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October 23, 2009

BY ELECTRONIC MAIL AND FIRST-CLASS MAIL

Mr. Michael T. Lesar
Chief, Rulemaking and Directives Branch, Office of Administration
U.S. Nuclear Regulatory Commission
Mail stop: TWB-05-B01M
Washington, DC 20555-0001

Subject: Nuclear Energy Institute Comments on NRC Draft Revised RIS 2005-02,
"Clarifying the Process for Making Emergency Plan Changes,"
74 Fed. Reg. 42,699 (Aug. 24, 2009) Docket ID NRC-2009-0365

Dear Mr. Lesar:

This cover letter and the attached enclosures contain comments on NRC Docket ID NRC-2009-0365 submitted by the Nuclear Energy Institute (NEI).¹ NEI appreciates the opportunity to comment on the Commission's important proposed revisions to NRC Regulatory Issue Summary 2005-02, "Clarifying the Process for Making Emergency Plan Changes," 74 Fed. Reg. 42,699 (Aug. 24, 2009) (Draft RIS).²

NEI's comments represent a comprehensive and substantive review of the Draft RIS, as well as relevant portions of the related rulemaking amending NRC emergency preparedness (EP) requirements. Because we have addressed both broad legal and regulatory concerns and specific editorial issues or suggestions relating to the Draft RIS, NEI's comments are divided

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

² On September 15, 2009, NEI requested an extension of the comment period for the draft RIS to facilitate better coordination of stakeholder comments on the RIS with comments on the broader NRC emergency planning rulemaking. The NRC subsequently extended the comment period on the Draft RIS from October 8 until October 23, 2009. See 74 Fed. Reg. 50, 840 (Oct. 1, 2009).

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Add: D. Johnson (daj3)

into two separate, stand-alone discussions in Enclosures 1 and 2. We note that because the Draft RIS addresses many of the same issues, and exhibits many of the same infirmities, as those portions of the EP proposed rule that deal with 10 CFR 50.54(q), NEI's comments on Draft Revised RIS 2005-02 are similar to portions of NEI's October 19, 2009, comments on that rulemaking (Docket ID NRC-2008-0122). For clarity, we opted to submit comments on both NRC dockets.

Enclosure 1 to this letter contains NEI's comments on the legal and regulatory positions and the case law presented in support of the Draft Revised RIS. The NRC has proffered these arguments in connection with its new interpretation of 10 CFR 50.54(q) in both the EP rulemaking and in the Draft Revised RIS. Under this changed NRC position, emergency plan changes submitted under 10 CFR 50.54(q) that reflect a reduction in effectiveness would be required to be submitted as a license amendment request (LAR). By contrast, the current change control process prescribed by Section 50.54(q) does *not* require a license amendment request, but rather submittal of a licensee report to the NRC under 10 CFR 50.4. This NRC requirement has been in effect for decades.

NRC's rationale for issuing a revision to RIS 2005-02 at this time appears to be based on two incorrect conclusions: (1) modifications to emergency plans resulting in a decrease in effectiveness are *de facto* license amendments; and (2) the proposed modifications to the emergency plan change process are mere "clarifications" of existing regulatory requirements. NEI does not believe that emergency plan changes are *de facto* license amendments provided the modified emergency plan continues to comply with 10 CFR 50.47(b) and 10 CFR part 50, appendix E. Therefore, we do not agree that the NRC is legally compelled to use the license amendment process to review and approve emergency plan changes, and we reject the assertions to the contrary in the Draft RIS (and in the Supplementary Information published with the EP proposed rule).

NEI also believes the modifications to the Section 50.54(q) emergency plan change process proposed in the Draft RIS are inconsistent with 10 CFR 50.54(q), as well as with relevant guidance and long-established NRC licensing precedent and case law. Thus, the agency's proposed revision to the emergency plan change process constitutes an attempt to amend the existing legally promulgated regulations without providing appropriate notice and comment, in violation of the Administrative Procedure Act (APA). Further, the Draft RIS is inconsistent with the NRC's Principles of Good Management, and the backfit discussion is inadequate.

In effect, the NRC Staff appears to be using the proposed revisions to RIS 2005-02 to compel licensees to prepare LARs in connection with emergency plan changes, *in advance of the completion of the ongoing emergency preparedness rulemaking that explicitly addresses this question*. Such actions by the NRC improperly predetermine or assume the outcome of this

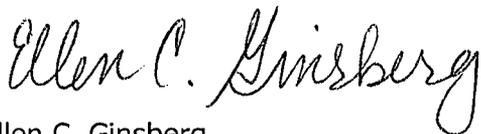
rulemaking, violate the APA, and are clearly inconsistent with the Commission's Principles of Good Regulation.

We therefore request that the NRC withdraw Draft Revised RIS 2005-02 immediately pending completion of the emergency preparedness rulemaking. Until those regulatory amendments are promulgated, implementing a revision to RIS 2005-02 would prematurely and improperly assume the outcome of public notice and comment in the related rulemaking. The Commission should direct the NRC Staff to discontinue immediately its ongoing informal efforts (through use of a non-public internal memorandum) to "direct" licensees to prepare LARs for emergency plan changes. These Staff actions lack a regulatory basis, and inappropriately predetermine the outcome of notice and comment on not only the proposed rule but also the Draft RIS. Instead, the Commission should direct the Staff to process any change requests received prior to completion of the pending rulemaking in accordance with current regulations.

Enclosure 2 to this cover letter contains additional, more specific industry comments on the Draft Revised RIS. We do not suggest that these changes be made to the current version of the Draft Revised RIS since, as noted above, NEI believes that guidance document should be withdrawn immediately and not re-issued until completion of the ongoing emergency planning rulemaking. Rather, if the NRC decides to re-issue the technical guidance in the Draft Revised RIS for comment when that rulemaking is final, these technical corrections should be incorporated in Draft Guide 1237.

If you have any questions concerning these comments, please contact Martin Hug (202/739-8129, mth@nei.org) or Jerry Bonanno (202/739-8140, jxb@nei.org).

Very truly yours,



Ellen C. Ginsberg

Enclosures

cc: NRC Document Control Desk
Howard Benowitz, NRC
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Christopher Miller, NRC
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**NUCLEAR ENERGY INSTITUTE COMMENTS ON PROPOSED REVISION 1 TO
NRC REGULATORY ISSUE SUMMARY 2005-02, *CLARIFYING THE PROCESS
FOR MAKING EMERGENCY PLAN CHANGES*, Docket ID NRC-2009-0365**

I. Overview and Recommendations

The Nuclear Energy Institute (NEI)¹ is pleased to comment on Draft Revision 1 to NRC Regulatory Issue Summary 2005-02, "Clarifying the Process for Making Emergency Plan Changes" (Docket ID NRC-2009-0365) (Draft RIS), published at 74 Fed. Reg. 42,699 (Aug. 24, 2009).² The Draft RIS addresses legal, regulatory and licensing issues that also are the subject of an ongoing NRC rulemaking amending NRC emergency planning (EP) regulations and guidance. See 74 Fed. Reg. 23,254 (May 18, 2009) (Docket ID NRC-2008-0122). We appreciate NRC's decision to allow stakeholders to coordinate input on the proposed rule and the draft revised RIS, which are closely related. NEI's comments on the proposed changes to the emergency planning rule were timely filed on October 19, 2009.

If implemented as written, the Draft RIS would supersede the existing 2005 RIS 2005-02. The stated purpose of the Draft RIS is "to inform stakeholders that reactor 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. . . ." It also provides updated guidance and "clarification" regarding the meaning of "decrease in effectiveness" (as that term is used in 10 CFR 50.54(q)), the process and method for evaluating proposed emergency plan changes, and what constitutes a "report" of emergency plan changes to be submitted to the NRC under 10 CFR 50.54(q).

In the name of "clarifying" the process for modifying NRC reactor emergency plans, this Draft RIS would direct NRC licensees to amend their operating licenses in order to effect emergency plan changes that decrease the effectiveness of the plan, despite the fact that the Commission's current regulations prescribe a change control process that does not require a license amendment. See 10 CFR 50.54(q). The proposed approach is inconsistent with NRC regulations, existing guidance, and licensing precedent. Thus, the Draft RIS actually reflects a change in NRC position, and effectively amends 10 CFR 50.54(q) via regulatory guidance. Such "regulation through guidance" constitutes improper use of an NRC RIS.³

¹ NEI is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

² On September 15, 2009, NEI requested an extension of the comment period for the draft RIS to facilitate better coordination of stakeholder comments on the RIS with comments on the broader NRC emergency planning rulemaking. The NRC subsequently extended the comment period on the Draft RIS from October 8 until October 23, 2009. 74 Fed. Reg. 50,840 (Oct. 1, 2009).

³ Additionally, the Draft RIS also reflects other new NRC regulatory positions that are discussed in the EP rulemaking. Implementation of these new positions by means of NRC regulatory guidance, rather than rulemaking, would be improper.

More fundamentally, we object to the Draft RIS because it seeks to impose a new Staff regulatory position concerning the emergency plan change process while that process is the subject of an ongoing NRC rulemaking. In fact, the stated purpose of the Draft RIS is to impose the proposed rule changes *before* the emergency planning rulemaking is finalized.⁴ If implemented, this Draft RIS would effectively predetermine the outcome of public notice and comment on the ongoing rulemaking. Such Commission action would render the notice and comment process meaningless and thus violate the Administrative Procedure Act (APA). Aside from contravening the APA, regulating in this fashion is patently unfair to NRC public stakeholders and inconsistent with the NRC's Principles of Good Regulation (e.g., openness, clarity, reliability).

Further, the NRC has inexplicably decided to impose the changes proposed in the Draft RIS and the rulemaking now, *before* the public comment period on even the Draft RIS has run its course. As detailed in one of the non-concurrences written by NRC staff on this topic⁵ and confirmed by NRC management at the NEI Licensing Forum on October 6, 2009, the NRC staff has been directing reactor licensees to withdraw pending requests for emergency plan changes that were submitted pursuant to the current regulations and resubmit them as license amendment requests (LAR). This Staff approach ignores the NRC's own processes and improperly assumes the outcome of notice and comment on both the proposed rule and the Draft RIS. Such an approach is unfair to stakeholders and inconsistent with the APA, NRC's Principles of Good Regulation, and 29 years of licensing precedent. The Commission and NRC management should not condone these actions.

In sum, NEI does not believe NRC should implement these far-reaching changes to RIS 2005-02 before completion of the related emergency planning rulemaking. As discussed below, NRC's rationale for revising the RIS at this time appears to be based on the incorrect conclusions that (1) modifications to emergency plans resulting in a decrease in effectiveness are *de facto* license amendments; and (2) the proposed modifications are mere "clarifications" of existing regulatory requirements. To the contrary, our view is that (1) emergency plan changes do not, *de facto*, amend the license so long as the modified plan continues to comply with

⁴ "The current schedule for the staff's emergency preparedness (EP) rulemaking calls for the final rule to be issued no earlier than the summer of 2010. Because of the timeframe associated with the rulemaking, the staff has determined that the prudent action is to issue a RIS to clarify that licensees must submit proposed emergency plan changes which represent a decrease in effectiveness for NRC approval as specified in § 50.54(q), and the license amendment process is the correct process for the staff to use in reviewing the proposed change." Draft RIS, p. 3.

⁵ The NRC's internal non-concurrence process in Management Directive 10.158 was invoked twice (April 24, 2009 and May 27, 2009) by Mr. Richard Ennis in connection with the Draft RIS. Mr. Ennis' first non-concurrence (ML080710029) provides his objections to the Draft RIS (hereinafter "RIS Non-concurrence"), and his second non-concurrence (ML091370012) provides his objections to a non-public memorandum that apparently instructs the NRC staff to impose the positions put forth in the Draft RIS and proposed rule before completion of the rulemaking. This was confirmed by NRC management at the October 6, 2009, NEI Licensing Forum. In addition, the September 9, 2009, comments of NRC Staff member John G. Lamb also express concerns about the draft RIS. In our view, these non-concurrences identify serious procedural and substantive deficiencies in the Draft RIS that the NRC's response ignores or fails to address effectively.

10 CFR 50.47(b) and 10 CFR Part 50, appendix E; and (2) the proposed modifications are inconsistent with 10 CFR 50.54(q) and thus constitute an attempt to amend the existing legally promulgated regulations without providing appropriate notice and comment, in violation of the APA. Further, the Draft RIS is inconsistent with the NRC's Principles of Good Management, and the backfit discussion is inadequate.

We therefore request that the NRC withdraw Draft Revised RIS 2005-02 immediately, pending completion of the associated NRC emergency planning (EP) rulemaking,⁶ and re-issue the Draft RIS for public comment (if at all) when that rulemaking is finalized. Until those regulatory amendments are promulgated, implementing a revision to RIS 2005-02 would prematurely and improperly assume the outcome of public notice and comment in the EP rulemaking. The Commission also should direct the NRC Staff to discontinue immediately its ongoing efforts to compel licensees to prepare LARs for emergency plan changes. These Staff actions lack a regulatory basis, and inappropriately predetermine the outcome of notice and comment on not only the proposed rule, but also the Draft RIS. Instead, the Commission should direct the Staff to process any change requests received prior to completion of the pending rulemaking in accordance with current regulations, which were promulgated in full compliance with the APA and – as explained in Section II – are otherwise on firm legal footing.

II. Bases for NEI Disagreement with the Draft Revised RIS

A. *Emergency Plan Changes Are Not De Facto License Amendments*

In the Draft RIS, the NRC concludes that emergency plan changes that would reduce (or decrease) the effectiveness of the plan expand the licensee's operating authority and thus constitute a *de facto* license amendment:

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

⁶ Further, as recommended in NEI's comments on NRC Draft Guide 1237 in the context of the EP rulemaking, the content of the Draft RIS would be more appropriately incorporated in RG 1237 and re-issued for public comment when the rulemaking is final, if it is re-issued at all.

expanding the licensee's operating authority is, according to the courts, a license amendment and must be accomplished through a license amendment process.

Draft RIS, p. 3. Identical language appears in the Supplementary Information published with the proposed EP rule amendments. 74 Fed. Reg. 23,272.

As a threshold matter, NEI agrees that the cases cited in the Draft RIS and proposed rule stand for the general proposition that agency approvals granting licensees "greater operating authority" or "alter[ing] the original terms of a license" are license amendments. See *Cleveland Electric Illuminating Co.* (Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315, 326-327 (1996) (*Perry*) ("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 a licensee any greater operating authority, or otherwise alter the original terms of a license?") (internal quotations omitted), citing *In re Three Mile Island Alert*, 771 F.2d 720, 729 (3d Cir. 1985) (TMI); *San Luis Obispo Mothers for Peace v. NRC*, 751 F.2d 1287, 1314 (D.C. Cir. 1984)); see also *Citizens Awareness Network, Inc. v. NRC*, 59 F.3d 284, 295 (1st Cir. 1995) (CAN) (authorization of component dismantling was a *de facto* license amendment because such actions were "beyond the ambit of the presumptive authority granted" in NRC licenses); *Sholly v. NRC*, 651 F.2d 780, 791 (D.C. Cir. 1980) (an NRC order allowing purging of the TMI 2 containment was a license amendment because it "granted the licensee authority to do something that it otherwise could not have done under the existing license authority.").

Significantly, however, the Draft RIS and the EP proposed rule lack any explanation of how this case law applies to the regulatory issue at hand: approval of emergency plan changes. Instead, the NRC simply assumes that allowing a change that reduces the effectiveness of an emergency plan constitutes an "expansion of operating authority" and, thus, warrants treatment as a *de facto* license amendment.⁷ The absence of analysis on this point dramatically undermines the NRC's position, since a careful reading of these cases reveals that emergency plan changes are not analogous to the types of actions that have been considered expansions of operating authority by reviewing courts. To the contrary, the case cited in the Draft RIS that most closely resembles the facts here – *Perry*, 44 NRC 315 – reveals that a license amendment is *not required* for emergency plan changes, unless such changes result in noncompliance with either Section 50.47(b) or appendix E to 10 CFR part 50, or otherwise jeopardize the Commission's

⁷ In response to the Non-concurrence on the Draft RIS (ML080710029), the NRC appears to argue that it was not relying on the case law cited in the above-quoted passage to support its argument that NRC approval of an emergency plan change resulting in a decrease (or reduction) in effectiveness would constitute a grant of greater operating authority. See RIS Non-concurrence, Attach. 3, p. 3. This explanation seems, at best, an ill-conceived, ad hoc response to the arguments raised in the Non-concurrence. If it is accurate, then the NRC has provided no relevant precedent to support the legal conclusions in the Draft RIS.

reasonable assurance that adequate protective measures will be taken in the event of an emergency.⁸

Only two of the four cases cited in the Draft RIS held that the NRC approval at issue must be treated as a license amendment. *See Sholly*, 651 F.2d 780; *CAN*, 59 F.3d 284. *Sholly*, which arose in the aftermath of the widely publicized accident at Unit 2 of the Three Mile Island nuclear plant, dealt with an NRC order that allowed the licensee to vent the reactor containment building to the environment. 651 F.2d. at 790. Petitioners argued that this order constituted a license amendment and, therefore, that Section 189a of the Atomic Energy Act required a hearing opportunity. The NRC countered that the order was not a license amendment because it merely lifted a prior suspension of the licensee's authority to vent and did not authorize a radioactive release greater than was allowed by the technical specifications of the original license. The D.C. Circuit disagreed with the NRC's argument, reasoning that the original operating license did not permit venting as part of accident clean-up because the license only covered releases associated with normal plant operation. Thus, the court held that the order allowing post-accident venting was a *de facto* license amendment because it granted the licensee authority to take an action that it otherwise could not have taken under the existing license. In *CAN*, the First Circuit held that Staff Requirements Memoranda (SRM) issued by the Commission allowing component dismantling prior to approval of a decommissioning plan constituted a *de facto* license amendment. The court found that – like the venting at issue in *Sholly* – major component dismantling was not an activity authorized under the possession-only license at issue in that case. 59 F.3d at 295.

These cases deal with NRC approval of activities that are readily distinguishable from the EP changes at issue in the Draft RIS. *Sholly* dealt with NRC's approval of a major operational occurrence at Three Mile Island – the post-accident venting of radioactive gases to the atmosphere – following the worst nuclear accident in our Nation's history. Likewise, in *CAN* the NRC approval in question would have allowed major plant changes, including the removal of four steam generators and a pressurizer from containment, removal of the core internals from the reactor pressure vessel, removal of four main coolant pumps, and dismantlement of the reactor core baffle plate – all prior to approval of a decommissioning plan. In contrast, the changes in question here are, in essence, modifications to a licensee's Final Safety Analysis Report (FSAR). See 10 CFR 50.34(b)(6)(v), 52.79(a)(21). While the emergency plan plays an important role in providing reasonable assurance that adequate protective measures will be taken in the event of an emergency, changes to FSAR documents are different in-kind from the major operational occurrence and plant modifications at issue in *Sholly* and *CAN*. In addition, a licensee's responsibilities with respect to the emergency plan are governed by a generic license condition, which requires all reactor licensee emergency plans to comply with 10 CFR 50.47(b) and Part 50, appendix E. This distinction will prove important, for the reasons the Commission explained in the *Perry* decision.

⁸ This is not an argument that the NRC cannot require a licensee to obtain agency approval before making changes to its emergency plan. The point here is simply that such changes do not require a license amendment.

Of the four cases NRC relies upon, the *Perry* decision involved facts most analogous to the licensing activity discussed in the Draft RIS.⁹ *Perry* involved transfer of the withdrawal schedule for reactor vessel material specimens from the plant's technical specifications to the facility's updated final safety analysis report (UFSAR). See 44 NRC 315, 316-17. Since this transfer involved a change to the technical specifications, a license amendment was required. But after removal of the schedule from the technical specifications and placement in the UFSAR, additional changes to the schedule could be made without a license amendment depending on the outcome of the licensee's analysis under 10 CFR 50.59. Several parties intervened in the amendment proceeding, claiming that removal of the schedule from the technical specifications was inconsistent with AEA Section 189a because *any* change to the *Perry* material specimen withdrawal schedule was a *de facto* license amendment. *Id.* at 319.

In *Perry*, the Commission reversed and vacated the Licensing Board's decision. In determining whether the schedule changes at issue were license amendments, the Commission looked to the actual terms of the operating license. *Perry*, 44 NRC at 328-29. The Commission determined that the license technical specifications required the licensee to conduct all testing and surveillance of material specimens in accordance with Appendix H to 10 CFR Part 50, which, in turn, required that withdrawal schedules meet the applicable American Society for Testing and Materials (ASTM) standard. The Commission reasoned:

This means in effect that the *Perry* license specifies an NRC-approved methodology—the ASTM standard—to be used in developing either an initial or a revised schedule. The ASTM standard establishes specific technical criteria for determining where in the reactor vessel to place surveillance capsules, how many capsules should be used, and how often capsules should be removed for testing. By effectively incorporating the ASTM standard, the *Perry* license provides delineated parameters for Cleveland Electric to use in calculating an appropriate withdrawal schedule.

As long as its withdrawal schedule meets the applicable ASTM standard, Cleveland Electric is not exceeding operating authority already granted in its *Perry* operating license. The ASTM standard anticipates that during the course of a nuclear power plant's life the withdrawal schedule may need to be revised; the standard allows and provides for such changes. The terms of the *Perry* license thus already provide for—already authorize—some possible schedule changes. Any revised schedule that conforms to the ASTM standard can be said to be "encompassed within delineated categories of authorized conduct."

.....

That the Staff may wish to verify in advance that a proposed revision conforms to the required technical standard does not make Staff approval a license amendment. By merely ensuring that required technical standards are met, the Staff's approval does not alter the terms of the license, and does not grant the Licensee greater operating

⁹ The Commission issued the *Perry* decision in December 1996, 16 years after the D.C. Circuit's *Sholly* opinion and almost 18 months after the First Circuit's *CAN* decision. In the *Perry* decision, the Commission did not discuss *Sholly* and actually distinguished the facts before it from those presented in *CAN*. See *Perry*, 44 NRC 315, 327-328.

authority. Such a review *enforces* license requirements. As an enforcement policy matter, the Staff may wish to police some licensee-initiated changes *before* they go into effect.

Perry, 44 NRC at 328 (citations omitted) (emphasis in original).

Similarly, here the terms of the license are contained in Section 50.54(q), which is a condition in every operating license issued under 10 CFR Part 50 and every combined license issued under 10 CFR Part 52.¹⁰ The affirmative requirement in the current version of Section 50.54(q) is that:

A holder of a nuclear power reactor operating license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain in effect emergency plans *which meet the standards in § 50.47(b) and the requirements in appendix E of this part.*

(emphasis added). This license condition requires that power reactor licensees maintain emergency plans *that meet the standards in 10 CFR 50.47(b) and appendix E.* Thus, so long as the licensee maintains a plan that meets these standards, the licensee is not exceeding the operating authority granted in its license and no license amendment is required. This is directly analogous to the situation addressed in *Perry* and described above. There, the Commission appropriately held that "any revised schedule that conforms to the ASTM standard can be said to be encompassed within delineated categories of authorized conduct." *Perry*, 44 NRC at 328 (internal citation omitted). Likewise, any emergency plan change that will result in continued conformance to Section 50.47(b) and appendix E can be said to be encompassed within delineated categories of authorized conduct and, therefore, need not be considered an amendment to the license. Indeed, the proposed EP rule clearly states that:

A determination that a change may result in a reduction in effectiveness does not imply that the licensee could no longer implement its plan and provide adequate measures for the protection of the public. *The NRC may approve a proposed emergency plan change that the licensee determined to be a reduction in effectiveness, if the NRC can find that the emergency plan, as modified, would continue to meet the requirements of Appendix E, and for nuclear power reactor licensees, the planning standards of § 50.47(b), and would continue to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.*

¹⁰ 10 CFR 50.54 states:

The following paragraphs with the exception of paragraphs (r) and (gg) of this section *are conditions in every nuclear power reactor operating license issued under this part.* The following paragraphs with the exception of paragraph (r), (s), and (u) of this section *are conditions in every combined license issued under part 52 of this chapter,* provided, however, that paragraphs (i), (i-1), (j), (k), (l), (m), (n), (w), (x), (y), and (z) of this section are only applicable after the Commission makes the finding under § 52.103(g) of this chapter. (emphasis added).

74 Fed. Reg. 23,272 (emphasis added). Thus, the NRC may only approve an emergency plan change if the modified plan will continue to meet the applicable regulatory requirements and continue to provide the required reasonable assurance. That is, NRC will only approve emergency plan changes that allow a licensee to continue to comply with the positive requirements of the license condition contained in Section 50.54(q). Consistent with the Commission's explanation in *Perry*, the NRC's review and approval of plan changes are best understood as enforcing existing license requirements (i.e., the positive requirement contained in Section 50.54(q)), rather than granting greater operating authority.

While neither the Draft RIS nor the proposed rule provides a sufficient explanation of the NRC's legal position, the NRC's response to the non-concurrence filed by Mr. Ennis provides some additional insight. The RIS non-concurrence cogently argues that emergency plan changes do not expand a licensee's operating authority. RIS non-concurrence, Attach. 2, pp. 11-13. The NRC offered the following response:

[T]he 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 the 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.

RIS non-concurrence, Attach. 3, p. 3. While the first sentence above inaccurately describes the NRC's regulations, it does suggest the flawed foundation for the agency's legal position. Section 50.34(b)(6)(v) requires that *applications* for operating licenses include an FSAR. The FSAR must, in turn, include "[p]lans for coping with emergencies, which shall include the items specified in appendix E." The Introduction to appendix E of Part 50 clearly states that the appendix "establishes minimum requirements for emergency plans for use in attaining an acceptable state of emergency response." Appendix E goes on to describe the minimum requirements for the content of emergency plans, covering areas such as organization, assessment actions, emergency facilities and equipment, and training. Section IV of Appendix E also requires applicants for reactor operating licenses to submit plans that demonstrate compliance with the planning standards in Section 50.47(b). Section 50.47 contains requirements that must be met *in order for the NRC to issue initial operating and combined licenses, and early site permits*.

Contrary to statements in NRC's response to the non-concurrence, neither Sections 50.34(b)(6)(v), 50.47, nor Appendix E to Part 50 requires that licensees maintain or implement "the approved emergency plan," in its entirety, in order to *hold* (as opposed to obtain) an operating license. As the Commission explained in *Perry*, to determine the extent of the operating authority granted to a licensee, the NRC must "look[] to the actual terms of the operating license." Turning to the license provision relevant in this case, we find that it is the license condition described in Section 50.54(q) that compels *licensees* (as opposed to applicants) to maintain emergency plans. As noted above, Section 50.54(q) simply requires licensees to maintain plans that comply with the requirements in Section 50.47(b) and appendix

E – a condition that, according to the proposed rule, the NRC staff will ensure is satisfied before any emergency plan change is approved.

In sum, a review of the case law NRC relies upon in the Draft RIS reveals that approval of emergency plan changes under Section 50.54(q) will not result in an expansion of a licensee's operating authority. Thus the NRC is not compelled to use the license amendment process to approve emergency plan changes. As the Commission explained in *Perry*, NRC prior review and approval of emergency plan changes resulting in a reduction in effectiveness is best understood as method to *enforce existing license and regulatory requirements, rather than as a grant of increased operating authority*. NRC's conclusion that it is legally compelled to impose the license amendment process to approve changes to emergency plans is therefore incorrect.¹¹

B. The Draft RIS is Inconsistent with the Current NRC Regulations

10 CFR 50.54(q) currently states:

A holder of a nuclear power reactor operating license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain in effect emergency plans which meet the standards in § 50.47(b) and the requirements in appendix E of this part. . . . The nuclear power reactor licensee may make changes to these plans without Commission approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of § 50.47(b) and the requirements of appendix E to this part. The research reactor and/or the fuel facility licensee may make changes to these plans without Commission approval only if these changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the requirements of appendix E to this part. . . . *Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission. The licensee shall submit, as specified in § 50.4, a report of each proposed change for approval.*

(emphasis added). Section 50.54(q) requires licensees to submit for review and approval a report describing proposed changes that will decrease the effectiveness of the approved emergency plan in accordance with 10 CFR 50.4. There is no requirement that NRC licensees submit a LAR in connection with proposed changes that may decrease the effectiveness of emergency plans. As the RIS non-concurrence points out:

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)(5)]. This paragraph does not mention use of the application for license amendment process.

¹¹ Further, even if the NRC were required to approve emergency plan changes via license amendment that would not permit the agency to ignore its current regulations and impose changes to those regulations under the guise of providing "clarifications" or "guidance."

It should be noted that the preceding paragraph [§ 50.4(b)(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 specific 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.

RIS non-concurrence, p. 3. In response, the NRC states:

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). . . . Section 50.4, however, is a broadly written provision that specifically includes the administrative requirements for filing amendment requests 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 filing 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.

RIS non-concurrence, Attach. 3, p. 1. In the first paragraph, the RIS non-concurrence argues that use of the word "report" to describe the submittal required by Section 50.54(q) is significant because it precludes any inference that what the NRC "really meant" was license amendment request. In addition, the fact that Section 50.4 separately references both "reports" and "applications for amendment of permits and licenses" further supports the position put forth in the RIS non-concurrence. See Section 50.4(b)(1) entitled "Applications for amendment of permits and licenses; reports; and other communications." In our view, the fact that 10 CFR 50.4 describes both "applications for amendment of licenses" and "reports" indicates that these words have distinct meaning: "report" does not mean "license amendment request" and vice versa. This interpretation, which gives effect to all of the terms of the NRC regulation, is consistent with the fundamental principle of statutory construction that courts should "give effect, if possible, to every clause and word of a statute, avoiding, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language it employed." *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883). The word "report" used to describe the submittal required for Section 50.54(q) simply does not mean LAR. As the RIS non-concurrence also explains, the presence of other change control provisions that specifically and unambiguously require a license amendment request indicates that the NRC knows how to direct licensees to use the license amendment process when that is its intent. See, e.g., 10 CFR 50.54(p), 10 CFR 50.59.

In its response, the NRC criticizes the RIS non-concurrence because it does not provide evidence, in the form of regulatory history, indicating that the Commission intended the words of Section 50.54(q) to mean what they plainly say. But it is well-settled that:

[T]o discern regulatory meaning, we are not free to go outside the express terms of an unambiguous regulation to extrinsic aids such as regulatory history. Aids to interpretation only can be used to resolve ambiguity in an equivocal regulation, never to create it in an unambiguous one.

Cleveland Electric Illuminating Co. (Perry Nuclear Power Plant, Unit 1), LBP-95-17, 42 NRC 137, 145 (1995), *rev'd on other grounds, Perry*, CLI-96-13, 44 NRC 315 (1996). Thus, contrary to the NRC's response, it is not necessary to comb through the regulatory history of Section 50.54(q) to resolve a non-existent ambiguity.

Further, as the RIS non-concurrence points out, this plain reading of Section 50.54(q) is confirmed by NRC practice in the area of emergency plan change approval. Specifically, the RIS non-concurrence cites three examples from 2008 where the NRC approved emergency plan changes that licensees had determined would result in a decrease in effectiveness. These changes were approved by letter, without issuing license amendments.

In response to three recent examples of actual approvals of emergency plan changes, the NRC cites to a single 1997 letter where the agency apparently requested that a licensee submit a license amendment request. Specifically, the NRC stated:

[T]he staff's approach over time in reviewing 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.

RIS non-concurrence, Attach. 3, p. 1. Notably, as the non-concurring individual points out in his subsequent non-concurrence (ML091370012), the emergency plan change referenced in the 1997 letter was eventually granted, in modified form, on February 5, 1999, *by letter and without a license amendment*. The NRC's response to this salient point was a simple, unsupported statement that "[t]he agency's practice has been at best inconsistent." Non-concurrence, "Memorandum from Joseph G. Gitter to Melvyn N. Leach, Processing Emergency Plan Reviews," May 27, 2009 (ML091370012), Response to non-concurrence, p. 1.

NEI's search of the publicly available emergency plan approvals dating back to 1980 did not uncover a single instance where an emergency plan change was given effect by license amendment – and the NRC has provided none. In fact, NEI's search revealed multiple examples, in addition to those cited in the RIS non-concurrence, of approvals to emergency plan changes described as decreases in effectiveness by licensees that were issued by letter within the last decade.¹² These approvals are far from "[s]taff actions that may have taken

¹² See Letter from S. Patrick Sekerak (NRC), to William A. Eaton (Entergy Operations, Inc.), "Grand Gulf Nuclear Station, Unit 1, Proposed Emergency Plan Table 5-1 Changes," Sept. 29, 2000 (ML003756919); Letter from Jack Donohew (NRC) to Garry L. Randolph (Union Electric Company),

place on limited occasions," as claimed in the NRC's response to the RIS non-concurrence.¹³ RIS non-concurrence, Attach. 3, p. 2. As the RIS non-concurrence points out, the results of NEI's research are not surprising because – in addition to the plain language of the regulations described above – NRR Office Instruction LIC-100, "Control of Licensing Basis for Operating Reactors," Rev. 1 clearly indicates that emergency plan change approvals are issued by letter, not by license amendment.¹⁴

In sum, NEI submits that 10 CFR 50.54(q) is plain on its face: emergency plan changes that will result in a decrease in effectiveness are to be submitted in the form of a report in accordance with Section 50.4. This reading is confirmed by 29 years of NRC practice of issuing letter approvals, as opposed to license amendments, in response to such requests. This reading of Section 50.54(q) is also consistent with the agency's internal NRR guidance. Thus, the direction provided in the Draft RIS and the proposed rule is clearly inconsistent with existing regulations.

"Radiological Emergency Response Plan (RERP) Change Related to Control Room Communicators for Callaway Plant, Unit 1," Feb. 14, 2003 (ML030450194); Letter from Jack Donohew (NRC) to Mr. Gregg Overbeck (Arizona Public Service Company), "Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2, and 3 – Emergency Plan Change to Reduce the Number of Shift Technical Advisors in the Emergency Response Organization Staffing," Mar. 19, 2004 (ML040860125); Letter from Douglas V. Pickett (NRC) to Karl W. Singer (Tennessee Valley Authority), "Sequoyah Nuclear Plant, Units 1 & 2 – Summary of the NRC Staff's Review on Proposed Emergency Action Levels," Oct. 24, 2005 (ML052870252); Letter from Kahtan N. Jabbour (NRC) to Christopher M. Crane (Exelon Generating Company, LLC), "Braidwood Station, Units 1 and 2, Byron Station, Units 1 and 2, Clinton Power Station, Unit 1, Dresden Nuclear Station, Units 1, 2, and 3, LaSalle County Station, Units 1 and 2, and Quad Cities Nuclear Power Station, Units 1 and 2 Re: Approval of Changes to the Exelon Nuclear Standardized Radiological Emergency Plan, and Byron and Quad Cities Stations Emergency Plan Annexes," Feb. 14, 2006 (ML060450538); Letter from G. Edward Miller (NRC) to Christopher M. Crane (Exelon), "Oyster Creek Nuclear Generating Station – Revision of Emergency Plan Emergency Action Levels HA5 and HU5," May 11, 2006 (ML061240062) (the licensee originally submitted an LAR in this case, but apparently was ultimately granted approval for the plan changes by letter); Letter from Jack Donohew (NRC) to Charles D. Naslund (Union Electric Company), "Callaway Plant, Unit 1 – Revision of Emergency Action Levels in Radiological Emergency Response Plan," Nov. 8, 2006 (ML062980278).

¹³ In addition, the NRC's claim that letter approvals have been frequently used for plan changes that are not decreases in effectiveness is striking in light of the fact that there is no requirement for prior approval of such changes. It is unclear why the NRC would devote resources to issuance of change approvals in situations where no approval is required.

¹⁴ The NRC responded to this point by stating: "NRR office procedures are not regulatory requirements and serve only as in internal guide. Thus, the non-concurring individual's deference to LIC 100 as authority is misplaced." This appears to be a statement of the obvious used to reach an irrelevant conclusion. Although it is true that office procedures are not regulatory requirements, and thus are of questionable value as legal authority, they most certainly are indicia of agency practice. If not, then NRC staff members would be free to ignore office instructions – and this is clearly not the case.

C. The Backfit Discussion in the Draft RIS Is Inadequate

Given the discussion provided above, NEI believes that the backfit discussion in the Draft RIS is inadequate. After a short discussion, the Draft RIS concludes that the revisions it imposes do not constitute a backfit under 10 CFR 50.109. First, the NRC states that the Draft RIS "clarifies existing regulatory requirements licensees must follow when proposing changes to their emergency plans." Draft RIS, p. 10. In actuality, the Draft RIS does not clarify an established legal, regulatory or licensing matter, but rather reflects an entirely new staff position on the need for a license amendment. Declarations by the NRC staff to the contrary are unconvincing and, in our view, misleading, and should not be countenanced. The NRC cannot avoid its responsibility to perform a backfit analysis by declaring that amendments to its regulatory requirements are merely "clarifications."¹⁵

Further, the Draft RIS states:

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 review process is not a licensee procedure required for operating a plant that would be subject to backfit limitations.

Draft RIS, p. 10. This statement ignores the fact that the proposed revisions to Section 50.54(q) will result in modifications or additions to licensee procedures necessary to operate nuclear power plants. At the very least, licensees will need to modify their procedures for seeking changes to emergency plans to account for the fact that such changes will now require submittal of an LAR. Procedures for screening and evaluating the need to obtain prior approval of emergency plan changes may also require modification as a result of the positions taken in the Draft RIS. In our view, the Staff's proffered backfit justification is inadequate.

The backfit discussion in the Draft RIS (p. 10) concludes with the following:

¹⁵ Even if the NRC were merely "clarifying" the meaning of the existing regulations, a proposition with which we disagree, such a clarification may still "impos[e] . . . a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position." 10 CFR 50.109(a). The Commission addressed this issue directly in its discussion of regulatory interpretations in the Supplementary Information published with the 1985 final backfitting rule:

It may also be noted that "cause" includes not only Commission rules and orders, but staff interpretations of those rules and orders. This is not to say that staff interpretations of rules are viewed by the Commission as being legal requirements. Clearly, they are not. Nevertheless, staff interpretations of broadly stated rules are often necessary to give a rule effect and in some instances may be a causal factor in initiating a backfit.

50 Fed. Reg. 38,102. Thus, the Commission has long recognized that new regulatory interpretations – clarifications or not – may be a causal factor in initiating a backfit.

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

As discussed in Section II.A, emergency plan changes do not constitute an expansion of the licensee's operating authority, where the modified emergency plan will continue to comply with Section 50.47, and appendix E to 10 CFR part 50. Thus, the NRC's statement that "[t]he 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" is irrelevant.

Moreover, the first sentence of the above-quoted paragraph appears to reflect a misunderstanding of the purpose of the Backfit Rule. NRC asserts that the purpose of the Backfit Rule is to protect licensees from arbitrary Commission action, but arbitrary Commission action is already prohibited by the APA and the Backfit Rule is not a mere redundancy. The backfitting process is explained in the Commission's backfitting guidance:

The backfitting process is the process by which the U.S. Nuclear Regulatory Commission (NRC) decides whether to issue new or revised requirements or staff positions to licensees of nuclear power reactor facilities. Backfitting is expected to occur and is an inherent part of the regulatory process. However, it is to be done only after formal, systematic review to ensure that changes are properly justified and suitably defined. Requirements for proper justification of backfits and information requests are provided by two NRC rules, Title 10 of the *Code of Federal Regulations*, Sections 50.109 and 50.54(f). Three types of backfits are recognized. Cost-justified substantial safety improvements require backfit analyses and findings of substantial safety improvement and justified costs. Two types of exceptions, compliance exceptions and adequate protection exceptions, do not require findings of substantial safety improvements and costs are not considered. However, they are still backfits and they require documented evaluations to support use of the exceptions.

"Backfitting Guidelines," NUREG-1409, June 1990, at Abstract. Thus, backfits are expected to occur as an inherent part of the regulatory process. The Backfit Rule is meant, however, to ensure that changes constituting backfits are "properly justified and suitably defined." More specifically, NUREG-1409 goes on to state that "the requirements of this process [backfitting] are intended to ensure order, discipline, and predictability and to enhance optimal use of NRC staff and licensee resources." NUREG-1409, at Executive Summary. The NRC staff's characterization of the purpose of the backfit rule (i.e., to prevent arbitrary Commission action) may have resulted in the staff taking untenable positions to avoid classifying changes in position as backfits. This approach undermines the Backfit Rule, which is to ensure that such changes in agency regulations or positions are properly justified and imposed in an orderly fashion.

Although NEI recommends that the NRC not finalize the Draft RIS before completion of the emergency planning rulemaking, if the NRC decides to promulgate the revisions to the Draft RIS in the future it should perform a suitable backfit analysis. Such an analysis should provide a clear determination of whether any changes in position described in the revised RIS are either cost-justified substantial safety improvements, or are properly captured under the compliance or adequate protection exemptions.

D. The Draft RIS and Staff Actions Imposing Proposed Modifications to 10 CFR 50.54(q) Violate the Administrative Procedure Act and the Commission's Principles of Good Regulation

As discussed in Section II.A., the NRC is not legally compelled to use the license amendment process to approve changes to emergency plans.¹⁶ As discussed in Section II.B., the plain language of Section 50.54(q) and 29 years of agency practice reveal that the NRC's long-standing regulations require licensees to submit reports requesting approval of emergency plan changes pursuant to Section 50.4 – not LARs. Thus, the Draft RIS and the NRC staff's current practice of directing licensees to resubmit pending requests for emergency plan changes are improper attempts to impose a rule change without awaiting the outcome of the ongoing rulemaking on this topic.

These tactics violate the APA. It is well-settled that under the APA, an agency is required to engage in notice and comment *before* amending its regulations. See 5 U.S.C. § 551(5); *Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997). The Draft RIS, along with NRC's informal actions to compel licensees to immediately comply with a new emergency plan change process, constitute an effort to amend NRC regulations prior to the completion of notice and comment on the rule change. Even if the NRC's new position is considered a changed interpretation of Section 50.54(q) rather than an overt rule change – a theory undermined by the fact that the NRC is currently engaged in a rulemaking to change Section 50.54(q) – allowing the NRC “to make a fundamental change in its interpretation of a substantive regulation without notice and comment obviously would undermine” the APA's notice and comment requirements. *Paralyzed Veterans of America*, 117 F.3d 579, 586.

Further, imposing proposed modifications to Section 50.54(q) prior to notice and comment is inconsistent with the Commission's principles of good regulation. Those principles include:

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. Open channels of communication must be maintained with Congress, other government agencies, licensees, and the public, as well as with the international nuclear community.

¹⁶ Even if the NRC were compelled to use the license amendment process, that does not give the agency license to ignore the requirements of the APA. Amendments to the agency's regulations must be given effect by adhering to the APA requirements for notice and comment rulemaking – not by RIS and certainly not by internal memoranda.

"Principles of Good Regulation," available at <http://www.nrc.gov/site-help/search.html?cx=014311028302829740899%3Avo1uexxrz88&q=principles+of+good+regulation&cof=FORID%3A11#1233>. Publishing proposed changes to a regulation for public comment, then publishing a Draft RIS to implement those changes before the rulemaking is finalized and immediately imposing the changes contained in both the proposed rule and Draft RIS before completion of notice and comment is neither a "public" nor a "candid" process. Thus, the principle of "openness" is undermined.

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.

Imposition of amendments to long-standing regulations outside of the APA's notice and comment process results in an incoherent, illogical, and impractical regulatory process. Such actions, and the Staff's ad hoc attempts to justify them, cloud rather than clarify the nexus between the agency's regulations, goals, and objectives.

Reliability: Regulations should be based on the best available knowledge from research and operational experience. Systems interactions, technological uncertainties, and the diversity of licensees and regulatory activities must all be taken into account so that risks are maintained at an acceptably low level. Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. 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.

Contrary to this precept, relegating the notice and comment rulemaking process to a formality destabilizes the nuclear operational and planning process by allowing the immediate imposition of new regulatory requirements, without notice and a meaningful opportunity for informed comment. This instability results in a perception that the Commission's regulations are unreliable and in a constant, unpredictable state of transition.

**NUCLEAR ENERGY INSTITUTE ADDITIONAL COMMENTS ON PROPOSED
REVISION 1 TO NRC REGULATORY ISSUE SUMMARY 2005-02, *CLARIFYING
THE PROCESS FOR MAKING EMERGENCY PLAN CHANGES,*
Docket ID NRC-2009-0365**

The comments below apply to the NRC's Draft Revision 1 to NRC Regulatory Issue Summary 2005-02, "Clarifying the Process for Making Emergency Plan Changes" (Docket ID NRC-2009-0365) (Draft RIS), published at 74 Fed. Reg. 42,699 (Aug. 24, 2009). The additional comments in this Enclosure 2 supplement, and are intended to be consistent with, NEI's comments in Enclosure 1, which focus on legal and regulatory concerns raised by the Draft RIS.

I. Applicability of Draft Revised RIS Guidance to Part 40, 70 or 76 Licensees

It is unclear why non-reactor licensees are included as addressees for the Draft RIS. As discussed on page 2, paragraph 1), of the Draft RIS, NRC guidance for 10 CFR Part 40, 70 or 76 licensees is contained in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." NRC states in the RIS: "[T]he NRC staff is working on updating Regulatory Guide 3.67 to include applicable elements of this RIS for fuel cycle facilities."

Draft Revised RIS 2005-02 has many references to reactor specific regulations (10 CFR 50.54(q), Appendix E to Part 50, 50.57, 50.90, etc.) and has expanded language with an additional 14 pages in areas for which there are no similar requirements in Parts 40, 70, or 76. See, for example, Enclosure 1, "10 CFR 50.54(q) Evaluation Procedure;" Attachment 1, "10 CFR 50.54(q) Flowchart;" Attachment 2, "10 CFR 50.54(q) Evaluation."

Further, many of the reduction of effectiveness examples in the definitions on pp. 5 and 6 of the Draft RIS, including the following, do not apply to fuel cycle facilities:

- 1(a)(2)(d) Changes to the onsite meteorological measurements program
- 1(a)(2)(e) Changes to the hazard assessments and radiation protection assignments
- 1(a)(2)(f) Changes that reduce the availability of off-site familiarization training presented to off-site assistant groups
- 1(a)(2)(g) Changes that delegate testing and maintenance of alert and notification systems to contractors
- 1(a)(3)(b) Emergency action level changes causing over classification (General Emergency)
- 1(a)(3)(c) Emergency action level changes to an initiating condition set point
- 1(a)(3)(d) Emergency action level offsite dose set point changes referenced in a safety evaluation report

In addition, none of the following guidance documents referenced in the Draft RIS is applicable to the fuel cycle:

- Regulatory Guide 1.101, "Emergency Planning and Preparedness for Nuclear Power Reactors"
- NUREG 0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants"

- NUREG 0696, "Functional Response Criteria for Emergency Response Facilities"
- NUREG 0737, "Clarification of Three Mile Island Action Plan Requirements"

As stated on p. 2 of the Draft RIS, a more appropriate method to inform stakeholders that certain fuel cycle facility emergency plan changes require prior NRC approval is to revise current regulatory guidance for non-reactor emergency plans in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities."

It would therefore seem that the NRC staff may have inadvertently caused confusion on the part of some stakeholders by distributing the Draft RIS to non-reactor licensees. We suggest that if the guidance in the Draft RIS is ultimately re-issued for comment (after completion of the pending NRC EP rulemaking), the staff should confirm explicitly that the new guidance is not intended to apply to non-reactor licensees. This correction could be accomplished by either eliminating 10 CFR Part 40, 70 or 76 licensees from the Addressee list or inserting the following change to the section on "Addressees" in paragraph 1), p. 2, before the last sentence: "... RIS for fuel cycle facilities. Therefore these facilities are not subject to the requirements of this RIS. The NRC will..."

II. Additional Specific Comments on Draft Revised RIS 2005-02

NEI performed a line by line review of the Draft RIS. Where appropriate in the following table, NEI recommends possible changes to the RIS (with accompanying rationale) for each comment. Again, we suggest these revisions be made only if the Draft RIS is re-issued for comment, which should only be undertaken (if at all) after completion of the EP rulemaking. As noted elsewhere in NEI's comments, if the NRC decides to re-issue the technical guidance in the Draft RIS for comment, these technical comments and corrections could more appropriately be incorporated into Draft Guide-1237.

NEI believes that certain sections of the Draft RIS, identified by comments 1, 2, 5, 7, 8, and 25 (see below) inappropriately implement concepts contained in the emergency preparedness proposed rule, "Enhancements to Emergency Preparedness Regulations," 74 Fed. Reg. 23,254 (May 18, 2009) (Docket ID NRC-2008-0122), Amended Emergency Plan Change Process.

#	Document Section of Draft Revised RIS	Comment or Markup	Basis
1	Page 4, 2 nd paragraph	Delete that portion of the second paragraph that states: "and although not required, the inclusion of the applicable licensee evaluation and justification for the change as part of [the licensee's report under 10 CFR 50.4] this report would be beneficial to the staff."	The stated intent of the Draft RIS (p. 2, last paragraph) is to "clarify the process for making changes to an emergency plan and to provide licensees with a consistent method for evaluating proposed emergency plan changes." The current rule does require a "justification" of the change to be submitted as part of the licensee's report. The stated purpose of the RIS is to clarify existing regulations, not impose a new position or new requirements. If that is true, the NRC staff should not use a RIS to attempt to impose new requirements, or urge licensees to undertake additional activities to comply with an existing requirement.
2	Page 4, Definitions 1)a)	This proposed new definition refers to an "emergency planning function." This definition should be reworded to exclude the reference to function. See October 19, 2009, NEI comments on EP proposed rule, pp. B.5-1.	The term "emergency planning function" is not defined in the existing regulation, which refers to 50.47 and Appendix E to Part 50. The NRC should not use guidance documents to introduce new regulatory definitions.
3	Page 5, Definitions section (2)	NEI does not agree that examples of "Reductions in Effectiveness" (RIEs) should be included in the Draft RIS, and thus recommends deleting section (2) of the Definitions.	As stated in Definitions section (2): "[I]t is also possible that site-specific situations may make a particular example inapplicable to a site." This recognition by the NRC seems inconsistent with the inclusion of the examples! For this reason, NEI believes adding these examples to the Draft RIS could cause confusion and this new language should be deleted.
4	Page 6, Definitions	NEI recommends the following changes:	In the cases where an EAL change was reviewed and

#	Document Section of Draft Revised RIS	Comment or Markup	Basis
	<p>section (3)(a) or (3)(b)</p>	<p>(3)(a) The proposed change to the EAL would potentially cause an underclassification, (e.g., what was considered an Alert in the approved emergency plan would now be considered an Unusual Event or not classified at all), <u>unless the change was previously reviewed and approved generically by the NRC (example: EAL FAQ process).</u></p> <p>(3)(b) The proposed change to the EAL would potentially cause an overclassification, (e.g., what was considered a Site Area Emergency in the approved emergency plan would now be considered a General Emergency with potential consequences for public health and safety), <u>unless the change was previously review and approved generically by the NRC.</u></p>	<p>approved generically by the NRC, this review and approval should be referenced as the basis change and the justification for a "no RIE" finding. Therefore the RIE has been generically approved.</p>
<p>5</p>	<p>Page 7, Definitions section 2 (emergency plan)</p>	<p>NEI recommends the following change: The document(s) prepared and maintained by the licensee that identify and describe the licensee's methods for maintaining and performing emergency planning functions. <u>the requirements of 50.47 and Appendix E to Part 50.</u> An emergency plan includes the plans as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under 10 CFR 50.54(q).</p>	<p>The term "emergency planning function" is not currently defined in the regulations. There can only be one Emergency Plan in effect at any given time. This proposed definition in the Draft RIS would have multiple historical plans simultaneously in effect (which is incorrect). As stated by the NRC Staff at the September 17 public meeting, the current Plan is the basis for the 50.54q evaluation. The presence of this sentence and the application of its concept would create unnecessary confusion regarding the scope and acceptance criteria for the 50.54q evaluation.</p>

#	Document Section of Draft Revised RIS	Comment or Markup	Basis
			Additionally, reconciling differences in the historical Plans and the basis for previous changes against the current proposed change creates a condition with ambiguous acceptance criteria.
6	Page 8, paragraph 4	NEI recommends deleting the second sentence "[I]t may be prudent..."	The stated purpose of the RIS is to clarify existing regulations, not impose a new position.
7	Page 8, 'Related Topics,' section 1.	NEI recommends the following change: Similar to security plan changes submitted via 10 CFR 50.54(p)(1), emergency plan changes that result in the reduction in the effectiveness of the approved emergency plan require prior NRC approval as currently required under § 50.54(q). and should to be submitted as license amendment requests under § 50.90.	The reference to NRC security plan change requirements should be deleted in this context because it incorrectly suggests that the regulatory basis for Section 50.54(p) is the same as that for 50.54(q). In addition, and as discussed elsewhere in NEI's comments, NEI does not agree that NRC is compelled to require license amendments requests under Section 50.90 for emergency plan changes. For this reason, the text in question should be deleted.
8	Page 9, section 3.	NEI recommends deletion of the last sentence, which states: "[A]lthough not required, the inclusion of the applicable licensee evaluation and justification for the change as part of this report would assist the staff in the review."	The stated purpose of the RIS is to clarify existing regulations, not impose a new position. See similar comment # 1, above.
9	Enclosure 1, p. 1, section 1.2.3	NEI recommends the following change: Historically, some licensees have developed emergency plan implementing procedures	Only sections of implementing procedures that contain requirements that would normally be included in the emergency plan are subject to 50.54(q).

#	Document Section of Draft Revised RIS	Comment or Markup	Basis
		<p>that included the necessary information needed for activities that are required to meet the regulations, for example, procedures for notifications, dose assessment, protective action recommendations, emergency classifications and emergency action levels. The staff is not making the use of § 50.54(q) to review all changes to lower tier documents a requirement, but acknowledges that using § 50.54(q) as the regulation to provide revision control of these lower tier documents has been in place and supported by the NRC through the inspection and licensing process. These requirements relocated from the emergency plan to other documents are subject to 50.54(q).</p>	<p>The stated purpose of the RIS is to clarify existing regulations, not impose a new position.</p>
10	Enclosure 1, p. 2, section 2.1 bullet 3.	<p>NEI recommends the following change:</p> <p>For the purposes of 10 CFR 50.54(q), activities may also originate outside of the licensee's <u>control</u> responsibility such as permanent road closings or substantive population increases. Changes in the emergency plan that address these activities should be treated as a change in basis for the emergency plan.</p>	<p>In this case there has been a change that is outside the licensee's purview. Therefore, if this change impacts the emergency plan and a plan change is warranted, it should be considered a change in basis for the emergency plan and the change to the emergency plan should be implemented without NRC approval.</p>
11	Enclosure 1, p. 2, section 2.3	Delete last sentence that starts: "An emergency plan includes"	There can only be one Emergency Plan in effect at any given time. This proposed new definition would have multiple historical plans simultaneously in effect. As

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			<p>stated by the Staff at the September 17 public meeting, the current Plan is the basis for the 50.54q evaluation. The insertion of this sentence and the application of its underlying logic would create unnecessary confusion regarding the scope and acceptance criteria for the 50.54q evaluation. Additionally, reconciling differences in the historical Plans and the basis for previous changes against the current proposed change creates a condition with ambiguous acceptance criteria.</p>
12	Enclosure 1, p. 2, section 2.3.1	NEI recommends modification of this section based on the discussion for comment 11 above.	
13	Enclosure 1, p. 3, section 2.5	Decrease (Reduction) in Effectiveness (RIE): A change in an emergency plan that results in reducing the licensee's capability to <u>implement 50.47 and Appendix E to Part 50 perform an emergency planning function in the event of a radiological emergency without a commensurate change in the basis.</u>	A reduction in capability may be acceptable if there was a change in basis for that capability (i.e., new technology, more reliable equipment). See Attachment 2, page 2, 1 st note box.
14	Enclosure 1, p. 3, section 2.5.1.3	Revise to reflect the NEI recommendation for item 4.	
15	Enclosure 1, p. 4, section 4.0	Section 4.0 discusses qualifications, but provides no meaningful information. NEI recommends deleting this section.	The "Summary of Issue" states that "[T]he information in this RIS revision clarifies the process for changing emergency plans to ensure that licensees maintain effective emergency plans..." A discussion of qualifications is not consistent with the intent of the

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			RIS.
16	Enclosure 1, p. 4, section 5.1	NEI recommends the following change: A 10 CFR 50.54(q) review <u>on the impact to the emergency plan</u> should also be performed for proposed revisions to other plant procedures or other non-EP documents that implement aspects of the site's EP program to ensure that changes are not made to non-EP procedures that adversely impact the EP program <u>Emergency Plan</u> .	A 50.54q evaluation is performed on an Emergency Plan change and is not used as a program assessment tool. Procedure changes are screened to determine if the Emergency Plan would require revision to support the procedure change.
17	Enclosure 1, p. 4, section 5.1.1	NEI recommends the following change: The following screening criteria should <u>could be used as an example</u> be used to screen for 10 CFR 50.54(q) applicability.	There are many acceptable methods currently used by licensees to screen for 50.54q evaluation applicability. The way this is currently stated will lead licensees to believe this method is required, which would be inaccurate.
18	Enclosure 1, p. 5	NEI recommends the following change: If any are checked YES, a 10 CFR 50.54(q) review of the proposed change(s) is needed <u>review the emergency plan to determine if the plan has to be revised for this change.</u>	Before a 50.54q evaluation is performed as a result of the screen, the emergency plan is reviewed. If the plan requires a modification, the proposed modification of the plan is written. A 50.54q evaluation is then performed on this proposed modification. If the change to the plan is not an RIE, the plan is modified and the proposed procedure change is made. If the proposed change to the plan is an RIE, then the proposed change cannot be made until the NRC reviews the change and determines the change still meets the requirements of 50.47 and Appendix E to Part 50.

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19	Enclosure 1, p. 5	<p>NEI recommends the following note be placed below the check list:</p> <p><u>Note: The above list provides examples of items that should be consider for a 50.54q screen check list. Each licensee should review their emergency plan for additional check list items. The check list should be designed so that someone that is not well versed in the contents of the emergency will know that the emergency plan should be reviewed to determine impact.</u></p>	<p>The purpose of the screen is to alert personnel that are making procedure changes that may impact the Emergency Plan to consult the Emergency Preparedness staff to help them determine if the change that they are about to make will require a change to the Emergency Plan.</p>
20	Enclosure 1, p. 5, section 6.1.	<p>A 10 CFR 50.54(q) review shall be performed for all proposed revisions to emergency plans and EALs that reduce the effectiveness of the emergency plans (except for EAL scheme changes). Although not required, a § 50.54(q) review should be conducted for applicable lower tier documents in accordance with Attachment 2, "10 CFR 50.54(q) Review".</p>	<p>A 50.54q review is performed to determine if the proposed change to the Emergency Plan is an RIE.</p> <p>A 50.54q review is only performed on Emergency Plan and EAL changes.</p> <p>An Emergency Plan screen is performed on lower tier documents to determine if the Emergency Plan is impacted by the lower tier document change.</p>
20	Attachment 1, first box on left.	<p>NEI recommends the following change: <u>Proposed plan procedure change or activity that could impact the Emergency Plan or EAL change(s).</u></p>	<p>Should enter this flow chart on the left side at the point where you are considering revising a procedure that may impact the Emergency Plan. That leads you to perform a 50.54q screen.</p>
21	Attachment 1, first diamond box on	<p>NEI recommends the following change:</p>	<p>If a change to the Emergency Plan is required, the modification to the Emergency Plan is made. A 50.54q</p>

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	left.	Require 10 CFR 50.54(q) review? Does the Emergency Plan require a change?	evaluation is then performed on this Emergency Plan modification as described in the next box.
22	Attachment 2, section 1.1	NEI recommends the following addition: Briefly document a description of the change to the Emergency Plan.	Added "Emergency Plan" for clarity.
23	Attachment 2, p. 3, 2.2.1.1	NEI recommends deleting 2.2.1.1	The stated purpose of the RIS is to clarify existing regulations, not impose a new position.
24	Attachment 2, p. 4, first paragraph box	NEI recommends the following change: Is the proposed change purely editorial in nature (see definition)? <i>[If YES, discontinue review process and process the procedure Emergency Plan change.]</i>	50.54q is applicable to proposed Emergency Plan changes, not lower tier implementing procedures.
25	Attachment 2, p. 3, sections 2.3.2 and 2.3.2	NEI recommends deletion of reference to 10 CFR 50.90 from both paragraphs and replacing with 50.4	As discussed elsewhere in NEI's comments, NEI does not agree that NRC is compelled to require license amendments requests under Section 50.90 for emergency plan changes.