

NON-CONCURRENCE PROCESS

SECTION A - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL

TITLE OF DOCUMENT Memorandum from Joseph G. Gitter to Melvyn N. Leach, "Processing Emergency Plan Reviews"	ADAMS ACCESSION NO. ML091370012
DOCUMENT SPONSOR Joseph G. Gitter	SPONSOR PHONE NO. 301-415-0208
NAME OF NON-CONCURRING INDIVIDUAL Richard B. Ennis	PHONE NO. 301-415-1420

DOCUMENT AUTHOR DOCUMENT CONTRIBUTOR DOCUMENT REVIEWER ON CONCURRENCE

TITLE Senior Project Manager	ORGANIZATION NRR/DORL
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REASONS FOR NON-CONCURRENCE

The draft memo would implement a new procedure for processing emergency plan reviews needing prior NRC approval in accordance with 10 CFR 50.54(q). The procedure would require licensees to submit emergency plan (EP) and emergency action level (EAL) changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests pursuant to 10 CFR 50.90. Presently, these changes are submitted to the NRC as reports pursuant to 10 CFR 50.4 and processed as letter approvals.

The issues raised by the proposed issuance of the draft memo are, to a great extent, the same as the issues raised by the proposed issuance of draft RIS 2005-02, Revision 1. As discussed in my non-concurrence on the draft RIS (provided as Attachment 2 to this non-concurrence), requiring licensees to submit EP and EAL changes, which represent a decrease in effectiveness prior to rulemaking would be:

- Inconsistent with the current regulations
- Inconsistent with current NRR procedures
- Inconsistent with prior direction from the Commission
- "De facto rulemaking"
- Inconsistent with the Perry decision
- A backfit
- Unenforceable
- Inconsistent with the "NRC Principles of Good Regulation"

Based on the detailed discussion in Attachments 1 and 2 to this non-concurrence, any change to the regulatory process for submittal of EP and EAL changes should be done through the rulemaking process. As such, the draft memo should not be issued.

Attachment 1 - "Information to Support Non-Concurrence by Richard Ennis on Memorandum from Joseph G. Gitter to Melvyn N. Leach Regarding "Processing Emergency Plan Reviews"" (20 pages)

Attachment 2 - Non-Concurrence by Richard Ennis on Draft Regulatory Issue Summary 2005-02, Revision 1, "Clarifying the Process for Making Emergency Plan Changes" (43 pages)

CONTINUED IN SECTION D

SIGNATURE 	DATE 5/27/09
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SUBMIT FORM TO DOCUMENT SPONSOR AND COPY TO YOUR IMMEDIATE SUPERVISOR AND DIFFERING VIEWS PROGRAM MANAGER

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT

Memorandum from Joseph G. Giitter to Melvyn N. Leach, "Processing Emergency Plan Reviews"

ADAMS ACCESSION NO.

ML091370012

SECTION B - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL'S SUPERVISOR

(THIS SECTION SHOULD ONLY BE COMPLETED IF SUPERVISOR IS DIFFERENT THAN DOCUMENT SPONSOR.)

NAME

Harold K. Chernoff

TITLE

Branch Chief

PHONE NO.

301-415-2330

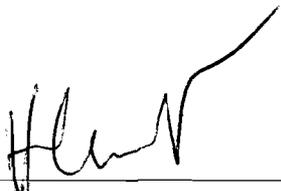
ORGANIZATION

NRR/DORL

COMMENTS FOR THE DOCUMENT SPONSOR TO CONSIDER

- I HAVE NO COMMENTS
 I HAVE THE FOLLOWING COMMENTS

This non-concurrence identifies substantive concerns associated with the subject memorandum. The concerns in some cases relate to the previous non-concurrence issued on the proposed RIS 2005-02, Revision 1. This non-concurrence raises additional concerns, as well as, documenting and discussing discrepancies in the responses associated with the RIS 2005-02, Rev. 1, non-concurrence.



CONTINUED IN SECTION D

SIGNATURE

Harold Chernoff

Digitally signed by Harold Chernoff
DN: cn=Harold Chernoff, o=NRC, ou=U.S. Nuclear Regulatory Commission, email=HChernoff@nrc.gov
Date: 2008.05.29 14:08:13 -0400

DATE

05/29/2008

SUBMIT THIS PAGE TO DOCUMENT SPONSOR

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT Memorandum from Joseph G. Giitter to Melvyn N. Leach, "Processing Emergency Plan Reviews"	ADAMS ACCESSION NO. ML091370012
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SECTION C - TO BE COMPLETED BY DOCUMENT SPONSOR

NAME Joseph G. Giitter	PHONE NO. 301-415-0208
TITLE Division Director	
ORGANIZATION Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation	

ACTIONS TAKEN TO ADDRESS NON-CONCURRENCE (This section should be revised, as necessary, to reflect the final outcome of the non-concurrence process, including a complete discussion of how individual concerns were addressed.)

As noted by Mr. Ennis, the issues he raises are, to a great extent, the same issues he raised concerning the draft Regulatory Issues Summary 2005-02, Revision 1. Therefore, the response to this non-concurrence refers to the previous response for many of these issues. The response is provided as an attachment to this form. No changes to the memorandum resulted from this non-concurrence.

CONTINUED IN SECTION D

SIGNATURE - DOCUMENT SPONSOR <i>Joseph G. Giitter</i>	DATE 6/16/09	SIGNATURE - DOCUMENT SIGNER <i>Joseph G. Giitter</i>	DATE 6/16/09
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NON-CONCURRING INDIVIDUAL (To be completed by document sponsor when process is complete, i.e., after document is signed):

<input type="checkbox"/> CONCURS	<input checked="" type="checkbox"/> WANTS NCP FORM PUBLIC
<input checked="" type="checkbox"/> NON-CONCURS	<input type="checkbox"/> WANTS NCP FORM NON-PUBLIC
<input type="checkbox"/> WITHDRAWS NON-CONCURRENCE (i.e., discontinues process)	

RESPONSE TO NON-CONCURRENCE

A summary of each of Mr. Ennis' concerns is provided followed by the response to that concern. The reader is referred to Mr. Ennis' submittal for a complete discussion of the concern.

1. History of Process for 10 CFR 50.54(q) Reviews

Mr. Ennis provides an expanded discussion supporting his position that the agency's practice has been to approve reductions in effectiveness (RIEs) by letter rather than license amendment. In addition, he provides additional information supporting his position that this is the intent of the regulations.

Response

The agency's practice has been at best inconsistent. However, past agency practice, whatever it may have been, should not dictate future action if that practice is not compliant with legal requirements. The Office of the General Counsel (OGC) has found that legal precedent has determined that such changes must be processed as license amendments.

2. 10 CFR 50.4 Submittal Requirements

Mr. Ennis attempts to rebut the response to the previous non-concurrence regarding the combined requirements of §§50.54(q) and 50.4. He presents his "clear reading" interpretation of §50.54(b)(1). In addition, he asserts that the response to the non-concurrence did not address his discussion of "§50.4(b)(4)." [We have confirmed that Mr. Ennis intended to reference §50.4(b)(4) rather than the non-existent §50.4(b)(3)(4).]

Response

Mr. Ennis misunderstands the legal import of the reference in §50.54(q) to §50.4, Section 50.4 is simply an administrative provision governing all written communications from applicants and licensees to the NRC. By its explicit terms, it applies to "applications." See 10 CFR 50.4(a). This renders untenable Mr. Ennis' argument that the § 50.54(q) requirement to submit, as specified in § 50.4, each change constituting a decrease in effectiveness for approval, was intended by the NRC to be an approval in a manner other than a license amendment.

As a general matter, we simply note that §50.4 establishes administrative requirements governing the submission of written materials to the NRC, and does not govern the regulatory process for obtaining an NRC approval – be it a license, an exemption, an approval of an alternative, or other licensing action or regulatory dispensation.

3. NRR Office Instructions

Mr. Ennis agrees NRR Office Instructions are not regulatory requirements. He states that the references to LIC-100 gives further credence to his position that the agency practice, consistent with his plain language interpretation of the regulations, is to process EP changes that require NRC approval, as letter approvals, not as license amendments

SUMMARY OF NON-CONCURRENCE

A summary of each of Mr. Ennis' concerns is provided followed by the response to that concern. The reader is referred to Mr. Ennis' submittal for a complete discussion of the concern.

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Response

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Response

Refer to the response to Issue 1 of this non-concurrence.

4. New Process versus Clarification of Existing Process

Mr. Ennis states that the assertion that the use of the §50.90 process for §50.54(q) changes is merely a clarification of the existing process is not supported by the current requirements, history and past practices, and NRR procedures and therefore, this assertion is misleading. He points to the previous three concerns to support his position.

Response

Refer to the responses to the first three issues.

5. Direction from the Commission

Mr. Ennis quotes the Commission direction regarding rule interpretations in the Perry decision: "The staff may not adopt an interpretation unsupported by the language and history of the rule."

Referring to his arguments supporting his previous four issues, he concludes that use of the §50.90 process is a position unsupported by the language and history of the rule. As such, it is inconsistent with the quoted Commission direction.

Response

As discussed in the response to Issue 1 of the RIS non-concurrence and in Issues 1 and 2 above, agency practice has been inconsistent, the statements of consideration are silent on this matter and the language of §§50.4 and 50.54(q) support the application of the license amendment process to EP changes that involve a reduction in effectiveness.

6. SECY-08-0024 and Commission Notification of Change in Direction

Mr. Ennis states that the response to the previous non-concurrence does not describe all of the circumstances related to this Commission paper. He issued a non-concurrence for the draft to this paper. In it, he challenged the use of the §50.90 process before rulemaking. The final Commission paper was issued without a discussion of the process to be used prior to rulemaking in order to resolve the non-concurrence. The paper stated that the staff intended to pursue the change through rulemaking. It was only after issuance of the staff requirements memorandum that the Office of Nuclear Security and Incident Response (NSIR) and OGC told the Office of Nuclear Reactor Regulation (NRR) of the intention to implement the §50.90 process prior to rulemaking.

He concludes that a new Commission paper should be issued and a Technical Assistants' brief held if NRR plans to issue the memo following review of the non-concurrence.

Response

The staff will issue a Commissioners' Assistants Note (CAN) prior to the issuance of the RIS revision. The CAN will include, or reference by the Agencywide Documents Access and

Management System accession number, the RIS package, which will include the RIS non-concurrence. Because the issues in the RIS and this non-concurrence are essentially the same, there is no need to again inform the Commission prior to issuing this memo. Given this approach, there is no need for another SECY. A Technical Assistants' brief will be held if requested by the Commission offices.

7. Change in Staff Position

Mr. Ennis states that the response to the previous non-concurrence incorrectly interprets the intent of his discussion. Mr. Ennis restates his position that the use of the license amendment process is clearly a change in staff position.

Response:

Refer to the response to Issue 1.

8. Perry Decision

Mr. Ennis states that the response to the RIS non-concurrence did not address the analysis he provided in Attachment 2 to the non-concurrence. He concludes, "In conclusion, a licensee's operating authority with respect to emergency preparedness is established based on the NRC staff's finding that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, not based on a "level of effectiveness." As such, the *Perry* decision does not support the proposed use of the license amendment process for approval of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q)."

Response:

Without directly addressing Mr. Ennis latest comments, the response to Issue 6 of the RIS non-concurrence is complete and accurate and requires no further elaboration.

9. Decision to Implement 10 CFR 50.90 Process Prior to Rulemaking

Citing responses to Issues 5 and 6 to the RIS non-concurrence and referring to his arguments in Issue 8 on this non-concurrence, Mr. Ennis states that he does not agree with the premise that based on *Perry*, the license amendment process needs to be used for approval of proposed emergency plan changes that would decrease the effectiveness of the plan. As such, there is nothing "illegal" about using the current letter approval process.

Mr. Ennis states that implementing the procedures in the memorandum would be a de facto rulemaking and, as such, a violation of the notice and comment provisions of the Administrative

Procedures Act (APA). He includes a citation from NUREG/BR-0053, and two court cases, *Appalachian Power v. EPA* and *Besler v. Bradley*, to support of his position.

Response:

OGC has consistently advised that, consistent with the proper application of the precedent in the *Perry* case, approval of proposed emergency plan changes that would decrease the effectiveness of the plan requires a license amendment and is not properly accomplished via a mere letter approval.

The agency has published a proposed rulemaking (74 FR 23254) that would clarify the regulations in this areas. In addition, as discussed in response to Issue 6 to the RIS non-concurrence and as cited my Mr. Ennis in this non-concurrence, when there is a legally defensible interpretation and a legally questionable interpretation that could be applied to a disputed regulation, the agency does not have the policy "option" of proceeding to apply the potential illegal interpretation while it pursues rulemaking to clarify that the legally defensible interpretation is the correct interpretation.

10. Interactions with the Nuclear Energy Institute (NEI)

Mr. Ennis discusses interactions with NEI and concludes that is further evidence that stakeholder involvement is needed through the rulemaking process before the license amendment process is utilized for approval of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q).

Response

The interactions and references cited by Mr. Ennis are not disputed. However, as discussed in the memo and the response to the RIS non-concurrence, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. OGC has advised the staff that NRC approval of a change expanding the licensee's authority in a manner not previously approved, or otherwise allowed under the NRC's requirements, effectively constitutes a license amendment and must be accomplished through the license amendment process. Because this rulemaking is not likely to be finalized for several years, the staff should not wait before processing for approval any new plan changes that reduce the level of effectiveness of the plan without also going through the 10 CFR 50.90 license amendment procedures. For such approvals to be legal and effective, they must be accomplished by license amendment.

4.11 Backfit Issues

Mr. Ennis concludes that the draft memo involves a backfit and should be formally provided to the Committee to Review Generic Requirements (CRGR) for review.

Response:

The staff acknowledges that there may have been inconsistent staff practice in the regulatory process for NRC approvals of RIEs (although we do not believe that Mr. Ennis has provided documentation demonstrating that the inconsistency occurred over a relatively long period of time or involved numerous individual letter approvals). Nonetheless, the staff has been advised

by OGC that despite such inconsistencies, the issuance of the memo by Mr. Giitter does not constitute backfitting as defined in 10 CFR 50.109(a)(1). Moreover, the positions presented in the memo, even if "imposed" upon licensees, would not constitute backfitting as defined in 10 CFR 50.109(a)(1), inasmuch as the definition does not include changes in the NRC's process or administrative requirements governing the licensing process. Therefore, there is no requirement for a formal review of this action by the CRGR.

In addition, we note that a formal CRGR review would not result in any change to OGC's legal conclusion that NRC approvals of RIEs must be accomplished by license amendment rather than by letter, consistent with the Commission's decision in *Perry*.

4.12 Enforceability

Mr. Ennis takes issue with the response to the RIS non-concurrence on this topic, stating that the staff cannot process a change as a license amendment unless it is submitted as such. He cites additional requirements that must be met. He concludes that the procedures in the draft memo are unenforceable.

Response

This is not an enforcement issue. While it is true that the additional requirements identified by Mr. Ennis must be met before the staff can conclude its review, the acceptance review process, as discussed in the draft memo, would be used to supplement the submittal, or the applicant would have the opportunity to withdraw it. Regarding Mr. Ennis' assertions of unintended consequences and an unstable regulatory environment, he provides little support for these positions.

13. No Significant Hazards Considerations

Mr. Ennis states that he has no disagreement with response to the RIS non-concurrence regarding the regulatory requirements which allow post-amendment hearings. However, he states that his focus was on providing stakeholder involvement through rulemaking to discuss this issue prior to implementation. For example, stakeholders may suggest a different process than the license amendment process having some of the same attributes (e.g., opportunity for as hearing) but not having all the same attributes (e.g., NSHC).

Response

The need to use the license amendment process for EP changes, involving a decrease in effectiveness, is a matter of law.

14. Openness

Mr. Ennis states that implementing the procedures in the draft memo would be a complete surprise to those outside the NRC. He asserts that addressing stakeholder concerns after the process change is implemented (i.e., through the rulemaking process as noted in NSIR's response) is contrary to the principle of openness.

Response

The draft memo would be issued in conjunction with the publication of the draft RIS in the *Federal Register* for comment. Therefore, our implementation will occur concurrent with stakeholders being informed of the change that is required by law.

15. Clarity

Mr. Ennis disagrees that that the RIS "...would provide clarity where none exists" as stated in the response to the RIS non-concurrence. He also argues that there is no reason to treat EAL scheme changes differently from individual EAL changes.

Response

All changes, regardless of size, involve some degree of uncertainty. The public comment period associated with the publication of the draft RIS will be used to receive and respond to questions and concerns. Regarding the five points listed in his comment, each of these has been addressed in response to another issue. Regarding EAL scheme changes compared to individual EAL changes, the scheme changes performed by licensees are to incorporate guidance that has already been evaluated and endorsed by the NRC. The review of the proposed scheme change is to ensure regulatory stability of the EAL scheme through adherence to NRC reviewed and endorsed guidance. Individual EAL changes are different due to the nature of the change to the approved EAL scheme and the change resulting in a reduction in effectiveness.

16. Reliability

Referencing the other issues he has raised, Mr. Ennis repeats the concern stated in his RIS non-concurrence that use of the 10 CFR 50.90 process, for submittal and review of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q), prior to rulemaking, is unsupported by the language and history of the rule. In addition, as also discussed above, the proposed process described in the draft memo involves a backfit.

Response

OGC notes that Mr. Ennis' "history" of the rule consists of a single instance of the staff's action with respect to a single licensee, dating from the 1997 time period. Given that: (i) the disputed language of the rule dates from well before 1997, (ii) Mr. Ennis presents no analysis of the statements of consideration for the proposed or final rule which adopted the original §50.54(q) provisions, (iii) Mr. Ennis presents no staff guidance contemporaneous with the adoption of the "reduction in effectiveness" criterion; and (iv) Mr. Ennis presents only a single instance where the NRC staff used a letter approval which occurred in 1999, OGC believes that Mr. Ennis' assertions are without merit. Mr. Ennis' claims on backfitting are addressed elsewhere in this response.

4.17 Potential Adverse Impact on Rulemaking

Mr. Ennis takes issue with the response to the non-concurrence. He states: there is nothing illegal with the current letter approval process. As I also noted above, compliance with 5 U.S.C. 553 of the APA requires that the NRC give the public an opportunity to comment on a rule proposed by the agency before the rule can be put into effect. Although not in compliance with the APA, at least the draft RIS is planned to be issued for public comment prior to implementation. The draft memo would implement the change in process without any stakeholder interaction. In either case (ie., draft RIS or draft memo)), implementation of the license amendment process prior to completion of rulemaking gives our stakeholders the impression that this change is a "done deal" and that their input doesn't matter.

Response:

While his observation that the draft RIS is "not in compliance with the APA" involves the issue of whether the RIS constitutes a 'substantive' or "interpretive" rule, as Mr. Ennis correctly notes, the draft RIS is being issued for public comment, which tends to ameliorate any concerns about the RIS as a substantive rule.

ATTACHMENT 1

INFORMATION TO SUPPORT NON-CONCURRENCE BY RICHARD ENNIS ON MEMORANDUM FROM JOSEPH G. GIITTER TO MELVYN N. LEACH REGARDING "PROCESSING EMERGENCY PLAN REVIEWS"

1.0 PURPOSE

The purpose of this document is to provide information supporting my non-concurrence on a draft memorandum from Joseph G. Giitter to Melvyn N. Leach titled "Emergency Plan Reviews" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML091370012) (hereinafter referred to as the "draft memo."). The intent of providing this information is to allow NRC management to make a fully-informed decision on the path going forward.

2.0 BACKGROUND

- 2.1 Currently, 10 CFR 50.54(q) and Section IV.B of Appendix E to 10 CFR Part 50 require that all emergency plan (EP) and emergency action level (EAL) changes that require prior NRC approval be submitted to the NRC in accordance with 10 CFR 50.4 as a report. The NRC staff issues the approvals/denials via letter with an attached safety evaluation.
- 2.2 As discussed on page 3 of the draft memo, the NRC staff would implement the following new procedures for review of emergency plans currently under review by the staff:
 1. The licensee should be informed that the staff has determined that emergency plan changes that require prior NRC approval, in accordance with 10 CFR 50.54(q), need to be submitted as license amendment requests in accordance with 10 CFR 50.90.
 2. NRC staff will continue its review of the emergency plan change pending completion of the §50.90 submittal requirements. However, approval of an emergency plan change or EAL change involving a decrease in effectiveness cannot be issued until those requirements are met.
 3. If the licensee does not want to have the change reviewed under §50.90, the request should be withdrawn.

As also discussed on page 3 of the draft memo, the NRC staff would implement the following new procedures for review of emergency plans that are newly submitted to the NRC:

The procedures in NRR Office Instruction (OI) LIC-109, "Acceptance Review Procedures," should be used. If the submittal requirements of §50.90 have not been met, then the licensee should be informed, as stated in the section for "Plans Currently Under Review," and the licensee should be given the opportunity to supplement its submission in accordance with the procedures in LIC-109.

- 2.3 The major difference between the process proposed in the draft memo compared to the present process (i.e., letter approvals) is that the license amendment process provides opportunities for public comment and to request a hearing. In addition, the license amendment process requires that the licensee provide its analysis of the issue of no significant hazards consideration (NSHC) and, unless covered by a categorical exclusion in 10 CFR 51.22, requires an environmental assessment pursuant to 10 CFR 50.21.
- 2.4 On May 18, 2008, the NRC staff issued a proposed rule, "Enhancements to Emergency Preparedness Regulations" for public comment (74 FR 23254). The proposed rule would include a change to 10 CFR 50.54(q) to require licensee submittal of emergency plan changes, which represent a reduction in effectiveness¹, as license amendment requests pursuant to 10 CFR 50.90. However, as discussed on page 2 of the draft memo:

Because this rulemaking is not likely to be finalized for several years, the staff should not wait before processing for approval any new plan changes that reduce the level of effectiveness of the plan without also going through the 10 CFR 50.90 license amendment procedures. For such approvals to be legal and effective, they must be accomplished by a license amendment.

A Regulatory Issues Summary is under development that will inform licensees, in part, that emergency plan changes that require prior NRC 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.

- 2.5 The draft memo represents the third time that the NRC staff has tried to implement the license amendment process, for EP and EAL changes which represent a decrease in effectiveness, prior to the completion of rulemaking for 10 CFR 50.54(q).

In the first instance, the NRC staff prepared a draft SECY paper which, in order to resolve an issue regarding NRR authority for approval or denial of emergency plan changes, proposed the use of the 10 CFR 50.90 process for changes which represent a decrease in effectiveness. On December 4, 2007, I issued a non-concurrence (ADAMS Accession Nos. ML080360379 (non-public version) and ML082310591 (public version)) on the draft SECY. The non-concurrence was resolved via revision of the draft SECY (which became SECY 08-0024) to remove discussion of the 10 CFR 50.90 process. However, the final SECY stated that the staff intended to pursue a change to 10 CFR 50.54(q), **through the planned rulemaking**, to require that decrease in effectiveness changes be submitted pursuant to 10 CFR 50.90.

In the second instance, the NRC staff developed draft RIS 2005-02, Revision 1, "Clarifying the Process for Making Emergency Plan Changes," (ADAMS) Accession No. ML080710029), which, in part, would instruct licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests (i.e., pursuant to 10 CFR 50.90). On April 24, 2009, I issued a non-concurrence on the draft RIS. The draft RIS is still going through the concurrence

¹ Note, the term "decrease in effectiveness," currently used in 10 CFR 50.54(q), would be changed to "reduction in effectiveness" as part of the proposed rulemaking.

process and, as such, the non-concurrence has not yet been added to ADAMS. Therefore, I have included it as Attachment 2 since it deals with many of the same issues raised by the proposed issuance of the draft memo.

3.0 SUMMARY OF ISSUES

The issues raised by the proposed issuance of the draft memo are, to a great extent, the same as the issues raised by the proposed issuance of draft RIS 2005-02, Revision 1. As discussed in my non-concurrence on the draft RIS (Attachment 2), requiring licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests prior to rulemaking would be:

- Inconsistent with the current regulations
- Inconsistent with current NRR procedures
- Inconsistent with prior direction from the Commission
- "De facto rulemaking"
- Inconsistent with the *Perry* decision
- A backfit
- Unenforceable
- Inconsistent with the "NRC Principles of Good Regulation"

As I concluded in the non-concurrence on the draft RIS, any change to the regulatory process for submittal of EP and EAL changes should be done through the rulemaking process. As such, the draft memo should not be issued.

I have already detailed my concerns on the above issues in the non-concurrence on the draft RIS. The Office of Nuclear Security and Incident Response (NSIR²) has provided a response to my concerns on these issues in Attachment 3 to that non-concurrence. Rather than providing another detailed discussion of the above issues, this non-concurrence focuses on those areas in the NSIR response that I believe are inaccurate, mischaracterize my arguments, or did not address my arguments. A discussion of these issues is included below in Section 4.0.

4.0 DISCUSSION OF ISSUES

4.1 History of Process for 10 CFR 50.54(q) reviews

In Section 4.1 (Issue 1) of my non-concurrence on the draft RIS I stated that:

The plain language interpretation of 10 CFR 50.54(q) clearly indicates submittal of emergency plan changes as reports in accordance with 10 CFR 50.4, not as

² Throughout this non-concurrence use of the phrase "NSIR response" refers to the statements made in Attachment 3 to my non-concurrence on draft RIS 2005-02, Revision 1. I recognize that the information provided by NSIR may have been based on input/advice from other offices including NRR and OGC.

license amendments pursuant to 10 CFR 50.90. In addition, the history of the process used by the staff (i.e., letter approvals/denials) consistent with the plain language interpretation of the rule has remained unchanged since promulgation of 10 CFR 50.54(q) in 1980.

In the response to Issue 1 of the non-concurrence on the draft RIS, NSIR's response stated, in part, that:

However, the staff's approach over time in reviewing the proposed changes to approved emergency plans that would result in reductions in effectiveness of the plans has not been consistent and unchanged. On at least one occasion, the NRC staff has advised a licensee that if they requested NRC review of a proposed change that would decrease the effectiveness of the licensee's emergency plan, such a request had to be submitted under 10 CFR 50.90. See Thomas, K.M., U.S. Nuclear Regulatory Commission, letter to J.M. Levine, Arizona Public Service Company, October 24, 1997.

The example used by NSIR to make their case (i.e., October 27, 1997 letter) doesn't tell the whole story. Here's a history of that review:

- 1) On June 1, 1997, the licensee submitted a proposed revision to the Palo Verde emergency plan for NRC review and approval "in accordance with 10 CFR 50.54(q) and 50.4." The proposed change involved a reduction in the number of radiation protection (RP) technicians available on-shift for emergency plan staffing. Enclosure 1 to the letter, which provided a summary/justification of the proposed changes concluded that each of the staffing changes would not decrease the effectiveness of the Palo Verde emergency plan. Note, as discussed in Attachment 3 to RIS 2005-02, dated February 14, 2005, "removal of current emergency responders" is considered an example of a plan change that constitutes a decrease in effectiveness.
- 2) On October 24, 1997, the NRC staff sent a letter to the licensee that, although not clearly stated³, could be interpreted to indicate that if the proposed changes would decrease the effectiveness of the licensee's emergency plan, the changes should be submitted in accordance with 10 CFR 50.90. Part of the reason for issuance of the letter appears to be that the licensee submitted the change for NRC review and approval pursuant to 10 CFR 50.54(q), however, their summary/justification of the proposed changes concluded that each of the staffing changes would not decrease the effectiveness of the Palo Verde emergency plan.
- 3) On September 8, 1998, the licensee once again submitted a proposed revision to the Palo Verde emergency plan for NRC review and approval "in accordance with 10 CFR 50.54(q) and 10 CFR 50.4." Although not exactly the same as the June 1, 1997, submittal, the proposed change also involved a reduction in the number RP-related emergency plan on-shift staffing. The submittal stated "APS believes the proposed

³ The October 24, 1997, letter states, in part, that "if a licensee determines that a planned change does not satisfy the requirements stated above, a licensee can request NRC review of the planned change in accordance with the regulatory requirements contained in 10 CFR 50.90." However, based on some of the earlier discussion in the letter, "the requirements stated above" could be interpreted to be "the standards of 10 CFR 40.47(b) and the requirements of Appendix E to 10 CFR Part 50." If this is the case, the licensee would need to request an exemption pursuant to 10 CFR 50.12, not a license amendment pursuant to 10 CFR 50.90. It should also be noted that this letter was sent by a project manager and had no higher level concurrence within the project manager's Division.

revision constitutes a reduction in the overall effectiveness in the Emergency Plan from what currently exists.”

- 4) On February 5, 1999, the NRC staff issued a letter approval with an attached safety evaluation for the changes proposed in the September 8, 1998 submittal. The safety evaluation stated that “The Emergency Plan changes were submitted for NRC staff review and approval as required by 10 CFR 50.54(q) and 10 CFR 50.4.”

To assert, based on the October 24, 1997, letter that “the staff’s approach over time **in reviewing** the proposed changes to approved emergency plans that would result in reductions in effectiveness of the plans has not been consistent and unchanged [emphasis added]” is contrary to the actual history of that review. Although the October 24, 1997, letter referenced by NSIR seems to indicate the licensee should re-submit the change pursuant to 10 CFR 50.90, the licensee re-submitted the change pursuant to 10 CFR 50.54(q) and 10 CFR 50.4 (consistent with the regulations) and the NRC staff review was documented by letter with an attached safety evaluation, not a license amendment.

It is not credible to argue that 10 CFR 50.54(q) has ever required that requests for NRC approval be submitted as license amendments. If this were the case it would surely be supported by amendments that were approved for changes that were submitted soon after the rule’s implementation in 1980 when individuals directly involved in the development of the rule would have been available to ensure its proper implementation. My research did not identify any instances of using the amendment process nor has any other party produced such evidence. As a result, the logical conclusion is that use of the amendment process was not part of the original intent or interpretation of the rule. This is further supported by the long history of approving changes by letters (sans amendment process) many examples of which can be obtained by researching the docket files. In addition, there is a history of NRC enforcement in this area where cited violations for failure to obtain prior NRC approval for changes that result in decreases in effectiveness were resolved by changes submitted to the NRC pursuant to 10 CFR 50.54(q) in accordance with 10 CFR 50.4 as a report and were subsequently approved by letter with an attached safety evaluation. As further evidence of the cognizance of using the letter approval rather than the amendment process, EPPOS No. 4⁴, “Emergency Preparedness Position (EPPOS) on Emergency Plan and Implementing Procedure Changes” issued on November 19, 1998 (ADAMS Accession No. ML023040483), states that “For changes that decrease the effectiveness of the plan, the licensee must request an **evaluation of the change** from the Commission prior to implementation” [emphasis added]. There is no credible argument that the phrase, “must request an evaluation of the change” would have been selected as an analogue for the license amendment process of 10 CFR 50.90. Rather this phrasing reflected the existing regulatory practice of NRC staff approving changes submitted as a report in accordance with 10 CFR 50.4 with letters and enclosed safety evaluations. In fact there is no reference whatsoever to the license amendment process or the need to submit a license amendment request in this entire document.

Note, NSIR stated in its response (under Issue 4) that the examples of letter approvals of decrease in effectiveness changes provided in Section 4.1 of my non-concurrence on draft RIS 2005-02, Revision 1, “are not of sufficient frequency, importance, or breadth to reasonably be considered as having established an “agency practice”.” As noted in the non-concurrence,

⁴ It is noted that EPPOS No. 4 was later withdrawn, due in part, to being superseded by the guidance in RIS 2005-02. However, that does not negate that it provides further evidence that there was no intent to use the license amendment process for NRC approval of changes under 10 CFR 50.54(q).

the examples from 2008 were provided only to counter claims by NSIR and OGC (in a meeting with the deputy EDO on January 14, 2009) that the staff had **never** approved a decrease in effectiveness emergency change via letter. A review of docketed correspondence would clearly show that NSIR's claim that an agency practice has not been established is incorrect. Further discussion of agency practice (i.e., letter approvals) is provided below in Section 4.3.

NSIR has not provided a single example where the NRC staff has issued a license amendment to approve a proposed decrease in effectiveness of a licensee's emergency plan. Over the years the NRC staff has received numerous emergency plans submitted for NRC approval pursuant to 10 CFR 50.54(q). By definition, a change submitted for NRC approval in accordance with 10 CFR 50.54(q) is a change a licensee has determined is a decrease in effectiveness. The history and practice for approval of these changes has been by letter, not by license amendment. To assert otherwise is without basis.

4.2 10 CFR 50.4 Submittal Requirements

As discussed in Section 4.1 of my non-concurrence, the requirements in 10 CFR 50.54(q) state, in part, that:

Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission. The licensee shall submit, **as specified in §50.4, a report** of each proposed change for approval. [emphasis added]

In the response to Issue 1 of the non-concurrence on the draft RIS, NSIR correctly noted that I cited the wrong section of 10 CFR 50.4 that specifically pertains to emergency plan submittals (references to "10 CFR 50.4(b)(3)(5)" should have been "10 CFR 50.4(b)(5)" which pertains to "Emergency plan and related submissions").

With respect to 10 CFR 50.4, NSIR's response also stated:

If the NRC's intent of § 50.54(q)'s general reference to § 50.4 was specifically to limit the obligations for filings made under § 50.54(q) to filings under § 50.4(b)(5), then the history of the rulemaking would certainly have contained some indication that such was the intent of this reference. We have located no information and the non-concurring individual does not identify any information indicating that the reference to § 50.4 generally was meant to be anything other than a reference to all procedures in § 50.4, including the procedures for filing license amendment requests.

10 CFR 50.4(b)(1) is titled "Applications for amendment of permits and licenses; **reports**; and other communications [emphasis added]." This paragraph of the regulation clearly shows "reports" as distinct and separate from "Applications for amendment of permits and licenses." As noted above, 10 CFR 50.54(q) clearly states that the proposed changes for NRC approval are to be submitted as "reports" not as "applications for amendments." This along with a history of licensee's submitting these changes pursuant to 10 CFR 50.54(q) and 10 CFR 50.4 without any reference to 10 CFR 50.90 show the assertion made in the NSIR response (i.e., reference in 10 CFR 50.54(q) to 10 CFR 50.4 was also intended to apply to the procedures for filing license amendment requests) is without merit.

I also note that NSIR's response to Issue 1, they did not directly address the following discussion provided in Section 4.1 of my non-concurrence on the draft RIS:

It should be noted that the preceding paragraph §50.4(b)(3)(4) which deals with security plan and related submittals clearly includes specific guidance related to applications for amendment pursuant to 10 CFR 50.90 conforming with the explicit requirement of 10 CFR 50.54(p), that for changes to the security plan that would decrease the effectiveness of the plan, "A licensee desiring to make such a change shall submit an application for an amendment to the licensee's license pursuant to §50.90."

While the statements of consideration for each of these regulations appears to be silent with respect to the reason why each regulation establishes a different process for submitting changes for approval related to a seemingly similar acceptance criteria, there is no basis to support that there was an intent in the promulgation 10 CFR 50.54(q) in 1980 (45 FR 55409, August 8, 1980) to follow the process delineated in 10 CFR 50.54(p) which had already been in place for approximately seven years (38 FR 30538, November 6, 1973). A logical inference is that there was a decision to provide a different administrative process for the submission and approval of licensee requests for approval pursuant to 10 CFR 50.54(q).

4.3 NRR Office Instructions

In Section 4.2 (Issue 2) of my non-concurrence on the draft RIS I made several references to NRR Office Instruction LIC-100 to demonstrate that emergency plan changes are to be processed as letter approvals, not as license amendments.

Under "Issue 2," the NSIR response stated, in part, that:

NRR office procedures are not regulatory requirements and serve only as an internal guide. Thus, the non-concurring individual's deference to LIC 100 as authority is misplaced.

NRR Office Instruction ADM-100, "Preparing and Maintaining NRR Office Instructions," defines "the process by which NRR staff and managers develop and maintain office instructions." ADM-100 states that "**[i]t is the policy of NRR to establish procedures and guidance for its staff to meet the requirements and performance goals established in legislation, regulations, the agency's strategic plan, and office-level operating plans. [emphasis added]**

ADM-100 also states that:

NRR Office Instructions may provide a procedure for the staff to follow in order to satisfy a regulation that imposes requirements upon the NRC (e.g., the Freedom of Information Act) or may provide a procedure for the staff to follow in interacting with stakeholders when they are required to submit a document to the NRC (e.g., licensing actions). An office instruction should not revise or interpret regulatory requirements.

Although, as the NSIR response states, NRR office procedures are not “regulatory requirements,” they are internal procedures intended, in part, to help ensure that the regulatory requirements are met.

The references to the statements in LIC-100 gives further credence to my position that the agency practice, consistent with the plain language interpretation of the regulations, is to process emergency plan changes, that require NRC approval pursuant to 10 CFR 50.54(q), as letter approvals, not as license amendments.

4.4 New Process versus Clarification of Existing Process

In Section 4.2 (Issue 2) of my non-concurrence on the draft RIS, I pointed out that the draft proposed emergency preparedness rulemaking referred to use of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes as a “new process.” I made this argument to counter the discussion in draft RIS 2005-02, Revision 1, that use of the of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes was merely a “clarification” of the current process. As noted by NSIR’s response in Issue 2:

The non-concurring individual cites to the draft proposed rule, which is simply a draft. The non-concurring individual notes the errors in the draft concerning references to the “new” process. These errors were corrected before publication in the Federal Register as the official proposed rule. As noted above, particularly when there are changes in language from the draft to the final version of a rulemaking, the better principle of statutory construction is that the change was made with intent and that the final version reflects the decision maker’s views, in this case the views of the Commission.

The assertion that use of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes is merely a “clarification” of the existing process is not supported by the current regulatory requirements, history and past practices for submittal and processing of 10 CFR 50.54(q) changes, and NRR procedures that reflect the current regulatory requirements. To assert that this major change in process is a clarification is extremely misleading. Specific evidence that use of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes would be a new process is discussed above in Sections 4.1, 4.2, and 4.3.

4.5 Direction from the Commission

In Section 4.3 (Issue 3) of my non-concurrence on the draft RIS, I stated that requiring licensees to submit emergency plan changes as license amendment requests, prior to rulemaking, is an interpretation of 10 CFR 50.54(q) which is unsupported by the language and history of the rule. I noted that the proposed action would be inconsistent with the following direction provided by the Commission regarding rule interpretations in the *Perry* decision:

The Staff is certainly free to change rule interpretations if appropriate. **But the Staff may not adopt an interpretation unsupported by the language and history of the rule.** [emphasis added]

Under Issue 3, NSIR countered my position based on their arguments for Issues 1 and 2. Based on the discussion above in Section 4.1, 4.2, 4.3, and 4.4, it is clear that use of the 10 CFR 50.90 process, for submittal and review of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q), is an interpretation unsupported by the

language and history of the rule. As such, it is inconsistent with the direction provided by the Commission regarding rule interpretations.

4.6 SECY 08-0024 and Commission Notification of Change in Direction

Under Issue 3, NSIR's response stated that:

SECY-08-0024 did not include any discussion of the process to be used in reviewing licensee emergency plan changes that would decrease the effectiveness of the plan prior to rulemaking because the non-concurring individual and members of his management did not want the SECY to address the process. This exclusion was intentional to recognize that the non-concurring individual and staff management were still discussing the potential non-concurrence and the inclusion of such a discussion was not crucial to the purpose of that particular SECY paper.

The above statement does not describe all the circumstances related to SECY 08-0024. As discussed above in Section 2.5, I issued a non-concurrence on a draft SECY paper (which later became SECY 08-0024). The draft SECY proposed the use of the 10 CFR 50.90 process for emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q). The basis for issuing a non-concurrence was that I believed rulemaking was needed before such a change in regulatory process could be made. The final SECY was issued without discussion of the process to be used prior to rulemaking in order to resolve the non-concurrence. However, the final SECY stated that, the staff intended to pursue a change to 10 CFR 50.54(q), **through the planned rulemaking**, to require that decrease in effectiveness changes be submitted pursuant to 10 CFR 50.90. Following issuance of the SECY, it was my understanding, as well as others in NRR, that use of the 10 CFR 50.90 process would not be pursued prior to the emergency preparedness rulemaking (this is clearly documented in e-mail). It was only after issuance of the Staff Requirements Memorandum (SRM) for the SECY in May 2008, that NSIR and OGC told NRR of the intention to once again pursue the use of the license amendment process prior to rulemaking.

In a meeting between NRR, NSIR, and OGC management on September 11, 2008, it was decided that in order to inform the Commission of the change in direction from that stated in SECY 08-0024, a Commission Technical Assistant (TA) brief would be held instead of issuing a new SECY paper. To date, this brief has not occurred. Note, I raised this concern during review and comment on draft RIS 2005-02, Revision 1. Consistent with my comment on the draft RIS, the draft memo from Joseph G. Giitter to Melvyn N. Leach represents a position contrary to that stated in SECY 08-0024. As such, a new SECY should be issued and a Commission TA brief should be held if NRR still plans to issue the memo following review of this non-concurrence.

4.7 Change in Staff Position

As discussed in Section 4.4 (Issue 4) of my non-concurrence on the draft RIS, "[r]equiring licensees to submit proposed emergency plan changes as license amendment requests, prior to rulemaking, is clearly a change in staff position. As such, the proposed action is an inappropriate use of a RIS and, in effect, would be "de facto rulemaking.""

Under Issue 4, NSIR's response stated that:

The non-concurring individual claims that "Requiring licensees to submit proposed emergency plan changes as license amendment requests, prior to rulemaking, is clearly a change in staff position." This statement is incorrect in two ways. First, the RIS addresses only those proposed emergency plan changes that would result in a decrease in effectiveness. The non-concurring individual's statement refers to all proposed emergency plan changes. Second, as noted under Issue 1 above, use of the license amendment process would not constitute a change in staff position. As noted above, the instances cited by the non-concurring individual are not of sufficient frequency, importance, or breadth to reasonably be considered as having established an "agency practice" as proposed in the non-concurrence documentation.

NSIR statement that my non-concurrence "refers to all proposed emergency plan changes," incorrectly interprets the intent of the discussion in Section 4.4. Throughout the non-concurrence on the draft RIS I used the term "the proposed action." Section 3.0 of the non-concurrence clearly indicates that for each of the issues, "the proposed action" refers to "issuance of a RIS that would instruct licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests."

Contrary to NSIR's response, the use of license amendment process is clearly a change in staff position as discussed above in Sections 4.1 through 4.5.

Also contrary to NSIR's response, the "agency practice" is letter approvals, not license amendments, as discussed above in Sections 4.1 and 4.3.

4.8 Perry Decision

In Section 4.6 (Issue 6) of my non-concurrence on the draft RIS, I concluded that:

Based on: (1) the lack of any prescriptive requirements related to emergency planning being incorporated in nuclear plant operating licenses; and (2) specific technical standards being included in the emergency planning regulations and guidance; NRC approval of an emergency plan change does not grant the licensee any greater operating authority, or otherwise alter the original terms of the license. As such, the proposed use of the license amendment process to approve or deny changes to emergency plans is inconsistent with the positions stated by the Commission in the *Perry* decision.

This conclusion was based on a detailed analysis of the *Perry* Decision with respect to emergency plan changes as provided in Attachment 2 to my non-concurrence on the draft RIS. As I discussed in Attachment 2:

On page 327 of the *Perry* decision, the Commission cited applicable case law that provided examples where certain NRC approvals did not trigger AEA section 189a hearing rights. The Commission clarified its position as follows:

Where the NRC approval does not permit the licensee to operate "in any greater capacity" than originally prescribed and all relevant safety

regulations and license terms remain applicable, the NRC approval does not "amend" the license.

Only those actions falling "beyond the ambit of prescriptive authority granted under the license" necessitate a license amendment.

On page 328 of the *Perry* decision, the Commission provided further insight regarding the issue of "greater operating authority" as follows:

That the staff may wish to verify in advance that a proposed revision conforms to the required technical standard does not make the Staff approval a license amendment. By merely ensuring that required technical standards are met, the Staffs approval does not alter the terms of the license, and does not grant the licensee greater operating authority. Such a review indeed enforces license requirements. As an enforcement policy matter, the Staff may wish to police some licensee-initiated changes before they go into effect. To insist-as the Intervenor do-that the NRC staff may never require prior approval for any change or activity without effecting some sort of major licensing action, would frustrate the agency's ability to monitor licensees and enforce regulations. As we have already noted, not every change that occurs at a nuclear power plant, even if significant, represents a license amendment.

NSIR's response did not address the analysis provided in Attachment 2. Of particular note, there was no discussion of my position that NRC approval of the initial submittal of an emergency plan did not result in prescriptive requirements, delineating a licensee's operating authority, being incorporated in the respective licenses. In addition, there also was no discussion regarding specific technical standards being included in the emergency planning regulations and guidance.

NSIR's response discusses the premise that operating authority is established based on a "level of effectiveness." As discussed on page 4 of Attachment 2 of my non-concurrence on the draft RIS, the decrease (reduction) in effectiveness criterion is used by the licensee to determine if a change needs prior NRC approval (i.e., sets the threshold for those changes needing prior NRC approval). This criterion identifies proposed changes where the NRC staff will verify, in advance, that the proposed revision conforms to the required technical standards. The NRC staff finding, consistent with the statements of consideration for the 1980 Emergency Planning rule, must conclude: "whether the state of onsite and offsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency." This finding establishes the authority under which the facility may continue to operate. In accordance with 10 CFR 50.54(s)(3), this finding is to be based on a NRC review of FEMA findings and, "...on the NRC assessment as to whether the licensee's onsite emergency plans are adequate and capable of being implemented." The use of the term "level of effectiveness" (which respect to operating authority) is a new concept that incorrectly reinterprets the current regulatory framework for a licensee's authority with respect to emergency preparedness.

In conclusion, a licensee's operating authority with respect to emergency preparedness is established based on the NRC staff's finding that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological

emergency, not based on a “level of effectiveness.” As such, the *Perry* decision does not support the proposed use of the license amendment process for approval of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q).

4.9 Decision to Implement 10 CFR 50.90 Process Before Rulemaking

In Section 4.5 (Issue 5) of my non-concurrence on the draft RIS I stated that draft RIS does not explain why this change in regulatory process can be implemented without rulemaking (i.e., given the plain language interpretation of 10 CFR 50.54(q) and the rulemaking procedures in the Administrative Procedure Act (APA)).

Under Issue 5, NSIR's response stated, in part, that:

Waiting until 2010 for rulemaking is unacceptable for purposes of properly handling the emergency preparedness licensing actions that rise to the level of approving an emergency plan change resulting in a reduction in effectiveness. Because the rulemaking will not be final until 2010 (at the earliest), staff should not wait before processing for approval any new plan changes that reduce the level of effectiveness of the plan without also going through the 10 CFR 50.90 license amendment and FRN procedures. For such approvals to be legal and effective, they must be done by license amendment.

Under Issue 6, NSIR's response stated, in part, that:

The non-concurring individual demonstrates an apparent misunderstanding in arguing that the agency should await rulemaking to implement *Perry*. This is not a question of policy but a question of whether, under *Perry*, licensees have the legal authority to act on proposed changes without appropriate NRC approval. When there is a legally defensible interpretation and a legally questionable interpretation that could be applied to a disputed regulation, the agency does not have the policy “option” of proceeding to apply the potentially illegal interpretation while it pursues rulemaking to clarify that the legally defensible interpretation is the correct requirement. It was, in fact, for this reason that OGC has been urging prompt issuance of this particular RIS since at least mid-2008.

Under Issue 6, NSIR's response also states that:

The non-concurring individual cites to 29 years of using the “current process” but neglects to consider the impact of the *Perry* decision in 1996. Given that *Perry* and the court cases cited in the RIS provide when a license amendment process should be used, what the staff did prior to *Perry* is irrelevant, and what the staff has done since *Perry*, to the extent that proposed changes that would result in reductions in effectiveness were approved using the letter approval process, has been legally and procedurally incorrect.

As discussed above in Section 4.8, I do not agree with the premise that, based on *Perry*, the license amendment process needs to be used for approval of proposed emergency plan changes that would decrease the effectiveness of the plan. As such, there is nothing “illegal” about using the current letter approval process.

Even if for some reason, there was a “legally questionable interpretation” regarding the application of a particular regulation, the remedy would be to fix the regulation through rulemaking (e.g., as was done with 10 CFR 50.91 as a result of the *Sholly* decision). Requiring licensees to submit proposed emergency plan changes, needing prior NRC approval in accordance with 10 CFR 50.54(q), as license amendment requests pursuant to 10 CFR 50.90, would be de facto rulemaking, and, as such, violation of the notice and comment provisions in the APA. As discussed on page 2 of NUREG/BR-0053, Revision 6, “United States Nuclear Regulatory Commission Regulations Handbook” (ADAMS Accession No. ML052720461):

Compliance with 5 U.S.C. 553 of the APA requires that the NRC give the public an opportunity to comment on a rule proposed by the agency before the rule can be put into effect. This section also requires that the effective date of a regulation be not less than thirty days from the date of publication unless there is good cause for implementation at an earlier date.

As discussed in *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), “[i]t is well-established that an agency may not escape the notice and comment requirements...by labeling a major substantive legal addition to a rule a mere interpretation.” In addition, as discussed in *Besler v. Bradley*, 361 N.J. Super. 168, “[u]nder the APA, even a minor procedural change in how an agency wishes the public to interact with the agency, as occurred in this case, can meet the definition of a rule.”

4.10 Interactions with Nuclear Energy Institute (NEI)

In Section 4.6 (Issue 6) of my non-concurrence on the draft RIS, I referenced a January 23, 2003, letter from the NRC to NEI which stated, in part, that “[t]he staff acknowledges that NRC regulations and practices include processes for obtaining NRC approval other than by a license amendment. It is not effective or efficient to revisit earlier processes that may have been established in the regulations for particular actions.” The letter indicated that the staff would focus on consistent application of the criteria from the *Perry* decision **in the future through rulemaking.**

Under Issue 6, NSIR’s response stated, in part, that:

The January 23, 2003, letter referenced by the non-concurring individual further supports the use of a license amendment process when a licensee proposes to reduce the effectiveness of its approved emergency plan. In that letter, the NRR Office Director stated, “A license amendment issued on a plant-specific basis is necessary where there is a change in the activity previously authorized or where staff judgment and discretion must be applied to determine whether the underlying requirements would be met, in the absence of objective, prescribed criteria for fulfilling those requirements.”

In Section 4.6 of my non-concurrence on the draft RIS, I also referenced a number of interactions between the NRC and NEI on the issue of operating authority and the *Perry* decision. One of these references (Reference 2 in the non-concurrence) included an NRC meeting summary dated December 27, 2002, for a meeting with NEI to discuss the threshold for license amendments. The meeting summary states, in part, that:

While there was universal agreement that altering the terms of a license required a license amendment, and about what altering the terms included, there were different views among the meeting participants as to how greater operating authority was to be judged and the role to be played, if any, by the existence of "objective, pre-established criteria" for purposes of judging acceptability. At the heart of the issue is the degree to which a staff approval could be done in a form other than a license amendment, in those cases where the process for approval has not already been defined.

Note, I was present at that meeting, and I remember it as extremely contentious, with a lack of consensus on the issues concerning greater operating authority. This is further evidence that stakeholder involvement is needed through the rulemaking process before the license amendment process is utilized for approval of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q).

4.11 Backfit Issues

In Section 4.7 (Issue 7) of my non-concurrence on the draft RIS, I stated, in part, that:

Imposition of the 10 CFR 50.90 process via the RIS is not "...a clarification of the existing regulatory requirements licensees must follow when making changes to their emergency plans," rather, it is an attempt to implement a revised **required** method for submitting licensee proposed changes in accordance with 10 CFR 50.54(q). As stated previously, the existing requirements call for submittal in accordance with 10 CFR 50.4, not 10 CFR 50.90. Since emergency plan changes have not been required to be submitted as license amendments since promulgation of 10 CFR 50.54(q) in 1980, the proposed action would clearly be imposition of a regulatory staff position interpreting the staff's regulations that is different from the previously applicable staff position.

Under Issue 7, NSIR's response stated, in part, that:

The RIS would not constitute a backfit for the reasons explained in the RIS. The non-concurring individual focuses on the first reason, based on his belief that use of the license amendment process would be a change in staff position. However, the proposed use of the license amendment process for emergency plan changes is not a new process, as explained above.

As discussed above in Section 4.4, the assertion that use of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes is merely a "clarification" of the existing process is not supported by the current regulatory requirements, history and past practices for submittal and processing of 10 CFR 50.54(q) changes, and NRR procedures that reflect the current regulatory requirements. Specific evidence that that use of the 10 CFR 50.90 process for 10 CFR 50.54(q) changes would be a new process is discussed above in Sections 4.1, 4.2, and 4.3.

NSIR's response also stated that:

Further, as explained in the RIS, "The NRC's regulatory review process is not a licensee procedure required for operating a plant that would be subject to backfit limitations." In essence, even if the non-concurring individual were correct that there is some established agency practice for these reviews, a change or

clarification to such procedures (which is not the case here) is not, by definition, a backfit.

NSIR focuses on the "NRC's regulatory review process" not the impact on licensees. As discussed in Section 4.7 of the non-concurrence on the draft RIS, licensee procedures for screening, evaluating and processing proposed emergency plan changes as well as procedures controlling the facility change process and temporary facility change process would need to be modified and/or developed.

NSIR's response further stated that:

Notably, the non-concurring individual does not address the second reason why the RIS would not constitute a backfit. As explained in the RIS, "[T]he 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." This Commission position dates back to the original Part 52 rulemaking in 1989 and was applied in the 2005 EAL rulemaking that the non-concurring individual frequently references.

As discussed in Attachment 2 to my non-concurrence on the draft RIS:

Based on the discussion in the August 19, 1980, *Federal Register* notice for the emergency planning rulemaking, the initial submittal of an emergency plan, and the subsequent finding by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, were prerequisites to either obtaining an operating license (for a new reactor) or for justifying continued operations (for an operating reactor). These prerequisites were really conditions of getting (or keeping) a license rather than being "license conditions." As such, **NRC approval of the initial submittal of an emergency plan did not result in prescriptive requirements, delineating a licensee's operating authority, being incorporated in the respective licenses nor amendment to the operating licenses.** [emphasis added]

NRC approval of a change to an emergency plan does not give a licensee "authority to do what is not currently permitted under its license" since such approvals do not change license terms and conditions.

10 CFR 50.109 states:

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position

As discussed above, licensees will be required to change their procedures as a result of the contemplated imposition of a requirement to make 10 CFR 50.54(q) plan changes through the

amendment process rather than the current agency practice and historically applied letter approval. Thus the definition of backfitting is met and a regulatory analysis should be performed.

Consistent with the discussion in Section 4.7 of my non-concurrence on the draft RIS, the draft memo involves a backfit and should be formally provided to CRGR for review.

4.12 Enforceability

In Section 4.8 (Issue 8) of my non-concurrence on the draft RIS, I concluded that requiring licensees to submit emergency plan changes, needing prior NRC approval in accordance with 10 CFR 50.54(q), as license amendment requests pursuant to 10 CFR 50.90, is unenforceable.

In regard to performing an acceptance review of licensee submittals I stated that:

In addition, the staff would have no regulatory basis to not accept the application for review just because the licensee did not submit the proposed change in accordance with 10 CFR 50.90 (as directed in the draft RIS). Specifically, as discussed in Section 3.1.2 of NRR Office Instruction LIC-109, "Acceptance Review Procedures" (ADAMS Accession No. ML081200811), the staff reviews the regulatory basis of the proposed change to determine whether the applicable regulations and criteria are properly applied.

Under Issue 7, NSIR's response stated, in part, that:

NRR office procedures are not regulatory requirements and serve only as an internal guide. Thus, the non-concurring individual's deference to LIC-109 as authority is misplaced.

As detailed above in Section 4.3, although, as the NSIR response states, NRR office procedures are not "regulatory requirements," they are internal procedures intended, in part, to help ensure that the regulatory requirements are met. LIC-109, in part, helps the NRC staff ensure that licensee submittals are consistent with applicable regulations. Based on the current requirements in 10 CFR 50.54(q), the NRC staff would have no regulatory basis to not accept an emergency plan change needing prior NRC approval just because it wasn't submitted pursuant to 10 CFR 50.90.

NSIR's response also stated that:

The RIS is simply notice as to how the NRC will process an "application to ... the Commission" (§ 50.54(q)) for approval of a proposed change that would reduce the effectiveness of an approved emergency plan. If a licensee does not submit an application for an amendment, the staff can go back to the licensee and state that the staff will process the proposed change as a license amendment and ask if the licensee wants to continue to pursue its application for approval.

Contrary to the above statement, the staff cannot process a proposed change as a license amendment unless it was submitted as such. For example, the regulatory requirements associated with license amendment requests (i.e., submitted pursuant to 10 CFR 50.90) includes the following items not required under 10 CFR 50.54(q):

- 10 CFR 50.30(b) requires that the application (and supplements to it) be submitted under oath or affirmation.
- 10 CFR 50.91(a)(1) requires that the licensee provides its analysis of the issue of no significant hazards consideration using the standards in 10 CFR 50.92.
- 10 CFR 51.21 requires an environmental assessment unless a categorical exclusion under 10 CFR 51.22 is applicable. None of the categorical exclusions of 10 CFR 51.22 is applicable for emergency plan changes.

Consistent with the discussion in Section 4.8 of my non-concurrence on the draft RIS, the procedures in the draft memo (discussed above in Section 2.2) are unenforceable. Implementing the procedures in the draft memo will likely cause licensee confusion on submittal requirements and NRC staff confusion on how to process proposed changes. In addition, issuance of the draft memo may result in some emergency plan changes being processed as license amendments and some being processed as letter approval/denials. These issues (i.e., confusion and different methods of processing) would result in an unstable regulatory process. It may also have an unintended consequence of a delaying or forestalling implementation of beneficial emergency plan changes by licensees.

4.13 No Significant Hazards Consideration (NSHC)

In Section 4.9 (Issue 9) of my non-concurrence on the draft RIS, I indicated that the license amendment process may be inappropriate from the standpoint that since emergency planning is not credited as part of the plant's accident analysis, it is highly unlikely that a proposed change to an emergency plan would ever result in a finding that it involves a significant hazards consideration. As such, if the license amendment process was used and a hearing was requested, the amendment could always be issued prior to the hearing pursuant to 10 CFR 50.91 and 10 CFR 50.92. This indicates that the license amendment process may not be a good fit for emergency plan changes, since it would appear disingenuous to stakeholders, as well as an unnecessary use of licensee and NRC staff resources, to apply a process using a regulatory standard which would never be satisfied. This provides further justification that the staff should not impose the license amendment process without allowing an adequate opportunity for stakeholder input through rulemaking. Stakeholder input from the rulemaking process is essential in evaluating this concern.

Under Issue 9, NSIR's response stated that:

A "no significant hazards" finding must be made on a case-by-case basis. It cannot be generically determined that proposed changes that reduce the effectiveness of approved emergency plans will never involve significant hazards considerations. In the event that a particular proposal does involve no significant hazards considerations, section 189.a of the AEA and well-established case law support existing NRC policy that having a hearing after issuing a license amendment is legally permissible. The non-concurring individual's view that such post-amendment hearings being allowed under the statutes and regulations is somehow an indication that the amendment process is not the correct process for these approvals is fundamentally inconsistent with statutory authority and the agency practice to allow post-amendment hearings. The non-concurring individual's discussion under this issue does not provide any basis for concluding

that the legally-required amendment process is inappropriate for reviewing and approving the changes at issue.

I have no disagreement with NSIR's response regarding the regulatory requirements which allow post-amendment hearings. However, my focus was on providing stakeholder involvement through rulemaking to discuss this issue prior to implementation. For example, stakeholders may suggest a different process than the license amendment process having some of the same attributes (e.g., opportunity for as hearing) but not having all the same attributes (e.g., NSHC).

4.14 Openness

In Section 4.10 (Issue 10) of my non-concurrence on the draft RIS, I discussed how the proposed action was inconsistent with the NRC "Principles of Good Regulation."

Under Issue 10, NSIR's response stated with respect to "Openness," that:

The NRC staff will address all stakeholders concerns on this issue during the rulemaking process.

As I noted in my non-concurrence, the public is aware of the NRC's intent to pursue, **through rulemaking**, a change to 10 CFR 50.54(q) to require that licensees submit decrease in effectiveness changes for NRC approval pursuant to 10 CFR 50.90. Implementing the procedures in the draft memo (discussed above in Section 2.2) would be a complete surprise to those outside the NRC. Addressing stakeholder concerns after the process change is implemented (i.e., through the rulemaking process as noted in NSIR's response) is contrary to the principle of openness.

4.15 Clarity

Under Issue 10, NSIR's response stated with respect to "Clarity" that:

The RIS would provide clarity where none exists. Each of the non-concurring individual's claims on this issue has been addressed above. Further, the non-concurring individual's claims rely on the EAL proposed rule FRN instead of the EAL final rule FRN. For the reasons provided above, this reliance is misplaced.

As I noted in Section 4.10 of my non-concurrence on the draft RIS the use of the license amendment process for emergency plan changes, prior to rulemaking, would not provide a clear nexus between the current regulations and agency goals and objectives because this proposed action is:

- (1) Inconsistent with the current regulations in 10 CFR 50.54(q) and 10 CFR 50.109;
- (2) Inconsistent with current NRR procedures that are based on the current regulations;
- (3) Inconsistent with prior direction from the Commission regarding interpretation of the regulations;
- (4) Inconsistent with a Commission decision (*Perry* decision) on the types of changes that should be treated as license amendments; and

(5) Unenforceable.

To assert that “[t]he RIS would provide clarity where none exists” is completely unfounded. There is no lack of clarity on the licensee’s part on how an emergency plan decrease in effectiveness change is to be submitted to the NRC (i.e., pursuant to 10 CFR 50.54(q) and 10 CFR 50.4). There is also no lack of clarity on how the NRC staff is to process such changes (i.e., as a letter with attached safety evaluation). The one major area where there is a lack of clarity is having a clear and common understanding on those changes that represent a decrease in effectiveness. Changing to the license amendment process does not remedy that problem. In fact, use of the license amendment process, prior to completion of the emergency preparedness rulemaking, unnecessarily muddies the water based on the five problems noted above.

With respect to EAL changes, the draft memo, draft RIS, and emergency preparedness rulemaking would all continue to use the letter approval process rather than the license amendment process for EAL scheme changes, while individual EAL changes, that would decrease the effectiveness of the plan, would be submitted and processed as license amendments. As I noted in Section 4.8 above, a licensee’s operating authority with respect to emergency preparedness is established based on the NRC staff’s finding that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, not based on a “level of effectiveness.” As such, there is no reason to treat EAL scheme changes differently than individual EAL changes. This is like saying that if a plant currently has custom technical specifications and wants to convert to the improved standard technical specifications, that change would be treated by letter approval while an individual technical specification change would be treated as a license amendment. As with a technical specification conversion, some of the individual changes are more restrictive and others are less restrictive. During an actual event/emergency, a single or small number of EALs may be exercised. As such, arguing that, as a whole, an entire EAL scheme change is more effective (and thus be evaluated by a different process) is meaningless.

4.16 Reliability

Under Issue 10, NSIR’s response stated with respect to “Reliability” that:

As explained above, the RIS is consistent with existing regulations, would not be a backfit, and would provide clarity to licensees.

As discussed above, use of the 10 CFR 50.90 process, for submittal and review of emergency plan changes requiring prior NRC approval in accordance with 10 CFR 50.54(q), prior to rulemaking, is unsupported by the language and history of the rule. In addition, as also discussed above, the proposed process described in the draft memo involves a backfit.

4.17 Potential Adverse Impact on Rulemaking

In Section 4.11 (Issue 11) of my non-concurrence on the draft RIS, I discussed how the proposed action may have an adverse impact on the emergency preparedness rulemaking. I noted, in part, that:

It is inappropriate for the NRC staff to take action which would predetermine, either in fact or perception, the outcome of a proposed rulemaking initiative. The

effect of such action would be to “bind the hands” of the Commission in the future deliberations regarding the prospective rule change. This type of action substantively undercuts the rulemaking process and the deliberative process of the Commission.

Under Issue 11, NSIR’s response stated that:

The proposed rule proposes to clarify the process to use when licensees propose to reduce the effectiveness of their emergency plans. The RIS would provide guidance to licensees until the final rule is issued. As with any rulemaking, the Commission would be free to revise the proposed rule provisions in the final rule as long as a reasonable basis existed for making the changes and other rulemaking requirements were met. If the final rule should differ from the RIS, the final rule provisions would provide the requirements for licensees, superseding the RIS. This is routinely the nature of the rulemaking process. Indeed, the non-concurring individual’s logic that the Commission is not supposed to deal with issues affecting regulated activities during the period when rulemaking is considering similar issues would result in the bizarre situation where the Commission would refrain from taking necessary actions to assure ongoing activities are appropriately and safely (and legally) conducted in accordance with our obligations under the AEA while rulemaking proceeds.

As I noted above, there is nothing illegal with the current letter approval process. As I also noted above, compliance with 5 U.S.C. 553 of the APA requires that the NRC give the public an opportunity to comment on a rule proposed by the agency before the rule can be put into effect. Although not in compliance with the APA, at least the draft RIS is planned to be issued for public comment prior to implementation. The draft memo would implement the change in process without any stakeholder interaction. In either case (i.e., draft RIS or draft memo), implementation of the license amendment process prior to completion of rulemaking gives our stakeholders the impression that this change is a “done deal” and that their input doesn’t matter.

ATTACHMENT 2

Attachment 2 contains the following:

- NRC Form 757 for Non-concurrence on Draft RIS 2005-02, Revision 1 (3 pages)
- Attachment 1, Information to Support Non-Concurrence by Richard Ennis (23 pages)
- Attachment 2, Analysis of Perry Decision with Respect to Emergency Plan Changes (5 pages)
- Attachment 3, Response to Non-Concurrence Issues (11 pages)

NON-CONCURRENCE PROCESS

SECTION A - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL

TITLE OF DOCUMENT Draft Regulatory Issue Summary 2005-02, Revision 1	ADAMS ACCESSION NO. ML080710029
DOCUMENT SPONSOR Christopher G. Miller	SPONSOR PHONE NO. 301-415-1086
NAME OF NON-CONCURRING INDIVIDUAL Richard B. Ennis	PHONE NO. 301-415-1420

DOCUMENT AUTHOR
 DOCUMENT CONTRIBUTOR
 DOCUMENT REVIEWER
 ON CONCURRENCE

TITLE Senior Project Manager	ORGANIZATION NRR/DORL
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REASONS FOR NON-CONCURRENCE

Draft Regulatory Issue Summary (RIS) 2005-02, Revision 1, would instruct licensees to submit emergency plan (EP) and emergency action level (EAL) changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests pursuant to 10 CFR 50.90. Presently, these changes are submitted to the NRC as reports pursuant to 10 CFR 50.4 and processed as letter approvals. The proposed action raises the following issues:

- Issue 1 - The proposed action is inconsistent with the current regulations
- Issue 2 - The proposed action is inconsistent with current NRR procedures
- Issue 3 - The proposed action is inconsistent with prior direction from the Commission
- Issue 4 - The proposed action would be "de facto rulemaking"
- Issue 5 - The NRC staff has not met its obligation to adequately document the decision to use the license amendment process prior to rulemaking
- Issue 6 - The proposed action is inconsistent with the Perry decision
- Issue 7 - The proposed action may be a backfit
- Issue 8 - The proposed action is unenforceable
- Issue 9 - The proposed action uses a process that may be inappropriate
- Issue 10 - The proposed action is inconsistent with the "NRC Principles of Good Regulation"
- Issue 11 - The proposed action may have an adverse impact on the planned rulemaking

Based on the detailed discussion provided in Attachments 1 and 2 to this non-concurrence, I recommend that the NRC staff either: (1) not issue the draft RIS; or (2) revise the draft RIS to remove any discussion regarding using the license amendment process for EP and EAL changes. Any change to the regulatory process for submittal of EP and EAL changes should be done through the rulemaking process.

In addition to the above issues related to the use of the license amendment process, the following issue is discussed in Section 4.12 of Attachment 1 to this nonconcurrency:

Issue 12 - The draft RIS contains inadequate and/or incorrect guidance

I recommend that the RIS (if issued) be revised to address the comments in Section 4.12 of Attachment 1.

Attachment 1 - "Information to Support Non-Concurrence by Richard Ennis on Draft Regulatory Issue Summary 2005-02, Revision 1, "Clarifying the Process for Making Emergency Plan Changes"" (23 pages)

Attachment 2 - "Analysis of Perry Decision With Respect to Emergency Plan Changes" (5 pages)

CONTINUED IN SECTION D

SIGNATURE



DATE

4/24/09

SUBMIT FORM TO DOCUMENT SPONSOR AND COPY TO YOUR IMMEDIATE SUPERVISOR AND
 OFFERING VIEWS PROJECT MANAGER

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT

Draft Regulatory Issue Summary 2005-02, Revision 1

ADAMS ACCESSION NO.

ML080710029

SECTION B - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL'S SUPERVISOR

(THIS SECTION SHOULD ONLY BE COMPLETED IF SUPERVISOR IS DIFFERENT THAN DOCUMENT SPONSOR.)

NAME

Harold K. Chernoff

TITLE

Branch Chief

PHONE NO.

301-415-2330

ORGANIZATION

NRR/DORL

COMMENTS FOR THE DOCUMENT SPONSOR TO CONSIDER

I HAVE NO COMMENTS

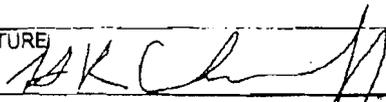
I HAVE THE FOLLOWING COMMENTS

This nonconcurrency provides a comprehensive well researched discussion of a number of substantive process concerns, as well as, noting deficiencies in the guidance included in the draft Regulatory Issue Summary. Collectively and severally these issues deserve focussed attention from NRC senior management. The issues raised are complex and in some cases require a thorough understanding of both NRC and licensee processes. It is likely that the expertise from several organizations will be required to fully address the concerns raised herein.

Extensive efforts have been made to address these concerns with the sponsor organization over more than a year. The initiator of the nonconcurrency remains receptive to a collaborative resolution of these concerns. Resolution of these concerns can then be properly documented as an official agency record.

CONTINUED IN SECTION D

SIGNATURE



DATE

05/04/2009

SUBMIT THIS PAGE TO DOCUMENT SPONSOR

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT

Draft Regulatory Issue Summary 2005-02, Revision 1

ADAMS ACCESSION NO.

ML080710029

SECTION C - TO BE COMPLETED BY DOCUMENT SPONSOR

NAME

Christopher G. Miller

TITLE

Deputy Director for Emergency Preparedness

PHONE NO.

301-415-1086

ORGANIZATION

NSIR/DPR/EP

ACTIONS TAKEN TO ADDRESS NON-CONCURRENCE (This section should be revised, as necessary, to reflect the final outcome of the non-concurrence process, including a complete discussion of how individual concerns were addressed.)

NSIR appreciates the thoughtful consideration provided on the topics in this non-concurrence. In 2007, NSIR and NRR were advised that the appropriate process for processing proposed actions that would decrease the effectiveness of an emergency plan (E-Plan) is the 10 CFR 50.90 license amendment process. Since that time, NSIR, NRR and OGC staff and management have met on numerous occasions to understand the issue, develop a plan to implement any necessary changes, inform stakeholders including industry, and issue any associated guidance or rulemaking. In parallel with this effort, based on feedback from industry as well as NRR and NSIR staff, it was determined that additional clarity was needed in the guidance for processing E-Plan changes contained in RIS 2005-02. The Draft RIS 2005-02 Revision 1 is being issued to provide clarification on processing E-Plan changes, and includes the result of input from staff and management in NRR, NSIR and OGC. As with any project with multiple team members, not every individual agreed on every point, but consensus was reached amongst the offices with a lot of give and take to develop the best product possible. In that consensus building process, many good ideas were provided and changes were included into the development of the RIS, including changes recommended by the individual providing the non-concurrence for this RIS. The majority of the items included in this non-concurrence represent a disagreement with the use of the 10 CFR 50.90 process for changes that represent a decrease in the effectiveness of an E-plan, and have been discussed and addressed in the numerous management and staff meetings amongst the three offices over the last two years. The response to this non-concurrence will be addressed using portions of material or advice that have been provided by and/or reviewed by members of the offices familiar with this issue, but for efficiency sake, do not involve all of the material that has been discussed over the last two years on this project. The need to align on a process and provide this guidance to the industry has been discussed on numerous occasions over the last two years, and NSIR appreciates the diligent work of all the members of the offices that were involved in improving this product such that this guidance can be provided to the stakeholders that have asked for it.

The non-concurrence raises 12 Issues which are addressed in Attachment 3. A change to the RIS was made to help clarify the applicability of lower tier documents to emergency plans. This was in response to an Item identified in issue 12.

Attachment 3 - "Response to Non-Concurrence Issues" (10 pages)

CONTINUED IN SECTION D

SIGNATURE - DOCUMENT SPONSOR

DATE

5-14-09

SIGNATURE - DOCUMENT SIGNER

DATE

5/14/09

NON-CONCURRING INDIVIDUAL (To be completed by document sponsor when process is complete, i.e., after document is signed):

CONCURS

NON-CONCURS

WITHDRAWS NON-CONCURRENCE (i.e., discontinues process)

WANTS NCP FORM PUBLIC

WANTS NCP FORM NON-PUBLIC

ATTACHMENT 1

INFORMATION TO SUPPORT NON-CONCURRENCE BY RICHARD ENNIS ON DRAFT REGULATORY ISSUE SUMMARY 2005-02, REVISION 1, "CLARIFYING THE PROCESS FOR MAKING EMERGENCY PLAN CHANGES"

1.0 PURPOSE

The purpose of this document is provide information supporting my non-concurrence on draft Regulatory Issue Summary (RIS) 2005-02, Revision 1, "Clarifying the Process for Making Emergency Plan Changes," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML080710029) being prepared by the Office of Nuclear Security and Incident Response (NSIR). The intent of providing this information is to allow NRC management to make a fully-informed decision on the path going forward.

2.0 BACKGROUND

- 2.1 During preparation and routing of concurrence for the RIS, I was tasked by my management in the Office of Nuclear Reactor Regulation (NRR) Division of Operating Reactor Licensing (DORL) to review the document. Along with DORL management, I have interfaced with NSIR staff and staff from the Office of the General Counsel (OGC) extensively throughout this process to present my concerns on certain issues which would result from issuance of the RIS. At present, these concerns have not been adequately addressed.
- 2.2 On December 4, 2007, I issued a non-concurrence (ADAMS Accession Nos. ML080360379 (non-public version) and ML082310591 (public version)) on a draft SECY paper related to the process for approving/denying certain types of emergency plan changes. Although the non-concurrence was resolved via revision of the draft SECY (which became SECY 08-0024), some of the same issues have resurfaced as part of the development of draft RIS 2005-02, Revision 1, and the proposed emergency preparedness rulemaking contained in SECY 09-0007 (ADAMS Accession No. ML082890481). Note, my concerns regarding the proposed rulemaking are briefly summarized in Enclosure 6 to SECY 09-0007 (ADAMS Accession No. ML090020095).
- 2.3 My primary concerns relate to the planned change in regulatory process for licensee submittal of emergency plan (EP) and emergency action level (EAL) changes that require prior NRC approval pursuant to 10 CFR 50.54(q) and Section IV.B of Appendix E to 10 CFR Part 50.
- 2.4 Currently, 10 CFR 50.54(q) and Section IV.B of Appendix E to 10 CFR Part 50 require that EP and EAL changes that require prior NRC approval be submitted to the NRC in accordance with 10 CFR 50.4 as a report. The NRC staff issues the approvals/denials via letter with an attached safety evaluation.
- 2.5 The RIS would instruct licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests (i.e., pursuant to 10 CFR 50.90). A decrease in effectiveness is the criteria in 10 CFR 50.54(q) that a licensee uses to determine if prior NRC approval is needed. The same process change (i.e., use of license amendment process) is planned as part of the

proposed rulemaking. As discussed on page 5 of SECY 09-0007: "The Office of the General Counsel has advised the staff that proposed changes to an emergency plan that would reduce the effectiveness of the plan must be submitted for NRC approval through a license amendment request." Note, the term "decrease in effectiveness" in 10 CFR 50.54(q) would be changed to "reduction in effectiveness" as part of the proposed rulemaking.

- 2.6 The major difference compared to the present process (i.e., letter approvals) is that the license amendment process provides opportunities for public comment and to request a hearing.
- 2.7 Based on interactions with OGC and NSIR it is my understanding that OGC believes hearing rights need to be provided for EP or EAL changes that would decrease the effectiveness of the approved emergency plan.

3.0 SUMMARY OF ISSUES

The following is a summary of the issues that are raised by the proposed issuance of a RIS that would instruct licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests:

- Issue 1 - The proposed action is inconsistent with the current regulations
- Issue 2 - The proposed action is inconsistent with current NRR procedures
- Issue 3 - The proposed action is inconsistent with prior direction from the Commission
- Issue 4 - The proposed action would be "de facto rulemaking"
- Issue 5 - The NRC staff has not met its obligation to adequately document the decision to use the license amendment process prior to completion of rulemaking
- Issue 6 - The proposed action is inconsistent with the *Perry* decision
- Issue 7 - The proposed action may be a backfit
- Issue 8 - The proposed action is unenforceable
- Issue 9 - The proposed action uses a process that may be inappropriate
- Issue 10 - The proposed action is inconsistent with the "NRC Principles of Good Regulation"
- Issue 11 - The proposed action may have an adverse impact on the planned rulemaking

Based on the detailed discussion of each of these issues (provided below in Sections 4.1 through 4.11, respectively), I recommend that the NRC staff either: (1) not issue the draft RIS; or (2) revise the draft RIS to remove any discussion regarding using the license amendment process for EP and EAL changes. Any change to the regulatory process for submittal of EP and EAL changes should be done through the rulemaking process.

In addition, to the above issues related to use of the license amendment process, the following issue is included in Section 4.12:

Issue 12 - The draft RIS contains inadequate and/or incorrect guidance

I recommend that the RIS (if issued) be revised to address the comments in Section 4.12.

4.0 DETAILED DISCUSSION OF ISSUES

4.1 The proposed action is inconsistent with the current regulations

The draft RIS would instruct licensee's to submit EP and EAL changes, which represent a decrease in effectiveness, to the NRC for prior approval as license amendment requests (i.e., pursuant to 10 CFR 50.90). Requiring licensees to submit proposed EP and EAL changes as license amendment requests, prior to rulemaking, would be inconsistent with the meaning and intent of the regulations as currently written. The first two subsections discuss EP and EAL changes requiring NRC approval, respectively. The last subsection, "Letter Approvals versus License Amendments," discusses some of the history of how emergency plan changes have been processed consistent with the current regulations.

EP Changes Requiring NRC Approval

The requirements in 10 CFR 50.54(q) state, in part, that:

Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission. The licensee shall submit, **as specified in §50.4, a report** of each proposed change for approval. [emphasis added]

The use of the word "report" and direction to submit in accordance with 10 CFR 50.4 is distinct from any inferred reliance on the license amendment application submittal process, which is also discussed in 10 CFR 50.4. 10 CFR 50.4 includes specific direction for the submittal of reports related to the licensee's emergency plan in §50.4(b)(3)(5). This paragraph does not mention use of the application for license amendment process.

It should be noted that the preceding paragraph §50.4(b)(3)(4) which deals with security plan and related submittals clearly includes specific guidance related to applications for amendment pursuant to 10 CFR 50.90 conforming with the explicit requirement of 10 CFR 50.54(p), that for changes to the security plan that would decrease the effectiveness of the plan, "A licensee desiring to make such a change shall submit an application for an amendment to the licensee's license pursuant to §50.90."

While the statements of consideration for each of these regulations appears to be silent with respect to the reason why each regulation establishes a different process for submitting changes for approval related to a seemingly similar acceptance criteria, there is no basis to support that there was an intent in the promulgation 10 CFR 50.54(q) in 1980 (45 FR 55409, August 8, 1980) to follow the process delineated in 10 CFR 50.54(p) which had already been in place for approximately seven years (38 FR 30538, November 6, 1973). A logical inference is that there was a decision to provide a different administrative process for the submission and approval of licensee requests for approval pursuant to 10 CFR 50.54(q).

The plain language interpretation of 10 CFR 50.54(q) clearly indicates submittal of emergency plan changes as reports in accordance with 10 CFR 50.4, not as license amendments pursuant to 10 CFR 50.90. In addition, the history of the process used by the staff (i.e., letter approvals/denials) consistent with the plain language interpretation of the rule has remained unchanged since promulgation of 10 CFR 50.54(q) in 1980. Further details on the history of using letter approvals are provided below.

EAL Changes Requiring NRC Approval

Based on the 2005 EAL rulemaking, the current regulations in Section IV.B of Appendix E to 10 CFR Part 50 state that:

A revision to an emergency action level must be approved by the NRC before implementation if:

- (1) The licensee is changing from one emergency action level scheme to another emergency action level scheme (e.g., a change from an emergency action level scheme based on NUREG-0654 to a scheme based upon NUMARC/NESP-007 or NEI-99-01);
- (2) The licensee is proposing an alternate method for complying with the regulations; or
- (3) The emergency action level revision decreases the effectiveness of the emergency plan.

A licensee shall submit each request for NRC approval of the proposed emergency action level change as specified in § 50.4. [emphasis added]

Similar to the discussion above for EP changes, it's clear that all EAL changes needing prior NRC approval are to be submitted in accordance with 10 CFR 50.4, not 10 CFR 50.90.

In the Federal Register (FR) notice dated January 26, 2005 (70 FR 3591), which published the final EAL rule, the NRC stated, in part, that:

There is an inconsistency in the emergency planning regulations regarding the threshold for when NRC approval of nuclear power plant licensee changes to EALs is required [emphasis added]. Section 50.54(q) states that licensees may make changes to their emergency 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 10 CFR part 50. By contrast, Appendix E states that "emergency action levels shall be * * * approved by NRC." [Reference page 3591]

The Commission believes that the current regulations are unclear and can be interpreted to require prior NRC approval for all licensee EAL changes. [Reference page 3595]

The Commission believes that prior NRC approval of every EAL change is not necessary to provide reasonable assurance that EALs will continue to provide an acceptable level of safety. **This final amendment focuses on EAL changes that are of sufficient significance that a safety evaluation by the NRC is appropriate before the licensee may implement the change. The Commission believes that EAL changes that reduce the effectiveness of the emergency plan are of sufficient regulatory significance that prior NRC review and approval is warranted. This standard is the same standard that the current regulations provide for when determining whether changes to emergency plans (except EALs) require NRC review and approval. As such, this regulatory threshold has a long history of successful application. Therefore, this standard should also be used for EAL changes [emphasis added].** On the basis of NRC's inspections of emergency plans, including EAL changes, the Commission believes that licensees have generally made appropriate determinations regarding whether an EAL change reduces the effectiveness of the emergency plan and that licensees have the capability to continue to do so. **Limiting the NRC's approval to EAL changes that reduce the effectiveness of emergency plans or to an alternate method for complying with the regulations will ensure adequate NRC oversight of licensee-initiated EAL changes. This both increases regulatory effectiveness (through use of a single consistent standard for evaluating all emergency plan changes) [emphasis added]** and reduces unnecessary regulatory burden on licensees (who would not be required to submit for approval EAL changes that do not decrease the effectiveness of the emergency plan). [Reference page 3591]

The final rule clarifies the requirements and represents the current practice of making changes under § 50.54(q) requirements [emphasis added] and is therefore not a backfit. [Reference page 3598]

The FR Notice which proposed the EAL rule (68 FR 43673, dated July 24, 2003) states that:

The Commission believes a licensee proposal to convert from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007-based) will always involve a potential reduction in effectiveness [emphasis added]. While the new EAL scheme may, upon review, be determined by the NRC to provide an acceptable level of safety and be in compliance with applicable NRC requirements, the potential safety significance of a change from one EAL scheme to another is such that prior NRC review and approval is appropriate to ensure that there is reasonable assurance that the proposed EAL change will provide an acceptable level of safety or otherwise result in non-compliance with applicable Commission requirements on emergency preparedness. [Reference page 43674]

Language would be added to the last sentence of 10 CFR 50.54(q), to clearly state that EAL changes that are made without NRC review and approval, as well as licensee requests for review and approval of EAL changes under the proposed language, must be submitted in accordance with the requirements of § 50.4. **The Commission proposes to follow the current practice of approving EAL changes without the use of a license amendment [emphasis added].** [Reference page 43676]

The following conclusions can be reached based on the 2005 EAL rulemaking as described in the above referenced FR notices:

- 1) The intent of the EAL rule was to clarify "an inconsistency in the emergency planning regulations regarding the threshold for when NRC approval of nuclear power plant licensee changes to EALs is required."
- 2) The Commission determined that the decrease (reduction) in effectiveness standard in 10 CFR 50.54(q) used for EP changes is the same standard that should be used to determine which EAL changes should be submitted to NRC for prior approval.
- 3) Since: (1) the FR Notice for the final rule states that: "Limiting the NRC's approval to EAL changes that reduce the effectiveness of emergency plans or to an alternate method for complying with the regulations will ensure adequate NRC oversight of licensee-initiated EAL changes" and; (2) the types of EAL changes needing prior NRC approval in Appendix E (per the final rule) are: scheme changes; alternate methods; and decreases in effectiveness, it's clear that EAL scheme changes are considered as changes that would potentially reduce the effectiveness of the emergency plan and thus need prior NRC approval in accordance with 10 CFR 50.54(q). This conclusion is further supported by the FR notice for the proposed rule which stated that: "The Commission believes a licensee proposal to convert from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007-based) will always involve a potential reduction in effectiveness."
- 4) Since the FR Notices associated with the 2005 EAL rulemaking: (1) discuss use of a "single consistent standard for evaluating all emergency plan changes"; (2) state that the "[t]he final rule clarifies the requirements and represents the current practice of making changes under § 50.54(q) requirements;" and (3) state that "[t]he Commission proposes to follow the current practice of approving EAL changes without the use of a license amendment," **it's clear that the Commission intended that EP and EAL changes which represent a decrease in effectiveness should be processed without the use of a license amendment.**

Letter Approvals versus License Amendments

Note, in a recent internal NRC meeting, there was disagreement over whether the staff has ever approved a decrease in effectiveness emergency plan change via letter (versus via license amendment). In 2008, the NRC staff approved three emergency plan changes that the licensee submitted for NRC approval because they determined the proposed changes represented a decrease in effectiveness pursuant to 10 CFR 50.54(q). The licensee's applications and NRC staff approvals are as follows:

Palo Verde

- Application dated 12/22/06 (ML070040323)
- NRC approval dated 6/24/08 (ML080170579)

Hope Creek and Salem

- Application dated 6/1/07 (ML071630331)
- NRC approval dated 6/26/08 (ML081690552)

San Onofre

- Application dated 6/18/07 (ML071700672)
- NRC approval dated 11/28/08 (ML083230608)

For two of the above changes (Hope Creek/Salem and San Onofre) the NRC's approval extended the response time goal for activation of the emergency response facilities from 60 to 90 minutes. Regulatory Issue Summary 2005-02, "Clarifying the Process for Making Emergency Plan Changes," was issued by the NRC to clarify the meaning of "decrease in effectiveness," and to clarify the process for making changes to emergency plans. Attachment 3 to the RIS provides specific examples of plan changes that constitute a decrease in effectiveness. One of the examples is: "Increase in facility activation time." Therefore, the Hope Creek/Salem and San Onofre submittals contain changes that the NRC staff would categorize as a decrease in effectiveness.

Based on the above, the NRC staff has approved emergency plan changes which represent a decrease in effectiveness. In each case, approval was via letter (not a license amendment). Note, to the best of my knowledge, the NRR staff has never approved a change submitted pursuant to 10 CFR 50.54(q) as a license amendment (based on extensive searches of official agency records).

4.2 The proposed action is inconsistent with current NRR procedures

NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," Revision 1 (ADAMS Accession No. ML033530249), Section 2.1.5.5, "10 CFR 50.90, License Amendments," states, in part, that:

The *Perry* decision (see Commission Memorandum and Order CLI 96-12) is sometimes referenced in the context of establishing or refining the NRC criteria for when a change being proposed by a licensee requires an application for amendment of their operating license. **Questions sometimes focus on what is the appropriate process (e.g., license amendment with associated requirements for noticing an opportunity for a hearing versus letter approvals such as used for program changes such as emergency planning and quality assurance) more than whether prior NRC approval is or is not warranted.** [emphasis added]

Section 3.4 "Emergency Preparedness Program," in LIC-100 states, in part, that:

If an evaluation performed in accordance with 10 CFR 50.54(q) concludes that a proposed change requires prior NRC approval, a licensee submits a request for NRC review and approval prior to implementation. Correspondence and meetings associated with these reviews are public. **No specific opportunity to comment or to request an adjudicatory proceeding are provided for licensee-specific reviews.** [emphasis added]

Based on the above, the existing NRC procedures call for emergency plan changes needing prior NRC approval be processed as letter approvals, not as license amendments.

It's important to note that the draft RIS implies that we are merely "clarifying" the regulatory process for NRC approval of emergency plan changes rather than changing the regulatory process. For example, page 1 of the RIS, under "Intent," states that the revision of the RIS will

"clarify the process for evaluating proposed changes to emergency plans." Page 2 of the RIS, under "Background Information," states that "the NRC staff clarifies herein that the license amendment process is the correct process to use when reviewing 10 CFR 50.54(q) submittals." Page 8 of the RIS, under "Backfit Discussion," states that "[t]his RIS revision provides review guidance for licensees and clarifies the existing regulatory requirements that licensees must follow when they propose to make changes to their emergency plans." It's clear from the above references to NRR Office Instruction LIC-100 (as well as the historical use of letter approvals as discussed in Section 4.1) that use of the license amendment process for emergency plan changes would be a change in the regulatory process, not a "clarification" of the current process. In addition, the notion that a change from the current process to the license amendment process is merely a "clarification" is not supported by statements made by the staff in the proposed emergency preparedness rulemaking (which would revise 10 CFR 50.54(q) and Section IV.B of Appendix E to 10 CFR Part 50 to require that EP and EAL changes which reduce the effectiveness of the approved emergency plan be submitted as license amendment requests (i.e., same changes proposed in draft RIS)). Specifically, page 2 of Enclosure 3 to SECY 09-0007 (ADAMS Accession No. ML082750453) states, in part, that:

Section 50.54(q)(4) defines the process by which a nuclear power reactor licensee or a non-power reactor licensee would request prior approval of a change to the emergency plan that the licensee has determined constitutes a reduction in effectiveness of the plan. The new rule language states that licensees pursuing such changes would be required to apply for an amendment to the license as provided in Section 50.90. Nuclear power reactors and non-power reactors must revise existing procedures and training documents to account for this **new process**...[emphasis added]

4.3 The proposed action is inconsistent with prior direction from the Commission

The proposed action is inconsistent with prior direction from the Commission in the *Perry* decision, 2005 EAL rulemaking, and in the Staff Requirements Memo (SRM) for SECY 08-0024 as discussed below.

Perry Decision

In the *Perry* decision (CLI-96-13, 44 NRC 315, 1996), the Commission (44 NRC 315 at 325) stated that:

The Staff is certainly free to change rule interpretations if appropriate. **But the Staff may not adopt an interpretation unsupported by the language and history of the rule.** [emphasis added]

Requiring licensees to submit emergency plan changes as license amendment requests, prior to rulemaking, is an interpretation of 10 CFR 50.54(q) which is unsupported by the language and history of the rule (as discussed in Sections 4.1 and 4.2 above). As such, it is inconsistent with the direction provided by the Commission regarding rule interpretations.

2005 EAL Rulemaking

As discussed on page 8 of the draft RIS some EAL changes would be processed as license amendments. However, this position is contrary to what the Commission told the public during the rulemaking process for the 2005 EAL rule. Specifically, as discussed in the Federal

Register notice which proposed the rule (68 FR 43673, dated July 24, 2003), the Commission stated that:

The Commission proposes to follow the current practice of approving EAL changes without the use of a license amendment.

Further discussion regarding the treatment of some EAL changes as license amendments (as proposed in the draft RIS) is provided in Section 4.10.

SRM for SECY 08-0024

The NRC staff (in SECY 08-0024, dated February 25, 2008, ADAMS Accession No. ML072900547) requested that the Commission delegate to the staff the authority to approve or deny proposed emergency plan changes that licensees submit based on their finding that the change represents a decrease in effectiveness. The staff stated that it should have this authority consistent with NRR's authority to approve or deny other routine licensing actions such as license amendments, relief requests, etc. The SECY also stated that the staff intended to pursue a change to 10 CFR 50.54(q), **through the planned rulemaking**, to require that decrease in effectiveness changes be submitted pursuant to 10 CFR 50.90.

The Commission (in the SRM for SECY 08-0024 dated May 19, 2008, ADAMS Accession No. ML081400510) approved the staff's recommendation that it be delegated the authority to approve or deny proposed emergency plan changes that represent a decrease in effectiveness. This approval included the condition that these changes are signed out by the NRR Office Director (or designated Acting Director). However, the approval from the Commission was not conditioned based on use of the license amendment process.

4.4 The proposed action would be "de facto rulemaking"

Exhibit 3 in NRR Office Instruction LIC-503, Revision 2, "Generic Communications Affecting Nuclear Reactor Licensees" (ADAMS Accession No. ML043150304), provides the format and guidance on the content for a RIS. Under the section titled "Summary of Issue," the staff should "[a]ffirm that the NRC has not changed its requirements or position on a matter." Requiring licensees to submit proposed emergency plan changes as license amendment requests, prior to rulemaking, is clearly a change in staff position. As such, the proposed action is an inappropriate use of a RIS and, in effect, would be "de facto rulemaking."

Treating guidance as requirements has been a criticism of NRC staff by our stakeholders (e.g., Nuclear Energy Institute (NEI) letter dated October 9, 2008, Appendix A, page A-3, items 11.0, 12.0, and 13.0, ADAMS Accession No. ML082840103). In addition, courts have found that issuance of guidance documents by Federal and State agencies, in some cases, were in effect "de facto rulemaking" and, as such, violated the rulemaking procedures in the Administrative Procedure Act (see *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000); *Besler v. Bradley*, 361 N.J. Super. 168).

The Office of Management and Budget (OMB) "Draft Report to Congress on the Costs and Benefits of Federal Regulations" dated March 28, 2002 (67 FR 15014), in the section titled "Review of Problematic Agency Guidance (67 FR 15034) noted that "[p]roblematic guidance documents have received increasing scrutiny by the courts, the Congress and scholars." OMB also made the following points:

- 1) To promulgate regulations, an agency must ordinarily comply with the notice-and-comment procedures specified in the Administrative Procedure Act (APA), 5 U.S.C. 553
- 2) Through guidance documents, agencies sometimes have issued or extended their "real rules"
- 3) The failure to comply with the APA's notice-and-comment requirements or observe other procedural review mechanisms can undermine the lawfulness, quality, fairness, and political accountability of agency policymaking.
- 4) Problematic guidance may take a variety of forms. An agency publication that is characterized as some kind of "guidance" document or "policy statement" may directly or indirectly seek to alter rights or impose obligations and costs not fairly discernible from the underlying statute or legislative rule that the document purports to interpret or implement. Such documents are occasionally treated by the agency as having legally binding effect on private parties. When that occurs, substantial question can arise regarding the propriety of the guidance itself specifically whether it should be considered a regulation subject to APA procedures.
- 5) As the Supreme Court confirmed in the *Mead* decision, the rule of law supports the use of regulations over guidance to bind the public.

4.5 The NRC staff has not met its obligation to adequately document the decision to use the license amendment process prior to completion of rulemaking

The "Background Information" section of draft RIS (page 2) provides the following explanation regarding the reason why the regulatory process is being changed prior to rulemaking:

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 currently planned rulemaking." The current schedule for the staff's emergency preparedness (EP) rulemaking calls for the final rule to be issued in September 2010. Because of the timeframe associated with the rulemaking, the staff has determined that the prudent action is to issue a RIS informing licensees that they must submit proposed emergency plan changes which represent a decrease in effectiveness of a licensee's emergency plan as license amendment requests.

The license amendment process has never been used for decrease in effectiveness emergency plan changes since promulgation of 10 CFR 50.54(q) in 1980. As such, the proposed use of the license amendment process would be a significant change in how we have historically processed emergency plan changes. The draft RIS does not adequately explain why this process change needs to be implemented prior to completion of rulemaking. In other words, the current process has been in place for 29 years, why can't we wait until the final rule is issued in 2010? More importantly, the draft RIS does not explain why this change in regulatory process can be implemented without rulemaking (i.e., given the plain language interpretation of

10 CFR 50.54(q) as discussed above in Section 4.1 and the rulemaking procedures in the APA as discussed in Section 4.4).

Consistent with 10 CFR 1.43, NRR has principal responsibility for developing, promulgating, and implementing the regulations under 10 CFR Part 50, and developing policies, programs, and procedures for all aspects of licensing (including emergency preparedness). It is important that NRR and its stakeholders have a clear understanding of the NRC staff's decision to use the license amendment process for emergency plan changes prior to completion of rulemaking.

The need to provide adequate documentation of significant agency decisions is something that has been raised by the Office of the Inspector General (e.g., Davis Besse reactor head issue, License Renewal reviews). In addition, the NRC staff is obligated to document significant decisions in accordance with Management Directive (MD) 3.53¹, "NRC Records and Document Management Program," Handbook 1, Part I, "Recordkeeping Requirements." Specifically, MD 3.53 requires that in order to provide adequate documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the NRC, records shall be created and maintained that are sufficient to document the formulation and execution of basic policies and decisions and necessary actions taken, including all significant decisions and commitments reached orally (person to person, by telecommunications, or in conference).

Currently, the NRC staff has not met its obligation (under the Federal Records Act and MD 3.53) to document the decision to use the license amendment process prior to completion of the rulemaking process.

4.6 The proposed action is inconsistent with the *Perry* decision

Page 2 of the draft RIS, under "Background Information" states that:

In addition, the NRC staff clarifies herein that the license amendment process is the correct process to use when reviewing 10 CFR 50.54(q) 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 would expand its operating authority beyond the authority granted by the NRC. Thus, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. Such a change must be accomplished through a license amendment.

¹ Note, as discussed in Commission Memorandum and Order CLI-08-23 dated October 6, 2008 (ADAMS Accession No. ML082800440), MD 3.53 provides the Commission's interpretation of its obligations under the Federal Records Act (which is codified in Title 44 of the United States Code, Chapters 21, 29, 31 and 33) and regulations promulgated by the National Archives and Records Administration (36 CFR Part 1220).

The above discussion in the draft RIS cites a number of court cases to make the argument that NRC approval of an emergency plan change, that would decrease the effectiveness of the current approved plan, would grant the licensee greater operating authority. Of the cases cited, the *Perry* decision is the case typically cited on the issue of operating authority. As discussed in Section 6.1.4 of NUREG-0386, "United States Nuclear Regulatory Commission Staff Practice and Procedure Digest - Commission, Appeal Board and Licensing Board Decisions July 1972 - January 3, 2004," Digest 13, dated January 2005 (ML050550499):

In evaluating whether an NRC authorization represents a license amendment within the meaning of section 189a of the Atomic Energy Act, courts repeatedly have considered whether the NRC approval granted the licensee any greater operating authority or otherwise altered the original terms of a license. Cleveland Electric Illuminating Co. (*Perry Nuclear Power Plant, Unit 1*), CLI-96-13, 44 NRC 315, 326 (1996).

Where an NRC approval does not permit the licensee to operate in any greater capacity than originally prescribed and all relevant regulations and license terms remain applicable, the authorization does not amend the license.: Cleveland Electric Illuminating Co. (*Perry Nuclear Power Plant, Unit 1*), CLI-96-13, 44 NRC 315, 327(1996).

It's not clear, in the context of the *Perry* decision, how NRC approval of an emergency plan change grants the licensee greater operating authority. In reviewing correspondence between the Nuclear Energy Institute (NEI) and the NRC staff in the 2002 - 2007 timeframe (References 1 - 6), it is clear that NEI repeatedly sought further guidance on application of the *Perry* decision from the NRC staff. However, the staff has not provided clear guidance as to when a proposed change meets the threshold for requiring a license amendment. As an example, in a letter from NEI dated September 27, 2007 (Reference 6), NEI submitted a White Paper entitled "Regulatory Issue Screening Process." White Paper Section 3.2.3, "Operating Authority," states that:

The *Perry* decision describes a threshold for regulatory approval based on whether, in the staff's opinion, a licensee's actions "exceed the operating authority already granted under the licensee's license." A too-narrow interpretation of "operating authority" pre-empts licensees from using the 10 CFR 50.59 change-control process to make changes without prior NRC approval. Both industry and the NRC would benefit from additional guidance on the concept of operating authority.

Due to the lack of documentation on the basis for the proposed change to use the licensee amendment process, I have performed my own review of the *Perry* decision which is included as Attachment 2. As concluded in Attachment 2:

Based on: (1) the lack of any prescriptive requirements related to emergency planning being incorporated in nuclear plant operating licenses; and (2) specific technical standards being included in the emergency planning regulations and guidance; NRC approval of an emergency plan change does not grant the licensee any greater operating authority, or otherwise alter the original terms of the license. As such, the proposed use of the license amendment process to approve or deny changes to emergency plans is inconsistent with the positions stated by the Commission in the *Perry* decision.

Consistent with the *Perry* decision, NRC approval of an emergency plan change that would decrease the effectiveness of the plan merely verifies that the emergency plan continues to meet the standards of 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50. It does not "expand the licensee's operating authority under its license" as discussed in the draft RIS.

It is interesting to note that in a letter dated January 23, 2003 (Reference 3), the NRC told NEI that "[t]he staff acknowledges that NRC regulations and practices include processes for obtaining NRC approval other than by a license amendment. It is not effective or efficient to revisit earlier processes that may have been established in the regulations for particular actions." The letter indicated that the staff would focus on consistent application of the criteria from the *Perry* decision in the future through rulemaking. As discussed in Section 4.5, the current regulatory process for emergency plan changes (i.e., letter approvals) has been in place since 1980. Implementation of the license amendment process, prior to completion of the emergency preparedness rulemaking (as in proposed in the draft RIS), revisits earlier processes that have been established in the regulations. Therefore, the draft RIS conflicts with what we told NEI regarding application of the *Perry* decision in the letter dated January 23, 2003. In addition, revisiting earlier processes, without the necessary rulemaking, results in an unstable regulatory process. Given the 29 year history of the current process, there does not appear to be any adverse consequences to waiting until rulemaking is completed to implement the proposed change in regulatory process.

4.7 The proposed action may be a backfit

As stated in 10 CFR 50.109(a)(1), backfitting is defined, in part, as the modification of "...the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the staff's regulations that is either new or different from a previously applicable staff position..."

The draft RIS on pages 8 and 9, under "Backfit Discussion," states that:

This RIS revision does not require any action or written response. This RIS revision provides review guidance for licensees and clarifies the existing regulatory requirements that licensees must follow when they propose to make changes to their emergency plans. The NRC's Backfit Rule, located at 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.
[emphasis added]

The Backfit Discussion in the RIS is incorrect. It states, in part, that:

This RIS revision **does not require any action** or written response. This RIS revision provides review guidance for licensees and **clarifies the existing regulatory requirements** that licensees **must follow** when they propose to make changes to their emergency plans. [emphasis added]

As highlighted in the emphasized portions above and delineated in detail below, these statements are remarkably incongruent. Clearly if licensees "must follow" the draft RIS guidance for proposing changes to their emergency plans, and there is no past practice of either licensees providing changes in this manner or NRC staff requiring this approach, then one can only conclude that licensee action is, in fact, required by the draft RIS.

Imposition of the 10 CFR 50.90 process via the RIS is not "...a clarification of the existing regulatory requirements licensees must follow when making changes to their emergency plans," rather, it is an attempt to implement a revised **required** method for submitting licensee proposed changes in accordance with 10 CFR 50.54(q). As stated previously, the existing requirements call for submittal in accordance with 10 CFR 50.4, not 10 CFR 50.90. Since emergency plan changes have not been required to be submitted as license amendments since promulgation of 10 CFR 50.54(q) in 1980, the proposed action would clearly be imposition of a regulatory staff position interpreting the staff's regulations that is different from the previously applicable staff position. Further discussion supporting the conclusion that the proposed use of the license amendment process for emergency plan changes is a new process and not merely a clarification of the existing regulatory requirements is provided above in Section 4.2.

The draft RIS further states that:

The NRC's Backfit Rule, located at 10 CFR 50.109, applies to, among other things, the procedures necessary to operate a nuclear power plant.

This statement is an imprecise adaptation from the regulation. 10 CFR 50.109 states that:

Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:

As stated in 50 FR 38102 dated September 20, 1985:

Section 50.109(a) sets out the definition of backfitting... . The definition focuses on modifications to systems, structures, components, designs, procedures or organizations which may be caused by new or modified Commission rules or orders or staff interpretations of Commission rules or orders. Thus, this definition includes both cause and effect of backfitting. It may also be noted that "cause"

includes not only Commission rules and orders, but staff interpretations of those rules and orders.

These excerpts clearly show that a backfit exists when the NRC staff promulgates an interpretation of a regulation that requires a licensee to modify its procedures required to design, construct, or operate a facility. Contrary to the discussion in the draft RIS implying that licensee procedures are not affected by the proposed action (i.e., "The NRC's regulatory review process is not a licensee procedure required for operating a plant that would be subject to backfit limitations."), licensees would be required to modify or add procedures to address the draft RIS statements regarding the process that licensees "must follow when they propose to make changes to their emergency plans." Specifically, licensee procedures for screening, evaluating and processing proposed emergency plan changes as well as procedures controlling the facility change process and temporary facility change process would need to be modified and/or developed.

The impact on licensee procedures is independently documented in the proposed emergency preparedness rulemaking package (SECY 09-0007). Specifically, Enclosure 2 to the SECY, "Draft Regulatory Analysis and Backfit Analysis" (ADAMS Accession No. ML082750457), Appendix A, Section A.8.a, "Reduction in Effectiveness - Nuclear Power Reactor Licensees," states, in part, that:

To comply with the proposed rule, nuclear power reactor licensees would need to revise procedures and training to address the new process for emergency plan changes (i.e., through 10 CFR 50.90 submittals).

The backfit rule does establish three "exceptions" under which the NRC may impose a backfit without preparing a backfit analysis which concludes that there is substantial additional overall protection of the public health and safety and that the direct and indirect costs of implementation are justified. These three "exceptions" are: (1) adequate protection; (2) redefining the level of protection; and (3) compliance. It is clear in this situation that imposition of the NRC staff position interpreting the Commission rules does not involve either an adequate protection or level of protection "exception."

As stated in 50 FR 38103:

The compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard.

It is clear that the compliance "exception" cannot be invoked in this situation. The draft RIS would promulgate a new NRC staff position of what constitutes compliance with 10 CFR 50.54(q) and therefore a regulatory analysis of this backfit, in accordance with the guidance of NUREG-1409, "Backfitting Guidelines" and NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" is required prior to promulgation of this position. This action is consistent with the requirements of NRR Office Instruction LIC-400, "Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees," since the proposed regulatory action involves a generic backfit question as determined by members of the NRC staff.

Note, on February 2, 2009, the NRC's Office of the Inspector General (OIG) issued a report titled "Audit of the Committee to Review Generic Requirements" (ADAMS Accession No. ML090330754). As discussed in the report, the mission for the Committee to Review Generic Requirements (CRGR) includes ensuring that unintended backfits are not imposed or implied by proposed new or revised generic requirements and that NRC-proposed actions are appropriately justified. The OIG noted that the CRGR no longer functions as originally intended. The OIG audit report recommended that the Executive Director for Operations:

1. Develop, document, implement, and communicate an agencywide process for reviewing backfit issues to ensure that generic backfits are appropriately justified based on NRC regulations and policy.
2. Determine what, if any, role the CRGR should perform in NRC's backfit review process, to include whether the CRGR function is still needed.

NRR Office Instruction LIC-503, Revision 2, "Generic Communications Affecting Nuclear Reactor Licensees" (ADAMS Accession No. ML043150304), Section 4.02.c, discusses the basic steps in preparing a RIS. With respect to CRGR review, this section of LIC-503 states that:

The CRGR reviews all new and revised power reactor related generic correspondence which could impose a backfit, and this can include regulatory issue summaries. NRR staff will exercise discretion in referring regulatory issue summaries to the CRGR for review. Those that provide staff guidance on regulatory, licensing or policy matters, or that document NRC endorsement of an industry-developed resolution approach to an issue, are likely candidates for CRGR review since the use of imprecise language may unintentionally, and incorrectly, impose requirements on licensees.

Based on the regulatory requirements in 10 CFR 50.109, NRC procedures, and the OIG audit report, the draft RIS involves a backfit and should be formally provided to CRGR for review.

4.8 The proposed action is unenforceable

NRR Office Instruction LIC-503, Revision 2, "Generic Communications Affecting Nuclear Reactor Licensees" (ADAMS Accession No. ML043150304) states that:

A regulatory issue summary is an informational document and may not request action and/or information, unless the action or response is strictly voluntary.

The draft RIS, on page 1 under "Intent," states, in part, that:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) revision to inform licensees that emergency plan changes that require prior NRC 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 [emphasis added]."

As discussed above in Section 4.1, the current requirements in 10 CFR 50.54(q) state, in part, that:

Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission. **The licensee shall submit, as specified in §50.4, a report of each proposed change for approval.** [emphasis added]

Since compliance with the guidance in the RIS would be voluntary, and the current regulatory requirements in 10 CFR 50.54(q) do not require emergency plan changes requiring prior NRC approval be submitted in accordance with 10 CFR 50.90, licensees may choose to continue to submit decrease in effectiveness changes in accordance with 10 CFR 50.4 as a report.

The NRC staff cannot process a licensee's submittal as a license amendment unless it is submitted as such (e.g., licensee needs to submit proposed no significant hazards consideration determination). In addition, the staff would have no regulatory basis to not accept the application for review just because the licensee did not submit the proposed change in accordance with 10 CFR 50.90 (as directed in the draft RIS). Specifically, as discussed in Section 3.1.2 of NRR Office Instruction LIC-109, "Acceptance Review Procedures" (ADAMS Accession No. ML081200811), the staff reviews the regulatory basis of the proposed change to determine whether the applicable regulations and criteria are properly applied. This section of LIC-109 states that: "[t]he NRC staff may utilize guidance documents such as the Standard Review Plan (SRP) or any specific review standards for specific RLAs [requested licensing actions] (e.g., EPU's [extended power uprates]), however, this is not a requirement and the NRC staff should be cognizant that the licensee may have evaluated the proposed change in a different manner."

Furthermore, if a licensee did not submit a proposed emergency plan change in accordance with 10 CFR 50.90, and the NRC staff decided to review the change, not following the submittal guidance in the draft RIS would not provide a regulatory basis for the staff to deny the proposed change. Consistent with 10 CFR 50.47 and Appendix E to 10 CFR Part 50, the NRC staff finding for an emergency plan change should relate to whether the proposed change provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency (not whether it was submitted as a license amendment request).

Based on the above considerations, the RIS "requirement" for licensee's to submit in accordance with 10 CFR 50.90 is unenforceable. Issuance of the RIS will likely cause licensee confusion on submittal requirements and NRC staff confusion on how to process proposed changes. In addition, issuance of the RIS may result in some emergency plan changes being processed as license amendments and some being processed as letter approval/denials. These issues (i.e., confusion and different methods of processing) would result in an unstable regulatory process.

4.9 The proposed action uses a process that may be inappropriate

One of the arguments supporting the use of the license amendment process for emergency plan changes is that the regulatory requirements associated with this process allow greater stakeholder input by providing an opportunity to request a hearing on the proposed change. However, since emergency planning is not credited as part of the plant's accident analysis, it is highly unlikely that a proposed change to an emergency plan would ever result in a finding that

it involves a significant hazards consideration². As such, if the license amendment process was used and a hearing was requested, the amendment could always be issued prior to the hearing pursuant to 10 CFR 50.91 and 10 CFR 50.92. This indicates that the license amendment process may not be a good fit for emergency plan changes, since it would appear disingenuous to stakeholders, as well as an unnecessary use of licensee and NRC staff resources, to apply a process using a regulatory standard which would never be satisfied (i.e., the amendment could in all cases be issued prior to any requested hearing). This provides further justification that the staff should not impose the license amendment process without allowing an adequate opportunity for stakeholder input through rulemaking. Stakeholder input from the rulemaking process is essential in evaluating this concern.

It is also important to note that use of the license amendment process prior to any rulemaking would also require the NRC staff to perform an environmental assessment for each emergency plan change since, at present, none of the categorical exclusions in 10 CFR 51.22(c) would be applicable to such a change. This could potentially have a significant impact on staff resources until 10 CFR 51.22(c) is revised. This is further argument against using the license amendment process for emergency plan changes at this time.

4.10 The proposed action is inconsistent with the NRC "Principles of Good Regulation"

As discussed on the NRC's public website at <http://www.nrc.gov/about-nrc/values.html> the NRC's values include "Principles of Good Regulation" that we are to adhere to. The following are excerpts from these principles with discussion regarding how the proposed action is inconsistent with each respective principle.

Independence

Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated.

As discussed above in Section 4.5, the current regulatory process for emergency plan changes has been in place since 1980. The NRC staff has not adequately documented the decision regarding why we need to use the license amendment process for emergency plan changes prior to completion of the rulemaking process in 2010 (i.e., what's the rush?). More importantly, the draft RIS does not explain why this change in regulatory process can be implemented without rulemaking (i.e., given the plain language interpretation of 10 CFR 50.54(q) as discussed above in Section 4.1).

In addition to not meeting the staff's obligation to document this decision in accordance with the Federal Records Act and MD 3.53, the proposed action is contrary to the NRC's principle regarding "Independence" since this decision has not been "documented with reasons explicitly stated."

² In accordance with 10 CFR 50.92(c), a proposed amendment is considered to involve no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated; or
2. Create the possibility of a new or different kind of accident from any accident previously evaluated; or
3. Involve a significant reduction in a margin of safety.

Openness

Nuclear regulation is the public's business, and it must be transacted publicly and candidly. The public must be informed about and have the opportunity to participate in the regulatory processes as required by law.

At present, the public is aware of the NRC's intent to pursue, **through rulemaking**, a change to 10 CFR 50.54(q) to require that licensees submit decrease in effectiveness changes for NRC approval pursuant to 10 CFR 50.90 (as discussed in SECY 08-0024 and SECY 09-0007). The public is not aware that the staff intends to implement this process prior to rulemaking.

The NRC staff held a public meeting on July 8, 2008, during which the proposed emergency preparedness rulemaking was discussed (See Transcript - Reference 7). During the meeting, representatives from NEI expressed a desire to hold follow-up meetings to specifically discuss 10 CFR 50.54(q). NEI stated that there may be unintended consequences in processing these changes in accordance with 10 CFR 50.90 such as licensee reluctance to submit beneficial emergency plan improvements. NEI mentioned the possibility of issuing a White Paper for staff endorsement to help define the threshold for requiring NRC approval. NEI stated that the public would be best served if the rulemaking was deliberate and transparent. The information provided by NEI during the meeting indicates that further discussion is necessary to resolve stakeholder concerns. Implementing the license amendment process prior to completion of rulemaking would be a surprise to NEI since it's clear from this meeting that they thought they would have time (during the rulemaking process) for further interactions with the staff to resolve their concerns regarding changes to 10 CFR 50.54(q). As such, the proposed action is inconsistent with the NRC's principle of "Openness."

Clarity

Regulations should be coherent, logical, and practical. There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions should be readily understood and easily applied.

The use of the license amendment process for emergency plan changes, prior to rulemaking, would not provide a clear nexus between the current regulations and agency goals and objectives because this proposed action is:

- (1) Inconsistent with the current regulations in 10 CFR 50.54(q) and 10 CFR 50.109 (see Sections 4.1 and 4.7);
- (2) Inconsistent with current NRR procedures that are based on the current regulations (see Section 4.2);
- (3) Inconsistent with prior direction from the Commission regarding interpretation of the regulations (see Section 4.3);
- (4) Inconsistent with a Commission decision on the types of changes that should be treated as license amendments (see Section 4.6); and
- (5) Unenforceable (see Section 4.8).

In addition, the proposed action would result in an Agency position that is not readily understood since it is contrary to positions stated as part of the 2005 EAL rulemaking. Page 8 of the draft RIS states the following regarding EAL changes:

A revision to an EAL scheme must be submitted as specified in Appendix E to 10 CFR Part 50 for NRC approval if the licensee is changing from one EAL scheme to another EAL scheme, or proposing an alternate method for complying with the regulations. Revisions of an EAL that results in a RIE [reduction in effectiveness], shall be submitted for Commission approval as specified in 10 CFR 50.54(q) and in accordance with 10 CFR 50.90.

Based on the draft RIS, **individual** EAL changes that would result in a decrease (reduction) in effectiveness would be submitted pursuant to 10 CFR 50.90 and processed as license amendments. However, changes to **all** the EALS (i.e., EAL scheme changes) would be submitted pursuant to 10 CFR 50.4 and processed as letter approvals.

The draft RIS position that EAL scheme changes are not considered as changes that would potentially reduce the effectiveness of the emergency plan is contrary to positions stated by the Commission in the 2005 EAL rulemaking. Specifically, the Federal Register notice which proposed the 2005 EAL rule (68 FR 43673, dated July 24, 2003) stated that:

The Commission believes a licensee proposal to convert from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007-based) will always involve a potential reduction in effectiveness.

In addition, the draft RIS position that **any** EAL changes should be processed as license amendments is also contrary to positions stated by the Commission in the 2005 EAL rulemaking. Specifically, the Federal Register notice which proposed the EAL rule states that:

The Commission proposes to follow the current practice of approving EAL changes without the use of a license amendment.

Based on the above, the proposed action is inconsistent with the NRC's principle of "Clarity."

Reliability

Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.

As discussed above in Section 4.1, the proposed action is inconsistent with the current regulations in 10 CFR 50.54(q).

As discussed above in Section 4.7, the proposed action may be a backfit and thus would not be fairly administered.

As discussed above in Section 4.8, the proposed action is unenforceable and would likely cause licensee confusion on submittal requirements and NRC staff confusion on how to process proposed changes. In addition, issuance of the RIS may result in some emergency plan changes being processed as license amendments and some being processed as letter approval/denials. These issues (i.e., confusion and different methods of processing) would result in an unstable regulatory process.

Based on the above, the proposed action is inconsistent with the NRC's principle of "Reliability."

4.11 The proposed action may have an adverse impact on the planned rulemaking

In the Staff Requirements Memorandum (SRM) for SECY 09-0007 dated April 16, 2009 (ADAMS Accession No. ML091060206), the Commission approved, with comments, the staff's recommendation to publish a proposed rule to amend certain emergency preparedness requirements in 10 CFR Part 50. As discussed in SECY 09-0007 (ADAMS Accession No. ML082890481), the proposed rulemaking would revise 10 CFR 50.54(q) and Section IV.B of Appendix E to 10 CFR Part 50 to require that EP and EAL changes which reduce the effectiveness of the approved emergency plan be submitted as license amendment requests pursuant to 10 CFR 50.90 (i.e., same changes proposed in draft RIS).

Consistent with the provisions regarding rulemaking in the APA (5 U.S.C. 553) and Subpart H of 10 CFR Part 2, one of the goals in the rulemaking process is to encourage meaningful participation by the public in the formation of rules. Use of the RIS to change the regulatory process prior to completion of the rulemaking proposed in SECY 09-0007 essentially pre-determines the end result of the rulemaking process rather than allowing stakeholder input to help mold the direction of the proposed rule change.

It is inappropriate for the NRC staff to take action which would predetermine, either in fact or perception, the outcome of a proposed rulemaking initiative. The effect of such action would be to "bind the hands" of the Commission in the future deliberations regarding the prospective rule change. This type of action substantively undercuts the rulemaking process and the deliberative process of the Commission.

4.12 The draft RIS contains inadequate and/or incorrect guidance

Sections 4.1 through 4.11 above address issues directly related to the proposed use of the license amendment process for EP and EAL changes. In addition to those issues, the draft RIS provides inadequate and/or incorrect guidance in a number of other areas. The following comments were provided by DORL to NSIR during review of the draft RIS. However, the comments were not adequately resolved in the version of the RIS provided for DORL concurrence. The comments are as follows:

Lower Tier Documents

Sections 2.2, 2.3 and 2.3.1 of Attachment 2 of the draft RIS indicate that lower tier documents are subject to 10 CFR 50.54(q) review. The 10 CFR 50.54(q) process applies to changes to emergency plans, not lower tier documents such as procedures. The regulations define information that must be contained in the emergency plan.

Qualifications for 10 CFR 50.54(q) Evaluations

Section 4.0 of Enclosure 1 of the draft RIS provides qualifications for preparers, reviewers and approvers of 10 CFR 50.54(q) evaluations. This portion of the RIS goes beyond what is required in 10 CFR 50.47(b)(16) and appears to establish new requirements.

Decrease in Effectiveness Guidance

Section 2.5.1.1 of Enclosure 1 of the draft RIS states, in part, that: "An RIE [reduction in effectiveness] 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 RIS contains very few examples of what is considered to be an RIE. Without more examples or further explanation, just about anything a licensee does could be construed as either a commensurate reduction or change in the bases or a measure put in place to reduce the impact. As such, this raises the concern that changes the NRC really should review to determine if the change is acceptable will not be submitted for our review. For example, the licensee may do something to reduce the impact of the change, but the question remains whether they did enough such that we can conclude that the proposed change provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

This RIS should be very clear on what changes we need to review. At present it does not do that. Note, Commissioner Svinicki's comments on the proposed rulemaking (ADAMS Accession No. ML091070264) acknowledged that the current language in 10 CFR 50.54(q) does not define what constitutes a decrease in effectiveness nor does it identify the type of changes that would constitute a decrease in effectiveness of the plan. She also noted the need to resolve this ambiguity.

10 CFR 50.54(q) Review Process

Attachment 2 of the draft RIS provides a typical 10 CFR 50.54(q) review process. This process would always result in the need to do an evaluation for any plan change (so why screen?). Also there is no actual attempt made to provide a method of evaluation. Simply documenting the conclusion on reduced effectiveness would not constitute an adequate evaluation record.

Guidance for Content of Licensee Applications

Enclosure 2 to the draft RIS provides licensee guidance for the content of emergency plan applications. Not all of the items in this enclosure are required by the regulations to be submitted as part of an application (e.g., table showing current approved wording, the proposed wording, and basis for the change). As such the enclosure should be formally reviewed for backfit considerations.

In addition, it appears that this enclosure would be used by the staff to perform an acceptance review on the licensee's application. Rather than creating a separate and diverse acceptance review standard, any changes needed with respect to aspects of the acceptance review for emergency plan changes should be consolidated into NRR Office Instruction LIC-109.

Level of Effectiveness

On page 2, under "Background Information," the draft RIS states that:

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 would expand its operating authority beyond the authority granted by the NRC. Thus, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. Such a change must be accomplished through a license amendment. [emphasis added]

At the top of page 4 of the draft RIS it states:

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. [emphasis added]

The above quoted sections seem to be misinterpreting the phrase "maintain in effect" that is currently shown in 10 CFR 50.54(q). Specifically, 10 CFR 50.54(q) states that licensees "shall follow and maintain in effect emergency plans which meet the standards in § 50.47(b) and in the requirements in appendix E." This just means licensees need to continue to have plans in place. It doesn't mean that the licensee's operating authority is based on a level of effectiveness that is above the requirements in 10 CFR 50.47 and Appendix E to 10 CFR Part 50. Note, this misinterpretation is also in the emergency preparedness rulemaking (see page 44 of Enclosure 1 of SECY 09-0007, ADAMS Accession No. ML082750444).

5.0 REFERENCES

1. Letter from Ralph E. Beedle (NEI) to Samuel J. Collins (NRC) dated July 10, 2002, "License Amendments," (ADAMS Accession No. ML021970416).
2. NRC Meeting Summary dated December 27, 2002, "Summary of December 10, 2002, Meeting with Nuclear Energy Institute (NEI) and other Stakeholders on the Threshold for License Amendments," (ADAMS Accession No. ML023640109).
3. Letter from Samuel J. Collins (NRC) to Stephen D. Floyd (NEI) dated January 23, 2003, "License Amendments," (ADAMS Accession No. ML023580087).
4. Letter from Stephen D. Floyd (NEI) to Samuel J. Collins (NRC) dated February 28, 2003, (ADAMS Accession No. ML030660657).
5. Letter from Christopher I. Grimes (NRC) to Tony Pietrangelo (NEI) dated April 9, 2003, "License Amendment Threshold," (ADAMS Accession No. ML030990125).
6. Letter from Jack W. Roe (NEI) to Catherine Haney (NRC) dated September 27, 2007, "NEI White Paper - Regulatory Issue Screening Process," (ADAMS Accession No. ML072740025).
7. Transcript, "Public Meeting to Discuss Comments on Emergency Preparedness," dated July 8, 2008 (ADAMS Accession No. ML082120357).

ATTACHMENT 2

ANALYSIS OF PERRY DECISION WITH RESPECT TO EMERGENCY PLAN CHANGES

Introduction

The following information further supports the discussion in Attachment 1, Section 4.6, "The proposed action is inconsistent with the *Perry* decision." As discussed in Section 4.6, due to the lack of documentation on the basis for the proposed change to use the licensee amendment process, I have performed my own review of the *Perry* decision.

Atomic Energy Act and the *Perry* Decision

The primary difference between processing a proposed licensing action as a license amendment (i.e., submitted pursuant to 10 CFR 50.90) or as a letter approval (as currently is the case for emergency plan changes submitted pursuant to 10 CFR 50.4), is that the license amendment process provides an opportunity for a hearing.

Section 189a of the Atomic Energy Act (AEA) requires that the Commission provide interested parties notice of, and an opportunity for a hearing on, the "granting, suspending, revoking, or **amending**" of any license or construction permit [emphasis added]. In the *Perry* decision (44 NRC 315, December 6, 1996), the Commission looked at the legislative history of the AEA. As discussed on page 326 of the *Perry* decision, the Commission stated that:

That history, unfortunately does not clarify what constitutes a license amendment within the meaning of section 189a. But it does make clear that Congress wished to provide hearing rights for only "*certain* classes of agency action," not all. As initially proposed, the AEA did not contain any hearing rights provision. A later draft proposed a hearing opportunity to parties "materially interested in any 'agency action.'" But this provision was found "too broad, broader than it was intended to be," and led to section 189a's very specific list of Commission actions warranting hearing rights. If a form of Commission action does not fall within the limited categories enumerated in section 189a, the Commission need not grant a hearing.

In evaluating whether challenged NRC authorizations effected license amendments within the meaning of section 189a, courts repeatedly have considered the same key factors: did the challenged approval grant the licensee any "greater operating authority," or otherwise "alter the original terms of a license"? If so, hearing rights likely were implicated.

On page 327 of the *Perry* decision, the Commission cited applicable case law that provided examples where certain NRC approvals did not trigger AEA section 189a hearing rights. The Commission clarified its position as follows:

Where the NRC approval does not permit the licensee to operate "in any greater capacity" than originally prescribed and all relevant safety regulations and license terms remain applicable, the NRC approval does not "amend" the license.

Only those actions falling "beyond the ambit of prescriptive authority granted under the license" necessitate a license amendment.

On page 328 of the *Perry* decision, the Commission provided further insight regarding the issue of "greater operating authority" as follows:

That the staff may wish to verify in advance that a proposed revision conforms to the required technical standard does not make the Staff approval a license amendment. By merely ensuring that required technical standards are met, the Staffs approval does not alter the terms of the license, and does not grant the licensee greater operating authority. Such a review indeed enforces license requirements. As an enforcement policy matter, the Staff may wish to police some licensee-initiated changes before they go into effect. To insist-as the Intervenor do-that the NRC staff may never require prior approval for any change or activity without effecting some sort of major licensing action, would frustrate the agency's ability to monitor licensees and enforce regulations. As we have already noted, not every change that occurs at a nuclear power plant, even if significant, represents a license amendment.

Emergency Planning Regulations and Associated Guidance

On August 19, 1980, the NRC published a final rule in the *Federal Register* (45 FR 55402) upgrading its emergency planning regulations. The final rule, which became effective November 3, 1980, stated, in part, that in order to continue operations or to receive an operating license, a licensee/applicant will be required to submit its emergency plans to the NRC and the NRC would then make a finding whether there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. As discussed on page 55403 of the *Federal Register* notice:

The standards that the NRC will use in making its determinations under these rules are set forth in the final regulation.

The standards are a restatement of basic NRC and now joint NRC-FEMA [Federal Emergency Management Agency] guidance to licensees and to State and local governments. See NUREG-0654; FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment," [January 1980].

In November 1980, the NRC and FEMA published Revision 1 to NUREG-0654/FEMA-REP-1 to incorporate comments on the interim version that was issued in January 1980. As discussed in the foreword of Revision 1:

This document is consistent with NRC and FEMA regulations and supersedes other previous guidance and criteria published by FEMA and NRC on this subject. It will be used by reviewers in determining the adequacy of States, local and nuclear power plant licensee emergency plans and preparedness.

Section II of NUREG-0654/FEMA-REP-1 provides the specific evaluation criteria to assess each of the 16 planning standards in 10 CFR 50.47(b). One of the planning standards, 10 CFR 50.47(b)(4), requires a standard EAL scheme to be in use by the licensee. Section IV.B of Appendix E of 10 CFR Part 50 provides additional specific requirements related to EALs. Appendix 1 of NUREG-0654/FEMA-REP-1 provides guidelines for development of EAL schemes.

Revision 1 to NUREG-0654/FEMA-REP-1 was endorsed in Regulatory Guide 1.101, "Emergency Response Planning and Preparedness for Nuclear Power Reactors," Revision 2, dated October 1981. The Regulatory Position in Revision 2 of Regulatory Guide 1.101 states that:

The criteria and recommendations in Revision 1 of NUREG-0654/FEMA-REP-1 are considered by the NRC staff to be generally acceptable methods for complying with the standards in Section 50.47 and 10 CFR Part 50 that must be met in onsite and offsite emergency response plans.

NRC Standard Review Plan, NUREG-0800, Section 13.3, "Emergency Planning," Revision 3, dated March 2007, cites NUREG-0654/FEMA-REP-1, Revision 1, as the guidance that NRC reviewers should use to determine compliance with 10 CFR 50.47(b) and Appendix E to 10 CFR Part 50.

As discussed in Revision 5 of Regulatory Guide 1.101, dated June 2005, the guidance for development of EAL schemes has evolved (e.g., based on lessons learned from using the NUREG-0654/FEMA-REP-1 guidance). Other guidance documents that have been found by the NRC staff to be acceptable alternatives to the NUREG-0654/FEMA-REP-1 guidance for EAL development include Nuclear Utilities Management and Resource Council (NUMARC) document NUMARC/NESP-007, "Methodology for Development of Emergency Action Levels," and Nuclear Energy Institute (NEI) document NEI 99-01, "Methodology for Development of Emergency Action Levels."

Emergency Plan Changes and the *Perry* Decision

Based on the discussion in the August 19, 1980, *Federal Register* notice for the emergency planning rulemaking, the initial submittal of an emergency plan, and the subsequent finding by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, were **prerequisites to either obtaining an operating license (for a new reactor) or for justifying continued operations (for an operating reactor)**. These prerequisites were really conditions of getting (or keeping) a license rather than being "license conditions." As such, NRC approval of the initial submittal of an emergency plan did not result in prescriptive requirements, delineating a licensee's operating authority, being incorporated in the respective licenses nor amendment to the operating licenses.

As originally required by 10 CFR 50.54(q) in the August 19, 1980, rulemaking, and consistent with the current requirements in that regulation, nuclear power plant licensees shall follow and maintain in effect emergency plans which meet the standards in 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50. When the NRC staff reviews an emergency plan change requiring prior approval (i.e., decrease in effectiveness under 10 CFR 50.54(q) or EAL scheme change under Appendix E), the staff reviews the change against the 16 planning standards in 10 CFR 50.47(b), the applicable requirements in Appendix E to 10 CFR Part 50, and the acceptance criteria and recommendations in the applicable technical guidance documents (e.g., NUREG-0654/FEMA-REP-1 and NEI 99-01). As discussed above, on page 328 of the *Perry* decision, the Commission noted that:

That the staff may wish to verify in advance that a proposed revision conforms to the required technical standard does not make the Staff approval a license amendment. By merely ensuring that required technical standards are met, the

Staffs approval does not alter the terms of the license, and does not grant the licensee greater operating authority.

Decrease in Effectiveness Criterion and Operating Authority

Page 2 of the draft RIS, under "Background Information" states that:

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 would expand its operating authority beyond the authority granted by the NRC. Thus, an emergency plan change that would reduce the effectiveness of the plan would expand the licensee's operating authority under its license. Such a change must be accomplished through a license amendment.

As required by 10 CFR 50.54(q), the decrease (reduction) in effectiveness criterion is used by the licensee to determine if an emergency plan change needs prior NRC approval (i.e., sets the threshold for those changes needing prior NRC approval). This criterion identifies proposed changes where the NRC staff will verify, in advance, that the proposed revision conforms to the required technical standards. **As discussed below, and contrary to the above statements in the draft RIS, the decrease in effectiveness criterion is not used to define the licensee's operating authority with respect to emergency preparedness.**

Consistent with the statements of consideration for the 1980 Emergency Planning rule (45 FR 55402) and the requirements in 10 CFR 50.47(a)(1)(i) and 10 CFR 50.54(s)(2)(ii), **to receive an initial operating license, or (for operating reactors) to continue operations, the NRC staff must make a finding that there is "reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency."** In accordance with 10 CFR 50.47(a)(2) and 10 CFR 50.54(s)(3), this finding is to be based on a NRC review of FEMA findings and determinations and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. As discussed above in the section titled "Emergency Planning Regulations and Associated Guidance," the standards used in determining whether an emergency plan is acceptable are the 16 planning standards in 10 CFR 50.47(b) as well as the requirements in Appendix E to 10 CFR Part 50. This is consistent with 10 CFR 50.54(q) which states that nuclear power reactor licensees may make emergency plan changes, without prior NRC approval, if the changes do not decrease the effectiveness of the plan and plan, as changed, continues to meet the standards of 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50.

As discussed in 10 CFR 50.54(s)(2)(ii), **if the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, and if the deficiencies are not corrected within four months of that finding, the Commission will determine whether the reactor will be shut down** until such deficiencies are remedied or whether other enforcement action is appropriate.

Based on the above, it is concluded that a licensee's operating authority with respect to emergency preparedness is established based on the NRC staff's finding that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, not whether the change is a decrease in effectiveness (as discussed in the draft RIS).

NRC approval of an emergency plan change that would decrease the effectiveness of the plan merely verifies that the emergency plan continues to meet the standards of 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50. It does not "expand the licensee's operating authority under its license" as discussed in the draft RIS.

Conclusion

Based on: (1) the lack of any prescriptive requirements related to emergency planning being incorporated in nuclear plant operating licenses; and (2) specific technical standards being included in the emergency planning regulations and guidance; NRC approval of an emergency plan change does not grant the licensee any greater operating authority, or otherwise alter the original terms of the license. As such, the proposed use of the license amendment process to approve or deny changes to emergency plans is inconsistent with the positions stated by the Commission in the *Perry* decision.

Consistent with the *Perry* decision, NRC approval of an emergency plan change that would decrease the effectiveness of the plan merely verifies that the emergency plan continues to meet the standards of 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50. It does not "expand the licensee's operating authority under its license" as discussed in the draft RIS.

Attachment 3
RESPONSE TO NON-CONCURRENCE ISSUES

Issue 1

In addressing this issue, the non-concurring individual indicates that the staff's approach over time in reviewing the proposed changes to approved emergency plans that would result in reductions in effectiveness of the plans has been unchanged since the promulgation of 10 CFR 50.54(q) in 1980. However, the staff's approach over time in reviewing the proposed changes to approved emergency plans that would result in reductions in effectiveness of the plans has not been consistent and unchanged. On at least one occasion, the NRC staff has advised a licensee that if they requested NRC review of a proposed change that would decrease the effectiveness of the licensee's emergency plan, such a request had to be submitted under 10 CFR 50.90. See Thomas, K.M., U.S. Nuclear Regulatory Commission, letter to J.M. Levine, Arizona Public Service Company, October 24, 1997.

Although the non-concurring individual correctly notes that § 50.54(q) refers to § 50.4 in relation to reporting emergency plan changes to the NRC, the individual has apparently incorrectly interpreted that reference as only referring to § 50.4(b)(5). (The non-concurring individual actually refers to "§50.4(b)(3)(5)," which does not exist. Section 50.4(b)(5) concerns emergency plans and related submissions to the NRC.) Section 50.4, however, is a broadly written provision that specifically includes the administrative requirements for filing amendment requests (see § 50.4(b)(1)). If the NRC's intent of § 50.54(q)'s general reference to § 50.4 was specifically to limit the obligations for filings made under § 50.54(q) to filings under § 50.4(b)(5), then the history of the rulemaking would certainly have contained some indication that such was the intent of this reference. We have located no information and the non-concurring individual does not identify any information indicating that the reference to § 50.4 generally was meant to be anything other than a reference to all procedures in § 50.4, including the procedures for filing license amendment requests.

The fact that the EAL final rule Federal Register Notice did not include language that the EAL proposed rule FRN contained is not insignificant. Not including in the final rule FRN any form of the sentence, "The Commission proposes to follow the current practice of approving EAL changes without the use of a license amendment," indicates that the Commission did not support the intent of that sentence. The final rule FRN is the Commission's official position on the issues addressed in the FRN. The non-concurring individual's reliance on the proposed rule FRN is misplaced and does not properly consider a basic premise of statutory construction that presumes changes from draft to final products are made intentionally.

Similarly, the EAL final rule FRN did not contain the proposed rule FRN language regarding how changing from one EAL scheme to another always involves a potential reduction in effectiveness. Under the EAL final rule, licensees were required to submit, for NRC prior approval, changes in EAL schemes and EAL changes that would decrease the effectiveness of the plan. The fact that these two types of changes were listed separately shows that the Commission did not consider changes in EAL schemes to be decreases in effectiveness. Otherwise, listing both types of changes would have been redundant. Significant portions of the non-concurrence rely on the draft language instead of the final rule language and supporting Statement of Considerations approved by the Commission.

Thus, several of the non-concurring individual's conclusions are incorrect, especially any conclusions concerning the clarity of the change process to be used when the change would result in a decrease in effectiveness.

Staff actions that may have taken place on limited occasions that are not consistent with the requirement for an amendment, when weighed against the much more frequent use of letter approvals only for changes to approved emergency plans that are not decreases in effectiveness, do not rise to the level of establishing an agency "practice."

Issue 2

NRR office procedures are not regulatory requirements and serve only as an internal guide. Thus, the non-concurring individual's deference to LIC 100 as authority is misplaced.

The non-concurring individual cites to the draft proposed rule, which is simply a draft. The non-concurring individual notes the errors in the draft concerning references to the "new" process. These errors were corrected before publication in the Federal Register as the official proposed rule. As noted above, particularly when there are changes in language from the draft to the final version of a rulemaking, the better principle of statutory construction is that the change was made with intent and that the final version reflects the decision maker's views, in this case the views of the Commission.

Issue 3

The non-concurring individual's *Perry* decision argument that the history of § 50.54(q) demonstrates consistent regulatory interpretation and the 2005 EAL rulemaking argument are addressed above.

SECY-08-0024 did not include any discussion of the process to be used in reviewing licensee emergency plan changes that would decrease the effectiveness of the plan prior to rulemaking because the non-concurring individual and members of his management did not want the SECY to address the process. This exclusion was intentional to recognize that the non-concurring individual and staff management were still discussing the potential non-concurrence and the inclusion of such a discussion was not crucial to the purpose of that particular SECY paper.

Issue 4

The non-concurring individual claims that "Requiring licensees to submit proposed emergency plan changes as license amendment requests, prior to rulemaking, is clearly a change in staff position." This statement is incorrect in two ways. First, the RIS addresses only those proposed emergency plan changes that would result in a decrease in effectiveness. The non-concurring individual's statement refers to all proposed emergency plan changes. Second, as noted under Issue 1 above, use of the license amendment process would not constitute a change in staff position. As noted above, the instances cited by the non-concurring individual are not of sufficient frequency, importance, or breadth to reasonably be considered as having established an "agency practice" as proposed in the non-concurrence documentation.

Issue 5

The RIS adequately explains why licensees must use the license amendment process when seeking NRC prior approval for proposed changes to their emergency plans that would reduce the effectiveness of the plans. The RIS explains that these proposed changes, if permitted, would allow licensees to operate beyond the authority previously granted to them. Legal precedent dictates that such changes must be processed as license amendments. Staff was made aware of this clarification in 2007. Since then, a great deal of time has lapsed for the staff

to have issued the RIS, much of that time having been spent attempting to address the views of the non-concurring individual. Waiting until 2010 for rulemaking is unacceptable for purposes of properly handling the emergency preparedness licensing actions that rise to the level of approving an emergency plan change resulting in a reduction in effectiveness. Because the rulemaking will not be final until 2010 (at the earliest), staff should not wait before processing for approval any new plan changes that reduce the level of effectiveness of the plan without also going through the 10 CFR 50.90 license amendment and FRN procedures. For such approvals to be legal and effective, they must be done by license amendment.

Issue 6

The non-concurring individual misinterprets the RIS's use of the court and *Perry* decisions. They are not used, as he thinks, "to make the argument that NRC approval of an emergency plan change, that would decrease the effectiveness of the current approved plan, would grant the licensee greater operating authority." The decisions are cited as support for the proposition stated in the RIS 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." The non-concurring individual even provides the language from *Perry* that the RIS relies on, in part, for this support. The non-concurring individual's misinterpretation of *Perry* is perhaps understandable because his focus may have been only on language supporting his pre-disposition, but a reading of the discussion of the case in context makes clear that the use of amendments was deemed appropriate for any expansion of authority to operate that goes beyond prior authorizations.

As a reading of § 50.54(q) indicates, a licensee's approved emergency plan has a level of effectiveness ("Proposed changes that decrease the level of effectiveness of the approved emergency plans..."). The licensee is authorized by the NRC to operate at that level of effectiveness, as reflected in the licensee's approved emergency plan. In fact, the NRC's regulations, in § 50.34(b)(6)(v), § 50.47 and Appendix E to Part 50, require that the licensee have and implement the approved emergency plan to obtain and hold an operating license. If the licensee proposes a change that would reduce that level of effectiveness, such a change would give the licensee a capability to operate at a level of effectiveness that was not previously authorized by the NRC. In other words, the licensee would have operating authority beyond what it originally had, as reflected in the approved 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 January 23, 2003, letter referenced by the non-concurring individual further supports the use of a license amendment process when a licensee proposes to reduce the effectiveness of its approved emergency plan. In that letter, the NRR Office Director stated, "A license amendment issued on a plant-specific basis is necessary where there is a change in the activity previously authorized or where staff judgment and discretion must be applied to determine whether the underlying requirements would be met, in the absence of objective, prescribed criteria for fulfilling those requirements." As explained above, a licensee proposal to reduce the effectiveness of its approved emergency plan would be "a change in the activity previously authorized." Moreover, the NRC's approval of a reduction in emergency plan effectiveness is more than a ministerial, non-discretionary act. The non-concurring individual demonstrates an apparent misunderstanding in arguing that the agency should await rulemaking to implement *Perry*. This is not a question of policy but a question of whether, under *Perry*, licensees have

the legal authority to act on proposed changes without appropriate NRC approval. When there is a legally defensible interpretation and a legally questionable interpretation that could be applied to a disputed regulation, the agency does not have the policy "option" of proceeding to apply the potentially illegal interpretation while it pursues rulemaking to clarify that the legally defensible interpretation is the correct requirement. It was, in fact, for this reason that OGC has been urging prompt issuance of this particular RIS since at least mid-2008.

Therefore, the RIS is consistent with *Perry*.

The non-concurring individual cites to 29 years of using the "current process" but neglects to consider the impact of the *Perry* decision in 1996. Given that *Perry* and the court cases cited in the RIS provide when a license amendment process should be used, what the staff did prior to *Perry* is irrelevant, and what the staff has done since *Perry*, to the extent that proposed changes that would result in reductions in effectiveness were approved using the letter approval process, has been legally and procedurally incorrect. Staff actions that may have taken place on limited occasions that are not consistent with the requirement for an amendment, when weighed against the much more frequent use of letters only for changes to emergency plans that are not decreases in effectiveness, do not rise to the level of establishing an agency "practice." Appropriate agency practice is not established by limited instances of procedural errors.

Issue 7

The RIS would not constitute a backfit for the reasons explained in the RIS. The non-concurring individual focuses on the first reason, based on his belief that use of the license amendment process would be a change in staff position. However, the proposed use of the license amendment process for emergency plan changes is not a new process, as explained above. Further, as explained in the RIS, "The NRC's regulatory review process is not a licensee procedure required for operating a plant that would be subject to backfit limitations." In essence, even if the non-concurring individual were correct that there is some established agency practice for these reviews, a change or clarification to such procedures (which is not the case here) is not, by definition, a backfit.

Notably, the non-concurring individual does not address the second reason why the RIS would not constitute a backfit. As explained in the RIS, "[T]he 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." This Commission position dates back to the original Part 52 rulemaking in 1989 and was applied in the 2005 EAL rulemaking that the non-concurring individual frequently references.

Issue 8

NRR office procedures are not regulatory requirements and serve only as an internal guide. Thus, the non-concurring individual's deference to LIC-109 as authority is misplaced.

The RIS is simply notice as to how the NRC will process an "application to ... the Commission" (§ 50.54(q)) for approval of a proposed change that would reduce the effectiveness of an approved emergency plan. If a licensee does not submit an application for an amendment, the staff can go back to the licensee and state that the staff will process the proposed change as a

license amendment and ask if the licensee wants to continue to pursue its application for approval.

Issue 9

A "no significant hazards" finding must be made on a case-by-case basis. It cannot be generically determined that proposed changes that reduce the effectiveness of approved emergency plans will never involve significant hazards considerations. In the event that a particular proposal does involve no significant hazards considerations, section 189.a of the AEA and well-established case law support existing NRC policy that having a hearing after issuing a license amendment is legally permissible. The non-concurring individual's view that such post-amendment hearings being allowed under the statutes and regulations is somehow an indication that the amendment process is not the correct process for these approvals is fundamentally inconsistent with statutory authority and the agency practice to allow post-amendment hearings. The non-concurring individual's discussion under this issue does not provide any basis for concluding that the legally-required amendment process is inappropriate for reviewing and approving the changes at issue.

Issue 10

Independence: The reasons for using the license amendment process have been provided in the RIS and, on numerous occasions, to staff.

Openness: The NRC staff will address all stakeholders concerns on this issue during the rulemaking process.

Clarity: The RIS would provide clarity where none exists. Each of the non-concurring individual's claims on this issue has been addressed above. Further, the non-concurring individual's claims rely on the EAL proposed rule FRN instead of the EAL final rule FRN. For the reasons provided above, this reliance is misplaced.

Reliability: As explained above, the RIS is consistent with existing regulations, would not be a backfit, and would provide clarity to licensees.

Issue 11

The proposed rule proposes to clarify the process to use when licensees propose to reduce the effectiveness of their emergency plans. The RIS would provide guidance to licensees until the final rule is issued. As with any rulemaking, the Commission would be free to revise the proposed rule provisions in the final rule as long as a reasonable basis existed for making the changes and other rulemaking requirements were met. If the final rule should differ from the RIS, the final rule provisions would provide the requirements for licensees, superseding the RIS. This is routinely the nature of the rulemaking process. Indeed, the non-concurring individual's logic that the Commission is not supposed to deal with issues affecting regulated activities during the period when rulemaking is considering similar issues would result in the bizarre situation where the Commission would refrain from taking necessary actions to assure ongoing activities are appropriately and safely (and legally) conducted in accordance with our obligations under the AEA while rulemaking proceeds.

Issue 12

The statement was made that the draft RIS provides inadequate and/or incorrect guidance in a number of areas. The following are the specific areas that were identified in the non-concurrence and a response in each area:

Lower tier documents

The statement that 10 CFR 50.54(q) applies to changes in emergency plans, not the lower tier documents such as procedures, is true unless a licensee has incorporated the lower tier document into the emergency plan or the emergency plan explicitly references the 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 (EIPs) 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 10 CFR 50.54(q) to review all changes to lower tier documents a requirement, but acknowledges that using 10 CFR 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.

Emergency Preparedness Position (EPPOS) on Emergency Plan Implementing Procedure Changes (which was superseded by RIS 2005-02) provided:

"Appendix E prescribes the information required to be contained in the emergency plan. The §50.54(q) process refers to changes that may be made to the emergency plan, not to procedures which implement the emergency plan. In some instances, the NRC has allowed the relocation of emergency plan information to implementing procedures based upon the staff's understanding that implementing procedures were a part of the emergency plan. In response to a request for legal advice as to whether emergency plan implementing procedures (EIPs) are a part of the emergency plan and, therefore, would receive the same level of review and determination under §50.54(q), the Office of General Counsel (OGC) concluded that EIPs or procedures which implement the emergency plan are not part of the emergency plan and, therefore, changes to these procedures are not subject to §50.54(q) review. If an EIP is *incorporated* into the emergency plan or is a *necessary* part thereof to comply with the requirements of Appendix E, then it *is* considered part of the plan and subject to §50.54(q) review; if it is merely referenced by the emergency plan, then it is *not* part of the plan."

The onsite and, except as provided in 10 CFR 50.47(d), offsite emergency response plans for nuclear power reactors must meet the standards established in 10 CFR 50.47(b) and applicable requirements of Appendix E to 10 CFR Part 50. Compliance with these regulations is determined by using the guidance in Regulatory Guide (RG) 1.101, Rev. 2, which endorses NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants." NUREG-0654/FEMA-REP-1, Revision 1, establishes an acceptable basis for NRC licensees to develop radiological emergency plans and procedures. RG 1.101 states that the criteria and recommendations in NUREG-0654/FEMA-REP-1, Revision 1, are considered by the NRC staff to be acceptable methods for complying with the standards in 10 CFR 50.47. Except in those cases in which an applicant of licensee proposes acceptable alternative methods for complying with specific portions of the regulations, the methods described in NUREG-0654/FEMA-REP-1,

Revision 1, will be used as a basis for evaluating the adequacy of the emergency plans. NUREG-0654/FEMA-REP-1, Revision 1, states, in part:

“FEMA, NRC, and other involved Federal agencies intend to use the guidance contained in this document in their individual and joint reviews of State and local government radiological emergency response plans and preparedness, and of the plans and preparedness of NRC facility licensees. The NRC Final Rule on Emergency Planning (45 FR 55402) of August 19, 1980 has an effective date of November 3, 1980. This document is supportive of the NRC Final Rule and is referenced therein.”

“The guidance does not specifically specify a single format for emergency response plans but it is important that the means by which all criteria are met be clearly set forth in the plans...Applicable supporting and reference documents and tables may be incorporated by reference, and appendices should be used whenever necessary. The plans should be kept as concise as necessary.”

Specific sections in NUREG-0654/FEMA-REP-1, Revision 1, provide guidance for licensees to consider in the development of their emergency plan, the use of procedures to implement the plan, specifically for emergency classification, emergency action levels and notifications. Although not requirements, the staff uses NUREG-0654/FEMA-REP-1, Revision 1, as a basis to evaluate the adequacy of the licensee emergency plan.

In Section II of NUREG-0654, Evaluation Criterion II.D.1 specifies an emergency classification and emergency action level scheme as set forth in Appendix 1 must be established by the licensee. The specific instruments, parameters or equipments shall be shown for establishing each emergency class, in the in-plant emergency procedures. The plan shall identify the parameter values and equipment status for each emergency class.

In Section II of NUREG-0654, Evaluation Criterion II.E.1 specifies each organization shall establish procedures which describe mutually agreeable bases for notification of response organizations consistent with the emergency classification and action level scheme set forth in appendix 1. These procedures shall include means for verification of messages. The specific details of verification need not be included in the plan.

In Section II of NUREG-0654, Evaluation Criterion II.P.7 specifies each plan shall contain as an appendix listing, by title, procedures required to implement the plan. The listing shall include the section(s) of the plan to be implemented by each procedure.

Although lower tier documents such as EIPs, would not normally be considered to be part of the emergency plan, they can in fact, provide the necessary information needed for activities that are required to meet the regulations. The location of the information that is a necessary part thereof to comply with the requirements of Appendix E should be administratively controlled to ensure changes to those documents are reviewed appropriately. As always, the licensee is required to maintain the effectiveness of their emergency plan, as well as their ability to implement the emergency plan. Activities that lessen the licensee's ability to implement their emergency plan as approved by the NRC should be reviewed in accordance with 10 CFR 50.54(q).

The draft RIS was revised to provide clarification in this area.

Qualifications for 10 CFR 50.54(q) Evaluations

The statement is made that the RIS provides qualifications for preparers, reviews and approvers of § 50.54(q) evaluations and goes beyond what is required in 10 CFR 50.47(b)(16). The RIS states that preparers, reviewers and approvers of the 10 CFR 50.54(q) evaluations should be qualified to do so in order to maintain a consistent and effective program. It further states that the screening should be performed by personnel knowledgeable of the proposed changes and its potential impact on the EP program.

10 CFR 50.47(b)(16) states, "Responsibilities for plan development and review and for distribution of emergency plans are established, and planners are properly trained."

This is supported by the existing guidance in NUREG-0654/FEMA-REP-1, Revision 1 and communicated in Information Notice (IN) 2005-19, "Effect of Plant Configuration Changes on the Emergency Plan," dated July 18, 2005.

Specific sections in NUREG-0654/FEMA-REP-1, Revision 1, provide guidance for licensees to consider in the development of their emergency plan. Although not requirements, the staff uses NUREG-0654/FEMA-REP-1, Revision 1, as a basis to evaluate the adequacy of the licensee emergency plan.

In Section II of NUREG-0654, Evaluation Criterion II.P.1 specifies each organization shall provide for the training of individuals responsible for the planning effort.

In Section II of NUREG-0654, Evaluation Criterion II.P.2 specifies each organization shall identify by title the individual with the overall authority and responsibility for radiological emergency response planning.

In Section II of NUREG-0654, Evaluation Criterion II.P.3 specifies each organization shall designate an Emergency Planning Coordinator with the responsibility for the development and updating of emergency plans and coordination of these plans with other response organizations.

IN 2005-19 was developed to inform licensees of inspection findings related to the failure to properly evaluate the effect of plant configuration changes (procedures, equipment, and facilities) on the emergency plan. The information notice was intended to inform licensees of the importance of properly evaluating changes to procedures, equipment, and facilities for potential impact on the licensee's ability to maintain an effective emergency plan. It also emphasized that 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.

Since a significant portion (over half) of inspection findings in the emergency preparedness cornerstone are related to inadequate 10 CFR 50.54(q) evaluations, it is clear that emphasis is needed for the proper training and qualification of personnel performing these evaluations. The expectation that a person performing any type of review and/or evaluation to any program at a nuclear power plant be qualified to do that review and/or evaluation is not an unrealistic expectation. However, the staff is not creating a requirement, but clarifying the expectations of 10 CFR 50.47(b)(16). In fact, the staff is making efforts to closely model the 10 CFR 50.54(q) process with that of the 10 CFR 50.59 process, which emphasizes training and qualification to ensure a consistent application of the program.

Decrease in Effectiveness Guidance

The statement is made that the RIS contains very few examples of what is to be considered a reduction in effectiveness.

The RIS states that 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.

The RIS provides some examples of plan changes and EAL changes 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 are not to be viewed as being all-inclusive or exclusive; rather, they are provided for licensees to use to help inform decisions involving various changes being considered.

The examples provided show a change to the plan and a basis for why the change reduces the function or capability such that it adversely affects the plan. It is important to note that it is not just the change per se; it is the change 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. Draft Guide 1237 was developed for the rulemaking and provides several examples for each of the 16 planning standards in 10 CFR 50.47(b).

It is important to understand that there may be potentially vastly differing emergency plans between licensees, and what may be a reduction in effectiveness for one site may not be a reduction in effectiveness for another site. The staff determined it to be appropriate to provide a comprehensive 10 CFR 50.54(q) program template based upon a collection of best practices. While some of these program elements may be conservative, the staff believes that providing a consistent model as a template would aid licensees in implementing an effective and comprehensive program to ensure licensees maintain an effective emergency preparedness program.

10 CFR 50.54(q) Review Process

The statement is made that "Attachment 2 of the draft RIS provides a typical 10 CFR 50.54(q) review process. This process would always result in the need to do an evaluation for any plan change (so why screen)? Also there is no actual attempt made to provide a method of evaluation. Simply documenting the conclusion on reduced effectiveness would not constitute an adequate evaluation record."

The flowchart provided in Attachment 1 to Enclosure 1 graphically depicts the process for evaluation of proposed changes. The process described in Enclosure 1 provides an example of a screening criterion for evaluating changes to procedures, equipment, and facilities for potential impact on the licensee's ability to maintain an effective emergency plan. If a change is proposed, for example, a change to a plant procedure or to the configuration of the facility that does not have any impact on the emergency plan, it would be screened as a "no" and not evaluated with Attachment 2. If a change is determined to have 10 CFR 50.54(q) applicability, a review should be conducted with the 10 CFR 50.54(q) review process. Attachment 2 to

Attachment 2 is not a "screening process," it is an example of a form that can be used to document a change that was determined to have 10 CFR 50.54(q) applicability during the screening process provided in Enclosure 1. The form in Attachment 2 provides a method to document this review. The form provides a listing of the 10 CFR 50.47 planning standards and the requirements of Appendix E to Part 50 that might be affected by the proposed change and a section to describe the change and to conduct the evaluation as described in the Attachment 2 guidance. Licensees are required to retain a record of each emergency plan change made without Commission approval for a period of three years from the date of the change. Attachment 2 is an example for a record of an emergency plan change, not a screening process.

This model template has been developed to be consistent with the screening process used in 10 CFR 50.59 evaluations.

Guidance for Content of Licensee Applications

The statement is made that not all of the items provided in Enclosure 2 to the draft RIS are required by regulations and NRR Office Instruction LIC-109 should be used to perform the acceptance reviews. The staff currently uses LIC-109 to conduct acceptance reviews for emergency plan changes submitted to the NRC for approval. LIC-109 was effective on May 2, 2008.

The staff has worked with the industry to improve consistency and clarity in the process for performing the reviews on emergency plan changes requested by licensees. Some of the issues related to these reviews were the content of licensees' submittals. On September 9, 2004, in a public meeting (ML042530011), NSIR and NEI met to discuss a draft smart application template to be used by licensees when proposing changes related to on-shift staffing and augmentation. This template was prepared by the NRC staff in an effort to improve the quality and completeness of applications. A separate template (ML041210096) had been developed previously, for licensees to use when requesting changes to Emergency Action Levels. Enclosure 2 was developed for a similar reason, and is a collective document that includes information from both templates and best practices developed during the reviews of multiple emergency plan changes. It does not contradict the information in LIC-109, but rather enhances it and provides licensees with one approach that the Technical Staff finds acceptable for the content of submittals.

Level of Effectiveness

Regarding the "Level of effectiveness" argument, the non-concurring individual focuses on the wrong clause in § 50.54(q). By requiring licensees to obtain NRC approval before implementing a change that would "decrease the effectiveness of the approved emergency plans," the NRC, in section 50.54(q), recognizes that each plan has a level of effectiveness, which a licensee could decrease by changing the plan.

This is the key point in the regulatory process related to emergency plans. The applicable regulations (10 CFR 50.47(b) and 10 CFR Part 50, Appendix E) were intentionally non-prescriptive as to the acceptable level of detail that is required in a licensee's emergency preparedness program so that licensees could have some flexibility in emergency plan development. NUREG-0654 and other NUREGs were subsequently developed to provide clarification as to the level of detail the NRC expect for each emergency planning element and requirements of Appendix E. Emergency preparedness inspection activities also serve to

provide reasonable assurance that licensees implement and maintain their emergency plans as required, thereby providing reasonable assurance that their ability to protect the health and safety of the public. As a result of the broad regulations and the somewhat more defined guidance, 10 CFR 50.54(q) emphasizes an effectiveness review against the licensee's approved emergency plan. This is an acknowledgement that the specific licensee emergency plan could be very different from an emergency plan at another site, even though both are based upon the same regulations.

With this RIS, the staff is attempting to ensure consistency in emergency preparedness programs by providing additional guidance, and a program template, to ensure licensees have all the tools necessary to evaluate whether a proposed emergency plan change requires NRC prior approval. Historically, it has not been clear what constitutes a change requiring prior NRC approval, and this RIS is an attempt to alleviate any confusion for licensees and for NRC staff performing inspection activities.