

PUBLIC COMMENTS RELATED TO BACKFIT

The staff of the U.S. Nuclear Regulatory Commission (NRC) has determined that there is no backfit related to the issuance of the final Interim Staff Guidance (ISG) document. Although members of the public submitted comments on the draft ISG raising backfitting concerns, the final ISG does not apply to existing licensees unless there is a voluntary request to amend or renew the license. Nevertheless, the NRC staff responds below to the backfitting-related comments that were submitted on the draft ISG.

The draft ISG was issued for public comment in the *Federal Register* on March 4, 2015 (80 Fed. Reg. 11692). On April 17, 2015, a supplemental *Federal Register* notice (FRN) (80 Fed. Reg. 21274) included a request for comments on backfit related information, and extended the public comment period to July 1, 2015. In response to the two FRNs, the staff received the following letters:

Nuclear Energy Institute (NEI) letter, dated June 30, 2015 (Agencywide Documents Access and Management System (ADAMS) accession number ML15189A076), that provided additional information regarding NEI's backfitting concerns. This letter also disputed the mischaracterization of information about some of the historical exposure events referenced in the April 17, 2015, FRN.

Westinghouse Electric Company LLC (WEC) letter, dated June 30, 2015 (ADAMS Accession No. ML15188A028), that 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 (ADAMS Accession No. ML15189A073), supporting the Draft ISG. A second anonymous commenter submitted a comment on June 30, 2015 (ADAMS Accession No. ML15189A074), regarding Petition for Rulemaking (PRM) 70-7 (the 1996 NEI proposal discussed in Enclosure 4).

BWX Technologies, Inc. (BWXT) letter, dated July 10, 2015 (ADAMS Accession No. ML15208A098), that 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.

Section A - NEI's June 2015 Comments

The June 30, 2015, letter from NEI references its earlier backfit arguments that the staff responded to in its letter dated September 15, 2014 (ADAMS Accession No. ML14251A150). As briefly summarized below, Attachment 1 to NEI's June 30, 2015, letter contains six additional backfitting concerns. The NRC staff's responses to each of these additional concerns is provided 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 pertaining to chemical safety hazards 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 establish 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.

Additionally, in 2016, the NRC staff audited the chemical safety programs at five of the six operating Part 70 fuel cycle facilities to better understand licensees’ current worker protection programs. The NRC staff did not audit the chemical safety program at the uranium enrichment

facility operated by Louisiana Energy Services because operations involving liquid UF₆ are in sealed systems which present limited potential for dermal or ocular exposures. Based on the audit results, the staff concluded that there are no immediate safety concerns related to dermal and ocular exposures at the facilities audited. The staff has reasonable assurance that the licensees meet the requirements in 10 CFR 70.61, with respect to the evaluation of acute chemical exposures. Based on the audit results and licensees' actions and commitments to address all exposure pathways, the staff plans to issue the ISG to ensure clear and consistent reviews of future licensing actions.

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 differences in the event details (e.g., location of the worker relative to the spill/release, magnitude of the spill/release, how fast a worker can exit an area, burn area, and timeliness and nature of medical treatment) could have resulted in more serious consequences. Furthermore, 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 below in the more detailed response to the BWXT comment on this specific event, the NRC staff acknowledges that its initial assessment of the event resulted in the NRC staff characterizing it as a serious ocular exposure event 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 at 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 NRC staff notes that there are two issues raised by this comment. The first issue involves the degree of effort necessary to describe a proposed standard that the staff would find acceptable. The second issue concerns the benefit of such standards.

Regarding the degree of effort aspect of its comment, 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 determining high consequence events from 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 NRC staff reviewed the licensee's proposed standard using information available in literature and from the manufacturer, and concurred that the licensee's standard of 805 cm² of worker's skin or eye, for greater than 30 minutes, with dilute HF, will describe a high consequence HF exposure event. This standard was subsequently adopted by five out of the six fuel cycle facility licensees. Only the uranium enrichment licensee (Louisiana Energy Services) is not using the proposed standard.

More recently, one of the licensees (BWXT), proposed alternate high and intermediate consequence 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) discusses the applicability of the compliance exception in the 1985 final backfitting rule. In response to the Commission's direction in its November 29, 2016, staff requirements memorandum (ADAMS Accession No. ML16334A462), the NRC staff is updating its backfitting guidance, including guidance on applying the compliance exception to the backfit analysis requirement. Separately, the NRC staff had previously decided to limit application of the ISG to the review of applications for:

(1) new licenses, (2) the renewal of licenses, and (3) license amendments submitted pursuant to 10 CFR 70.72(d)(1), which include requests seeking approval of new facilities or new processes at existing fuel cycle facilities. Therefore, any imposition of the ISG by the NRC staff would constitute forward-fitting, not backfitting.

Additionally, NEI's June 2015 submittal (attachment 1) states that requiring dermal and ocular exposure standards represents a reinterpretation of Subpart H. 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. The NRC staff does not agree that in the NRC documents approving the ISA Summaries, the absence of any discussion regarding non-inhalation exposure demonstrates acceptance of what was an unstated industry assumption. The staff rejected such an assertion in its June 12, 2009, response to an NEI letter [as detailed in Enclosure 4 of this SECY package]. The current licensee ISAs and ISA Summaries contradict 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.

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 need for quantitative standards. The lack of guidance for any particular exposure pathway doesn't negate the requirements to identify and analyze all credible chemical hazards in the ISA. Just as examples in the NRC Enforcement Policy are neither exhaustive nor controlling (ADAMS Accession No. 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)(1)(ii) and (iii), regardless of how much NRC staff review 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)(1)(iv) and (v). These are existing requirements. Licensee concerns with a lack of guidance concerning dermal and ocular exposures are valid, and the ISG addresses those concerns. However, the lack of specific guidance doesn't limit the scope of the regulations or grant relief from the regulations.

Section 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 subject 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 documenting NRC staff follow up for 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 the NRC only issued Severity Level IV violations to the licensee in connection with the event.

The NRC 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 National Institute for Occupational Safety and Health 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 should not have been characterized as an intermediate or high consequence event, it was clearly a serious one and small differences 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).

Staff response: The NRC staff understands these concerns. The staff notes that there are different requirements applicable to OSHA-regulated hazards and NRC-regulated hazards. NRC regulations do not require that personal protective equipment (PPE) be identified as IROFS. Staff has previously discussed 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 a lock-out tag-out program, sense and flee procedures, etc.

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 highlighted 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 (ADAMS Accession No. 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 the subsequent enforcement process, the NRC's Office of Enforcement (OE) stated in its proposed February 2010 finding (ADAMS Accession No. 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 (ADAMS Accession No. 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 concluded that but for the timely and effective emergency and medical response, the operator would likely 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, OE also noted in its 2010 letter to BWXT that BWXT 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 (ADAMS Accession No. 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.

Staff response: The NEI proposal referenced by the commenter pertains to a 1996 NEI petition for rulemaking (PRM), specifically, PRM-70-7. As indicated by the commenter, this PRM considered only air pathways criteria, and identified hydrogen fluoride as the only chemical hazard that should be covered by the subpart H rule that was then being developed. In SECY-97-137, "Proposed Resolution to Petition For Rulemaking Filed by the Nuclear Energy Institute," (ADAMS Accession No. ML003672841), the staff rejected this approach, for the reasons detailed in SECY-97-137, Attachment 1, "Proposed Resolution to Petition for Rulemaking."

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)