CHRONOLOGY OF EVENTS RELEVANT TO THE DEVELOPMENT OF THE INTERIM STAFF GUIDANCE

This enclosure presents a chronology of events relevant to the subject of dermal and ocular exposures that is discussed in the interim staff guidance (ISG) document titled, "Guidance for the Evaluation of Acute Chemical Exposures and Quantitative Standards" (provided as Enclosure 1 of this package).

The chronology below includes: (1) a summary of the relevant Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H, rulemaking history that led to issuance of the final rule in 2000; (2) a discussion of the two Subpart H guidance documents the U.S. Nuclear Regulatory Commission (NRC) staff issued in 2001 and 2002; (3) the subsequent NRC staff approval of the initial integrated safety analysis (ISA) summaries and a summary of the NRC's 2007 information notice, as well as licensee actions taken in response to the 2007 notice; and (4) a discussion of the 2008-2014 correspondence between the Nuclear Energy Institute (NEI) and the NRC staff that preceded the NEI's initial backfit claim (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14086A270) in March 2014.

Chronology

In January 1986, a Model 48Y cylinder filled with uranium hexafluoride (UF_6) ruptured while it was being heated at the Sequoyah Fuels Corporation (SFC) facility in Oklahoma. The incident killed one worker and injured several others as a result of their exposure to hydrofluoric (HF) acid vapor, a corrosive and irritating reaction product of UF_6 and airborne moisture. As stated in the NRC's March 1986 report,[1] the primary pathways of acute exposure to HF acid include inhalation and direct contact with the skin and eyes. The SFC worker fatality was due to pulmonary edema. Several other SFC workers suffered HF acid skin burns, acute irritation of the eyes and mucosal surfaces, and acute respiratory irritation. As documented in the March 1986 report, NRC follow up to the January 1986 incident was the first time the agency had occasion to assess the effects of acute chemical exposures at an NRC-licensed facility.

As a result of the SFC accident and political inquiries, the NRC established an independent group, the Materials Safety Regulation Study Group (MSRSG), to assess the regulatory practices at fuel cycle facilities, including those regulated under 10 CFR Parts 40 and 70. The MSRSG concluded that there was a regulatory implementation gap regarding hazardous chemicals at NRC regulated facilities.[2] The SFC accident and the MSRSG conclusions led to the development of an interagency memorandum of understanding (MOU) between the NRC and the Occupational Safety and Health Administration (OSHA) that was published in the *Federal Register* (FR) on October 31, 1988 (53 FR 433950). This MOU clarified NRC

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1 U.S. Nuclear Regulatory Commission, "Assessment of the Public Health Impact from the Accidental Release of UF6 at the Sequoyah Fuels Corporation Facility at Gore, Oklahoma," NUREG 1189, Vol.1, March 1986 (ADAMS No. ML070080310), Section 6.2.1.1. ("Humans").

2 SECY-00-0111- Final Rule to Amend 10 CFR Part 70, Domestic Licensing of Special Nuclear Material. Attachment 9, "Part 70 Amendment Regulatory Analysis March 27, 2000". (ADAMS No. ML003715338).

responsibility for chemical hazards resulting from processing of licensed radioactive materials at NRC regulated facilities. The MOU defined this NRC responsibility to consist of chemical safety issues related to: (1) radiation risks of licensed materials; (2) chemical risks of licensed materials; and (3) plant conditions that affect or may affect the safety of licensed materials and thus present an increased radiation risk to workers. The later Subpart H rulemaking (finalized in 2000 as discussed below) added the definition of "hazardous chemicals produced from licensed materials" to 10 CFR 70.4, consistent with the 1988 MOU. The NRC staff notes that OSHA is preempted from enforcing any of its standards, rules, or other requirements with respect to chemical hazards at the nuclear facilities covered by NRC rules. The pertinent provision is in Section 4(b)(1) ("Applicability of This Act")[3] of the 1970 OSH Act which states the following:

> Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

After entering into the 1988 MOU with OSHA, the NRC began initiatives to exercise its regulatory authority over chemical hazards. On January 16, 1996, the NRC issued Inspection Manual Chapter (IMC) 2603, "Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities." This IMC established the inspection program for chemical safety oversight. In this IMC, the purpose statement defines NRC's responsibility for chemical safety and states that this includes:

> Chemical or physical hazards derived from hazardous materials, whether intimately involved with nuclear material operations or not, that can impact the ability of the plant operators to perform their duties. IMC 2603, page (p.) 1, paragraph 2, items 2 and 3.

Additionally, the IMC provides guidance on the type of information to be reviewed during an inspection which, includes process safety information such as the material safety data sheets, process description, and process flow diagrams. Each material safety data sheet provides information on toxicity and exposure pathways for the chemical it covers.

History of Subpart H

The Subpart H rulemaking record shows that chemical safety was a central concern of the NRC staff as the rulemaking progressed from its early stages in the mid-1990s to when the final Subpart H requirements were issued in 2000.

In April 1996, the NRC staff provided six rulemaking alternatives for the Commission's consideration in SECY-96-079, "Alternatives For Regulating Fuel Cycle Facilities." Alternative 3, "Amend the current Part 70 to include the performance of an ISA" laid the foundation of what became the 10 CFR 70, Subpart H requirements issued as a final rule in 2000. In a December 1996 SRM responding to SECY-96-079, the Commission directed the staff to factor into its SECY-96-079 analysis NEI's petition for rulemaking (PRM-70-7[4]) dated September 30, 1996.

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[3] See OSHA Act of 1970, Section 4, at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=OSHACT&p_id=3358.

[4] 61 FR 60058, November 26, 1996

Accordingly, the staff reviewed PRM-70-7 and re-examined the six alternatives presented in SECY-96-079. In May 1997, the staff submitted SECY-97-097, "Additional Alternative for Regulating the Safety of Fuel Cycle Facilities: Nuclear Energy Institute Petition for Rulemaking," to the Commission (ADAMS Accession No. ML992920141), and in June 1997 the staff submitted SECY-97-137 [5] evaluating the PRM-70-7 approach. This PRM considered only air pathways criteria, and identified hydrogen fluoride as the only chemical hazard that should be covered by the rule. The staff rejected this position in SECY-97-137, Attachment 1, "Proposed Resolution to Petition for Rulemaking," stating in relevant part as follows:

> Further, the ISA will need to identify and consider all radiological and non-radiological hazards related to the processing of licensed material. With regard to non-radiological hazards, the Petition would limit consideration of chemical hazards to those associated with hydrogen fluoride. Staff's view is that chemicals other than hydrogen fluoride will need to be considered. Specific consequence limits will be established during the rulemaking process. In establishing these limits, staff will consider the Petition's recommendations and the relevant requirements of NRC, OSHA, and EPA. Staff agrees that worker safety (i.e., accidental exposure of a worker to radiological or chemical hazards) is an important issue and plans to address it in the proposed rule. The ISA requirement is intended to focus on the identification of potential accidents and the items relied on to prevent or mitigate the consequences of those accidents.

Attachment 1 to SECY-97-137, at p. 7.

In Attachment 2 to SECY-97-137 ("Summary of Staff's Proposed Resolution to Petition for Rulemaking), the staff further stated that contrary to PRM-70-7, criteria for hazardous chemicals would not be limited to hydrogen fluoride, and that such criteria would address "accidental exposures of a worker to radiological or chemical hazards (i.e., worker safety)." Attachment 2 to SECY-97-137, at p. 3.

In an SRM dated August 22, 1997, the Commission approved the staff's proposal to revise Part 70 and directed the staff to submit a draft proposed rule by July 31, 1998. The staff forwarded a draft proposed rule to the Commission in SECY-98-185, "Proposed Rulemaking—Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated July 30, 1998 (ADAMS Accession No. ML992910107). This proposed rule included a discussion of air pathway concentration limits (i.e., Acute Exposure Guideline Limits (AEGL) and Emergency Response Planning Guidelines (ERPG) values) along with a more general discussion of effects (e.g., exposure to hazardous chemicals at concentrations that would cause death or life-threatening injuries). The Commission issued SRM-98-185 on December 1, 1998 ("Proposed Rulemaking—Revised Requirements for the Domestic Licensing of Special Nuclear Material," ADAMS Accession No. ML003755356), directing the staff not to publish the proposed rule for public comment. Instead, the Commission directed the staff to obtain further stakeholder input and revise the draft proposed rule to clarify the basis for use of chemical safety and chemical consequence criteria in the rule, particularly within the context of the 1988 MOU with OSHA.

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[5] SECY-97-137, "Proposed Resolution to Petition For Rulemaking Filed by the Nuclear Energy Institute", June 30, 1997, ADAMS Accession No. ML003672841.

Accordingly, in June 1999, a revised proposed rule was submitted to the Commission in SECY-99-147, "Proposed Rulemaking Domestic Licensing of Special Nuclear Material," (ADAMS Accession No. ML992850039). Shortly thereafter, the Commission approved publication of the proposed rule for public comment ("SRM-SECY-99-147-Proposed Rulemaking—Domestic Licensing of Special Nuclear Material," ADAMS Accession No. ML991900004), and it was published in the *Federal Register* on July 30, 1999. The 1999 proposed ISA rule reflected a performance-based "all chemical hazards approach," under which licensees would be responsible for identifying and addressing all acute chemical exposures that are credible and that could result in intermediate to high consequences. This approach is reflected in the following excerpt from the 1999 Statement of Considerations (SOC):

> Section 70.61(b)(4). An acute chemical exposure to hazardous chemicals produced from licensed material at concentrations that either (1) could cause death or life-threatening injuries to a worker; or (2) could cause irreversible health effects to an individual located outside of the controlled area, is considered a high consequence event. Chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures (i.e., a single exposure or multiple exposures occurring within a short time—24 hours or less) have been developed, or are under development, by a number of organizations. Of particular interest, the National Advisory Committee for Acute Guideline Levels for Hazardous Substances is developing Acute Exposure Guideline Limits (AEGLs) that will eventually cover approximately 400 industrial chemicals and pesticides.
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> The qualitative language in the performance requirement allows the applicant/licensee to propose and adopt an appropriate standard, which may be an AEGL or ERPG [Emergency Response Exposure Guideline] standard, or where there is no AEGL or ERPG value available, the applicant may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals.

64 FR 41338 (July 30, 1999), at 41343.

As published for comment in 1999, the performance requirements included provisions in 10 CFR 70.61(b)(4) and (c)(4) addressing acute chemical exposures that could affect either workers or members of the public (i.e., individuals located outside the controlled area). The 1999 proposed rule also addressed the required contents of ISA summaries in 10 CFR 70.65(b). The required contents of ISA summaries included descriptions of proposed quantitative standards to assess the consequences arising from credible high-consequence and intermediate-consequence events, and in this regard the proposed 10 CFR 70.65(b)(7) provision referenced the 10 CFR 70.61(b)(4) and (c)(4) performance requirements. The 1999 wording of the proposed 10 CFR 70.61(b)(4) and (c)(4) provisions, and the wording of the proposed 10 CFR 70.65(b)(7) provision, was retained without change in the final rule. The wording of these provisions remains the same today, and the staff's interpretation of these requirements has not changed in the 16 years that Subpart H has been in place.

The SOC for the final rule, 65 FR 56211 *et seq*. (September 18, 2000), includes an explanation of the changes made to the final rule in response to comments on the proposed rule. No changes in the 1999 proposed requirements regarding acute chemical exposures stated in

10 CFR 70.61(b)(4), 70.61(c)(4), and 70.65(b)(7) were made in the final rule issued in 2000. The SOC's section-by-section analysis summarized the 10 CFR 70.61 performance requirements as follows:

> This section identifies the performance requirements that licensees subject to Part 70, Subpart H must satisfy. These performance requirements explicitly address the risks to workers or members of the public and the environmental releases caused by accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the Part 70 changes seek to ensure adequate protection of workers, members of the public, and the environment by limiting the risk (product of likelihood and consequence) of such accidents. If, without the implementation of controls, a high consequence event under § 70.61(b) is highly unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule. Similarly, if, without the implementation of controls, an intermediate consequence event under § 70.61(c) is unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule.

65 FR at 56222.

In sum, the ISA requirements were added to the 10 CFR Part 70 regulations in 2000 to obtain increased confidence in the margin of safety at fuel cycle facilities.[6] These Subpart H regulations were specifically intended to complement and be consistent with similar OSHA and EPA regulations,[7] and cover operations not covered by the OSHA regulations.

Guidance Documents

The staff's initial guidance for implementing the 2000 final ISA Rule is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document," that was published in May 2001 (ADAMS Accession No. ML011440260). Section 2.6, "Conducting the ISA," addresses the scope of the licensee's analysis to ensure compliance with 10 CFR 70.61, specifically, that all credible radiological, nuclear criticality, and certain chemical consequences that can affect worker or public safety are considered in an ISA's development. Section 2.6.1.1, "Consequences of Concern," states as follows regarding the consideration of chemical hazards:

> In particular, section 70.61 of NRC's revision to Part 70 defines two categories of consequences of concern to the ISA, high consequence and intermediate consequence events. High consequence events are defined in terms of specific exposure levels or health effects to workers and persons off-site. In particular, they include any acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:
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> (i) Could endanger the life of a worker, or

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6 SECY-00-0111- Final Rule to Amend 10 CFR Part 70, Domestic Licensing of Special Nuclear Material. Attachment 9, "Part 70 Amendment Regulatory Analysis March 27, 2000." ADAMS No. ML003715338.

7 64 FR at 41340, July 30, 1999, third column.

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area.

NUREG-1513, p. 10-11.

The NUREG-1513 discussion does not suggest that a licensee's evaluation of chemical effects is limited to those arising from the inhalation exposure pathway, or that hydrogen fluoride was the only chemical of concern. Nor does the NRC guidance suggest that dermal or ocular exposure pathways are excluded from consideration.

The NUREG-1513 guidance includes Tables 2.1 and 2.2, which provide a "comprehensive list of process safety information that may be needed to perform an ISA." NUREG-1513, p. 12. Table 2.2, "Common Material Property Data for Hazard Identification," contains a list of material properties to be assessed when determining hazards and consequences of hazardous chemicals that are within the scope of NRC jurisdiction at a fuel cycle facility. NUREG-1513, p. 14. Dermal toxicity is specifically listed in Table 2.2 (column 1, under "Acute Toxicity" and "Chronic Toxicity"). This demonstrates a consistent NRC position that ISAs should consider all credible chemical hazards associated with licensed material (not just those associated with the inhalation pathway).

In March 2002, NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (ADAMS Accession No. ML12205A492) (NUREG 1520), was published. Section 3 of NUREG-1520, "Integrated Safety Analysis (ISA) and ISA Summary," reflects the concept that the fuel cycle facility licensee should evaluate a broad range of chemical hazards in developing the ISA, and that a licensee's evaluation of chemical hazards should not be limited to those arising from the inhalation exposure pathway.

In particular, Section 3.4.3.2 (7), "Quantitative Standards for Chemical Consequences," contains an extended discussion of the staff's review criteria for acute chemical exposures. NUREG-1520, p. 3-22 through 3-23. As with the NUREG-1513 guidance discussed above, the NUREG-1520 guidance does not suggest that a licensee's evaluation of chemical risks is limited to those involving hydrogen fluoride, or is limited to consideration of effects arising from the inhalation exposure pathway. Similarly, the NUREG-1520 guidance does not suggest that dermal or ocular exposure pathways are excluded from consideration.

NRC Approval of the Integrated Safety Analysis Summaries and Information Notice 2007-022

During the implementation phase of the Subpart H requirements, existing licensees were required by 10 CFR 70.62(c)(3)(ii) to submit their ISA summaries for NRC approval within 4 years of the rule's effective date. The ISA summaries were approved based on staff review of: (1) whether the applicant's commitments to establish a safety program and to perform and maintain an ISA are adequate; and (2) the appropriateness and adequacy "of the ISA method(s) and completeness of the ISA and accuracy of analysis of accident sequences via horizontal and vertical slice reviews." NUREG 1520, at p. 3-32. The entire ISA was not reviewed during the staff's onsite ISA evaluations; rather, consistent with the review guidance in NUREG-1520, the staff's review of ISAs and ISA summaries focused on a sample of selected processes.

Given the 10 CFR 70.62(c) requirement that a licensee "conduct and maintain" its ISA, and the implementing guidance summarized above, the NRC staff's expectation was that fuel cycle

facility licensees would take into account new information on potential chemical exposures arising from operational experience when updating their ISAs and ISA summaries. ISA summary approvals did not imply that ISA analyses were frozen in time.

In 2007, the NRC staff issued Information Notice (IN) 2007-22, "Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities" (ADAMS Accession No. ML071410230). The IN explained that hydrogen fluoride (HF) presents a hazard in different stages of the nuclear fuel cycle. The IN reported two exposure events that had occurred in fuel cycle facilities regarding acute chemical exposures, including one dermal exposure (ADAMS Accession Nos. ML072620314 and ML070650158). The IN pointed out that HF represented both a dermal and inhalation hazard and that ISAs should consider both catastrophic and smaller releases. The IN also stated that it was not imposing any new NRC requirements.

Following the 2007 issuance of IN 2007-22, several fuel cycle facility licensees began properly classifying potential HF exposure events, including those involving the dermal and ocular exposure pathways. Licensees modified their ISA summaries to include quantitative standards for dermal and ocular exposures to HF at their facilities, and these standards have been reviewed and approved by the NRC staff. Specifically, in January 2009, Nuclear Fuel Services was the first fuel fabrication licensee to propose a quantitative standard for dermal and ocular exposure to HF, and this standard was based on available toxicity information. This standard was approved by the NRC in May 2009 (ADAMS Accession No. ML090490686), and was subsequently adopted by the other four fuel fabrication licensees. In June of 2015, BWXT proposed to revise its standard for dermal and ocular exposures to HF identified in its ISA summary. The quantitative standard proposed by BWXT was also based on available toxicity information. In August 2015, the staff approved the BWXT standard. (ADAMS Accession No. ML15226A610).

2008-2014 *Correspondence Between NRC Staff and NEI*

By letter dated September 8, 2008 (ADAMS Accession No. ML083360632), NEI stated that the industry had addressed internal (i.e., inhalation) chemical exposures in its ISAs, and that the NRC appeared to be addressing the issue of chemical dermal exposures at fuel cycle facilities on a licensee-by-licensee basis without the benefit of industry input. NEI expressed its willingness to participate in a working group to develop guidance for addressing dermal exposures, stating that such guidance would, "facilitate a consistent, industry-wide acceptable approach to addressing chemical skin exposures at fuel cycle facilities if needed." Prior to its receipt of this 2008 letter, the NRC staff was not aware of any industry position that dermal exposure events need not be considered when estimating event consequences as part of the ISA development process. This position had not been stated in any previous ISA summaries that had been approved by the staff.

In its response to the NEI letter dated November 10, 2008 (ADAMS Accession No. ML082900889), the NRC staff recognized the need to provide, "greater clarity in our guidance" by developing "a uniform approach to accident scenarios, exposure pathways, health effects, and consequence thresholds," and added that such guidance could include revising the

Standard Review Plan (NUREG-1520), or developing an interim staff guidance document. November response, at 1. The staff further stated as follows:

> However the lack of guidance does not mitigate the hazard to workers nor eliminate the requirement for the licensee to propose standards in accordance with 10 CFR 70.65. As a result, the staff will continue to work with licensees on a case by case basis using the best available information to ensure that the requirements of 10 CFR Part 70 are met and that workers are adequately protected from the risk of acute chemical exposures from the licensed materials or hazardous chemicals produced from licensed material, including dermal exposures to hydrofluoric acid.

November 2008 response, at 1-2.

Characterizing the staff's position described in its November 10, 2008, response as an "apparent new interpretation" of Subpart H requirements, NEI stated in its February 2009 letter (ADAMS Accession No. ML090690732) that the subject regulations had been interpreted by NEI to require that licensees propose quantitative standards only for individuals outside of controlled areas as specified in 10 CFR 70.61(b)(4)(ii) and (c)(4)(ii), and not for workers. NEI requested the NRC staff to provide the regulatory basis that 10 CFR 70.61 and 70.65 require the development of quantitative standards for dermal exposures of workers, stating in relevant part that it did not "interpret 10 CFR 70.65(b)(7) to modify 10 CFR 70.61 to further require" NRC licensees to propose quantitative chemical exposure standards for workers. February 2009 letter, at 2.

In its response dated June 12, 2009 (ADAMS Accession No. ML090920296), the NRC staff concluded that its interpretation and implementation of the Subpart H regulations remained "unchanged." The staff noted that the pertinent performance requirements for workers are specified in the 10 CFR 70.61(b)(4)(i) and (c)(4)(i) regulations – provisions NEI did not reference in its February 2009 letter – and that 10 CFR 70.65(b)(7) references both the 10 CFR 70.61(b)(4) high consequence events and the 70.61(c)(4) intermediate consequence events, without distinguishing between workers and members of the public. See June 2009 response, at 1. The staff further stated as follows:

> Your letter asserts that the NRC staff implicitly agreed with industry's interpretation (i.e., that the Commission's regulations only require the evaluation of internal chemical exposures) when staff approved past site-specific ISA Summaries. I note for your information that the staff's approval of an ISA Summary is based on the Summary's compliance with the minimum content requirements listed in 70.65(b), conformance with the site's previously-approved ISA plan and methodology, and examination of a sample of risk significant scenarios in an on-site "vertical slice" review.
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> The NRC staff has examined several prior approved ISA Summaries, and has determined that contrary to your claims, a number of these summaries address both internal and external chemical exposures, and some make specific reference to hydrofluoric acid spills and/or dermal exposures.

June 2009 response, at 1-2.

After detailing examples of licensee ISAs or ISA Summaries such as those addressing (1) liquid hydrofluoric acid (HF) spills involving personnel exposure to liquid HF; (2) exposures to wet nitric acid and HF; and (3) a postulated large spill of HF that could result in serious injury to a worker from both inhalation (respiratory) and contact (skin) exposure, the NRC staff concluded as follows:

> As these examples demonstrate, the industry and the staff have previously considered chemical exposures to the skin, including exposure to liquid HF, and therefore there was no implicit staff agreement with the interpretation you advocate in your letter.
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> … As indicated above, there has been no new or revised interpretation of Part 70, nor has NEI provided specific reference, citation, or evidence to support its contentions otherwise.

June 2009 response, at 1-2.

As a follow-up response to areas of concern identified at a November 2009 public meeting between the NRC staff and industry representatives discussing the matter of dermal/ocular chemical safety hazards, the staff sent NEI another letter dated August 16, 2010 (ADAMS Accession No. ML093440038) regarding: (1) the need for worker quantitative standards; (2) the staff's position on mitigation; and (3) whether definitions of "serious long lasting health effects" and "mild transient health effects," as used respectively in the 10 CFR 70.61(b)(4)(ii) and (c)(4)(ii) regulations, should be established.

In 2013, the NRC staff held a public meeting with industry to present a proposed approach for identifying dermal and ocular exposure standards (ADAMS Accession No. ML13262A131). The staff reiterated its willingness to work with industry in developing guidance regarding this issue.

The NRC staff's interpretation of the requirements of 10 CFR Part 70, Subpart H has not changed, and the regulatory wording has not changed since the final rule was established in 2000. The NRC adopted Subpart H as a set of performance-based requirements which are not limited to specific exposure pathways. Instead, the NRC's regulatory approach embodied in Subpart H requires the applicant/licensee to identify and justify in the ISA summary the relevant and credible exposure pathways.

On March 26, 2014, NEI sent a letter (ADAMS Accession No. ML14086A270) to the NRC stating that the ISA need only consider inhalation pathways when analyzing for acute chemical exposures. The letter stated NEI's position that requiring licensees to develop dermal and ocular exposure standards "is impractical, unnecessary and constitutes an unanalyzed backfit," and that one of the "fundamental tenets" supporting its backfit claim was the fact that 10 CFR Part 70 "does not explicitly require the development of dermal or ocular quantitative exposure limits for workers." March 26, 2014, cover letter, at 2. The attachment to NEI's March 2014 letter (ADAMS Accession No. ML14086A271) stated that the NRC staff's "approval of site specific analyses (i.e., ISA summaries only analyzed inhalation exposures) reflects a clear position that the regulation was not interpreted to require the development of quantitative dermal and ocular exposure limits for workers at the time the approvals were issued." NEI attachment, at 5.

Regarding this initial NEI backfit claim, the staff notes that 10 CFR Part 70 also does not explicitly require the development of quantitative inhalation exposure limits for workers. The previous staff review and approval of dermal and ocular standards for HF exposure (as summarized above in this section), as well as the proposed ISG, demonstrate the staff's willingness to review proposed quantitative standards using existing data. This shows that development of such standards does not require extensive animal and human testing. Thus, the NEI's backfit argument is contradicted by the fact that as of March 2014, licensee submittals describing proposed quantitative standards had already been reviewed and approved by the staff in accordance with 10 CFR 70.65(b)(7).

By letter dated September 15, 2014 (ADAMS Accession No. ML14251A150; enclosure: ML14251A149), the NRC staff responded to NEI's backfit claim. The staff concluded that: (1) NEI had not identified any NRC action falling within the 10 CFR 70.76(a)(1) definition of a backfit; and (2) even assuming issuance of the ISG (that was then being drafted) would be a backfit, none of NEI's arguments establish a legal bar negating the staff's reliance on the 10 CFR 70.76(a)(4)(i) compliance exception. NEI's November 7, 2014, letter (ADAMS Accession No. ML14322B019) and its June 2015 comments (ADAMS No. ML15189A076) on the draft ISG, largely reiterated its March 2014 backfit claim. To the extent that these two NEI submittals made new backfit arguments, the staff addresses them in Enclosure 2 of this paper.