NRC FORM 757
NRC MD 10.158
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

SECTION A - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
Draft Regulatory Issue Summary 2005-02, Revision 1	ML080710029
DOCUMENT SPONSOR	SPONSOR PHONE NO.
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TITLE	ORGANIZATION
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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 nonconcurrence:

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
/RBEnnis/	4/24/09

SUBMIT FORM TO DOCUMENT SPONSOR AND COPY TO YOUR IMMEDIATE SUPERVISOR AND DIFFERING VIEWS PROGRAM MANAGER

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 <u>The proposed action is inconsistent with prior direction from the Commission</u>

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 certainty 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 <u>The NRC staff has not met its obligation to adequately document the decision to use the license amendment process prior to completion of rulemaking</u>

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) 3.53[1], "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 t**he 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 reivew.

4.8 <u>The proposed action is unenforceable</u>

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., EPUs [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 <u>The proposed action uses a process that may be inappropriate</u>

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 consideration[2]. 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 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 amendment 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 though 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 Intervenors 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.

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NRC MD 10.158
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
Draft Regulatory Issue Summary 2005-02, Revision 1	**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	PHONE NO.
Branch Chief	**301-415-2330**
ORGANIZATION	
NRR/DORL	

COMMENTS FOR THE DOCUMENT SPONSOR TO CONSIDER

☐ I HAVE NO COMMENTS

☒ I HAVE THE FOLLOWING COMMENTS

This nonconcurrence 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 nonconcurrence 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
HKC	05/04/2009

SUBMIT THIS PAGE TO DOCUMENT SPONSOR

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(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
Draft Regulatory Issue Summary 2005-02, Revision 1	ML080710029

SECTION C - TO BE COMPLETED BY DOCUMENT SPONSOR

NAME	
Christopher G. Miller	
TITLE	PHONE NO.
Deputy Director for Emergency Preparedness	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)

*Signature provided to support release of draft Regulatory Issue Summary (RIS) 2005-02, Revision 1 for public comment. Acceptability for signature regarding issuance of final RIS 2005-002, Revision 1 is withheld until public comment period is complete and comments have been addressed.

Section C Interim Signature
Document Signer

☐ CONTINUED IN SECTION D

SIGNATURE - DOCUMENT SPONSOR	DATE	SIGNATURE - DOCUMENT SIGNER	DATE
Rac for Chris Miller	5/19/09	*	

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 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 (EPIPs) that included the necessary information needed for activities that are required to meet the regulations, for example, procedures for notifications, dose assessment, protective action recommendations, emergency classifications and emergency action levels. The staff is not making the use of 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 (EPIPs) 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 EPIPs 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 EPIP 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 EPIPs, 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

Enclosure 1 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 evaluation procedure 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 changed 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.