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ELECTRONIC DELIVERY

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Director, Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

References:
1) Docket No. 70-7027
2) TRISO-X letter from Jennifer Wheeler to Director, Office of Nuclear Material Safety and Safeguards, "TRISO-X Fuel Fabrication Facility License Application Submittal," dated April 5, 2022
3) NRC letter from Matthew Bartlett, Senior Project Manager, Fuel Facility Licensing Branch, to Jennifer K. Wheeler, Director, Regulatory Affairs " Request For Additional Information Set 5 For The Radiological And Chemical Review Regarding The TRISO-X, LLC License Application For A New Fuel Fabrication Facility (Enterprise Project Identification Number L-2022-NEW-0005)," dated October 25, 2023

Subject: **Response to Request for Additional Information Set 5 (Chemical Safety and Radiation Protection) for the TRISO-X License Application**

TRISO-X, LLC (TRISO-X) hereby submits responses to the subject Request for Additional Information (RAI), regarding the review of the License Application for the TRISO-X Fuel Fabrication Facility (Reference 2). The enclosed responses are for the RAI Set 5 transmitted by letter dated October 25, 2023 (Reference 3).

Request for Withholding

None. The enclosed submittal contains public information.

Summary of this Submittal

The following Enclosures are included with this letter.

Enclosure 1 – Radiation Protection RAI Responses

Enclosure 2 – Chemical Safety RAI Responses

If there are questions or if additional information is required, please contact me at (865) 850-0893 or jwheeler@triso-x.com.

Sincerely,

Jennifer Wheeler

Jennifer K. Wheeler, P.E.
Vice President, Regulatory Affairs

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Copy: Mr. Matthew Bartlett, US NRC, NMSS
TRISO-X Regulatory Records File

Enclosure 1 - Radiation Protection RAI Responses for the TRISO-X License Application

RAI-1 Respiratory protection and controls to restrict internal exposures:

Regulatory Basis:
Title 10 to the Code of Federal Regulations (10 CFR) 20 Subpart H, “Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas,” Section 10 CFR 20.1703 requires, “The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.” The regulation in 10 CFR 20.1704 states, “The Commission may impose restrictions in addition to the provisions of 10 CFR 20.1702, 10 CFR 20.1703, and Appendix A to Part 20, in order to: (a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and (b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.” Specifically, 10 CFR 20.1703(c)(5) requires “Determination by a physician that the individual user is medically fit to use respiratory protection equipment: (i) Before the initial fitting of a face sealing respirator; (ii) Before the first field use of non-face sealing respirators, and (iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.”

Describe Issue:
Section 4.6.4 of the license application (LA) discusses the respiratory protection policy, stating that the determination of fitness to use respiratory protection is performed prior to the initial fitting of respirators and the respiratory protection program requires that individuals must be medically qualified. This section also states that approved procedures guide the selection, fitting, issuance, maintenance, testing, training of personnel, monitoring, and recordkeeping for individual respiratory protection equipment and for specifying when such equipment is to be used. These procedures are revised to reflect changes in processes, the facility, or equipment that are significant enough to impact respirator use. However, the LA does not discuss the process or procedures used to medically qualify individuals for respiratory use and how individuals maintain medical qualifications.

Information Needed:
Please provide a description of the process or procedures used to medically qualify individuals for respiratory use and how individuals maintain medical qualifications.

TRISO-X Response to RAI-1:
The initial medical evaluation to determine a worker’s fitness to use respirators is accomplished prior to respirator fit testing and respirator use in the work setting. Workers that may be required to use respiratory protection are medically re-evaluated every 12 months. Evaluations are tracked through the training database.

Compliance with 10 CFR 20 Subpart H is achieved through compliance with 29 CFR 1910.134. TRISO-X uses a local occupational medical provider (the provider) to provide the respiratory clearance physical in accordance with 29 CFR 1910.134. Medical information important to respirator use is gathered through use of the OSHA Respirator Medical Evaluation Questionnaire contained in Appendix C to 29 CFR 1910.134. The physical focuses on pulmonary, cardiovascular, and gastrointestinal systems and includes a spirometry test and, at the doctor’s discretion, a chest x-ray and/or electrocardiogram.

The provider performs quantitative fit tests for approved full and half-face respirators in accordance with 29 CFR 1910.134 Appendix A, using the TSI PortaCount Respirator Fit Tester.

The medical provider submits a Medical Surveillance Written Opinion to TRISO-X signed by the attending physician. The written opinion includes any limitations on respirator use and lists the types and sizes of respirators tested and approved for each individual.

RAI-2 Monitor exposures to radiation and radioactive material:

Regulatory Basis:
The regulation in 10 CFR 20.1502(a)(1) states, in part, that, "Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum – (a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by – (1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a) …"

Describe Issue:
Section 4.7.2 of the LA states that dosimetry is provided to adults likely to receive greater than 0.5 rem in a year. However, the LA does not describe how TRISO-X determines which individuals may receive greater than 0.5 rem per year.

Information Needed:
Please provide a description of how TRISO-X determines which individuals may receive greater than 0.5 rem per year.

TRISO-X Response to RAI-2:
External exposures for a source term of unirradiated <20% enriched uranium are not anticipated or are expected to be very low as most of the radioactivity is from alpha particles, and the emitted gammas are relatively weak. Due to the radiotoxicity of alpha particles, containment and ventilation are used extensively to control internal exposures.

Initially, monitoring for external and internal exposures will be performed on a continuous basis for all workers in the Restricted Area (RA). To monitor for external exposure, dosimeters will be supplied to all workers until it is demonstrated that monitoring for external exposure for some or all workers is not warranted. Similarly, personal air samplers (PAS) will be issued to all individuals that work with dispersible forms of radioactive material. Stationary air sampling (SAS) will be performed in all areas with dispersible forms of radioactive material. Where it can be demonstrated over time that the SAS is representative of the air that a worker breathes, PAS for some or all workers may be reduced or eliminated.

RAI-3 Occupational dose training requirements:

Regulatory Basis:
The regulation in 10 CFR 19.12 specifies training requirements for all individuals who, in the course of their employment, are likely to receive in a year an occupational dose in

excess of 100 mrem. In addition, 10 CFR 70.22 requires in part that, "(a) Each application for a license shall contain the following information: … (6) The technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations in this chapter."

Describe Issue:
Chapter 2 of the LA describes training and qualification requirements for managers, radiation workers, and process operators to be qualified for employment. In addition, LA chapter 4, section 4.5 describes the radiation safety training program. However, the level of training and requalification is generic, and the different levels of training required for different positions of individuals at the facility is unclear. Also, there is no discussion of the relationship between training and escort requirements, if utilized. The NRC staff also reviewed the training requirements in LA section 11.3, but that information is not specific to a particular position or area of responsibility.

Information Needed:
Please provide clarification of training and refresher training or requalification requirements for engineers, operating technicians, and process operators above the annual refresher training requirement for radiation workers. Describe training and escort requirements for visitors or other non-TRISO-X staff who may require access to the controlled area.

TRISO-X Response to RAI-3:
Radiological orientation is required for all individuals who work at TRISO-X. Radiological Worker Training (RWT) is required for engineers, operators, and other individuals who routinely access the RA. Operators will receive specialized training for the equipment for which they are responsible. Health Physics personnel responsible for radiation safety are trained in advanced radiation safety concepts and practices and receive specialized training for their areas of responsibility. RWT refresher training is provided every three years and addresses changes in policies, procedures, requirements, and the facility ISA.

Health Physics personnel may authorize access to the RA for individuals without instruction or training where such individuals are continuously under the control of a designated escort. The designated escort will be instructed and trained in accordance with the requirements of 10 CFR 19.12 and the guidance in Regulatory Guides 8.13 and 8.29 and will be instructed on the duties and responsibilities associated with being an escort.

RAI-4 TRISO-X contamination control program:

Regulatory Basis:
The regulations in 10 CFR 20.1501(a)(2)(iii) state that each licensee shall make or cause to be made, surveys of areas, including the subsurface that are reasonable under the circumstances to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected.

Describe Issue:
Section 4.7.3 of the LA describes the TRISO-X contamination control program. Contamination survey limits and survey frequencies are shown in LA table 4.1. Survey limits are provided only for air sampling (alpha contamination) surveys. The LA does not describe the survey requirements, procedures, or surveys performed for personnel or areas to detect contamination.

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Information Needed:
Please provide additional description of how the survey requirements, procedures, or surveys performed for personnel or areas to detect contamination.

TRISO-X Response to RAI-4:
License Chapter 4, Table 4-1, *Minimum Survey Frequencies*, does not provide contamination limits. Table 4-1 describes the air sampling and removable surface contamination survey frequencies. Contamination limits for unrestricted release are shown in Attachment 1 to License Chapter 4. Contamination limits for RCAs are defined in implementing procedures.

10 CFR 20.1501 (a)(2)(iii) addresses Surveys and Monitoring, while the RAI references License Chapter 4, Section 4.7.3, *Contamination Control Program*. License Chapter 4, Section 4.7, *Radiation Survey and Monitoring Programs*, provides a description of the survey requirements, types of surveys, survey procedures, and survey instrumentation used in the facility and for personnel to detect contamination.

RAI-5 Radiation protection training program:

Regulatory Basis:
The regulation in 10 CFR 20.2102(a)(2) states in part that, "(a) Each licensee shall maintain records of the radiation protection program, including: (1) The provisions of the program; and (2) Audits and other reviews of program content and implementation. In addition, 10 CFR 70.22 requires in part that, "(a) Each application for a license shall contain the following information: … (6) The technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations in this chapter."

Describe Issue:
The TRISO-X radiation protection program includes training. Section 4.5 of the LA states TRISO-X provides an effective safety training program that meets regulatory requirements to ensure that the working environment is safe, and the employees and visitors understand the risks associated with exposure to radioactive materials. However, TRISO-X did not provide an explanation of how the training program will be assessed for effectiveness.

Information Needed:
Please provide a description of how the radiation protection training program is included in periodic assessments of the radiation safety program and how the effectiveness of the training and instructors are evaluated.

TRISO-X Response to RAI-5:
As stated in License Chapter 4, Section 4.5, the Radiation Safety Training program will be evaluated every three years by an assessor independent of the training program. The evaluations will determine the following:

- Program objectives are being achieved,
- Each radiation worker is receiving training related to his/her work,
- Initial training and refresher training are timely,
- Adequate training records are being created and maintained to ensure accessibility, completeness, and usefulness,

- The program is supported by management with adequate facilities, number and quality of instructors, and training aids,
- The program is responsible to the radiation worker's need for knowledge and skills, and
- Each radiation worker's on-the-job performance confirms training and instructor effectiveness (conducting random worker interviews, direct observation of worker performance, and examination of performance as related to ALARA goals, contamination incidents, etc.).

RAI-6 Review of radiation protection program:

Regulatory Basis:
The regulation in 10 CFR 20.1101 states in part, "(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation."

Describe Issue:
Section 2.4 of the LA states that the regulatory component establishes a safety review committee with membership from manufacturing, engineering, safety & regulatory and safeguard. Section 4.2 of the LA states that this committee also serves as the ALARA committee. The application does not provide an adequate description of the ALARA program, the make-up of the ALARA committee, the interface between the ALARA committee and operations or the management commitment to the program.

Information Needed:
Describe the ALARA program at TRISO-X, to include any document that serves as the basis of your ALARA program and the evidence of documented management commitment to the program. Explain how the ALARA program interfaces with operational programs and ALARA principles are implemented in work using radioactive materials.

TRISO-X Response to RAI-6:
The TRISO-X ALARA Program document states the following in Section 1.0, *Introduction*:

"In accordance with 10 CFR 20, Subpart B, the purpose of the radiation protection program (RPP) is to maintain occupational and public doses below regulatory limits and as low as is reasonably achievable (ALARA) consistent with the requirements of 10 CFR 20.1101. It is the policy of TRISO-X to maintain a comprehensive RPP intended to keep doses to workers and off-site releases of radioactivity ALARA. To achieve this, the ALARA program will include:

- A documented management commitment to the RPP and ALARA,
- A safety committee to serve as the ALARA committee to review the RPP and ensure that exposure to radiation and the release of radioactivity are maintained ALARA.

- A trained and qualified staff with sufficient authority and well-defined responsibilities, and
- Adequate facilities, equipment, and procedures to effectively implement the program.

The construction and subsequent modifications of TX-1 incorporate the ALARA concepts specified in 10 CFR 20. The ALARA program will function as a mechanism to facilitate interaction between radiation protection and operations personnel."

In addition, the TRISO-X ALARA Program document states the following in Section 2.0, *ALARA Program [10 CFR 20.1101]*:

"The TRISO-X ALARA Program provides specific guidance for ALARA philosophy implementation. It was developed using the guidance in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA," and includes:

- A published Radiation Safety policy, signed by the President of TRISO-X, that declares, to all employees, the policy and intent of TRISO-X to maintain radiation exposures ALARA.
- Requiring training in ALARA philosophy for all radiation workers.
- Appointing radiation protection personnel and identifying their authority and responsibilities for implementing the radiation protection program functions.
- Requiring the development, approval, and implementation of specific ALARA goals.
- Requiring the measurement and monitoring of progress toward goal achievement and the issuance of regular progress reports to management and supervision.
- Requiring the performance of specific ALARA reviews during the design phase of engineering projects for the initial design and for facility and/or equipment modification.
- Defining, as appropriate, specific long-term ALARA goals; ALARA goals will incorporate, when appropriate, new approaches, technologies, operating procedures, or changes that could reduce potential radiation exposures at a reasonable cost.
- Establishing an ALARA technical review committee composed of the safety review committee to review all proposed major facility modifications and their ALARA evaluations, operating procedures, and ALARA reports.
- Requiring a periodic (quarterly) report of radiation and other safety-related monitoring and audits to appropriate levels of management together with recommendations on methods for lowering exposures, both occupational and environmental.
- Requiring the analysis of monitoring data for trends which might indicate an increase in radiation exposures.
- Conducting a periodic audit of the ALARA program implementation, and
- Requiring routine inspections of operating areas focused on implementation of radiological controls."

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RAI-7 Effectiveness of ventilation systems:

Regulatory Basis:
The regulation in 10 CFR 20.1101(b) states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). In addition, 10 CFR 20.1101(d) states, in part, a constraint on air emissions shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem per year from these emissions.

Describe Issue:
Section 4.2 and 4.6 describe several actions taken by TRISO-X to maintain exposure to the area inside the TRISO-X building consistent with ALARA. Engineered controls such as ventilation provide primary radiation functions. However, TRISO-X did not provide any explanation on how ventilation systems are used to prevent the spread of contamination to outside areas of the facility to ensure that doses to members of the public are below dose limits and are ALARA. The NRC staff also reviewed section 9.1 on environmental ALARA. The section confirms TRISO-X intends to comply with the regulations but does not provide information on how the ventilation system supports public doses to be ALARA.

Information Needed:
Please provide a description of the effectiveness of ventilation systems as it relates to public exposure so that the dose to public does not exceed the regulatory limits.

TRISO-X Response to RAI-7:
Engineering controls are implemented at TRISO-X that will ensure doses to the public are maintained ALARA. This is accomplished through containment, ventilation, and filtration. The annual effluent activity concentration estimated at the boundary of the restricted area (the stack), weighted for the anticipated source term, is below the limits in 10 CFR 20 Appendix B Table 2. Evaluations using HOTSPOT result in off-site dose estimates well below the 10 CFR 20.1101 dose constraint of 10 mrem/year.

RAI-8 Monitor exposures to radiation and radioactive material:

Regulatory Basis:
The regulation in 10 CFR 19.13(b) states, in part, that, “Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year ….” Also, 10 CFR 20.2206(b) states, in part, that “Each licensee in a category listed in paragraph (a) of this section shall submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by § 20.1502 during that year.”

Describe Issue:
Section 4.7.2 of the LA states that internal and external occupational doses are combined in accordance with criteria in 10 CFR Part 20, and in applicable guidance contained in both Regulatory Guide 8.7, “Instructions to Exposure Data,” and in Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses.” However,

TRISO-X did not provide any explanation on how the exposure information is reported to the employees.

Information Needed:
Provide a description of how TRISO-X will report individual exposures annually to employees.

TRISO-X Response to RAI-8:
10 CFR 20.2106 has details on records of individual monitoring results. When monitoring is required under 10 CFR 20.1502, the monitoring results must be recorded on an NRC Form 5 or equivalent. The form requires detailed intakes by individual radionuclides and solubility classes (F, M, or S) as well as maximum organ committed dose equivalent (CDE) and whole-body committed effective dose equivalent (CEDE), along with external dose quantities. NRC Regulatory Guide 8.7 contains guidance on completing the form.

10 CFR 19.13 requires annual dose reporting to individuals when such monitoring is required under 10 CFR 20.1502 and either the annual TEDE or the dose to any individual organ or tissue exceeds 1 mSv (100 mrem). 10 CFR 19.13 also requires reporting doses if an individual is required to be monitored and requests his or her annual dose report, regardless of dose levels. Additionally, certain reports (whether estimated or final values) are required to be provided to, or on behalf of, the individual within 30 days when a terminated worker requests dose information. Dose to the individual will be reported using NRC Form 5 (or equivalent).

RAI-9 Personnel dosimeters:

Regulatory Basis:
The regulation in 10 CFR 20.1502 states that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits.

Describe Issue:
Section 4.7.2.1 states that personnel dosimeters are issued to measure external exposure to beta and gamma. The application does not provide information on the type of dosimeters, sensitivity of dosemeters, the type of data collected and processed, the administrative dose limits set for monitoring and investigation, or what action, if any, will be taken if the administrative limit is not met.

Information Needed:
Please provide in the LA the following:

1. a list of the type and sensitivity of dosimeters;
2. a description of how often dosimeters are collected and processed; and
3. in addition to annual limits specified in LA section 4.7., a description of the administrative control limits which, if exceeded, prompt an investigation into circumstances of the exposure.

TRISO-X Response to RAI-9:
License Chapter 4, Section 4.7.2.1, *External Dosimetry*, presents information regarding the type and sensitivity of dosimeters, and dosimeter processing. In addition, License

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Chapter 4, Section 4.7.2, *Dosimetry Program*, presents information regarding administrative control limits in the 2nd and 4th paragraphs. Both of these license sections will be revised per the changes shown at the end of this response.

The following paragraphs present additional descriptions of the source term, dosimeter type and collection frequency, and administrative limits. Significant external exposures are not anticipated, given the unirradiated <20% enriched uranium source term.

Source Term Description
The external radiation emitted from the uranium source materials is expected to experience a high degree of self-attenuation/self-shielding due to the high atomic number (Z=92) of uranium and high degree of containment. External doses are expected to be generated primarily by outer-most layers of materials. Uncontained materials will have some potential to generate lower-level beta exposure to the skin and lens of eye, and some gamma radiation will be able to penetrate through materials and create a whole-body deep dose equivalent. However, for normal uranium fuel fabrication operations, external dose levels are expected to be below the 10% monitoring threshold established for workers by NRC in 10 CFR 20.1502(a). Nonetheless, for verification and liability purposes, individuals who routinely work with (directly handle) and are in close proximity to uranium materials will be monitored with individual dosimetry devices for whole-body SDE, LDE, and DDE. Over time, the external dosimetry monitoring frequency may be reduced or eliminated if proven to be unnecessary.

Dosimeter Type and Collection Frequency
The frequency for collecting and processing personnel dosimeters depends on the measurement method and associated lower limit of detectability. The collection/processing frequency is chosen so that it is unlikely that an individual will receive a dose equivalent equal to or greater 10% of the dose limits in 10 CFR 20 from external radiation without detection and quantification. Generally, for those required to be monitored at TRISO-X, whole-body measurements of DDE, LDE, and SDE will be performed with TLDs which are normally exchanged quarterly. Abdominal DDE dosimeters assigned to declared pregnant workers and used to measure external dose to the embryo-fetus are normally exchanged monthly. Extremity measurements (e.g., using finger rings) may be performed initially in some areas simply to verify that continued use of extremity dosimeters is not required; when these are utilized, they will normally be exchanged monthly.

TRISO-X may use either TLDs (thermoluminescent dosimeters) or OSLDs (optically-stimulated luminescent dosimeters) as individual dosimetry devices. TLDs have a nominal detection sensitivity of about 10 mrem for the radiations of concern, whereas OSLDs have a nominal detection sensitivity of about 1 mrem. The dosimeters will be obtained from a NVLAP-accredited vendor, deployed during use, and then returned to the vendor for processing. Each batch of dosimeters is provided by the vendor with control dosimeters. Control dosimeters are returned with the worn dosimeters and subtracted to correct for natural background exposures and possible exposures experienced during the shipping process. Control dosimeters will be stored in areas which are at normal background radiation levels and not in radiation areas impacted by radioactive material storage and use. It is also not advisable to store control dosimeters in shielded containers since one of their functions is to allow for correction of worker exposures due to natural background radiations. According to Table 8.1 of NCRP Report 160, the average background external exposure from cosmic and terrestrial radiation is around 54 mrem a year for individuals in

the U.S. population, but this can vary regionally and even locally. In contrast, the average background internal exposure from inhalation of radon and thoron and ingestion of various primordial radionuclides is around 257 mrem for a total (internal and external) average background exposure of 311 mrem.

OSLDs are slightly more sensitive (1 mrem) compared to TLDs (10 mrem); however, this level of sensitivity is not generally needed for worker monitoring given the higher limits and exchange frequencies. OSLDs also have an added benefit of being able to be re-read, whereas TLDs can only be read once. While this may be useful in some industries where exposures can be relatively high, the lower external exposures anticipated at TRISO-X provide for use of the most cost-effective of the two badges, and typically a TLD is more cost-effective (since offered by multiple vendors) and is acceptable. OSLDs may be used for offsite environmental monitoring where the lower detection levels are more desirable.

Doses to the skin of extremities are not generally expected to exceed 10% of the dose limit for extremities for routine operations. However, for start-up operations or significant changes to operations which could increase extremity doses, a small group of individuals will be monitored with extremity dosimeters to collect limited data to justify the absence of extremity monitoring moving forward. In addition, monitoring a small critical group initially will serve to verify that the overall exposures are generally uniform over the body. Measurements for extremity characterizations will be made with thin-window survey meters capable of detecting beta radiations and extrapolated to worst-case annual doses to demonstrate compliance. It is noteworthy that the last sentence in 10 CFR 20.1201(c) states, “The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.” Therefore, extremity measurements will be performed early in the process and documented relative to the whole-body (torso) results. If needed, extremity dosimeters will be worn on the hand likely to receive the highest exposure. However, SDE may be determined by way of the whole-body dosimeter noting that the radiation field is uniform or nearly uniform, and providing data that support that approach. Finally, it is noted that the limit applies to the most exposed location; if that location is not directly monitored, then a correction factor may be applied based the gradient between the location monitored and the most exposed location (or the dose equivalent at contact if there is direct source-to-skin or -extremity contact). In the event of skin contamination or a wound, use of NRC’s VARSKIN+ computer code will be used to estimate the dose.

Following a pregnancy declaration in writing (which is a voluntary act by the worker), a declared pregnant worker (DPW) who continues to work in controlled areas should continue to wear their dosimeter in the normal manner if entering areas or performing work for which individual monitoring is required. A supplemental monthly dosimeter will be assigned by the dosimetry health physicist to be worn on or near the DPW’s abdomen and evaluated to ensure doses are kept below the limit (0.5 rem/gestation period) as well as uniformly low over the gestation period. Guidance for determining the dose to the embryo/fetus is provided in NRC Regulatory Guide 8.36. Guidance for instructing workers about prenatal radiation exposures is provided in NRC Regulatory Guide 8.13. The DPW will be provided a copy of this regulatory guide, which has common questions and answers as well as a template form for declaring the pregnancy. TRISO-X management will maintain a written policy describing how to handle job assignments for a DPW who normally works in the restricted area (RA). Management will strive to reach a mutually

agreeable decision with the DPW on whether or not the DPW will work in the RA during the pregnancy and, if so, the limitations thereof. The DPW may undeclare (in writing) the pregnancy at any point in time.

Administrative Limits
Due to the very low expected exposures from external radiation, the action level for external monitoring doses will initially be established as 10% of the whole-body annual effective dose limit for adults (which is also the monitoring threshold for adults) unless a lower annual ALARA goal for external doses is established in written policies.

Actions to be taken in the event of an exceedance include following up with the individual and their supervisor about the result, determining to the extent possible if the elevated dosimeter result could have been caused by medical testing with radiopharmaceuticals, and further validating the result. If the result is determined to be valid, then consideration will be given to whether any work area or individual work assignment changes are warranted. If the result is not valid, then the dosimetry health physicist will determine if a corrected dose should be determined and documented with both the vendor and with any internal dose tracking systems. The investigation results in all cases will be documented by health physics staff and approved by appropriate individuals per written procedures.

License Changes:
License Chapter 4, Section 4.7.2, *Dosimetry Program*, last paragraph, will be revised as follows (changes in red).

> The monitoring requirements in 10 CFR Part 20 are summarized in Table 4-2. In accordance with the requirements of 10 CFR Part 20.1202, the TEDE is calculated by adding the Deep Dose Equivalent (DDE) to the CEDE for each person who requires both internal and external dose monitoring. The TEDE will not exceed the 10 CFR Part 20 dose limits. Investigation levels and action guides for external and internal exposure are established in RPP procedures. Work activity restrictions are imposed when an individual's exposure exceeds 80 percent of the applicable 10 CFR 20.1201 limit.

License Chapter 4, Section 4.7.2.1, *External Dosimetry*, will be revised as follows (changes in red).

> Monitoring for exposure to external radiation is established according to the requirements in 10 CFR 20.1502(a) if external occupational dose is likely to exceed 10% of the dose limit appropriate for the individual (adult, minor, or declared pregnant woman). External radiation monitoring is also provided according to 10 CFR 20.1502(a)(3) for any individual entering a high or very high radiation area (areas requiring HRA and VHRA posting are not anticipated at the TRISO-X FFF). Beta-gamma sensitive thermoluminescent type dosimeters (TLDs) capable of measuring deep dose to the whole body, shallow dose to the skin or extremities, and dose to the lens of the eye are individually assigned for routine external exposure monitoring based on work area surveys, occupancy time, or other exposure information such as area monitor results. Personnel dosimeters, with sensitivities and exchange frequencies that are appropriate for the source term, are provided~~, exchanged,~~ and processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited dosimetry vendor or supplier. Other types of dose measuring devices may be used including electronic dosimeters,

direct-reading dosimeters, extremity dosimeters, neutron dosimeters and/or measurements made with portable radiation surveys instruments.

RAI-10 Assessing organ dose weighting factors, Derived Air Concentration (DAC) and Annual Limit on Intake (ALI):

Regulatory Basis:
Appendix B to Part 20, entitled “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage” specifies the values that must be utilized for calculating the regulatory dose limits in Part 20 (e.g., 10 CFR Subpart C, “Occupational Dose Limits,” and Subpart D, “Radiation Dose Limits for Individual Members of the Public.”). To utilize values other than those specified in Appendix B requires an exemption. In addition, 10 CFR 70.17(a) states in part that exemptions must be, “… authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.”

Describe Issue:
Sections 1.3.4, 4.6.1, and 4.7.2.3 of the LA describe using International Commission on Radiological Protection (ICRP) 68. Section 4.6.1 of the LA includes the phrase, “ICRP- 68 or later” in evaluating DAC and ALI values based on the dose coefficients published in the International Commission on Radiation Protection Publication 68. The exemption can only be applied to a specific ICRP standard for us in place of the DAC and ALI values specified in 10 CFR Part 20, Appendix B. The use of the phrase, “ICRP-68 or later” is problematic because it implies the exemption, if approved, would allow use of multiple ICRP standards.

Information Needed:
Please limit the exemption request to apply to use of ICRP 60 and 68 and remove the phrase “or later,” where applicable, which implies other standards may be used.

TRISO-X Response to RAI-10:
License Chapter 4, Section 4.6.1, *Building/Area Ventilation*, uses the phrase “and later,” which will be removed from the license as shown below. This phrase is not used in any other locations within the license.

License Changes:
License Chapter 4, Section 4.6.1, *Building/Area Ventilation*, will be revised as follows (changes in red).

> Barriers in the form of containment, ventilation, and filtration are designed to reduce discharges of radioactive material to ALARA levels. Appropriately sized ventilation is provided in areas of the facility where the potential exists for airborne concentrations of radionuclides to exceed the Derived Air Concentration (DAC) values during normal operations based on the dose coefficient values in ICRP Publication 68 ~~and later~~. The design of the confinement ventilation system ensures the desired airflow during normal operations. Air that is recirculated is filtered through at least one stage of HEPA filtration.

Enclosure 2 - Chemical Safety RAI Responses for the TRISO-X License Application

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 exposures 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 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.

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[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."

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

TRISO-X Response to RAI-1:
License Chapter 6, *Chemical Process Safety*, will be updated per the redline text below to evaluate credible unmitigated accidents that involve acute chemical exposure under NRC jurisdiction. The acute chemical exposure pathways evaluated are inhalation, dermal, and ingestion. The ISA Summary will be updated similarly with the addition of the methodology for evaluating acute dermal exposures as listed below.

License and ISA Summary Changes:
License Chapter 6, Section 6.2.2, *Identification and Evaluation of Chemical Accident Sequences*, will be revised as follows (changes in red).

> Potential accident sequences involving chemical hazards related to the safety of licensed materials are incorporated as part of the ISA. Accident sequence identification, consequence and likelihood determination, and risk assessment methods are discussed in Chapter 3 and the ISA Summary.
>
> The ISA includes evaluations of chemical risks of licensed materials, risk of chemicals derived from licensed materials, and chemical risks introduced by facility conditions that could affect the safety of licensed materials. The ISA identifies and evaluates credible unmitigated accidents involving acute chemical exposures under NRC regulatory jurisdiction. The acute chemical exposure pathways evaluated are inhalation, dermal, and ingestion. Analysis assumptions consider the maximum foreseeable inventories of chemicals at specific locations. Routine, non-routine, and credible abnormal operational scenarios are included in the analysis, along with conservative physical properties of the associated chemicals. Results of the evaluations are compared to the performance criteria in 10 CFR 70.61, and unmitigated scenarios that could result in Intermediate or High consequences are documented in the ISA Summary. IROFS and appropriate management measures are applied to Intermediate or High consequence scenarios to ensure that the performance criteria in 10 CFR 70.61 are met.

ISA Summary Section 5.8, *Chemical Consequence Analysis*, will be revised as follows (changes in red). Note that the 3rd paragraph below was moved from ISA Summary Section 5.8.3 to 5.8.

> This methodology applies to chemical hazards associated with licensed materials and hazardous chemicals produced from licensed materials. Chemical risks of plant conditions that could affect the safety of licensed materials are required to be evaluated by 10 CFR 70.61. Credible unmitigated accidents involving acute chemical exposures under NRC regulatory jurisdiction are evaluated. The acute chemical exposure pathways evaluated are inhalation, dermal, and ingestion. Some of the methods to ~~calculate inhalation~~evaluate exposures to the workers and individuals located offsite are presented below for use with potential accidents identified by the ISA process. Other industry accepted techniques may also be used to perform the evaluations or calculations (e.g., ALOHA, RASCAL)~~, provided the methods are confirmed to provide similar results to the methodologies prescribed in this section, or~~ if the methods in this section do not cover the specific condition.

Each potential accident sequence that involves acute inhalation from a chemical release under the scope of the ISA and not screened out per Section 5.8.2 is evaluated to determine the exposure concentration to the worker and the public in mg/m^3 or ppm. These exposure concentrations are then compared to Table 5-1 to determine the chemical consequences of low, intermediate, or high where "CHEM" represents the chemical exposure standard (AEGL, ERPG, or TEEL).

Per Section 3.4.3.2 (7) of NUREG-1520, "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." Therefore, these airborne concentration exposure standards are provided in Section 7 and are used to determine the chemical exposure consequence levels.

ISA Summary Section 5.8.2, Chemical Screening Criteria, will be revised as follows (changes in red).

5.8.2 Chemical Screening Criteria

The following steps provide a systematic ~~pre-~~screening process to identify chemicals with potential acute exposure consequences, as well as to eliminate chemicals that pose no risk to workers or the public ~~due to a release scenario as well as identify chemical with potential acute exposure consequences~~. Documentation of the screening results ~~will be~~is provided in the ACE for potential chemical accident sequences that are identified by the PHA ~~and then screened out by this process. These events are listed as low consequence events for resolution and inclusion in the ISA summary~~.

Acute Inhalation Pathway Screening

The Protective Action Criteria (PAC) database (https://edms3.energy.gov/pac) includes AEGL, ERPG, and TEEL acute inhalation exposure limits. The EPA database (https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values#chemicals) is an additional source of AEGL acute inhalation exposure limits. Chemicals identified within the PAC or EPA database are evaluated for potential acute chemical exposures as part of the ISA process, whereas chemicals not listed in the PAC or EPA database are screened out.

Acute Dermal Pathway Screening

Chemicals are screened using information found in a variety of industry-accepted chemical databases. These databases include, but are not limited to:

1. The GESTIS database, which uses the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS defines different types of hazards (physical, health, and environmental) and establishes methods for assigning standardized GHS hazard statements used to communicate information about the severity of the hazard for specific exposure routes.
2. NIOSH Skin Notation Profiles, if available for the chemical, provide information regarding whether a chemical has systemic, direct, and/or sensitizing skin effects. NIOSH Skin Notation Profiles are further categorized depending on the toxicity and corrosive or irritant effects that chemicals may cause to exposed skin.

3. The NIH PubChem Database provides an additional source of information for GHS hazard statements and skin corrosion categories.

Information relevant to the screening process is presented below for GHS hazard statements, GHS skin corrosion/irritation categories, and NIOSH skin notations.

The GHS hazard statements relevant to dermal exposures are:

- H310 (fatal in contact with skin)
- H311 (toxic in contact with skin)
- H314 (causes severe skin burns and eye damage)
- H312 (harmful in contact with skin)
- H313 (may be harmful in contact with skin)
- H315 (causes skin irritation)
- H316 (causes mild skin irritation)
- H317 (may cause an allergic skin reaction)

The GHS skin corrosion/irritation categories are:

- Category 1 (skin corrosion) irreversible damage to skin
- Category 2 (skin irritation) reversible damage to skin
- Category 3 (mild skin irritation)

The NIOSH Skin Notations are:

- SK:SYS (FATAL) – highly or extremely toxic and have the potential to be lethal or life-threatening following acute contact with the skin
- SK:SYS – systemic toxicity through dermal absorption
- SK:DIR (COR) – skin corrosion at point of contact
- SK:DIR (IRR) – skin irritation at point of contact
- SK:SEN – causes or contributes to allergic contact dermatitis

The databases referenced above should also be used to gather information related to chemical concentration and effects based on potential exposure times. Additionally, information based on human data should be prioritized over animal data. By considering information from a variety of industry accepted chemical databases, enough information may be obtained for each chemical to be screened and evaluated.

Chemicals listed in the databases with any of the below listed hazard statements, categories, or skin notation profiles require further evaluation per Section 5.8.10.

- **Corrosion Evaluation Required for:**
  - H314 hazard statement
  - Category 1 (skin corrosion)
  - SK:DIR (COR) skin notation profile

- **Toxicity Evaluation Required for:**
  - H310 hazard statement
  - H311 hazard statement
  - SK:SYS (FATAL) skin notation profile
  - SK:SYS skin notation profile

Chemicals listed in the databases without these GHS hazard statements, GHS skin corrosion/irritation categories, or NIOSH skin notations do not require further evaluation.

~~***Retail Chemicals***~~
~~Chemicals that that are commonly available and used by the general public, including any substance to the extent it is used for personal, family, or household purposes and that is present in the same form, quantity, and concentration as a product distributed for use by the general public do not require further evaluation.~~

~~***Laboratory Standards and Laboratory Quantities***~~
~~Laboratory standards that have low concentrations or small quantities of hazardous constituents do not require further evaluation. This pertains to small-scale use quantities of chemicals similar to the intent of 29 C.F.R. § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories (i.e., containers that are designed to be easily and safely manipulated by one person).~~

~~***Chemical Reagents***~~
~~Chemicals that are not listed in the Protective Action Criteria (PAC) database (https://edms.energy.gov/pac) will be evaluated under the chemical safety/industrial hygiene program as described in Chapter 6 of the License Application to provide the necessary controls to prevent or mitigate credible exposures.~~

ISA Summary Section 5.8.3, *Inhalation Exposure Pathway*, will be revised as follows (changes in red). The first paragraph was deleted to focus on the ISA evaluation of acute chemical exposure under NRC jurisdiction.

5.8.3 ~~Inhalation~~ Chemical Exposure Pathways

~~TRISO-X commits to providing a Chemical Safety Program in License Chapter 6 to provide protection and mitigation for workers. The Chemical Safety Program implements an industrial hygiene safety program that includes several barriers to protect the worker and prevent/limit dermal and ocular exposure(s). The primary barrier is utilization of passive engineered controls to maintain containment of the chemicals through construction of chemically compatible vessels and piping as well as incorporating chemical metering vessels that limit the volume of chemicals transferred. Active engineered controls also provide level measurement and interlocks for level control. 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. Lastly, the industrial hygiene program provides mitigating measures for chemical exposures that include safety showers, eye wash stations, first aid, and medical attention.~~

Acute chemical consequences are based on inhalation and dermal ~~as the~~ exposure pathways, and ~~. The~~evaluation methodologies ~~for evaluating inhalation and dermal exposure pathways~~ are provided in Sections 5.8.4 and 5.8.10, respectively. ~~since inhalation is considered most impactful for toxic chemical exposures based on DOE-HDBK-1224-2018, *Hazard and Accident Analysis Handbook*, Page 300, Section 9.4.2. Furthermore, Crowl, D. A., et al., *Chemical Process Safety Fundamentals with Applications*, Fourth Edition, Pearson Educational, Inc., 2019, Page 56, Section 2-1, demonstrates that toxic blood levels are significantly higher from inhalation as compared to dermal and ocular exposures. The chemical safety/industrial hygiene program elements provide the necessary controls to prevent/limit dermal and ocular exposures, whereas~~

~~additional controls, such as IROFS, may be required to prevent or mitigate more severe chemical exposures as determined by using airborne concentration chemical exposure standards.~~

~~Per Section 3.4.3.2 (7) of NUREG 1520, "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." Therefore, these airborne concentration exposure standards are provided in Section 7 and are used to determine the chemical exposure consequence levels.~~

The following stresses can lead to chemicals becoming airborne for inhalation exposure:

- free-fall spills and impacts
- fires and explosions
- thermal
- evaporation
- chemical reactions.

ISA Summary Section 5.8.10, *Acute Dermal Exposure*, will be added as a new section (additions in red).

5.8.10 Acute Dermal Exposure

Corrosive Evaluation

Chemicals listed with an H314 hazard statement, Category 1 (skin corrosion), or SK:DIR (COR) skin notation must be evaluated for a skin corrosion hazard. The evaluation should consider an unmitigated release (i.e., spill or spray) from the chemical supply and should consider process parameters such as volume, flow rate, and pressure. In addition, the evaluation should consider the potential for a worker to be in the area of the spill or spray, and the potential exposure time. A total exposure time of 1 minute is typically assumed for the worker to detect the release or spill and leave the immediate area of exposure. IROFS may be applied to prevent or mitigate the consequences of a spill or spray to the worker. Unless designated as an IROFS, PPE may not be credited to prevent or mitigate the consequences of a spill or spray.

The evaluation compiles industry database information for the chemical of concern and focuses on relevant and appropriate information for the potential exposure scenario. This information serves as the standard used to conclude whether dermal exposure to a corrosive chemical is classified as a low, intermediate, or high consequence.

Screening guidelines for comparison to 10 CFR 70.61 are provided below.

Comparison of GHS hazard statements to 10 CFR 70.61:

- Evaluate for Potential Intermediate Consequence
  - H314 (causes severe skin burns and eye damage)
- Less than Intermediate Consequence
  - H312 (harmful in contact with skin)

- H313 (may be harmful in contact with skin)
- H315 (causes skin irritation)
- H316 (causes mild skin irritation)
- H317 (may cause an allergic skin reaction)

Comparison of GHS skin corrosion/irritation categories to 10 CFR 70.61:

- Evaluate for Potential Intermediate Consequence
  - Category 1 (skin corrosion) irreversible damage to skin
- Less than Intermediate Consequence
  - Category 2 (skin irritation) reversible damage to skin
  - Category 3 (mild skin irritation)

Comparison of NIOSH Skin Notations to 10 CFR 70.61:

- Evaluate for Potential Intermediate Consequence
  - SK:DIR (COR) – skin corrosion at point of contact
- Less than Intermediate Consequence
  - SK:DIR (IRR) – skin irritation at point of contact
  - SK: SEN – causes or contributes to allergic contact dermatitis

Toxicity Evaluation

Chemicals which have an H310 hazard statement, H311 hazard statement, SK:SYS (FATAL) skin notation, or SK:SYS skin notation must be evaluated for a skin toxicity hazard. The evaluation should consider an unmitigated release (i.e., spill or spray) from the chemical supply and should consider process parameters such as volume, flow rate, and pressure. In addition, the evaluation should consider the potential for a worker to be in the area of the spill or spray, and the potential exposure time. IROFS may be applied to prevent or mitigate the consequences of a spill or spray to the worker. Unless designated as an IROFS, PPE may not be credited to mitigate the consequences of a spill or spray.

Screening guidelines for comparison to 10 CFR 70.61 are provided below.

Comparison of GHS Hazard Statements to 10 CFR 70.61:

- Evaluate for Potential High Consequence
  - H310 (fatal in contact with skin)
- Evaluate for Potential Intermediate Consequence
  - H311 (toxic in contact with skin)

Comparison of NIOSH Skin Notations to 10 CFR 70.61:

- Evaluate for Potential High Consequence
  - SK:SYS (FATAL) – highly or extremely toxic and have the potential to be lethal or life-threatening following acute contact with the skin
- Evaluate for Potential Intermediate Consequence
  - SK:SYS – systemic toxicity through dermal absorption

A quantitative evaluation is performed to compare the acute dermal absorbed dose to the calculated acute inhalation absorbed dose via the lung. The below calculations quantitatively evaluate the toxicity of a given chemical. The chemical flux rate into the skin, J (mg/cm^2-hr) is calculated based on methodology from the OSHA Technical Manual, Section II, Chapter 2, *Surface Contaminants, Skin Exposure, Biological Monitoring and Other Analyses* (2014):

$J = K_p \; x \; Concentration$	**Equation Chem-25**

Where:

K_p = Dermal permeability factor (from EPA/540/R99/005 or other industry reference) (cm/hr); and
Concentration = Concentration of chemical on skin (mg/cm^3)

The acute dermal absorbed dose (mg) is calculated:

$Dermal\ Absorbed\ Dose = Area \; x \; J \; x \; time$	**Equation Chem-26**

Where:

Area = Exposed skin area (cm^2) – assumed to be 1000 cm^2 , approximately a 12.5-inch by 12.5-inch area. Based on the release potential from either small diameter process lines or limited size vessels within the uranium processing area;
J = Flux rate (mg/cm^2-hr); and
Time = Exposure time (hr) – assumed to be 1 minute, based on 'see and flee.'

The acute dermal absorbed dose (mg) can then be compared to an AEGL or PAC inhalation exposure limit (mg/m^3) using the calculation below:

$Inhalation\ Absorbed\ Dose = Inhalation\ exposure\ limit \; x \; breathing\ rate \; x \; time$	**Equation Chem-27**

Where:

Inhalation exposure limit = AEGL (or PAC) value (mg/m^3)
Breathing rate = 3.3x10^{-4} m^3/sec (10 CFR 20, Appendix B, Table 1 "Occupational Values")
Time = Acute exposure time (sec) based on AEGL or PAC exposure limit

This calculation allows the acute dermally absorbed dose (mg) from a toxic liquid chemical exposure to be compared to the calculated acute inhalation absorbed dose via the lung (mg) for a gas or vapor chemical exposure to determine if the dermal exposure reaches an intermediate or high consequence.

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."

Enclosure 2 - Chemical Safety RAI Responses for the TRISO-X License Application

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-HDBK1224-2018 (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 noninhalation 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).

[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.

TRISO-X Response to RAI-2:
The TRISO-X response to RAI-1 includes a description of the methodology for assessing the applicable chemical hazards of licensed material and hazardous chemicals produced from licensed material for the applicable exposure pathways. This also includes a description of the databases used for the evaluation. This information is included in the changes to ISA Summary Sections 5.8.2 and 5.8.10.

License and ISA Summary Changes:
See the changes to the ISA Summary Sections 5.8.2 and 5.8.10 in the TRISO-X response to RAI-1.

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.

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

[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.

information) or propose a methodology for assessing the consequences without a quantitative standard.

TRISO-X Response to RAI-3:
The TRISO-X Response to RAI-1 describes the method for classifying credible non-inhalation exposure accident sequences consistent with 70.65(b)(7) and the technical basis for assessing acute dermal exposures. References are provided to industry-accepted chemical databases to support consequence determination. This information is included in the new ISA Summary Section 5.8.10.

License and ISA Summary Changes:
See the new ISA Summary Section 5.8.10 added by the TRISO-X Response to RAI-1.

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.

TRISO-X Response to RAI-4:
Section 5.8.3 of the ISA Summary will be revised to remove the discussion of occupational exposures and PPE. PPE is not identified as IROFS.

License and ISA Summary Changes:
See the changes to the ISA Summary Section 5.8.3 in the TRISO-X Response to RAI-1.

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.

TRISO-X Response to RAI-5:
The ISA Summary provides the functional requirements for the IROFS. The ISA Risk Assessment (Document TX0-RPT-ISA-006) currently available on the online portal provides additional details for the IROFS basis; however, design details such as setpoint and detection values will be available in IROFS design packages which will be placed in the online portal for review when complete. Operator actions pertaining to IROFS are implemented through procedures, training, and postings.

ISA Summary Changes:
None.

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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.

TRISO-X Response to RAI-6:
The ISA Risk Assessment (Document TX0-RPT-ISA-0006), Chemical Accident Consequence Evaluation report (Document XE-iFOA-RPT-0087), and associated PHA reports are available in the online review portal. These reports provide additional details for the accident sequences.

ISA Summary Changes:
None.

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.

TRISO-X Response to RAI-7:
The ISA Risk Assessment (Document TX0-RPT-ISA-0006), Chemical Accident Consequence Evaluation report (Document XE-iFOA-RPT-0087), and associated PHA reports are available in the online review portal. These reports provide additional details for the accident sequences. Potential exothermic reaction hazards are identified during the PHA for each part of the manufacturing process. As part of the PHA, the NOAA CAMEO Chemicals database is used to screen chemical compatibility and flag chemicals which could potentially present an exothermic reaction hazard when mixed. Exothermic reaction hazards are then evaluated as part of the ISA risk assessment.

License and ISA Summary Changes:
None.

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.

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TRISO-X Response to RAI-8:
ISA Summary Section 5.8.2 has been revised (see the TRISO-X response to RAI-1) to clarify the screening criteria which uses chemical database information, including GHS hazard statements.

ISA Summary Changes:
The TRISO-X response to RAI-1 provides additional information on the screening criteria discussed in section 5.8.2 of the ISA Summary and removes the elimination of chemicals solely based on retail availability and/or low chemical concentration.

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.

TRISO-X Response to RAI-9:
ISA Summary Section 5.8.4 will be updated to clarify that the consequence evaluation is determined based on the room/compartment volume, and not the entire building volume. The Chemical Accident Consequence Evaluation report (Document XE-iFOA-RPT-0087) available in

the online portal demonstrates that the chemical concentrations were calculated with room/compartment volumes, rather than the entire building volume.

License and ISA Summary Changes:
ISA Summary Section 5.8.4, *Occupational Exposure*, will be revised as follows (changes in red).

> **5.8.4 Occupational Acute Inhalation Exposure**
> The occupational acute inhalation exposure is determined for the airborne concentration at the location of the release. The release is assumed to occur at ground level unless otherwise specified in the evaluation. The concentration of the material is estimated per *Mathematical Models for Estimating Occupational Exposure to Chemicals*, Section 2.3, by assuming that the airborne Source Term (ST) is instantaneously and homogenously mixed throughout the volume of the room or workspace without considering building ventilation. 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 airborne concentration of the material is determined using Equation Chem-1 below:

$C_i = \frac{ST_i}{V_D}$	**Equation Chem-1**

> Where:
>
> Ci = Airborne concentration of material "i"(mg/m^3)
> STi = Airborne source term of material "i" (mg)
> VD = Volume of ~~building~~ room available for dispersion of the material (m^3)
>
> When the ST is based on a release rate that is estimated from the evaporation rate from liquid spills and release rate of gases, Equation Chem-2 is used to calculate the airborne concentration.

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.

TRISO-X Response to RAI-10:
Visual, audible, and cutaneous senses may be used to identify releases through the events that cause the release or the properties of the release itself. For example, the sound created by a guillotine break resulting in a loud pressurized release would be heard by a nearby operator. Use of the methodology presented in the ISA Summary, Section 5.8.4 has resulted in high consequence events for releases of carbon monoxide, hydrogen, acetylene, propylene, and MTS based on a 10-minute exposure time. A see and flee time longer than 10 minutes would still result in a high consequence event for these invisible or odorless gases.

License and ISA Summary Changes:
None.

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.

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TRISO-X Response to RAI-11:
The Chemical Accident Consequence Evaluation report (Document XE-iFOA-RPT-0087), which includes calculation sheets in Appendix A, is available in the online review portal. Additional evaluations to address acute dermal exposures will be added to the online review portal.

ISA Summary Changes:
None.