

**Summary of Public Comments Received on Proposed Revisions
to 10 CFR Parts 50 and 52
Enhancements to Emergency Preparedness Regulations**

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Office of Nuclear Security and Incident Response

[Insert Date]

**THIS DOCUMENT PREPARED FOR PUBLIC
COMMENTS RECEIVED ON THE PROPOSED RULE AND ALL OF THE
SUPPORTING GUIDANCE DOCUMENTS. AN OFFICIAL COPY IS
BEING PREPARED TO SUPPORT THE FINAL RULEMAKING. THE
EXCERPT IS PROVIDED HERE IN ADVANCE OF THE RULEMAKING
TO ADDRESS THE CHANGES IN GOING FROM THE DRAFT GUIDE TO
THE FINAL GUIDE IN SUPPORT OF THE CONCURRENCE PROCESS
ON THE FINAL GUIDE RG-1.219.**

4.5 Amended Emergency Plan Change Process

4.5.1 10 CFR 50.54(q): Amended Emergency Plan Change Process

4.5.3 DG-1237: Draft Regulatory Guide – Amended Emergency Plan Change Process

General Comments on the Draft Regulatory Guide

Comments: One commenter noted that the NRC is prematurely requesting comments on DG-1237 given that the proposed rule language is subject to comment. [0089]

NRC Response: The NRC disagrees with the commenter. The NRC has adopted the policy that, whenever possible, guidance documents that support a proposed rulemaking should be available for public comment at the time that the proposed rule is published for public comment, as was done in the current proceeding (see SRM-SECY-07-0134 – “Evaluation of the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan,” dated October 25, 2007, ML072980427). Stakeholders have explained to the NRC that they cannot fully evaluate a proposed rule if the supporting guidance that the NRC will use to evaluate licensee compliance with the rule is not available for review. No change was made to the guidance document in response to this comment.

Comment: Two commenters argued that an additional comment period is necessary to evaluate the draft Regulatory Guide against the finalized rule language. [0089, 0102]

NRC Response: The NRC disagrees with the commenters. As noted in the responses to comments on the proposed rule, the NRC disagreed with a majority of the substantive comments on 10 CFR 50.54(q) of the proposed rule. As such, the changes being incorporated into the final guide do not constitute a substantive revision from the draft guide. Accordingly, no additional review period is warranted. Further, the NRC process provides for only one comment period during the development of a regulatory guide. No change was made to the guidance document in response to this comment.

Comment: A commenter stated that the NRC’s use of examples throughout the document is problematic. The commenter suggested that the examples convey a standard of acceptance for making changes that actually varies from one licensee to another. [0089]

NRC Response: The NRC agrees with the commenter. The NRC intended to use the examples to convey a standard of acceptance for making changes that varies from one licensee to another. Emergency preparedness is inherently local, and the adage “one size doesn’t fit all” applies especially to EP. The apparent standard of acceptance will be appropriately different from one licensee to another because of plant-specific, site-specific, and EPZ-specific considerations that establish planning or response constraints that need to be addressed. For example, a plant in a rural area may need a dedicated onsite fire department if the response time for a public department to arrive would be protracted. Sections C.1.6, C.4.a, and C.5.2.2 of the draft and final Regulatory Guide address the need to consider plant-specific, site-specific, and EPZ-specific considerations in performing 10 CFR 50.54(q) analyses. No change was made to the guidance document in response to this comment.

Comment: Two commenters recommended that the NRC move the examples to an industry guidance document equivalent to NEI 96-07, Revision 1, which provides guidance on the implementation of the 10 CFR 50.59 rule, or to a resource manual. [0089, 0102]

NRC Response: The NRC agrees with the commenters that the examples could be relocated to an industry guidance document. Any stakeholder is free to submit an alternative approach to a published regulatory guide for NRC consideration. This activity would need to be initiated by the industry. In the absence of such an approved alternative approach, the NRC is proceeding with issuance of the final guidance document. No change was made to the guidance document in response to this comment.

Comments: Two commenters suggested that the 10 CFR 50.54(q) evaluation should be based on the planning standards set forth in 10 CFR 50.47(b) and not “emergency planning functions” introduced in DG-1237 and proposed rule language, or discussed in NRC Inspection Manual Chapter 0609, Appendix B (Emergency Preparedness Significance Determination Process). [0089, 0102] With regard to Section B. of the draft Regulatory Guide, a commenter suggested that the introduction of emergency planning functions creates an unnecessary complication of the rule intent. [0102] Another commenter agreed that the NRC should revise all references to “emergency planning functions” to “emergency planning standards.” [0089] This commenter asked whether, if the NRC retains the “emergency planning function” concept, the basis for violations cited by the NRC will be the emergency planning function or the emergency planning standard. [0089] With regard to Section C., a commenter suggested that the use of emergency planning functions as evaluation criteria during 10 CFR 50.54(q) evaluations is inappropriate. The commenter urged that evaluations of proposed changes to emergency plans should be evaluated against the current emergency planning standards to determine compliance. [0102]

NRC Response: The NRC disagrees with the commenters. As discussed in the NRC responses to similar comments on use of “emergency planning functions” in the proposed rule, the NRC decided for the reasons stated therein to retain the use of the phrase in the final rule and in the final guide. Further, as explained in a prior comment response, 10 CFR 50.54(q)(2) explicitly identifies the planning standards of 10 CFR 50.47(b) and/or the requirements in Appendix E, but not emergency planning functions, as the bases for compliance. In addition, the 10 CFR 50.54(q) change process establishes a two-criteria test to establish whether the licensee has the authority to make a change without prior NRC approval. As discussed in previous NRC comment responses, even if the proposed change resulted in the licensee’s compliance with the regulations, the proposed change still could result in a reduction in effectiveness. No change was made to the guidance document in response to these comments.

Comment: A commenter also recommended that the NRC clarify the evaluation of reduction in effectiveness to address the issue of “significance.” [0102]

NRC Response: The NRC disagrees with the commenter. A similar comment was made in the context of the proposed 10 CFR 50.54(q). As discussed in the NRC response to that comment, the NRC decided for the reasons stated therein not to revise the definition of “reduction in effectiveness” in the final rule or in the final guide. No change was made to the guidance document in response to this comment.

Comment: One commenter recommended that the NRC provide clear guidance in the draft RG and the inspection guidance for inspectors regarding the retroactive application of the new emergency plan change standard. [0089]

NRC Response: The NRC agrees with the commenter. The final rule and the final guide will not be applied retroactively to changes made under the requirements of former 10 CFR 50.54(q). The NRC has revised Section D of the final guide to emphasize this protocol. Changes were made to the guidance document in response to this comment. Conforming changes will be made to the inspection procedures in a future revision.

Comment: One commenter stated that the proposed rule and the associated implementation guidance provided in DG-1237 restrict licensee authority. The commenter stated that the guidance indicates that prior approval is needed for changes to actions that implement the planning standards. In particular, licensees would need NRC review and approval of changes in operation of a volunteer fire department which might affect effectiveness. The commenter suggested that NRC establish specific criteria and standards to require prior NRC approval and any other provision should rest solely within the licensee's purview. [0135]

NRC Response: The NRC agrees in part with the commenter. Section 50.54(q) of the Commission's regulations authorizes the licensee to make changes to its emergency plan without prior NRC approval if the change (1) complies with the planning standards of 10 CFR 50.47(b) and the requirements of Appendix E to Part 50, and (2) the change does not reduce the effectiveness of the plan. The proposed and final rule do not in any way restrict the licensee's authority that has always existed under 10 CFR 50.54(q). However, the proposed guidance addressing the particular example of a volunteer fire department was unclear. In response to similar comments, the NRC revised or deleted the examples considered to be ambiguous. The NRC notes that it is important to recognize that 10 CFR 50.54(q), as amended by the final rule, has two major requirements: 10 CFR 50.54(q)(2), which requires a licensee to follow and maintain the effectiveness of an emergency plan, and 10 CFR 50.54(q)(3) and (4), which establishes a change process. If a volunteer fire department relied upon in the plan ceases operation, the licensee must take action to restore the lost capability that was relied upon in the plan. If in doing so, the licensee has cause to revise its plan, then the change is subject to 10 CFR 50.54(q)(3) and (4). If the response time of the replacement fire department is longer than that for the original fire department, then there may be a reduction in effectiveness. The final regulatory guide was revised to make this clarification.

Recommended Changes to Draft Regulatory Guide

Comments: Two commenters recommended that the NRC remove the reference to 10 CFR 50.90 being the vehicle for applying for emergency plan changes that result in a reduction in effectiveness from Section B., page 4, third bullet. [0102, 0110] One of the commenters suggested that the 10 CFR 50.4 process to obtain NRC approval has been effective. [0110]

NRC Response: The NRC disagrees with the commenters. Similar comments were made in the context of the proposed rule. As discussed in the NRC response to the comment on use of the license amendment process in the proposed rule, the NRC decided for the reasons stated therein to retain the requirement in the final rule and in the final guide. No change was made to the guidance document in response to these comments.

Comment: A commenter asked what the acceptable threshold is for a plan change. The commenter argued that the FRN and Section C.1.1 present the threshold as the effective

preservation of compliance with the planning standards, but examples in the emergency planning functions appear to provide the threshold at a level of “anything less than the standard currently contained in the emergency plan.” [0089]

NRC Response: The NRC disagrees with the commenter. The licensee is free to relax requirements in its emergency plan without prior NRC review and approval, if, under 10 CFR 50.54(q)(3), the licensee can show that, first, the emergency plan, as modified, continues to comply with regulations and, second, the change does not reduce the effectiveness of the emergency plan. As explained in Section C.4.a of the guide, the examples identify changes that could require prior NRC approval. The guidance also states that the licensee should use the examples only to inform their decisions involving various changes. The examples are not intended to be all-inclusive or exclusive, may not be applicable to all sites, and are not to be used as thresholds or standards. Instead, the licensee must evaluate the change under consideration against the two criteria test of 10 CFR 50.54(q)(3) within the context of the licensing basis for the plant’s emergency plan. No change was made to the guidance document in response to this comment.

Comments: A commenter stated that the discussion in Section C.1.1.c regarding “minimal impact” further confuses the issue. The commenter asked the NRC to clarify the evaluation standards. [0089]

NRC Response: The NRC disagrees with the commenter. The phrase “minimal impact” appears in Section C.1.1.c. of the draft Regulatory Guide in a general, narrative context intended only to introduce the term “reduction in effectiveness,” which is defined later in Section C.3.7. As specified in the first sentence of this regulatory position, the 10 CFR 50.54(q) change process does not establish whether a proposed change would impact the reasonable assurance determination. The licensee is required only to assess whether or not the change constitutes a reduction in effectiveness. The definition of “reduction in effectiveness” is set forth in 10 CFR 50.54(q)(iv) of the final rule, and expanded upon in Section C.3.7 of the final guide, neither of which require the licensee to assess the magnitude of the impact of the change on the reasonable assurance determination. No change was made to the guidance document in response to these comments.

Comment: A commenter stated that Section C.1.1 conveys the concept that preservation of reasonable assurance is the minimum performance standard for any implemented change process. Therefore, the NRC must clearly establish the “reasonable assurance” delimiter to be used by the licensee to determine when prior NRC review and approval is required. [0102]

NRC Response: The NRC agrees in part with the commenter. The commenter is correct in stating that preservation of reasonable assurance is the minimum performance standard. However, the licensee does not assess whether the change affects a reasonable assurance determination; this is the NRC’s burden. The first sentence in Section C.1.1.c provides that the 10 CFR 50.54(q) change process does not establish whether a proposed change would impact the NRC’s reasonable assurance determination. See also 10 CFR 50.54(q)(3) of the final rule. As stated in the guide, the 10 CFR 50.54(q) change process establishes only whether the licensee has the authority to implement the proposed change without prior NRC approval. The determination of whether there continues to be reasonable assurance after the emergency plan is modified rests with the NRC. Accordingly, the NRC need not establish a reasonable assurance delimiter as suggested. No change was made to the guidance document in response to this comment.

Comment: A commenter requested that NRC revise the second sentence of Section C.1.1.c to replace the word “exclude” with “identify.” [0102]

NRC Response: The NRC disagrees with the commenter. In the context of the sentence, “exclude” is the correct word. The intent of the change process is to identify those changes that are reductions in effectiveness for which NRC approval is necessary. As such, the change process excludes from the requirement to seek NRC approval those changes that are not reductions in effectiveness. No change was made to the guidance document in response to this comment.

Comment: A commenter recommended that NRC delete the phrase “through appropriate analysis” from the third sentence of Section C.1.1.c because it adds ambiguity to the discussion. [0102]

NRC Response: The NRC agrees with the commenter. The phrase “through appropriate analysis” is unnecessary in this context because the guidance on performing a thorough analysis is provided elsewhere in the guide (e.g., Section C.5.2.5). Changes were made to the guidance document in response to this comment.

Comment: A commenter stated that the examples in Section C.1.1.b should be deleted (e.g. “For example, changes that ...”). [0102]

NRC Response: The NRC disagrees with the commenter. The examples help to explain the concepts discussed in Section C.1.1.b. No change was made to the guidance document in response to this comment.

Comment: A commenter suggested that the purpose of Section C.1.2 needs clarification. In particular, the commenter recommended that Section C.1.2 should convey the guiding principles and define the characteristics and criteria for the application of conservatism and not just offer a specific application. [0102]

NRC Response: The NRC agrees in part with the commenter. The detailed discussion in the example in Section C.1.2 detracts from the clarity of this section. Nonetheless, the specific application provided is an example that helps to explain the concepts addressed in the section. The NRC has condensed the example in the final guide. Changes were made to the guidance document in response to this comment.

Comment: A commenter asked for the NRC to clarify whether “ERO actively performing its function” in Section C.1.4.a aligns with the regulatory requirements. [0102]

NRC Response: The NRC disagrees with the commenter. Section 50.47(b)(2) calls for timely augmentation of response capabilities. The fundamental objective for augmentation is relieving the control room personnel of emergency response functions and allowing them to focus on plant control manipulation. Augmentation is not complete until the response functions assigned to the augmented staff in the individual emergency response facilities are being performed. If the control room is still performing the functions of the TSC and the EOF, then augmentation hasn’t fully occurred. The NRC’s position derives from the stated function of the TSC and EOF in regulatory guidance (NUREG-0696, NUREG-0737) and Appendix E to Part 50. In considering this comment, the NRC decided to revise the subject example in the interest of clarity. Changes were made to the guidance document in response to this comment.

Comment: A commenter suggested that the language of Section C.1.7 of the draft regulatory guide (i.e., “notify all offsite organizations within 15 minutes”) incorrectly interprets Appendix E, Section IV.D.3. The commenter claimed that the current language of Appendix E, Section IV.D.3, “does not mean to notify ALL agencies_and complete the notifications within 15 minutes.” The commenter recommended that the NRC correct the statement to reflect the intent of the current regulation. [0102]

NRC Response: The NRC disagrees in part with the commenter. The subject example properly reflects current regulatory intent. Appendix E, Section IV.D.3 requires the licensee to have the capability to notify responsible State and local government agencies within 15 minutes after declaring an emergency. Although the commenter is correct in stating that the language in Appendix E does not explicitly state “all” State and local government agencies, it does provide that the licensee have the capability to notify “responsible agencies” (note the plural form of “agency”). A failure to notify any single responsible agency could result in the public in the areas under the cognizance of that agency not being adequately protected. This is obviously not the regulatory intent.

NUREG-0654, Section II.E.3 identifies the information that is expected to be provided in initial notifications. Although Section IV.D.3 of Appendix E does not explicitly state that the licensee have the capability to “complete” the notification within 15 minutes, it does require the licensee to have the capability of notifying responsible State and local agencies, that is, providing the information with which to initiate and carry out their emergency response functions, including protective measures. Section 50.47(b)(4) provides, in part, that “State and local response plans call for reliance on information provided by the facility licensees for determinations of minimum offsite response measures.” The fundamental objective of the notification hasn’t been achieved until the requisite information has been provided to the responsible State and local agencies.

Although the statement quoted in the comment is consistent with regulatory intent, the NRC has decided to re-phrase the statement in a manner that identifies the regulatory intent as an NRC expectation rather than a regulatory requirement. Changes were made to the guidance document in response to this comment.

Comment: A commenter asked what the first sentence in the first paragraph of Section C.2 means: “submitted to the NRC for review and approval under 50.4.” [0102] Another commenter stated that Section 2 uses the word “should” rather than “shall.” The commenter recommended that NRC make this change or clarify if the intent is not all changes to the emergency plan listed in Section 2 need NRC prior review. [0110]

NRC Response: The NRC agrees with the commenters. The NRC’s intent was to suggest to licensees considering a change involving one or more of the items in Section C.2.a-f that they interface with the NRC and obtain NRC input before finalizing the change evaluation that determines that the change is NOT a reduction in effectiveness. The section does not apply to changes that the licensee has determined are reductions in effectiveness. Based on these comments and the questions raised at the various public meetings on this rulemaking, the NRC recognizes that the proposed language is not fully consistent with that intent. Changes were made to the guidance document in response to these comments.

Comments: A commenter recommended that the NRC use the reference “10 CFR 26.4(a)(1)-(5) and (c)” in Section C.2.b. to include other NUREG-0654, Table B-1, functions such as fire brigade and security. [0110] With regard to Section C.2.b, two commenters recommended that

the NRC replace “(see 10 CFR 26.4(a)(2) and (c))” with a reference to 10 CFR Part 26. [0089, 0102]

NRC Response: The NRC agrees with the commenters that the positions need to be included and that the less specific reference is appropriate because it inherently incorporates 10 CFR 26.4(a)(1)-(5) and (c). Changes were made to the guidance document in response to these comments.

Comments: A commenter stated that Section C.2.f imposes additional requirements on submittals to the NRC. Based upon this, updates to the ETEs as a result of the availability of new census data (every 10 years) will require all licensee to submit the updated ETE for approval from the NRC prior to its being available for use. [0102] With regard to Section C.2.f, two commenters recommended that the NRC delete the expectation for requesting review and approval under 10 CFR 50.4 for updated ETEs. The commenters suggested that separate regulatory guidance is being promulgated for this activity, so there is no value added to the process by submitting this for “review and approval.” [0102, 0110]

NRC Response: The NRC agrees with the commenters. The submittal requirements for ETE updates are provided in 10 CFR 50.47(b)(10) and Appendix E to Part 50, as amended by the EP final rule. Changes were made to the guidance document in response to these comments.

Comment: A commenter recommended that the NRC add a new item to Section C.2 on page 9: “Revision to the Emergency Action Level scheme as specified in 10 CFR Part 50, Appendix E, Section IV.B.2.” [0110]

NRC Response: The NRC disagrees with the commenter. The regulatory requirement for EAL scheme changes is already addressed in Part 50, Appendix E, Section IV.B. No change was made to the guidance document in response to this comment.

Comment: A commenter suggested that the NRC relocate paragraph C.3.3.b entirely to Section C.5.1 or C.5.2 of the Regulatory Guide. [0102]

NRC Response: The NRC agrees in part with the commenter. The information in Section C.3.3.b, a definition section, would be useful in Section C.5.2, the evaluation section, because it could facilitate the evaluation and because the information in Section C.3.3.b is fundamental to the discussion in Section C.3.3. Section C.3.3.b will be retained in the final guide. Changes were made to the guidance document in response to this comment.

Comment: A commenter identified a conflict between the definition of regulatory requirement in Section C.3.4 and a similar definition in Inspection Manual Chapter 0609, Appendix B. [0102]

NRC Response: The NRC agrees with the commenter. The definitions differ and they should be made consistent. The NRC has revised the definition in Section C.3.4 and will revise the definition in IMC 0609, Appendix B upon its next revision. Changes were made to the guidance document in response to this comment.

Comment: A commenter stated that NRC should relocate paragraph C.3.4.b entirely to Section C.5.1 or C.5.2 of the Regulatory Guide. [0102]

NRC Response: The NRC agrees in part with the commenter. The NRC has revised the final guide to address the intent of Section C.3.4.b in Section C.5.2.2 as suggested, but will retain Section C.3.4.b since the information is fundamental to the discussion in Section C.3.4 because

it applies to “commitments made in the emergency plans.” Changes were made to the guidance document in response to this comment.

Comment: A commenter asked if the NRC can clarify the applicability of 44 CFR 350.14 versus 10 CFR 50.54(q) as they apply to emergency notification ANS Design Reports. [0102]

NRC Response: The NRC disagrees that additional clarification is necessary. As stated in Section C.1.6.f.c, footnote 3 on Page 11, and Sections C.4.5.c, and 5.1.4.d of the guide, if the licensee has assumed responsibility for the installation and maintenance of the ANS on behalf of the State or local governments, and the licensee makes changes to its commitments documented in the approved ANS design report, then the licensee should evaluate those changes against the criteria of 44 CFR 350.14, “Amendments to State Plans.” If the licensee deems it warranted, the proposed changes are to be submitted to FEMA via the cognizant State official for review and approval as provided in 44 CFR 350.14. No review under the 10 CFR 50.54(q) change process is necessary unless the licensee makes a change to its onsite emergency plan. No change was made to the guidance document in response to this comment.

Comment: Two commenters suggested that the definition of “Emergency Plans” in Section C.3.5 is structurally flawed. In particular, the commenters stated that there can only be one emergency plan, so the NRC should delete the second sentence. [0089, 0102]

NRC Response: The NRC disagrees with the commenters. Similar comments were made in the context of the proposed rule. As discussed in the NRC response to the comment on the definition of “emergency plan” in the proposed rule, the NRC has decided for the reasons stated therein to retain the requirement in the final rule and in the final guide. No change was made to the guidance document in response to this comment.

Comment: A commenter stated that “emergency plan,” and “emergency plans” are used interchangeably throughout the document. [0089]

NRC Response: The NRC agrees with the commenter regarding the inconsistent use of singular and plural and performed a global search to use “emergency plan” except where the context was to emergency plans of multiple sites or licensees. Changes were made to the guidance document in response to this comment.

Comment: Two commenters also identified inconsistencies in the guidance with respect to the application of the word “change.” Part of the time, the text presents a “change” as being the effect the activity has on the physical emergency plan document, while frequently the text provides examples of changes based on the attribute of the activity and not its effect on the emergency plan. The commenters first identified this issue in Sections C.3.5.a and b and C.3.6, but requested that the NRC check elsewhere in the draft Regulatory Guide as well. [0089, 0102]

NRC Response: The NRC agrees with the commenters that there are inconsistencies. The NRC intended to focus the licensee’s attention on the content of the emergency plan, but as identified by the commenter, this focus was not always apparent. Changes were made to the guidance document in response to this comment.

Comment: A commenter recommended the NRC delete paragraph C.3.5.d in its entirety. The commenter stated that the requirement or expectation to aggregate activities and evaluate incremental changes is unworkable. The commenter also stated that 10 CFR 50.47 is the required acceptance standard. The commenter stated that if Section C.3.5.d remains in the

final guide, that incremental conservatisms added at licensee discretion must be credited to the licensee and kept available for reduction without being considered a reduction in effectiveness. [0102]

NRC Response: The NRC disagrees with the commenter. The commenter did not substantiate the assertion that the requirement to consider the original NRC-approved plan and changes made by the licensee without prior NRC approval is unworkable. The NRC expects the licensee to consider its EP licensing basis in performing 10 CFR 50.54(q) evaluations. Unless the licensee understands the basis for the current emergency plan, it cannot adequately evaluate whether a reduction in effectiveness is involved. The NRC disagrees with the commenter's implication that there is margin between the content of its plan and the planning standards (and Appendix E) and that the licensee somehow "owns" that margin. The NRC also disagrees with the implication that reducing this margin does not cause a reduction in effectiveness. The change process in 10 CFR 50.54(q)(3) has two criteria. First, the emergency plan as modified will continue to comply with regulations, and second, that the changes will not reduce the effectiveness of the plan. The fact that there may be apparent margin between the commitments in the plan and the associated regulatory requirements only addresses the first criterion—compliance with regulations. It does not address the second criterion—reduction in effectiveness. The licensee's burden is to demonstrate that the change does not decrease the effectiveness of the plan. The existence of margin does not necessarily equate to no reduction in effectiveness. The NRC added a new Section C.1.8 to further clarify its position. Changes were made to the guidance document in response to this comment.

Comments: Two commenters recommended that Section C.3.6.b should be relocated to the implementation guidance in Section C.5.1 and broken into separate discussions regarding the treatment of recognized degraded/nonconforming conditions versus planned activities such as maintenance. The commenters argued that the current paragraph mixes multiple concepts. [0089, 0102] With regard to Section C.3.6.d, a commenter suggested that the NRC relocate this section to Section C.5 on implementation guidance. [0102]

NRC Response: The NRC agrees in part with the commenters. The NRC has replaced the proposed Sections C.3.6.b and C.3.6.d as part of its response to earlier comments regarding the dual treatment of the term "changes" in the rule and the guide. Changes were made to the guidance document in response to these comments.

Comments: A commenter suggested that the NRC revise the definitions for Resources, Capabilities, and Methods in Section C.3.6.c to make them stand-alone (i.e., their own C.3.6.x sections) given their critical contribution to the change screening process. Regarding Section C.3.6.d, the commenter suggested that the NRC relocate this section to Section C.5 on implementation guidance. [0102]

NRC Response: The NRC disagrees with the commenter. Although the definitions are used in Section C.3.6.b as revised in the final guide, they no longer make a critical contribution to the change screening process because the final rule language no longer includes the three terms. Standalone treatment is not necessary. No change was made to the guidance document in response to this comment.

Comment: A commenter stated that, in Section C.3.7.a, the definition of "capabilities" should be deleted and should instead reference the prior definition, and the definition of "emergency" should be a stand-alone definition. [0102]

NRC Response: The NRC disagrees with the commenter. As discussed in the response to an earlier comment, the NRC decided that a standalone treatment of the definitions for “Resources,” “Capabilities,” and “Methods, was not necessary. As such, the definition of “capabilities” must be retained in Section C.3.7.a because the term “Capabilities” is used in Section C.3.7.a discussion. The commenter provided no justification for the suggestion regarding a standalone definition of “emergency.” No change was made to the guidance document in response to this comment.

Comment: A commenter recommended that the NRC divide Section C.4 of the draft Regulatory Guide into two categories: one that applies to operating power reactors and one that applies to non-power reactors. [0102]

NRC Response: The NRC disagrees with the commenter. The title of the proposed and final guide is “Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors.” Because the guide applies to only nuclear power reactors, the suggestion to divide Section C.4 into two categories, one for power reactors and one for non-power reactors, is unnecessary. No change was made to the guidance document in response to this comment.

Comment: A commenter suggested that for operating power reactors, Section C.4 should contain discussions on significant reduction in effectiveness to meet a planning standard and non-power reactors should have a section on emergency planning functions. [0102]

NRC Response: The NRC disagrees with the commenter. A similar comment was made in the context of the proposed rule. As discussed in the NRC response to that comment, the NRC decided for the reasons stated therein not to revise the definition of “reduction in effectiveness” in the final rule or in the final guide to incorporate significance. No change was made to the guidance document in response to this comment.

Comment: With regard to Section C.4.14.b(1), a commenter stated that the first sentence is problematic because when taken literally, “the effect of reducing the challenge” prohibits drill variation and undermines the basis for the rulemaking. The commenter recommended that this emergency planning function should simply indicate that a variety of challenge levels are required. [0089]

NRC Response: The NRC agrees in part with the commenter. The proposed sentence contained an editorial error that may have made the sentence unclear. The corresponding sentence in the final guide was revised to read: “A change in the conduct of drills and exercises that would have the effect of reducing the challenge to ERO personnel such that they are not provided an opportunity to practice key functional areas and major tasks, including use of plans, procedures, and equipment associated with those functions and tasks.” However, as the proposed text that started with “such that” indicated, to the extent that the licensee’s program allows key functional areas and major tasks to be exercised over the planning cycle, as allowed by regulation, variation in drills and exercises are not circumscribed by this sentence. Changes were made to the guidance document in response to this comment.

Comment: A commenter recommended that the NRC remove the word “Effectiveness” from the title of Section C.5.0, because this section’s purpose is to convey the overall review process. [0102]

NRC Response: The NRC agrees with the commenter. Section C.5.0 does address aspects of the change process beyond determination of whether a plan change reduces the

effectiveness of the plan. Accordingly, the commenter's suggestion is appropriate. Changes were made to the final guidance in response to this comment.

Comment: A commenter requested that the NRC provide more clarity in Section C.5.1 of the draft Regulatory Guide on licensee commitment above planning standard(s) to address the ability to reduce capability without significantly reducing effectiveness of the emergency plan. [0102]

NRC Response: The NRC disagrees with the commenter. The guide, taken as a whole, provides sufficient guidance for licensees to perform an adequate analysis of a proposed change to an emergency plan.

The NRC disagrees that consideration of licensee commitment above planning standards (the so-called "margin") is properly involved in determining whether a change constitutes a reduction in effectiveness. The change process in 10 CFR 50.54(q)(3) has two criteria. First, the emergency plan as modified will continue to comply with regulations, and second, that the changes will not reduce the effectiveness of the plan. The fact that there may be apparent margin between the commitments in the plan and the associated regulatory requirements only addresses the first criterion—compliance with regulations. It does not address the second criterion—reduction in effectiveness. The licensee's burden is to demonstrate that the change does not decrease the effectiveness of the plan. The existence of margin does not necessarily satisfy this burden. The NRC added a new Section C.1.8 to the final guide to further clarify its position. Changes were made to the guidance document in response to this comment.

Comment: A commenter recommended that the NRC remove the words "to the emergency plans" from the first sentence of Section C.5.1 because the focus is on the "change" activity and not just the plan. [0102]

NRC Response: The NRC disagrees with the commenter. As stated in the response to an earlier comment, the NRC acknowledged some inconsistency regarding the proper focus of the change process. The NRC performed a review on the entire document and corrected inconsistent references to ensure the proper focus. The use of the phrase "emergency plan" is necessary in the first sentence of Section C.5.1 to ensure that all licensee documents meeting the 10 CFR 50.54(q)(1)(ii) definition of "emergency plan" are considered. No change was made to the guidance document in response to this comment. In response to an earlier editorial comment, the NRC did change all references to "plans" to read "plan" unless the reference was to plans of multiple sites.

Comment: A commenter disagreed with the second sentence in Section C.5.2.2 and the concept of multiple simultaneous "plans" being in effect at the same time. The commenter recommended that the NRC delete the word "original." [0102]

NRC Response: The NRC disagrees with the commenters. The final Section C.5.2.2 is consistent with the final rule. As discussed in the NRC responses to similar comments on the definition of "emergency plan" in the proposed rule, licensees will not have multiple simultaneous emergency plans in effect at the same time. For the reasons stated in those comment responses, the NRC has decided to retain the definition in the final rule and in the final guide. No change was made to the guidance document in response to this comment.

Comment: A commenter recommended that the NRC replace the word "change" with "reduction in effectiveness" in the last sentence of Section 5.2.4. [0102]

NRC Response: The NRC agrees with the commenter. The NRC's intent with Section C.5.2.4 was to determine whether or not a reduction in effectiveness is involved. The last sentence is inconsistent with this intent, and has been omitted. Changes were made to the guidance document in response to this comment.

Comment: A commenter stated that Section 5.2.6 is problematic. The commenter suggested that effective review criteria and good guidance should negate the necessity for addressing cases where the "licensee is unsure" of the outcome of the 10 CFR 50.54(q) review. [0102]

NRC Response: The NRC agrees in part and disagrees in part with the commenter. Effective review criteria and good guidance should negate the need for consultation with the NRC. The NRC has provided improved guidance with the issuance of the final guide. However, the NRC is also aware that these determinations are necessarily subjective and that there will be unanticipated change situations that fall outside of the guidance. The NRC included Section 5.2.6 as a suggestion to assist licensees with these situations. No change was made to the final rule or the guidance document in response to this comment.

Comment: A commenter suggested that the draft Regulatory Guide needs to reference 10 CFR 51.22 in Section C.5.3. [0102]

NRC Response: The NRC disagrees with the commenter. The final guide provides guidance on making emergency plan changes; it does not provide guidance on how to submit a license amendment. Also, 10 CFR 51.22 addresses categorical exclusions for the preparation of environmental assessments or environmental impact statements. Since there are currently no categorical exclusions for most if not all emergency plan changes, the reference is unneeded. No change was made to the guidance document in response to this comment.

Comment: A commenter asked if the NRC evaluated the attributes of a license amendment request submitted under 10 CFR 50.90 for their appropriateness to an EP amendment requesting a reduction in effectiveness. For example, the commenter identified the No Significant Hazards Consideration (NSHC), which asks a number of questions that the commenter suggested are not pertinent to EP. [0102]

NRC Response: The NRC disagrees with the commenter. The requirements for a license amendment request for a change to an emergency plan are no different than the requirements for any other license amendment request under 10 CFR 50.90 and 50.91. The NRC is aware of the three determinations of 10 CFR 50.92(c) related to an NSHC. Although it may be unlikely that an emergency plan change would (1) cause an increase in the probability or consequences of an accident, (2) create a new or different accident, or (3) involve a significant reduction in a margin of safety, this does not change the NRC's statutory obligations under the Atomic Energy Act and the National Environmental Policy Act. Many non-EP license amendments do not result in a significant hazards concern. No change was made to the guidance document in response to this comment.

Comment: A commenter recommended that the NRC change the word "made" in the first sentence of Section C.5.4 to "implemented." [0102]

NRC Response: The NRC agrees in part with the commenter. As discussed in the NRC responses to a similar comment on the proposed rule, the NRC has decided for the reasons stated therein to change the word "made" in the first sentence of Section C.5.4 to read "put into

effect” in the final rule and in the final guide. Changes were made to the guidance document in response to this comment.

Comment: A commenter stated that the last sentence of Section C.5.4 eliminates the use of a screening tool to show that a proposed change does not impact any of the 16 planning standards and, by inference, would require a statement be made for each planning standard indicating why each proposed change does not impact that planning standard item. The commenter suggested that the NRC revise this sentence so that licensees provide documentation similar to what is required under 10 CFR 50.59(d)(2). [0102]

NRC Response: The NRC agrees in part with the commenter. In considering this comment, the NRC recognized that the structure of the first paragraph of Section C.5.4 may lead to confusion as it interspersed requirements for retaining a record and making reports. The NRC expects that all 10 CFR 50.54(q) evaluations will be rigorously performed and well documented. Some screening steps (such as those discussed in Section C.5.1) could be dispositioned by a simple yes or no, but other determinations, such as the applicability of a particular planning standard, should include documentation of the basis of those determinations. A check mark in and of itself cannot explain why the planning standard was considered not to be affected. What did the analyst consider in coming to that conclusion? What was the basis of the conclusion? The NRC expects the evaluation to provide a clear record of why the change is not a reduction in effectiveness. However, the NRC recognizes that the provision in Section C.5.4 may be overly restrictive in certain cases. Changes were made to the guidance document in response to this comment.

Comment: A commenter urged that the NRC needs to resolve the ambiguity of the last paragraph in Section 5.4 and the NRC’s option “to review all emergency plan changes that have been made.” Specifically, the commenter stated that if the NRC wants a permanent record of the changes, then it should be the stated position. [0102]

NRC Response: The NRC agrees in part with the commenter. In considering this comment, the NRC recognizes the need to clarify the statement in question. The current language implies that the NRC has a right to inspect the 10 CFR 50.54(q) change evaluation for the duration of the license. Once the licensee has disposed of change evaluations more than three years old, they are no longer inspectable. Nonetheless, the NRC has the authority and the responsibility to inspect the emergency plan for the duration of the facility license. If the inspector identifies a questionable plan provision that was not implemented as approved by the NRC, the inspector will ask for a justification for the change, generally starting with the 10 CFR 50.54(q) change evaluation. If the change evaluation isn’t available, the licensee will be asked to provide a justification for the change. The fact that the 10 CFR 50.54(q) analysis was greater than three years old and had been disposed of, does not excuse the licensee from needing to justify the change. Changes were made to the guidance document in response to this comment.

Comment: A commenter suggested that the records retention guidance in Section 5.4 is inconsistent with the finite retention period prescribed by regulation (current and proposed). The commenter suggested that NRC delete the infinite records retention guidance in DG-1237, and instead describe NRC’s role during the 3-year records retention period. [0135]

NRC Response: The NRC agrees in part with the commenter. The subject text in the proposed guide was a suggestion and remains as such in the final regulatory guide. As suggested by the commenter, the final guide was revised to clarify the NRC’s role by noting that a lack of change documentation (because evaluations greater than three years old were destroyed) does not absolve the licensee from having to justify any change which is

subsequently questioned regarding its impact on the effectiveness of the licensee's emergency plan. As such, it may be prudent to save change evaluations longer than required. Changes were made to the guidance document in response to this comment.

Comment: One commenter suggested that the NRC does not provide guidance on implementation in Section D. The commenter asked what process will be used to revise or rescind RIS 2005-02 after the new 10 CFR 50.54(q) is implemented. [0102]

NRC Response: The NRC agrees with the commenter. The proposed Section D did not provide implementation guidance. Included in the examples cited by the commenter was the lack of guidance to NRC inspectors on inspecting 10 CFR 50.54(q) evaluations performed prior to the effective date of the final rule. The revised Section D states that the final guide supersedes all such communications issued before the effective date of this guide, which includes RIS 2005-02, Revision 0. Section D also states that RIS 2005-02, Revision 1, may be used in conjunction with this guide to the extent that it does not conflict with the regulatory positions of this guide. In response to an earlier comment, the NRC also revised Section D to provide that the final guide will not be applied retroactively in evaluating emergency plan changes which were put into effect prior to the effective date of the guide. NRC inspectors will evaluate such changes using the prior rule language. Changes were made to the guidance document in response to this comment.

Comment: A commenter stated that the NRC does not reference RIS 2005-02, Rev. 0, in the References section of the draft Regulatory Guide. The commenter urged that absence of this revision or draft Revision 1 leads to conflicting guidance. [0102]

NRC Response: The NRC agrees in part with the commenter. Section D of the final guide was revised to state that the final guide supersedes all generic communications issued before the effective date of this guide, which includes RIS 2005-02, Revision 0. RIS 2005-02, Revision 1, was prepared to address, in the interim time period until the final guide was published, the use of license amendment submittals as the mechanism for requesting approval for changes that reduce the effectiveness of the emergency plan. Section D of the guide states that RIS 2005-02, Revision 1, may be used in conjunction with this guide to the extent that it does not conflict with the regulatory positions of this guide. Since neither regulatory issue summary was used in the preparation of the final guide, their inclusion in the "References" is unnecessary. Changes were made to the guidance document in response to this comment.

Comments: A commenter provided several comments on Appendix A of the draft Regulatory Guide. [0102]

- Flowchart is flawed and missing key steps. Flowchart is not consistent with proposed rule language.
- Reference to DG sections is needed in flowchart.
- Flowchart does not align with DG1237 sections.
- Appendix A, flowchart, third block down – The block includes "complies with regulations". It is not clear what the intent of this block is.
- Determination regarding compliance should be reflected as a decision block.

- Appendix A, flowchart, first block – Using the draft guide’s definition of change, there should first be the determination of whether the activity constitutes a change.
- Appendix A, block containing “Submit for NRC review and approval under 10 CFR 50.4” – Section C.2 describes this as a “recommended” action. Revise the Appendix to reflect this as a recommendation.

NRC Response: The NRC agrees with the commenter. The NRC deems these suggestions as desirable improvements to the final guide and the Appendix was revised accordingly. With regard to the first bulleted suggestion, the NRC revised the illustration to reflect changes made to the final guide in response to the comments on the proposed rule and proposed guide. With regard to the last bulleted suggestion, which is related to the first suggestion, the NRC decided instead to omit the action block as being unnecessary given changes made to Section C.2 in response to other comments. Changes were made to the guidance document in response to this comment.

Comments: A commenter stated that Appendix A, Section C.2, and Section C.5.1. all refer to NRC’s “review and approval” of changes not constituting reductions in effectiveness but strongly suggested for review, and these sections indicate that the proposed change is submitted under 10 CFR 50.4. The commenter asked what form and submittal format licensees would use for such submittals. The commenter also asked if these changes do not constitute reductions in effectiveness, what form of approval by the NRC would be provided. [0102]

NRC Response: The NRC agrees in part with the commenter. The NRC has revised Appendix A and Section C.5.1 for consistency with Section C.2 as revised in response to earlier comments. Changes were made to the guidance document in response to this comment.

4.5.4 Other: Amended Emergency Plan Change Process

Conforming Change to 10 CFR 51.22

Comments: Two commenters urged the NRC to make a conforming change to 10 CFR 51.22, “Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.” The commenters stated that many emergency plan changes requiring an amendment per 10 CFR 50.90 would not qualify for the categorical exclusion established in 10 CFR 51.22 because of the specificity of that language. Thus, generally administrative emergency plan changes would necessitate an environmental assessment. The commenters argued that the NRC should include a conforming change in the rule to avoid this unintended consequence. [0089, 0095]

NRC Response: The NRC disagrees with the commenters. A revision to 10 CFR 51.22 is not necessary to avoid preparation of an environmental assessment for “generally administrative plan changes.” The NRC has previously developed environmental assessments for license amendment requests that were essentially administrative changes. Also, truly administrative changes would not cause a reduction in effectiveness and would not be required to be submitted for prior NRC approval. No change was made to the final rule or the guidance document in response to this comment.

Other Comments

Comment: One commenter recommended that the NRC and licensees use quantitative analytical methods to evaluate emergency plan changes and whether they reduce the effectiveness of the plan. [0048]

NRC Response: The NRC disagrees with the commenter. Although the NRC agrees in concept that a quantitative analytical approach could be advantageous, the Commission's EP regulations include few numerical criteria that could be evaluated in a quantitative analytical approach. Such numerical criteria could be counterproductive as the prescriptiveness of that approach would largely preclude needed flexibility to develop resources, capabilities, and methods that are reflective of plant-specific, site-specific, and EPZ-specific considerations. The Commission noted in *Long Island Lighting Company* (Shoreham), CLI 86 13, 24 NRC 22, 30 (1986): "Our emergency planning requirements do not require that an adequate plan achieve a preset minimum radiation dose saving or a minimum evacuation time for the plume exposure pathway emergency planning zone in the event of a serious accident. Rather they attempt to achieve reasonable and feasible dose reduction under the circumstances; what may be reasonable or feasible for one plant site may be for another." No change was made to the final rule or guidance document in response to this comment.

Comment: A commenter stated that the NRC did not provide a sound justification for the amended emergency plan change process rule changes being proposed. [0102]

NRC Response: The NRC disagrees with the commenter. The NRC provided its justification in the proposed rule SOC and in its supporting regulatory analysis. The commenter provided no substantiated evidence that the proposed changes were unnecessary or that the proposed approach would not be an improvement over the former approach. No change was made to the final rule or guidance document in response to this comment.

Comment: A commenter mentioned that the NRC would continue to use the letter approval process for EAL scheme changes, while individual EAL changes that would reduce the effectiveness of the plan would be submitted and processed as license amendments. The commenter suggested that there is no reason to treat EAL scheme changes differently than individual EAL changes. [0095]

NRC Response: The NRC disagrees with the commenter. The provisions of Appendix E, Section IV.B.2 allow a licensee to submit an EAL scheme change under 10 CFR 50.4. The NRC determined that such changes would not likely engender a reduction in effectiveness because the NRC had already reviewed and endorsed the EAL scheme that the licensee was adopting. Nonetheless, the NRC reserved the right to review the EAL scheme change to ensure that the licensee's implementation of the endorsed scheme was appropriate. See 2005 EAL final rule (70 FR 3591; January 26, 2005). If the NRC determined in its review that the specific implementation of the EAL scheme constituted a reduction in effectiveness, the licensee would be directed to resubmit under 10 CFR 50.90. No change was made to the final rule or guidance document in response to this comment.