Enclosure 1 – Supplemental Information for Management Measures and Quality Assurance RAI Responses

RAI 1-1 – Construction Qualifications:

TRISO-X Supplemental Information for Response to RAI 1-1:
This response is a complete replacement of the RAI 1-1 response dated July 28, 2023.

License Section 2.6 presents TRISO-X responsibilities for the transition from design to construction to operations. The TRISO-X organization is responsible for the construction and commissioning of the facility and equipment using written plans and procedures. For initial facility construction, an architect/engineering (A/E) firm has been contracted to specify facility structures and systems, as well as to ensure the design meets applicable codes and standards. During the construction phase, construction activities and preparation of construction documents are completed using appropriately experienced contractors. TRISO-X oversight of the A/E and construction contracts may involve one or more disciplines/functions depending on the scope of the design or construction activity. Construction phase oversight of IROFS is provided by TRISO-X personnel within the Engineering, Regulatory Affairs, and Quality Assurance disciplines that meet the minimum requirements of a BS/BA and/or advanced degree, and at least one year of relevant applicable to the technical discipline, scope, and complexity of the construction oversight assignment. When a construction management function is used, the same minimum qualifications apply. Oversight activities typically include, but are not limited to, witnessing of construction activities, verifying material inputs, or confirming completion in accordance with stated requirements. If a code, standard, or specification governing a particular element of construction identifies specialty training or experience is required to conduct certain construction oversight activities, appropriate resources will be identified and assigned.

License Figure 2-1 provides a facility-specific organizational chart that is further described in License Section 2.2. Figure 2-1 demonstrates the independence of manufacturing, regulatory affairs, and quality assurance.

Authority to stop work is described in License Section 2.5.1, which was updated by the response to Chapter 2 RAI-3 dated August 25, 2023 (ML23237B484).

License Application Changes
License Section 2.6 “Transition from Design and Construction to Operations” will be revised as follows:

2.6 Transition from Design ~~and~~ to Construction to Operations

The TRISO-X organization as described in Sections 2.2 and 2.3 represents the personnel responsible for safe operations, and the organization is also responsible for providing direct supervision of planning, organizing, and overseeing the construction, installation, initial testing, and commissioning of the facility and equipment, including modifications in the future, using written plans and procedures. Construction oversight plans and procedures include description of oversight actions to be performed by TRISO-X personnel for IROFS.

For initial facility construction, an architect/engineering (A/E) firm has been contracted to specify facility structures and systems, as well as to ensure the design meets applicable codes and standards. During the construction phase, construction activities and preparation of construction documents are completed using appropriately experienced contractors. TRISO-X oversight of the A/E and

construction contracts may involve one or more disciplines/functions depending on the scope of the design or construction activity.

Construction phase oversight of IROFS is provided by TRISO-X personnel within the Engineering, Regulatory Affairs, and Quality Assurance disciplines that meet the minimum requirements of a BS/BA and/or advanced degree, and at least one year of relevant experience applicable to the technical discipline, scope, and complexity of the construction oversight assignment. When a construction management function is used, the same minimum qualifications apply. Oversight activities typically include, but are not limited to, witnessing of construction activities, verifying material inputs, or confirming completion in accordance with stated requirements. If a code, standard, or specification governing a particular element of construction identifies specialty training or experience is required to conduct certain construction oversight activities, appropriate resources will be identified and assigned.

As the construction of systems is completed, they undergo functional and acceptance testing, as appropriate, ~~as contained in~~in accordance with approved procedures. Following successful completion of testing and commissioning, detailed ~~transition~~ plans describe the transition from commissioning/start-up phase to operations. ~~and~~ O~~o~~perational readiness reviews led by the TRISO-X organization are used to confirm the equipment in each process area is functionally tested and ready to operate, items relied on for safety are in place, license-required programs and commitments are implemented, operating procedures are approved, and the assigned staff is trained and ready to safely commence operations when authorized to do so.

The turnover will include physical systems and corresponding design information and records. Following turnover, the manufacturing organization will be responsible for system maintenance and configuration control. The design basis is maintained following the configuration management system described in Chapter 11, “Management Measures”.

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RAI 1-2 – Quality Standards for IROFS

TRISO-X Supplemental Information for Response to RAI 1-2:
This response is a complete replacement of the RAI 1-2 response dated July 28, 2023.

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." License Chapter 11 contains descriptions of the eight management measure programs as required by 10 CFR 70 and as outlined in NUREG-1520, Chapter 11. In addition to the industry specific commitments in License Chapter 11, TRISO-X implements a Quality Program consistent with elements 4-8 and 10 of ISO 9001:2015. ISO 9001:2015 is referenced in License Chapter 2, Section 2.3.5 and License Chapter 11, Section 11.8.2. Section 11.8.2 will be revised to state that ISO 9001:2015 is the basis of the quality program, and aspects of the quality program are applied to IROFS based on criteria including, but not limited to, type of IROFS (passive, active, enhanced administrative, or administrative), complexity of design or fabrication, uniqueness of the item (commercially available or custom design), history of supply and performance, evaluation of the supplier's qualifications, and/or industry accepted practices.

NUREG-1520, Section 11.4.3.8.A, Element 17, states that for Quality Assurance (QA) Records, QA records and records management systems may be used in lieu of or in conjunction with each other. In either case, the applicant should describe the methods used to document, prepare, maintain, and manage records, including records associated with IROFS. TRISO-X uses a records management system and describes the required information in License Chapter 11, Section 11.7, Records Management; Section 11.1.2, Design Requirements; Section 11.1.3, Document Control; and Section 11.8.17, Quality Assurance Records. Specifically, License Chapter 11, Section 11.1.2 commits to addressing the baseline design criteria identified in 10 CFR 70.64(a) for IROFS, which includes the retention period specified for quality standards and records.

During the design process, individual requirements and applicable codes and standards (if any) for IROFS components are defined in design documents which make up the IROFS design package. IROFS design packages provide information to NRC reviewers and inspectors about supporting systems that directly affect the effectiveness of the IROFS and the reliability and availability of the IROFS as required by 10 CFR 70.62(d). TRISO-X developed IROFS design packages based on the guidance provided for "IROFS boundary packages" on page 3 and the associated footnote in the Introduction to NUREG-1520, Rev. 2. NUREG-1520, page 3-3, discusses IROFS boundary descriptions as "documentation supporting the ISA" that is "normally maintained at the facility." TRISO-X is using the term "IROFS design package" as equivalent to the NUREG-1520 term "IROFS boundary package."

The following document types are available in each IROFS design package, as applicable:

- Design Interface and Requirements (DIR)
- Engineering Design Specification (EDS)
- Design Analysis and Calculation (DAC), which may include:
    - Probability of Failure Upon Demand Calculation
    - Setpoint Calculation

- Drawings, which may include:
  - Piping and Instrumentation Diagram (P&ID)
  - Safety Loop Diagram
  - Flow Diagram

New ISA Summary Section 4.5, Quality Standards for IROFS, is included in Enclosure 2.

License Application Changes

License Chapter 11, Management Measures, first paragraph, will be revised as follows (changes in red):

> As specified in 10 CFR 70.62(d), management measures are applied to Items Relied on For Safety (IROFS) to provide reasonable assurance that the IROFS are designed, implemented, and maintained to ensure they are available and reliable to perform their functions when needed. 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. IROFS may be engineered controls (passive or active), enhanced administrative controls (active features that prompt a person to take an action), or administrative controls (actions of people). Management measures are applied to IROFS ~~using a graded approach~~ based on the type of control (passive, active, enhanced administrative, administrative) as identified in Table 11-1 ~~and may also consider the reduction of risk credited to that control and/or the item's importance in meeting the performance requirements~~. Methods used to select and assign management measures to IROFS are documented in approved procedures.

License Chapter 11, Section 11.1.2, Design Requirements, will be revised as follows (changes in red).

> Design requirements and documents are prepared by the engineering organization. Applicable codes and standards are identified in design documents. Prior to approval, the design documents are reviewed for adequacy, accuracy and completeness as per approved procedures. Changes to design documents or the ISA are subject to the change control processes as described in Chapter 1 and Section 11.1.4.

License Chapter 11, Section 11.8, Other Quality Assurance (QA) Elements for IROFS, will be revised as follows (changes in red). The Other QA Elements not included here will remain unchanged.

> **11.8 Other Quality Assurance (QA) Elements for IROFS**
>
> The TRISO-X quality system consists of the organizational structure, procedures, processes, and resources needed to implement quality management. ~~The following elements, as appropriate, are applied on individual projects using a graded approach based on the degree of importance to safety.~~ Other Quality assurance (QA) elements are applied to IROFS to ensure that there is reasonable assurance that IROFS are available and reliable to perform their functions when needed, as further described in approved procedures. The same level of management measures, including QA elements, are uniformly and consistently applied to IROFS irrespective of whether they are needed to prevent or mitigate intermediate or high consequence events.

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2. Quality Assurance Program
The QA Program is based on, but is not limited to, applicable requirements and guidance in ISO 9001:2015, under the overall responsibility of the Quality Assurance discipline. Aspects of this program ~~may be~~are applied to IROFS ~~using a graded approach~~ based on ~~the degree of importance to safety~~criteria including, but not limited to, type of IROFS (passive, active, enhanced administrative, administrative), complexity of design or fabrication, uniqueness of the item (commercially available or custom design), history of supply and performance, evaluation of the supplier's qualifications, and/or industry accepted practices.

4. Procurement Document Control
Procurement documents include those necessary requirements to ensure that IROFS will be of the desired quality. These include the following, as appropriate:

- Scope of work – description of services or items being procured.
- Basic technical requirements including drawings, specifications, codes, and industrial standards with applicable revision data, test and inspection requirements, special requirements such as for designing, fabricating, cleaning, identification marking, erecting, packaging, handling shipping and storage.
- QA requirements – the extent to which will depend upon the type and use of the item or services being procured.
- Requirements for the control of nonconformances and changes, including provisions to control and report nonconformance and changes to products being delivered.
- Requirements on sub-tier suppliers including the pass down of relevant technical and quality requirements.
- Procurement documents and changes thereto are reviewed to ensure they include the appropriate requirements.
Applicable 10 CFR 21, *Reporting of Defects and Noncompliance*, reporting requirements (if any).

7. Control of Purchased Items and Services
The procurement of IROFS is controlled to ensure conformance with documented requirements. The controls provide the following, as appropriate: supplier (source) evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; and examination of items or services upon delivery or completion. Suppliers will provide written quality documentation for evaluation prior to selection.

Sourcing activities are planned and documented to ensure a systematic approach to the procurement process. Supplier selection is based, in part, on an evaluation of the supplier's capability to provide items or services in accordance with the requirements of sourcing documents. Additional considerations may include complexity of design or fabrication, uniqueness of the item (commercially available or custom design), history of supply and performance, and/or industry accepted practices.

Supplier nonconformances may be identified either by TRISO-X or by the supplier. Nonconforming items are not released for use until the nonconforming condition is reviewed and accepted by TRISO-X and implementation of the disposition is verified, except where otherwise controlled and documented according to approved procedures. Records of supplier nonconformance are maintained.

Acceptance of purchased IROFS equipment will be performed to document evidence of compliance with the technical, quality and other requirements of the procurement document.

10. Inspection
    Acceptance testing and/or inspection is a part of the Configuration Management Program which ensures that IROFS meet specified requirements prior to initial use. The Surveillance and Monitoring, Preventive Maintenance, and Functional Testing functions, as described in Section 11.2, provide assurance that IROFS continue to meet specified requirements by assuring that these testing and inspection activities are scheduled and implemented. Characteristics of items inspected, including those identified as IROFS, will be specified in approved procedures, specifications, or plans.

11. Test Control
    Acceptance testing and/or inspection is a part of the Configuration Management Program which ensures that IROFS meet specified requirements prior to initial use. The Surveillance and Monitoring, Preventive Maintenance, and Functional Testing elements, as described in Section 11.2, provide assurance that IROFS continue to meet specified requirements by assuring that these testing and inspection activities are scheduled and implemented. Characteristics verified through testing are stated in approved test instructions.

License Chapter 11, Management Measures, will have the following new Table 11-1, Management Measures for IROFS, added. This table will also replace ISA Summary Table 4-4.

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Table 11-1
Management Measures for IROFS

Management Measures[1]	Passive Engineered Control	Active Engineered Control	Enhanced Administrative Control	Administrative Control
Configuration Management	X	X	X	X
Controlled Listing Identification	X	X	X	X
Drawing Identification	X	X	X	
Set point analyses	X	X	X	
Design Specifications	X	X	X	
Safety Installation Verification	X	X	X	
Pre-operational Safety Review	X	X	X	X
Maintenance	X	X	X	X
Periodic Functional Test	X	X	X	X – Note 2
Calibration		X	X	
Verification after Maintenance	X	X	X	
Pre-operational Tests	X	X	X	
Training and Qualification	X	X	X	X
Procedures	X	X	X	X
Procedural Identification			X	X
Posting Identification	X	X	X	X
Audits and Assessments	X	X	X	X
Records Management	X	X	X	X
Incident Investigations	X	X	X	X
Other quality assurance elements	X	X	X	X

Note 1 – The management measures identified for each type of control are the minimum required, if applicable. For example, it is not possible to calibrate certain types of active engineered controls.

Note 2 – For frequently used equipment, functionality is readily apparent at each use (e.g., leaking valve visually noticed at use point when valve is operated). Therefore, a periodic functional test is not required.

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RAI 1-4 – Quality Assurance Elements for IROFS

TRISO-X Supplemental Information for Response to RAI 1-4:
This response is a complete replacement of the RAI 1-4 response dated July 28, 2023.

TRISO-X does not use a graded approach. IROFS protecting against intermediate consequence events are not graded to fewer management measures than those for high consequence events. Management measures are applied to IROFS based on the type of control (passive, active, enhanced administrative, administrative) as identified in License Table 11-1. Methods used to select and assign management measures to IROFS are documented in approved procedures. Other Quality assurance (QA) elements are applied to IROFS to ensure that there is reasonable assurance that IROFS are available and reliable to perform their functions when needed, as further described in approved procedures. The same level of management measures, including QA elements, are uniformly and consistently applied to IROFS irrespective of whether they are needed to prevent or mitigate intermediate or high consequence events.

License Application Changes
See the License Application changes in the response to RAI 1-2.