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June 16, 2016

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

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

**Project Number: 689**

Dear Mr. McCree:

I am writing to express the Nuclear Energy Institute's (NEI) <sup>1</sup> support for the backfitting appeal filed by Exelon Generation Company (EGC) on June 2, 2016,<sup>2</sup> as well as to express our continuing concern regarding the generic implications of NRC staff's application of the "compliance exception" to the backfitting rule.<sup>3</sup> As you know, NEI submitted a letter<sup>4</sup> supporting EGC's First-Level Appeal<sup>5</sup> earlier this year. That letter also expressed our policy

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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> "Appeal of Imposition of Backfit Regarding Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and Licensing Basis," June 2, 2016 ("Second-Level Appeal").

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

<sup>4</sup> "Nuclear Energy Institute Comments in Support of Exelon Generating Company Backfit Appeal," January 20, 2015 ("NEI January Letter").

<sup>5</sup> Letter from J.B. Fewell, Exelon Generating 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)(ML15342A112)("First-Level Appeal").

concerns regarding use of the compliance exception. Unfortunately, the agency's May Response<sup>6</sup> to EGC's First-Level appeal did not adequately address those concerns.

Over the past 18 months, we have 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 modified interpretation[] of what constitutes compliance."<sup>7</sup> 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.<sup>8</sup>

Consistently and accurately making this distinction is critical to successful implementation of the Commission's backfitting requirements. More specifically, carefully applying the Commission's direction on use of the exception allows the NRC to enforce its existing requirements in those relatively rare instances where noncompliance exists due to an agency approval based on a clear and readily identifiable mistake of fact or omission, while also ensuring that new or modified interpretations of what constitutes compliance will substantially increase safety or security and can be justified in light of their costs. This careful approach promotes predictability; ensures fidelity to the agency's Principles of Good Regulation; and, most importantly, ensures that safety-focus is maintained. In contrast, the approach taken in the staff's Documented Evaluation<sup>9</sup> and May Response continue to blur the line between the

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<sup>6</sup> "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 (ML16095A204)("May Response").

<sup>7</sup> See NEI January Letter; 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). Although it has come to the fore recently, misuse of the compliance exception is not a new concern for the industry. See, e.g., "Nuclear Energy Institute Comments in Support of Southern Company Backfit Appeal," Nov. 14, 2011 (arguing, in part that "[i]nterpreting 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 provided by the backfit rule."); "Summary of July 11, 2000, Meeting with the Nuclear Energy Institute and Nuclear Utility Backfitting & Reform Group Regarding the Compliance Backfit Provision Issues (describing a meeting during which NEI presented views regarding the appropriate application of the compliance exception and to identify what it viewed as inappropriate use of the exception).

<sup>8</sup> "Revisions of Backfitting Process for Power Reactors," 50 Fed. Reg. 38,097, 38,103 (Sept. 20, 1985).

<sup>9</sup> Letter from A.T. Boland, NRC, to B.C. Hanson, Exelon Generating Company, "Braidwood Station, Units 1 and 2, and Byron Station, Units 1 and 2—Backfit Imposition Regarding Compliance with 10 CFR 50.32(b), GDC 15, GDC 21, GDC 29, and Licensing Basis," (Oct. 9, 2015)(ML154225A871)("Documented Evaluation").

imposition of new or different interpretations of existing requirements and legitimate compliance backfits.

We are also particularly concerned with the staff's reliance on broad NRC licensing standards such as the General Design Criteria (GDC) and FSAR content requirements as the basis for imposing compliance backfits on operating plants. Compliance with such standards is typically determined, in the first instance, through the licensing process, which is informed by agency guidance (*e.g.*, Standard Review Plans) that is available at the time the licensing review is being undertaken. Use of the compliance exception in such situations presents difficulties because—while the positions articulated in SRPs and other guidance are definitive statements of one possible method of compliance that is acceptable to the staff<sup>10</sup>—they are not legally binding requirements. Thus, failure to require licensee adherence to the positions provided in such guidance does not necessarily reveal an omission or mistake of fact on the part of the NRC reviewer. Also, because backfitting related to GDC compliance often involves new or different staff positions regarding the acceptability of a *method of compliance* with a broad, unchanged design requirement, the risk of misusing the exception to impose “new or modified interpretations of what constitutes compliance”<sup>11</sup> is inherently high. Thus, use of the compliance exception to justify the backfitting of new or different methods of compliance with broad licensing standards (such as the GDC) should be subject to a high level of scrutiny by NRC management.

Unfortunately, in this case, the staff has not adequately addressed these issues. We continue to believe that use of the compliance exception to avoid the analysis required by 10 C.F.R. § 50.109(a)(3) and (c) in this case undermines important policy objectives of the agency's backfitting requirements. Our specific concerns with both the Documented Evaluation and May Response are explained in detail below.

### **Staff Failed to Identify the “Known and Established” Standard at Issue**

The compliance exception permits the NRC to impose a backfit, without the benefit of the analysis required by sections 50.109(a)(3) and (c), when “a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into

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<sup>10</sup> “The SRP delineates the scope and depth of staff review of licensee submittals associated with various licensing activities. It is an NRC staff interpretation of measures which, if taken, will satisfy the requirements of the more generally stated, legally binding body of regulations primarily found in 10 C.F.R.” “Backfitting Guidelines,” NUREG-1409 (July 1990), at p. 17.

<sup>11</sup> 50 Fed. Reg. 38,103 (Sept. 20, 1985).

compliance with written commitments by the licensee.”<sup>12</sup> In the supplementary information published with the 1985 final backfitting rule, the Commission provided the following direction on use of the compliance exception:

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>13</sup>

Thus, an important first step in evaluating the applicability of the exception is to identify the “known and established” standard at issue. At this point, it is useful to revisit the backfit that is being imposed in this case. In the May Response, the Director of NRR concluded that the Braidwood and Byron Updated Final Safety Analysis Report (UFSAR):

[D]oes not demonstrate compliance with GDCs 15, 21, and 29 and the plant-specific design basis with respect to progression of Condition II events. The UFSAR analyses of reactor coolant system mass addition (Condition II) events predict water relief through pressurizer relief valves that are not water qualified, which could result in a relief valve sticking open and causing a small break loss of coolant accident (Condition III event). Thus, Braidwood and Byron are not in compliance with 10 C.F.R. 50.34(b).<sup>14</sup>

The NRC’s Documented Evaluation acknowledged that this conclusion differed from a previous NRC position:

Parts of the current Byron and Braidwood IOECCS analysis were accepted as part of a stretch power uprate license amendment in 2001 (Reference 1) and other UFSAR changes to these three analyses were made under 10 C.F.R. 50.59. 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

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<sup>12</sup> 10 C.F.R. § 50.109(a)(4)(i).

<sup>13</sup> 50 Fed. Reg. 38,103 (September 20, 1985).

<sup>14</sup> May Response, at p. 1.

2011 measurement uncertainty recapture uprate, was found to be unsubstantiated.<sup>15</sup>

Further, the staff's May Response states "NRC requirements at the time [of the 2001 approval] provided that the valves should have been water qualified, and EGC did not demonstrate that they were."<sup>16</sup>

Thus, the backfit at issue involves a change in NRC's position on whether crediting the pressurizer valves to open and reseal during the relevant mass addition events is appropriate. As EGC points out in its Second-Level Appeal, "the crux of the matter is what constitutes water "qualification" and whether the PSVs are water qualified ."<sup>17</sup>

Instead of addressing the relevant "requirement" (*i.e.*, qualification of the valves in question), the staff misidentified the standard as the prohibition on the progression of condition II events to more serious condition III events.<sup>18</sup> There is no dispute that the non-progression criteria has not changed and continues to apply. But that fact is not dispositive or even probative in determining whether application of the compliance exception is appropriate in this case. The underlying backfit is not a change in the agency's position regarding whether condition II events may progress to more severe condition III events. Rather, the underlying backfit deals with a changed NRC position regarding what is required to demonstrate qualification of the valves so that they may be credited to function during the relevant condition II events (*i.e.*, mass addition events).

As a result, the staff focuses on demonstrating that the non-progression criteria has not changed, but glosses over the most important threshold questions: (1) Was there a "known and established standard," in effect at the time of the prior agency approvals, that the valves credited by the licensee to function during the relevant mass addition events be "qualified" for water relief, and, if so (2) was the staff's current view of what constitutes "qualification" a

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<sup>15</sup> Documented Evaluation, at p. 12; *see also* May Response, enclosure at p. 3.

<sup>16</sup> May Response, enclosure at p. 5. We also note that in approving a 2004 pressurizer safety valve set point amendment the NRC once again concluded that, based on analysis provided by the licensee, the pressurizer safety valves would remain operable following a spurious SI event (*i.e.*, a mass addition event).

<sup>17</sup> Second-Level Appeal, at p. 4.

<sup>18</sup> *See* May Response, enclosure at p. 4 ("In its appeal, the licensee acknowledged that the Agency's position on the unacceptability of Condition II events transitioning to Condition III events has not changed. This is the 'known and established standard' at issue."). The prohibition on the progression of Condition II to more serious Condition III events will be referred to as the "non-progression criteria."

“known and established standard” applicable to the licensee at the time the prior approvals were issued?

As demonstrated in EGC’s Second-Level Appeal, the NRC’s Documented Evaluation and May Response fail to identify a “known and established standard” that is consistent with the staff’s current view on water qualification (*i.e.*, that qualification for this purpose requires conformance to specific ASME codes) and that was applicable to the valves in question at the time of the 2001 and 2004 approvals. Instead, the staff relies upon a 2005 Regulatory Issue Summary<sup>19</sup> (RIS) and a 2007 revision to Sections 15.5.1–15.5.2 of the Standard Review Plan (SRP),<sup>20</sup> both of which post-date the approvals in question. This fact alone limits the value of these documents in establishing that the staff’s current view of what constitutes “water qualification” existed in the form of a legally binding requirement or standard at the time of the 2001 and 2004 approvals.

Perhaps more importantly, while the RIS and SRP are appropriately used to communicate one method of compliance acceptable to the staff, the methods they describe are not exclusive and are not legally binding requirements with which licensees must comply. Alternatives to the methods of compliance articulated in agency guidance are always a possibility. Thus, even if the positions articulated in the 2007 revision to Section 15.5.1–15.5.2 or 2005 RIS existed in 2001 or 2004, they would not have precluded the staff from approving the licensee’s reliance on the EPRI test data to demonstrate compliance with the relevant GDC.

As explained in EGC’s Second-Level Appeal, the applicable standard for water qualification of the valves in question was established through several NUREGs addressing lessons-learned from the Three Mile Island accident. The EPRI testing relied upon by the licensee was the qualification testing performed in response to the referenced NUREGs. Subsequently, the licensee provided additional analysis and adequately addressed staff concerns related to reliance on the EPRI testing to credit the functioning of the pressurizer valves during mass addition events in both the 2001 stretch power uprate and 2004 set point amendments.

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<sup>19</sup> NRC Regulatory Information Summary, RIS 2005-029, “Anticipated Transients that Could Develop into More Serious Events,” dated December 14, 2005.

<sup>20</sup> NUREG-0800, Standard Review Plan, Sections 15.5.1-15.15-2, “Inadvertent Operation of ECCS and Chemical and Volume Control System Malfunction that Increases Reactor Coolant Inventory,” Rev. 2 (March 2007).

### **Staff Failed to Identify a Mistake of Fact Resulting in the Prior Approvals**

Because the staff did not accurately characterize the “known and established standard” at issue, the Documented Evaluation and May Response also fail to identify a mistake of fact upon which the staff’s prior positions were based. Indeed, the Documented Evaluation does not even use the phrase mistake of fact. The May Response attempts to fill the hole in the Documented Evaluation, but further muddies the water.

On one hand, the May Response states:

The fact that, at the time, the NRC staff appeared to have some awareness of an approach inconsistent with the requirements discussed here, in this case references to EPRI reports on the ability of these non-water qualified PSVs to reseal in certain circumstances, is not sufficient to support the licensee’s position. NRC requirements at the time provided that the valves should have been water qualified, and EGC did not demonstrate that they were. As discussed in the NRC’s backfit analysis, this is the mistake of fact.<sup>21</sup>

This statement does not identify a mistake of fact. Instead, as discussed above and in EGC’s Second-Level Appeal, it is simply an unsupported, conclusory statement that requirements reflecting the staff’s current view on water qualification existed when the prior approvals were issued and that the licensee did not meet those alleged requirements. As discussed above and in the EGC’s Second-Level Appeal, no such requirement existed at the time of the 2001 and 2004 approvals. Further, EGC met the relevant qualification standard and adequately addressed the concerns expressed by the staff at the time the 2001 and 2004 approvals were issued.

On the other hand, the May Response also states:

[B]ut for the mistake of fact that the PSVs were thought to be water qualified, the NRC would not have approved UFSAR analyses that do not demonstrate compliance regarding the prohibition of progression of Condition II events.<sup>22</sup>

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<sup>21</sup> May Response, at enclosure p. 5 (emphasis added).

<sup>22</sup> *Id.* at enclosure p. 6 (emphasis added).

Similarly, the cover letter providing the May Response states:

The NRC has consistently applied the prohibition of progression on Condition II events, and the 2001 and 2004 approvals occurred because the NRC staff understood the PSVs to be qualified for water relief when, in fact, they were not.<sup>23</sup>

These statements are utterly inconsistent with the record in this appeal. As described in EGC's First-Level Appeal, NEI's January 2016 Letter, and EGC's Second-Level Appeal, during the 2001 approval of EGC's stretch power uprate the staff issued several requests for additional information (RAIs) that directly addressed whether the pressurizer valves would reseal after opening to vent liquid during a mass addition event (*i.e.*, inadvertent operation of the emergency core cooling system during power operation). The licensee's responses relied upon the EPRI testing program and provided additional analysis describing the expected duration of the safety injection transient and the expected temperature of the water being vented. Based on the exchange contained in the RAIs, the staff concluded:

[T]he EPRI tests 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 the spurious SI event. . . . Therefore, the staff finds the licensee's crediting of the PSVs to discharge liquid water during the spurious SI event to be acceptable.<sup>24</sup>

In approving EGC's 2004 set point amendment the staff once again concluded that, based on analysis provided by the licensee, the pressurizer safety valves would remain operable following a spurious SI event. There is simply nothing in the record indicating that the staff understood that these valves were "qualified for water relief" pursuant to its current position on what constitutes qualification (*i.e.*, through application of the ASME codes referenced in the Documented Evaluation and May Response). Indeed, the May Response recognizes that at the time of the 2001 and 2004 approvals the "staff appeared to have some awareness of an

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<sup>23</sup> *Id.* at pp. 1-2 (emphasis added).

<sup>24</sup> First-Level 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," at p. 12, dated May 4, 2001.

approach inconsistent with” its current view of water qualification.<sup>25</sup> This statement is inconsistent with the idea that the staff who approved the 2001 and 2004 licensing actions believed that the valves in question had been qualified pursuant to the ASME codes discussed in the Documented Evaluation. It also ignores the extensive regulatory history on this topic described in EGC’s Second-Level Appeal (*e.g.*, post-TMI NUREGs and associated activities) and mischaracterizes the extensive nature of the RAIs and responses supporting the 2001 and 2004 approvals.

### **Conclusions Regarding EGC’s Backfitting Appeal**

This appeal demonstrates why it is vitally important for NRC management to closely scrutinize alleged “compliance backfits” that the NRC staff believes are necessary to satisfy broad design criteria. Specifically, if the staff fails to identify a specific “known and established standard” that was clearly applicable at the time the licensee’s current method of compliance was approved by the agency, then—as is the case here—the staff may misidentify noncompliance with a new or different interpretation as a mistake of fact, and impose that new interpretation without the benefit of the analysis required by 10 CFR50.109(a)(3) and (c). This type of circular logic promotes an approach to the compliance exception that would allow imposition of virtually any new or different interpretation of what is required to satisfy broad design criteria without the benefit of a backfitting analysis. Such result allows the exception to swallow the rule, and is clearly inconsistent with the Commission’s statements in the 1985 final rule regarding the proper use of the exception.

In sum, this backfit does not present a situation “in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact.”<sup>26</sup> Instead, this is clearly a situation where the staff’s view of what is required to credit pressurizer valves during a mass addition event has evolved since the 2001 and 2004 approvals were issued. Now, the staff wishes to impose this “new or modified interpretation[] of what constitutes compliance”<sup>27</sup> on the licensee. In such circumstances the agency’s regulations require that the staff address the backfit in a straightforward manner in order to determine whether “there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this

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<sup>25</sup> May Response, at enclosure p. 5.

<sup>26</sup> 50 Fed. Reg. 38,103.

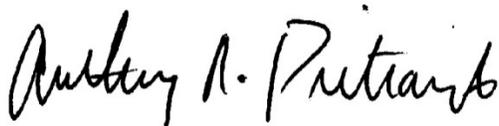
<sup>27</sup> *Id.*

Mr. Victor M. McCree  
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increased protection."<sup>28</sup> Therefore, we request that you grant EGC's appeal, and direct the staff to perform the required analysis and make the required findings prior to imposing any backfits related to the subject matter addressed in this appeal.

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, reading "Anthony R. Pietrangelo". The signature is written in a cursive, flowing style.

Anthony R. Pietrangelo

cc: Ms. Margaret M. Doane, General Counsel  
Ms. Annette Vietti-Cook, Secretary of the Commission  
Mr. William M. Dean, NRR Director

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<sup>28</sup> 10 C.F.R. § 50.109(a)(3).

## **NRCExecSec Resource**

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**From:** PIETRANGELO, Tony <arp@nei.org>  
**Sent:** Thursday, June 16, 2016 4:01 PM  
**To:** McCree, Victor  
**Cc:** Doane, Margaret; NRCExecSec Resource; Dean, Bill  
**Subject:** [External\_Sender] Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Backfit Appeal  
**Attachments:** 2016 06 16\_Second-Level-Appeal\_NEI-Supporting-Exelon-Backfit.pdf

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Over the past 18 months, we have 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 modified interpretation[] of what constitutes compliance."<sup>[7]</sup> 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.<sup>[8]</sup>

### ***THE LETTER IN ITS ENTIRETY IS ATTACHED***

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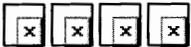
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- [2] "Appeal of Imposition of Backfit Regarding Compliance with 10 CFR 50.34(b), GDC 15, GDC 21, GDC 29, and Licensing Basis," June 2, 2016 ("Second-Level Appeal").
- [3] See 10 C.F.R. § 50.109(a)(4)(i).
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Concerns Regarding Generic Letter (GL) 2015-01, Treatment of Natural Phenomena Hazards (NPH) in Fuel Cycle Facilities, " (April 24, 2015). Although it has come to the fore recently, misuse of the compliance exception is not a new concern for the industry. *See, e.g.*, "Nuclear Energy Institute Comments in Support of Southern Company Backfit Appeal," Nov. 14, 2011 (arguing, in part that "[i]nterpreting 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 provided by the backfit rule."); "Summary of July 11, 2000, Meeting with the Nuclear Energy Institute and Nuclear Utility Backfitting & Reform Group Regarding the Compliance Backfit Provision Issues (describing a meeting during which NEI presented views regarding the appropriate application of the compliance exception and to identify what it viewed as inappropriate use of the exception).

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