UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, DC 20555-0001

August xx, 2009

NRC REGULATORY ISSUE SUMMARY 2005-02, REVISION 1 CLARIFYING THE PROCESS FOR MAKING EMERGENCY PLAN CHANGES

ADDRESSEES

All holders of licenses for nuclear power reactors under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of licenses for research and test reactors under Part 50.

All holders of and applicants for nuclear power plant construction permits, early site permits and limited work authorizations under Part 50.

All holders of a combined license for a nuclear power plant under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

All holders of licenses for fuel facilities under the provisions of 10 CFR Part 40 "Domestic Licensing of Source Material" required to have an emergency plan under § 40.31(j)(1)(ii).

All holders of licenses for fuel facilities under the provisions of 10 CFR Part 70 "Domestic Licensing of Special Nuclear Material" required to have an emergency plan under § 70.22(i)(1)(ii).

All holders of certifications for gaseous diffusion plants under the provisions of 10 CFR Part 76 "Certification of Gaseous Diffusion Plants" required to have an emergency plan under § 76.35(f).

All holders of site-specific licenses for Independent Spent Fuel Storage Installations under 10 CFR Part 72 "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) revision to inform stakeholders that reactor emergency plan changes that require prior NRC

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approval, in accordance with 10 CFR 50.54(q), will need to be submitted as license amendment requests in accordance with 10 CFR 50.90, "Application for Amendment of License, Construction permit, or Early Site Permit." In addition, this revision will (1) clarify the meaning of "decrease in effectiveness," as stated in 10 CFR 50.54(q); (2) clarify the process for evaluating proposed changes to emergency plans; (3) provide a method for evaluating proposed changes to emergency plans; (4) provide clarifying guidance on the appropriate content and format of applications submitted to the NRC for approval prior to implementation; and (5) clarify what constitutes a report of emergency plan changes to be submitted to the NRC in accordance with 10 CFR 50.54(q). This revision supersedes RIS 2005-02, dated February 14, 2005, in its entirety.

1) For non-reactor facilities, the regulations in 10 CFR 40.35(f), 70.32(i), and 76.91(o) provide direction to licensees seeking to revise their emergency plan. An emergency plan includes the plan as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under these regulations. The current practice for non-reactor facilities concerning emergency plan changes that require prior NRC approval is to submit the changes as a license amendment request. Current regulatory guidance for non-reactor emergency plans is contained within Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." The NRC staff is working on updating Regulatory Guide 3.67 to include applicable elements of this RIS for fuel cycle facilities. The NRC will publish a *Federal Register* Notice of the issuance for public comment and availability of the draft updated Regulatory Guide.

2) For Independent Spent Fuel Storage Installations (ISFSI), the emergency plan change process should be followed in accordance with 10 CFR 72.44(f). The information in this RIS provides useful examples of the type of evaluations NRC expects ISFSI licensees to conduct in reviewing changes to their Part 72 approved emergency plans (refer to § 72.24(k) and § 72.32) and determining if the changes may be made without prior NRC approval as required by § 72.44(f). The current practice for non-reactor facilities concerning emergency plan changes that require prior NRC approval is to submit the changes as a license amendment request. Additional guidance on emergency planning for ISFSI licensees is provided in Spent Fuel Storage and Transportation Interim Staff Guidance - 16, "Emergency Planning."

This RIS revision requires no action or written response on the part of addressees.

BACKGROUND INFORMATION

The regulation in 10 CFR 50.54(q) provides direction to licensees seeking to revise their emergency plan. The requirements related to nuclear power plant emergency plans are given in the standards in 10 CFR 50.47, "Emergency Plans," and the requirements of Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities" to 10 CFR Part 50. The standards in § 50.54(q) and Appendix E to Part 50 also establish the requirements related to emergency plans for research and test reactors. Based upon feedback from the nuclear power industry, the research and test reactor community, and experience gained by the NRC staff after reviewing emergency plan changes, the NRC staff has identified a need to clarify the process for making changes to an emergency plan and to provide licensees with a consistent method for evaluating proposed emergency plan changes.

In addition, the NRC staff clarifies herein that the license amendment process is the correct process to use when reviewing decrease (reduction) in effectiveness submittals. Courts have found that Commission actions that expand licensees' authority under their licenses without formally amending the licenses constitute license amendments and should be processed through the Commission's license amendment procedures. See Citizens Awareness Network, Inc. v. NRC, 59 F.3d 284 (1st Cir. 1995); Sholly v. NRC, 651 F.2d 780 (D.C. Cir. 1980) (per curiam), vacated on other grounds, 459 U.S. 1194 (1983); and In re Three Mile Island Alert, 771 F.2d 720, 729 (3rd Cir. 1985), cert. denied, 475 U.S. 1082 (1986). See also Cleveland Electric Illuminating Co. (Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315 (1996). A proposed emergency plan change that would reduce the effectiveness of the plan would give the licensee a capability to operate at a level of effectiveness that was not previously authorized by the NRC. In this situation, the licensee's operating authority would be expanded beyond the authority granted by the NRC as reflected in the emergency plan without the proposed change. Thus, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. A change expanding the licensee's operating authority is, according to the courts, a license amendment and must be accomplished through a license amendment process.

The staff also stated in SECY-08-0024, "Delegation of Commission Authority to Staff to Approve or Deny Emergency Plan Changes that Represent a Decrease in Effectiveness," dated February 25, 2008, "To make the process by which the NRC will address proposed 10 CFR 50.54(q) changes that represent a decrease in effectiveness clearer, the staff intends to incorporate language similar to that which currently exists in 10 CFR 50.54(p)(1), as part of the planned rulemaking." The current schedule for the staff's emergency preparedness (EP) rulemaking calls for the final rule to be issued no earlier than the summer of 2010. Because of the timeframe associated with the rulemaking, the staff has determined that the prudent action is to issue a RIS to clarify that licensees must submit proposed emergency plan changes which represent a decrease in effectiveness for NRC approval as specified in § 50.54(q), and the license amendment process is the correct process for the staff to use in reviewing the proposed change. For purposes of discussion and to incorporate the possibility of future regulatory changes, the term "decrease in effectiveness" is considered synonymous with "reduction in effectiveness (RIE)."

SUMMARY OF ISSUE

Licensees routinely evaluate proposed revisions to their emergency plan, to determine if these changes reduce the effectiveness of their current approved emergency plan or adversely affect their ability to implement the emergency plan. Clarification is needed of an acceptable method for licensees to use in consistently evaluating proposed changes to the emergency plan to ensure the licensee's ability to maintain and implement the approved emergency plan. Additionally, licensees should understand the process for submitting proposed emergency plan changes to the NRC for approval prior to implementation when there is a determination of a decrease (reduction) in effectiveness.

The change process is described below and clarified by providing a screening criterion that would ensure consistency of emergency plan change determinations of a decrease (reduction) in effectiveness. Enclosure 1, "10 CFR 50.54(q) Evaluation Procedure," presents a suggested outline for applying the screening criteria for the evaluation of a proposed emergency plan change, which is graphically depicted in Attachment 1 to Enclosure 1, "10 CFR 50.54(q) Flowchart." In addition, Enclosure 2, "Guidance for Content of Emergency Plan Submittals to

NRC Requiring Prior NRC Approval," provides guidance to licensees in the development of their application for NRC prior approval of proposed emergency plan changes. The information in this RIS revision clarifies the process for changing emergency plans to ensure that licensees maintain effective emergency plans thereby maintaining reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. This RIS revision also provides a consistent methodology for licensees to evaluate changes to their emergency plans and provides clarifying guidance for the development of applications for NRC prior approval. This will help ensure that NRC review activities and decisions are effective, efficient, predictable, and consistent.

The regulations require licensees to submit a report of each change within a specified period of time after the change is made. The NRC Inspectors use this report to evaluate the effectiveness of a licensee's emergency plan change management program in accordance with NRC Inspection Procedures, and although not required, the inclusion of the applicable licensee evaluation and justification for the change as part of this report would be beneficial to the staff.

Regulation

In part, 10 CFR 50.54(q) states the following:

> The nuclear power reactor licensee may make changes to these plans without Commission approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of § 50.47(b) and the requirements of appendix E to this part. The research reactor and/or the fuel facility licensee may make changes to these plans without Commission approval only if these changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the requirements of appendix E to this part…. Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission.

Definitions

1) Decrease (Reduction) in Effectiveness (RIE)

   a) A change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

      i) Note that other licensee activities could affect the ability to implement the emergency plan effectively. Licensees must maintain the effectiveness of their NRC approved emergency plans, up to and including, ensuring that changes made to other programs, structures, systems or components do not adversely impact the licensee's ability to effectively implement its emergency plan. See Information Notice 2005-19, "Effect of Plant Configuration Changes on the Emergency Plan," dated July 18, 2005, for additional information.

         (1) An RIE will occur if there is 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. The overall impact of proposed changes on the effectiveness of the emergency plan or its

implementation is to be determined, not just the effect that individual changes have on a specific part of the emergency plan.

(2) The following provides some examples of RIEs that would require prior NRC approval 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. These examples should not be viewed as being all-inclusive or exclusive; rather, licensees should use them to inform decisions involving various changes being considered. It is also possible that site-specific situations may make a particular example inapplicable to a site. Even if a particular example completely encompasses the change being considered, the licensee's emergency plan change evaluation should explain why the site-specific implementation of the change would not be an RIE for that particular site. It is not sufficient for such an analysis to simply cross-reference an example in this RIS revision.

(a) A change that would cause any of the major functional areas or major tasks identified in the emergency plans to be unassigned. An example of this would be a technical specification change eliminating on-shift radiation technician coverage without making an alternative arrangement for providing the requisite technical expertise in a timely manner.

(b) A change that would impede site access for offsite assistance relied on in the plan without viable alternate arrangements being made. An example would be the closure or planned closure of a major river bridge in a case where the route via the nearest available crossing would incur a substantial increase in response time.

(c) A change to the emergency response organization (ERO) callout procedures or hardware that would delay ERO notification such that the augmentation times in the emergency plans can no longer be achieved. A change to communications hardware that would reduce the capability to initiate and complete required emergency notifications within 15 minutes of the emergency declaration.

(d) A change to the onsite meteorological measurements program such that meteorological data currently readily available in emergency response facilities in accordance with the emergency plan would no longer be readily available.

(e) A change to hazard assessment and radiation protection assignments in re-entry and recovery procedures that would not provide an adequate level of personal protection in uncertain reentry conditions.

(f) A change that reduces the availability of site familiarization training currently presented to offsite assistance groups (e.g., firefighters, local law enforcement, and medical services, including mutual aid companies that would support these groups).

(g) A change that delegates the responsibility for performance of various aspects of emergency plan maintenance to contractors or other external groups without adequate supervisory oversight to ensure that program elements continue to be met (e.g., a change delegating testing and maintenance of the Alert and Notification System to an external group not subject to typical nuclear facility work process and configuration controls).

(3) For proposed changes to individual emergency action levels (EALs) (i.e., not an entire EAL scheme change), an RIE will occur in the following cases:

(a) The proposed change to the EAL would potentially cause an underclassification, (e.g., what was considered an Alert in the approved emergency plan would now be considered an Unusual Event or not classified at all).

(b) The proposed change to the EAL would potentially cause an overclassification, (e.g., what was considered a Site Area Emergency in the approved emergency plan would now be considered a General Emergency with potential consequences for public health and safety).

(c) If the proposed change to the EAL is to change an Initiating Condition setpoint (or threshold) without a commensurate change in the regulatory basis for the EAL Initiating Condition setpoint (or threshold).

(d) The actual numerical setpoint of a given EAL may be revised without prior NRC approval under the following conditions via the 10 CFR 50.54(q) emergency plan change process:

(i) The regulatory basis for the EAL setpoint has been revised and is approved via a letter to the licensee or a Safety Evaluation (SE). For example, a site receives NRC approval (via a SE) for power up-rate. Power up-rate implementation causes the “normal” radiation levels to increase, thus necessitating an increase in EAL setpoints based on “normal” radiation levels. The regulatory basis for the setpoint has been changed, thus this change can be processed via the emergency plan change process because the effectiveness of the emergency plan has not been reduced.

(ii) The regulatory basis for the EAL setpoint has not been changed but the method for detection of the setpoint has been changed. For example, a given EAL setpoint is based upon exceeding 1 Rem total effective dose equivalent (TEDE). The radiation monitor reading setpoint is based upon a reading that would give the equivalent of exceeding 1 Rem TEDE. The radiation monitor is replaced and operates differently. The actual numerical value of the EAL needs to be revised to that which is equivalent to 1 Rem TEDE. The regulatory basis for the setpoint has not been changed, thus this change can be processed via the emergency plan change process as the effectiveness of the emergency plan has not been reduced.

2) Emergency plan

a) The document(s) prepared and maintained by the licensee that identify and describe the licensee's methods for maintaining and performing emergency planning functions. An emergency plan includes the plans as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under 10 CFR 50.54(q).

i) The licensee's emergency plan consists of:

(1) The emergency plan as approved by the NRC via a Safety Evaluation Report, SE, or license amendment (LA) from the Office of Nuclear Reactor Regulation (NRR) or the Office of Federal and State Materials and Environmental Management Programs (FSME).

(2) Changes to the emergency plan explicitly reviewed by the NRC through an SE, or LA from NRR or FSME, and found to meet the applicable regulations.

(3) Changes to the emergency plan explicitly reviewed by the NRC through an SE, or LA, and found to be an approved amendment to the licensee's emergency plan.

(4) Changes made by the licensee without NRC review and approval after the licensee concluded that the change(s) do not constitute a decrease RIE.

Emergency Plan Change Process

1. Process Overview

Reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency is based on the licensee's emergency plan, and the successful implementation of that emergency plan. The body of an emergency plan contains statements that describe how a licensee will meet regulatory requirements. The standards of 10 CFR 50.47(b) and the requirements of Appendix E to 10 CFR Part 50 establish the contents of the nuclear power reactor emergency plan. The standards in § 50.54(q) and Appendix E to Part 50 establish the requirements related to emergency plans for research and test reactors. Subsequent changes to the emergency plan must comply with § 50.54(q). Enclosure 1 outlines the emergency plan change process, and Attachment 1 to Enclosure 1 graphically depicts the process in a flowchart.

2. Emergency Plan Review

Changes to an emergency plan may result from advances in technology, new or revised rules, site-specific needs, processes, guidance (such as Nuclear Energy Institute guidance endorsed by the NRC), technical specification changes, or modifications to instrumentation. Changes that the licensee has identified as RIEs must be submitted to the NRC for review and prior approval. The NRC staff will review the emergency plan change against the standards, regulations, guidance documents and the approved emergency plan. The NRC will review and approve

submittals on a case-by-case basis. An emergency plan change approved for one licensee does not mean that the same or similar change would be approved for another licensee.

For the purposes of determining whether a change to a licensee's emergency plan constitutes an RIE, the licensee should use the last emergency plan reviewed and approved by the NRC. If the emergency plan change process has been properly implemented over the years, comparing a proposed emergency plan change to either the latest emergency plan reviewed and approved by the NRC or the emergency plan as changed by the licensee should result in the same RIE determination. For example, if a licensee made a series of changes over time to the same specific provision of the emergency plan, where each change was separately determined not to constitute an RIE, then there should be no RIE. Therefore, there should be no RIE when comparing the latest emergency plan to the emergency plan reviewed and approved by the NRC. If a licensee or the NRC concludes that there is a RIE due to a series of changes over time, then the provisions of the emergency plan change process have not been correctly followed.

The EP requirements are a framework for how the licensee will meet the applicable standards and requirements of the regulations. If a licensee has determined that an EP requirement should be increased in order to meet the planning standards or Appendix E to Part 50 requirements, these changes must follow the emergency plan change process and revise the emergency plan to reflect this increase to the EP requirement. Nevertheless, whether or not an emergency plan change results in a RIE is not determined by assessing whether NRC regulatory requirements continue to be met after the EP requirement has been changed. The licensee's emergency plan may include EP requirements that exceed the baseline standards and requirements as set forth in § 50.47(b) and Appendix E to Part 50. For the RIE determination, the change or changes should be evaluated against the capability to perform the functions and the associated time requirement of performing the function, if applicable. The evaluation should document whether the capability or timeliness to perform a function is lost and/or degraded. In addition to the RIE determination, the change or changes should also be evaluated to verify that they continue to meet the standards and requirements as set forth in § 50.47(b) and Appendix E to Part 50.

The current Commission requirements for document retention in § 50.54(q), specify that changes that do not warrant NRC approval must be retained for 3 years. The licensee must retain changes that reduce the effectiveness of the emergency plan until the Commission terminates the license. It may be prudent to save emergency plan change documentation to show the historical progression of changes, since the Commission, through its staff, may review at any time, the emergency plan changes that have been made.

<u>Related Topics Regarding Emergency Plan Changes</u>

1. Regulatory Process for Evaluating Licensee Requests for NRC Prior Approval of Emergency Plan Changes Determined To Be a RIE in Accordance with 10 CFR 50.54(q)

Similar to security plan changes submitted via 10 CFR 50.54(p)(1), emergency plan changes that result in the reduction in the effectiveness of the approved emergency plan require prior NRC approval, under § 50.54(q), and should to be submitted as license amendment requests under § 50.90.

2. Emergency Action Level Changes

A revision to an entire EAL scheme, from NUREG-0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," to another NRC-endorsed EAL scheme, must be submitted for prior NRC approval as specified in Section IV.B. of Appendix E to 10 CFR Part 50. The Statement of Considerations for the final rule amending the NRC's regulations relating to NRC approval of EAL changes, dated January 26, 2005, stated in part, "The Commission believes a licensee's proposal to convert from one EAL scheme (e.g., NUREG-0654-based) to another EAL Scheme (NUMARC/NESP-007 or NEI 99-01 based) ... is of sufficient significance to require prior NRC review and approval. NRC review and approval for such major changes in EAL methodology is necessary to ensure that there is reasonable assurance that the final EAL change will provide an acceptable level of safety." Regulatory Guide 1.101, Revisions 3 and 4, "Emergency Planning and Preparedness for Nuclear Power Reactor," endorsed NUMARC/NESP-007 and NEI 99-01 EAL guidance, respectively, as acceptable alternatives to the guidance provided in NUREG-0654 for development of EALs to comply with § 50.47 and Appendix E to Part 50. A change in an EAL scheme to incorporate the improvements provided in NUMARC/NESP-007 or NEI 99-01 would not decrease the overall effectiveness of the emergency plan and would not expand a licensee's operating authority beyond that previously authorized by NRC, but due to the potential safety significance of the change, the change needs prior NRC review and approval. This approval is given via SE and letter.

Revisions of an individual EAL that results in a decrease in effectiveness must be submitted for NRC approval as specified in § 50.54(q), and the license amendment process is the correct process for the staff to use in reviewing the proposed change. As discussed previously, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. A change expanding the licensee's authority is, according to the courts, a license amendment and must be accomplished through a license amendment process. For research and test reactors, NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," issued October 1983, provides guidance on EALs and how changes should be made on a case-by-case basis with consideration of the provisions of § 50.54(q).

3. Inspection Activities

For power reactors, the NRC inspectors use Inspection Procedure (IP) 71114.04 to conduct a review of the effectiveness of the licensee's implementation of the 10 CFR 50.54(q) change process. For research and test reactors, the NRC inspectors use IP 69011, "Class I Research and Test Reactor Emergency Preparedness," and IP 69001, "Class II Research and Test Reactors." The inspector will perform a screening review of the change relative to the emergency plan; however, this will not constitute NRC approval of the plan as changed. The documentation of the change reviewed by the inspectors will be the report provided by the licensee as stated in § 50.54(q). Although not required, the inclusion of the applicable licensee evaluation and justification for the change as part of this report would assist the staff in the review.

4. Lower Tier Documents

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 §50.54(q) review. Historically, some licensees have developed emergency plan implementing procedures that

included the necessary information needed for activities that are required to meet the regulations, for example, procedures for notifications, dose assessment, protective action recommendations, emergency classifications and emergency action levels. The staff is not making the use of § 50.54(q) to review all changes to lower tier documents a requirement, but acknowledges that using § 50.54(q) as the regulation to provide revision control of these lower tier documents has been in place and supported by the NRC through the inspection and licensing process.

BACKFIT DISCUSSION

This RIS revision does not require any action or written response. This RIS revision provides non-regulatory review guidance for licensees and clarifies existing regulatory requirements licensees must follow when proposing changes to their emergency plans. The NRC's Backfit Rule, 10 CFR 50.109, applies to, among other things, the procedures necessary to operate a nuclear power plant. To the extent that using a license amendment process for making modifications to emergency plans that reduce the effectiveness of the plans is considered a change, it would be a change to the NRC's regulatory process for addressing modifications to the emergency plan. The NRC's regulatory review process is not a licensee procedure required for operating a plant that would be subject to backfit limitations.

Further, the Backfit Rule protects licensees from Commission actions that arbitrarily change license terms and conditions. In 10 CFR 50.54(q), a licensee requests Commission authority to do what is not currently permitted under its license. The licensee has no valid expectations protected by the Backfit Rule regarding the means for obtaining the new authority that is not permitted under the current license. For these reasons, this RIS revision does not constitute a backfit under 10 CFR 50.109, and the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS revision was published in the *Federal Register* on XXXX XX, 2009. There were xx comments from stakeholders, which were considered before issuance of this RIS revision.

PAPERWORK REDUCTION ACT STATEMENT

This RIS revision does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of1995 (44 U.S.C. 3501 et seq.).

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

CONTACT

Please direct any questions about this matter to the technical contact listed below or to the appropriate Office of Nuclear Reactor Regulation (NRR) project manager.

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Enclosures:
1. 10 CFR 50.54(q) Evaluation Procedure (typical)
2. Guidance for Content of Emergency Plan Submittals to the NRC Requiring Prior NRC Approval

Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

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Enclosure 1: 10 CFR 50.54(q) Evaluation Procedure (typical)

1.0 **Purpose**

1.1. This document 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 this regulatory issue summary (RIS) revision, nor to direct the U.S. Nuclear Regulatory Commission (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.

1.1.1. Note that many aspects of this procedure are not based upon explicit regulatory requirements, but are rather based upon sound conservative decision making by licensees to ensure a quality emergency plan change management program.

1.2. This document provides instructions for performing an effectiveness review of proposed changes that may affect the Emergency Preparedness (EP) Program.

1.2.1. Changes to the emergency plan require a 10 CFR 50.54(q) evaluation to identify if those changes decrease (reduce) the effectiveness (RIE) of the emergency plan.

1.2.2. NRC Information Notice (IN) 2005-19, "Effect of Plant Configuration Changes on the Emergency Plan," dated July 18, 2005, was issued to inform licensees of inspection findings related to licensees' failure to properly evaluate the effect of plant configuration changes (procedures, equipment and facilities) on the emergency plan. Changes to emergency procedures, or modifications to equipment or facilities used to implement the emergency plan, should be reviewed with a 10 CFR 50.54(q) screening process, and possible evaluation, to ensure those changes do not directly or indirectly reduce the effectiveness of the emergency plan. Some examples include, but are not limited to, the following: emergency plan implementing procedures (EPIPs); emergency action level (EAL) technical bases document (for sites that do not have NUREG-0654 EALs); site staffing procedures; emergency response facility ventilation, power, and/or spacing requirements; and modifications to equipment required to determine an EAL threshold.

1.2.3. 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 §50.54(q) review. Historically, some licensees have developed EPIPs that included the necessary information needed for activities that are required to meet the regulations, for example, procedures for notifications, dose assessment, protective action recommendations, emergency classifications and emergency action levels. The staff is not making the use of § 50.54(q) to review all changes to lower tier documents a requirement, but acknowledges that using § 50.54(q) as the regulation to provide revision control of these lower tier documents has been in place and supported by the NRC through the inspection and licensing process.

2.0 **Definitions & applicability of terms:** *{Implementation of the 10 CFR 50.54(q) process is dependent upon the use of key terms. The following definitions have been identified as key*

terms necessary to complete a 10 CFR 50.54(q) evaluation that meets the intent of 10 CFR 50.54(q)}

2.1. Activity: A series of events or actions that may result in a change to the emergency plan or affect the implementation of the emergency plan.

- An activity sets in motion the need to determine impact on certain licensing bases documents using regulatory review criteria such as 10 CFR 50.54(q).
- Activities may range from something as simple as making an editorial change or an organizational change, to making complicated facility modifications.
- For the purposes of 10 CFR 50.54(q), activities may also originate outside of the licensee's responsibility such as permanent road closings or substantive population increases.

2.2. Change: An action that results in modification or addition to, or removal from, the licensee's emergency plan, or the resources, capabilities and methods identified in the plan, and affects an emergency planning requirement.

2.3. Emergency Plan: The document(s) prepared and maintained by the licensee that identify and describe the licensee's methods for maintaining and performing emergency planning functions. An emergency plan includes the plans as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under 10 CFR 50.54(q).

2.3.1. The licensee's emergency plan consists of:

- The emergency plan as approved by the NRC via a Safety Evaluation Report (SER), Safety Evaluation (SE), or license amendment (LA) from the Office of Nuclear Reactor Regulation (NRR) or the Office of Federal and State Materials and Environmental Management Programs (FSME);
- Changes to the emergency plan explicitly reviewed by the NRC through an SE, or LA, from NRR and found to meet 10 CFR 50.47(b) and the requirements of Appendix E to 10 CFR Part 50;
- Changes to the emergency plan explicitly reviewed by the NRC through an SE, or LA, and found to be an approved amendment to the licensee's emergency plan, and
- Changes made by the licensee without NRC review and approval after the licensee concluded the change(s) does not constitute a decrease (reduction) in effectiveness.

2.4. Emergency Planning Function (Requirement): A capability or resource necessary to prepare for and respond to a radiological emergency as set forth in the elements of Section IV of Appendix E to 10 CFR Part 50 and, for nuclear power reactors, the planning standards of 10 CFR 50.47(b).

2.4.1. Note that other licensee changes, other than to the emergency plan, could adversely impact an emergency planning function. The licensee is responsible for evaluating these changes and for maintaining the ability to implement the approved emergency plan.

2.5. Decrease (Reduction) in Effectiveness (RIE): A change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

2.5.1. Note that other licensee activities could affect the ability to implement the emergency plan effectively. Licensees must maintain the effectiveness of their NRC approved emergency plans, up to and including, ensuring that changes made to other programs, structures, systems or components do not adversely impact the licensee's ability to effectively implement their emergency plan. Reference IN 2005-19 for additional information.

2.5.1.1. An RIE will occur if there is 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. The overall impact the proposed changes have on the effectiveness of the emergency plan or its implementation is to be determined, not just the effect individual changes have on a specific part of the emergency plan.

2.5.1.2. For example, if a licensee proposes to remove an emergency response organization position (function) that the approved emergency plan expects to respond in 30-minutes, and no other measures are put in place to reduce the impact of the proposed change to the emergency plan, the change may be considered an RIE.

2.5.1.3. For proposed changes to individual EALs (i.e., not an EAL scheme change), an RIE will occur if the proposed change to the EAL that would potentially cause an underclassification, e.g., what was considered an Alert in the approved emergency plan would now be considered an Unusual Event or not classified at all; an overclassification, e.g., what was considered a Site Area Emergency in the approved emergency plan would now be considered a General Emergency and may have potential consequences to public health and safety; or, if the proposed change to the EAL is to change an setpoint (or threshold) without a commensurate change in the regulatory basis for the EAL setpoint (or threshold).

2.6. Editorial Change: Editorial changes do not require a 10 CFR 50.54(q) review. The following are examples of Editorial Changes:

- Procedure title change
- Reference or annotation change
- Correction of location description
- Correction of typographical errors and punctuation
- Reformatting changes that do not change intent, purpose, or order of procedural steps
- Changes on plant drawing grid coordinates
- Change to position titles when no responsibilities for that position have changed
- Correction in page or step numbering.

3.0 Regulatory Guidance

3.1. EP standards are provided in 10 CFR 50.47(b) and requirements are provided in Appendix E to 10 CFR Part 50. Clarifications and expectations are provided in the various guidance documents, particularly the following:

3.1.1. NUREG-0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,"

3.1.2. NUREG-0696, "Functional Criteria for Emergency Response Facilities,"

3.1.3. NUREG-0737, "Clarification of TMI Action Plan Requirements," and

3.1.4. Regulatory Guide 1.101, "Emergency Planning and Preparedness for Nuclear Power Reactors."

3.2. A licensee's emergency plan must meet the standards and requirements. The regulatory guidance details the methods by which the staff verifies compliance and provides methods that have been determined to be acceptable in the development and maintenance of an effective EP program. The emergency plan therefore, becomes a culmination of various requirements that the NRC will evaluate and determine whether the licensee has the capability to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

3.3. Changes to the emergency plan must be evaluated to ensure that an emergency planning function has not been modified, or if the function has been changed, that the basis for the change is justifiable. Licensees need to determine if the proposed changes cause an RIE.

4.0 Qualifications

4.1. Preparers, reviewers, and approvers of 10 CFR 50.54(q) evaluations should be qualified to do so in order to ensure a consistent and effective program.

4.1.1. A § 50.54(q) screening should be performed by personnel knowledgeable of the proposed change and its potential impact on the EP Program. However, the EP Program Manager should be consulted whenever questions as to applicability arise.

5.0 10 CFR 50.54(q) screening

5.1. A 10 CFR 50.54(q) review 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.

5.1.1. The following screening criteria should be used to screen for 10 CFR 50.54(q) applicability:

Is this a change to shift staffing levels?	☐ YES	☐ NO
Is this a reduction in department staffing levels that impacts the emergency plan's 24-hour staffing requirements?	☐ YES	☐ NO
Is this a change to systems, equipment, setpoints, procedures, etc., that are used to determine EAL Initiating Conditions?	☐ YES	☐ NO
Is this a change to site Operations, Fire Brigade, and/or Security response protocols (i.e., security events, medical response, 10 CFR 50.54(x) protocol, etc.)?	☐ YES	☐ NO
Is this a change to Emergency Response Facilities or equipment?	☐ YES	☐ NO
Is this a change to non-EP procedures that has the potential to affect the EP program?	☐ YES	☐ NO

If any are checked YES, a 10 CFR 50.54(q) review of the proposed change(s) is needed.

6.0 **<u>10 CFR 50.54(q) review</u>**

6.1. A 10 CFR 50.54(q) review shall be performed for all proposed revisions to emergency plans and EALs that reduce the effectiveness of the emergency plans (except for EAL scheme changes). Although not required, a § 50.54(q) review should be conducted for applicable lower tier documents in accordance with Attachment 2, *"10 CFR 50.54(q) Review".*

6.1.1. Some changes to EP procedures/processes may potentially affect other department's programs and may thus require a 10 CFR 50.59 Applicability Review, or other review based upon the proposed activity.

6.1.1.1. The following regulatory requirements must be addressed, when applicable, to the program being affected:

- QA Program: 10 CFR 50.54(a)
- ISI/IST Program: 10 CFR 50.55(a)
- Appendix J: 10 CFR 50.54(o)
- Security Program: 10 CFR 50.54(p)
- Maintenance Rule: 10 CFR 50.65
- Fire Plan: Site Fire Plan

- ISFSI 10 CFR 72.48
- Changes, Tests, or Experiments: 10 CFR 50.59

6.2. Perform the 10 CFR 50.54(q) review in accordance with the instructions contained in Attachment 2, "10 CFR 50.54(q) Review".

7.0 References

10 CFR 50.54(q)

10 CFR 50.47(b)

10 CFR App. E. IV

10 CFR App. E. V

10 CFR App. E VI

10 CFR 50.4

NRC Significance Determination Process, Appendix B

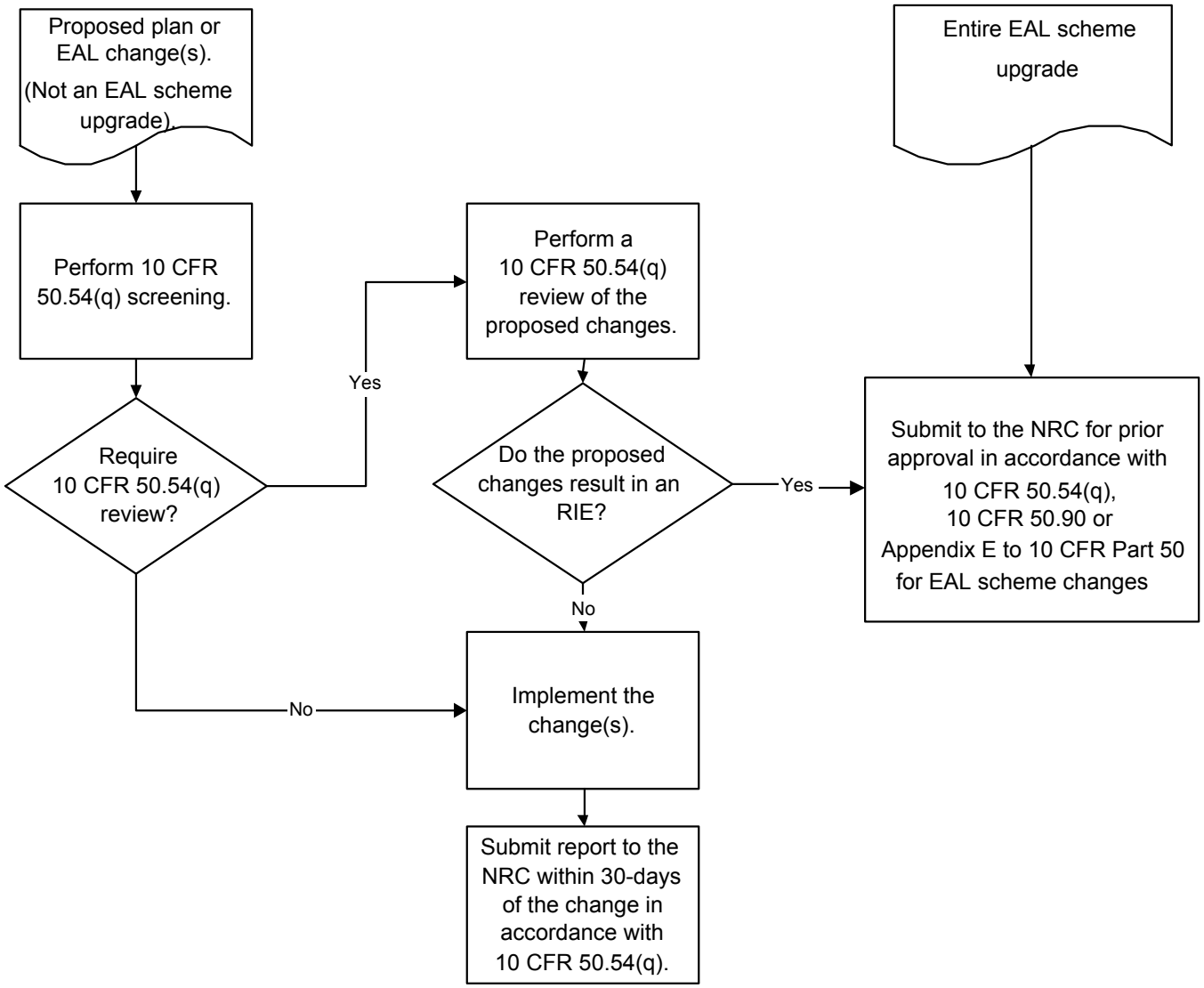
FEMA-REP-10

8.0 Attachments

Attachment 1: 10 CFR 50.54(q) Review Flowchart

Attachment 2: 10 CFR 50.54(q) Review

ATTACHMENT 1: 10 CFR 50.54(q) FLOWCHART



ATTACHMENT 2: 10 CFR 50.54(q) REVIEW

1.0 On the 10 CFR 50.54(q) Form:

> **NOTE**
>
> This form should be complete and detailed enough to allow an NRC Inspector or other reviewer to evaluate its merits without referring to other documents or references.

1.1. Briefly document a description of the change

1.2. Check if this is change is due to a procedure change, modification or other.

1.3. Check if this change is purely editorial in nature (see definition).

1.3.1. If yes, document the Background and Scope of the change (*Background & Scope: A description of the reason for and scope of the change)*.

1.3.1.1. Then the document may be revised, approved, and implemented.

1.3.1.2. Submit to the NRC, as specified in 10 CFR 50.4, within 30 days of the effective date of change.

2.0 Determine if the proposed change impacts the items that describe the Planning Standards of 10 CFR 50.47(b) and requirements of Appendix E to 10 CFR Part 50.

2.1. If any questions are checked YES, then a 10 CFR 50.54(q) review is required.

2.1.1. Evaluate each change against the specific elements of 10 CFR 50.47(b), Appendix E to 10 CFR Part 50, the emergency plan and other applicable regulations and requirements.

2.1.2. Determine if the proposed changes maintain or improve the capability to:

- To respond to an emergency, or meet actions or other requirements described in the Emergency Plan, Implementing Procedures, or EAL's.
- To protect the health and safety of plant personnel and the general public in the event of an emergency.
- To implement Federal regulations or requirements.

2.1.3. Determine if the change reduces the effectiveness of the plan by the following:

- If the change still implements the planning standard utilizing a different method, then document the new method and state why the change does, or does not; reduce the effectiveness of the plan.
- If a setpoint was changed, then state why the change is, or is not, a reduction in

the effectiveness of the plan.

- If an instrument/tool type was substituted and the instrument still performs the same function, then state why the change does, or does not; alter the effectiveness of the plan.

> **NOTE**
>
> A reduction in effectiveness in the emergency plan/EAL is determined to have occurred if there has been a change to an EP requirement without a commensurate change in the bases for that EP requirement.

2.1.4 Document the review in the outline format below:

2.1.4.1 Background and Scope: A description of the reason for and scope of the change.

2.1.4.2 Program Requirements: A description of the regulation standard or requirement for which the EP program must demonstrate compliance.

> **NOTE**
>
> For changes that are large in scope, in which a one-to-one comparison is not practical, a detailed discussion of the change that compares the current content with the proposed content may be developed.

2.1.4.3 Change Comparison: A comparison showing both old and new wording, including step or section number references as applicable. Changes that incorporate new information are marked as "Added to Document." Changes that involve the deletion of information are marked as "Removed from Document."

> **NOTE**
>
> Ensure that the comparison also accounts for wording from the **APPROVED EMERGENCY PLAN/EALs** to ensure that a gradual relaxation in program standards or requirements has not occurred.

2.1.4.4 Change Assessment: A discussion of how the change degrades, does not affect, or enhances the effectiveness and abilities of the EP Program as it relates to the program requirements.

2.1.4.5 Justification: A formal justification that describes the basis and reasons the change is appropriate and necessary for any degradation (otherwise, not required). Sufficient level of detail must be provided to support the basis for complex and significant changes and conclusion regarding effectiveness.

2.1.4.6 References: A list of references such as regulations, guidance documents, information notices, inspection reports or other sources which contain criteria incorporated by the

emergency plan related to the change.

2.2. If the proposed change is to the fleet/station emergency plan, EALs, EAL bases document (if applicable), or a lower tier document, but does not reduce their effectiveness, then,

2.2.1. Submit to the NRC, as specified in 10 CFR 50.54(q) and Appendix E to 10 CFR Part 50, a report of the change within 30 days of the effective date of change.

2.2.1.1. Although not required, it would be beneficial to the staff for the report to include the 10 CFR 50.54(q) evaluation and justification for the applicable change(s).

2.3. If the proposed change is to the emergency plan, EALs, EAL bases document (if applicable), or a lower tier document that is incorporated into the emergency plan or is explicitly referenced as a method to implement a specific requirement in the emergency plan, and does, by definition, reduce the effectiveness of the emergency plan or EAL, then**:**

2.3.1. If the proposed change is to the emergency plan or a lower tiered document (if applicable), submit the revised document and the 10 CFR 50.54(q) review to the NRC for approval prior to implementation in accordance with 10 CFR 50.90.

2.3.2. If the proposed change is to the EALs (not a scheme change) and/or EAL bases document (if applicable), submit the revised document and the 10 CFR 50.54(q) review to the NRC for approval prior to implementation in accordance with 10 CFR 50.90.

2.3.2.1. If the proposed change is approved by the NRC, then the document may be revised, approved, and implemented.

2.4. If all questions are checked NO, then further review is not required.

2.4.1. Document the Background and Scope of the change *(Background & Scope: A description of the reason for and scope of the change)*.

2.4.2. Then the document may be revised, approved, and implemented.

2.4.2.1. Submit to the NRC, as specified in 10 CFR 50.4, within 30 days of the effective date of change.

10 CFR 50.54(q) REVIEW FORM

Description of Change:

_____

_____

_____

☐ **Plan Sections/Procedure(s) #:** _____ **Revision(s) #:** _____

☐ **Mod #:** _____

☐ **Other:** _____

Is the proposed change purely editorial in nature (see definition)? *[If YES, discontinue review process and process the procedure change.]*

☐ **YES** ☐ **NO**

Does the proposed change affect any of the following: [*Check 'yes' or 'no'. Reference the actual standards/requirements.]*

50.47	PARAPHRASED STANDARD	YES	NO
(b)(1)	Primary responsibilities of the *{applicable site and offsite response}* organizations.	☐	☐
	Responsibilities of supporting organizations.	☐	☐
	Initial staffing or augmentation	☐	☐
(b)(2)	On-shift responsibilities for emergency response.	☐	☐
	Staffing for initial accident response	☐	☐
	Timely augmentation	☐	☐
	Interfaces among onsite and offsite response activities.	☐	☐
(b)(3)	Arrangements for requesting and using assistance resources.	☐	☐
	Accommodations at the EOF for *{applicable site and offsite response}* staff.	☐	☐
	Other organizations capable of augmenting response are identified.	☐	☐

50.47	PARAPHRASED STANDARD	YES	NO
(b)(4) RSPS	Emergency classification and action level scheme.	☐	☐
	State/county minimum response based on site information.	☐	☐
	EAL Initiating Condition setpoints or thresholds.	☐	☐
(b)(5) RSPS	Process for notification of state/county response organizations.	☐	☐
	Notification of emergency personnel.	☐	☐
	Procedure for initial and follow-up messages.	☐	☐
	ANS notification within the 10-mile EPZ	☐	☐
(b)(6)	Provisions for prompt communication among principal response organizations to emergency response personnel and to the public.	☐	☐
(b)(7)	Public information distributed on a periodic basis.	☐	☐
	News media points of contact established.	☐	☐
	Procedures for coordinated dissemination of info to the public.	☐	☐
(b)(8)	Emergency response facilities, equipment, and maintenance.	☐	☐
(b)(9) RSPS	Methods, systems, or equipment for assessing and monitoring actual or potential offsite consequences.	☐	☐
(b)(10) RSPS	Range of protective actions for the Plume EPZ established (offsite).	☐	☐
	Guidelines for choice of PARs in place.	☐	☐
	Protective actions for Ingestion Pathway EPZ established.	☐	☐
(b)(10)	Range of protective actions for the Plume EPZ established (onsite).	☐	☐
(b)(11)	Controlling radiological exposure for emergency workers.	☐	☐
(b)(12)	Arrangements for medical service for contaminated injured individuals.	☐	☐
(b)(13)	General plans for recovery and reentry.	☐	☐
(b)(14)	Exercise or drill conduct and corrective action system.	☐	☐
(b)(15)	Radiological emergency response training.	☐	☐

50.47	PARAPHRASED STANDARD	YES	NO
(b)(16)	Responsibilities for plan development, review, and distribution of emergency procedures established.	☐	☐
	EP Staff is properly trained.	☐	☐
EP	Implementation of other federal regulations and requirements related to the Emergency Preparedness Program.	☐	☐
ERDS	The operation, maintenance, or testing requirements of the ERDS.	☐	☐

App. E	PARAPHRASED REQUIREMENT	YES	NO
IV. A	Organization	☐	☐
IV. B	Assessment actions	☐	☐
IV. C	Activation of emergency response	☐	☐
IV. D	Notification procedures	☐	☐
IV E	Emergency facilities and equipment	☐	☐
IV. F	Training	☐	☐
IV. G	Maintaining emergency preparedness	☐	☐
IV. H	Recovery	☐	☐

STANDARDS AND/OR ELEMENTS EFFECTED	DESCRIPTION OF EFFECT	REDUCED EFFECTIVENESS. YES	REDUCED EFFECTIVENESS. NO
	Background and Scope:	☐	☐
	Program Requirements:		
	Change Comparison:		
	Change Assessment:		
	Justification:		

	YES	NO
This procedure change requires prior NRC approval.	☐	☐

Document all references used for this review:			

Prepared By: _____ **Date:** _____

Qualified Preparer

Reviewed By: _____ **Date:** _____

Qualified Reviewer

Approved By: _____ **Date:** _____

Manager - EP

Enclosure 2: GUIDANCE FOR CONTENT OF EMERGENCY PLAN SUBMITTALS TO REQUIRING PRIOR NRC APPROVAL

Note: The intent of this enclosure is to provide guidance to licensees in the development of their application for NRC prior approval of proposed emergency plan changes

APPLICATION CONTENT		YES	NO	N/A
COVER LETTER	Specifically state what change(s) are requested for NRC review and approval.	☐	☐	☐
	State why the change(s) are being requested.	☐	☐	☐
	Identify which regulation or NRC guidance document under which the application is being submitted.	☐	☐	☐
	Provide the names of the licensing and technical contacts.	☐	☐	☐
	Request a specific date for NRC approval. If less than one year, provide an acceptable reason.	☐	☐	☐
	Reference all attachments.	☐	☐	☐
SUBMITTAL BODY	State each proposed change and discuss the justification for the change and any measures that will be implemented.	☐	☐	☐
	State the basis for the proposed change and why it is considered a reduction in effectiveness in sufficient detail to support a technical review.	☐	☐	☐
	Define any terms that are unique to the site, related to new technology, etc.	☐	☐	☐
	Provide a table showing the current approved wording, the proposed wording, and the basis for the change(s).	☐	☐	☐
	Provide an acceptable level of detail to support a technical review of the proposed change(s).	☐	☐	☐
	Discuss the use of any precedents and a justification for why these stated precedents are applicable to this submittal.	☐	☐	☐
	For an EAL scheme upgrade from NUREG-0654, follow the guidance from RIS 2003-18, including its' supplements.	☐	☐	☐
	Provide discussion on any drills, table-tops, or walkthroughs that validate these proposed change(s), if applicable.	☐	☐	☐