Request for Additional Information Regarding Chapter 2 - Organization and Administration for the TRISO-X License Application Review

RAI-1 Management Hierarchy:

Regulatory Basis:

The information below is necessary to demonstrate compliance with the regulations in Title 10 to the *Code of Federal Regulations* (10 CFR) 70.22, “Contents of applications,” sub-section (a)(6), which requires the application to include, “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.”

Guidance for demonstrating compliance with these regulations is provided in NUREG-1520, revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications” (NUREG-1520) in sub-section 2.4.3 Regulatory Acceptance Criterion A.1, which states, “The applicant has identified and functionally described the specific organizational groups that are responsible for managing the design, construction, operations, and modifications of the facility or licensed activities. The application also includes organizational charts.”

Describe Issue:

In License Application (LA) section 2.3, “Organizational Responsibilities, Authority, and Qualifications,” the second paragraph identifies two levels of managers including plant manager and discipline manager. Other management terms that are used throughout LA chapter 2, “Organization and Administration,” include “function” (LA section 2.3.4 and the associated sub-sections), “analyst” (LA section 2.3.4.3), and “individual(s) responsible” (LA sections 2.3.4 and associated sub-sections). The layout in LA figure 2-1, “Functional Organization Chart,” also indicates multiple layers of managers but does not identify which positions correspond to the various management terms used throughout LA chapter 2.

Information Needed:

Clarify the different levels of managers utilized by TRISO-X (e.g., plant manager, discipline, function, analyst, individual(s) responsible) and their hierarchy relative to each other within the TRISO-X management structure. Clarify how the different types of managers identified in the LA are represented in LA figure 2-1.

RAI-2 Key Management Roles:

Regulatory Basis:

This RAI has the same regulatory basis as RAI-1.

Describe Issue:

In LA section 2.3, the third paragraph states that the organizational information provided in LA chapter 2, including the management structure provided in figure 2-1, is generic and does not represent the actual management structure of the TRISO-X facility. In addition, the LA section 2.3 middle of the third paragraph also states, “Similarly, functional areas shown in LA figure 2-1 and described in this chapter may be grouped within their disciplines as needed….” These statements appear to indicate that the organizational information described in the LA does not represents the organizational structure that will be used at the facility.

Information Needed:

Provide the names of the management disciplines and functional positions that will be utilized to fill key roles at the facility and include them in LA figure 2-1. Remove or clarify the purpose of the statements in LA section 2.3 in the third paragraph that indicate all management positions, including those in LA figure 2-1 are, “generic in nature and do not reflect specific organizational or job titles.” Clarify that the level of training required for each manager will include all the functional areas he/she is responsible to oversee. Provide sufficient descriptions of the actual management breakdown to distinguish independence between regulatory compliance (e.g., safety and security) and operations.

RAI-3 Role of Regulatory Affairs on the Screening Committee:

Regulatory Basis:

The information below is necessary to demonstrate compliance with the regulations in Title 10 CFR 70.22(a)(6), which requires the application to include, “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.”

Guidance for demonstrating compliance with these regulations is provided in NUREG-1520, in sub-section 2.4.3 Regulatory Acceptance Criterion A.2, which states, “Clear, unambiguous management controls and communications exist among the organizational units responsible for managing the design, construction, operations, and modifications of the facility or licensed activities.”

Describe Issue:

LA section 2.5.1, “Reporting of Potentially Unsafe Conditions or Activities” includes a description of the problem identification system, but does not describe the make of this system, (e.g., it is unclear if it is a computer system, committee, procedure). The section indicates that problems are reported to the Regulatory Affairs discipline, but once in the problem identification system, issues are reviewed by a safety committee that has representation by Regulatory Affairs and other disciplines. It is unclear if this process could lead to Regulatory Affairs being overruled by other disciplines (e.g., operations) which may promote production over safety. The introduction of a screening committee mentioned twice in 2.5.1 is not well defined.

Information Needed:

Provide additional information on the problem identification system, including what it consists of and how it works. Clarify the role of the Regulatory Affairs staff in the screening committee. Clarify the roll of the screening committee in the corrective action program, who serves on it, and how it differs from the safety committee. Please update the application, as appropriate.

RAI-4 Role of Regulatory Affairs

Regulatory Basis:

This RAI has the same regulatory basis as RAI 3.

Describe Issue:

The description of Regulatory Affairs in LA section 2.3.4 states, “Functional areas include nuclear criticality safety; radiation protection; environmental protection; industrial, chemical, and fire safety; integrated safety analysis; licensing; material control and accounting; security; and emergency preparedness. Emergency preparedness and response programs are supported by each functional area as needed. The integrated safety analysis (ISA) process is supported by each functional area providing ISA team members as needed.” Some of the technical areas identified appear to be important for operations as well as safety (industrial and chemical). In addition, there is a statement in LA section 2.3.4 that Regulatory Affairs discipline is administratively independent of the manufacturing but both disciplines may report to a common management position. The connection between Regulatory Affairs seems to undermine the independence of Regulatory Affairs from operations in order to focus on safety.

Information Needed:

Clarify the various technical staff (including industrial and chemical) of the Regulatory Affairs are focused on compliance, safety, and security and these roles are independent from manufacturing. Provide additional basis for the statement of independence between Regulatory Affairs and operations despite a common management of both. Clarify that Regulatory Affairs has stop work authority for issues related to safety, security, or protection of the environment.

RAI-5 Regulatory Affairs in the Safety Committee

Regulatory Basis:

This RAI has the same regulatory basis as RAI 3.

Describe Issue:

In LA section 2.3.4, the second sentence of the third paragraph states that the chairperson of the safety review committee is considered a member of the council. The term “council” is not defined in the application. In addition, LA section 2.4 indicates that the safety review committee consists of discipline managers, but the relationship of the Regulatory Affairs manager to the safety committee and council is unclear. Also, the

discussion of the membership of the safety committee in the middle of the Regulatory Affairs section in 2.3.4 (third paragraph) seems to imply a relationship between the members of safety committee and the Regulatory Affairs manager, but the relationship is not clearly described LA section 2.4.

Information Needed:

Clarify the role of the Regulatory Affairs Manager in the safety committee (e.g., see LA section 2.3.4, second sentence of the third paragraph, and LA section 2.4, second paragraph, and the relationship to the chairman of the safety committee. Define the term "council" as used in LA section 2.3.4, third paragraph, and throughout the LA. Clarify the purpose and role of the council and clarify how it fits into the overall discussion on Regulatory Affairs. Revise the LA, as needed, to reflect these clarifications.

RAI-6 Staff Qualifications

Regulatory Basis:

The information below is necessary to demonstrate compliance with the regulations in 10 CFR 70.22, subsection (a)(6), which requires the application to include, "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."

Guidance for demonstrating compliance with these regulations is provided in NUREG-1520, revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications" (NUREG-1520) in sub-section 2.4.3 Regulatory Acceptance Criterion A.3, "The personnel responsible for managing the design, construction, operation, and modifications of the facility or licensed activities have substantive breadth and level of experience and are appropriately available. The qualifications, responsibilities, and authorities for key supervisory and management positions with HS&E [health, safety, and environmental] responsibilities are clearly defined in position descriptions that are accessible to all affected personnel and to the U.S. Nuclear Regulatory Commission (NRC), upon request."

Describe Issue:

LA section 2.3.4 and the corresponding sub-sections that provide the minimum educational requirements for the discipline and functional managers state that individuals must have a Bachelor of Science or Arts (BS/BA) and/or advanced degree in science or engineering. The level of required education appears unclear because of the use of the "and/or", which seems to indicate that in some cases both a BS/BA and advanced degree are required and in other cases a BS/BA or an advanced degree is required. Also, it is unclear under what conditions both a BS/BA and advanced degree would be required.

Information Needed:

Clarify the educational requirements for discipline and function managers described in LA section 2.3.4 and corresponding sub-sections. Revise the requirement for a BS/BA and/or advanced degree in science or engineering to clarify when both degrees are appropriate (and) and when one or the other is appropriate (or). Consider replacing the and/or statement with one or the other (e.g., and, or). Identify what is considered an advanced degree in science or engineering (e.g., masters or doctorate). Provide the criteria for the amount of experience that can be substituted for education, if any. Revise the LA, as appropriate, to reflect these clarifications.

RAI-7 Experience for the Manufacturing Function:

Regulatory Basis:

This RAI has the same regulatory basis as RAI 6.

Describe Issue:

The experience requirement for the manufacturing discipline described in LA Section 2.3.2 states, “and a sufficient background in manufacturing-related activities to provide the capability for making sound safety decisions.” The phrase “sufficient background” is not well defined. Section 2.3.2 provides additional information on the education and experience required for the managers of the manufacturing discipline. This includes a number of “and/or” statements which make the level of education and experience uncertain.

Information Needed:

Clarify what is meant in LA section 2.3.2 by the phrase “sufficient background in manufacturing-related activities” for the manufacturing discipline. Also, clarify the use of “and/or” in the requirements for manufacturing experience in LA section 2.3.2.

RAI-8 Transition to Operations:

Regulatory Basis:

The information below is necessary to demonstrate compliance with the regulations in 10 CFR 70.22(a)(2), which require the application to include, “The activity for which the special nuclear material is requested, or in which special nuclear material will be produced, the place at which the activity is to be performed and the general plan for carrying out the activity.”

Guidance for demonstrating compliance with these regulations is provided in NUREG-1520, revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications” (NUREG-1520) in sub-section 2.4.3 Regulatory Acceptance Criterion A.4, “The applicant has described specific plans to commission the facility’s startup and operation, including the transition from the startup phase to operations, under the direct supervision of the applicant’s personnel responsible for safe operations. The application clearly describes the roles and responsibilities of the different functions engaged in these commissioning activities.”

Describe Issue:

LA section 2.6, “Transition from Design and Construction to Operations” refers to functional and acceptance testing to support the transition from design and construction to operations. The description of testing states that following successful testing and commissioning of equipment, a transition plan will be developed to test the equipment. The section does not describe the roles and responsibilities of the different disciplines or functions involved in the transition. Also, it does not provide a description of how corrective actions will be identified, tracked, or resolved.

Information Needed:

Clarify how the first, second, and third tests mentioned in LA section 2.6 relate to each other and support the transition plan. Identify a process that goes beyond testing for the transition to include written procedures, corrective actions, management oversight, established goals, etc., as applicable. Identify the management disciplines and functions that will be responsible for implementing the transition plan and clarify the role, if any, of the Regulatory Affairs managers. Describe how TRISO-X will ensure staff have the appropriate training to transition from construction to operations. Update the LA as appropriate.