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NUCLEAR ENERGY INSTITUTE

Ms. Margaret Doane
Office of the General Counsel
United States Nuclear Regulatory Commission
Mail Stop: 15D21
Washington, DC 20555-0001

Dear Ms. Doane:

I am writing to express my concern regarding the staff's response to a March 26, 2014, letter submitted by the Nuclear Energy Institute (NEI)[1] addressing the requirements contained in 10 C.F.R. § 70.65.[2] In the March Letter, NEI asserted that the staff's position requiring certain Part 70 licensees to create quantitative standards evaluating dermal and ocular exposure to chemicals constitutes an unanalyzed backfit.

The staff addressed the issues raised by NEI in a letter dated September 15, 2014.[3] Unfortunately, the September Letter does not adequately respond to NEI's concerns. Rather, the rationale put forth by the staff raises additional, generic concerns regarding the agency's implementation of the backfitting requirements contained in section 70.76. Specifically, the September Letter mistakenly asserts that if a regulation contains a performance-based standard, the staff may reinterpret what specific licensee actions are required to meet that standard without complying with the analytical requirements of section 70.76. Based on this flawed premise, the staff concludes that its admittedly new position requiring the development of quantitative dermal and ocular exposure standards is, in fact, not a change at all; and, even if it were, that it is a compliance backfit.

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[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

[2] Letter from J.R. Schlueter (NEI) to M.G. Bailey (NRC), *Dermal and Ocular Quantitative Exposure Standard – Current Industry Programs are Adequate and NRC Proposed Approach is Impractical, Unnecessary, and Constitutes an Unanalyzed Backfit*, March 26, 2014 ("March Letter").

[3] Letter from M.G. Bailey (NRC) to J.R. Schlueter (NEI), *Response to March 26, 2014, Nuclear Energy Institute Letter on Dermal and Ocular Quantitative Exposure Standard*, Sept. 15, 2014 ("September Letter").

Definition of Backfitting

Although the purpose of the September Letter is apparently to provide a documented evaluation for invocation of the compliance exception, it begins by asserting that "[n]either the relevant Subpart H requirements, nor the NRC's interpretation of these requirements, has changed."[4] But just a few pages later, the staff concedes – as asserted in NEI's March Letter – that licensee ISA Summaries were approved by the NRC "without consideration of dermal or ocular exposures."[5] Although Subpart H of 10 C.F.R. Part 70 may be performance-based, the staff's current position is clearly different from the position taken when licensees' ISA Summaries were approved. Thus, the staff's current position that Part 70 licensees must modify approved ISAs to include quantitative exposure standards for dermal and ocular exposures is clearly a "regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position."[6] Further, if this regulatory staff position is imposed on Part 70 licensees generically, it would require licensees to modify their ISAs, which are certainly "procedures . . . required to operate a facility."[7]

Thus, the staff's current position that licensees must develop quantitative dermal and ocular exposure standards, and modify their ISAs to incorporate such standards, clearly meets the definition of backfitting provided in section 70.76.[8]

The Compliance Exception

Turning to the applicability of the compliance exception, the September Letter seems to argue that because the staff now believes that quantitative exposure standards for the dermal and ocular exposure pathways are required to comply with the broad performance objectives of section 70.61, the compliance exception may be invoked to excuse the staff from meeting the standard provided in section 70.76(a)(3). In other words, the September Letter seems to argue that the compliance exception applies because the staff now believes that quantitative dermal and ocular standards are required for compliance. This logic is circular and so vague that it would render the substantive requirements of section 70.76 inapplicable to any reinterpretation of what the staff believes is required to comply with broad, performance-based standards.

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[4] September Letter, at 1.

[5] September Letter, at Encl. pg. 3.

[6] 10 C.F.R. § 70.76(a)(1).

[7] Id.

[8] "Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position." 10 C.F.R. § 70.76(a)(1).

The Commission precisely explained the purpose of the compliance exception in the 1985 final rule promulgating the modern iteration of the backfitting provisions contained in 10 C.F.R. § 50.109, stating:

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.[9]

There was no omission or mistake of fact that prompted approval of licensee ISA Summaries without quantitative standards for dermal and ocular exposures. To the contrary, the September Letter concedes that the ISA Summaries were approved "without consideration of dermal or ocular exposures," and provides the staff's rationale for those approvals, stating:

At the time of NRC approval of the original ISA summaries, the air pathway was: (i) the only exposure pathway that was considered by industry and reviewed by NRC to have the potential for offsite consequences, and (ii) the more dominant (but not exclusive) pathway for worker exposure following an accident. Accordingly, during the 2005-2007 timeframe, ISA summaries were approved without explicitly documenting a finding on dermal and/or ocular exposure. Approval of the initial ISA summaries without consideration of dermal or ocular exposures was consistent with the performance-based requirements of 10 CFR 70.61.[10]

So, according to the staff's own rationale, the original position taken by the agency – which was to approve the ISA Summaries without quantitative dermal and ocular exposure standards –was a conscious decision based upon the idea that the air pathway was the more dominant (although not exclusive) exposure pathway. Far from arguing that its original approvals were the result of an omission or mistake of fact based on what the agency and licensees knew when those approvals were issued, the September Letter explains that operating experience accumulated after the ISA Summaries were approved has, in essence, caused the staff to reinterpret what licensee actions are required to comply with Subpart H. According to the Commission's prescient explanation quoted above, this is precisely the type of "new or modified interpretation[] of what constitutes compliance [that] would not fall within the exception."

Conclusion

In sum, industry continues to believe that the staff's position that certain fuel cycle licensees must now develop quantitative standards in order to comply with Subpart H to 10 C.F.R. Part 70 is a backfit and that the compliance exception does not apply. The explanation provided in the September Letter is not

[9] 50 Fed. Reg. 38,103 (Sept. 20, 1985).

[10] September Letter, at Encl. pg. 3.

responsive to the issues raised in NEI's March Letter and, for the reasons outlined above, does not constitute an adequately documented evaluation supporting invocation of the compliance exception.

I respectfully request that the staff and your office reconsider the response provided in the September 15 Letter and evaluate the staff's new or modified interpretation of the Subpart H requirements pursuant to sections 70.76(a)(3) and (b), prior to imposing this interpretation on licensees. Further, if the staff declines to modify its position on this issue, I respectfully request that the Interim Staff Guidance currently being developed by the staff be formally reviewed by the Committee to Review Generic Requirements prior to being issued in draft for public comment.

I would welcome the opportunity to discuss industry's concerns regarding this matter at your earliest convenience.

Sincerely,

Ellen C. Ginsberg

Ellen C. Ginsberg

Enclosures

cc: Catherine Haney, NMSS

Enclosure 1

JANET R. SCHLUETER
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NUCLEAR ENERGY INSTITUTE

March 26, 2014

Ms. Marissa G. Bailey
Director
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Dermal and Ocular Quantitative Exposure Standard – Current Industry Programs are Adequate and NRC Proposed Approach is Impractical, Unnecessary, and Constitutes an Unanalyzed Backfit

Project Number: 689

Dear Ms. Bailey:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)[1] has appreciated the recent public interactions with the U.S. Nuclear Regulatory Commission (NRC) staff on October 3, 2013, and March 5, 2014. Specifically, our discussions regarding the feasibility of developing quantitative standards for dermal and ocular chemical exposure events involving workers at NRC-regulated fuel cycle facilities. The industry's goal is the same as NRC's, to fully resolve this matter in the very near future.

It has been six years since this issue was first raised. Since then, we have mutually expended resources to conduct a detailed and thorough review of the regulations, related guidance, NRC's recent research, national standards, industry work practices and in-depth discussions with and research by industrial hygienists. As a result, we believe that NRC must reconsider its position that would require licensees to develop dermal and ocular quantitative exposure standards for workers. We recognize that the staff has been directed by the Commission to issue draft guidance for comment. However, industry believes that our collective attention and resources should be focused on issues that are of higher significance. Such a step would be consistent with the NRC's Principles of Good Regulation and the on-going cumulative effects initiatives.

[1] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

We found the staff's October 2013 draft white paper on this topic to be complete in its references and discussion. However, the fact remains that no scientifically-credible dermal and ocular quantitative exposure standard for workers exists or can be established absent extensive primary research including both animal and human studies for each chemical of concern. The NRC staff's research, as well as the industry's supports the following conclusions:

1) the facility-specific worker protection programs in place today are adequate to protect workers and meet the intent of the rule;
2) there are no existing scientifically-credible standards available to implement; and
3) requiring licensees to develop new quantitative dermal and ocular exposure standards is impractical, unnecessary and constitutes an unanalyzed backfit.

The attachment provides additional details and the basis for industry's conclusions and position, and is based on the following fundamental tenets:

- Part 70 does not explicitly require the development of dermal or ocular quantitative exposure limits for workers.
- Rather, the facility-specific Integrated Safety Analyses (ISAs) established quantitative inhalation exposure standards for workers. Dermal and ocular exposures are addressed via strong demonstrated historical licensee chemical safety programs consistent with chemical industry practices. During the fall 2009 NRC public meeting, OSHA indicated that this is their approach and practice as well.
- Through the ISA development process, NRC accepted the industry's position that dermal and ocular exposures for the public were not credible, and thus only inhalation standards were developed for members of the public as well.
- The performance-based approach to demonstrate compliance with the Part 70 performance objectives is consistent with the intent of the original Part 70 rule promulgated in 2000.
- Any further guidance provided by the NRC via letters to NEI (2008-2010) and NUREG-1520, Revisions 0 and 1 (2002; 2011) were developed and issued after the rule went into effect and after the facility-specific ISA methodologies and summaries were submitted to and approved by NRC.

Industry's Recent Research

Both prior to and after the October 3, 2013, public meeting, industry representatives have spent considerable time working with senior facility experts (e.g., industrial hygienists) to determine the feasibility of developing quantitative dermal and ocular standards for workers exposed to all chemicals in a facility's inventory (over 20 chemicals at some sites). More specifically, the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (GHS) categories do not easily translate to the Part 70

event consequence categories since they were developed for a different purpose. Further, all the chemicals mentioned in the staff's white paper were acids. Acids behave differently than many other chemicals used at fuel facilities due to the mechanisms of interaction with body tissues (e.g., acids destroy tissue so dermal absorption modeling is impractical). Finally, while we recognize that a few facilities have a quantitative worker exposure standard in place for hydrofluoric acid; this standard may not be bounding for other chemicals in use today at all fuel facilities.

Related Part 40 Rulemaking

During the proposed Part 40 rulemaking, industry suggested that NRC modify Part 40 and make conforming changes to Part 70 to full resolve the issue of the appropriate exposure standard for workers.[2] Specifically, the industry suggested that proposed 10 CFR 40.81(b)(4) and (c)(4) be modified to read: "an acute chemical exposure from inhalation" and that conforming changes be made to Part 70.61(b)(4) and (c)(4) to clarify and acknowledge that the appropriate exposure pathway for the worker is inhalation, not the dermal or ocular exposure pathway. Industry continues to support this suggestion if NRC were to opt to resolve this issue through rulemaking.

We trust that we can continue these discussions in the near future and reach a mutually acceptable resolution. If you have any questions, please feel free to contact me or Andrew Mauer (202-739-8018; anm@nei.org).

Sincerely,

Janet R. Schlueter

Attachment

c: Ms. Catherine Haney, NMSS, NRC
Mr. Anthony T. Gody, Jr., R-II/DFFI, NRC
Mr. Geary S. Mizuno, OGC/GCLR/RMR, NRC

[2] Letter from J. Schlueter, NEI to A. Vietti-Cook dated September 9, 2011, Industry comments on Domestic Licensing of Source Material.

Technical Basis for Industry Position that Development of New Quantitative Dermal and Ocular Exposure Standards for Workers is Impractical, Unnecessary and Constitutes an Analyzed Backfit

The NRC has taken the position that 10 C.F.R. § 70.65(b)(7) requires the development of quantitative standards for dermal and ocular chemical exposure of workers to licensed material, or chemicals produced from licensed material, that are either on-site or expected to be on-site at fuel cycle facilities licensed pursuant to 10 C.F.R. Part 70, Subpart H.[1] As explained in more detail below, the industry continues to believe that development of such quantitative worker exposure standards is both impractical and unnecessary. Further, imposition of this position on Part 70 licensees, after approval of facility-specific Integrated Safety Analysis (ISA) Summaries pursuant to section 70.66, is an unanalyzed backfit, as defined in section 70.76. We address each of these issues in greater detail below.

(1) Development of Quantitative Dermal and Ocular Exposure Standards is Impractical and Unnecessary

Impracticality

- The NRC has no regulatory guidance on how to develop such standards. The NRC has no acceptance criteria (other than the SRP, which does not require development of dermal/ocular standards) for evaluating the adequacy of such standards.
- During the Occupational Safety and Health Administration's (OSHA) 1992 final rule on occupational exposure to 4,4' Methylenedianiline (MDA), the agency declined to adopt a quantitative dermal exposure standard, despite the importance of reducing dermal exposure to the chemical.[2] The final rule explains:

> "While OSHA was able to make estimates of risks which might result from dermal exposure, OSHA was unable to establish allowable exposure limits. There are a number of reasons why this is impractical, among which are the difficulty of quantifying dermal exposures, the inability to select a reliable biological indicator, and finally the difficulty in correlating the amount absorbed with a precise adverse health effect.[3]"

Although the agency could not quantify a dermal exposure limit, OSHA concluded that worker safety could be ensured by other means.

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[1] *See* Letters from D. Dorman (NRC) to F. Killar (NEI), "Chemical Exposures at Fuel Cycle Facilities Licensed by the U.S. Nuclear Regulatory Commission," dated Nov. 10, 2008, Letter from M. Tschiltz (NRC) to F. Killar, (NEI) dated June 12, 2009, Letter from M. Tschiltz (NRC) to J. Schlueter (NEI) dated August 16, 2010.

[2] In the evaluation of benefits provided in the final rule, OSHA stated: "A significant proportion of the estimated lives saved are the result of the reduction in dermal exposure, whereas the reduction in airborne exposure levels makes a much smaller contribution to the reduction in risk." Occupational Exposure to 4,4' Methylenedianiline (MDA): Final Rule, 57 Fed. Reg. 35630, 35643 (Aug. 10, 1992).

[3] Id. at 35637.

- Dermal and ocular exposures are addressed via licensee chemical safety programs consistent with chemical industry practice. For example, OSHA addresses dermal/ocular exposures through programs requiring use of Personnel Protective Equipment (PPE), hygiene practices and (in some instances) medical monitoring.
    - "Although it is true that many of the reported cases of occupational illnesses are skin disorders, OSHA believes that reducing employee airborne exposures will contribute to a reduction in the number of cases of dermatitis. As a general rule, workplaces that have many cases of dermatitis are also more likely to use poor work practices and to be lacking in engineering controls; such facilities will have higher airborne exposures. On the other hand, a well-engineered facility with low airborne exposures generally also controls its employees' dermal/ocular exposures, and therefore has few, if any, cases of dermatitis. Therefore, OSHA believes that promulgation of these exposure limits for air contaminants will encourage the use of improved work practices, which will, in turn, reduce the incidence of dermatitis."[4]
    - During the fall 2009 NRC public meeting, OSHA representatives discussed this very point and stipulated they were not aware of any such dermal or ocular quantitative standards; and that their approach is through prevention using good material condition programs to maintain containment integrity and PPE to prevent risk of exposure in upset or maintenance functions.
- Personnel Exposure Limits (PELs) are for controlling inhalation exposure and the risk profiles between inhalation and dermal/ocular exposures are different. Specifically, a dermal/ocular exposure is self-identifying and its source is self-evident, e.g., leak, rupture. An atmospheric exposure via inhalation cannot be self-evident all the time and can occur over a period of time. Therefore, prevention of dermal/ocular exposures is more easily performed, e.g., system integrity, PPE and needs no special detection equipment.
- Also, expert bodies other than OSHA (e.g., American Conference of Governmental Industrial Hygienists, U.S. Environmental Protection Agency, National Institute for Occupational Safety and Health, etc.) have not developed quantitative dermal/ocular exposure standards due to its extreme difficulty, complexity, and the unwarranted burden associated with doing so. While there is toxicological data available regarding such exposures, that data has not been translated into generally applicable and accepted exposure standards.
- Finally, professional organizations and federal agencies with extensive experience studying and regulating chemical exposures have not been able to or determined a need to develop such standards for widespread use. Therefore, it is not a matter of simply filling a guidance gap but rather the recognition that it is not practical or possible or even necessary, from a worker or public health and safety perspective, to do so.

[4] 54 FR 2332, 2778 (Jan. 19, 1989)

Unnecessary

The fuel cycle facilities, as well as the at-large chemical industry, have applied practices and methods to maintain safe working environments with clearly hazardous materials for decades of time.

- The fuel cycle industry does not believe that the development of quantitative dermal/ocular exposure standards is necessary: (1) to ensure worker safety at fuel cycle facilities, or (2) to adequately characterize consequences pursuant to 70.61.
- Licensees often use a three-layered approach to their industrial hygiene safety program. The first layer is "equipment integrity" to contain the chemicals so that employees are not exposed in such a manner that could cause intermediate or high consequence events, and, as appropriate, this integrity may be called out within the context of the ISA as an IROFS with management measures applied. The second is the PPE that employees wear to protect them while performing tasks and during upset conditions that could expose them to chemicals (e.g. respirators, safety glasses with side shields, face shields, coveralls, aprons, gloves, etc.). The last layer is the "mitigating actions" that are taken if an employee is exposed to a chemical (e.g. safety showers, eye wash stations, seeking quick medical attention, etc.).
- The emphasis by OSHA and fuel cycle industry practices is to prevent and mitigate and, when required, report the event to the appropriate agency. With regard to NRC, the Part 70 Appendix A reporting requirements can be met without a quantitative standard to assess actual rare exposure events. That is, the reporting would be based on the exposure results and the 70.61 performance requirement definitions and not a quantitative standard. Creating meaningless standards and related paper trails do little for and may actually detract from assuring a safe work environment.

(2) Imposition of an Interpretation of 10 CFR § 70.65(d) Requiring Development of Quantitative Dermal and Ocular Exposure Standards is an Unanalyzed Backfit.

Summary: 10 C.F.R. § 70.65(b)(7) does not explicitly require development of quantitative dermal and ocular exposure standards. Further, the NRC's definitive explanation of measures that, if taken, would satisfy the requirements of § 70.65(b)(7) is provided in section 3.4.3.2 of NUREG-1520. NUREG-1520 does not mention dermal/ocular exposure standards and, to the contrary, endorses several existing standards developed by professional associations and federal agencies that provide limits for airborne rather than dermal/ocular exposures. Finally, in reviewing ISA summaries submitted by applicants and licensees, the NRC specifically evaluated compliance with 10 CFR § 70.65(b)(7) and explicitly stated that use of the exposure standards endorsed in NUREG-1520 met the requirements of § 70.65(b)(7) and were consistent with 10 CFR § 70.61. The staff's current position that licensees with approved ISA summaries must now develop quantitative dermal/ocular exposure standards in order to comply with 10 CFR § 70.65(b)(7) constitutes a new or modified interpretation of the regulations and must be analyzed pursuant to the requirements of § 70.76 prior to being imposed on licensees.

Backfitting Defined: Backfitting is defined in 10 C.F.R. § 70.76(a)(1) as:

> the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

Section 70.76 requires that the NRC perform a systematic and documented analysis prior to imposing backfits on licensees, unless one of the exceptions provided in § 70.76(a)(4) applies. Exceptions aside, the NRC may require backfitting of a facility *only* if the systematic and documented analysis reveals that the backfit will result in a *substantial* increase in the overall protection of the public health and safety or the common defense and security, and that the direct and indirect costs of implementation are justified in view of this increased protection.[5] Through this analysis, consistent application of the backfitting rule ensures that industry and NRC resources are focused on implementation of the safety significant regulatory initiatives whose costs are justified by the increased protection provided. Although a full cost-justified, substantial increase analysis is not required if the NRC determines that an exception applies, invocation of an exception must be supported by an "appropriately documented evaluation."[6] The backfitting provision contained in 10 C.F.R. § 70.76 applies to Subpart H requirements "as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66."[7] In addition, Management Directive 8.4 "Management of Facility-Specific Backfitting and Information Collection," (Oct. 9, 2013)(MD 8.4) states: "The NRC staff shall be responsible for identifying potential facility-specific backfits. The staff shall evaluate any proposed facility-specific position with respect to whether or not the proposed position qualifies as a backfit."[8] MD 8.4 goes on to specify that: "No staff position shall be communicated to the licensee unless the NRC official communicating that position has ascertained whether the proposed position is a backfit and, if so, ensured that the proposed position is identified as a backfit and the appropriate material (i.e., documented evaluation or backfit analysis) has been prepared and approved."[9]

The NRC's Position on Dermal and Ocular Exposures Meets the Definition of Backfitting: Industry believes that the NRC staff's position that 10 C.F.R. § 70.65(b)(7) requires development of quantitative dermal and ocular exposure standards is a "regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position." If this regulatory staff position is imposed on Part 70 licensees generically, it would require licensees to modify their ISAs, which are certainly "procedures...required to operate a facility."[10] Thus, imposition of this new or different regulatory staff position would represent an unanalyzed backfit.

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[5] 10 C.F.R. § 70.76(a)(3).
[6] 10 C.F.R. § 70.76(a)(4).
[7] 10 C.F.R. § 70.76(a).
[8] MD 8.4, at pg. 9.
[9] Id.
[10] 10 C.F.R. § 70.76(a)(1).

10 C.F.R. 70.65(b)(7) states:

> b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of § 70.72. The integrated safety analysis summary must contain:
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> * * * * *
>
> (7) 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 which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

While the rule text explicitly requires that an ISA summary contain a description of the proposed quantitative standards used to assess the consequences of acute chemical exposures, the rule text is silent on the exposure pathways that must be addressed by those standards. That is, the rule does not explicitly require development of quantitative standards for dermal and ocular exposure.

Although the rule text of § 70.65(b)(7) is silent with respect to the specific exposure pathways that must be considered in an ISA, the NRC's interpretation of this provision through guidance and through its approval of site-specific analyses reflects a clear position that the regulation was not interpreted to require development of quantitative dermal and ocular exposures limits for workers at the time the approvals were issued. The NRC guidance used to review license applications for fuel cycle facilities is contained in NUREG-1520 "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Rev. 0 (March 2002) and Rev. 1 (May 2010). NUREG-1520 contains "defined acceptance criteria" for the requirement contained in § 70.65(b)(7),[11] and the ISA summaries submitted by current fuel cycle licensees were reviewed and approved using these "defined acceptance criteria." Specifically, the "defined acceptance criteria" for compliance with § 70.65(b)(7) provided in NUREG-1520 state:

> (7) Quantitative Standards for Chemical Consequences. The applicant's description in the ISA Summary of proposed quantitative standards used to assess consequences from acute chemical exposure to licensed material or chemicals incident to the processing of licensed material is acceptable, provided that the following criteria are met:
>
> a. Unambiguous quantitative standards exist for each of the applicable hazardous chemicals that meet the criteria of 10 CFR 70.65(b)(7) on site, corresponding to, and consistent with, the quantitative standards in 10 CFR 70.61(b)(4)(i), 70.61(b)(4)(ii), 70.61(c)(4)(i), and 70.61(c)(4)(ii).
>
> b. The quantitative standard of 10 CFR 70.61(b)(4)(i) addresses exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger," so as to include exposures that could result in death for some workers,

[11] NUREG-1520, at pgs. 3-13, 3-25 – 3-26 .

consistent with the methods used in the EPA's acute exposure guidelines in Appendix A, "Table of Toxic Endpoints," to 40 CFR Part 68, "Chemical Accident Prevention Provisions."

c. The quantitative standards for 10 CFR 70.61(b)(4)(ii) and 10 CFR 70.61(c)(4)(i) will correctly categorize all exposures that could lead to irreversible or other serious, long-lasting health effects to individuals. As with criterion (b) above, the standard selected should have appropriate conservatism.

d. The quantitative standard for 10 CFR 70.61(c)(4)(ii) will correctly categorize all exposures that could cause mild transient health effects to an individual.

> The NRC finds the use of the Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels (AEGLs) established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and exposure limits established by the Occupational Safety and Health Administration or contained in International Organization for Standardization (ISO) standards to be acceptable. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the ISA Summary must describe how an alternative exposure standard was established for use in the ISA. The ISA Summary must list the actual exposure values for each chemical, specify the source of the data (e.g., ERPG, AEGL, ISO), and provide information or a reference supporting the claim that they meet the acceptance criteria stated above. (See also Section 6.4.3.1 of this SRP.) [12]

As outlined above, NUREG-1520 provides detailed guidance on how the NRC staff will evaluate compliance with § 70.65(b)(7). Of particular relevance here, the NUREG endorses several standards developed by professional associations and federal agencies that have substantial expertise in chemical safety, including the OSHA. None of the standards endorsed by the NRC in NUREG-1520, including the Permissible Exposure Limits (PEL) established by OSHA, provide quantitative dermal or ocular chemical exposure standards.[13] The issue of whether and, if so, how to develop dermal/ocular exposure limits has been considered by OSHA and, to our knowledge, the agency has declined to develop such standards.

For example, in OSHA's 1992 final rule on occupational exposure to 4,4' Methylenedianiline (MDA) the agency declined to adopt a quantitative dermal exposure standard, despite the importance of reducing dermal exposure to the chemical.[14] The final rule explains:

> While OSHA was able to make estimates of risks which might result from dermal exposure, OSHA was unable to establish allowable exposure limits. There are a number of reasons why this is impractical, among which are the difficulty of quantifying dermal exposures, the inability to select a

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[12] NUREG-1520, at pgs. 3-25– 3-26.

[13] The American Industrial Hygiene Association's 2013 ERPG/WEEL Handbook explains, "The primary focus of ERPGs® is to provide guideline levels for once-in-a-lifetime, short-term (typically 1-hour) exposures to airborne concentrations of acutely toxic, high-priority chemicals." (emphasis added); EPA's website explains that "AEGLs are intended to describe the risk to humans resulting from once-in-a-lifetime, or rare, exposure to airborne chemicals." http://www.epa.gov/oppt/aegl/index.htm (emphasis added)

[14] In the evaluation of benefits provided in the final rule, OSHA stated: "A significant proportion of the estimated lives saved are the result of the reduction in dermal exposure, whereas the reduction in airborne exposure levels makes a much smaller contribution to the reduction in risk." Occupational Exposure to 4,4' Methylenedianiline (MDA): Final Rule, 57 Fed. Reg. 35630, 35643 (Aug. 10, 1992).

> reliable biological indicator, and finally the difficulty in correlating the amount absorbed with a precise adverse health effect.[15]

Although the agency could not quantify a dermal exposure limit, OSHA concluded that worker safety could be ensured by other means:

> In order to adequately regulate dermal exposure to MDA, OSHA requires adherence to permissible exposure limits (which reduces surface contamination by MDA thereby reducing the opportunity for skin contact and reduces potential for re-entrainment into the air) and the use of personal protective clothing and equipment and the other standard provisions, all of which aid in preventing dermal exposure.[16]

These types of protective measures are common and are employed by fuel cycle facilities as part of their required chemical safety programs. Indeed, OSHA representatives at the fall 2009 NRC public meeting stated that the agency had not developed dermal/ocular exposure standards for the chemicals in use at fuel cycle facilities, and that the agency did not plan to do so.

The longstanding recognition of the impracticality of developing quantitative dermal/ocular exposure standards by expert agencies and other groups focused on chemical safety demonstrates that the NRC's endorsement of airborne concentration limits in the NUREG was not accidental or the result of a mistake—there simply were (and currently are) no widely accepted dermal/ocular exposure standards that could serve as such a reference. Further, this is not merely a case of a "lack of guidance." Rather, the Standard Review Plan (SRP) provided in NUREG-1520 establishes applicable staff positions regarding what information is sufficient to satisfy the requirements contained in § 70.65(b).

As explained in the NRC's guidance on implementation of the backfitting provision in § 70.76:

> [Standard Review Plans] delineate the scope and depth of staff review of licensee submittals associated with various review activities. They are *definitive* NRC staff explanations of measures which, if taken, will satisfy the requirements of the more generally stated, legally binding body of regulations, primarily found in Title 10 of the Code of Federal Regulations (CFR).[17]

The guidance goes on to explain that:

> [U]sing acceptance criteria more stringent than those contained explicitly in SRPs or proposing licensee actions more stringent than or in addition to those specified explicitly in SRPs may be considered backfits if: (1) the facility has a current license, and (2) NRC's approval of the license means compliance with the SRP.

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[15] Id. at 35637.

[16] Id.

[17] Office of Nuclear Material Safety and Safeguards Policy and Procedures Letter 1-82, 10 CFR Part 70 Backfit Guidance, Rev. 1 (Oct. 2005), at Appendix A, pg. 1 (emphasis added).

This passage precisely describes the current situation. Fuel cycle facilities received licenses after a robust review of license applications by the NRC. Licensees covered by Subpart H to 10 CFR Part 70 submitted ISA Summaries to the NRC for approval, including the information required by § 70.65(b). In reviewing and approving those ISA summaries, the NRC staff applied the "defined acceptance criteria" in NUREG-1520 and determined that licensees and applicants that referenced one of the pre-approved standards provided in the NUREG had met the requirements of § 70.65(b). The staff explicitly approved the use of these airborne concentration limits during the initial licensing reviews and did not require creation of quantitative dermal or ocular exposure standards at that time.

For example, section 2.6.4, of the staff's Technical Evaluation Report (TER) for the AREVA NP, Inc., Richland, Washington fuel fabrication facility states:

> "[T]he proposed chemical consequences for high, intermediate, and low consequence categories are mainly based on limits mentioned in NUREG-1520, such as Emergency Response Planning Guideline Levels, Acute Emergency Guideline Limits, and Occupational Safety and Health Administration exposure limits . . . [T]he licensee indicated that if more than one exposure limit was applied to a specific chemical consequence category, the licensee selected the limit with the lowest numerical limit and/or shortest exposure time."

Based on its review, the staff determined that the licensee's chemical consequence standards are in conformance with 10 CFR 70.61(b)(4) and (c)(4), as required by 10 CFR 70.65(b)(7) and are acceptable.[18]

Another example is the staff's Safety Evaluation Report (SER) for the National Enrichment Facility in Lea County, New Mexico. It states:

> ISA Summary Section 3.1 and Tables 3.1-3 and 4 . . . contains information regarding the selection of quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed material. Based on the review conducted in Section 3.3.3.2.2.2 of this SER, the staff has determined that this information is sufficient to comply with 10 CFR 70.65(b)(7).[19]

In Section 3.3.3.2.2.2 of the SER, under a subheading "Quantitative Standards for Chemical Consequences," the staff explained that the applicant used the AEGL values for HF and UF_6 to meet the requirement for provision of quantitative chemical exposure standards in § 70.65(b)(7). As discussed above, the AEGL values provide quantitative exposure standards for airborne concentrations of chemicals. They are not directly applicable to dermal/ocular exposures. Nonetheless, the staff found:

> [U]se of the AEGL standards . . . acceptable because these are unambiguous quantitative standards developed by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances

[18] "Technical Evaluation Report for AREVA-NP, Richland, Washington," pg. 22-23 by letter from M. Tschiltz, NRC to Robert Link, AREVA-NP, Inc. dated October 25, 2007.

[19] "Safety Evaluation Report for the National Enrichment Facility in Lea County, New Mexico," NUREG-1827,(June 2005), pg. 3-43.

(AEGLs) that are used nationally in a broad application for emergency planning, response, and prevention in the community, the workplace, transportation and remedial action.[20]

Thus, the staff concluded that "[t]he quantitative standards that the consequence categories are based on are in accordance with 10 CFR 70.65(b)(7) and are consistent with the standards in 10 CFR 70.61."[21]

These types of ISA Summary reviews and approvals are not unique to AREVA Inc. or the National Enrichment Facility. In fact, we are not aware of any instance where NRC took the position, prior to approving the ISA Summaries, that dermal/ocular exposure standards for workers were needed. We recognize that several facilities have attempted to produce meaningful quantitative dermal/ocular exposure standards at the staff's urging, however that does not obviate the fact that imposition of this new interpretation of § 70.65(b)(7) is a backfit and has not been analyzed pursuant to 10 CFR § 70.76.

In sum, 10 C.F.R. § 70.65(b)(7) does not explicitly require development of quantitative dermal and ocular exposure standards. Further, NRC's definitive explanation of measures that, if taken, would satisfy the requirements of § 70.65(b)(7) is provided in section 3.4.3.2 of NUREG-1520. As explained above, NUREG-1520 does not mention dermal/ocular exposure standards and, to the contrary, endorses several existing standards developed by professional associations and federal agencies that provide limits for airborne, rather than dermal/ocular exposures. Finally, in reviewing ISA Summaries submitted by applicants and licensees, the NRC specifically evaluated compliance with 10 CFR § 70.65(b)(7) and explicitly stated that use of the exposure standards endorsed in NUREG-1520 met the requirements of § 70.65(b)(7) and were consistent with 10 CFR § 70.61. The staff's current position that licensees with approved ISA Summaries must now develop quantitative dermal/ocular exposure standards in order to comply with 10 CFR § 70.65(b)(7) is a new or modified interpretation of the regulations and must be analyzed pursuant to the requirements of § 70.76 prior to being imposed on licensees.

[20] Id. at 3-46.
[21] Id. at 3-46 – 3-47.

Enclosure 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 15, 2014

Ms. Janet R. Schlueter, Director
Fuel and Materials Safety
Nuclear Generation Division
Nuclear Energy Institute
1201 F Street, NW Suite 1100
Washington, DC 20004

SUBJECT: RESPONSE TO MARCH 26, 2014, NUCLEAR ENERGY INSTITUTE LETTER ON DERMAL AND OCULAR QUANTITATIVE EXPOSURE STANDARD

Dear Ms. Schlueter:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed your letter dated March 26, 2014, and its enclosure, arguing that the Integrated Safety Analysis (ISA) need only consider inhalation pathways when analyzing for acute chemical exposures to NRC-licensed material, or chemicals produced from such material. You state that developing dermal and ocular exposure standards for use in demonstrating compliance with the performance requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H, "is impractical, unnecessary and constitutes an unanalyzed backfit." The staff has reviewed the NRC documentation supporting the development of the Subpart H rule, and finds that the rule's requirements for analyzing chemical hazards (specifically, hazards arising from acute chemical exposures) are not limited to consideration of the inhalation pathway. The staff concludes that failure to consider all reasonable worker exposure pathways would create a regulatory gap in the oversight of chemical hazards that are under NRC's jurisdiction.

Neither the relevant Subpart H requirements, nor the NRC's interpretation of these requirements, have changed. However, even if the staff's position on dermal and ocular exposure pathways is deemed to be the imposition of a new regulatory position that falls within the definition of backfitting, the compliance exception stated in 10 CFR 70.76(a)(4)(i) would be applicable. The enclosure to this letter provides a detailed evaluation of the compliance backfit exception.

Accordingly, the staff will evaluate ISA summaries to ensure that the licensee has considered all reasonable exposure pathways in the ISA chemical hazard analysis. For all credible event consequences as defined in 10 CFR 70.61(b)(4) and (c)(4), the staff will review the ISA summary "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," as stated in 10 CFR 70.65(b)(7). For license amendments, renewals or new applications such staff evaluations do not constitute backfitting.

The NRC is developing an Interim Staff Guidance (ISG) that addresses chemical exposures at fuel cycle facilities subject to Subpart H. The ISG will discuss the criteria staff will apply when reviewing event consequences and proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure in the ISA. The ISG will provide

guidance on the staff review of all credible exposure pathways to demonstrate compliance with 10 CFR 70.61. Development of this ISG should help promote a common understanding of proposed quantitative standards for non-inhalation pathways supporting chemical safety analyses in the ISA. The NRC will engage stakeholders, as appropriate, to discuss an implementation plan.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Marissa G. Bailey, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-1257
License: SNM-1227

Enclosure:
Documented Evaluation for
Compliance Backfit Exception

September 15, 2014

DOCUMENTED EVALUATION FOR COMPLIANCE BACKFIT EXCEPTION: DERMAL AND OCULAR CHEMICAL EXPOSURES AT FUEL CYCLE FACILITIES

INTRODUCTION

This document provides the U.S. Nuclear Regulatory Commission (NRC) staff's (staff's) detailed evaluation of a backfit claim presented in a letter dated March 26, 2014, from the Nuclear Energy Institute (NEI) to Marissa Bailey, Director, Office of Nuclear Materials Safety and Safeguards (Agencywide Documents Access Management System [ADAMS] ML14086A267). In an attachment to this letter, NEI presents its position that the staff requires currently-licensed fuel cycle facilities to develop and adopt quantitative exposure standards as part of assessing the consequences of an individual from acute chemical dermal and ocular exposure. NEI's position is that this constitutes backfitting under Title 10 of the *Code of Federal Regulations* (10 CFR) 70.76(a)(1).

The staff's position is that 10 CFR Part 70, Subpart H, promulgated in 2000 (65 FR 56211; September 18, 2000), establishes a set of performance requirements which must be met by the licensee throughout the term of its license. Therefore, changes to the NRC-approved Integrated Safety Analysis (ISA) summary (and underlying ISA) are necessary to ensure continued compliance with the Subpart H performance requirements. As discussed below, following the initial ISA summary approvals, new information showed that dermal and ocular exposures are likely to occur or result in an intermediate or high consequence event. Even if the staff's current position, that fuel cycle facilities ISAs do not meet Subpart H requirements with respect to consideration of dermal and ocular exposure pathways, is considered to be a change constituting backfitting under 10 CFR 70.76, the backfitting would fall within the compliance exception under 10 CFR 70.76(a)(4)(i). This provision excepts the NRC, with an appropriately documented evaluation, from preparing a backfit analysis to support a backfitting action needed for compliance with the NRC's Subpart H requirements. This document constitutes the documented evaluation required by 70.76(a)(4) and Office Instruction NMSS-LIC-253 (ADAMS ML13161A115).

DISCUSSION

A. 10 CFR 70.61, 70.62 and 70.65 are performance-based requirements

The compliance backfit is properly invoked with respect to dermal and ocular exposures, because Subpart H contains performance-based requirements under which the applicant/licensee must address *all credible hazards,* and there is no regulatory language limiting consideration of chemical hazards to specific exposure pathways. Hence, all fuel cycle facility applicants and licensees are under the obligation to address all relevant exposure pathways.

Within 10 CFR part 70 Subpart H, 70.62(c) requires, in relevant part, that a licensee conduct and maintain an ISA that identifies the chemical hazards of licensed material and hazardous chemicals produced from licensed material. 10 CFR 70.61(b) requires that the risk of each credible high-consequence event be limited, and such events include those arising from an

acute chemical exposure as specified in 10 CFR 70.61(b)(4). Similarly, 10 CFR 70.61(c) requires that the risk of each credible intermediate-consequence event be limited, and such events include those arising from an acute chemical exposure as specified in 10 CFR 70.61(c)(4). For all credible event consequences as specified in 10 CFR 70.61(b)(4) and (c)(4), the ISA summary must describe "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," in accordance with 10 CFR 70.65(b)(7).

The regulatory history of the rulemaking adding Subpart H to 10 CFR Part 70 shows that the NRC always intended for 10 CFR Subpart H to be a performance-based regulation. In the drafting of the proposed rule, staff considered various alternative approaches to develop the rule. For example, in SECY-97-097 (ADAMS ML992920141)[1], the staff considered NEI's proposed approach which considered only air pathways criteria and hydrofluoric acid as the only chemical hazard in the rule. However, staff rejected this approach and stated in SECY-97-137 (ADAMS ML003672841) that "all hazards should be identified and considered to determine which hazards could result in accidents which exceed consequence limits" and "chemicals other than hydrogen fluoride will need to be considered." Then, the staff presented a draft proposed rule for Commission consideration[2] including a discussion of air pathway concentration limits (i.e. AEGL and 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 did not support the proposed rule with regards to chemical safety[3] and directed the staff to consider clarifying the basis for use of chemical safety and chemical consequence criteria in the rule, particularly within the context of the Memorandum of Understanding with the U.S. Occupational Safety and Health Administration (OSHA) and other government agencies.

Accordingly, in 1999, the staff prepared a revised proposed rule[4] including discussions on the clarification of the basis for chemical safety and chemical consequence criteria. Changes to the rule were made to clarify the interface in chemical regulatory authority between NRC and OSHA, changes that were acceptable to NEI and OSHA. Shortly thereafter, the proposed rule was published for public comment (64 FR 41338; July 30, 1999). The statement of considerations (SOC) for the proposed rule stated that Subpart H would establish risk-informed performance requirements (64 FR 41339), and that the ISA would be expected to identify and analyze "all" hazards (64 FR 41346). The 1999 SOC also stated that the requirements for chemical hazards and accident analysis, that NRC was then proposing to add, were intended to "complement and be consistent with the parallel OSHA and EPA regulations" (64 FR 41340).

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[1] SECY-97-097 (May 2, 1997), "Additional Alternative for Regulating the Safety of Fuel Cycle Facilities: Nuclear Energy Institute Petition for Rulemaking", ADAMS ML992920141

[2] SECY-98-185 (July 30, 1998), "Proposed Rulemaking- Revised Requirements for the Domestic Licensing of Special Nuclear Material". Appendices to the draft proposed rule presented AEGL and ERPG values. ADAMS ML992910107

[3] SRM-98-185, (December 1, 1998), "Proposed Rulemaking- Revised Requirements for the Domestic Licensing of Special Nuclear Material". ADAMS ML003755356

[4] SECY-99-147 (June 2, 1999), "Proposed Rulemaking- Domestic Licensing of Special Nuclear Material". ADAMS ML992850039

This language supports the staff position that the NRC has interpreted Subpart H as requiring consideration of *all* relevant and credible exposure pathways, which is consistent with OSHA regulations that also require consideration of all exposure pathways. In discussing proposed standards used to assess consequences of hazards (64 FR 41342-43), the 1999 SOC focused on air pathway limits because at the time of the rulemaking, the air pathway standards were the ones that were readily available for a broad suite of chemicals. National efforts were then underway to improve the emergency response following major chemical release accidents, and were therefore available for adoption in ISAs.

In sum, the NRC's interpretation of the requirements of Subpart H has not changed, and the regulatory wording has not changed. 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.

B. Compliance of ISA summaries with the performance requirements of 10 CFR 70.61

At the time of NRC approval of the original ISA summaries, the air pathway was: (i) the only exposure pathway that was considered by industry and reviewed by NRC to have the potential for offsite consequences, and (ii) the more dominant (but not exclusive) pathway for worker exposure following an accident. Accordingly, during the 2005-2007 timeframe, ISA summaries were approved without explicitly documenting a finding on dermal and/or ocular exposure. Approval of the initial ISA summaries without consideration of dermal or ocular exposures was consistent with the performance-based requirements of 10 CFR 70.61.

Shortly after the initial ISAs were approved, the NRC issued Information Notice (IN) 2007-22, "Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities" (ADAMS ML071410230). The IN explained that hydrogen fluoride (HF) presents a hazard in different stages of the nuclear fuel cycle. During conversion, HF is used in the production of uranium hexafluoride (UF6). During fuel fabrication, UF6 is sublimed and hydrolyzed. The IN reported two exposure events that had occurred in fuel cycle facilities regarding acute chemical exposures including dermal exposures (ADAMS ML072620314 and ML070650158). The IN stated that licensees should consider all routes of exposures that could lead to intermediate and high consequence. Since IN 2007-22, there have been other events reported to the NRC in which fuel cycle facility workers experienced dermal and ocular exposures to HF and other hazardous chemicals[5]. These events demonstrate the continued potential for dermal or ocular exposures and therefore, the need to consider them in the ISA. Hence, ISAs that do not consider dermal and ocular exposure events at NRC-licensed fuel cycle facilities -- are no longer acceptable[6]. Therefore, the NRC position that dermal and ocular exposure pathways must be considered in ISAs when

[5] Event Notification (EN) 46749 (ML111330552), EN46799 (ML11144A184) and EN49437 (ML13316A254).

[6] Licensees modified their ISA summaries to include consideration of dermal and ocular exposure for HF and propose a quantitative standard for HF. These actions support the NRC's position that dermal and ocular exposure pathways are credible, and therefore must be analyzed in accordance with 10 CFR 70.65.

analyzing acute chemical exposures, in order to meet the subpart H performance requirements, represents compliance backfitting[7].

In sum, the original NRC approval of ISA summaries which do not explicitly address dermal and ocular exposure pathways was based on the NRC understanding (shared by the industry) that dermal and ocular exposures were not likely to result in an intermediate or high consequence. Subsequent information showed that the NRC and licensee understanding in this regard was incorrect. Thus, any backfitting with respect to dermal and ocular exposures is needed for compliance with the NRC staff's unchanged interpretation of the requirements of Subpart H.

CONCLUSION

Existing fuel cycle facilities, regulated under Subpart H, must consider all relevant and credible pathways when analyzing for acute chemical exposure in the ISAs, including dermal and ocular exposure pathways. Existing NRC-approved ISA summaries, which do not consider such pathways, are not in compliance with the performance requirements of Subpart H. Licensees whose ISA summaries do not explicitly address dermal and ocular exposure pathways must modify their existing ISAs to include such consideration of dermal and ocular exposures, and must describe in their ISA summaries the quantitative standards for such exposures, in accordance with 10 CFR 70.65(b)(7). This position will also be applied to future fuel cycle facility applications. This would not constitute backfitting, as future applicants are not protected by 10 CFR 70.76 with respect to backfitting.

[7] NRC letters to NEI, dated November 10, 2008, June 12, 2009, and August 16, 2010 (ML082900889, ML090920296, and ML093440038),