

**INTERIM STAFF GUIDANCE ZZ, REVISION 0
GUIDANCE FOR THE EVALUATION OF ACUTE CHEMICAL EXPOSURES AND PROPOSED
QUANTITATIVE STANDARDS**

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A. Introduction

This interim staff guidance (ISG) document provides additional guidance for the staff of the U.S. Nuclear Regulatory Commission (NRC) when reviewing the applicant's (or licensee's) evaluation of acute chemical exposures, and proposed quantitative standards, as part of the chemical safety review required by the Title 10 of the *Code of Federal Regulation* (10 CFR) part 70 integrated safety analysis (ISA) regulations. This ISG supplements the guidance in NUREG 1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," in order to clarify the criteria for reviewing all chemical exposure issues addressed in either an ISA or ISA summary.

In performing chemical safety reviews, the NRC staff reviewer needs to be familiar with the relevant ISA regulations that are summarized below in Section C (Regulatory Basis). Section 70.4 of 10 CFR defines the term *integrated safety analysis* as a systematic analysis that identifies: (a) facility and external hazards; (b) the potential of these hazards to initiate accident sequences; (c) what these potential accident sequences are, including their likelihood and consequences; and (d) the items relied on for safety (IROFS). The definition further states that "integrated" means joint consideration of, and protection from, "all relevant hazards, including radiological, nuclear criticality, fire, and chemical." The phrase "all relevant hazards" is thus quite broad, and covers all chemical exposure pathways as stated in Information Notice 2007-22 'Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities'.

This ISG provides guidance on evaluating proposed quantitative standards, and presents information sources that the staff can refer to when reviewing an applicant's or licensee's proposed quantitative standards that are used to show compliance with the 10 CFR 70.61 performance requirements. Some of these information sources have been published since NUREG-1520 was initially issued in 2002, and are relevant for exposure pathways other than inhalation (e.g., dermal and ocular pathways).

As indicated above, this ISG provides supplementary guidance to the NRC staff regarding the review of an applicant's or licensee's chemical safety information, specifically focusing on the following:

- (1) chemical hazards and accident sequences (topic covered in NUREG-1520, Section 6.5.2.2, "Chemical Hazard and Accident Sequences");
- (2) chemical accident likelihood and consequences (topic covered in NUREG-1520, Section 6.5.2.3, "Chemical Accident Likelihood and Consequences"); and
- (3) quantitative standards for chemical consequences (topic covered in NUREG-1520, Section 3.4.3.2, "Integrated Safety Analysis Summary and Documentation," Item (7)).

This ISG will be incorporated into a future revision of NUREG-1520.

B. Discussion

Requirements in 10 CFR 70.62, "Safety Program and Integrated Safety Analysis," (specifically, provisions in 10 CFR 70.62[c][1]) state that an applicant must conduct and maintain an ISA identifying "chemical hazards of licensed material and hazardous chemicals produced from licensed materials" that are present in its facility. The staff should ensure that the applicant has demonstrated compliance with 10 CFR 70.62 by having considered all chemical exposure pathways for credible exposure events identified in the ISA. This includes inhalation, dermal and ocular exposures, or exposures by any other pathway that could lead to credible "high" or "intermediate" consequence events, as described in the 10 CFR 70.61 "Performance Requirements."

The applicant's or licensee's chemical safety information will be acceptable if there is reasonable assurance that it adequately addresses and satisfies the regulatory requirements in 10 CFR 70.22, 10 CFR 70.61, 10 CFR 70.62 and 10 CFR 70.65, "Additional Content of Applications".

B.1 Review of Chemical Hazards and Accident Sequences

The staff should find the applicant's or the licensee's identification of hazards to be acceptable if the license application and/or ISA summary identifies hazards that are relevant to determining compliance with the performance requirements of 10 CFR 70.61. When reviewing a license application, license amendment, or ISA summary, the staff must be reasonably assured that the applicant or licensee has identified and analyzed the hazards and accident sequences that could produce serious consequences. The reviewer also should examine the method and information used to identify hazards and accident sequences that could result in acute chemical exposure to workers and individuals outside the controlled area. The method should be systematic and use information about the applicant's material quantities, process, process equipment, and operations. The reviewer should consider the results in light of historical experience at similar facilities and operations.

When reviewing chemical hazards, the staff should consider typical material properties such as toxicity, flammability, and reactivity. The reviewer should evaluate the applicant's or licensee's identification of chemical hazards that can have the potential to produce "high" or "intermediate" acute chemical exposure events as defined in 10 CFR 70.61(b)(4) and 70.61(c)(4). Table 1 of this ISG provides information on the toxic or hazardous characteristics of some common fuel-cycle chemicals. The table references sources of publically-available information on toxic or hazardous characteristics of chemicals commonly present in fuel-cycle facilities, but does not contain an exhaustive list of chemicals that may be used at such facilities. Table 1 provides insight into the potential severity of accidents involving the chemicals it references. In evaluating an applicant's or licensee's identification of chemical hazards at its facility, the staff reviewer may need to examine the information sources listed in Table 1 to find information for other chemicals of concern that may be identified by the applicant or licensee. The reviewer should also verify that the Table 1 information has not become outdated by new information on the toxic or hazardous characteristics of relevant chemicals.

The staff reviewer should recognize that accidents often occur (1) during non-routine operations including maintenance where the hazards and controls are different from those of normal operation, (2) as a result of unanalyzed plant modifications where new hazards might be introduced, and (3) as a result of operations being conducted outside of conditions examined in previous safety analyses. (A general but useful reference is "What Went Wrong, Case Histories of Process Plant Disasters and How They Could Have Been Avoided," by Trevor Kletz, IChemE/Butterworth-Heinemann, Oxford, England, 2009.) Any locations where hazardous licensed material, including fissile material, could be located inadvertently should also be considered. A review of accident history in similar operations can be useful when evaluating the hazards present in a facility.

B.2. Review of Chemical Accident Consequences

For hazardous chemicals that are within the NRC's jurisdiction, applicants and licensees must limit the risk of accidents involving such chemicals at their facilities. More specifically, as stated in the 10 CFR 70.61 (b)-(c) performance requirements, the risk of each credible high-consequence and intermediate-consequence event must be limited. Acute chemical exposures that are credible high-consequence events are specified in 10 CFR 70.61(b)(4). Acute chemical exposures that are credible intermediate-consequence events are specified in 10 CFR 70.61(c)(4). The staff reviewer should ensure that the estimation and classification of the consequences as "high," "intermediate," or "low" is clear and consistent with the nature of the chemicals and processes that the ISA Summary describes.

The estimation and classification of chemical exposure consequences generally involves a multistep process, and the staff reviewer should examine how the licensee or applicant has evaluated these consequences as discussed below. When reviewing chemical exposure consequences, it is important to know whether the receptor is a worker inside the controlled area, or is an individual outside the controlled area. This is important because the high-consequence and intermediate-consequence events described in the 10 CFR 70.61 performance requirements are different, depending on whether the receptor is a worker or an individual outside the controlled area.

The first step involves assessing the material's form and its concentration as it moves from the release point to the receptor location, and the major physical processes involved in the initial release and subsequent transport. Estimating and classifying chemical exposure consequences further involves an assessment of multiple parameters such as vessel size and pressure, hole size, building ventilation characteristics, building dimensions, and local meteorology. Methods for conducting these types of analyses are discussed in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," and the Center for Chemical Process Safety's "Guidelines for Chemical Process Quantitative Risk Analysis," published in 1999. The technical literature may present other methods that the staff reviewer might find useful. The reviewer should determine if the methods for estimating release rate and release conditions are reasonable (i.e., the results are not clearly biased in a way that underestimates consequences) for the physical properties of the material being released.

The second step involves determining the nature (e.g., inhalation, dermal) and the approximate duration of the chemical exposure. This estimate requires an understanding of the properties of the transported material (developed by the first step), an estimate of the effectiveness of any protective equipment, and of any actions of the exposed individual that would influence exposure (e.g., exposure time). The reviewer should determine if the methods the licensee or applicant uses for estimating exposure are reasonable given factors such as the layout of the plant and the qualifications and training of the workers. In general, for chemical exposures via the inhalation pathway, it is reasonable to expect that both workers and individuals outside the controlled area may be subject to such exposures. For chemical exposures via the dermal and ocular pathways, it is reasonable to expect that only workers would be subject to such exposures.

The third step involves the assessment of the consequences from the exposure event. This evaluation requires an understanding of the estimated exposure (developed by the second step) and information on the toxic characteristics of the released material or its anticipated reaction products. The same information on chemical toxic characteristics that is used to estimate consequences is generally used to identify proposed standards as discussed in this document's Section B.4.

Estimation of accidental dermal and ocular exposure consequences for workers is generally more challenging than estimating inhalation exposure consequences. Dermal and ocular exposure often involve liquids or aerosols (gas-liquid mixtures), and the estimation of exposure parameters—such as exposure location on the receptor (e.g., hand vs. chest), the percent of body surface area, and the duration of exposure may be difficult. Effects of dermal and ocular exposure often correlate to the concentration of the material involved in the exposure (e.g., severe skin burns are associated with short exposure to nitric acid in concentrations greater than 20 percent). So in many cases it may be more practical to estimate whether exposure is likely and, if it is, correlate exposure effects to the concentration of the material involved in the exposure.

The reviewer should examine the method(s) the licensee or applicant used to estimate exposure of the worker or the individual outside the controlled area. The reviewer should examine the reasonableness of any model used for the analysis and the specific parameters used in the analysis.

B.3 Review of Chemical Accident Likelihood

In accordance with 10 CFR 70.65(b)(9), the ISA summary must contain definitions of “unlikely,” “highly unlikely,” and “credible,” and these definitions are relevant in reviewing an ISA's assessment of a chemical accident's likelihood. The staff reviewer should examine the methods the licensee or applicant used to estimate the likelihood of an acute chemical exposure event. The reviewer should use the guidance in Chapter 3 of NUREG-1520, “Integrated Safety Analysis and Integrated Safety Analysis Summary” when evaluating these methods.

B.4 Review of Proposed Quantitative Standards for Acute Chemical Exposure

In accordance with 10 CFR 70.65(b)(7), an applicant's ISA Summary must describe the proposed quantitative standards used to identify "high" and "intermediate" consequence events. The parameters of "high" and "intermediate" acute chemical exposure events are stated in 10 CFR 70.61(b)(4) and (c)(4), respectively. The proposed quantitative standards serve to identify the event consequence categories for the ISA's chemical safety discussions. As stated in NUREG 1520, Section 6.5.2.3., the staff reviewer needs to verify that the proposed quantitative standards used to assess consequences to an individual from acute chemical exposures are acceptable.

When reviewing proposed quantitative standards, the staff reviewer should consider specific event sequences described in the ISA Summary. If the event sequence is determined to be highly unlikely, no proposed quantitative standards are required to demonstrate compliance with the 10 CFR 70.61 performance requirements. In a similar manner, if the event sequence is determined to result in consequences that are less than the intermediate events described in 10 CFR 70.61(c)(4), no proposed quantitative standards are required to demonstrate compliance with the 10 CFR 70.61 performance requirements.

B.4.1 General Criteria for Reviewing Proposed Quantitative Standards

The proposed quantitative standards should be based on generally available information from independent sources (e.g., government agencies or organizations, well recognized professional organizations) describing the chemical's toxicity and hazardous properties. The applicant's or licensee's discussion of any proposed quantitative standard should describe the information on which the proposed standard is based. As indicated in the following discussion sections, evaluation of such information is necessary in determining whether the 10 CFR 70.61 performance requirements are met. Due to the various information sources identified in this ISG, it is not expected that applicants will need to conduct their own experimental testing or toxicity tests to generate data supporting their proposed standards.

Standards may have many forms. For inhalation exposures, the standard may be based on air concentration for a given exposure time. For dermal exposures, the standard may be based on body surface area (BSA) exposure for a given time. The staff should ensure that the proposed standard is consistent with available toxicological information, and that the use of the proposed quantitative standard provides a reasonable estimate of event consequence (i.e. does not result in an underestimate of the event's severity).

The following sections provide specific examples of information sources that are acceptable to the staff when evaluating an applicant's proposed quantitative standards for classifying acute chemical exposure events as high or intermediate.

B.4.2 Reviewing Proposed Quantitative Standards for Air Exposure Pathway

For exposure scenarios where inhalation dominates the consequences, the staff has identified several useful information sources to evaluate an applicant's proposed quantitative standards. Acceptable exposure standards include, but are not limited to, those based on the Emergency Response Planning Guidelines (ERPGs), the Acute Exposure Guidelines Levels (AEGs), Temporary Emergency Exposure Levels (TEELs), the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and the exposure limits established by OSHA or other Federal agencies and scientific organizations.

As previously stated in NUREG 1520, the two most common data sources for the staff to use when reviewing proposed quantitative standards for inhalation exposures are the AEGLs and ERPGs. The AEGLs¹ are intended to describe the risk to humans resulting from once-in-a-lifetime, or rare, typically accidental exposure to airborne chemicals. The American Industrial Hygiene Association (AIHA) establishes the ERPGs². While these standards were developed for other purposes, such as emergency guidelines for once in a lifetime exposures, the staff accepts the ERPG values to define “high” and “intermediate” consequences in ISAs. These are inhalation exposure limits that the NRC staff has accepted previously as meeting the quantitative standards requirement stated in 10 CFR 70.65(b)(7).

Acceptable quantitative standards for classifying “high” consequence events would be exposure of workers to AEGL-3 or ERPG-3 levels. For individuals outside the controlled area, acceptable quantitative standards for classifying “high” consequence events would be exposure to AEGL-2 or ERPG-3 levels. Acceptable quantitative standards for classifying “intermediate” consequence events would be exposure of workers to AEGL-2 or ERPG-2 levels. For individuals outside the controlled area, acceptable quantitative standards for classifying “intermediate” consequence events would be exposure to AEGL-1 or ERPG-1 levels.

As stated above, another data source the staff can use when reviewing proposed quantitative standards for inhalation exposures are the TEELs, commissioned by the U.S. Department of Energy (DOE). TEELs are temporary and alternative guidelines used for chemicals that do not have established ERPGs and AEGLs values³. Acceptable quantitative standards for classifying “high” consequence events would be exposure of workers to TEEL-3 levels, and exposure to individuals outside the controlled area to TEEL-2 levels. Acceptable quantitative standards for classifying of “intermediate” consequence events would be exposure of workers to TEEL-2 levels, and exposure to individuals outside the controlled area to TEEL-1 levels.

A fourth acceptable data source which can be used in staff’s evaluation of proposed quantitative standards for inhalation exposures is the database on which the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is based. The GHS is an internationally standardized system for characterizing and labeling chemical hazards to help protect consumers, workers, transportation workers, and emergency responders. The GHS defines different types of hazards (physical hazards, health hazards, environmental hazards) and establishes methods for assigning standardized GHS hazard statements used to communicate information about the severity of the hazard for specific exposure routes⁴. OSHA’s Hazard Communication Standard has been aligned with the GHS to improve the quality and consistency of hazard information in the workplace.⁵

¹ The history and nature of AEGLs is discussed on an Environmental Protection Agency Web site: <http://www.epa.gov/oppt/aeql/index.htm>

² ERPGs are discussed on an American Industrial Hygiene Association Web site: <https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPGIntroText.pdf>

³ TEELs are discussed in a DOE Handbook DOE-HDBK-1046: http://orise.orau.gov/emi/scapa/files/doe-hdbk-1046-2008_ac.pdf

⁴ Globally Harmonized System of Classification and Labelling of Chemicals (GHS), fifth revised edition, 2013, Part 3 Health Hazards

⁵ Occupational Safety and Health Administration, Final Rule on Hazard Communication, *Federal Register*, Vol. 77, No. 58, March 26, 2012, pp. 17574-17896.

Several databases present hazardous property information including:

- European Chemical Agency Classification and Labelling Inventory Database:
<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>
- GESTIS database on hazardous substances:
<http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Stoffdatenbank/index-2.jsp>

The staff may also use the information available in the GHS database when evaluating a proposed standard. Table 1 provides GHS hazard statements for common chemicals in the fuel cycle process. The GHS hazard statements specific for the inhalation exposure pathway that can be used to support proposed quantitative standards are H330 (fatal if inhaled), H331 (toxic if inhaled), and H332 (harmful if inhaled). Acceptable proposed quantitative standards for classifying “high” consequence events would be exposure of workers to a chemical that has a hazard statement of H330 and exposure to individuals outside the controlled area to a chemical that has a hazard statement of H331. Acceptable quantitative standards for classifying of “intermediate” consequence events would be exposure of workers to a chemical that has a hazard statement of H331 and exposure to individuals outside the controlled area to a chemical that has a hazard statement of H332. The staff review of the derivation of the proposed standard should also involve a general review of the literature to confirm that the information in the GHS database is consistent with the general literature.

Table 2 presents the descriptions from the various information sources (i.e. AEGLs, ERPGs and GHS) and compares it to the descriptions of “high” and “intermediate” consequence events specified in 70.61(b)(4) and (c)(4). The hazard statements in the GHS database are considered useful when reviewing proposed standards, particularly when AEGLs, ERPGs, or TEELs are not available.

B.4.3 Reviewing Proposed Standards for the Dermal Exposure Pathway

Staff has accepted the National Institute for Occupational Safety and Health (NIOSH) Skin Notations, and the GHS hazards statements as useful data on which an applicant may base its proposed quantitative standards for dermal and ocular exposures. The reviewer needs to verify that an applicant’s proposed dermal standards are consistent with available and technically sound information or well established data sources. If the applicant proposes other sources of information as the basis for a proposed standard, the reviewer should evaluate the adequacy of the information the applicant is using.

The NIOSH Skin Notations involve the assignment of multiple skin notations for distinguishing systemic (SYS), direct (DIR), and sensitizing (SEN) effects caused by exposure of skin (SK) to chemicals. These skin notations use standardized terms including: (1) the system label/sub-notation SYS (FATAL), which indicates a chemical is highly or extremely toxic, and may be potentially lethal or life-threatening following skin exposures; (2) the direct label/sub-notation DIR (IRR) indicates that a chemical is a skin irritant and; (3) DIR (COR) identifies the chemical as a corrosive agent.⁶ The FATAL subnotation is applied if the median lethal dose (LD₅₀) values are consistently lower than the critical cutoff value of 200 mg/kg of animal body weight. The IRR sub-notation is assigned when the data indicate that exposure of the skin causes reversible effects. The COR sub-notation is used when exposure to the chemical causes irreversible adverse effects.⁷

For chemicals that have a NIOSH skin notation of SYS (FATAL) for dermal exposure, staff has accepted the SYS notation as a proposed standard with “high” consequences to workers. Additionally, the applicant may consider establishing the proposed standard based on the LD₅₀ data that may be stated on the skin notation profile. For chemicals that have a NIOSH skin notation of DIR (COR) for dermal exposure, staff has accepted the DIR notation as a proposed standard with “intermediate” consequences to workers. For chemicals that have a NIOSH skin notation of DIR (IRR), the staff has accepted this notation as a proposed standard of “less than intermediate.”

The databases supporting the GHS statements discussed earlier are another source of useful information which can be used to support dermal exposures standards. The GHS database uses hazard statements for two hazard classes: acute toxicity, and skin corrosion/irritation.

Acceptable proposed quantitative standards for classifying “high” consequence events would be exposure of workers to a chemical that has a hazard statement of H310 (fatal in contact with skin). Acceptable quantitative standards for classifying of “intermediate” consequence events would be exposure of workers to a chemical that has a hazard statement of H311 (toxic in contact with skin) and H314 (causes severe skin burns and eye damage). The staff will generally consider dermal exposure to a chemical with the GHS hazard statements of H312 (harmful in contact with skin), H313 (may be harmful in contact with skin), H315 (causes skin irritation), H316 (causes mild skin irritation), and H317 (may cause an allergic skin reaction) as being associated with less than “intermediate” worker exposure events.

Dermal exposure effects would generally be considered to be minimal if (1) the chemical is not listed in Table A-1 of OSHA’s Technical Manual, Section II, Chapter 2 “Surface Contaminants, Skin Exposure, Biological Monitoring and Other Analyses” or (2) the chemical does not have a NIOSH Skin Notation of SYS or DIR notations or (3) the chemical does not have a GHS hazard statement of H310, H311, H312, H313 or H314.

⁶ NIOSH skin notations are discussed on a NIOSH Web page:
http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html

⁷ “A Strategy for Assigning New NIOSH Skin Notations” (National Institute for Occupational Safety and Health), *Current Intelligence*, Bulletin 61, , , July 2009. This document notes that the NIOSH skin notation strategy is consistent with the classification strategy being used by the UN GHS efforts.

Table 3 below lists these information sources for the dermal pathway, and includes language in these information sources which describes specific effects. Table 3 also compares these descriptions of specific effects with the consequence severity language used in 70.61. The table focuses on workers because dermal exposure of individuals outside the controlled area is generally expected to be highly unlikely or not credible.

B.4.4 Reviewing Proposed Standards for the Ocular Exposure Pathway

The databases supporting the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) discussed earlier are generally applicable sources of useful information for ocular exposure standards. The reviewer needs to verify that an applicant's proposed ocular standards are consistent with available and technically sound information or well established data sources. If the applicant proposes other sources of information as the basis for a proposed ocular standard, the reviewer should evaluate the adequacy of the information the applicant is using.

Acceptable proposed quantitative standards for classifying "intermediate" consequence events would be exposure of workers to a chemical that has a hazard statement of H318 (causes serious eye damage). The staff will generally consider ocular exposure to a chemical with the GHS hazard statements of H319 (causes serious eye irritation) and H320 (causes eye irritation) as being associated with less than "intermediate" worker exposure events.

Table 4 lists these information sources for the ocular exposure pathway, and includes language in these information sources which describes specific effects. Table 4 also compares these descriptions of specific effects with the consequence severity language used in 10 CFR 70.61. The table focuses on workers based on the assumption that ocular exposure of individuals outside the controlled area is generally expected to be highly unlikely or not credible.

The Section B.4 discussion above illustrates the potential need to consider a broad range of information sources when reviewing licensee or applicant-proposed quantitative standards.

Regulatory Basis

The bases for this ISG are the requirements in subpart H of 10 CFR Part 70. Subpart H includes the following provisions: (1) 10 CFR 70.62(c)(1)(ii), requiring that applicants conduct and maintain an integrated safety analysis (ISA) that identifies the chemical hazards of NRC-licensed material and hazardous chemicals produced from such material; (2) 10 CFR 70.61(b), requiring the risk of each credible high-consequence event be limited by controls designated as IROFS, and further specifying under 10 CFR 70.61(b)(4) that high consequence events include acute chemical exposures that could "endanger the life of a worker" or "lead to irreversible to other serious, long-lasting health effects to any individual outside the controlled area"; (3) 10 CFR 70.61(c), requiring that the risk of each credible intermediate-consequence event be limited by controls designated as IROFS, and further specifying under 10 CFR 70.61(c)(4) that intermediate consequence events include acute chemical exposures that could "lead to irreversible or other serious, long-lasting health effects to a worker" or "cause mild transient health effects to any individual outside the controlled area"; and (4) 10 CFR 70.65(b)(7), requiring that for all credible event consequences specified under 10 CFR 70.61(b)(4) and (c)(4), the ISA summary 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." Also relevant here is the definition of an *integrated safety analysis* in 10 CFR 70.4, stating that the term means an

analysis that identifies: (a) facility and external hazards; (b) the potential of these hazards to initiate accident sequences; (c) what these potential accident sequences are, including their likelihood and consequences; and (d) the items relied on for safety (IROFS). The definition further states that “integrated” means joint consideration of, and protection from, “all relevant hazards, including radiological, nuclear criticality, fire, and chemical.”

C. Technical Review Guidance

In considering an applicant’s or licensee’s analysis of acute chemical exposures as part of the ISA review, the reviewer should use the information contained in this ISG, as applicable, to ensure that the ISA is complete in this regard. An Applicant or licensee’s ISA should consider all credible exposure pathways when analyzing acute chemical exposures. The reviewer should recognize the flexibility that Subpart H provides applicants, in that for any given facility, the ISA summary will contain site-specific definitions of “unlikely,” “highly unlikely,” and “credible,” under 10 CFR 70.65(b)(9). The reviewer should further recognize the uncertainty in estimating the consequences of acute chemical exposures, which are functions of release location and rate, as well as worker location, position and initial actions. The reviewer also should use this ISG to evaluate the applicant’s description in the ISA summary of proposed quantitative standards used to assess consequences from acute chemical exposures to licensed materials or chemicals incident to the processing of licensed material.

D. Recommendation

Use this ISG, in addition to guidance in Chapter 3, “Integrated Safety Analysis and Integrated Safety Analysis Summary,” and Chapter 6, “Chemical Process Safety” of NUREG 1520, when reviewing new license applications, amendments to applications, and ISAs related to chemical safety.

E. References

U.S. Code of Federal Regulations, “Domestic Licensing of Special Nuclear Material,” Part 70, Chapter I, Title 10, “Energy.”

U.S. Code of Federal Regulations, “Occupational Safety and Health Administration: Subpart Z—Toxic and Hazardous Substances, Tables Z-1 and Z-2,” Chapter XVII, Title 29, Section 1910.100, “Labor.”

U.S. Nuclear Regulatory Commission/Occupational Safety and Health Administration, “Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, ‘Worker Protection at NRC-Licensed Facilities,’” September 6, 2013, Agencywide Documents Access and Management System (ADAMS) Accession No. ML11354A432.

U.S. Nuclear Regulatory Commission, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” NUREG-1520, Rev.1, May 2010.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

U.S. Nuclear Regulatory Commission, "Review of Models Used for Determining Consequences of UF₆ Release," NUREG/CR-6481, November 1997.

American Industrial Hygiene Association, "Emergency Response Planning Guidelines," as revised. The latest available list of approved guidelines, dated January 1, 2008, is available on the home page of the Subcommittee on Consequence Assessment and Protective Actions (<http://orise.orau.gov/emi/scapa/default.htm>).

National Research Council, "Acute Exposure Guidelines Levels for Selected Airborne Chemicals," National Academy of Sciences (ISBN: 978-0-309-12755-4), Volume 7, Washington DC, 2008.

U.S. Department of Energy, "Temporary Emergency Exposure Limits for Chemicals: Methods and Practice," DOE Handbook DOE-HDBK-1046-2008, August 2008

United Nations, Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 2011, 4th ed.

Current Intelligence, Bulletin 61, "A Strategy for Assigning New NIOSH Skin Notations" (National Institute for Occupational Safety and Health), July 2009. This document notes that the NIOSH skin notation strategy is consistent with the classification strategy being used by the UN GHS efforts.

Table 1 – Acute Exposure Hazard Information for Common Fuel Cycle Process Chemicals⁸

Chemical	GHS Hazard Statement in GHS database⁹ (Inhalation, dermal, ocular, ingestion exposure)	NIOSH skin notation¹⁰ (Dermal exposure)	Noted by OSHA list for skin adsorption¹¹ (Dermal exposure)	AEGL; ERPG¹²; TEEL (Inhalation exposure)
ammonium hydroxide (NH ₄ OH)	H314 1B (causes severe skin burns and eye damage) H335 (may cause respiratory irritation): C ≥ 5 %	No	No	Yes
ammonium fluoride (NH ₄ F)	H301 (toxic if swallowed) H311 (toxic in contact with skin) H331 (toxic if inhaled)	No	No	No
hydrochloric acid (HCl)	H314 1B (causes severe skin burns and eye damage): C ≥ 25% for 1 hour exposure H335 (may cause respiratory irritation): C ≥ 10 %	No	No	Yes
hydrofluoric acid (HF)	H300 (fatal if swallowed) H310 (fatal in contact with skin) H314 (causes severe skin burns and eye damage): C ≥ 7% for 3 minute exposure; 1% ≤ C < 7% for 1 hour exposure H330 (fatal if inhaled)	SK: SYS (FATAL)-DIR (COR): may be potentially lethal or life-threatening following exposure of the skin ; corrosive following exposure of the skin	Yes	Yes
hydrogen peroxide (H ₂ O ₂)	H302 (harmful if swallowed) H314 (causes severe skin burns and eye damage): C ≥ 70% for 3 minute exposure; 50% ≤ C < 70% for 1 hour exposure H322 (harmful if inhaled) H335 (may cause respiratory irritation) C ≥ 35%	No	No	Yes
nitric acid (HNO ₃)	H314 (causes severe skin burns and eye damage): C ≥ 20% for 3 minute exposure; 5% ≤ C < 20% for 1 hour exposure	No	No	Yes
perchloroethylene (C ₂ Cl ₄ , also called tetrachloroethylene)	H315 (causes skin irritation)	No	No	Yes
sodium hydroxide (NaOH)	H314 (causes severe skin burns and eye damage): C ≥ 5% for 3 minute exposure; 2% ≤ C < 5% for 1 hour exposure	SK: <u>DIR (COR), corrosive following exposure of the skin</u>	No	Yes
sulfuric acid (H ₂ SO ₄)	H314 (causes severe skin burns and eye damage): C ≥ 15% for 3 minute exposure	No	No	Yes
Tributyl phosphate ((CH ₃ CH ₂ CH ₂ CH ₂ O) ₃ PO)	H302 (harmful if swallowed) H315 (causes skin irritation)	No	No	Yes
uranyl nitrate (UO ₂ (NO ₃) ₂)	H300 (fatal if swallowed) H330 (fatal if inhaled)	No	No	Yes

⁸ The reviewer should verify that current information is used because the sources identified in Table 1 are occasionally revised.

⁹ GHS information source: <http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Stoffdatenbank/index-2.jsp>

¹⁰ NIOSH skin notation profiles: http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html

¹¹ Table A-1 of OSHA Technical Manual Section II, Chapter 2: https://www.osha.gov/dts/osta/otm/otm_ji/otm_ji_2.html

¹² The AEGL and ERPG levels were established considering the more vulnerable receptors in the exposed public (elderly, children).

Note: Exposure to chemicals with hazard or skin notation statements in bold would generally be considered a high consequence event in the context of an ISA. Exposure to chemicals with a hazard or skin notation statement that is underlined would generally be considered an intermediate consequence event in the context of an ISA. Skin Corr 1A is for exposure less than 3 minutes. Skin Corr 1B is for exposure less than 1 hour.

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Table 2 – Inhalation Exposure description and statements related to the performance requirements in 70.61

	Description in 70.61	Description in AEGL ¹³	Description in ERPG ¹⁴	Description in GHS Hazard Statements
High Consequences	Could endanger the life of a worker	AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.	ERPG-3 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.	H330 Fatal if inhaled
	Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area	AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.	ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.	H331 Toxic if inhaled
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.	ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.	H331 Toxic if inhaled
	Could cause mild transient health effects to any individual located outside the controlled area	AEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.	ERPG-1 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor.	H332 Harmful if inhaled

¹³ The Acute Exposure Level Guidelines have been developed primarily to provide guidance in situations where there can be a rare, typically accidental exposure to a particular chemical that can involve the general public. They are based primarily on acute toxicology data and not subchronic or chronic data. They are designed to protect the general population including the elderly and children, groups that are generally not considered in the development of workplace exposure levels.

¹⁴ The Emergency Response Planning Guideline (ERPG) values are intended to provide estimates of concentration ranges where one reasonably might anticipate observing adverse effects as described. The ERPG values should not be expected to protect everyone but should be applicable to most individuals in the general public. Since these values have been derived as planning and emergency response guidelines, not exposure guidelines, they do not contain the safety factors normally incorporated into exposure guidelines. They are estimates, by the committee, of the thresholds above which there would be unacceptable likelihood of observing the defined effects. The estimates are based on the available data that are summarized in the documentation. In some cases where the data are limited, the uncertainty of these estimates is large. Users of the ERPG values are encouraged strongly to review carefully the documentation before applying these values.

Table 3 – Dermal Exposure descriptions and statements related to the performance requirements in 70.61

	Description in 10 CFR 70.61	Description in GHS Hazard Statements	Description in NIOSH Skin Notation
High Consequences	Could endanger the life of a worker	H310 Fatal in Contact with skin	SYS:(FATAL) - highly or extremely toxic, and may be potentially lethal or life-threatening following skin exposures
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	H311 Toxic in contact with skin H314 Causes severe skin burns and eye damage	DIR:(IRR) indicates that a chemical is a skin irritant, DIR: (COR) which indicates that a chemical is a corrosive.

Note: The information contained in this table reflects information at the time of its preparation. Staff should review validity of classification using currently available information.

Table 4 -Ocular Exposure descriptions and statements related to the performance requirements in 70.61

	Description in 10 CFR 70.61	Description in GHS Hazard Statements
High Consequences	Could endanger the life of a worker	
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	H318 Causes serious eye damage H314 Causes severe skin burns and eye damage

Note: The information contained in this table reflects information at the time of its preparation. Staff should review validity of classification using currently available information.