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January 20, 2016

Mr. William M. Dean  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

**Subject:** Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal

**Project Number: 689**

Dear Mr. Dean:

I am writing to express the Nuclear Energy Institute's<sup>1</sup> (NEI) support for the backfit appeal filed by Exelon Generation Company (EGC) on December 8, 2015,<sup>2</sup> as well as to express concerns regarding the generic implications of NRC staff's interpretation of the "compliance exception" to the backfitting rule.<sup>3</sup> As explained in greater detail below, NEI agrees with EGC that the NRC staff has not articulated an adequate basis for invoking the compliance exception

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<sup>1</sup> 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.

<sup>2</sup> Letter from J.B. Fewell, Exelon Generation Company, to W.M. Dean, NRC, "Appeal of Imposition of Backfit Regarding Compliance with 10 CFR § 50.34(b), GDC 15, GDC 21, GDC 29, and Licensing Basis," (Dec. 8, 2015)("Appeal"). *See also*, Letter from A.T. Boland, NRC, to B.C. Hanson, Exelon Generating Company, "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").

<sup>3</sup> *See* 10 C.F.R. § 50.109(a)(4)(i).

to the backfitting rule in this case, and we continue to be concerned that misuse of the compliance exception is seriously undermining the efficacy of the agency's backfitting program.

### **Background on the compliance exception**

Backfitting is defined at 10 C.F.R. § 50.109(a)(1) as:

[T]he modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position. . . .<sup>4</sup>

Thus, by definition, backfitting includes "modifications or additions" that flow from interpretations of the Commission's regulations that are "either new or different" from previously applicable staff positions.

Once a new or amended requirement is identified as a backfit, the NRC staff must demonstrate—through a "systematic and documented analysis"—that the change will result in a substantial increase in the overall protection of public health and safety or the common defense and security. If the NRC determines that the change will result in a substantial increase, it must also make a finding that the direct and indirect costs of implementation are justified in view of the increased protection.<sup>5</sup>

The three exceptions to the backfitting rule describe scenarios in which a backfit may be imposed without the benefit of the "systematic and documented analysis" described above.<sup>6</sup> The so-called "compliance exception" at issue in the EGC appeal provides that the "systematic and documented analysis" need not be performed where "[a] modification [is] necessary to bring a facility into compliance with a legally binding requirement (*e.g.*, a license, rule, or

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<sup>4</sup> 10 C.F.R. § 50.109(a)(1)(emphasis added).

<sup>5</sup> See 10 C.F.R. § 50.109(a)(2) and (3).

<sup>6</sup> See 10 C.F.R. § 50.109(a)(4)(i)-(iii).

order of the Commission), or into conformance with written commitments made by the licensee.”<sup>7</sup>

The Commission shed additional light on how the compliance exception should be interpreted in the Supplementary Information published with its 1985 final backfitting rule:

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.<sup>8</sup>

The Commission’s explanation makes it abundantly clear that the compliance exception was not intended to cover “new or modified interpretations of what constitutes compliance.” Instead, the exception was clearly meant to be applied to the much more limited scenario where a licensee “has failed to meet known and established standards . . . because of omission or mistake of fact.” By providing this explanation, the Commission harmonized the compliance exception with the definition of backfitting, which explicitly *includes* modifications resulting from imposition of reinterpretations of the Commission’s regulations.

**The compliance exception does not apply in this case.**

With respect to the backfits at issue here, the staff has not explained how imposition of its current interpretation of the Byron and Braidwood licensing bases—which is clearly different from the interpretation and conclusions reached by the NRC staff in approving the 2001 and 2004 licensing actions described in EGC’s appeal<sup>9</sup>—is necessary to correct an omission or mistake of fact associated with those prior approvals. Put another way, the staff has not set forth the specific omission or mistake of fact that was previously relied upon, nor has the staff explained why that omission or mistake warrants imposition of the different interpretation that it now seeks to impose.

The very issue that seems to be the lynchpin of the staff’s current position—*i.e.*, the acceptability of assuming that pressurizer relief valves will adequately reseal following a

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<sup>7</sup> 10 C.F.R. § 50.109(a)(4)(i).

<sup>8</sup> Revisions of Backfitting Process for Power Reactors, 50 Fed. Reg. 38,097, 38,103 (September 20, 1985) (codified at 10 C.F.R. Part 2 and 50).

<sup>9</sup> See Appeal, at pp. 3-4.

spurious safety injection event—was explicitly addressed through several Requests for Additional Information (RAI) issued in association with the staff's 2001 approval of stretch power uprates for both Byron and Braidwood. The licensee's response to those RAIs referenced an EPRI study, which supported its position that it was reasonable to assume the valves would adequately reseal after a spurious safety injection event. After reviewing the RAI responses, the staff concluded:

The EPRI tests adequately demonstrate the performance of the valves for the expected water temperature conditions and that there is reasonable assurance that the valves will adequately reseal following a spurious SI event. . . . Therefore, the staff finds the licensee's crediting of the PSVs to discharge liquid water during a spurious SI event to be acceptable.<sup>10</sup>

The staff's only attempt to address its previous conclusion in the Documented Evaluation is a cryptic reference stating:

The staff's acceptance of the IOECCS analysis in 2001 was based, among other things, on the use of water qualified PSV's which upon further review, during the 2011 measurement uncertainty recapture uprate, was found to be unsubstantiated.<sup>11</sup>

The Documented Evaluation provides no direct citation or reference documenting the 2011 finding, nor does it provide any further explanation of the finding. An unsupported assertion that a previous staff conclusion was found to be "unsubstantiated"—a decade after being documented in a Safety Evaluation Report—does not support use of the compliance exception to avoid a backfitting analysis. This is particularly true in a case such as this, where the very assumption at issue was the subject of multiple RAIs and was explicitly approved by the staff.

On its face, this appears to be a situation where the current staff simply disagrees with the 2001 conclusion that "there is reasonable assurance that the valves will adequately reseal

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<sup>10</sup> Appeal, at p. 5, *citing* "Safety Evaluation by the Office of Nuclear Reactor Regulation Related to Amendment No. 119 to Facility Operating License No. NPF-37, Amendment No. 119 to Facility Operating License No. NPF- 66, Amendment No. 113 to Facility Operating License No. NPF-72, Amendment No. 113 to Facility Operating License No. NPF-77, Exelon Generation Company, LLC, Byron Station, Unit Nos. 1 and 2, Braidwood Station, Unit Nos. 1 and 2, Docket Nos. STN 50-454, STN 50-455, STN 50-456, and STN 50-457," dated May 4, 2001.

<sup>11</sup> Documented Evaluation, at p. 12.

following a spurious SI event”<sup>12</sup> and, thus, is imposing a “new or modified interpretation[] of what constitutes compliance.”<sup>13</sup> As explained above, such reinterpretations do not fit within the compliance exception. Thus, the staff’s reinterpretation may be imposed on the licensee only after the staff demonstrates that imposition is necessary to ensure or redefine adequate protection,<sup>14</sup> or will yield a cost-justified, substantial safety increase.<sup>15</sup>

### **Policy concerns regarding misuse of the compliance exception**

NEI has expressed concerns regarding the misuse of the compliance exception, at both the NRC staff and Commission levels.<sup>16</sup> The Commission has long recognized the importance of subjecting new or different interpretations of its regulatory requirements to the analytical requirements of the backfitting rule. For example, in the 1985 final rule amending § 50.109, the Commission stated:

Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of detail that is expressed in staff guidance documents which interpret the intent of broad, generally worked regulations. The NRC has determined that the correct focus for backfit regulation is the establishment of effective management controls on existing staff processes for the interpretation of regulations that are known to result in valuable upgrades in industry safety performance. Thus, the Commission opts to adopt a management process not only for the promulgation of regulations as backfit instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes.<sup>17</sup>

Loosely interpreting the compliance exception to include what amount to new or different interpretations of existing requirements—as opposed to actions necessary to meet known and

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<sup>12</sup> *Supra* note 10.

<sup>13</sup> 50 Fed. Reg. 38,103.

<sup>14</sup> *See* 10 C.F.R. §§ 50.109 (a)(4)(ii), (iii).

<sup>15</sup> *See* 10 C.F.R. § 50.109(a)(3).

<sup>16</sup> *See, e.g.*, Letter from A.R. Pietrangelo, NEI, to R.W. Borchardt, NRC, “Nuclear Energy Institute Comments in Support of Southern Company Backfit Appeal,” (Nov. 14, 2011); Letter from E.C. Ginsberg, NEI, to M. Doane, NRC, (Nov. 7, 2014); 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).

<sup>17</sup> 50 Fed. Reg. 38,101.

established standards of the Commission—raises substantial policy concerns. First, allowing the staff to apply the compliance exception to impose new or different interpretations of unchanged regulatory requirements would defeat the fundamental purpose of the backfit rule. This is particularly true of backfits that are imposed in the inspection and enforcement context because such backfits inherently involve questions of compliance. More specifically, a well-known objective of the 1985 revisions to the backfit rule was to promote regulatory stability and increase overall safety by ensuring that only cost-justified, substantial safety enhancements are mandated, and that they are assigned a proper priority in view of existing NRC and licensee activities. Interpreting the compliance exception in a manner that would allow imposition of unanalyzed backfits in the form of virtually any new or different interpretation—even in the face of an explicit NRC approval to the contrary—would undermine stability, efficiency, and safety focus that the backfitting rule was intended to provide.

This approach to the compliance exception is also inconsistent with the agency's "Principles of Good Regulation." For example, the guiding principle of "reliability" states that "[o]nce established, regulation should be perceived to be reliable and not unjustifiably in a state of transition."<sup>18</sup> Performance of the cost-justified, substantial increase analysis required by § 50.109 would ensure that imposition of the modified interpretation now proposed by the staff is adequately justified and, thus, that the principle of reliability is fulfilled. Also, the guiding principle of "efficiency" states that "[r]egulatory activities should be consistent with the degree of risk reduction they achieve."<sup>19</sup> In this vein, proper application of the backfitting rule would require a demonstration that imposition of the backfit in question will result in "a substantial increase in the overall protection of public health and safety or the common defense and security," thus ensuring efficiency.

Finally, an undisciplined approach to the compliance exception yields hazy documented evaluations that lack transparency and fail to address the relevant facts. The agency's organizational values require open, transparent, and forthright communications and decision-making. These values are undermined when documented evaluations do not clearly distinguish situations where the staff is imposing reinterpretations of known and established standards on licensees, from situations where backfitting is required ensure compliance with known and established standards. As explained below, documented evaluations that clearly address the facts required to make this distinction would strengthen the agency's backfitting

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<sup>18</sup> "Principles of Good Regulation," available at <http://www.nrc.gov/about-nrc/values.html> (last accessed Jan. 12, 2016).

<sup>19</sup> *Id.*

program by increasing the transparency of decisions to invoke the compliance exception, as well as facilitating more targeted backfitting appeals.

### **Proposed Solution**

Proper application of the compliance exception hinges on the ability to discern situations where backfitting is necessary to correct a licensee failure to meet the “known and established standards of the Commission because of omission or mistake of fact,”<sup>20</sup> from situations in which the staff seeks to impose “new or modified interpretations of what constitutes compliance.”<sup>21</sup> Both scenarios could involve backfitting, but only in the case of the former can the staff forego the cost-justified, substantial-increase analysis.

In order to ensure proper application of the compliance exception, every documented evaluation prepared to justify invocation of the compliance exception must—at a minimum—provide a clear and thorough description of:

- 1) The “known and established standards” at issue;
- 2) The prior NRC staff approval(s) of the licensee’s method of compliance with such “known and established standards;”
- 3) The specific omission or mistake of fact that undermines the prior NRC staff approval(s);<sup>22</sup>
- 4) An evaluation explaining that, but-for the identified omission or mistake of fact, the NRC staff would not have issued the prior approval; and
- 5) A description of how the NRC has interpreted the “known and established standards” at issue (with respect to the specific licensee in the case of a facility-specific backfit, or generically in the case of a generic backfit).

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<sup>20</sup> 50 Fed. Reg. 38,103.

<sup>21</sup> *Id.*

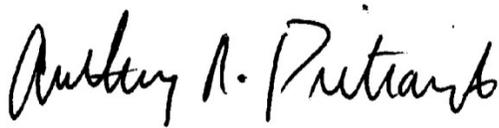
<sup>22</sup> NEI provided a detailed description of how the terms “mistake of fact” and “omission” should be interpreted when invoking the compliance exception. See Letter from J.R. Schlueter, NEI, to C. Bladley, NRC, “Draft Interim Staff Guidance ZZ, Revision 0 Guidance for the Evaluation of Acute Chemical Exposures and Proposed Quantitative Standards (80 Fed. Reg. 11,692 and 80 Fed. Reg. 21,274),” at Attachment 1 (June 30, 2015).

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This type of thorough evaluation, which was not provided in the case of the EGC backfits, would provide assurance that the compliance exception is being applied in a manner that is consistent with the Commission's long-standing direction.

We appreciate your consideration of our views on this issue and would be happy to discuss our concerns, either in the context of the EGC appeal or in another appropriate forum. Please feel free to contact me if you have any questions.

Sincerely,

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

Anthony R. Pietrangelo

Cc: Mr. Victor M. McCree, EDO, NRC  
Ms. Margaret Doane, General Counsel  
Ms. Marissa G. Bailey, NRR, NRC  
Ms. Anthony T. Gody, Jr., Region II Office, NRC  
Mr. Adam S. Gendelman, OGC, NRC  
Ms. Annette Vietti-Cook, Secretary of the Commission