

ANTHONY R. PIETRANGELO

*Senior Vice President and
Chief Nuclear Officer*

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8081
arp@nei.org
www.nei.org



October 31, 2016

Dr. Edwin M. Hackett
Chair, Committee to Review Generic Requirements
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Nuclear Energy Institute Comments on September 13, 2016 Public Meeting with Committee to Review Generic Requirements (CRGR)

Project Number: 689

Dear Dr. Hackett:

I am writing to thank the CRGR for the opportunity to present industry's views on the agency's backfitting program during the public meeting held on September 13, 2016. We are encouraged by the CRGR's willingness to consider stakeholder input before developing its response to the tasking memorandum issued by the Executive Director for Operations ("EDO") on June 9, 2016.¹ We would welcome additional opportunities to interact with the CRGR in the future, and would support any additional public meetings that are necessary for the Committee to adequately respond to the tasking memorandum.

As you know, shortly after the September public meeting the EDO issued a decision granting a facility-specific appeal challenging use of the compliance exception to support imposition of a backfit at the Byron and Braidwood nuclear power facilities ("Exelon Appeal").² Although industry representatives provided perspectives on the Exelon Appeal at the September meeting, the implications of the EDO's decision (which had yet to be issued) were not discussed. This letter is intended to reinforce several comments provided during the September public meeting, and to supplement those comments in light of the EDO's resolution of the Exelon Appeal.

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

² Letter from V.M. McCree (NRC) to J.B. Fewell, "Response to Appeal of Backfit Imposed on Braidwood and Byron Stations Regarding Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and the Licensing Basis" (Sept. 15, 2016); *see also*, Letter from V.M. McCree (NRC) to A.R. Pietrangelo (NEI), "Response to Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Appeal" (Sept. 15, 2016); "Backfit Appeal Review Panel Findings Associated with Byron and Braidwood Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and the Licensing Basis" (Aug. 24, 2016) ("Panel Findings").

NEI supported the Exelon Appeal in letters submitted to the Director of the Office of Nuclear Reactor Regulation³ and to the EDO.⁴ In addition to supporting the result sought by Exelon, NEI's letters raised concerns regarding the adequacy of the analyses put forward in support of both the staff's initial backfitting decision,⁵ and the decision denying Exelon's first-level appeal.⁶ The EDO's decision and the supporting analysis address many of the concerns raised in our letters.

Although we are encouraged by the EDO's decision and the quality of the analysis provided by the Backfitting Review Panel ("Panel"), we note that the supporting materials made available with the decision revealed that the Office of Nuclear Reactor Regulation did not agree with the Panel's recommendation to the EDO.⁷ It is my understanding that the EDO's decision adopting the Panel's recommendation effectively resolves any disagreement among the staff; however it is vitally important that the analytical framework employed by the Panel to evaluate use of the compliance exception be institutionalized in a durable fashion, and used by the NRC staff to guide application of the compliance exception in the future.

With the resolution of the Exelon Appeal in mind, I would like to stress the following points for your consideration as the CRGR develops its response to the EDO's June 9 Tasking Memorandum.

- 1) Clear and consistent direction from the NRC senior management to the staff on application of the compliance exception and identification of backfits is needed to improve the quality, consistency, and clarity of the agency's backfitting decisions.

NEI strongly believes that the evaluation provided by the Panel should serve as an example of the analytical rigor required in documented evaluations examining use of the compliance exception.⁸ While the results of analyses evaluating use of the compliance exception will vary in specific cases, there are several important concepts captured in the Panel's analysis that should apply whenever a documented evaluation examining application of the compliance exception is prepared.

³ Letter from A.R. Pietrangelo (NEI) to W.M. Dean (NRC), "Nuclear Energy Institute Comments in Support of Exelon Generating Company Backfit Appeal" (Jan. 20, 2016)("NEI Letter First-Level Appeal").

⁴ Letter from A.R. Pietrangelo (NEI) to V.M. McCree (NRC), "Nuclear Energy Institute Comments in Support of Exelon Generating Company Second-Level Backfit Appeal" (June 16, 2016)("NEI Letter Second-Level Appeal").

⁵ "Braidwood Station, Units 1 and 2, and Byron Station, Unit Nos. 1 and 2 – Backfit Imposition Regarding Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and Licensing Basis" (Oct. 9, 2015)("Documented Evaluation").

⁶ "U.S. Nuclear Regulatory Commission Response to Backfit Appeal – Braidwood Station, Units 1 and 2, and Byron Station, Units 1 and 2" (May 3, 2016) ("First-Level Appeal Decision").

⁷ Memorandum from V.M. McCree (EDO) to W.M. Dean (Director, NRR), "Result of Appeal to the Executive Director for Operations of Backfit Imposed on Byron and Braidwood Stations Regarding Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and the Licensing Basis" (Sept. 15, 2016). The Enclosure to this memorandum includes a response by the EDO to NRR's perspectives on the findings of the EDO's Backfitting Appeal Panel. Based on the Enclosure, NRR's perspectives—which appear to disagree with the Panel's conclusions—were provided to the EDO on September 2, 2016.

⁸ Although the analyses would consider different factors, we also believe that the rigor of the Panel's evaluation should serve as a model for documented evaluations examining use of the adequate protection exceptions to the agency's backfitting rules. See, e.g., 10 CFR § 50.109(a) (4) (ii), (iii).

For example, after outlining its rigorous review of the relevant requirements and regulatory history, the Panel stated:

Given that the Backfit Rule creates a structured process for changes to previous NRC staff positions—in effect, placing the burden of proof on the NRC staff—the Panel determined that this level of historical review and staff interaction was necessary to establish the appropriate context for consideration of the validity of the backfit directed by the NRC staff.⁹

This statement communicates a foundational concept that should be stressed in the agency's backfitting guidance. That is, once a backfit is identified the burden of proof is on the NRC staff to demonstrate that the analytical standard provided in 10 CFR 50.109 is met, or that one of the exceptions to the rule applies. And that burden must be met by the staff prior to imposing the backfit on the licensee. To the contrary, in the case of the Exelon Appeal the licensee was required to exhaust the facility-specific appeal process in order to obtain an analysis of the scope, depth, and rigor necessary to adequately evaluate and resolve the issue.

In addition to appropriately framing the need for a more rigorous examination of relevant requirements, the Panel's analysis also clearly identified the applicable rule language and important Commission direction on interpreting the compliance exception.¹⁰ On page 6 of its evaluation, the Panel expanded upon the rule language and relevant Commission direction, explaining:

The failure to meet a known and established standard is grounds for a compliance backfit if this failure is due to "omission or mistake of fact." Thus, if a licensee obtains NRC approval of an alternative to a specific standard set forth in guidance, the standard and guidance could not be used to support a compliance backfit unless the NRC's approval of the alternative was based on omission or mistake of fact. "Known and established standards" are to be distinguished from "new or modified interpretations of what constitutes compliance," which do not fall within the compliance exception. The Panel understands this term "new or modified interpretations" to include situations where the NRC staff has, in effect, "changed its mind" on how to interpret the language of a requirement or on how much assurance is necessary to conclude that the requirement is met. Levels of assurance might be established in terms such as acceptable probabilities or consequences, conservative assumptions, or sufficient margin.¹¹

As we have stressed many times in the recent past,¹² these concepts are vitally important to ensuring appropriate use of the compliance exception. We respectfully request that the concepts communicated

⁹ Panel Findings, at Enclosure p. 3.

¹⁰ Panel Findings, at Enclosure pp. 5-6, 22-23.

¹¹ Panel Findings, at Enclosure p. 6.

¹² See, e.g., Letter from A.R. Pietrangelo (NEI) to V.M. McCree (NRC), "Nuclear Energy Institute Comments on Tasking Memorandum Dated June 9, 2016" (July 19, 2016); Letter from A.R. Pietrangelo, NEI, to V.M. McCree, NRC, "Nuclear Energy Institute Comments in Support of



above be incorporated into the NRC's backfitting guidance and consistently applied in the future. Also, we request that the NRC consider the positions put forth in NEI's letters dated January 20, 2016,¹³ June 16, 2016,¹⁴ and July 19, 2016,¹⁵ regarding guiding principles for identifying "known and established standards" and "omissions or mistakes of fact," as well as use of broadly worded requirements (such as General Design Criteria) to support imposition of compliance backfits. We believe the concepts described in these letters are generally consistent with the EDO's decision on the Exelon Appeal and should be clearly captured in the agency's backfitting guidance.

Further, although application of the definition of backfitting was not a central issue in the Exelon Appeal (*i.e.*, the fact that a backfit was being imposed was not at issue), backfitting identification continues to be critical to a healthy backfitting program. The materials provided in Appendix A of the Panel's evaluation reinforce important concepts regarding what constitutes an "applicable regulatory staff position," and how such positions are established. Identifying "applicable regulatory staff positions," and deviations from them, is fundamental to consistent identification of backfits, which, in turn, is the vital first step in implementation of the agency's backfitting rules. The important concepts covered in Appendix A (and others described in NUREG-1409) relevant to backfitting identification should be reinforced and brought to the fore when the staff is considering whether imposition of a regulatory position will meet the definition of backfitting. The work described in SECY-14-0002,¹⁶ which is discussed below under point 2, provides an opportunity to institutionalize the analytical framework used by the Panel to evaluate use of the compliance exception, as well as reinforce concepts important to identifying potential backfits.

Finally, consistent with the discussion of transparency under point 4 below, we respectfully request that any staff recommendations on appropriate application of the exceptions to the backfitting rule—or implementation of the agency's backfitting rules more generally—be made publicly available before being acted upon by the EDO or the Commission.

2) *CRGR oversight of the on-going efforts to revise the NRC's cost-benefit guidance is essential to ensure holistic consideration of how changes to those documents will affect the agency's backfitting program.*

Exelon Generation Company Second-Level Backfit Appeal" (June 16, 2016); Letter from A.R. Pietrangelo, NEI, to W.M. Dean, NRC, "Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal" (Jan. 20, 2016); 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).

¹³ Letter from A.R. Pietrangelo, NEI, to W.M. Dean, NRC, "Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal" (Jan. 20, 2016).

¹⁴ Letter from A.R. Pietrangelo, NEI, to V.M. McCree, NRC, "Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Backfit Appeal" (June 16, 2016).

¹⁵ Letter from A.R. Pietrangelo (NEI) to V.M. McCree (NRC), "Nuclear Energy Institute Comments on Tasking Memorandum Dated June 9, 2016" (July 19, 2016).

¹⁶ "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost-Benefit Guidance," SECY-14-0002 (Jan. 2, 2014).

The NRC staff is in the process of revising the agency's guidance on the performance of cost-benefit analysis.¹⁷ These guidance documents cover a wide-range of topics, including: issues with a technical focus (*e.g.*, assessing changes to core damage frequency and conditional containment failure probabilities, methods to address uncertainty); issues with a regulatory or policy focus (*e.g.*, identification of backfits, appropriate use of the exceptions to the backfitting rules); and issues that raise both technical and policy considerations (when and how qualitative factors should be used to support agency decision-making). The multi-phased effort described in SECY-14-0002 will undoubtedly require participation by a variety of NRC offices—each bringing its specific technical or regulatory expertise to bear. At the same time, this activity presents an important opportunity to both reinforce existing agency backfitting policy, and institutionalize policy changes to improve the agency's backfitting program. Thus, it is very important that the agency's backfitting "center of expertise" review the modifications to these guidance documents in a holistic fashion, with an emphasis on how the changes will affect the agency's backfitting program.¹⁸

Given that one of the CRGR's primary responsibilities is "to provide guidance and assistance to the NRC program offices to help them implement the Commission's backfit policy,"¹⁹ the Committee is well positioned to provide this type of oversight. Thus, we respectfully request that the CRGR provide independent oversight of the work described in SECY-14-0002 in order to ensure that policy issues affecting implementation of the agency's backfitting rules—in addition to the more technical issues related to the performance of cost-benefit analyses—are appropriately addressed. This request is consistent with NEI's view that focused, independent, high-level management oversight is essential to maintaining a healthy backfitting program.²⁰

3) The facility-specific process should be improved to ensure that the generic implications of potential facility-specific backfits are consistently evaluated.

¹⁷ See "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost-Benefit Guidance," SECY-14-0002 (Jan. 2, 2014). It is our understanding that this will include changes and additions to the following guidance documents:

- *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission* (NUREG/BR-0058, Rev. 4)(Sept. 2004);
- *Regulatory Analysis Technical Evaluation Handbook* (NUREG/BR-0184)(Jan. 1997);
- *Backfitting Guidelines* (NUREG-1409) (July 1990).

¹⁸ NEI participated in a public meeting with the NRC staff on work described in SECY-14-0002 earlier this year, and we anticipate that a portion of the revised guidance will be published for public comment sometime in early 2017. See Letter from Hon. S.G. Burns (Chairman, NRC) to Hon. G.L. Dodaro (Comptroller General, GAO), Sept. 19, 2016. We encourage the NRC staff to continue its current practice of making drafts of the revisions and additions to these important guidance documents publicly available, with ample time for public comment.

¹⁹ "Charter: Committee to Review Generic Requirements," Rev. 8 (March 2011), at p. 1.

²⁰ Letter from E. Ginsberg (NEI) to J.E. Lyons (NRC), Dec. 16, 2009 (arguing that reinvigoration of the CRGR's role in the backfitting process "will help to ensure a rigorous and meaningful application of the rule through independent, high-level management review of significant backfitting decisions," as well as assisting the EDO in carrying out his duties under 10 CFR 50.109).

Another insight from the EDO's Backfitting Appeal Panel is the importance of carefully considering the potential generic implications of issues that initially come to light through facility-specific processes. For example, the Panel concluded:

On the basis of its review, the Panel also noted that the issue of pressurizer valve performance following water discharge appears to have generic applicability, and is not specific to only Byron and Braidwood. The Panel believes that resolution of this issue would have benefited from consideration of the generic nature of the issue through the appropriate NRC processes.²¹

The Panel described the generic nature of the pressurizer valve performance issue in detail in Appendices B and C of its report. Although we do not propose a fully developed solution in this letter, NEI believes that the agency needs to better utilize an existing process, or develop a new process, to ensure that the generic implications of regulatory issues raised in a facility-specific context (*e.g.*, through facility-specific backfits, the inspection and enforcement process) are adequately evaluated. A review of proposed facility-specific backfits by the CRGR—with an emphasis on evaluating any potential generic implications, as well as ensuring that the agency's backfitting procedures and policies are being consistently applied—could address this concern.²² Such a process would ensure that generic regulatory positions are well-understood, carefully evaluated, and consistently applied on a facility-specific basis. In contrast, failing to consider the generic implications of facility-specific regulatory positions promotes a culture where facility-specific regulatory outcomes drive agency regulatory policy (*i.e.*, a "regulation by inspection" culture). We would welcome the opportunity to explore improved use of existing processes, or development of a new process to address this issue in the future.

4) Increased transparency in the backfitting process is needed to ensure a common understanding of the agency's policies, guidance, and decision-making process.

As discussed during the September 13 public meeting, the industry believes that increased transparency in the agency's backfitting process is an important aspect of improving the program. More specifically, we recommend that: (1) CRGR meetings with the staff be conducted as public meetings, (2) the CRGR consider conducting periodic, public meetings with industry and other stakeholders to discuss trends and current issues of import related to the backfitting program, (3) all documented evaluations supporting use of an exception to impose generic backfits be made publicly available in draft form with the draft documents communicating the backfit (*e.g.*, proposed rules, draft guidance, draft Interim Enforcement Policies), and (4) to the maximum extent possible, all training

²¹ Panel Findings, at Enclosure p. 25.

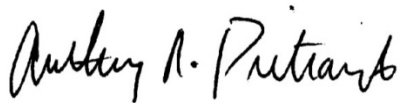
²² We recognize that such reviews are outside of the CRGR's current mandate and that this approach may require a revision of the Committee's charter. Other approaches may also be sufficient to address this issue in backfitting space. For example, instituting an approach to provide inspectors and licensees with a prompt, preliminary review of potential backfitting issues that arise during the inspection process could also be part of a viable solution. This type of preliminary review could address issues related to backfitting identification and the applicability of exceptions, as well as identification of potential generic implications of facility-specific backfits.

materials and other internal guidance regarding implementation of the backfitting rules should be made available to the public.

We appreciate your consideration of our views on this issue and your continuing efforts to improve the agency's backfitting program. Industry recognizes its role in ensuring that legitimate backfitting concerns are clearly and promptly communicated to the staff, and we endeavor to continue improving industry knowledge and practice in this area.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony R. Pietrangelo". The signature is written in a cursive, slightly slanted style.

Anthony R. Pietrangelo

c: Victor McCree, EDO
William Dean, NRR
K. Steven West, NSIR
Brian J. McDermott, NRR
Scott W. Moore, NMSS
Vonna L. Ordaz, NRO
Leonard D. Wert, RII
Edward L. Williamson, OGC
Annette Vietti-Cook, Secretary of the Commission