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.

[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:
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> 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).
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> 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

[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.