Chemical Safety Request for Additional Information for the TRISO-X License Application Review

RAI-1 Methodology for identifying non-inhalation exposure sequences:[1]

Regulatory Basis:

This information is necessary to demonstrate compliance with the regulations in Title 10 of the *Code of Federal Regulations (*10 CFR) 70.62 (c), which require, in part, "(1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:…(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material."

Guidance:

Guidance in NUREG-1520 (Chapter 3) calls for analysis of all credible accident sequences with no restrictions on exposure pathways. Guidance in NUREG-1520 (Chapter 6) specifically states that multiple acute chemical exposure pathways (e.g., dermal) need to be considered in the Integrated Safety Analysis (ISA).

Describe Issue:

Section 3.1.2 of the license application (LA) states that TRISO-X LLC (TRISO-X) will identify and analyze credible accident scenarios. This commitment does not identify any restrictions based on exposure pathway and is consistent with the regulations and guidance.

Section 5.8 of the ISA Summary limits consideration of consequences to inhalation exposure based on an argument that inhalation consequences dominate. The application also needs to evaluate non-inhalation exposure events (e.g., dermal exposure might occur as a direct result of a spill or as part of spill cleanup)[2]. The ISA Summary presents many unmitigated spill accidents, but none appear to involve dermal exposure (e.g., spilled liquid on exposed skin). Dermal exposure scenarios are not discussed in the ISA Summary even though several of the TRISO-X process chemicals (e.g., acetic acid, ammonium hydroxide, formaldehyde, hydrogen peroxide, nitric acid, sodium hydroxide, resorcinol) are recognized as dermal exposure hazards in the safety literature.

The current ISA methodology in Chapters 3 and 6 of the LA appears to exclude chemical accident sequences that are from exposure pathways that involve non-vapor exposures, e.g., involve liquid or non-vapor releases. In particular, the ISA methodology does not appear to include evaluation of chemicals for which hazard information suggests dermal or ocular exposure that could result in intermediate or high consequences (e.g., a Globally Harmonized System (GHS) dermal hazard statement or a National Institute for Occupational Safety and Health (NIOSH) skin notation

[1] The first three RAIs are related and address different aspects of the TRISO-X methodology for assessing chemical exposure pathways. The RAIs respectively seek to ensure the TRISO-X methodology can: 1) appropriately identify applicable exposure pathways, 2) accurately assess the severity of the exposures, and 3) appropriately bin the associated consequences.
[2] SRM-SECY-17-006, "Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities," (ML18302A268) states, "Licensees and applicants are required to limit the risk of acute chemical exposures, including dermal and ocular exposures, in a manner consistent with the performance requirements of 10 CFR 70.61."

profile). Considering only inhalation exposure pathways is inconsistent with ISA requirements and guidance and can result in ignoring important worker hazards.

Information Needed:

Provide a commitment in the LA to identify and evaluate credible unmitigated accidents that involve chemical hazards under NRC regulatory jurisdiction regardless of the release forms (e.g., vapor and non-vapor releases) and exposure pathways.

Update the ISA Summary and supporting documents as necessary to demonstrate implementation of this commitment.

RAI-2 Methodology for assessing chemical exposure consequence:[1]

Regulatory Basis:

This information is necessary to demonstrate compliance with the regulations in 10 CFR 70.62(c), which require, in part, "(1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:…(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material."

Describe Issue:

Section 3.1.3 of the LA discusses ISA consequence determination, but it only discusses evaluation of chemical exposure involving the inhalation pathway. There is no discussion or evaluation of accident sequences involving other exposure routes (e.g., dermal).

Section 5.4 of the ISA Summary discusses consequence analysis and the use of Acute Exposure Guideline Levels, Emergency Response Planning Guidelines and Temporary Emergency Exposure Limits as standards for chemical exposure consequences. There is no discussion of assessment of exposure to non-gaseous/non-aerosol releases, particularly those that come in direct contact with the receptor's skin. TRISO-X states that inhalation is the dominant exposure pathway. While this may often be true for air or aerosol releases, it is less likely to be true for releases that are liquid, come in direct contact with worker skin, and involve a chemical that is a recognized dermal hazard.

Section 5.8.3 of the ISA Summary states that acute chemical consequences are based on inhalation as the exposure pathway since inhalation is considered the most impactful for toxic chemical exposures. The discussion cites the U.S. Department of Energy (DOE) DOE-HDBK-1224-2018 (Hazard and Accident Analysis Handbook) which says that the consequences of inhalation exposure are greater than dermal. This section of the ISA Summary does not recognize that the DOE statement is for hazardous material released to the atmosphere and does not apply for situations where there is liquid contact on the skin. This is clearly stated a few sentences later in the DOE document cited by TRISO-X. The DOE document (DOE-HDBK-1224-2018) says "Accordingly, for aerosol-type releases, an inhalation only analysis should be adequate using conservative parameters; thus precluding any unnecessary analyses of alternate pathway exposure." This statement is qualified for aerosol-type releases. The TRISO-X statement does not make it clear that the DOE statement is for contaminants released to the air.

The TRISO-X LA and ISA Summary does not include information sources that can provide insight into potential consequences resulting from exposure to non- gaseous/non-aerosols releases[3]. Several examples of the types of data sources that can be used include, but are not limited to the Cameo database (https://cameochemicals.noaa.gov/), NIOSH skin notation profiles (https://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html), and National Institutes of Health (NIH) database(https://pubchem.ncbi.nlm.nih.gov/) which present safety information on chemicals including GHS hazard statements. Note: Use of the Protective Action Criteria (PAC) database is not valid when evaluating consequences from liquid or non-vapor source terms and non-inhalation exposure pathways.

Information Needed:

Update the LA and ISA Summary to include a description of an appropriate methodology for assessing the applicable chemical hazards of licensed material and hazardous chemicals produced from licensed material for all applicable exposure pathways (e.g., inhalation and non-inhalation exposure). Clarify that the methodology utilizes data sources that are appropriate for the exposure pathway associated with the unmitigated accident scenario (e.g., Cameo database, NIOSH skin notation profiles, NIH database).

RAI-3 Classification of consequence for credible accident sequences that involve non-inhalation exposure scenarios:[1]

Regulatory Basis:

This information is necessary to assess compliance with the regulations in 10 CFR 70.62 (c), which require, in part, "(1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:…(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material." In addition, 10 CFR 70.65(b)(7) states in part that "(b) … The integrated safety analysis summary must contain:… (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 10 CFR 70.61(b)(4) and (c)(4)"[4].

Describe Issue:

Section 3.1.3 of the LA discusses standards that will be used for classifying consequences that involve chemical inhalation. There is no discussion of how the consequences of accident sequences that involve non-inhalation exposure pathways (e.g., dermal or ocular exposure) would be classified relative to the performance criteria of 10 CFR 70.61.

[3] SRM-SECY-17-006 states that the Commission finds it unnecessary to require licensees and applicants to propose an additional quantitative exposure standard specific to dermal and ocular exposures because licensees and applicants have sufficient process safety information, such as toxicity data, to assess the consequences of acute dermal and ocular chemical exposures. Therefore, if an additional quantitative standard is not identified, it is necessary to identify sufficient process safety information, such as toxicity data, to evaluate consequences.

[4] While SRM-17-006 states that is "unnecessary to require licensees and applicants to propose an additional quantitative exposure standard specific to dermal and ocular exposures," it does not relieve licensees and applicants from assessing the consequences of acute dermal and ocular exposures in a manner that meets the performance requirements in 10 CFR 70.61.

Section 6.2.3 of the LA discusses chemical exposure standards. This section also only discusses standards for inhalation exposure.

The TRISO-X ISA summary does not identify a methodology to accurately classify the consequences of non-inhalation exposure accident sequences that might be identified in the ISA.

Information Needed:

Describe the process used to assess the consequences of applicable chemical exposures consistent with the acceptance criteria in 10 CFR 70.61 for credible accident sequences that involve non-inhalation exposure. Either describe the method for classifying credible non-inhalation exposure sequences consistent with 70.65(b)(7) and the technical basis for the standards used for classification (e.g., a GHS hazard statement information or NIOSH skin notation profile information) or propose a methodology for assessing the consequences without a quantitative standard.

RAI-4 Clarification of program for managing dermal/ocular hazards that are under NRC regulatory jurisdiction:

Regulatory Basis:

This information is necessary to assess compliance with the regulations in 10 CFR 70.62(c)(vi), which states in part that for the, "(c) Integrated safety analysis. (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies: …(vi) Each item relied on for safety identified pursuant to 10 CFR 70.61(e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of 10 CFR 70.61."

Describe Issue:

Section 5.8.3 of the ISA Summary states that "The Chemical Safety Program implements an industrial hygiene safety program that includes barriers to protect the workers and prevent/limit dermal and ocular exposures". There is no discussion of the process for determining the nature and performance of the "barriers" and whether they are items relied on for safety (IROFS) because the hazard being managed is under the NRC's regulatory jurisdiction.

Section 5.8.3 of the ISA Summary also states, "The industrial hygiene program also prescribes the Personnel Protective Equipment (PPE) required to protect the worker based on a review of the job assignment, hazards, and work scope." Again, there is no discussion of whether this applies to chemical hazards under the NRC's regulatory jurisdiction and how they relate to complying with the requirements of 10 CFR part 70, subpart H, including the performance requirements of 10 CFR 70.61.

The LA and ISA summary do not describe the methodology for evaluating dermal and ocular exposures in order to comply with the performance requirements of 10 CFR 70.61.

Information Needed:

Clarify if the “chemical safety program” and the “industrial hygiene program” play a role in managing chemical hazards under the NRC’s regulatory jurisdiction as suggested by statements in Section 5.8.3 of the ISA Summary. If so, explain this role in the ISA Summary. Clarify in the ISA Summary if any of the PPE identified by the process mentioned in Section 5.8.3 of the ISA Summary are IROFS, and if appropriate, include them in Section 6 of the ISA Summary.

RAI-5 Update, clarify IROFS, program implementation: Regulatory Basis:
This information is necessary to assess compliance with the regulations in 10 CFR 70.65(b)(6), which states in part that, “(b) … The integrated safety analysis summary must contain: … (6) A list briefly describing each item relied on for safety which is identified pursuant to 10 CFR 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of 10 CFR 70.61”.

Describe Issue:

Table 6-1.24 of the ISA Summary identifies IROFS related to radiological, chemical and fire hazards. There is not sufficient detail to understand their function relative to the performance requirements of 10 CFR 70.61. Some of the IROFS are presented in terms of design options with no information on which option is selected or how it is implemented. Other IROFS involve detection systems, but these do not include sufficient description.

Other IROFS are administrative controls that involve continuing actions, but there is no discussion on how critical criteria are monitored. Such information helps assess the reliability of the administrative control.

Certain IROFS require sampling of chemicals. However, there is no discussion of how this general statement is implemented. The ISA Summary does not clearly indicate which sampling activities are IROFS, what is the key criteria for monitoring.

Information Needed:

Clarify the nature of the IROFS (not its design options) in the ISA Summary. Provide the design details, e.g., the set point or detection values used to activate individual engineered safety systems, which can be provide through the on-line portal or during the horizontal and vertical slice review. Clarify the monitoring that is applied to operator actions to assure process parameters that are IROFS are adequately controlled; and update the IROFS accordingly.

RAI-6 Chemical process description, program implementation: Regulatory Basis:
This information is necessary to assess compliance with the regulations in 10 CFR 70.65 (b)(3), which states in part that, “The integrated safety analysis summary must contain: … (3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to 10 CFR 70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences.”

Describe Issue:

There is process description information in both the LA and the ISA Summary. The process description discusses the major process steps. The description lacks process flow diagrams that would provide useful information for the staff review, particularly for complex operations such as the uranium and chemical recovery operations. It also lacks information on how manual operations such as chemical additions are conducted that would support the review of hazards and accident sequences involving the spill or release of chemicals in the immediate vicinity of a worker. There is no information on how workers control manual operations (e.g., controlled chemical addition rate) that will facilitate the review of accident consequence calculations.

Information Needed:

Provide additional chemical process description information to support the review of the hazard identification and accident sequence identification results for the manual chemical handling operations, the waste processing and recycling operations, and the methods used by operators to manually control operations involving hazardous or reactive chemicals.

RAI-7 Reactive hazard identification, methodology:

Regulatory Basis:

This Request for Additional Information (RAI) has the same regulatory basis as RAI-6.

Describe Issue:

The ISA Summary identifies various reaction hazards in some of the hazard summary tables, but there is no identification of the specific chemical reactions, or the quantities involved in the accident sequence. There is no discussion of the process used to identify and evaluate the various reaction hazards in the TRISO-X operations.

Information Needed:

Provide additional information in the LA on TRISO-X's method used to identify various reaction hazards in the TRISO-X ISA. State the specific reaction considered, and the amounts of reactive materials involved in the reaction scenario identified and analyzed in the ISA. Identify documents that demonstrate a review and evaluation of reactive chemical hazards.

RAI-8 Screening Chemical Hazards from ISA, methodology:

Regulatory Basis:

This information is necessary to assess compliance with the regulations in 10 CFR 70.62 (c), which require, in part, "(1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:…(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material."

Guidance:

Guidance in NUREG-1520 (Chapter 3) calls for analysis of all credible accident sequences with no restrictions on exposure pathways. The use of a screening analysis and GHS hazards statements/information for the chemical of concern would be consistent with the general guidance in NUREG-1520, section 6.4.3.3.

Describe Issue:

Section 5.8.1 of the ISA Summary discusses three screening criteria that are used to eliminate consideration of the chemical from the ISA. The section asserts that the criteria would eliminate chemicals that would pose no risk to workers or the public in a release scenario. It seems quite possible that chemicals that would be eliminated under the criteria (e.g., common retail chemicals) might represent a hazard to workers, particularly if the chemical is used in a relatively small, confined area or is a reactive hazard (e.g., combustible).

The section does not discuss the use of simplified calculations to show concentrations would be below PAC-1 levels or the review of GHS hazard statements for the chemical to verify that that intermediate or high consequence events are not possible.

Information Needed:

Provide additional information on the screening criteria discussed in section 5.8.1 of the ISA Summary. Clarify the screening criteria discussed in section 5.8.1 of the ISA Summary to be more specific and whenever possible rely on screening consequence calculations and/or GHS hazard statement information that is in chemical safety databases or provide detailed justification for the determination.

RAI-9 Low estimates of indoor chemical concentration, methodology:

Regulatory Basis:

This RAI has the same regulatory basis as RAI-8.

Describe Issue:

Section 5.8.4 of the ISA Summary discusses estimation of airborne concentration for occupational exposure. The discussion states that “NUREG/CR-6410, Section 4.8 concludes that the highest concentration is reached when only the volume of the primary compartment or facility is considered (i.e., no material released to interconnected compartment).” The staff agrees that section 4.8 addresses the calculation of facility concentration. However, the section discusses the uncertainty in such analysis and presents two simple calculation methods: a one compartment model with a continuous release and a two-compartment model with a puff release. The staff does not find the statements made in section 5.8.4 of the TRISO-X ISA Summary consistent with the staff’s interpretation of section 4.8 of NUREG/CR-6410.

Section 5.8.4 also presents equation Chem-1, which states that the airborne concentration (Ci) is the source term (STi) divided by the building volume. The use of the building volume is not the same as the “primary compartment” volume attributed to NUREG/CR-6410. The use of the

building volume rather than the “primary compartment volume” can significantly reduce the calculated concentration to an unrealistically low level.

The discussion in the ISA Summary should accurately reflect the information in the documents it cites, and the formulas presented should not result in concentrations that are biased low.

Information Needed:

Provide additional information on the chemical consequence estimation methodology discussed in the application and the ISA Summary with documentation that provides assurance that the ISA methodology is capable of assessing performance against the requirements of 10 CFR 70, Subpart H.

Clarify that the chemical consequence estimation methodology discussed in the application and the ISA Summary use methods that provide results based on realistic assumptions for the estimated chemical room concentrations.

RAI-10 Validity of “see and flee” methodology:

Regulatory Basis:

This RAI has the same regulatory basis as RAI-8.

Describe Issue:

Section 5.8.4 of the ISA Summary (page 15 of 32) states that a 10-minute worker exposure time is assumed based on a “see and flee” assumption. While this may be a valid assumption for releases that produce a clearly visible plume or some other sensible effect (e.g., smell) at levels that do not cause serious effects, there are some invisible, odorless chemicals (e.g., carbon monoxide) that may not trigger a see and flee response. There is no statement that the reasonableness of the “see and flee” assumption will be analyzed in the ISA.

Information Needed:

Provide a commitment in the LA to verify that the use of the “see and flee” methodology is valid for each case where it is used.

Provide access to documentation that demonstrate that the ISA Analysis uses realistic working exposure time estimates.

RAI-11 Chemical accident source term and consequence calculations, program implementation:

Regulatory Basis:

This information is necessary to assess compliance with the regulations in 10 CFR 70.65 (b)(4), which states in part that, “The integrated safety analysis summary must contain: … (4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;”

Describe Issue:

Tables 4-2.1 through 4-2.7 identify consequence calculation packages that are used to determine worker and public chemical safety consequences for various process area and accident sequences.

The staff needs to be able to review these calculation packages and understand the relationship between facility design features (e.g., room dimensions, ventilation characteristics), process conditions (e.g., chemical concentrations, temperature, and inventory) and receptor location to assess the reasonableness of the consequence calculations.

Information Needed:

Provide access to calculation packages that identify chemical accident sequence source terms (i.e., release quantify and rate) and consequences. Access to these calculation packages is required after the design is essentially complete and the chemical hazard identification methodology and consequence assessment methodology is revised to include non-inhalation exposure sequences and consequences. The packages should discuss the basis for the source term and the assumptions and parameters used on the consequence analysis. Provide the information that demonstrates the licensee's compliance with the performance requirements of 10 CFR 70.61.

Access to these calculation packages is required after the design is essentially complete and the chemical hazard identification methodology and consequence assessment methodology is revised to include non-inhalation exposure sequences and consequences.