportable, the CAP should ensure that the issue is reported to the NRC when required. Licensees may choose how the reporting is accomplished (i.e.,

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		<p>procedure, protocol, etc.), but the overall responsibility for screening the issue to determine whether it is reportable should reside in the CAP or be in a process that correlates to the CAP. An effective CAP is also responsible for reporting safety and security issues (i.e. conditions adverse to safety and security) in a manner that supports the timely and effective assessment and correction of the issues. In some cases, this may require reporting to the NRC in order to not only meet regulatory requirements, but also to enable NRC assessment of the issue and potential oversight. In cases where the CAP is not the repository for guidance related to the reporting of conditions, the CAP should ensure that reports are made as needed and that necessary corrective actions are taken. The RG was clarified to better describe the relationship between the CAP and reporting conditions to the NRC, and now states that “The CAP should include a process for tracking and trending of issues and should ensure the reporting of these issues to the NRC when required.”</p>
C, item 4.b.2	<p>Two edits in italics [and underlined] are suggested to read as follows: (2) the extent of condition.....other items, <i>conditions</i>, and activities including <i>activities</i> work in progress.....be taken.</p>	<p>The NRC staff agreed with industry’s comment and made the suggested changes. The changes provide an increased level of clarity in the statement, which now reads “For significant conditions adverse to safety and security, the CAP should include measures to ensure that: ...2) the extent of condition and cause is evaluated, including assessing the extent to which other items, conditions, and activities, including activities in progress, may be affected so that appropriate action can be taken.”</p>
C, item 5.b	<p>Add the words “or management” after resolution.</p>	<p>The staff disagreed with the edit because it adds ambiguity since it implies that issues may not be resolved (i.e., managed) and, therefore, the issues being “managed” would remain in the CAP without resolution. No changes were made to the RG due to this comment.</p>

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Appendix D	<p>Several examples in D-2 are overly broad and, from industry’s perspective, not representative of the “significant condition” level. Specifically, industry suggests that bullets 2–5 be removed from section D-2 and moved to a new section D-3 entitled, “Classification of Other Conditions Adverse to Safety and Security.” Additionally, CASS examples should be added for completeness since SCASS examples are provided.</p>	<p>The NRC staff disagreed with the creation of a new section D-3 because the “other” category of conditions adverse to safety and security would be inconsistent with current industry CAP practices (i.e., how conditions to safety and security are classified (significant and non-significant)). Also, the NRC staff disagreed with industry’s determination that bullets 2-5 are not representative of the “significant condition” level as explained below:</p> <p>2nd and 3rd bullets – anything that requires <u>substantial</u> repairs, rework, or replacement should be evaluated to determine if it is a significant condition.</p> <p>4th bullet – if the software is released for use the non-conservative error could create a substantial safety hazard; therefore, it may be a significant condition.</p> <p>5th bullet – anything that is repetitive should be evaluated to determine if it is a significant condition.</p> <p>The staff notes that the list in Section D-2 of the RG provides examples of conditions that may be significant in terms of safety and security. The licensee should apply its CAP elements to evaluate conditions and determine their significance.</p> <p>The staff disagreed with adding the examples of conditions adverse to safety and security (CASS) because the definition of condition adverse to safety and security provides sufficient information for licensees to determine what is a condition adverse to safety and security.</p> <p>No changes were made to the RG due to this comment.</p>

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Regulatory Analysis	<p>The draft Regulatory Analysis which accompanied DG-3044 is deficient in its scope, level of detail, and the statement regarding expected cost savings. Industry disagrees with the conclusion that development of an NRC-approved CAP for disposition of certain violations would yield cost savings for the industry. Quite the contrary is true when one considers the potential costs associated with CAP enhancements to meet NRC's expectations, NRC qualification inspections and reviews, and ongoing NRC inspections as part of program maintenance versus the costs associated with the very low number of Severity Level IV violations cited annually.</p>	<p>The NRC staff agreed with the comment because the benefits of CAP development may not be primarily associated with cost savings and may be difficult to quantify in monetary terms. No changes were made to the RG due to this comment. However, the staff revised the regulatory analysis to focus on the safety and security improvements due to the implementation of an adequate CAP instead of the cost savings.</p>