

Regulatory Issue Summary (RIS) 2005-02, Revision 1 Public Comment Resolution

Comment: Some commenters stated that, based in part on agency practice, the NRC's use of the license amendment process to review a licensee's proposed change to an emergency plan that would reduce the effectiveness of the plan would not constitute a clarification of an existing regulatory position, but instead would reflect a new position on what emergency plan changes require a license amendment. [0003, 0006, 0009, 0011] Several commenters stated that the RIS would be a *de facto* rulemaking [0008, 0010] and the NRC did not explain that it needs to issue the RIS in final form before an ongoing related rulemaking concludes. [0007, 0008, 0010]

NRC Response: The NRC agrees, in part, with the comments. The intent of the revision to the RIS is to clarify the process for licensees to evaluate proposed changes to their emergency plans. As such, discussions of NRC administrative review processes do not meet the intent of this revision to the RIS. The NRC's regulatory review process is set forth in the NRC's regulations and procedures. Therefore, the NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary."

Comment: Several commenters stated that issuing the RIS would predetermine the outcome of the ongoing EP rulemaking, thereby rendering the notice and comment process in that proceeding meaningless and violating the Administrative Procedure Act. Some of these commenters also maintain that regulating in this manner would be unfair to NRC stakeholders and inconsistent with the NRC's Principles of Good Regulation, in particular the principles of openness, clarity, and reliability. [0003, 0006, 0009, 0011]

NRC response: The NRC disagrees with the comments. However, the NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary..

Comment: Commenters stated that licensees would need to modify their procedures for obtaining NRC approval of emergency plan changes by requesting a license amendment. These procedure changes would constitute backfitting under § 50.109(a)(1). [0006, 0008, 0009, 0011]

NRC Response: The NRC disagrees with the comments. However, the NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: Several commenters maintained that NRC approvals of changes to emergency plans constituting a decrease in effectiveness do not constitute an expansion of the licensee's operating authority. Therefore, no license amendment is required to make the plan change. [0006, 0009, 0011]

NRC response: The NRC disagrees with the comments. However, the NRC removed from the RIS revision the language on which these comments were based because the language was

not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: Some commenters contended that so long as a modified emergency plan meets the standards of § 50.47(b) and Appendix E to 10 CFR Part 50, the licensee is not exceeding the operating authority granted in its license and no license amendment is required for the modification. [0006, 0009, 0011]

NRC response: The NRC does not agree with the commenters' reading of the NRC's regulations. The staff has removed the reference to the use of the license amendment process for proposed changes to emergency plans that would reduce the effectiveness of the plans from the revision to the RIS. The NRC's regulatory review process is provided in regulations and NRC procedures. As such, the discussions of NRC administrative review processes do not meet the intent of this revision to the RIS. The NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: A few commenters maintained that the NRC is not legally compelled to use the license amendment process to approve or deny changes to an emergency plan that would constitute a decrease in the plan's effectiveness. [0006, 0009, 0011]

NRC response: The NRC disagrees with the comments. However, the NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: Several commenters stated that the draft RIS's backfit discussion, which states that "[t]he Backfit Rule protects licensees from Commission actions that arbitrarily change license terms and conditions," reflects a misunderstanding of the purpose of the Backfit Rule. The fundamental purpose of the Backfit Rule is not to prohibit arbitrary or otherwise illegal agency action but to ensure that changes in agency regulations or positions are properly justified and imposed in an orderly fashion. [0006, 0009, 0011]

NRC Response: The NRC agrees in part with the comment that the purposes of the Backfit Rule are not solely "to prohibit arbitrary or otherwise illegal agency action," and that an objective of the Backfit Rule is to ensure that changes in NRC regulations or positions interpreting the regulations (and other NRC requirements) are justified and imposed in an orderly fashion, as well as to "ensure order, discipline, and predictability and to enhance optimal use of NRC staff and licensee resources." U.S. Nuclear Regulatory Commission, "Backfitting Guidelines," NUREG-1409, July 1990, ADAMS Accession No. ML032230247. The draft RIS's discussion was intended to be a "shorthand" for the full panoply of regulatory/policy concerns to which the Backfit Rule is addressed.

However, the NRC disagrees with the comment's implicit assertion that the Backfit Rule protects a licensee from changes in all NRC requirements. The Backfit Rule does not apply to changes in the NRC's procedural and administrative requirements governing the manner in which a licensee must obtain an otherwise undisputed NRC approval (that is, the need for NRC approval is unquestioned). Clearly, any such changes may not be illegal or arbitrary, and should be

imposed in an orderly fashion to ensure optimal use of NRC and licensee resources. However, the NRC uses the regulatory analysis and Paperwork Reduction Act clearance processes, rather than the Backfit Rule, to achieve those objectives. The comment did not mention these processes, which are generally applicable to all Federal agencies. The NRC assumes that the comment is not implicitly suggesting that all other Federal agency decision-making is defective because they are not subject to restrictions analogous to the Backfit Rule – restrictions which were voluntarily adopted by the NRC without statutory mandate or direction from the President.

Comment: Some commenters stated that the RIS is not the appropriate method to communicate a change in staff position related to the use of the license amendment process for approving emergency plan changes that reduce the effectiveness of the plan. [0003, 0008, 0010, 0011)

NRC response: The NRC disagrees, in part, with the commenters. A RIS is an informational document that is used to communicate with the nuclear industry on a broad spectrum of matters having generic applicability. It does not involve a request for action or information unless the request is strictly voluntary. Listed below are several examples of ways a RIS may be used:

- Announce staff technical or policy positions on matters that have not been broadly communicated to the nuclear industry or are not fully understood.
- Announce changes in regulatory practices that could impact licensees.
- Announce changes in agency practices that could impact licensees.

However, the NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: Some commenters stated that the request to submit 10 CFR 50.54(q) evaluations under § 50.4 is a change in practice outside the scope of the intent of the draft RIS. (0006, 0008, 0010)

NRC response: The NRC agrees with the commenters and removed the wording in the final RIS.

Comment: Some commenters stated that the example 10 CFR 50.54(q) procedure is not necessary. (0008, 0010)

NRC response: The NRC disagrees with the commenters. The 10 CFR 50.54(q) procedure is a compilation of best practices developed by licensees to implement an effective emergency plan change management program. It is not intended to direct licensees to develop their program as stated in the RIS revision, nor to direct the NRC inspectors on what the regulatory requirements are for an emergency plan change management program. It is intended to provide an example of a quality program for licensees to consider for their own use.

Comment: One commenter stated that the reference to the terms “reduction” and “reduction in effectiveness” is premature unless the RIS was issued after the rulemaking. (0008)

NRC response: The NRC agrees with the commenter and revised the wording in the final RIS revision to be consistent with RIS 2005-02 and the current 10 CFR 50.54(q).

Comment: Some commenters stated that the process for submitting EAL changes is not clear, specifically for an EAL scheme change. (0008, 0010)

NRC response: The NRC agrees with the commenters, and revised the RIS, Attachment 1 and the wording in Attachment 2 of the draft RIS to explain the process more clearly. Specifically, a revision to an EAL scheme must be submitted as specified in Appendix E to 10 CFR 50 for NRC approval before implementation if the licensee is changing its entire EAL scheme to another EAL scheme, such as the most current NRC-approved EAL scheme applicable to the design of the licensee's power plant. Additionally, revisions of an individual EAL that results in a decrease in effectiveness must be submitted for NRC approval as specified in 10 CFR 50.54(q).

Comment: One commenter stated that the Enclosure 2 did not reference the significant attributes required by the license amendment process. (0008)

NRC response: The NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: One commenter stated that there was a fundamental issue regarding the threshold for a decrease in effectiveness. The commenter states in part, "Through review of the proposed rulemaking and interaction with the Staff during public meetings, it is observed that a significant discontinuity in philosophy permeates this document regarding the threshold for a decrease in effectiveness. The Commission's finding of the acceptability of the site's Emergency Plan was based on the station's ability to effectively implement the plan in a manner such that the standards of 10 CFR 50.47 and the requirements of Appendix E were met (or demonstrated). However, the Staff does not follow this philosophy but rather imposes a higher, albeit undefined, standard." (0008)

NRC response: The NRC disagrees with the commenter. The 10 CFR 50.54(q) change process does not establish whether a proposed change would impact reasonable assurance determinations; the change process establishes only whether the licensee has the authority to implement the proposed change without prior NRC approval. The change process uses the characteristic "decrease in effectiveness" to exclude from the requirement to seek prior NRC approval those changes that would not be decreases in effectiveness. Because these changes would not result in decreases in effectiveness of the licensee's plans, the changes would be expected to have a minimal impact on the NRC's reasonable assurance determination. If the licensee determines through appropriate analysis that the proposed change would decrease the effectiveness of the licensee's plans, NRC evaluation of the impact of the change on the reasonable assurance determination is required. A licensee's determination that a proposed change would decrease the effectiveness of the emergency plan does not mean that the licensee could not or would not implement appropriate protective measures to protect public health and safety during an accident; all that is meant is that prior NRC review is required.

While there is a presumption that an emergency plan that complies with the planning standards would be effective, the planning standards are broadly worded and are generally subjective rather than objective. For example, 10 CFR 50.47(b)(2) requires adequate on-shift staffing and

the capability for augmentation; it does not establish numeric staffing levels. These staffing levels are identified in the emergency plan. At the time of licensing, applicants may have had to go beyond the specific requirements to compensate for site-specific response constraints so that the NRC could make its required reasonable assurance determination that adequate protective measures can and will be taken in the event of a radiological emergency. If the licensee can show by analysis, for example, that those constraints are no longer applicable, then the licensee would not decrease the effectiveness of its emergency plan by removing the requirement that originally addressed those constraints.

Comment: One commenter stated that it was unclear why non-reactor licensees are included in the draft RIS and that the staff should confirm explicitly that the new guidance is not intended to apply to non-reactor licensees. (0006)

NRC response: The NRC disagrees with the commenter. Non-reactor licensees are required to submit proposed changes that decrease the effectiveness of their emergency plan to the NRC for prior approval as reactor licensees are required to do. The intent of the RIS is to clarify the process for evaluating proposed changes to emergency plans; provide a method for evaluating proposed changes to emergency plans; and provide clarifying guidance on the appropriate content and format of applications submitted to the NRC for approval prior to implementation. Non-reactor facilities may find the information provided in the RIS related to the emergency plan review process useful for enhancing their emergency plan change processes.

Comment: One commenter provided a line by line review of the draft RIS in the form of a table of comments, several of which were similar comments to other commenters and addressed earlier in this document. The following comments are from that table: (0006)

Comment: The commenter stated that the proposed new definition for decrease in effectiveness refers to the term "emergency planning function." This definition should be reworded to exclude the reference to function. The commenter states, "The term 'emergency planning function' is not defined in the existing regulation, which refers to 50.47 and Appendix E to Part 50. The NRC should not use guidance documents to introduce new regulatory definitions."

NRC response: The NRC disagrees with the comment. In response to comments related to the use of the term "emergency planning function" in the draft RIS, the NRC decided to retain the concept in the final version of the RIS. The comments did not establish a substantiated concern that would cause the NRC to reconsider the proposed emergency planning function construct and language set forth in the draft RIS.

The reactor oversight program (ROP) is anchored in the NRC's mission to ensure public health and safety in the operation of commercial power plants. The objective is to monitor performance in three broad areas -- reactor safety (avoiding accidents and reducing the consequences of accidents if they occur); radiation safety for both plant workers and the public during routine operations; and protection of the plant against sabotage or other security threats. To measure plant performance, the oversight

program focuses on seven specific "cornerstones" which support the safety of plant operations in the three broad strategic areas.

During the development of the Emergency Preparedness (EP) Cornerstone of the ROP, a group of emergency preparedness subject matter experts, including NRC staff and nuclear power industry stakeholders, with input from the public, developed a series of planning standard functions that are used in determining the significance of inspection findings. These planning standard functions are paraphrases of the broadly-worded 10 CFR 50.47(b) planning standards and the corresponding requirements in Appendix E to Part 50 in terms of the significant functions that need to be accomplished, or the capabilities that need to be in place, to maintain the effectiveness of a licensee's emergency plan and emergency response capability. Within the EP Cornerstone, the significance of inspection findings depends on whether the planning standards can be accomplished (i.e., loss of planning standard function) or can be accomplished only in a degraded manner (i.e., degraded planning standard function). The characterization of a decrease in effectiveness in the RIS capitalizes on this earlier effort in that any degradation or loss of a planning standard function is deemed to constitute a decrease in effectiveness. The NRC is using the phrase "emergency planning function" in the RIS in lieu of "planning standard function" as used in the ROP to allow the definition to be applicable to licensed facilities that are subject to Appendix E, but are not subject to the planning standards of § 50.47(b). As such, the RIS will retain the concept.

Comment: The commenter recommended deleting the examples of "Reductions in Effectiveness" in the RIS. The commenter stated, "As stated in Definitions section (2): "[I]t is also possible that site-specific situations may make a particular example inapplicable to a site." This recognition by the NRC seems inconsistent with the inclusion of the examples! For this reason, [the commenter] believes adding these examples to the Draft RIS could cause confusion and this new language should be deleted."

NRC response: The NRC disagrees that the use of examples in the document is confusing. The examples provided in the RIS clearly show a change or reduction in an emergency planning function without a commensurate reduction or change in the bases for that emergency planning function or without measures put in place to reduce the impact of the proposed change to the emergency plan. As such, the RIS will retain the examples.

Comment: The commenter suggested the following inclusion of wording "(3)(a) The proposed change to the EAL would potentially cause an underclassification, (e.g., what was considered Alert in the approved emergency plan would now be considered a Unusual Event or not classified at all), unless the change was previously reviewed and approved generically by the NRC (example: EAL FAQ process)."

NRC response: The NRC disagrees with the comment. The letter from Roy Zimmerman to Stephan Floyd, "Subject: Frequently Asked Question Process for Emergency Preparedness Guidance," dated August 31, 2005 stated the following:

"The EP FAQ process is intended to clarify the staff's interpretation of existing regulatory guidance issued or endorsed by NRC, and will not be used to create new regulatory positions or guidance. The EP FAQ process should also not be used by NEI or the

industry to determine whether a proposed change would constitute a decrease in effectiveness as defined in 10 CFR 50.54(q) or to bypass enforcement action.”

Due to site-specific differences in emergency plans and implementation methods of licensees, the NRC does not generically approve emergency plan changes.

Comment: The comment suggested the removal of the reference to 10 CFR 50.54(p)(1).

NRC response: The NRC removed from the RIS revision the language on which these comments were based because the language was not needed to support the RIS revision. As a result, additional response to the commenters is unnecessary.

Comment: The commenter suggested making the following changes to the definition of “activity” in Enclosure 1: “For the purposes of 10 CFR 50.54(q), activities may also originate outside of the licensee’s control responsibility such as permanent road closings or substantive population increases. Changes in the emergency plan that address these activities should be treated as a change in basis for the emergency plan.”

NRC response: The NRC disagrees with the comment. With the site-specific differences and implementation methods of licensees, the NRC does not agree that this would be a true statement generically, in all cases.

Comment: The commenter suggested the deletion of the last sentence in the definition of emergency plan that starts: “An emergency plan includes” The basis provided was that there can only be one emergency plan in effect.

NRC response: The NRC agrees that there can only be one plan in effect, but the plan does include all subsequent changes from when it was originally approved by the NRC. The RIS was revised to change the word “plans” to “plan” to clarify that there is only one plan.

Comment: The commenter recommended that Enclosure 1, Section 4.0’s reference to qualifications be revised because it provided no meaningful information.

NRC response: The NRC agrees in part with the comment. The NRC attempted to suggest that a person knowledgeable in emergency preparedness should perform the review. In addition, the person performing the screening should be knowledgeable of the changes being considered. The NRC did not suggest that a screener/reviewer should be “qualified” as is typically used in the nuclear industry (e.g., qualification cards, testing, oral boards, etc.). The reference to qualifications was removed.

Comment: The commenter suggested revising Enclosure 1, Section 5.1 to state, “A 50.54(q) review on the impact to the emergency plan should also be performed for proposed revisions to other plant procedures or other non-EP documents that implement aspects of the site’s EP program to ensure that changes are not made to non-EP

procedures that adversely impact the ~~EP program~~ Emergency Plan.” The justification states that a § 50.54(q) evaluation is performed on an emergency plan change and is not used as a program assessment tool.

NRC response: The NRC agrees that Section 5.1 is used to screen changes to other plant procedures and non-emergency plan documents for the impact to the emergency plan. This suggested wording clarifies this Section and is incorporated into the final RIS.

Comment: The commenter suggested revising Enclosure 1, Section 5.1.1 to state, “The following screening criteria ~~should~~ could be used as an example be used to screen for 10 CFR 50.54(q) applicability.” The justification states that there are many acceptable methods currently used by licensees to screen for § 50.54(q) evaluation applicability. The way this is currently stated will lead licensees to believe this method is required, which would be inaccurate.

NRC response: The NRC agrees in part with the comment. The NRC did not suggest that the use of this specific screening criterion was required. The NRC provided an example for licensees to review for potential enhancements to their program. The suggested wording clarifies this Section and is incorporated into the final RIS.

Comment: The commenter recommended revising Enclosure 1, Section 5.1.1 to state, “If any are checked YES, ~~a 10 CFR 50.54(q) review of the proposed change(s) is needed~~ review the emergency plan to determine if the plan has to be revised for this change.” The justification states that before a § 50.54(q) evaluation is performed as a result of the screen, the emergency plan is reviewed.

NRC response: The NRC agrees that if a box is checked YES, a review of the emergency plan is required to determine if there are any changes as a result of the review to the non-emergency plan procedure or documents. If the emergency plan requires changes, then a 10 CFR 50.54(q) evaluation of the changes to the emergency plan should be performed. The suggested wording clarifies this Section and is incorporated into the final RIS.

Comment: The commenter recommend a note be placed below the check list in Enclosure 1, Section 5.1.1 to state, “Note: The above list provides examples of items that should be consider [*sic*] for a 50.54q screen check list. Each licensee should review their emergency plan for additional check list items. The check list should be designed so that someone that is not well versed in the contents of the emergency will know that the emergency plan should be reviewed to determine impact.”

NRC response: The NRC agrees that the inclusion of this note will enhance the guidance provided in the RIS. The suggested wording clarifies this Section and is incorporated with minor grammatical edits into the final RIS.

Comment: The commenter suggested revising Enclosure 1, Section 5.1.1 to state, “A 10 CFR 50.54(q) review shall be performed for all proposed revisions to emergency plans and EALs ~~that decrease the effectiveness of the emergency plans~~ (except for EAL

scheme changes). ~~Although not required, a 10 CFR 50.54(q) review should be conducted for applicable lower tier documents in accordance with Attachment 2, "10 CFR 50.54(q) Review."~~ The justification states that a § 50.54(q) review is performed to determine if the proposed change to the emergency plan is RIE. The justification further states that a § 50.54(q) review is only performed on emergency plans and EAL changes. An emergency plan screen is performed on lower tier documents to determine if the emergency plan is impacted by the lower tier document change.

NRC response: The NRC agrees in part with the comment. The NRC agrees with removing the wording, "that decrease the effectiveness of the emergency plans" because 10 CFR 50.54(q) is the process to determine whether or not the change is a decrease in effectiveness. The NRC disagrees with the second suggested change because if a licensee has incorporated a lower tier document into the emergency plan or the emergency plan explicitly references a lower tier document as a method to implement a specific requirement in the emergency plan, then it is considered part of the plan and subject to 10 CFR 50.54(q) review. The first suggested wording clarifies this Section and is incorporated into the final RIS.