PUBLIC COMMENTS RELATED TO BACKFIT

Although the staff of the U.S. Nuclear Regulatory Commission (NRC) has determined that there is no backfit related to the issuance of the Interim Staff Guidance (ISG), the staff acknowledges there are contrary views on this issue, as reflected in the comments submitted on the Draft ISG. The Draft ISG was issued for public comment in the *Federal Register* on March 4, 2015 (80 FR 11692). On April 17, 2015, a supplemental *Federal Register* notice (FRN) (80 FR 21274) included a request for comments on backfit related information, and extended the public comment period to July 1, 2015. In response to these two FRNs, the staff received the following letters:

- A Nuclear Energy Institute (NEI) letter of June 30, 2015 (Agencywide Documents Access and Management System accession number ML15189A076), provided additional information regarding its backfitting concerns. This letter also disputed the mischaracterization of information about some of the historical exposure events referenced in the April 17, 2015, FRN.
- A Westinghouse Electric Company LLC (WEC) letter dated June 30, 2015 (ML15188A028), endorsed the NEI comments and provided information on one of the exposure events referenced in the April 2015 FRN.
- An anonymous commenter submitted a comment on June 30, 2015 (ML15189A073), supporting the Draft ISG. A second anonymous commenter submitted a comment on June 30, 2015 (ML15189A074), regarding Petition for Rulemaking (PRM) 70-7 (the 1996 NEI proposal discussed in the above Background section).
- A BWX Technologies, Inc. (BWXT) letter dated July 10, 2015 (ML15208A098), endorsed the NEI comments and provided information on one of the exposure events referenced in the April 2015 FRN.

Section A, below addresses NEI's June 2015, comments. Section B, below addresses the WEC, BWXT, and anonymous comments.

A. NEI's June 2015 Comments

The NEI June 30, 2015, comment letter and its Attachment 1 references its earlier backfit arguments that the staff responded to in its letter dated September 15, 2014 (ML14251A150). As briefly summarized below, NEI's Attachment 1 contains six additional backfitting concerns that the staff responds to below.

1 – NRC has not clearly articulated how implementation of a new quantitative standard will increase safety.

Staff Response: There is no new quantitative standard that is being imposed. The existing Title 10 of the *Code of Federal Regulations* (10 CFR) Paragraph 70.65(b)(7) provision requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials.

The NRC staff continues to maintain that the consideration of all exposure pathways in an Integrated Safety Analysis (ISA) is important to understand the risk of potential accident

sequences at a given facility. The standards referenced in the 10 CFR 70.65(b)(7) provision help the licensee understand the severity of potential accident sequences, enabling the licensee to make an informed decision on expending resources to effectively manage the hazard. The licensee proposed standards for inhalation serve this purpose for accident sequences where the physiological (i.e., human health) consequences are determined by the inhalation exposure pathway. Dermal and ocular exposure standards serve the same purpose for those accident sequences where the physiological consequences are dominated by the dermal or ocular exposure pathway.

2 – NEI states that the 10 CFR Part 70 Appendix A ("Reportable Safety Events") reporting requirements can be met without the quantitative standards, and that quantitative standards are not necessary to properly categorize the consequences of events involving dermal and ocular exposures.

Staff Response: The NRC staff finds that NEI has not adequately articulated its concern here. The 10 CFR Part 70 Appendix A reporting requirements are outside the scope of the ISG, which is focused on the review of ISA summaries and whether the 10 CFR Section 70.61 performance requirements have been met. However, NRC staff notes that one of the reporting requirements clearly refers to quantitative standards. Part 70, Appendix A, Paragraph (a)(3) states the following:

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that *exceeds the quantitative standards established to satisfy the requirements in § 70.61(b)(4).*

3 – NEI states that existing current worker protection programs adequately address protection from dermal and ocular exposure to chemicals.

Staff Response: Regulations in 10 CFR part 70 Subpart H established chemical safety requirements covering licensee operations that are under the NRC's regulatory authority. Worker protection cannot be made wholly dependent on a licensee's following U.S. Occupational Safety and Health Administration (OSHA) regulations, which do not apply in areas where the NRC has regulatory authority. The 1988 OSHA-NRC Memorandum of Understanding in this regard is discussed in Enclosure 1 of this package.

4 – NEI states that the NRC staff mischaracterized two events in Table 1 of the April 2015 FRN as intermediate or high consequence.

Staff Response: The NRC staff acknowledges that the events numbered five and six in the April 2015 FRN Table 1 were not accurately characterized. Specifically, the parenthetical statement below the FRN Table 1 title – stating that these two events (shaded in the Table) resulted in high or intermediate consequences – was incorrect and should not have been included in the title. Table 1 below corrects this mistake by deleting the erroneous statement, and by deleting its two footnotes.

Event number five was a case where a worker at a Westinghouse facility received a chemical burn while working with a UF6 cylinder. As discussed in the more detailed response to the Westinghouse comment below, the staff acknowledges that the specific event was not classified

as an intermediate or high consequence event. However, the staff notes that the event was characterized as a serious event, and that small changes (e.g., location of the worker relative to the spill/release, magnitude of the spill/release, how fast a worker can exit an area, timeliness and nature of first aid) could have resulted in more serious consequences. Further, this specific event is a valid illustration of the potential for dermal exposures to chemicals at a fuel cycle facility to result in an intermediate or high consequence event.

Event number six was an exposure event that occurred on April 28, 2008, where a BWXT process operator received an exposure of liquid hydrogen fluoride (HF) to the eye, while trying to neutralize a liquid HF spill. As discussed in the more detailed response to the BWXT comment on this specific event, the staff acknowledges that the NRC's initial assessment of the event characterized it as a serious event ocular exposure that "could have led to irreversible or other serious, long-lasting health effects."

Serious health effects from HF exposure should not be taken lightly. The significance of events five and six, and the other 14 events listed below in Table 1, is to demonstrate that dermal and ocular exposure events have the potential to result in intermediate or high consequences. If not for the prompt and proper medical care provided, the Westinghouse and BWXT workers would likely have sustained at least intermediate consequences from the respective dermal and ocular exposures.

Table 1 below demonstrates that dermal and ocular exposure events do occur in fuel cycle facilities. There is nothing that inherently limits the consequences of dermal and ocular exposure events to less than intermediate effects. Therefore, when analyzing events in an ISA, the NRC staff maintains that dermal and ocular exposure events should be considered for their potential to result in intermediate or high consequences.

5 - NEI states that efforts to derive quantitative standards addressing dermal and ocular exposures would represent additional regulatory burden that would yield no commensurate safety benefit.

Staff Response: The staff finds there are two issues raised by this comment. The first issue is the degree of effort necessary to describe a proposed standard that the staff would find acceptable. The second issue is the benefit of such standards.

Regarding the degree of effort issue, NEI stated in its initial backfit claim that "the fact remains that no scientifically-credible dermal and ocular quantitative exposure standard for workers exist or can be established absent extensive primary research including both animal and human studies for each chemical of concern." (March 26, 2014 letter, at 2.)

The error of this statement is demonstrated by the fact that two dermal ocular exposure standards have been proposed by licensees and accepted by the NRC staff using existing toxicological information. On January 22, 2009, a licensee proposed a standard for high consequences for dermal exposure to HF based on publically available HF toxicity information. The proposed standard was approved as part of a license amendment that was issued on May 11, 2009 (ML090490686). The staff reviewed the licensees proposed standard using information available in literature and from the manufacturer and concurred that the licensee's standard of 805 cm^2 of worker's skin or eye, for greater than 30 minutes, with dilute HF will describe a high consequence HF exposure. This standard was subsequently adopted by all the five out of six licensees. Only the enrichment licensee is not using the proposed standard.

More recently one of these fuel fabrication licensees proposed an alternate high and intermediate standards for dermal and ocular HF exposure on June 8, 2015 (ML15180A163). The proposed alternate standard was reviewed by the NRC staff and approved on August 26, 2015 (ML15226A610).

Based on this experience and the staff review of toxicity information from common fuel cycle chemicals, the staff finds that standards for classifying dermal and ocular exposure events can be established based on existing and publically available toxicity information. The ISG identifies information sources that can be used by licensees in this regard.

The response to NEI comment 1 above discusses the benefits of standards used to classify event severity.

6 – NEI states that the NRC staff has reinterpreted 10 CFR 70.65(b) to require development of quantitative dermal and ocular exposure standards, and that this is a new staff position and an unanalyzed backfit.

Staff Response: NEI's June 2015 submittal (attachment 1, at 4-5) discusses contract law principles regarding the omission or mistake of fact issues referenced in the 1985 statement of considerations (SOC) excerpt that NEI relies upon. The staff finds that contract law is not applicable here, inasmuch as the NRC materials licenses issued under 10 CFR Part 70 are regulatory approvals rather than contracts. Backfitting is essentially an equitable protection given by the NRC to its licensees by discretion (i.e., it is not required by law). Therefore, contract principles are inapplicable to analysis of the compliance exception.

Moreover, even if contract law principles were deemed to apply, other contract law concepts, such as force majeure, frustration of purpose, or impracticality would be more relevant. Inasmuch as "mistake" and "omission" are not in the words of the backfit regulation but instead appear in a 1985 SOC – which makes no mention of "contract law" as constraining the compliance exception – the staff's approach to implementing the compliance exception here is reasonable and legally defensible.

Additionally, NEI's June 2015 submittal (attachment 1, at 5) discusses the Commission's recent Staff Requirement Memorandum and votes on SECY-15-0045, "Issuance of Generic Letter 2015-01, 'Treatment of Natural Phenomena Hazards in Fuel Cycle Facilities'" (ML15035A389). The NEI quotes Commissioner Ostendorff's vote stating that the natural phenomena hazards (NPH) generic letter mishandles backfit policy, and reflecting his disagreement with the staff's interpretation there of the 10 CFR 70.76 compliance exception. The vote also references the NPH generic letter as having made the case that the "requirement for licensees to maintain the ISA equates to a living licensing basis."

Assuming that these NPH-related actions are even within the scope of the ISG issues, the staff notes that the Commission's Staff Requirements Memorandum (SRM) on the NPH generic letter does not contain any wording directly stating that the basis for removal of the backfit justification discussion was Commission disagreement with the staff's interpretation of the 10 CFR 70.76 compliance exception requirements. Further, the NEI-quoted language from Commissioner Ostendorff's vote was not included in the SRM and, therefore, does not constitute the Commission's formal position.

Part 70 licenses subject to the Subpart H requirements do not involve an approval of operational hardware, but approval of a safety program and ISA methods. For example, the NRC staff does not review and approve all individual processes for compliance with the safety performance requirements of 10 CFR 70.61; it reviews and approves methods by which the licensee demonstrates such compliance. In its Draft ISG, the NRC staff finds that a licensee ISA method which does not consider dermal-ocular exposures at all is deficient by omission. The deficiency is that potentially unsafe conditions may be overlooked and controls may be inadequate so that risk is not limited (10 CFR 70.61). The staff is not 'escalating safety standards' in this case. The guidance for approval of licensee demonstration of the performance requirements in the applicable Standard Review Plans (NUREG-1520 and NUREG-1513) is unchanged. Dermal and ocular exposures is just a different mode of exposure, not an increase in standards of protection, such as level of likelihood or level of consequences.

The NEI has also stated that requiring such standards represents a change in NRC position. More specifically, NEI stated that when NRC accepted the initial ISA Summaries in the 2005-2007 timeframe it was aware that only inhalation pathways were considered. However, the ISA Summaries made no such disclosure. Staff does not agree with NEI's assertion that the failure of the documents approving the ISA Summaries to discuss non-inhalation exposure demonstrates acceptance of the unstated industry assumption. The staff rejected this assertion in its June 12, 2009, response an NEI letter (as detailed in the Enclosure 1 chronology). The current licensee ISA and ISA Summaries contradicts this assertion as well. Five of the six fuel cycle licensees that are subject to the subpart H requirements (i.e., the five fuel fabrication facility licensees) include an HF standard in their ISA Summaries.

The NEI also makes the argument that at the time of the initial ISA reviews, NRC guidance only gave inhalation standards as examples, and that this was the NRC's position on the issue. The lack of guidance for any particular exposure pathway doesn't exclude a credible chemical hazard from the requirements to identify and analyze the hazard in the ISA. Just as examples in the NRC Enforcement Policy are neither exhaustive nor controlling (ML15029A148, Section 2.2.2 and Section 6.0), the ISA guidance is neither exhaustive nor controlling. An ISA must identify chemical hazards in accordance with 10 CFR 70.62(c)(ii) regardless of how much guidance exists for the particular exposure pathway. Potential accident sequences involving chemical hazards, as well as the associated consequences and likelihood of these potential accident sequences, must also be identified pursuant to 10 CFR 70.62(c)(iv) and (v). These are existing requirements. Licensee concerns with a lack of guidance concerning dermal and ocular exposures are valid, and the ISG was prepared to address those concerns. However, the lack of specific guidance doesn't limit the scope of the regulations or grant relief from the regulations.

B. WEC, BWXT, and Anonymous Comments

1 – WEC submitted a comment letter on June 30, 2015, which endorsed the NEI comments and also commented about the characterization of a historical exposure event identified in the April 17, 2015, FRN.

Staff response: Westinghouse's comment letter of June 30, 2015, presented a review of the event history pointing out that two months after the event the employee's forearm had a scar. The letter stated that the employee did not have any long-lasting health effects. The letter also noted that the NRC inspection report on the event stated that the medical consultant "believes

that the HF burn did not endanger the life of the worker." Based on Westinghouse's determination of no "long-lasting health effect," and the NRC medical consultant's belief that the burn did not endanger the life of the worker, Westinghouse stated that the event was neither an intermediate nor a high consequence event under 10 CFR 70.61. Westinghouse also noted that NRC only issued Severity Level IV violations for the event.

The staff agrees with the facts presented in the Westinghouse letter, and acknowledges that this event should not have been characterized as an intermediate or high consequence event in the April 2015 table published in the *Federal Register*. The staff points out that the above-referenced NRC inspection report documents that the medical consultant characterized the injury as a serious burn. The seriousness of the event is illustrated by noting that while the specific event involved less than 1 percent of the body surface area, the NISOH skin notation for HF states that there have been fatalities when as little as 2.5 percent of the body surface area is exposed to concentrated HF. The NRC inspection report also noted that the medical treatment with calcium gluconate that the worker received was important in limiting the consequences of the event.

In summary, while the specific event was not characterized as an intermediate or high consequence event, it was clearly a serious one and small changes in the event details (larger burn area, further delay in medical treatment) would likely have resulted in more serious consequences. The event is a valid illustration of the potential for dermal exposures to chemicals at a fuel cycle facility to result in an intermediate or high consequence event.

2 – WEC workers have expressed concerns about implementing OSHA controls as items relied on for safety (IROFS).

The NRC staff understands at least some of the concerns from manager and operators that were included in this letter, but it notes that nothing in the NRC regulations or ISG would require that personal protective equipment (PPE) be identified as IROFS. Even if PPE were identified as IROFS the staff believe WEC would be capable of managing this issue. Staff has previously discuss the issue of PPE as IROFS with WEC. The NRC staff does not encourage PPE to be identified as the only measure to prevent an exposure. Personal protective equipment is the least effective in the hierarchy of controls in the principles of process safety management.

While the NRC prefers passive or active engineered controls to administrative controls as IROFS, administrative controls are allowed and may be necessary. The NRC staff has mentioned in the past that other controls can be identified as IROFS such as log out tag out program, sense and flee procedures, etc., when conducting the ISA.

3 – BWXT submitted a comment letter in July 2015, which endorsed the NEI comments and also commented about the characterization of one of the events highlight in Table 1 of historical the April 17, 2015, FRN.

Staff response: BWXT's July 2015 comment letter presented a clarification pertaining to the 2008 chemical exposure event (number 6 as listed in Table 1). BWXT stated that the event was neither an intermediate nor a high consequence event under 10 CFR 70.61.

Regarding this event, NRC Inspection Report No. 70-27/2008-002 (ML082960026) states that under different circumstances the event:

> …could have resulted in a more severe consequence to the operator. In addition, the lack of procedures and formal guidance for responding to a spill involving HF could have resulted in the operator adding a larger quantity of the incorrect neutralizing agent, resulting in a more violent exothermic reaction with more severe consequences.

During its subsequent enforcement process the NRC's Office of Enforcement (OE) stated in its proposed February 2010 finding (ML100540701) that the 2008 HF spill event resulted in a violation due to the "failure to ensure that engineered and/or administrative controls were available and adequate to prevent an acute chemical exposure from a hazardous chemical produced from licensed material as required by 10 CFR 70.61(c)." In its letter dated June 15, 2010 imposing a civil monetary penalty of $32,500 (ML101580256), OE further described the 2008 event as one in which a process operator took inappropriate actions to neutralize a spill of hydrofluoric acid (HF) by adding sodium hydroxide (NaOH), a strong base, which reacted violently with the HF acid on the floor. The operator sustained an ocular exposure from the resulting flash of HF that required medical attention. OE further found that but for the timely and effective emergency and medical response, the operator could have sustained a more serious, long-lasting health effect. Consequently, in accordance with the NRC's enforcement policy, OE categorized the event as a severity level III violation.

However, this 2010 letter also states that, because BWXT then requested and was granted a hearing that led to settlement negotiations. The NRC and BWXT agreed that it was in the public's interest to terminate the enforcement proceeding without further litigation and entered into a settlement agreement (ML102630584) under which the civil penalty was withdrawn and a violation was issued with no severity level.

Therefore, the NRC staff maintains that the 2008 event at BWXT is a valid illustration of the potential for intermediate or high consequence events at fuel cycle facilities caused by ocular exposures to chemicals.

> **4 – An anonymous commenter submitted a comment on June 30, 2015, which noted an NEI proposal to limit the chemical consequence criteria in 70.61 to inhalation exposure to HF. This proposal was rejected by the NRC as the regulations for 10 CFR Part 70 Subpart H were being developed.**

NRC agrees with the commenter. The Section I discussion above addresses NEI's petition (PRM-70-7).

Table 1. Fuel Cycle Facility Dermal and Ocular Exposure Events Known to the NRC Staff

	Date	Event Description (drawn from NMED text)
1.	12/3/1992	Employee sprayed with an acid/uranium mixture
2.	1/27/1998	UF_6 release, three workers received minor HF acid burns on necks and arms (NRC Event Notification (EN) 33601)
3.	8/10/2001	UF_6 release, two workers treated for HF acid burns (EN38198)
4.	4/4/2006	UF_6 release, "minor reddening of the skin … as an apparent result of HF exposure" (NRC Press Release (ML061170441))
5.	2/26/2007	UF_6 release, worker received chemical burn while working with UF_6 cylinder. (NRC Inspection Report 70-1151/2007-022, ML071980047)
6.	4/28/2008	HF spill, the spill resulted in an operator receiving an ocular exposure requiring onsite and offsite emergency medical treatment. (EA-08-204-ML082960026, IR 70-27/2008-0287)
7.	2/12/2009	Holes in glove resulted in second degree nitric acid burns (EN44848)
8.	4/5/2011	KOH exposure on both facial cheeks (EN46730)
9.	4/13/2011	Residual HF passed through zipper of chemical resistant suite and onto the skin of abdomen (EN46749)
10.	4/28/2011	Chemical exposure on ring finger, treated for weak HF or caustic exposure (EN46799)
11.	4/30/2011	Loose HF tubing allowed HF to spray into the atmosphere. Employee noticed redness around his right eye (EN46806)
12.	6/1/2011	Irritation to the eye occurred while cleaning out an HF filter bowl (EN46915)
13.	4/23/2012	Exposure to dilute nitric acid on left forearm and left foot from exposure to uranium bearing acid (EN47861)

14.	10/14/2013	HF exposure to an employee's face (EN49437)