

**Request for Additional Information for the TRISO-X, LLC (TRISO-X)  
License Application Review (Set 1)**

This enclosure contains the following requests for additional information (RAIs):

1. Quality Assurance and Management Measures – Part 1 (5 RAIs)
2. Human Factors Engineering – Part 1 (1 RAI)
3. Structural – Part 1 (2 RAIs)

1. QUALITY ASSURANCE AND MANAGEMENT MEASURES – PART 1

**RAI 1-1 – Construction Qualifications:**

**Regulatory Basis:**

The regulations in title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(6), 70.23(a)(2), and 70.62(d) require a management system and administrative procedures for the effective implementation of health, safety, and environment functions concerning the applicant's corporate organization, qualifications of the staff, and adequacy of the proposed equipment, facilities, and procedures to provide adequate safety for workers, the public, and the environment.

Guidance for meeting these requirements can be found in NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," Chapter 2, Section 2.4.3(A). NUREG-1520, Revision 2, Chapter 11, "Management Measures," also provides guidance on this topic.

**Description of Issue:**

Chapter 2, "ORGANIZATION AND ADMINISTRATION", Section 2.3, "Organizational Responsibilities, Authority, and Qualifications," of the TRISO-X License Application (LA) only mentions construction activities as a responsibility of the engineering discipline. The outlined organizational positions and disciplines do not include the need to have training, qualification, or experience in executing construction projects.

**Information Needed:**

Please provide additional detail on organizational roles and responsibilities (e.g., Plant Manager, Regulatory Affairs, Quality Assurance) during the construction phase of the facility. Also, discuss any special qualifications or experience that may be required for each discipline participating in the construction phase.

**RAI 1-2 – Quality Standards for IROFS**

**Regulatory Basis:**

The 10 CFR 70.64(a)(1) states, "Quality standards and records. The design must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility."

**Description of Issue:**

The LA does not include a commitment to established quality standards or describe how they would be applied to items relied on for safety during facility construction or operations.

**Information Needed:**

Provide a comprehensive list of all quality standards that will be utilized and describe how each will be applied to items relied on for safety (IROFS). Include details on any published standards that TRISO-X intends to implement that are applicable to the maintenance of quality records relating to IROFS that ensure adherence to the retention period specified in 10 CFR 70.64(a)(1).

**RAI 1-3 – IROFS Basic Components**

**Regulatory Basis:**

10 CFR 21.3(3) states, “When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear powerplants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.”

**Description of Issue:**

The LA does not identify which IROFS are considered basic components. The LA also has insufficient detail on how TRISO-X will comply with the requirements of 10 CFR 21, “Reporting of Defects and Noncompliance.”

**Information Needed:**

Identify which IROFS (if any) are considered basic components as defined in 10 CFR 21.3(3). Describe how TRISO-X will adhere to all the requirements of 10 CFR 21. At a minimum, provide the following aspects of the 10 CFR 21 program: (1) procurement processes, (2) dedication processes, and (3) reporting processes.

**RAI 1-4 – Quality Assurance Elements for IROFS**

**Regulatory Basis:**

In accordance with 10 CFR 70.62(d), each applicant must establish management measures to ensure that IROFS, as documented in the Integrated Safety Analysis (ISA) Summary, provide reasonable assurance that they will be designed, implemented, and maintained in such a way as to ensure that they are available and reliable to perform their intended functions, when needed, to comply with the performance requirements of 10 CFR 70.61. The degree to which measures are applied may be a function of the item’s importance in meeting the performance requirements.

NUREG-1520, Revision 2, Chapter 11, “Management Measures,” gives examples of how “the other QA elements” portion of a management measures program may be applied in a graded manner. NUREG-1520, Revision 2, discusses how certain elements are amenable to being applied in that way and identifies these elements as: (1) QA program; (2) Design Control; (3) Procurement Document Control; (4) Instructions, Procedures, and Drawings; (5) Document Control; (6) Control of Purchased, Material, Equipment, and Services; (7) Inspection; (8) Test Control; (9) Control of Measuring and Test Equipment; (10) Handling, Storage, and Shipping; (11) Corrective Action; (12) Quality Assurance Records; (13) Audits.

**Description of Issue:**

The LA does not contain sufficient detail on how the “other quality assurance elements” portions of the TRISO-X management measures program will be applied to IROFS in a manner consistent with an item’s importance to safety.

**Information Needed:**

Describe how the “Other Quality Assurance (QA) Elements for IROFS,” as described in LA Section 11.8 of the TRISO-X management measures program, are applied to IROFS. Specifically, discuss how the TRISO-X QA program will grade IROFS commensurate with the reduction of risk attributable to that item and how each of the quality assurance elements is applied to IROFS in a manner consistent with their grade.

**RAI 1-5 – Qualify Special Processes**

**Regulatory Basis:**

In accordance with 10 CFR 70.62(d), each applicant must establish management measures to ensure that IROFS, as documented in the ISA Summary, provide reasonable assurance that they will be designed, implemented, and maintained in such a way as to ensure that they are available and reliable to perform their intended functions, when needed, to comply with the performance requirements of 10 CFR 70.61. The degree to which measures are applied may be a function of the item’s importance in meeting the performance requirements.

NUREG-1520, Revision 2, Chapter 11, “Management Measures,” gives examples of how some QA elements of a management measures program are not conducive to grading. Special processes are one such QA element. It provides the following guidance regarding special processes:

“Control of Special Processes:

Where used, special processes such as welding, heat treating, and nondestructive examination should be performed by qualified personnel using qualified procedures.”

**Description of Issue:**

The LA does not contain sufficient detail on how TRISO-X will adequately implement the Control of Special Processes element of the “Other Quality Assurance (QA) Elements for IROFS” portion of its management measures program.

**Information Needed:**

Describe how TRISO-X plans to qualify personnel and procedures involved in special processes.

## 2. HUMAN FACTORS ENGINEERING – PART 1

### RAI 2-1 – Human Factors Program

#### **Regulatory Basis:**

The 10 CFR 70.61(e) states, in part, that required administrative controls shall be designated as an IROFS and that the safety program of 10 CFR 70.62 shall ensure that each IROFS will be available and reliable to perform its intended function when needed.

The 10 CFR 70.62(d) states, in part, that applicants shall establish management measures to ensure compliance with the performance requirements of 70.61, that the measures applied to a particular administrative control may be graded commensurate with the reduction of the risk attributable to that control, and that management measures shall ensure that administrative IROFS required by 70.61(e) are designed, implemented, and maintained as necessary to ensure they are available and reliable to perform their function when needed.

NUREG-1520, Revision 2, Section 3.4.3.1, “Safety Program and Integrated Safety Analysis Commitments,” and Appendix E, “Human Factors Engineering [HFE] for Personnel Activities,” provide guidance for one acceptable method to determine that HFE has been applied to personnel activities identified as safety significant.

#### **Description of Issue:**

Section 11 of the LA states that the ISA Summary identifies IROFS applied to facility systems and activities to assure they function to satisfy the performance requirements of 10 CFR 70.61. Section 5.10 of the ISA Summary describes the consideration of human factors within the context of both administrative controls and enhanced administrative controls. However, neither the LA nor ISA Summary describe an HFE program. This HFE programmatic information is necessary to establish assurance in the reliability of administrative IROFS that are credited under the ISA.

#### **Information Needed:**

Please describe how the TRISO-X Human Factors Engineering (HFE) program will address the areas that are associated with personnel activities including:

- Identification of Personnel Activities;
- HFE Design Review Planning;
- Operating Experience Review;
- Functional Allocation Analysis and Task Analysis;
- Human-Systems Interfaces Design, Inventory, and Characterization;
- Staffing;
- Procedure Development;
- Training Program Development; and
- Verification and Validation.

### 3. STRUCTURAL – PART 1

#### **RAI 3-1 – Design-Basis for Local Intense Precipitation**

##### **Regulatory Basis:**

This information is necessary to demonstrate compliance with the regulations in 10 CFR 70.64(a)(2), which states, in part, that the design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site. The guidance in NUREG-1520, Revision 2, describes, in part, one acceptable approach to demonstrate compliance with the regulation and includes the acceptance criteria used for the NRC staff's review.

##### **Description of Issue:**

Section 1.1.2, "Facility Building and Structures," of the LA describes the design-basis values and their corresponding annual probability of exceedance of each natural phenomena hazard considered in the design of the facility. However, the application does not include the design-basis values for the design of the facility against local intense precipitation and/or local storm runoff. A description of the design-basis values for each design-basis event applicable to the site (e.g., meteorological, seismic, hydrological and geological events) is necessary to demonstrate that the design of the new facility will provide adequate protection against natural phenomena hazards.

##### **Information Needed:**

Provide the values used for the design-basis of the facility against local intense precipitation (i.e., 15-minute and 60-minute precipitation design intensities applicable for the site) and their corresponding annual probability of exceedance.

#### **RAI 3-2 – Evaluation for local intense precipitation**

##### **Regulatory Basis:**

This information is necessary to demonstrate compliance with the regulations in 10 CFR 70.61 which states, in part, in sections (b) and (c) that the risk of credible high- and intermediate- consequence events must be limited, and section (e) which requires the implementation of items relied on for safety. The guidance in NUREG-1520, Revision 2, describes, in part, one acceptable approach to demonstrate compliance with the regulation and includes the acceptance criteria used for the NRC staff's review.

##### **Description of Issue:**

Section 1.1.1.3, "Hydrology," of the LA and Sections 1.4.1, "Flood," and 4.2.5.5, "Design Basis Flood," of the ISA Summary describe and evaluate the effects of flooding due to nearby water bodies (e.g., river, wetland, creek, etc.). However, the application does not evaluate the effects of flooding due to other flood-related events like local intense precipitation and local storm runoff at the site. As discussed in Appendix D of NUREG-1520, Revision 2, flooding hazards may also be related to local intense precipitation/runoff, storm surge, and other similar events. Therefore, additional information is necessary to demonstrate how the facility was evaluated to prevent or mitigate the consequences of flooding events not related to nearby water bodies, and if additional items relied on for safety need to be identified to demonstrate compliance with the performance requirements in 10 CFR 70.61.

##### **Information Needed:**

Provide an evaluation of the effects of flooding due to local intense precipitation and local storm runoff.