Radiation Protection Request for Additional Information for the TRISO-X License Application Review

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.

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.

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.

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.

Information Needed:

Please provide additional description of how the survey requirements, procedures, or surveys performed for personnel or areas 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.

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.

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.

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.

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.

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.