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July 19, 2016

Mr. Victor M. McCree
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Nuclear Energy Institute Comments on Tasking Memorandum Dated June 9, 2016

Project Number: 689

Dear Mr. McCree:

I am writing regarding your June 9 memorandum, "Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance."¹ As you know, the Nuclear Energy Institute (NEI)² has consistently expressed concern regarding implementation of the agency's backfitting rules.³ Given industry's concerns, we welcome the direction provided in the Tasking Memorandum, as well as the associated efforts to reintroduce the Committee to

¹ "Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance," June 9, 2016 ("Tasking Memorandum.")

² NEI is responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory, financial, technical and legislative issues. NEI members include all companies licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

³ See, e.g., Letter from A.R. Pietrangelo, NEI, to V.M. McCree, NRC (June 16, 2016), "Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Backfit Appeal;" Letter from A.R. Pietrangelo, NEI, to W.M. Dean, NRC (Jan. 20, 2016), "Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal;" Letter from E.C. Ginsberg, NEI, to the Hon. S.G. Burns, NRC, "Industry Backfit Concerns Regarding Generic Letter (GL) 2015-01, Treatment of Natural Phenomena Hazards (NPH) in Fuel Cycle Facilities," (April 24, 2015); Letter from E.C. Ginsberg, NEI, to M. Doane, NRC (Nov. 7, 2014)(describing backfitting concerns related to a requirement for certain Part 70 licensees to develop quantitative exposure standards for dermal and ocular chemical exposures).

Review Generic Requirements (CRGR) into the review of proposed rules.⁴ The reviews directed by the Tasking Memorandum are an important step forward in ensuring that the NRC maintains two key features of its regulatory framework: (1) that agency and licensee resources are devoted to regulatory activities that will yield demonstrable safety and security benefits; and (2) that the agency's regulatory programs evolve in a predictable, transparent, cost-effective manner.

To these ends, we offer the following perspectives:

Forum for Stakeholder Views

Although we support the efforts directed in the Tasking Memorandum, it's important that the agency provide a forum for consideration of stakeholder views when considering the need for potential improvements to the agency's backfitting program.

There would have been value in providing industry (and other stakeholders) the opportunity to share views on the Open Phase Condition (OPC) Documented Evaluation prior to endorsement by the Committee to Review Generic Requirements (CRGR). Unfortunately, no such opportunity was provided in this case.⁵ While the process used by the staff may comport with the agency's current procedures for CRGR review, it lacks transparency and does not promote informed decision-making.

Compliance Exception-Historical Definition

Recent exchanges regarding use of the compliance exception to the backfitting rule demonstrate how such an interaction could be useful. For example, our written communications on this issue have consistently stressed that the lynchpin to appropriate application of the compliance exception is distinguishing between: (1) situations in which a "licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact," and (2) situations in which the staff seeks to impose a "new or

⁴ See "CRGR Response to Staff Requirements – SECY-15-0129 Commission Involvement in Early Stages of Rulemaking," SECY-16-0064 (May 23, 2016).

⁵ The Documented Evaluation is dated March 30, 2016, with CRGR review occurring during an internal meeting held on May 17, 2016. A CRGR meeting summary dated June 2, 2016 indicates that the CRGR endorsed the OPC Documented Evaluation based on the discussion during the May 17 internal meeting. SECY-16-0068, which provided the OPC Documented Evaluation to the Commission, is dated May 31, 2016. The OPC Documented Evaluation was not added to the public ADAMS database until June 7, 2016—after the evaluation was reviewed and endorsed by the CRGR, and provided to the Commission for approval.

modified interpretation[] of what constitutes compliance.”⁶ The Commission has made it clear that use of the exception is appropriate in the case of the former, but that a backfitting analysis pursuant to 10 CFR 50.109(a)(3) and (c) is required in the case of the latter.⁷

Compliance Exception-Recent Misapplication

Thus far, the staff responses to our written communications have failed to adequately address this vital distinction. For example, despite the fact that the staff applied the analytical framework suggested in our January 20 letter⁸ to develop the documented evaluation addressing OPC in electric power systems,⁹ the OPC Documented Evaluation illustrates that the core issues regarding use of the compliance exception remain unresolved.¹⁰ After identifying the “known and established standard” as General Design Criteria (GDC) 17 (or analogous principle design criteria for pre-GDC plants), the OPC Documented Evaluation states:

An omitted fact **(i.e. “new” information)** may be information which: **(i) did not exist**, (ii) was not recognized as relevant and significant by all relevant stakeholders; or **(iii) could not have reasonably been known to all of the relevant stakeholders at the time of NRC staff approval**. In this case, the Omitted Fact was an unknown design inadequacy (*i.e.*, the offsite power protective relay scheme would not detect and isolate certain OPCs) which, had it been known at the time of original plant licensing, would have led to the NRC to conclude that the plant design was inadequate (*i.e.*, did not meet (as applicable)

⁶ See Letter from E.C. Ginsberg, NEI, to M. Doane, NRC (Nov. 7, 2014)(describing backfitting concerns related to a requirement for certain Part 70 licensees to develop quantitative exposure standards for dermal and ocular chemical exposures); Letter from E.C. Ginsberg, NEI, to the Hon. S.G. Burns, NRC, “Industry Backfit Concerns Regarding Generic Letter (GL) 2015-01, Treatment of Natural Phenomena Hazards (NPH) in Fuel Cycle Facilities,” (April 24, 2015); Letter from A.R. Pietrangelo, NEI, to W.R. Dean, NRC, “Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal” (Jan. 20, 2016); Letter from A.R. Pietrangelo, NEI, to V.M. McCree “Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Backfit Appeal” (June 16, 2016).

⁷ “Revisions of Backfitting Process for Power Reactors,” 50 Fed. Reg. 38,097, 38,103 (Sept. 20, 1985).

⁸ Letter from A.R. Pietrangelo, NEI, to W.R. Dean, NRC, “Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal” (Jan. 20, 2016).

⁹ “Evaluation for Compliance Backfit Exception: Open Phase Condition Design Vulnerability in Electric Power System,” March 30, 2016 (“OPC Documented Evaluation”).

¹⁰ The OPC Documented Evaluation was provided to the Commission as an enclosure to “Interim Enforcement Policy for Open Phase Conditions in Electric Power Systems for Operating Reactors,” SECY-16-0068 (May 31, 2016).

GDC 17, the proposed GDC in the 1967 rule, the three AIF criteria, and the principle design criteria as set forth in pre-GDC plants[]]. This omitted fact was discovered as a result of an operational event, and did not exist or could not have reasonably been known to all of the relevant stakeholders at the time of NRC staff approval.¹¹

Misapplication of GDC as Known and Established Standard

This passage is problematic for several reasons. First, it relies solely on GDC 17 (and analogous criteria for pre-GDC plants) as the “known and established standard” supporting the backfit. The GDC were added to Title 10 of the Code of Federal Regulations in order to “establish the minimum requirements for the principal design criteria for water-cooled nuclear power plants”¹² and “are cast in broad, general terms.”¹³ Further, while the GDC may be viewed as legally binding, “issues associated with licensing, inspection or enforcement are usually tied to more explicit NRC requirements (technical specifications or specific regulations).”¹⁴ In this vein, the staff has concluded that “[t]he GDC are requirements only to the extent that the applicant is required to describe conformance with them in the PSAR. The staff’s plant specific design review verifies that the overall plant design satisfies the GDC requirements and that the plant can be safely operated.”¹⁵

The imprecise nature of the GDC limits their utility as “known and established standards” in determining whether application of the compliance exception is appropriate. For example, in promulgating the 1988 station blackout (SBO) rule, the Commission explained:

The Commission's existing regulations establish requirements for the design and testing of onsite and offsite electric power systems that are intended to reduce the probability of losing all ac power to an acceptable level. (See General Design Criteria 17 and 18, 10 CFR Part 50, Appendix A.) The existing regulations do not

¹¹ OPC Documented Evaluation, at p. 7 (emphasis added).

¹² 36 Fed. Reg. 3255 (Feb. 20, 1971).

¹³ *Petition for Emergency Remedial Action*, CLI-78-6, 7 NRC 400, 406 (1978); see also, *Northeast Nuclear Energy Company* (Millstone Nuclear Power Station, Unit No. 3), CLI-01-10, 53 NRC 353 (2001).

¹⁴ *Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc.* (Vermont Yankee Nuclear Power Station), 62 NRC 389, 398 (2005)(quoting LIC-100, “Guideline for Managing Licensing Bases for Operating Reactors”).

¹⁵ “Final Safety Evaluation by the Office of Nuclear Reactor Regulation Regarding Loss of Spent Fuel Pool Cooling Events,” Susquehanna Steam Electric Station, Units 1 and 2, Pennsylvania Power and Light Company, Docket Nos. 50-387 and 50.388 (June 19, 1995), at p. A-8.

require explicitly that nuclear power plants be designed to assure that core cooling can be maintained for any specified period of loss of all ac power.

As operating experience has accumulated, the concern has arisen that the reliability of both the onsite and offsite emergency ac power systems might be less than originally anticipated, even for designs that meet the requirements of General Design Criteria 17 and 18. Many operating plants have experienced a total loss of offsite power, and more occurrences can be expected in the future. Also, operating experience with onsite emergency power systems has included many instances when diesel generators failed to start. In a few cases, there has been a complete loss of both the offsite and the onsite ac power systems. During these events, ac power was restored in a short time without any serious consequences.¹⁶

Proper Consideration of GDC in Known and Established Standard Analysis

The original SBO rule (like the current OPC issue) involved a potential design deficiency that was brought to light through operating experience. But in considering whether GDC 17 could serve as the basis for applying the compliance exception, the Commission concluded that the new station blackout measures:

[C]annot be imposed on licensees as a matter of compliance with GDC 17, under the compliance exception in the backfit rule, § 50.109(a)(4)(i). GDC 17 does not explicitly require that each plant be able to withstand station blackout for a specified time, or that each licensee perform a coping assessment and make whatever modifications may be necessary in the light of that assessment. Nor are any of these highly specific requirements logically compelled by any part of GDC 17. Moreover, GDC 17 has never been interpreted by the staff or the Commission to contain these specific requirements. Thus, to impose them under GDC 17 would amount to a backfit which resulted from a new staff and Commission interpretation of GDC 17.¹⁷

So, in the example of the SBO rule, the Commission declined to use GDC 17 as the basis to impose a compliance backfit because it was seeking to impose new design requirements aimed at addressing a vulnerability that—up to that point—had not specifically been required or otherwise addressed under GDC 17. The Commission concluded that imposition of such a requirement would amount to a new interpretation of GDC 17. Thus, the station blackout requirements were evaluated prior to imposition, pursuant to 10 CFR § 50.109(a)(3) and (c).

¹⁶ "Station Blackout: Final Rule," 53 Fed. Reg. 23,203 (June 21, 1988).

¹⁷ *Id.* at 23,207.

It is unclear why the staff today feels compelled to deviate from this clear and concise analysis and precedent regarding “known and established standards” in the case of the OPC Documented Evaluation.

Misapplication of Omission or Mistake Standard

The interpretation of “omission” that is provided in the OPC Documented Evaluation has been created out of thin air, with total disregard for precedential Commission direction on use of the compliance exception. As we have stressed in our prior letters, the Commission provided important policy guidance on use of the exception in the 1985 final backfitting rule, stating:

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.¹⁸

The definition of “omitted fact” put forward in the OPC Documented Evaluation includes both information that did not exist and information that could not have reasonably been known at the time an NRC approval is issued. Interpreting “omission” this way, coupled with the use of non-specific design criteria as “known and established standard,” makes it impossible to meaningfully distinguish between reinterpretations and legitimate compliance backfits. Even more to the point, reinterpretations of what specific actions are required to comply with broad requirements (such as GDC 17) will generally be based on either the consideration of “new information” (*i.e.*, information that could not have been known at the time a prior NRC approval was issued), or a different view of the information that was available and considered at the time of the initial approval. Thus, defining an “omission” to include such information hopelessly conflates “new or different interpretations of what constitutes compliance” with legitimate compliance backfits. It also promotes the type of “if we knew then what we know now” analysis put forward in the OPC Documented Evaluation, which continues to cloud implementation of the backfitting requirements and to undermine the important policy goals that gave rise to the agency’s backfitting rules. This type of opaque decision-making is exactly what the backfitting rules were intended to prevent.

¹⁸ “Final Rule, Revision of Backfitting Process for Power Reactors,” 50 Fed. Reg. 38,097, 38,103 (Sept. 20, 1985).

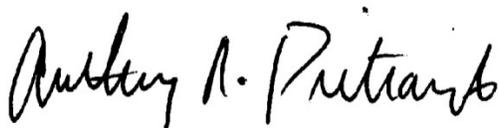
Proper Application of Compliance Exception

In contrast, consistent with the Commission's statement on use of the compliance exception, legitimate compliance backfits occur in situations where the staff must correct licensee noncompliance with a "known and established standard" that is caused by an "omission or mistake of fact."¹⁹ In order to distinguish this situation from reinterpretations of existing requirements, the "known and established standard" must be: (1) specific (so that compliance can be evaluated in an objective fashion); (2) in existence at time of prior NRC approval; (3) applicable to the licensee at time of prior NRC approval; and (4) a legally binding requirement, or licensee commitment necessary to comply with a legally binding requirement. Further, properly defined, an "omission" would include the failure to consider information *that was in existence at the time of a prior NRC approval*, and which the staff or licensee knew or should have known.²⁰ Interpreting the terms in this way allows application of the exception to avoid requiring a full backfitting analysis to correct readily identifiable errors or omissions that result in noncompliance with clear and objective standards, while preserving the utility of the backfitting rules as applied to reinterpretations.

We appreciate your consideration of our views on this issue and would welcome the opportunity to discuss potential improvements to the agency's backfitting program as the staff prepares its response to the Tasking Memorandum, and as backfitting issues are addressed in the future.

Please feel free to contact me if you have any questions.

Sincerely,



Anthony R. Pietrangelo

cc: Ms. Margaret M. Doane, General Counsel
Ms. Annette Vietti-Cook, Secretary of the Commission
Mr. Edwin M. Hackett, Chair, Committee to Review Generic Requirements

¹⁹ *Id.*

²⁰ Likewise, a "mistake of fact" would properly be defined as a factual error based on information *in existence at the time of the prior NRC approval*, which the staff or licensee knew or should have known.