Safety Evaluation Report for Rare Element Resources Inc. Proposed Demonstration Plant Upton, Wyoming

Materials License No. SUA-1603

Docket No. 040-38415

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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

1.0 Introduction

Rare Element Resources, Inc. (RER), the applicant, submitted an application to the US Nuclear Regulatory Commission (NRC) for a source material license to support a pilot project proposed to be located in Upton, Wyoming. The application and supporting documentation was submitted in a series of initial documents dated May 4, 2022 (RER,2022e); May 24, 2022 (RER, 2022f); August 26, 2022 (RER, 2022c); September 13, 2022 (RER, 2022b), and September 30, 2022 (RER 2022a), and modified by submittals dated November 7, 2022, (RER, 2022g)December 1, 2022 (RER, 2022d), March 21, 2023 (RER 2023a), and April 7, 2023 (RER 2023b).

RER is proposing to conduct a Rare Earth Element Separation and Demonstration Project to demonstrate the domestic production of neodymium-praseodymium and other rare earth oxides from an exploration sample (ore) containing uranium and thorium. For this proposed pilot project, RER plans to use approximately 1,000 tons of exploration sample (ore) removed previously from the Bear Lodge project in Wyoming. RER plans to design, construct, and operate a demonstration-scale hydrometallurgical, separation, and refining plant capable of processing ore at a rate of up to 3 tons of feed material per day as a research and development scale-up. The Demonstration Plant is planned to operate for approximately one year.

RER is not processing the material in an effort to obtain uranium or thorium, in this case, the pilot project is interested in the recovery of rare earth elements. The exploration ore has uranium and thorium in quantities that require RER to obtain a source material license and be subject to NRC regulations, including those under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, “Domestic Licensing of Source Material” and 10 CFR Part 20, “Standards for Protection Against Radiation.”

The applicant’s intent to retrieve rare earth elements (REE) for distribution requires review against the criteria of NUREG-1556, Volume 12, Revision 1,” “Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution”, (NRC, 2018). Therefore, the NRC’s evaluation of this application for a license to authorize possession of source in this SER reflects a review of the application against regulatory standards including, radiation protection, source material and uranium-thorium regulatory requirements, and relies upon a variety of NRC guidance documents that are considered applicable to this application.

The Atomic Energy Act of 1954, as amended by the Uranium Mill Tailings Radiation Control Act of 1978, authorizes the NRC to issue licenses for the possession and use of source material and byproduct material. The NRC must license facilities in accordance with NRC regulatory requirements to protect public health and safety from radiological hazards. In accordance with 10 CFR 40.32, “General Requirements for Issuance of Specific Licenses,” the NRC staff is required to make the following safety findings when issuing a source material license:

- The application is for a purpose authorized by the Atomic Energy Act.
- The applicant is qualified by reason of training and experience to use the source material for the purpose requested in such a manner as to protect health and minimize danger to life or property.

- The applicant's proposed equipment, facilities, and procedures are adequate to protect health and minimize danger to life or property.
- The issuance of the license will not be inimical to the common defense and security or to the health and safety of the public.

The applicant's license application for the source material license consisted of technical and environmental reports. During staff's review process, the applicant revised the application package in response to a request for supplemental information (RSI) and requests for additional information (RAIs). The initial documents supplemented by the revised application documents formed the basis for staff's review. This Safety Evaluation Report (SER) documents the staff's review of the safety aspects to the license application under the applicable provisions of NRC's regulations including 10 CFR Parts 20 and 40. The documents relied on in the review are tied to the license by reference (date and ML number) in license condition (LC) 11.

An Environmental Assessment (EA) is being prepared in parallel with this SER to address environmental impacts of the proposed action in accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions", the NRC's implementation regulations for the National Environmental Policy Act (NEPA).

The NRC staff's review of the application was performed using NUREG-1556, Volume 12, Revision 1 (NRC, 2018). Due to the processing of ore that contains uranium and thorium, guidance documents used for uranium recovery, such as NUREG-2126, "Standard Review Plan for Conventional Uranium Milling and Heap Leach Facilities", (NRC, 2014) and NUREG-1569, "Standard Review Plan for In-Situ Leach Uranium Extraction Licenses", (NRC, 2003), were also used to assess adequacy of some aspects of the applicant's program. It should be noted that not all of the regulatory provisions cited in these guidance documents applies to this license application because the scope of these guidance documents is broad and covers areas outside the scope of this application. For example, NUREG-1566, Volume 12, Revision 1 (NRC,2018) also covers byproduct and special nuclear materials license reviews under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" and Part 70,"Domestic Licensing of Special Nuclear Material" respectively. The review presented in this SER focuses on the regulatory sections and accompanying guidance that is relevant to the source material license application at hand.

In areas where review of this application was based on the applicant's commitments to comply with NRC regulatory requirements, license conditions have been added to formalize those commitments. Any such conditions are discussed in the relevant section of the SER. Table 1 (below) provides a cross reference of the license conditions with sections of the SER. Sections 1-9 of the license are not included in this table since they are basic information, such as company name, address, license number, etc.

License Condition	SER Section(s)
LC 10 – location of possession, use and storage of licensed material	Section 2 Proposed Activities
LC 11 – tiedowns to application and documents modifying the application	All Sections [Documents in LC 11 were used to prepare this SER and the EA]
LC-12 Radiation Safety Staff	Section 4 Individuals responsible for the Radiation Protection Program and their training and qualifications
LC-13 Pre-operational Conditions	Section 4 Individuals responsible for the Radiation Protection Program and their training and qualifications (specifically 4.2 Authorized Users) Section 7 Radiation Safety Program Section 10 Public Dose
LC-14 Radioactive Waste Disposition	Section 14 Transportation and Section 15 Waste Management
LC-15 SERP language	Section 7 Radiation Safety Program (specifically Section 7.5 SERP) and Section 11 Safe Use of Radioactive Material and Emergency Procedures
LC-16 Radiation Protection Plan and procedures	Section 7 Radiation Safety Program Section 8 Material Receipt and Accountability Section 9 Occupational Dose Section 10 Public Dose Section 11 Safe Use of Radioactive Material and Emergency Procedures Section 12 Surveys and Leak Tests Section 13 Maintenance Section 14 Transportation Section 15 Waste Management
LC-17 Standard Operating and Emergency Procedures	Section 7 Radiation Safety Program Section 11 Safe Use of Radioactive Material and Emergency Procedures
LC-18 Radiation Work Permits	Section 11 Safe Use of Radioactive Material and Emergency Procedures
LC-19 Records retention	Section 7 Radiation Safety Program (specifically 7.4 Records) Section 12 Leak Tests and Surveys (specifically 12.10 Records)
LC-20 Reporting and Notifications to NRC	Section 9 Occupational Dose Section 10 Public Dose
LC-21 Courtesy Notifications	Not discussed in the SER
LC-22 System Equipment Modifications	Section 11 Safe use of radioactive materials and emergency operating procedures
LC-23 Financial Assurance	Section 16 Conclusion

Table 1 – License condition and SER section cross reference.

The NRC staff finds that issuance of the source materials license, including the conditions added to the license, for the pilot project complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (The Act), and the NRC's regulations. Based on its review, as documented in this SER, the NRC staff also concludes that issuance of this license will not be inimical to the common defense and security or to the health and safety of the public.

2.0 Proposed Activities

Regulatory Requirements

Section 8.6 "Purpose(s) for Which Licensed Material Will Be Used" of NUREG -1556 Volume 12, Revision 1 (NRC, 2018) identifies the relevant regulatory requirements for possession and use for purposes authorized by the Atomic Energy Act for the radioactive materials requested by the applicant. For purposes of this source material SER, the relevant regulatory requirements are 10 CFR 40.4 (Definitions); and 10 CFR 40.32 (General Requirements for Issuance of Specific Licenses). The requirements of 10 CFR 110, "Export and import of Nuclear Equipment and Materials" are not applicable as the applicant is using ore from the State of Wyoming and plans to dispose of the uranium and thorium waste streams at a licensed disposal facility in Texas.

Regulatory Acceptance Criteria

To satisfy the regulatory requirements in this area the applicant should specify the purpose of use for each sealed or unsealed radionuclide requested. Although additional requirements are identified for sealed source related to use in accordance with the manufacturer's instructions as specified in the sealed source and device registration certificate, but these requirements are not applicable in this case as the exploration sample (ore) will yield uranium and thorium in an unsealed form.

Staff Review and Analysis

The applicant submitted an application for a new license on an NRC Form 313 which was provided as Appendix A to their September 2022 submission (RER, 2022a). The proposed action is NRC's issuance, under 10 CFR 40, of a source material license authorizing the possession, use, and storage of source material to enable the applicant to conduct and operate a proposed rare earth element (REE) separation and processing demonstration plant in Upton, Wyoming. The applicant proposes to conduct this pilot project using its' proprietary process to extract and concentrate neodymium-praseodymium (NdPr) and other rare earth oxides (REO) from an approximately 1000-ton (907 metric-ton) exploration sample (ore) obtained from the applicant's Bear Lodge site in the Black Hills National Forest in Wyoming. During processing, uranium and thorium in the exploration sample (ore) would be concentrated to levels necessitating a source material license. The applicant intends for the pilot project to demonstrate the potential to produce NdPr and other rare earth oxides (REOs) at a purity level sufficient to be economically viable. The information submitted by the applicant indicates that greater than 99 percent of the uranium and thorium in the ore will end up in the waste stream

and will be neutralized, solidified, and shipped offsite for disposal pursuant to the appropriate disposal strategy.

Evaluation Findings

The NRC staff finds that the applicant's description of its facility location and details on processing, storage and disposition of the proposed activities were provided in sufficient detail to satisfy NUREG-1556, Volume 12 Revision 1 and the applicable regulatory requirements and is therefore acceptable. License Condition 10 limits possession and storage of the source material to the demonstration plant in Upton, Wyoming as described in the application and supporting documentation.

3.0 Site Characterization

Regulatory Requirements

Section 8.3, "Address(es) Where Licensed Material Will Be Used or Possessed," of NUREG - 1556 Volume 12, Revision 1 (NRC, 2018) identifies the relevant regulatory requirements for site characterization. For purposes of this source material application, the relevant regulatory requirement is found in 10 CFR 40.41(c) (Terms and Conditions of Licenses).

Regulatory Acceptance Criteria

Title 10 CFR 40.41(c) requires the licensee to "confine his possession and use of source or byproduct material to the locations and purposes authorized in the license." The guidance provided in NUREG-1556, Volume 12 Rev.1 explains that the applicant should provide an address or addresses where material will be stored or used by the applicant as sufficient to satisfy this condition, and operation or storage outside these addresses is considered a violation of the regulatory requirement.

As stated in NUREG-1556 Volume 12 Revision 1, Section 8.3,

> "The applicant can satisfy this requirement by specifying the street address, city, and state or other descriptive address… for each facility at which licensed material will be used or stored. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable… In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate. If licensed material is to be possessed or possessed and used at more than one location, give the specific address of each location."

Staff Review and Analysis

The applicant provided the location of use of the requested exploration sample (ore) and its derived source material (natural uranium and natural thorium) on an NRC Form 313, included as Appendix A to the September 2022 submission (RER, 2022a). According to the application, the demonstration plant site is an approximately 8-acre parcel of privately-owned land in an

area referred to as the Upton Logistics Center Industrial Park. The primary roads that will be used to access the demonstration plant, including Interstate 90, US 14, US 16, WY 113, and WY 116. Northwest of the site, US 16 exits Interstate 90 at Moorcroft (Exit 154). To the northeast, WY 116 exits Interstate 90 at Sundance (Exit 185). Interstate 90 is a 4-lane divided highway and US 14, US 16, WY 113, and WY 116 are paved, 2-lane rural highways. Buffalo Creek Road, which leads from US 16 to the demonstration plant site, is the only Weston County Road that will be used to access the demonstration plant site located in the Upton Logistics Center Industrial Park, at 131 Buffalo Creek Road in Upton, WY 82730.

Evaluation Findings

The NRC staff finds that the applicant's description of its facility, location, including the location for processing, storage, and disposal of the source material, is provided in sufficient detail consistent with the guidance in NUREG-1556 Volume 12, Revision 1 and with the requirements of 10 CFR 40.41(c) limiting use of the licensed material to the location(s) specified in the license. The information provided was also sufficient to allow NRC inspectors to find the location to conduct inspections. Therefore, NRC staff determined the information provided is acceptable.

4.0 Individuals Responsible for Radiation Safety Program and Their Training and Experience

Regulatory Requirements

Section 8.7, "Individual(s) Responsible for the Radiation Protection Program and Their Training and Experience" of NUREG-1556 Volume 12, Revision 1, (NRC, 2018) identifies the relevant regulatory requirements for this area of review as 10 CFR 40.32(b) (General Requirements for Issuance of Specific Licenses). Section 8.7 is subdivided into two main sections – Section 8.7.1 and 8.7.2 each with different requirements.

Subsection 8.7.1 "Radiation Safety Officer" (RSO) identifies the relevant regulatory requirements for RSOs as 10 CFR 37 (Physical Protection of Category 1 and 2 Quantities of Radioactive Material) and 10 CFR 40.32(b) and Subsection 8.7.2 "Authorized Users" identifies the relevant regulatory requirements for individuals authorized to use the licensed material as 10 CFR 20.1101(b) (Radiation Protection Program – ALARA), 10 CFR 40.32(b) 10 CFR 71.5 (Transportation of Licensed Material); the regulations associated with the requirements of 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material" (10 CFR 110.26 through 10 CFR 110.30, and 10 CFR 110.42 through 10 CFR 110.44), and 49 CFR Parts 170 through 180 (as appropriate to the mode of transport) (U.S. Department of Transportation Rules).

Regulatory Acceptance Criteria

Title 10 CFR 20.1101(b) requires the "use of procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are as low as reasonably achievable (ALARA)." The adequacy of the applicant's program to satisfy the requirement of 10 CFR 20.1101(b) are more appropriately discussed in Section 7.0 (Radiation Protection Program) of this SER. This portion of the SER will only address the

responsibilities of the RSO associated with establishing the appropriate standard operating procedures or engineering controls to keep exposures ALARA and the RSO's and AU's respective responsibilities associated with ensuring the established protective measures are maintained.

To demonstrate compliance with 10 CFR 40.32(b), required for both the RSO and any authorized user, the applicant must demonstrate that they are qualified based on training and experience to use the source material for the purpose requested in "a manner as to protect health and minimizes danger to life or property."

Section 8.7 of NUREG-1556 Volume 12, Rev.1 establishes the following criteria for individuals responsible for the radiation protection program:

> "Executive management, the Radiation Safety Officer (RSO) (and his or her staff, as necessary), and authorized users work as a team to implement the Radiation Protection Program. Each individual and position plays a critical role within his or her area of responsibility. The roles and responsibilities of executive management, the RSO, the Radiation Safety Office staff, authorized users, and others in restricted areas are discussed, …"

While potentially applicable to source material applications, the NRC staff determined that 10 CFR Part 37 does not apply to this applicant's proposed application. The only isotope produced at the demonstration plant that is regulated under 10 CFR Part 37 is Ra-226. Based on Table 8 in Appendix F to the Environmental Report (RER, 2022a), there will be a total of 0.034 Ci of Ra-226 processed during the entire Demonstration Project. This is significantly less than the amount required for classification as Category 2 (10.8 Ci), and thus, less than an amount that would require compliance with 10 CFR Part 37.

Staff Review and Analysis

The application describes the roles and responsibilities of management, radiation protection staff, authorized users, and others in the restricted area, in Section 7.0 of the applicant's September 2022 submittal (RER 2022a). The application includes detailed descriptions of the duties and responsibilities associated with the radiation safety program as assigned to the following executive managers in the applicant's September 2022 TR (RER 2022a). The responsibilities for these executive managers related to the radiation safety program are summarized below but will not be discussed further in this SER since the radiation safety officer is primarily responsible for the radiation safety program.

- President and Chief Executive Officer – ultimately responsible for environmental, safety and health (ES&H) including radiation protection compliance, has stop work authority.
- Technical Specialist- responsible for implementation of ES&H programs and ensuring compliance with safety goals and directives.
- Principal Investigator – allocates funding to ensure compliance with ES&H goals and directives.

- Safety Supervisor -responsible for implementation of site safety and fire prevention requirements, standard operating procedures (SOPs) and emergency response plan.
- Plant Manager – implementation of ES&H programs, has stop work authority.

4.1 Radiation Safety Officer

Regulatory Requirements

As detailed in Section 4.0 (above) the applicable regulatory requirement is 10 CFR 40.32(b) (General Requirements for Issuance of Specific Licenses).

Regulatory Acceptance Criteria

NUREG-1556, Volume 12, Rev.1, Section 8.7.1 establishes criteria for the Radiation Safety Officer (RSO), indicating that the individual designated as RSO must have adequate training and specific experience with the types and quantities of licensed material to be authorized in the license. The NUREG also provides a generic list of duties and responsibilities assigned to the RSO. Regulatory Guide 8.31, “Information Relevant to Ensuring that Occupational Radiation Exposure at Uranium Mills will be As Low As Reasonably Achievable” provides details on what is considered adequate training and experience for RSOs at Uranium facilities and is considered applicable to this site due to the processing of ore and the resulting concentration of uranium and thorium.

Section 8.7.1 of the NUREG specifies that the RSO have independent authority to stop operations that they consider unsafe and have sufficient time and commitment from management to fulfill duties and responsibilities to ensure that radioactive materials are possessed and used in a safe manner, procedures are being implemented and the required records are maintained.

Staff Review and Analysis

The application documents (RER, 2022a), indicate that the RSO is responsible for the technical accuracy and implementation of the radiation protection and the as low as is reasonably achievable (ALARA) programs required under 10 CFR 20.1101(b) (Radiation Protection Program – ALARA). The RSO has continuing responsibility for surveillance and supervisory action in the enforcement of these programs at the demonstration plant. The RSO reports directly to the President/CEO, and coordinated through the Technical Specialist, provides operational input to the Managing Principal. The Managing Principal is the senior individual, reporting to the President/CEO and is responsible for managing day-to-day engineering and operations work. They supervise the Engineering Director and the Plant Manager. The duties and responsibilities of the RSO assigned in the application documents (SER, 2022a) are consistent with those identified in Appendix D of NUREG-1556 Volume 12, Rev.1 (NRC, 2018). The application documents grant the RSO stop work authority. Additionally, the training and qualification requirement identified in the Technical Report (TR)(RER, 2022a) mirror the education, training, and experience model provided in Section 2.4.1 of Regulatory Guide 8.31 and the applicant specifically committed to have an RSO who met the education, training and experience guidance detailed in RG 8.31.

Evaluation and Findings

The NRC staff finds that the applicant's description of the training and qualification requirements for the RSO, as well as the RSO's duties and responsibilities, are sufficiently detailed such that they are consistent with the guidance provided in NUREG-1556 Volume 12 Revision 1, Section 8.7, Appendix D of the NUREG, and Regulatory Guide 8.31, as well as the regulatory requirements of 10 CFR 40.32(b). The RSO and radiation protection staff training and qualification requirements are addressed in LC 12 of the applicant's license, which specifically ties the RSO and his staff to meeting the training, education and qualification recommendations outline in RG 8.31.

4.2 Authorized Users

Regulatory Requirements

Section 8.7.2, "Authorized Users" of NUREG-1556 Volume 12 Rev.1 (NRC, 2018) identifies the following regulations associated with authorized users for source materials: 10 CFR 20.1101(b) (Radiation Protection Program – ALARA) and 10 CFR 40.32(b) (General Requirements for Issuance of Specific Licenses).

Regulatory Acceptance Criteria

Section 8.7.2 of NUREG-1556, Volume 12, Revision 1 states, "AUs must have adequate training and experience to provide reasonable assurance that they will use licensed material safely. Training for AUs should include maintaining the security of, and controlling access to, licensed material, and responding appropriately to events or accidents involving licensed material to prevent the spread of contamination." For this particular applicant, the authorized users should have training and experience with the handling associated with uranium and thorium as well as detection and monitoring of the associated daughter products from uranium and thorium.

According to NRC guidance in NUREG-1556, Volume 12, Revision 1, to demonstrate adequate training and experience, the AU should have: "(1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects: (1) radiation protection principles, (2) characteristics of ionizing radiation, (3) units of radiation dose and quantities, (4) radiation detection instrumentation, (5) biological hazards of exposure to radiation; and (6) hands on use of radioactive materials." The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested. An AU is "considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to ensure that areas are not contaminated."

Staff Review and Analysis

Section 7.4 of the applicant's Technical Report (TR) (RER, 2022a) does not provide the names and qualifications of the AUs as those individuals have not been identified However, the applicant did specify that at a minimum, the President & CEO, the Plant Manager, the Principal Investigator, and the RSO will all be AUs. The applicant committed that the AU training and qualifications program will be consistent with those described in section 8.7.2 of NUREG-1556 Volume 12 Revision 1.

The resumes for the President/CEO, Principal Investigator, Plant Manager, and RSO were provided as Appendix D to the applicant's TR (RER, 2022a). While it is clear that the RSO has sufficient training and experience to meet the requirements consistent with NUREG-1556, Volume 12, Revision 1 to be an AU, and the Principal Investigator does have the education and some experience working with radioactive materials that could be supplemented to meet the AU requirements, the information provided also indicates that the President/CEO and Plant Manager do not have the education or experience with radioactive materials.

Therefore, the license will be issued with only the RSO identified as an AU. Once the AU training and qualification process is developed and the education and training are completed for the President/CEO and Plant Manager, and supplemented as needed for the Principal Investigator, these other proposed AUs can be added to the license. Discussions with the RSO indicate that he plans to use the pre-operational phase of the license to train and qualify the other proposed AUs. During the pre-operational inspection required in LC 13, NRC inspectors will verify that the program used to train and qualify individuals proposed as AUs is consistent with the commitments in the application, and those individuals who successfully completed the program will be added to the license as authorized users in LC 12.

Evaluation Findings

The NRC staff finds that the applicant's description of the training and qualification requirements for the AUs, specifically as stated in Section 7.4 of the TR (RER 2022a) that "the qualifications of an authorized user will be consistent with those described in NUREG-1556 Volume 12 Revision 1 Section 8.7.2," is sufficient.

As detailed above, the NRC staff finds that the individual identified as the RSO for the application meets the requirements of an AU based on the resume provided in the applicant's TR. Therefore, the license includes a condition (LC 12) authorizing the RSO as an AU.

In addition to this RSO, a discussion with the applicant revealed that the applicant intends to complete the training and qualification process for the other proposed AUs during the construction phase of the project, prior to operations. Based on this commitment, the NRC staff has also included a license condition (LC 13) requiring that the applicant provide the completed training and qualification documentation for each proposed authorized user for NRC verification prior to or during the pre-operational inspection. Upon confirmation that the additional proposed AUs have completed the necessary training, the additional AUs will be added to the license.

5.0 Training for Individuals Working in or Frequenting Restricted Areas

Regulatory Requirements

Section 8.8 “Item 8: Training for Individuals Working in or Frequenting Restricted Areas,” of NUREG -1556 Volume 12, Revision 1, (NRC, 2018) identifies the relevant regulatory requirements for this area of review. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 19.11 (Posting of Notices to Employees); 10 CFR 19.12 (Instructions to Workers); 10 CFR 19.13 Notification and Reports to Individuals); 10 CFR 20.1801 (Security of Stored Material); and 10 CFR 20.1802 (Control of Material not in Storage).

Regulatory Acceptance Criteria

Title 10 CFR 19.12 (a) states:

> “All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be: (1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material; (2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; (3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material; (4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and, (6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.”

Title 10 CFR 19,12(b) states,

> “In determining those individuals subject to the requirements of paragraph (a) of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.”

As explained in NUREG-1556 Volume 12 Revision 1, Section 8.8,

> “Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources), and in the course of their employment, are likely to receive, in a year, an occupational dose of radiation greater than 1 mSv [100 mrem], whether from all external sources, all internal sources, or any combination, must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12.”

Before beginning work with licensed material, individuals must receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. Each of these individuals should also receive periodic (at least annually) refresher training. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations, or terms of the license. Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately. Training may be in the form of lecture, demonstrations, videotape, or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure.

The guidance in NUREG-1556 Volume 12 Revision 1, Appendix H, Radiation Safety Training Topics, may be used to develop a training program. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Staff Review and Analysis

In Section 8 of the applicant’s September 2022 TR (RER, 2022a), the applicant committed to the performance of initial training for all workers or individuals frequently working in the restricted area. Training will cover the risks of exposure to radiation and fundamentals of protection against exposure to natural uranium and thorium and their progeny. Training will include the guidance provided in NRC Regulatory Guides 8.29 *Instructions Concerning Risks form Occupational Radiation Exposure* (NRC, 1996) and 8.13 *Instructions Concerning Prenatal Radiation Exposure* (NRC, 1999). The applicant provided the topics to be covered in initial training in Table 3 of the September 2022 TR. This table is shown below as Table 2 (below), The applicant committed to having each worker complete a written or oral test relevant to the principles of radiation safety and health protection at the site and as covered in the training course. The applicant will require workers to receive a score of 70 or greater to pass the test.

The applicant also committed to the completion of annual refresher training for all workers or individuals frequenting restricted areas. The instructor for the initial and refresher training was identified by the applicant as the RSO or an RSO designee.

Workers will also receive task-specific training as relevant to their job. Examples of task-specific training include shipping of radioactive materials, areas where radioactive material is used and stored, response to spills, emergencies and other safety conditions, waste management, and instrumentation use and conduct of surveys.

Evaluation Findings

The NRC staff finds that the applicant's description of worker training (initial, refresher, and task-specific) in terms of topics covered, conduct of tests, implementation, and documentation of training meets the occupational worker training requirements as specified in 10 CFR Part 19.12 as identified above. Furthermore, the training as outlined in Table 2 (extracted from the applicant's TR (RER,2022a)) addresses the requirements of 10 CFR 19.11; 10 CFR 19.12,10 CFR 19.13; 10 CFR 20.1801; and 10 CFR 20.1802 and is consistent with the guidance in NUREG-1556, Volume 12, Revision 1 and therefore is acceptable to meet the occupational worker training requirements identified above. Furthermore, these training commitments were made in the applicant's Technical Report dated September 2022 or in either the RSI or RAI for the Technical Report, and all three of these documents are tied to the license in LC 11.

Topic	Content	
Radiation Safety	• Radiological and toxic hazards of exposure to natural uranium and thorium and their progeny (biological effects) • How natural uranium and thorium and their progeny enter the body (inhalation, ingestion, and skin penetration) • Why exposures to ionizing radiation should be kept ALARA • Methods to mitigate internal and external exposure to ionizing radiation	
Non-Radiological Safety	• Non-radiological hazards of the Demonstration Project processes and facilities • Occupational safety elements from the Health and Safety Plan and emergency response	
Personal Hygiene	• Proper wearing of protective clothing and its associated risk • Using respirators correctly and their associated risk • Administrative rules to mitigate work dose such as eating, drinking, and smoking only in designated areas • Using proper methods for decontamination	
Facility- Provided Protection	• Ventilation systems and effluent controls • Cleanliness of the workplace • Features designed for radiation safety for process equipment. • SOPs specific to trainee's job function • Security and access control to designated areas	
Health Protection Measurements	• Measurement of airborne radioactive materials • Bioassays to detect radionuclides. • Surveys to detect contamination of personnel and equipment personnel dosimetry	
Radiation Protection Regulations	• Regulatory authority of Wyoming • Authority of RSO • Material control and accountability • Employee rights in 10 CFR Part 19 • Radiation protection requirements in 10 CFR Part 20 • Audit program.	
Emergency Procedures	• Emergency/contingency plans	

ALARA – as low as is reasonably achievable.
CFR – Code of Federal Regulations
NRC – US Nuclear Regulatory Commission
RSO – Radiation Safety Officer
SOP – standard operating procedure

Table 2. Topics to be included in initial training for workers.
[Extracted from the Technical Report (RER,2022a) Table 3]

6.0 Facilities and Equipment

Regulatory Requirements

Section 8.9 "Item 9 Facilities and Equipment" of NUREG -1556 Volume 12, Revision 1, (NRC, 2018) identifies the relevant regulatory requirements for this area of review. For purposes of a

source material application, the relevant regulatory requirements are 10 CFR 20.1101(b) (Radiation Protection -ALARA); 10 CFR 20.1406 (Minimization of Contamination); 10 CFR 40.32(c) (General Requirements – Facilities and Equipment); and 10 CFR 40.34(a) (Special Requirements for Issuance of Specific Licenses)

Regulatory Acceptance Criteria

As explained in Section 8.9 of NUREG-1556 Volume 12, Revision 1, in order to satisfy regulatory requirements in this area, applicants must demonstrate that facilities and equipment are adequate to protect health and minimize danger to life or property. in accordance with the requirements of 10 CFR 40.32(c). Applicants can demonstrate compliance with this requirement by keeping dose to workers and the public ALARA and minimizing the possibility of contamination. Applicants should also describe how facility design and use of engineering controls or standard operating procedures will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste.

Staff Review and Analysis

Section 9 of the applicant's TR (RER, 2022a) provides detailed information associated with the buildings and equipment that will be onsite during the pilot project and the purposes of the buildings and equipment. Buildings and covered areas are shown in Figure 5 of the TR (see Figure 1 (below)).

According to the application, the Demonstration Plant consists of the four processing stages: (1) Physical upgrade (PUG) which covers crushing and screening of the exploration sample containing source material; (2) primary processing (PP) which is a hydrometallurgical process that converts exploration sample materials to produce pure total rare earth oxide with thorium concentrate (TREO (Th)) and removes a significant portion of the radioactive materials from the sample; (3) Thorium-cerium separation (TCS) which removes radioactivity, mainly thorium and its progeny, together with cerium using an innovative technology and recycling of the process waste streams; and (4) Neodymium/praseodymium separation (NPS) and refining of REE groups using an innovative technology controlled by a network controlled by proprietary software.

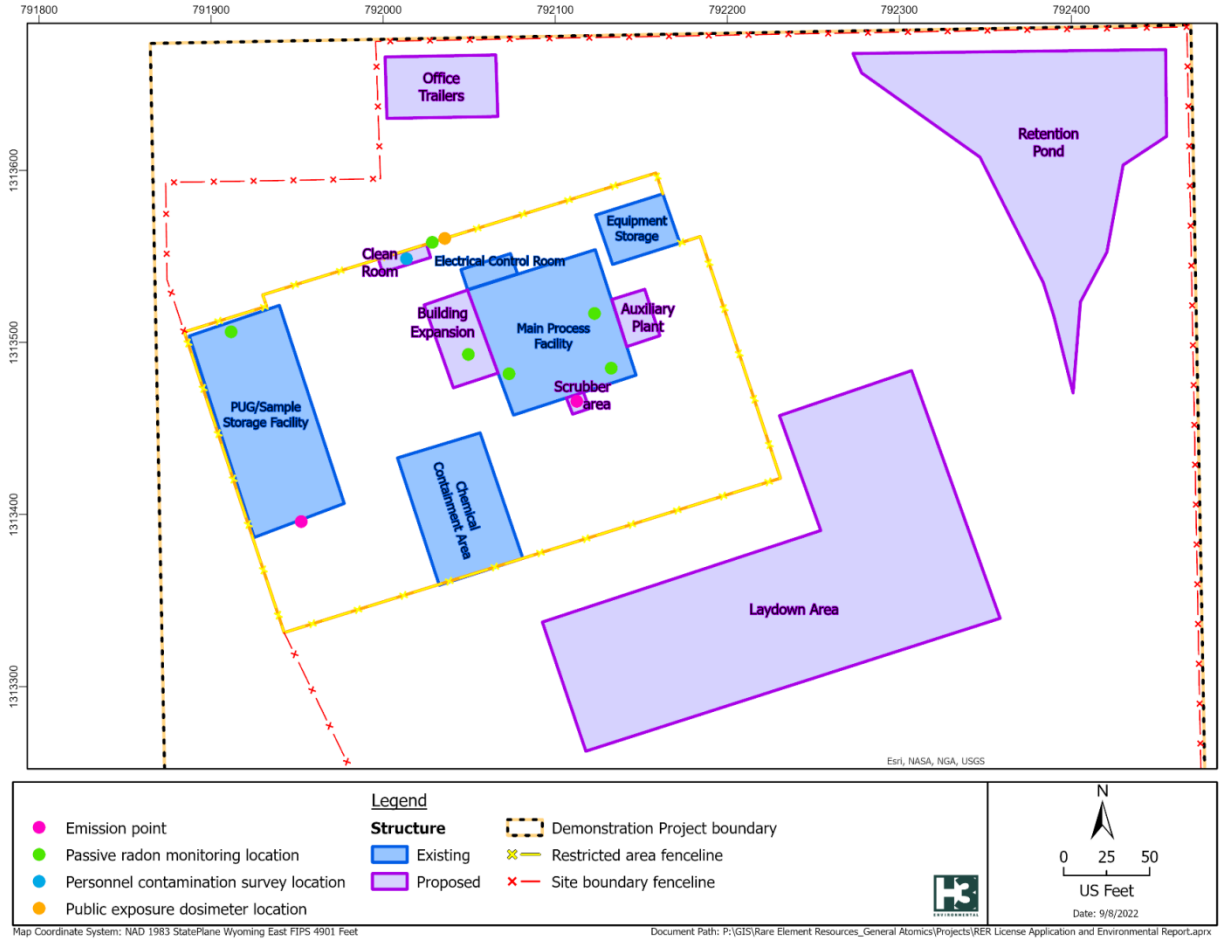

Figure 1. Demonstration Plant Restricted Area Map (Figure 5 of RER TR) (RER, 2022a)

PUG processing will take place in the PUG/Sample storage facility. This facility will be used to store the exploration sample, crush, and screen the sample, and store the sample materials in supersacks before transfer to the main processing facility. The PUG/Sample facility will be a basic shell and will also be used to store small portable equipment. The building will be designed so areas that have to potential to contact licensed material will drain to an internal collection point to prevent discharge to the environment. The south side of the PUG/Sample Building will be open to the environment; therefore, air emissions will come from ground level on the south side. Dust and particulate emissions monitoring will be conducted during the crushing and screening process. During processing, a screen will be installed across the open southern end of the building to limit particulate emissions. A dustless bag-loading system will be used to transfer the crushed/screen sample to supersacks for storage. This bag-loading system will have a local emissions control system. Details of which were provided in the EA (RER, 2022a). During processing the south side of the PUG/Sample building will be monitored for radioactive gases and particulate.

The Main Process Facility will house the process units (PP, TCS, NPS), built on modular self-contained skids. The applicant states that the overall design of these process units will minimize

contamination and facilitate decommissioning. All areas that have the potential to contact licensed materials will be designed to drain to the facility sump. The interior surfaces of the sump will be sealed to prevent environmental release. In Section 9.2.2 of the Technical Report (RER, 2022a), the applicant committed to the sample, treatment, and proper disposal of all releases to the building floor. The application also included the following additional commitments in the TR (RER, 2022a): (1) No underground piping will be used in the Main Processing Facility; (2) Building materials will be nonporous and piping lengths will be minimized when possible; (3) Process controls and level monitoring with alarms will be used in the facility to indicate the release of liquid; and (4) Spills will be handled in accordance with the standard operating and emergency procedures.

Furthermore, the Main Process Facility is designed to be a zero-emissions facility. Specifically, all process equipment other than the calciner will be vented through the main scrubber system; the calciner will have its own dedicated scrubber, and the heating, ventilation, air conditioning (HVAC) system for the Main Processing Facility will have a high-efficiency particulate air filtration system. All of these commitments related to the materials and equipment that will be used in the Main Process Facility will help ensure that radioactive materials releases to the environment are prevented or minimized to the extent possible and contamination controls will be in place to limit occupational exposure.

The chemical containment area will be used for chemical storage and is within an existing 80 feet (ft) by 50 ft concrete containment structure that previously housed two large tanks. The applicant indicated they will retrofit this building to accommodate seven process tanks. This building will be used as a secondary containment for the process chemicals (primary acids). Secondary containment capacity (in the form of berms) is approximately 180,000 gallons which is greater than 110 percent of the capacity of the largest tanks (12,200 gallons). This building is not enclosed but will have an all-weather canopy cover.

The applicant also plans to construct a clean room, to be used as an access control point for entering and leaving the restricted area and a maintenance and equipment shed. The access control point will serve as a contamination control point for personnel and the maintenance and equipment shed will keep potentially contaminated equipment inside the restricted area unless specifically surveyed and released by radiation staff.

Evaluation Findings

The NRC staff finds that the applicant’s description of its facilities and equipment, in terms of design, construction materials, renovations planned, and engineering controls proposed to be implemented, are consistent with NRC guidance and sufficient to protect the health and safety of workers, the public and the environment. Because the applicant’s description of its facilities and equipment meets the requirements of 10 CFR 20.1101(b); 10 CFR 20.1406; and 10 CFR 40.32(c); it is therefore acceptable. Furthermore, the commitment made above is captured in the Technical Report submitted by the applicant or revised in accordance with the applicant’s response to the RSI or RAI. All three of these documents are tied to the license by reference in LC 11.

7.0 Radiation Safety Program

7.1 Audit and Review of Program

Regulatory Requirements

Section 8.10.1 “Audit and Review of Program” in NUREG-1556, Volume 12 Rev 1 (NRC, 2018), identifies the relevant regulatory requirements for review of this area. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 20.1101 (Radiation Protection Program), 10 CFR 20.2102 (Records of Radiation Protection Program), 10 CFR 20.2110 (Form of Records), 10 CFR 21.21(a) (Notification of Failure to Comply or Identification of Defect and its Evaluation), 10 CFR 37.33 (Access Authorization Program Review), and 10 CFR 37.55 (Security Program Review).

The NRC staff determined that 10 CFR 37.33 and 37.55 do not apply to the applicant’s proposed operations. The only isotope produced at the demonstration plant that is regulated under 10 CFR Part 37 is Ra-226. Based on Table 8 in Appendix F to the Environmental Report (RER, 2022a), there will be a total of 0.034 Ci of Ra-226 processed during the entire Demonstration Project. This is significantly less than the amount required for classification as Category 2 (10.8 Ci). This evaluation assumes Ra-226 is in secular equilibrium with U-238 in the exploration sample (NRC, 1980).

The NRC staff determined that the requirements of 10 CFR 21.21(a) related to notification of failure or defects that could result in a significant safety hazard are addressed in Section 9.0 (Occupational Dose) and will not be addressed in this section of the SER.

Regulatory Acceptance Criteria

The applicant’s description of the proposed review of the content and implementation of its radiation safety programs was reviewed for compliance with 10 CFR 20.1101(a), 10 CFR 20.1101(c), 10 CFR 20.2102, and 10 CFR 20.2110 by comparing it to the recommended information to be submitted in Section 8.10.1 of NUREG-1556, Volume 12 Rev. 1 (NRC, 2018).

Staff Review and Analysis

The NRC staff determined that the applicable regulations for the review of the of the content and implementation of the applicant’s radiation safety programs are 10 CFR 20.1101 (a) and (c), 10 CFR 20.2102, and §20.2110. These regulations contain requirements for a licensee to periodically review (at least annually) the radiation protection program content and implementation and maintenance of records associated with this program. In this section, the NRC staff determines whether the applicant has demonstrated that its proposed review of the content and implementation of its radiation safety programs comply with these requirements regarding its rare earth separation and processing demonstration plant.

Unless otherwise stated, the information reviewed in this section is from information, data, and maps submitted by the applicant (RER, 2022a, 2022b, 2022c).

7.2 Radiation Protection Program

The applicant provided an overview of its proposed radiation protection program (RPP) in Section 10 of the Technical Report (TR) (RER, 2022a). The applicant's proposed RPP includes provisions for complying with 10 CFR Parts 19 and 20. The proposed RPP was designed by the applicant to follow the requirements of 10 CFR Part 20 Subpart B and will limit potential radiological doses to workers and the public to dose levels as specified in Subparts C and D of Part 20. As discussed in Section 5 of this SER workers will receive an appropriate level of radiation safety training based on their job responsibilities and will be informed of their rights and responsibilities. Also as addressed in several other sections of this SER, the requirements of 10 CFR 20.1101(b) (Radiation Protection Program – ALARA) to keep doses ALARA is included in the proposed RPP in the form of a policy statement which includes a commitment to operate under the "fundamental principles and practices recommended in Regulatory Guide 8.10 *Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable*."

Because a radiation protection program is critical for ensuring appropriate handling, processing, and control (security) of source material, the license requires confirmation that the radiation protection program has been implemented as described in the applicant's Technical Report (TR) (RER,2022a). A license condition (LC 13) requiring a pre-operational inspection, including of the radiation safety program, is detailed in LC 13 of the applicant's license.

7.3 Periodic Review and Audit of RPP

The applicant described its review and audit program for its RPP in Sections 10.1.3 and 10.1.4 of the TR (RER, 2022a). The applicant stated that it will review the RPP at least annually. This review will include a compliance assessment against NRC and U.S. Department of Transportation regulations, as well as other areas of compliance. (RER, 2022a)

In addition, the applicant will conduct a third-party audit at least once during the year of operation of the demonstration plant (RER, 2022a). A written report, consistent with the information provided in Appendix G of NUREG-1556, Volume 12, Revision 1, will be prepared on the audit (RER, 2022a).

7.4 Records

The applicant described its proposed recordkeeping program in Section 10.10.1 of the TR (RER, 2022a). This information included examples of types of records, form of records, and how long to maintain records. The information provided is consistent with the regulatory requirements of 10 CFR 20.2102 and 10 CFR 20.2110 and the recommendations in NUREG-1556,Volume 12, Revision 1 Section 8.10.1, and is therefore acceptable.

Evaluation Findings

The NRC staff reviewed the description of the applicant's RPP, proposed periodic review and audit of its RPP, and recordkeeping program, for the demonstration plant against the regulations and guidance in NUREG-1556 Volume 12 Revision 1. The Staff finds there is sufficient

information to allow the staff to conclude that the applicant's RPP, review and audit of its RPP and recordkeeping program can be conducted safely and will comply with 10 CFR 20.1101(a), §20.1101(c), §20.2102, and §20.2110.

7.5 Safety and Environmental Review Panel (SERP)

Regulatory Requirements

There are no regulatory requirements specifically related to source material licensees using SERP to review and determine whether or not a license amendment is required to change a process or procedure or conduct a test or experiment in Title 10 of the Code of Federal Regulations. However, SERPs for making these types of evaluations are based on the language in 10 CFR 50.59 (used by nuclear power reactor licensees) to perform evaluations for the conduct of tests, changes to processes or procedures, or experiments to determine if those activities can be conducted without the need for an NRC license amendment. As part of the NRC's initiative to transition to a performance based, risk-informed inspection and licensing model detailed in SECY-98-144 (NRC,1998), the NRC staff has adopted sections of 10 CFR 50.59 language for source and special nuclear materials users and incorporated this flexibility to evaluate the need for license amendments into source and special nuclear material licenses using license condition language.

Regulatory Acceptance Criteria

Standard SERP language mirrors the requirements of 10 CFR 50.59 (Changes, Tests and Experiments) and can be used or modified to represent site conditions, provided the modifications do not change the intent of the requirements. Additional guidance related to SERPs at facilities processing uranium ore is provided in NUREG-2126 "Standard Review Plan for Conventional Uranium Mill and Heap Leach Facilities - Draft Report for Comment," (NRC, 2003) and NUREG-1569, "Standard Review Plan for In Situ Leach Uranium Extraction License Applications" (NRC, 2014).

Staff Review and Analysis

The NRC staff reviewed the applicant's request to implement the use of a SERP using both the NRC guidance found in NUREG-2126 (NRC, 2014) and NUREG-1569 (NRC, 2003). While the guidance in NUREG-1569 is for In Situ Leach facilities, the guidance can be used to inform this review for the use of a SERP at this rare earth elements (REE) processing facility. The SERP guidance in NUREG-1569 is found in Section 5 of that document. The SERP guidance in NUREG-2126 is found in Section 4 of that document. Although neither document is specifically written for a REE processing facility, the NRC staff has determined that the guidance provided in each document is appropriate because of the detailed information in both documents related to issues to consider when reviewing a license application where the radiological hazards are due to the presence of natural uranium and/or thorium and their associated daughter products.

As outlined in NUREG-2126 guidance, NRC staff expects that a SERP will evaluate all proposed changes to operations and will record the decision of whether the change requires a license amendment. The SERP records will include written health and safety evaluations and provide the basis for determining whether changes, tests, or experiments were implemented.

The applicant's proposed SERP program in the September 30, 2022, TR (NRC, 2022a) Section 7.5 of the applicant's September 30, 2022, TR states:

> "The purpose of the SERP will be to evaluate, discuss, approve, and record any changes to any SOP, the facility, or tests and experiments involving safety or the environment. The changes will not require a license amendment pursuant to 10 CFR 40.44 if the changes do not:
> - create a possibility of an accident unlike what is evaluated in the license application (as updated);
> - create a possibility of a malfunction of a structure, system, or control unlike what is evaluated in the license application (as updated); and,
> - result in a departure from the method of evaluation described in the license application (as updated) using in establishing the final safety evaluation report or the environmental assessment or technical evaluation reports or other analysis and evaluations for license amendments."

The applicant indicated in the TR that the staffing of the SERP will, at a minimum, consist of the RSO, the site principal (e.g., President/CEO), and the site manager (e.g., Plant Manager) and allows each of these individuals to delegate their role on the SERP provided the designee has similar qualifications. The applicant also requested that additional members may be included in the SERP, as appropriate, to address specific technical issues.

The applicant identified the RSO as being a consultant and requested a modification to standard SERP language to account for this, in response the NRC staff evaluated this request and modified the NRC standard language for SERPs to allow one of the three principal members to be a consultant. The RSO consultant will also be required to meet the qualifications of RG 8.31 Section 2.4.1 per LC 12.

Under NRC standard SERP language for source material licensees[1], one member of the SERP will have expertise in management and will be responsible for implementing managerial and financial changes (President/CEO). One member will have expertise in operations and will have responsibility for implementing any schedule changes (Plant Manager). Additionally, principles and designees must have the same qualifications and responsibilities. One member will be the RSO, or equivalent, with the responsibility for assuring that changes conform to radiation safety and environmental requirements. NRC guidance allows temporary additional members to include consultants. In response to the applicant's request, NRC agreed to a consultant being allowed to serve as one of the three principal members for the SERP provided the individual is either approved by the NRC or in the case of the RSO, meets the qualifications specified in the license.

The NRC staff finds that the applicant has proposed a SERP that will consist of at least three individuals with specific qualifications in management, operations, and radiation safety consistent with guidance in NUREG-2126. Staff reviewed the process for determining the need for additional members and finds it to be acceptable because it is consistent with the guidance in NUREG-2126 and that the applicant has provided an adequate description of when additional members will be used.

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[1] The standard language used for source material licensees was adopted from the SERP language in 10 CFR 50.59, "Changes, Tests or Experiments.".

Evaluation Findings

Based upon this review, the NRC staff determined the description of the SERP membership, evaluation criteria, record keeping, and use of SOPs and a radiation protection plan to support the SERP to be adequate. The NRC staff concludes that the applicant's proposed program utilizing a SERP meets the requirements of 10 CFR 40.32(b) and (c) as they relate to the acceptability of management programs and audits to ensure protection of health and minimize danger to life and property. The SERP language was incorporated into the license as LCs 15 and 16.

7.6 Radiation Monitoring Instruments

Regulatory Requirements

Section 8.10.2 "Radiation Monitoring Instruments" of NUREG-1556, Volume 12, Revision 1, (NRC, 2018), identifies the relevant regulatory requirements for review of the applicant's proposed selection and calibration of radiation monitoring instruments. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 20.1501 (General – Surveys and Monitoring), 10 CFR 20.2103(a) (Records of Surveys), and 10 CFR 40.32(c)(General Requirements for Issuance of Specific Licenses).

Regulatory Acceptance Criteria

The applicant's description of the proposed selection and calibration of radiation monitoring instruments and associated record keeping was reviewed for compliance with 10 CFR 20.1501(c), §20.1501(d), §20.2103(a), and 10 CFR 40.32(c) by comparing it to the guidance in Section 8.10.2 and Appendix H of NUREG-1556, Volume 12 Revision 1 (NRC, 2018).

Staff Review and Analysis

Unless otherwise stated, the information reviewed in this section is from information, data, and maps submitted by the applicant (RER, 2022a, 2022b, 2022c).

The NRC staff determined that the applicable regulations for the review of the applicant's proposed selection and calibration of radiation monitoring instruments are 10 CFR 20.1501(c), §20.1501(d), §20.2103(a), and 10 CFR 40.32(c). These regulations contain requirements for radiation instrument calibration, records associated with these calibrations, personnel dosimetry processing, and having available equipment for protecting health and minimizing danger to life and property. In this section, the NRC staff determines whether the applicant demonstrated that its proposed selection and calibration of radiation monitoring instruments and associated record keeping will comply with these requirements regarding its rare earth separation and processing demonstration plant.

7.7 Available Radiation Monitoring Instruments

The applicant described its proposed radiation monitoring instruments in Section 10.2.1 of the applicant's September 2022 TR (RER, 2022a). Table 6 in the TR provides instrument type, intended use, estimated sensitivity, and other information.

The NRC staff compared the radiation monitoring instruments provided in Table 6 in the TR with the applicant's proposed routine radiological surveys and monitoring in Table 18 in the TR and the revised instrumentation information provided in the applicant's response to the request for additional information (RAI) (RER, 2023b). The NRC staff finds that the proposed radiation monitoring instruments support the proposed routine radiological surveys and monitoring and are consistent with the recommendations in NUREG-1556,Volume 12, Revision 1, Section 8.10.2, and are therefore acceptable. In short, the applicant has a proposed radiation survey inventory that is adequate to ensure surveys are conducted using the appropriate survey meters for each type of survey committed to in Table 18 of the TR.

7.8 Surface contamination dose rate limit

Note 6 to Table M-2 in NUREG-1556, Vol. 12, Rev. 1[2] specifies that: "The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad per hour (mrad/h) at 1 centimeter (cm) and 1.0 mrad/h at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber."

The applicant provided a calculation (Equation 1) to demonstrate that the dose rate limits specified in Table M-2 would not be exceeded at the contamination levels associated with the limits specified in Table M-2. This calculational approach is based on a previous NRC staff finding for a uranium in-situ recovery (ISR) facility (NRC, 2015).

$$\dot{D}_{\beta} = 3.6 \times 10^{-2} \times C_a \times \bar{E} \times \mu_{\beta,t} \times e^{(-\mu_{\beta,a} \times d)} \times e^{(-\mu_{\beta,t} \times 0.007)}$$

Equation 1. Dose rate to the basal cells of the skin (from Section 10.2.3.3 in RER, 2022a)

The NRC staff notes that the mixture of radionuclides expected in a uranium ISR facility will be different than what is expected at the applicant's facility. These differences are due to the different starting materials used in the respective industrial processes (i.e., pregnant uranium lixiviant versus ore containing uranium, thorium, and associated radioactive decay products.)

While the end result of the NRC staff's previous assessment (NRC, 2015) is correct for uranium in-situ recovery, the explanation is not accurate in this context of a REE due to differences in the processing of the ore and resulting mixture of radionuclides Specifically, assessing the dose rate from the most energetic beta-emitting radionuclide is not necessarily a conservative

[2] Table M-2 is a reprint of the Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material (The Guidelines). The latest version is dated April 1993. ADAMS Accession No. ML003745526. The NRC staff notes that the Guidelines will be the official compliance document and is included as a license condition in materials licenses unless an applicant requests and justifies an alternative.

approach for this applicant. The NRC staff plotted Equation 1 for various maximum beta energies. Average energies were approximated by dividing the maximum energy by three (Shleien, et al, 1998). The NRC results demonstrated that the maximum dose rate using the most energetic beta energy is (0.6 million electron volts (MeV)) for the indicated contamination level and decreases as energy increases. This same trend is demonstrated in the applicant's calculations, shown in Table 2 (below).

Nuclide	C_a	E_{max}	$\bar{E}$	$\mu_{\beta,t}$	$\mu_{\beta,a}$	$e^{(-\mu_{\beta,t}\times 0.007)}$	$e^{(-\mu_{\beta,a}\times d)}$	$\dot{D}_\beta$
Pa-234m	0.83	2.28	0.82	6.146	5.160	0.958	0.994	0.14
Bi-214	0.83	3.27	1.27	3.725	3.094	0.974	0.996	0.14
Bi-212	0.83	2.25	0.83	6.276	5.272	0.957	0.994	0.15
Ac-228	0.83	2.08	0.75	6.985	5.881	0.952	0.993	0.15
Pa-234m	2.50	2.28	0.82	6.146	5.160	0.958	0.994	0.43
Bi-214	2.50	3.27	1.27	3.725	3.094	0.974	0.996	0.21
Bi-212	2.50	2.25	0.83	6.276	5.272	0.957	0.994	0.45
Ac-228	2.50	2.08	0.75	6.985	5.881	0.952	0.993	0.44

Ac-228 – actinium-228
Bi-212/214 – bismuth-212/bismuth-214
Pa-234m – protactinium-234 metastable

Table 2. The applicant's estimated beta skin dose rate for most energetic emissions (excerpted from Table 16 of RER, 2022a)

According to the applicant, the calculations recorded in Table 2 provide "the results of conservative, empirical dose rate estimate for the two most energetic beta emitters in the thorium-232 and uranium-238 series for the Demonstration Project." However, using the applicant's results, the highest energy beta particle (Bismuth-214 (Bi-214), E_{Max}= 3.27 MeV) results in a lower dose in both surface contamination scenarios (i.e., C_a= 0.83 and C_a= 2.5).

This trend is particularly noticeable for the case of higher surface contamination where, the highest energy beta particle (Bi-214, E_{Max}= 3.27 MeV) results in a dose rate calculated by the applicant that is less than half of the dose rate from the lowest energy beta particle in Table 2 (Actinium-228, E_{Max}= 2.08 MeV). Therefore, the use of max beta energy in the dose rate determination worked until a peak value was reached and then results appeared to underestimate the dose rates. A reasonable calculational approach should consider all of the energy beta particles for the expected mixture of radionuclides at the facility and evaluated accordingly. In addition, Note 6 to Table M-2 in NUREG-1556, Vol. 12, Rev. 1, includes gamma emitters. The applicant did not evaluate gamma emitters in addition to its dose rate estimate for beta emitters.

Therefore, in the March RAI (NRC, 2023), the NRC staff requested that the applicant provide additional justification of the proposed calculational approach to demonstrating compliance with the radiation levels associated with average and maximum surface contamination levels of beta-gamma emitters.

In their response to the RAI (RER, 2023b), the applicant performed an expanded calculation of potential average and maximum beta dose rates for all beta emissions associated with the thorium-232 and uranium-238 decay chain using Equation 1 (identified above). The uranium-235 decay chain was ignored due to its low abundance in natural uranium. The results of the

expanded calculations are provided in Table 3 “Estimated beta skin dose” and Table 4 “Estimate gamma skin dose.”

The expanded calculations using the average beta energies resulted in none of the estimated skin dose rate exceeding 0.2 mrad/hour (hr) from an average surface rate concentration of 1000 disintegrations per minute over a 100 square centimeter area (dpm/100cm^2) or 1.0 mrad/hr using the maximum surface rate concentration of 3000 dpm/100cm^2. Measurements were made through a total absorber with a thickness no greater than 7.0 mg/cm^2.

The evaluation of potential gamma-only dose raters was performed for uniformly contaminated surfaces using Equation 2.

Equation 2

$$\dot{H} = 950 \times \pi \times \Gamma \times C_a \times \ln\left(\frac{r^2 + d^2}{d^2}\right)$$

Count [a]	Nuclide	E_{max}	$\overline{E}$	$\mu_{\beta,t}$	$\mu_{\beta,a}$	$e^{(-\mu_{\beta,t}\times 0.007)}$	$e^{(-\mu_{\beta,a}\times d)}$	$\dot{D}_{\beta,avg}$	$\dot{D}_{\beta,max}$
1	Radium-228	0.039	0.007	55722	57117	0.000	0.000	0.000	0.000
2	Actinium-228	0.983	0.316	20	17	0.869	0.980	0.032	0.097
3	Actinium-228	1.014	0.327	19	17	0.874	0.981	0.032	0.097
4	Actinium-228	1.115	0.365	17	14	0.889	0.983	0.032	0.096
5	Actinium-228	1.170	0.385	16	13	0.896	0.984	0.032	0.096
6	Actinium-228	1.740	0.610	9	8	0.939	0.991	0.031	0.092
7	Actinium-228	2.080	0.747	7	6	0.952	0.993	0.030	0.089
8	Lead-212	0.158	0.041	332	304	0.098	0.700	0.006	0.017
9	Lead-212	0.334	0.093	98	87	0.505	0.903	0.025	0.075
10	Lead-212	0.573	0.171	44	38	0.737	0.956	0.032	0.095
11	Bismuth-212	1.590	0.533	10	9	0.931	0.990	0.030	0.090
12	Bismuth-212	2.246	0.834	6	5	0.957	0.994	0.030	0.090
13	Thallium-208	1.280	0.442	14	12	0.908	0.986	0.033	0.098
14	Thallium-208	1.520	0.535	11	9	0.927	0.989	0.032	0.096
15	Thallium-208	1.800	0.649	9	7	0.942	0.992	0.031	0.093
1	Thorium-234	0.076	0.022	1530	1450	0.000	0.182	0.000	0.000
2	Thorium-234	0.095	0.028	898	841	0.002	0.372	0.000	0.000
3	Thorium-234	0.096	0.028	878	822	0.002	0.381	0.000	0.000
4	Thorium-234	0.189	0.054	244	222	0.181	0.770	0.011	0.033
5	Protactinium-234 metastable	2.280	0.821	6	5	0.958	0.994	0.029	0.086
6	Polonium-218	0.330	0.167[b]	100	89	0.498	0.901	0.045	0.134
7	Lead-218	0.670	0.205	35	30	0.784	0.965	0.032	0.097
8	Lead-218	0.730	0.226	31	27	0.807	0.969	0.032	0.097
9	Lead-218	1.030	0.335	19	16	0.877	0.981	0.032	0.097
10	Bismuth-214	1.420	0.420	12	10	0.920	0.988	0.027	0.082
11	Bismuth-214	1.505	0.525	11	9	0.926	0.989	0.032	0.095
12	Bismuth-214	1.540	0.539	11	9	0.928	0.989	0.032	0.095
13	Bismuth-214	3.270	1.268	4	3	0.974	0.996	0.028	0.083
14	Lead-210	0.063	0.016	2621	2513	0.000	0.052	0.000	0.000
15	Bismuth-210	1.161	0.389	16	14	0.895	0.984	0.033	0.098

[a] Beta emissions from isotopes with a branch ratio less than 1% or maximum beta energy less than 0.036 MeV were excluded from this table.
[b] Average beta energy of the emission was not available in NuDat 3.0 so the value was approximated as 1/3 of the maximum.
Note: Values in this table were calculated using Equation 1 with variables defined below:

$$\dot{D}_{\beta} = 3.6 \times 10^{-2} \times C_a \times \overline{E} \times \mu_{\beta,t} \times e^{(-\mu_{\beta,a}\times d)} \times e^{(-\mu_{\beta,t}\times 0.007)}$$

$\dot{D}_{\beta}$	mrad h^{-1}	Dose rate to the basal cells of the skin at a depth of 0.007 g cm^{-2} • $\dot{D}_{\beta,avg}$ = beta dose rate at average beta-gamma contamination level ($C_{a,avg}$) • $\dot{D}_{\beta,max}$ = beta dose rate at maximum beta-gamma contamination level ($C_{a,max}$)
3.6×10^{-2}	constant	Constant calculated as: $0.5\ (\beta^-\ \text{directed upward}) \times 1.25\ (25\%\ \text{scattered upward}) \times \frac{1.6\times10^{-12}\ \text{J}}{\text{MeV}} \times \frac{3600\ \text{s}}{\text{h}} \times \frac{10^{6}\ \text{g mGy}}{\text{J}} \times \frac{100\ \text{mrad}}{\text{mGy}}$
C_a	Bq cm^{-2}	Surface area concentration of beta contamination, calculated as: • $C_{a,avg} = \frac{1000\ \text{dpm}}{100\ \text{cm}^2} \times \frac{\text{Bq}}{60\ \text{dpm}} = 0.17\ \frac{\text{Bq}}{\text{cm}^2}$ • $C_{a,max} = \frac{3000\ \text{dpm}}{100\ \text{cm}^2} \times \frac{\text{Bq}}{60\ \text{dpm}} = 0.5\ \frac{\text{Bq}}{\text{cm}^2}$

Table 3. Estimated beta skin dose rate for series of beta emissions using Equation 1 (extracted RER, 2023b)

Count [a]	Nuclide	Γ	$\dot{H}_{avg}$	$\dot{H}_{max}$
1	Thorium-232	0.032	3E-05	5E-05
2	Radium-228	0.043	5E-05	6E-05
3	Actinium-228	0.609	7E-04	9E-04
4	Thorium-228	0.040	4E-05	6E-05
5	Radium-224	0.007	8E-06	1E-05
6	Lead-212	0.159	2E-04	2E-04
7	Bismuth-212	0.107	1E-04	2E-04
8	Thallium-208 [b]	1.564	2E-03	2E-03
1	Uranium-238	0.030	3E-05	4E-05
2	Thorium-234	0.045	5E-05	6E-05
3	Protactinium-234 metastable	0.011	1E-05	2E-05
4	Uranium-234	0.041	4E-05	6E-05
5	Thorium-230	0.035	4E-05	5E-05
6	Radium-226	0.008	9E-06	1E-05
7	Lead-214	0.220	2E-04	3E-04
8	Bismuth-214	0.756	8E-04	1E-03
9	Lead-210	0.145	2E-04	2E-04

[a] Isotopes with a branch ratio less than 1% or a gamma constant of zero were excluded from this evaluation.
[b] Thallium-208 has a branch ratio of 36%.
Note: Values in this table were calculated using Equation 2 with variables defined below:

$$\dot{H} = 950 \times \pi \times \Gamma \times C_a \times \ln\left(\frac{r^2 + d^2}{d^2}\right)$$

$\dot{H}$	mrad h^{-1}	Gamma dose rate associated with average contamination level ($\dot{H}_{avg}$) and maximum contamination level ($\dot{H}_{max}$) of gamma emitters
$950 \times \pi$	mrad R^{-1}	Conversion calculated as $\frac{1000\ \text{mrad}}{\text{rad}} \times \frac{0.95\ \text{rad}}{\text{R}} \times \pi$ where π is the unitless constant pi (approximately 3.14…)
Γ	R m^2 Ci^{-1} hr^{-1}	Gamma exposure rate constant for the isotope of interest (Johnson and Birky 2012, Table 6.5)
C_a	Ci m^{-2}	Surface area concentration of contamination, calculated as: • $C_{a,avg} = \frac{1000\ \text{dpm}}{100\ \text{cm}^2} \times \frac{\text{Bq}}{60\ \text{dpm}} \times \frac{10^4\text{cm}^2}{\text{m}^2} \times \frac{\text{Ci}}{3.7\times10^{10}\ \text{Bq}} = 4.5 \times 10^{-8} \frac{\text{Ci}}{\text{m}^2}$ • $C_{a,max} = \frac{3000\ \text{dpm}}{100\ \text{cm}^2} \times \frac{\text{Bq}}{60\ \text{dpm}} \times \frac{10^4\text{cm}^2}{\text{m}^2} \times \frac{\text{Ci}}{3.7\times10^{10}\ \text{Bq}} = 1.4 \times 10^{-7} \frac{\text{Ci}}{\text{m}^2}$
r	m	Source radius – radius of a 1 m^2 disc source for average contamination level, of a 100 cm^2 disc source for maximum contamination level
d	m	Source distance – 1 cm
$\ln\left(\frac{r^2 + d^2}{d^2}\right)$	unitless	Correction for different source radius and distance from gamma exposure rate constant assumptions • 8.07 for average contamination level, 1 m^2 disc source • 3.49 for maximum contamination level, 100 cm^2 disc source

Bq – becquerels
Ci – curies
cm – centimeters
dpm – decays per minute
g - grams
h – hours
J – joules

Uranium series beta emitters
Thorium series beta emitters

MeV – mega electron volts
mGy – milligray
mrad – millirad
R – roentgen
s – seconds

Table 4. Estimated exposure rate for gamma emissions (extracted from RER,2023b)

The NRC staff finds the expanded data sufficient to address the concern raised in the RAI that use of the maximum beta energies rather than the average beta energies was not conservative and above a peak value actually underestimated the dose. The applicant resubmitted its dose estimates using the average beta energies which eliminated the dose underestimation issue and provided the gamma dose rates that had previously be omitted from the application documents. (NRC, 2023). NRC staff reviewed the revised and new data and determined it was appropriate and representative of anticipated site conditions and is therefore acceptable.

7.9 Personnel Dosimeters

The applicant provided details on the processing of dosimeters used to monitor external dose to personnel and are shown in Table 5 below. According to Table 5, the applicant proposed using a National Voluntary Laboratory Accreditation Program (NVLAP)-approved provider.

Instrument Type	Use	Make/Model Example [a]	Number of Units [a]	Estimated Sensitivity [b]
TLD or OSL dosimeters from a NVLAP-approved provider	External dose monitoring (personnel)	Landauer OSL	1 per worker per quarter	1 mrem

[a] Instrument make/model and number of units are estimates for planning purposes. RER will modify the inventory of instruments, as necessary.
[b] Estimated sensitivity values are based on manufacturer specifications for example units and the MDC equations presented in Table 8.

cpm – counts per minute
dpm – decays per minute
dpm 100 cm^{-2} – decays per minute per 100 square centimeters
MDC – minimum detectable concentration
mrem – millirem
µCi mL^{-1} – microcuries per milliter
µR hr^{-1} – micro-Roentgen per hour

NIST – National Institute of Standards and Technology
NVLAP – National Voluntary Laboratory Accreditation Provider
OSL – optically-stimulated luminescent dosimeter
pCi g-1 – picocuries per gram
pCi L^{-1} – picocuries per liter
RER – Rare Element Resources, Inc.
TLD – thermoluminescent dosimeter

Table 5. Personnel dosimeter details [excerpted from Table 6. in the TR (RER, 2022a)]

The applicant proposed the use of a NAVLP accredited vendor for the processing of dosimeters used to monitor external dose to personnel. Landauer is a well-known dosimetry vendor accredited for processing of external dosimeters for beta, gamma, and neutron exposures. This commitment satisfies the requirements of 10 CFR 20.1501(d) to use a NAVLP accredited vendor to process dosimeters for the radiation types at the site. meets the requirements in 10 CFR 20.1501(d) and is therefore acceptable.

7.10 Instrument Calibration

7.10.1 General

In Section 10.2.2 of the September 2022 TR (RER, 2022a), the applicant stated that portable instruments for radiation protection will be calibrated “before first use, at least annually thereafter, and after any repair.”

The NRC staff finds this commitment meets the requirement in 10 CFR 20.1501(c) requiring that instruments and equipment used for quantitative measurements are periodically calibrated for the radiation measured and is therefore acceptable.

7.10.2 Surface contamination detection capability

Appendix H of NUREG-1556, Volume 12, Rev. 1 recommends that licensees should possess, and use calibrated and operable radiation detection and measurement instruments that are sufficiently sensitive to detect and measure the type and energy of the radiation used. Detection capability is comprised of both static (keeping the detector still over a surface) and scan (moving the detector slowly over a surface) minimum detectable concentrations. The typical unit of static and scan minimum detectable concentrations (MDC) is disintegrations per minute per 100 square centimeters (dpm/100cm^2). Once calculated, the MDC can be compared to regulatory limits for surface contamination (e.g., Table M-2 in NUREG-1556, Vol. 12, Rev. 1).

7.10.3 Static MDC

The applicant discussed its methodology for calculating static and scan MDC in Section 10.2.3 of the TR (RER, 2022a). The applicant proposed the following equation for calculating the static MDC (variables defined in Table 7 of RER, 2022a):

$$MDC = \frac{2.71 + 3.29 \times \sqrt{R_b \times T_g \times \left(1 + \frac{T_g}{T_b}\right)}}{T_g \times \varepsilon_{total} \times \frac{probe\ area\ \mathrm{cm}^2}{100\ \mathrm{cm}^2}}$$

Equation 3. Static MDC (RER, 2022a)

According to the applicant (RER, 2022a), Equation 3 is derived from Equation 3.11 provided in NRC guidance document NUREG-1507, Revision 1 (NRC, 2020). Equation 3.11 in NUREG-1507 is provided as Equation 4 below:

$$MDC = \frac{3 + 3.29\sqrt{R_B\, T_{S+B}\left(1+\frac{T_{S+B}}{T_B}\right)}}{KT_{S+B}}$$

Equation 4. Static MDC from Equation 3.11 in NUREG-1507 (NRC, 2020)

Equation 3 and Equation 4 are similar, except for the initial constants 2.71 (Equation 3) and 3 (Equation 4) in the top portion of the equations. The NRC staff recognizes that there are various formulas for determining MDC and that they yield similar results. However, each MDC formula has its own set of assumptions. The assumptions for Equation 3.11 from NUREG-1507 for static MDC determination, including the constant value of 3, can be found in a paper by various authors recommending that equation (Strom and Stansbury, 1992; NRC, 1986). The applicant did not discuss why the constant was revised from 3 to 2.71 for the static MDC calculation. Therefore, the NRC staff could not determine that the applicant's proposed Equation 1 was correct and requested, in the March 2023 RAI (NRC, 2023b), that the applicant include a justification for the difference in the constant. . In its response to the RAI (RER, 2023b) the applicant agreed to return the static MDC constant to 3 in alignment with Equation 3.11 for static MDC determination in NUREG-1507 (NRC, 2020). The NRC staff finds agreement to use the NRC equation as documented in the NUREG-1507 to be satisfactory.

7.10.4 Scan MDC

The applicant proposed the following equation for calculating the scan MDC (variables defined in Table 7 of RER, 2022a):

$$MDC_{scan} = \frac{d' \times \sqrt{C_b} \times \frac{60}{i}}{\varepsilon_{sureyor} \times \varepsilon_{instrument} \times \varepsilon_{surface} \times \frac{probe\ area\ \mathrm{cm}^2}{100\ \mathrm{cm}^2}}$$

Equation 5. Scan MDC (RER, 2022a)

According to the applicant (RER, 2022a), Equation 5 is derived from Equation 6.4 Scan MDC Determination provided in NUREG-1507.

The NRC staff finds that the applicant's proposed scan MDC formula is consistent with the guidance in NUREG-1507 for beta or alpha plus beta scans. However, as described in Section 6.2.4.2 of NUREG-1507, and the previous NRC staff evaluation (NRC, 2015), Equation 5 is not the correct formula for alpha-only scans. The recommended formula for alpha-only scan MDC is:

$$\frac{\left[-\ln\left(1-P(n\geq 1)\right)\right]\times(60/i)}{\varepsilon_i\times\varepsilon_s\times\frac{probe\ area}{100}}$$

Equation 6. Alpha-only scan MDC (NRC, 2020)

In the NRC staff RAI (NRC, 2023), a request for information associated with selection of an alpha-only scan MDC was part of RAI-2. In its response to the RAI (RER, 2023b) the applicant agreed to use the example scan MDC formula (Equation 6 listed above) for alpha-only surveys. The NRC staff finds agreement to use the NRC equation as documented in NUREG-1507 to be sufficient.

7.10.5 Instrument efficiency

For the calibration of surface contamination measurement instruments, Appendix H to NUREG-1556 Volume 12 Revision 1, provides the following guidance:

> The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

NUREG-1507 provides the following guidance on calibration sources:

> Depending on whether a single source or multisource calibration will be performed, different approaches are presented in national and international guidance with respect to calibrations and the determination of instrument efficiencies. For example, ANSI N323AB-2013 (American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments) indicates that "calibration should include adjustment and/or determination of readings of at least three points selected over the energy range appropriate to the needs of the user application," and that "single point calibrations are only valid for application to field measurement energies that are greater than the calibration energy."

The guidance in NUREG-1507 cited above, and similar guidance, was used in a previous NRC staff evaluation of counting efficiency (NRC, 2015).

Consistent with the guidance cited above and previous NRC staff findings (NRC, 2015), the NRC staff requested (NRC, 2022b) information on how the applicant would determine instrument efficiency for each radionuclide. The applicant incorporated its response to the NRC staff's request in its September 2022 TR (RER, 2022a).

The applicant discussed instrument efficiency in Section 10.2.3.2 of the TR (RER, 2022a). According to the applicant, it will determine instrument efficiency using the radioactive sources described in Table 6 below. The applicant described the emission energies of the calibration sources (see Energy Notes in Table 6) as "similar to those of the radionuclides of interest".

Source Type	Radionuclide	Energy Notes
Alpha	Polonium-210	5.3 MeV α
Beta	Technitium-99	0.11 MeV mean β^-

Table. 6 Calibration sources [excerpted from Table 9 of the TR (RER, 2022a)]

The applicant provided an analysis of the alpha and beta particle emission energies of the Thorium-232 (Th-232) and Uranium-238 (U-238) radioactive decay series in Tables 10 – 13 in the TR (RER, 2022a). As part of the emission energy analysis, the applicant calculated a weighted average energy for each of the decay series. In other words, the applicant treated each series as a mixture and calculated a weighted average energy for the mixture. The applicant's analysis is demonstrated in Table 7.

Isotope	Alpha energy (MeV)	Emission fraction	Weighted emission energy (MeV)
Uranium-238	4.15	21%	0.87
	4.20	79%	3.32
	Subtotal	100%	4.19
Uranium-234	4.77	71%	3.41
	4.72	28%	1.34
	Subtotal	100%	4.75
Thorium-230	4.69	76%	3.58
	4.62	23%	1.08
	Subtotal	100%	4.66
Radium-226	4.78	94%	4.49
	4.60	6%	0.28
	Subtotal	100%	4.77
Radon-222	5.49	100%	5.48
Polonium-218	6.00	100%	6.00
Polonium-214	7.69	100%	7.69
Polonium-210	5.30	100%	5.30
Uranium series		**8 alphas per decay**	**5.36 average energy**

Table 7. The applicant's emission weighted alpha decay energies for the U-238 series [from Table 11 in the TR (RER, 2022a)]

The guidance in NUREG-1507 allows for weighted energy averaging on a radionuclide basis. The details are discussed in Appendix A to NUREG-1507 and demonstrated in Tables A-5 and A-6 of that appendix. The NRC staff did not find any guidance, nor did the applicant cite any guidance, that allows for the weighted energy averaging on a mixture basis.

As discussed above, the guidance in NUREG-1507 states the following regarding calibration sources:

> single point calibrations are only valid for application to field measurement energies that are greater than the calibration energy.

The applicant selected polonium-210 (Po-210) as its calibration source for determining instrument efficiency for alpha particles. Po-210 undergoes radioactive decay with a 5.3 MeV alpha particle. The NRC staff compared the Po-210 5.3 MeV alpha particle energy to the alpha

particle energies in Table 7 for the U-238 decay series. The NRC staff notes that the U-238, U-234, Th-230, and radium-226 (Ra-226) alpha particle energies are all below the Po-210 5.3 MeV alpha particle energy. Consistent with the guidance in NUREG-1507 (see the example in Table A-3), the instrument efficiency would be assigned zero for the U-238, U-234, Th-230, and Ra-226 alpha particles.

The applicant has the option of either choosing a lower energy calibration source or calculating a calibration curve with multiple alpha energy calibration sources. A typical calibration curve is demonstrated in Figure 2. Actual alpha particle calibration curves for different alpha detection instruments are shown in Figures A-5 and A-11 of NUREG-1507 and have the same characteristics (i.e., higher instrument efficiency for higher energy alpha particles). The applicant did not address how this difference in energy response will be addressed in its calibration program.

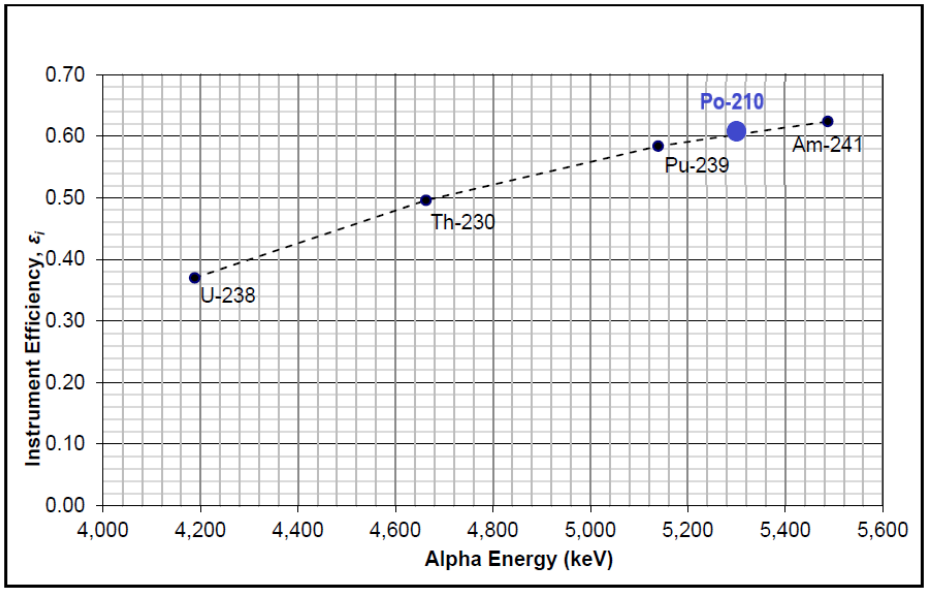

Figure 2. Example alpha detector source calibration curve with the applicant's Po-210 calibration source added (adapted from Figure A-1 in NUREG-1507)

Based on the information submitted by the applicant in the September 2022 TR (RER, 2022a), the NRC staff could not conclude that the proposed method for determining instrument efficiency for use in calculating the MDC for comparison to surface contamination release limits would meet the requirements in 10 CFR 20.1501(c). Therefore, in RAIs (NRC, 2023), the NRC staff requested that the applicant provide justification and additional discussion regarding the use of Po-210 as the only calibration source for determining instrument efficiency for alpha particles.

In its response to the RAI (RER, 2023b) the applicant committed to working with the instrument manufacturer to calculate a calibration curve with multiple alpha energy calibration sources rather than move forward with the proposed single point calibration reference using Po-210. The applicant agreed to develop this calibration curve similar to the examples provided in the NRC's

RAI (NRC, 2023) and NUREG-1507. The applicant further stated that Po-210 sources will still be used but only for the purpose of performing survey equipment functional testing.

Based on the applicant's response to the RAI (RER, 2023b), the NRC staff determined the proposed approach of using multiple alpha energy calibration sources rather than the single point calibration using Po-210 meets the intent of the requirements and will follow-up on the development and implementation of this proposed program for alpha calibration to support surveys as part of the pre-operational inspection required in LC 13, before the applicant will be authorized to conduct operations.

The NRC staff notes that concepts discussed above for alpha particles also applies to beta particle emissions. However, the NRC staff also recognizes that the calibration source chosen by the applicant for beta particle emissions (technetium-99) is a relatively low-energy beta emitter relative to most of the beta energy emissions in the U and Th decay series [Tables 12 and 13 in the TR (RER, 2022a)]. Therefore, the applicant's methodology for calculating instrument efficiency will also have to address any energy differences between the calibration source and individual radionuclides in the U and Th decay series.

7.10.6 Example MDC demonstrations

The applicant provided the results of example MDC calculations in Table 8 of the TR (RER, 2022a). These example MDC calculations incorporated instrument efficiencies based on a manufacturer-reported efficiency for a specific instrument based on the response to a plutonium-239 (Pu-239) alpha calibration source. The applicant justified the use of the manufacturer-reported efficiency by comparing the Pu-239 alpha energy to the weighted average energy for the Th-232 and U-238 radioactive decay series.

The NRC staff did not find the applicant's proposed averaging technique consistent with current guidance nor did the applicant provide justification for an alternate methodology. Although the energy of the Pu-239 alpha particle (5.139 MeV) is less than the Po-210 alpha particle (5.3 MeV), it is still higher than several of the alpha particles in the Th-232 and U-238 radioactive decay series. Therefore, the efficiency differences (e.g., Figure 3) are still present and the guidance for assigning an instrument efficiency of zero to lower energy alpha particles applies.

Based on the discussion above and information provided in the TR (RER,2022a), the NRC staff could not conclude that the examples provided for calculated MDC for comparison to surface contamination release limits would meet the requirements in 10 CFR 20.1501(c). Therefore, in the NRC RAIs (NRC, 2023) the applicant was requested to reassess the example calculations demonstrating the radionuclide-weighted surface contamination detection capability (MDC concentrations) including the scan MDC for portable instruments used to release equipment and materials for unrestricted release.

In addition to the formulas provided for calculating MDC and determining instrument efficiency, the applicant discussed how it would control other factors affecting the MDC during operations. For example, the applicant stated that it would incorporate details such as scan speed and distance from detector to source into activity-specific standard operating procedures (SOP) and

on-the-job training. The NRC staff finds this practice a reasonable method to ensure the validity of the assumptions used in the applicant's MDC demonstrations.

In the applicant's response to RAIs (RER,2023b), the applicant submitted a revision to Table 8 in the Technical Report (TR) (labelled as Table 4 in the RAI response document) incorporating the noted changes to MDC calculations, and committed to set the instrument efficiency for purposes of MDC calculations and surface release surveys to the lowest alpha energy in the calibration curve. Based on a review of the thorium-232 series alphas, the applicant expects this lowest energy setting to be based on the 3.9 MeV alpha from Th-232.

The applicant also conducted a mixture specific analysis of surface release criteria appliable to the Demonstration Project. The detailed mixture specific analysis was provided as Enclosure 3 to the applicant's response to RAIs (RER, 2023b) and provides an average limit and maximum limit for the exploration sample, primary process leach residue, primary process wastewater, primary process tailings, thorium -only process stages, and total tailings.

Table 4. Example MDC calculations

Type	Instrument [a]	Measurement	$\varepsilon_{instrument}$	$\varepsilon_{surface}$	R_b	MDC Equation	MDC [b] (dpm 100 cm^{-2})	Comparison Value	Allowable Use(s)
Alpha scintillator	43-5 and 2241	Static alpha	0.277	0.25	3	3	200	1,000	Unrestricted release surveys; unrestricted area surveys
								220	Personnel contamination surveys
		Scanning alpha	0.277	0.25	3	4	3,600	22,000	Restricted area surveys
Alpha/beta scintillator	43-93 with 2360	Static alpha	0.277	0.25	1	3	70	1,000	Unrestricted release surveys; unrestricted area surveys
								220	Personnel contamination surveys
		Scanning alpha	0.277	0.25	1	4	1,400	3,000	Unrestricted release surveys; unrestricted area surveys
		Static beta	0.3	0.25	300	3	890	1,000	Unrestricted release surveys; unrestricted area surveys
		Scanning beta	0.3	0.25	300	5	2,500	3,000	Unrestricted release surveys; unrestricted area surveys
Pancake Geiger-Mueller	44-9 with 12	Scanning all	0.3	0.25	60	5	7,100	22,000	Restricted area surveys
	44-40 with 12	Scanning all	0.3	0.25	25	5	4,600	22,000	Restricted area surveys
Benchtop sample counter	3030	Removable alpha	0.64	0.25	0	3	4	200	Unrestricted release surveys; unrestricted area surveys
		Removable beta	0.54	0.25	50	3	190	200	Unrestricted release surveys; unrestricted area surveys

[a] See instrument list in RER's *Technical Report*, Table 6 (RER 2022a)
[b] MDC values were rounded to two digits.
Note: Values in this table were calculated using the following equations with variables defined below:

Equation 3

$$MDC = \frac{3 + 3.29 \times \sqrt{R_b \times T_g \times \left(1 + \frac{T_g}{T_b}\right)}}{T_g \times \varepsilon_{total} \times \frac{probe\ area\ \mathrm{cm}^2}{100\ \mathrm{cm}^2}}$$

Equation 4

$$MDC_{scan,\alpha} = \frac{\left[-\ln\left(1 - P(n \geq 1)\right)\right] \times \frac{60}{i}}{\varepsilon_{sureyor} \times \varepsilon_{instrument} \times \varepsilon_{surface} \times \frac{probe\ area\ \mathrm{cm}^2}{100\ \mathrm{cm}^2}}$$

Equation 5

$$MDC_{scan,\alpha\beta} = \frac{d' \times \sqrt{C_b} \times \frac{60}{i}}{\varepsilon_{sureyor} \times \varepsilon_{instrument} \times \varepsilon_{surface} \times \frac{probe\ area\ \mathrm{cm}^2}{100\ \mathrm{cm}^2}}$$

C_b	counts	Background counts estimated using manufacturer specifications for sensitivity or expected values
T_b	minutes	Background count time of 1 minute for all instruments
$R_b = \frac{C_b}{T_b}$	cpm	Background count rate estimated using manufacturer specifications for sensitivity or expected values

Table 8. Revised Example Minimum Detectable Activities Calculations (Table 4 extracted from the RER response to the RAI (RER 2023b)).

Based on the information provided in the TR and the applicant's response to RAIs (RER, 2023b), NRC staff has determined that the program as described meets the intent of the regulatory guidance in NUREG-1507 (NRC, 2020) and the requirements of 10 CFR 20.1501 and is therefore acceptable. Review of the program as implemented will be part of the pre-operational inspection prior to the authorization for operations.

7.10.7 Records

In Section 10.10 of the TR (RER, 2022a), the applicant stated that records will be maintained in accordance with the applicable requirements of 10 CFR Part 20, Subpart L, including instrument calibrations.

The NRC staff finds this commitment consistent with the recommendation in NUREG-1556, Volume 12 Revision 1, Section 8.10.2, and is therefore acceptable.

Evaluation Findings

The NRC staff finds that the applicant's description of its radiation protection plan (RPP) as described in the TR (RER, 2022a) and the applicant's response to RAIs (RER, 2023b) is sufficient. Specifically, , the commitment to have an RPP and standard and emergency procedures; establish audit and quality assurance programs; to evaluate potential dose from surface contamination; the selection and use of radiation survey instrumentation; conduct of radiation surveys and other radiation protection requirements proposed to be implemented meet the intent to protect the health and safety of workers, the public and the environment, and comply with the requirements of 10 CFR 20.1101(a), §20.1101(c), §20.1501(c), §20.1501(d); §20.2102, §20.2103(a), §20.2110, §40.32, the applicable guidance in Section 8.10 of NUREG-1556 Volume 12 Revision 1 (NRC, 2018) and are therefore acceptable.

8.0 Material Receipt and Accountability

Regulatory Requirements

NUREG-1556, Volume 12, Revision 1, Section 8.10.3 "Material Control and Accountability," (NRC, 2018), identifies the relevant regulatory requirements for review of this area. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 20.1501(a) (General – Surveys and Monitoring); 10 CFR 20.1801 (Security of Stored Material); 10 CFR 20.1802 (Control of Material not in Storage); 10 CFR 20.1906 (Procedures for Receiving and Opening Packages);10 CFR 20.2001 (General – Waste Disposal); 10 CFR 20.2108 (Records of Waste Disposal); 10 CFR 20.2201 (Reports of Theft or Loss of Licensed Material); 10 CFR 20.2207 (Reports of Transactions involving Nationally Tracked Sources); 10 CFR 37.49 (Monitoring and Assessment); 10 CFR 37.71 (Additional Requirements for Transfer); 10 CFR 37.75 (Pre-planning and Coordination of Shipment);10 CFR 37.77 (Advance Notification of Shipment); 10 CFR 40.36(f) (Financial Assurance and Recordkeeping for Decommissioning); 10 CFR 40.41(e) (Terms and Conditions of Licenses); 10 CFR 40.51 (Transfer of Source or Byproduct Material); and 10 CFR 40.61 (Records);

Regulatory Acceptance Criteria

The NRC staff determined that the applicable requirements for this section are: 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2001; 10 CFR 20.2108; 10 CFR 20.2201; 10 CFR 40.36(f); 10 CFR 40.41(e); 10 CFR 40.51; and 10 CFR 40.61.

As stated previously, while potentially applicable to source material applications, the NRC staff determined that 10 CFR Part 37 does not apply to this applicant's proposed operations. The only isotope produced at the demonstration plant that is regulated under 10 CFR Part 37 is Ra-226. Based on Table 8 in Appendix F to the Environmental Report (RER, 2022a), there will be a total of 0.034 Ci of Ra-226 processed during the entire Demonstration Project. This is significantly less than the amount required for classification as Category 2 (10.8 Ci), and thus, less than an amount that would require compliance with 10 CFR Part 37.

NRC staff also determined that the reporting requirements for sources covered under the National Source Tracking System defined in 10 CFR 20.2207 are also not applicable to this application for source material because the licensee does not have any Category 1 or Category 2 quantities as defined by the International Atomic Energy Agency (IAEA) and adopted by the NRC. Specifically, the only radionuclide at the demonstration plant that is regulated under 10 CFR Part 20 Appendix E is Ra-226. Based on Table 8 in Appendix F to the Environmental Report (RER, 2022a), there will be a total of 0.034 Ci of Ra-226 processed during the entire Demonstration Project. This is significantly less than the amount required for classification as Category 2 (11 Ci) under Appendix E to 10 CFR Part 20 and thus, less than an amount that would require compliance with 10 CFR 20.2207 and Appendix E.
.
As to the regulations that do apply, they require licensees to develop, implement, and maintain written procedures for a variety of radiation safety tasks. These tasks include but are not limited to, safely opening packages, controlling access to and use of radioactive materials, maintaining records of receipt, transfer and disposal of licensed materials, maintaining records of occupational exposure, conduct of physical inventories, performing leak tests at the required frequencies, and conducting routine surveys for the identification of contamination in restricted and unrestricted areas.

Staff Review and Analysis

In Section 10.3 of the TR (RER, 2022a), the applicant commits to the development, implementation, and maintenance of SOPs for ensuring accountability of licensed materials. In other sections of the application, the licensee made commitments to develop SOPs for occupational exposure records, routine surveys, leak tests, and disposal and receipt surveys when shipping offsite. The applicant indicates that physical inventories will be conducted every six months to account for all radioactive source material received and possessed under the license.

The applicant also indicated that future use might include nuclear density gauges, and non-exempt sources but those potential additions to the license were not evaluated as part of this SER. A separate license amendment will be needed if the applicant decides to add these devices and sources to their license.

Evaluation Findings

The NRC staff finds that the applicant's commitment to the development and implementation of a materials accountability program meets the intent of the requirements. As specified in LC 13,

a pre-operational inspection including the RPP and the development and implementation of procedures as described in the documents tied to the license in LC 11 will be conducted to verify the applicant implemented the programs as described in the application.

9.0 Occupational Dose

Regulatory Requirements

NUREG-1556, Volume 12 Rev 1, Section 8.10.4 “Occupational Dose” (NRC, 2018), identifies the relevant regulatory requirements for review of this area. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 19.11(a)(3) (Posting of Notices to Employees);10 CFR 20.1902–1905 (Subpart J- Precautionary Procedures); 10 CFR 20.2201–2203 (Subpart M- Reports); 10 CFR 21.21 (Notification of Failure to Comply or Identification of Defect); 10 CFR 37 (Subpart B – Background Investigations and Access Authorization Program); 10 CFR 37.21 (Personnel Access Authorization Requirements); 10 CFR 37.45 (LLEA (Local Law Enforcement Agency) Coordination); 10 CFR 37.49 (Monitoring and Assessment); 10 CFR 40.41(e) (Terms and Conditions of Licenses); and 10 CFR 40.60 (Reporting Requirements).

Regulatory Acceptance Criteria

The NRC staff determined that this section will be evaluated against the criteria of 10 CFR 19.11(a)(3), 10 CFR 20.1902–1905; 10 CFR 20.2201–2203; 10 CFR 21; 10 CFR 40.41(e); and 10 CFR 40.60.

10 CFR Part 37 Subpart B, 10 CFR 37.21, 10 CFR 37.45 and 10 CFR 37.49 will not be evaluated as they are related to the security requirements to be implemented for Category 1 and Category 2 quantities of radioactive material, as stated previously. The only isotope regulated under 10 CFR Part 37 that will be produced at the Demonstration Plant is Ra-226. The projected quantity of Ra-226 produced for the pilot program (0.034 Ci) is significantly less than the amount required for classification as Category 2 (10.8 Ci).

To satisfy these requirements, the applicant must have in place, programs for determining internal and external dose for occupationally exposed individuals, minors, declared pregnant workers and embryo/fetus. The applicant must have a commitment to keep doses ALARA and ensure the security of licensed material and make all required notifications to the NRC.

Staff Review and Analysis

In Section 7.3 of the Technical Report (RER,2022a) the applicant assigned responsibility for ensuring proper posting, labelling and notification requirements to the RSO and his/her staff to ensure compliance with the requirements of 10 CFR Part 19 and Part 20.

Section 7.3 of the TR also assigned the responsibility for monitoring individuals in accordance with the guidance in NUREG-1556 Volume 12 Revision 1, Section 8.10.4 (NRC, 2018) to the RSO and his designee. Specifically, Section 8.10.4 of the NUREG details the requirements of

10 CFR 20.1502(a), related to external dose limits and monitoring requirement for occupational workers, minors, and declared pregnant workers (including embryo/fetus); and 10 CFR 20.1502(b) which establishes internal exposure monitoring requirements for occupational workers, minors, and declared pregnant workers (including embryo/fetus).

In Section 10.4 of the Technical Report (RER,2022a) the applicant committed to monitoring individuals for external exposure if they are onsite more than 5 days/year using optically stimulated luminescent (OSL) badges. The applicant established this 5 days annually criteria based on the most limiting external dose scenario for the demonstration plant, standing 1 meter away from a wall of an area containing exploration sample held in supersacks. The anticipated external doses for individuals onsite for less than 5 days per year are not expected to exceed 10 millirem (mrem). A copy of the assessment performed for individuals onsite less than 5 days per year will be available onsite for review by NRC inspection staff.

Section 10.4 of the Technical Report also have a commitment to the development and implementation of a standard operating procedure to document occupational exposure, for declared pregnant worker dose determination and embryo/fetal exposure Section 10.6 of the Technical Report commits to the development and implementation of SOPs for the safe use, and security of radionuclides and during emergencies. This commitment to the development of standard operating procedures (SOPs) was tied to the license as LC 17. This LC requires the licensee to develop SOPs for all licensed activities and requires the SOPs to specify the radiation safety practices used by personnel and include provisions for response to reasonably foreseeable accidents.

Evaluation Findings

The NRC staff reviewed the applicant's statements in the TR (RER, 2022a) and determined that the proposed program is consistent with NRC's guidance and will be sufficient to meet the requirements of applicable posting, labelling, dose monitoring, and notification requirements in 10 CFR Parts 19, 20, and 21.

10.0 Public Dose

Regulatory Requirements

Section 8.10.5 "Public Dose" of NUREG-1556, Volume 12, Revision 1 (NRC, 2018), identifies the relevant regulatory requirements for review of the applicant's proposed methods for compliance with public dose limits. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 20.1003 (Definitions), 10 CFR 20.1101(d) (Radiation Protection Program), 10 CFR 20.1301 (Dose Limits for Individual Members of the Public), 10 CFR 20.1302 (Compliance with the Dose Limits for Individual Members of the Public), and 10 CFR 20.2107 (Records of Dose to Individual Members of the Public). These regulations contain requirements for a licensee to ensure that a dose to members of the public from its licensed operation does not exceed regulatory limits and for maintenance and retention of records associated with this program.

In this section, the NRC staff determines whether the applicant has demonstrated that its methods for compliance with public dose limits comply with regulatory requirements regarding its rare earth separation and processing demonstration plant.

Regulatory Acceptance Criteria

The applicant's description of the proposed methods for compliance with public dose limits was reviewed for compliance against 10 CFR 20.1003, 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302, and 10 CFR 20.2107 by comparing it to the recommended information to be submitted in Section 8.10.5 and Appendix J of NUREG-1556 Volume 12, Revision 1 (NRC, 2018).

Staff Review and Analysis

Unless otherwise stated, the information reviewed in this section is from information, data, and maps submitted by the applicant (RER, 2022a, 2022b, 2022c).

10.1 General Approach for Compliance

In Section 10.5 of the Technical Report (RER,2022a) and Sections 1.3 and 3.3 in Appendix F to the Environmental Report (ER) (RER, 2022a), the applicant described its assumptions for modeling compliance with public dose limits and clarified the methodology in its response to the RAI (RER, 2022c). Conservative assumptions include –

- Air particulate concentrations will be at the OSHA permissible exposure limits (5 mg/m^3) rather than the anticipated concentration (1mg/m^3) when benchmarked against similar processing facilities air particulate concentrations.
- One hundred percent of the radon gas (Rn-220 and Rn-222) in the exploration sample (ore) will be released during processing of the sample in the PUG building

The applicant stated in Section 10.5 of the TR (RER, 2022a) that compliance with public dose limits would be demonstrated as follows:

> During operations, compliance will be shown with the annual dose limit in 10 CFR 20.1301 consistent with 10 CFR 20.1302 and NUREG-1736 Section 3.20.1302 (NRC 2001). Public dose will be evaluated according to the method specified 10 CFR 20.1302(b)(1), "demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit." Airborne effluents (particulates and radon) from the Demonstration Plant facilities will be monitored and the dose received by the member of the public receiving the highest dose from the licensed activity will be calculated.

and (footnote d to Table 18 of the TR (RER, 2022a)):

> Radon monitoring will have the ability to discriminate between radon-220 and radon-222. NRC's recommended equilibrium fractions of 0.5 for indoor exposures and 0.7 for outdoor exposures will be used (NRC 2019). A radon track-etch and OSL dosimeter will be installed at the Met station indicated in Figure 6. Results from this location will be subtracted as a background value for public dose assessment.

Based on a set of source term assumptions (particulate, radon, external), the applicant calculated a public dose estimate for a hypothetical maximally exposed individual. The applicant used the CAP-88 software to make these public dose calculations. According to the U.S. Environmental Protection Agency (EPA),[3] CAP-88 (Clean Air Act Assessment Package - 1988):

> …is a computer code for estimating the dose and risk from emissions of radioactive material to the air. CAP88-PC is a regulatory compliance tool under the National Emissions Standard for Hazardous Air Pollutants (NESHAPs).

According to the applicant, the hypothetical maximally exposed individual was located 100 meters (m) north-northwest of the PUG/Sample Storage Facility. The calculated total dose was 0.9 mrem. The applicant's calculations indicate that a negligible portion of this dose is attributable to radon and daughters (see Table 12 of Appendix F to the ER (RE, 2022a)). This is significantly less than the 10 mrem dose constraint due to airborne effluent in 10 CFR 20.1101(d) and the 100 mrem maximum annual total public dose limit in 10 CFR 20.1301.

The dose conversion factors (DCFs) used in CAP-88 are not the same as those used in Appendix B to 10 CFR Part 20. This could cause the calculated dose to be higher or lower than what would be calculated using the values in Appendix B. The applicant evaluated various DCFs from other guidance documents[4] and found differences ranging from 1.3 to 7 times higher, depending on the radionuclide and route of exposure (e.g., inhalation, ingestion) using the Appendix B values.

Based on the applicant's analysis, the use of CAP-88 is not conservative. However, because of the significant margin between the calculated dose (0.9 mrem) and the regulatory limit (10 mrem), the NRC staff has reasonable assurance that the calculated dose is a reasonable estimate. For example, if the DCFs in Appendix B for each radionuclide were all seven times higher than the DCFs used in CAP-88, the calculated dose (6 mrem) would still be below the regulatory limits of 10 mrem (airborne effluent, not including radon and daughters) and 100 mrem (total dose).

If the applicant were to use DCFs during operations that were not consistent with the values in Appendix B, an exemption to the requirements in 10 CFR Part 20 would be required. However, the applicant stated in the request of supplemental information (RER, 2022c):

> The scope of ER Appendix F was limited to a prospective dose evaluation as identified in Section 6.4.12.2 of NUREG-1748 Environmental Review Guidance for Licensing Actions Associated with Nuclear Materials Safety and Safeguards (NMSS) Programs

[3] See EPA website: https://www.epa.gov/radiation/cap88-pc.(accessed January 31, 2023).
[4] See footnote 6 in Appendix F to the ER (RER, 2022a).

(NRC 2003, Section 2.5) and was not intended to identify specific components of the RPP. ***ICRP 30 (ICRP 1978) DCFs will be used for operational compliance with 10 CFR 20 and no exemption request will be submitted***.(emphasis added)

Based on the information provided by the applicant regarding public dose modeling assumptions, and the commitment to use ICRP 30 DCFs to demonstrate compliance with 10 CFR Part 20 the NRC staff has determined that the proposed methodology for calculating and modeling public dose is consistent with the guidance provided in NUREG-1556 Volume 12 Revision 1 and sufficient to meet the requirements of 10 CFR Part 20 and is therefore acceptable. .

10.2 Location of Public Dose Compliance

The regulations addressing dose limits for individual members of the public in 10 CFR Part 20, Subpart D, apply to an actual person (or group of people) receiving a radiation dose from licensed operations. The public dose limit does not apply to hypothetical exposure scenarios.

In its evaluation of public dose, the applicant used multiple terms to refer to public dose: “hypothetically maximally exposed member of the public”, “nearest resident”, “nearest actual receptor”, “members of the public in the nearest neighborhood”, and “critical group”. The use of the term “critical group” as used in the applicant’s documentation was in conflict with the NRC use of the term in 10 CFR Part 20, Subpart E, Radiological Criteria for License Termination. The history of the term “critical group” is explained in the final rule for license termination, 62 FR 39057, when it was first introduced into 10 CFR Part 20. The NRC staff has determined that the term “critical group” is not relevant to the evaluation for compliance with public dose limits during operations at the applicant’s facility. In its response to the RAI (RER, 2023b) the applicant agreed to use “the individual most likely to receive the highest dose from licensed operations” consistently when referring to public dose rather than the multiple terms identified above.

The applicant indicated that it would take measurements to demonstrate compliance with the public dose limits at one location at the restricted area fence. This monitoring location is shown in Figure 4 below.

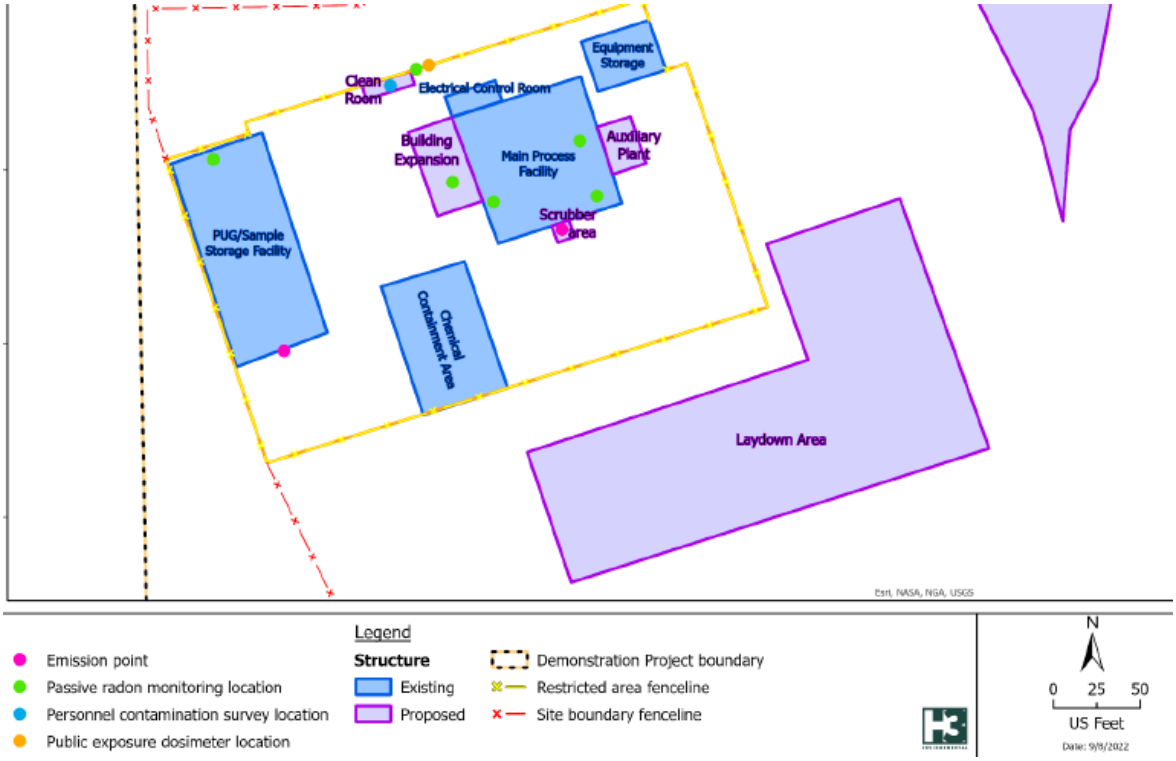

Figure 4. Public exposure monitoring location (orange dot) at Demonstration Project [adapted from Figure 5 in RER Technical Report (RER, 2022a)].

The applicant indicated the nearest residents were located as shown in Figure 5 below (label A). The nearest resident (label A) is approximately 1.2 kilometers (km) (0.75 miles (mi)) from the proposed public exposure monitoring location.

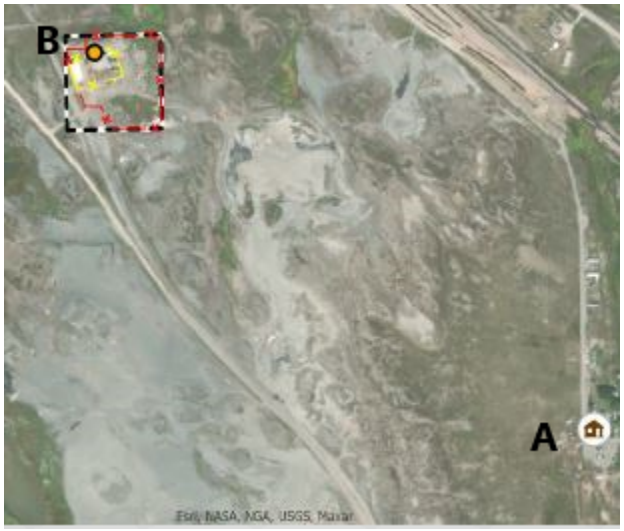

Figure 5. Nearest residents (label A) and proposed public exposure monitoring location (label B) at Demonstration Project [adapted from Figure 6 in the applicant's Technical Report (RER, 2022a)].

The NRC staff used Google Earth Pro to visualize downwind sectors based on a wind rose provided by the applicant (Figure 10 in the ER (RER, 2022a)). The wind rose and downwind sectors are shown in Figure 6 below.

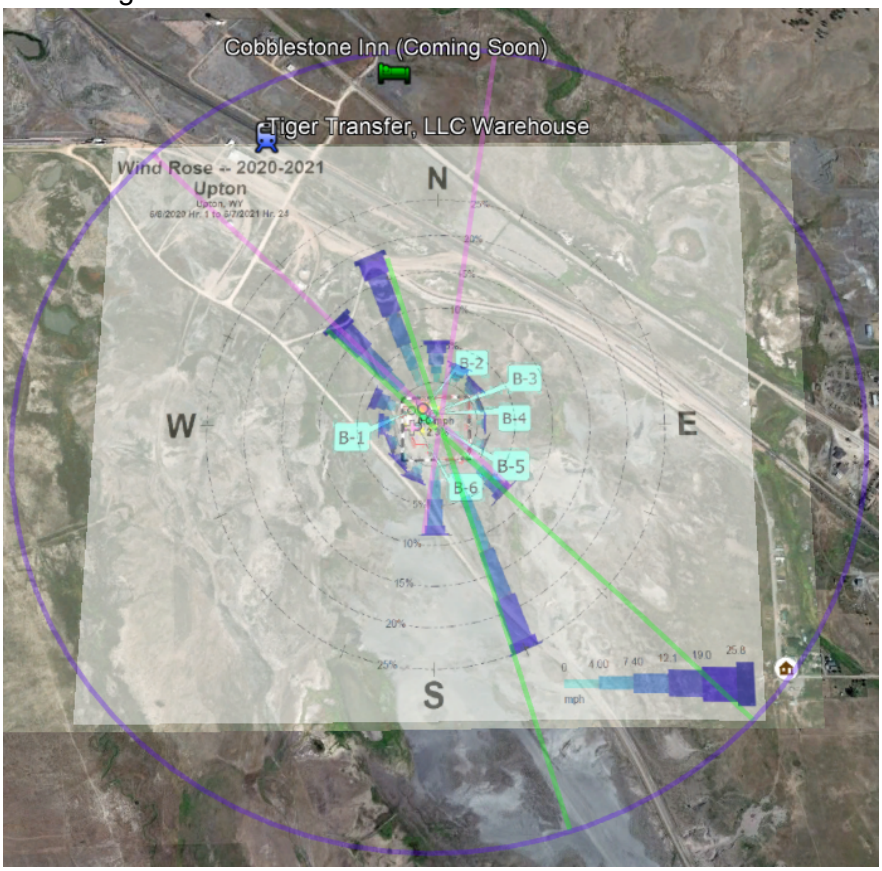

Figure 6. Google Earth Pro representation of Upton wind rose and Demonstration Project [adapted from Map 4 in the applicant's ER (RER, 2022a)].

The NRC staff also evaluated other potential receptors in the area near the Demonstration Project that could be located downwind from the facility. The NRC staff identified two additional potential receptors. Tiger Transfer, LLC appears to be an operating business and the Cobblestone Inn appears to be a business in the construction phase. Both of these locations appear closer in distance to the Demonstration Project than the nearest residents identified by the applicant. In the RAIs (NRC, 2023), the staff requested from the applicant justification for not using either of these two identified businesses for public dose.

In its response to the RAI (RER, 2023b), the applicant agreed to add the additional locations identified by the NRC and committed to reviewing and updating the public dose analysis prior to the start of operations to verify that the identified resident was the individual likely to receive the highest public dose from licensed operations using methodology consistent with 10 CFR 20.1302 and NUREG-1736 Section 3 as detailed above.

The NRC staff finds that use of the nearest resident is adequate to support regulatory compliance because of the conservative assumptions included in the determination of the public dose, such as the assumption of one hundred percent of the radon is released from the sample

when it is being crushed, and the dust concentration being set to the OSHA limit rather than a lower value obtained by benchmarking with standard ore crushing concentrations. The dose determined for the closest resident was modeled at 0.9 mrem per year using the conservative assumptions mentioned above and assuming the residence is continuously occupied (100% occupancy or 8760 hours/year) at a residence located 1,143 meters northwest of the site. Persons at the nearest business, on the other hand, would be modeled using the same conservative assumptions but based on a occupancy of 2080 hours (8/day, 5 days/week, 52 weeks per year). Therefore, the staff finds that identification and use of the nearest resident as the maximally exposed individual, as opposed to dose of individuals at the nearby businesses, demonstrates a dose within regulatory limits and is acceptable given the conservatism built into the assumptions.

Moreover, in addition to demonstrating regulatory compliance, the applicant has committed to verify that the dose estimate for an individual at the nearby businesses is bounded by that of the nearest resident. As reflected in LC 13, this updated public dose assessment is to be completed and provided to the NRC prior to, or as part of, the NRC's pre-operational inspection. This additional license condition adds additional assurance that the dose assessment will be based on the maximally exposed individual.

10.3 Surveys to Demonstrate Compliance with Public Dose Limits

In addition to Figures 4 and 5 above, the applicant described its monitoring program for public dose compliance in Table 18 of the TR (RER, 2022a). The relevant aspects of this monitoring program are shown in Table 9 below.

Building	PUG/Sample Storage Facility	Main Process Facility	Other Facilities
Airborne Effluent Release Monitoring	• Mobile, continuous area air sampling outside of south side of building during PUG processing for emissions/public dose assessment • Real-time, continuous radon [d] monitoring at open end of facility during PUG processing	• Weekly, isokinetic stack monitoring for radon [d] from each scrubber stack for emissions/public dose assessment • Semi-annual particulate emission evaluation for stack by a third party for emissions/public dose assessment	• Passive radon [d] track etch and OSL dosimeter monitoring at restricted area fence over project duration for public dose assessment (Figure 6)

[a] Personnel onsite for less than 5 days are unlikely to receive an external dose exceeding 10 mrem based on the estimated external dose rate for a worker standing 1 meter away from a "wall" of stored exploration sample in super sacks, which is the most limiting external dose scenario for the Demonstration Project. The conservatively estimated external dose rate to this individual is 0.58 mrem hr^{-1}. 100% occupancy for 5 working days (40 hours) could result in an external dose of 23 mrem, however no more than 25% occupancy is considered realistic for the PUG/Sample Storage facility, which is open to the elements, does not have any office space, and will not have a routine use other than sample storage. Note: Any activity when the potential for exposure to radioactive material exists and for which no SOP already exists will be covered by a radiation work permit with appropriate dose monitoring.
[b] Radioactivity levels on surfaces for unrestricted release will meet the levels listed in Table M-2 of Appendix M to NUREG–1556, Volume 12, which are consistent with the "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material" (NRC 1987a).
[c] Occupational air monitoring in the Main Process Facility will be used to establish exposure potential. After exposure potential is established, frequency of sample collection may be reduced to monthly.
[d] Radon monitoring will have the ability to discriminate between radon-220 and radon-222. NRC's recommended equilibrium fractions of 0.5 for indoor exposures and 0.7 for outdoor exposures will be used (NRC 2019). A radon track etch and OSL dosimeter will be installed at the Met station indicated in Figure 6. Results from this location will be subtracted as a background value for public dose assessment.
[e] Frequency of contamination surveys is consistent with NUREG 1156, Volume 12, Appendix M, Table M-1 (NRC, 2000). However, expected contamination levels are low since processing occurs in a closed system with ventilation controls.
[f] An SOP, training, and signage within the restricted area will be used to direct all personnel to perform a contamination survey before exiting the restricted area.
DOT – US Department of Transportation
PUG – physical upgrade
SOP – standard operating procedure

Table 9. Proposed routine radiological surveys and monitoring (excerpted from Technical Report Table 18 (RER, 2022a))

The NRC staff notes that, in the original application, there was no proposed monitoring for airborne particulates at any location for public dose compliance purposes (including the background location, see footnote d to Table 9) nor was there a proposed justification for not doing so.

Demonstration Project Area	Activities	External (mrem)	Inhalation (mrem)	Ingestion (mrem)	Total (mrem)
PUG/Sample Storage Facility	Airborne emissions from the PUG/Sample Storage Facility (particulates)	0.178	0.624	0.062	0.865
PUG/Sample Storage Facility	Airborne emissions from the PUG/Sample Storage Facility (radon)[a]	0	0.002	0	0.002
Main Process Facility	Airborne emissions from the Main Process Facility	Not estimated	Not estimated	Not estimated	Not estimated

Table 10. Radiation dose estimates for hypothetical maximally exposed member of the public (from Table 12 in Appendix F of the ER (RER, 2022a))

The results of the applicant's dose assessment for a hypothetical maximally exposed member of the public are shown in Table 10. As the applicant's assessment indicates, the dose from airborne particulates, while small, represents over 70 percent of the total calculated dose. Based on the discussion above, the NRC staff could not conclude that the proposed monitoring program for public dose compliance would meet the requirements in 10 CFR Part 20 and requested additional information from the applicant in the RAIs (NRC, 2023).

In its response to the RAIs (RER, 2023b), the applicant, rather than providing justification for not monitoring airborne particulate, committed to adding two particulate monitoring stations, as a "best practice." One monitoring location will be established in an area representative of the individual likely to receive the highest dose from operations and another at the Met station, which will serve as the background location. The results of the difference between the particulate levels measured at the highest dose location minus the particulate levels at the meteorological station will be used to determine the air particulate levels, and the resulting particulate information will be included in the calculation and modeling of public dose.

Evaluation Findings

The NRC staff finds the application, modified by the applicant's responses to the RAIs (RER, 2023b), adequate to demonstrate compliance with the regulatory requirements regarding public dose. Moreover, the applicant also agreed to verify public dose calculations prior to commencing operations, which has been included as LC 13.

11.0 Safe Use of Radioactive Materials and Emergency Procedures

Regulatory Requirements

Section 8.10.6 (Safe Use of Radionuclides and Emergency Procedures) of NUREG-1556, Volume 12, Revision 1 (NRC, 2018), identifies the relevant regulatory requirements for review of the applicant's proposed methods for compliance with the safe use of radioactive materials and establishment of emergency procedures. For purposes of this source materials license, the relevant regulatory requirements are 10 CFR 19.11(a)(3) (Posting of Notices to Employees); 10 CFR 20.1406 (Minimization of Contamination), 10 CFR 20.1801 (Security of Stored Material), 10 CFR 20.1802 (Control of Material not in Storage), 10 CFR 20.1902–1905 (Subpart J – Precautionary Measures).

Regulatory Acceptance Criteria

The applicant's description of the safe use of radionuclides and emergency procedures was reviewed for compliance with 10 CFR 19.11(a)(3); 10 CFR 20.1406, 10 CFR 20.1801, 10 CFR 20.1802, and 10 CFR 20.1902–1905, comparing it to the recommended guidance outline in information to be submitted in Section 8.10.6 of NUREG-1556, Volume 12 Rev. 1 (NRC, 2018).

10 CFR Part 37 Subpart B will not be evaluated in this SER as it is related to the security requirements to be implemented for Category 1 and Category 2 quantities of radioactive material, as stated previously. The only isotope regulated under 10 CFR Part 37 that will be produced at the Demonstration Plant is Ra-226. The projected quantity of Ra-226 produced for the pilot program (0.034 Ci) is significantly less than the amount required for classification as Category 2 (10.8 Ci).

Staff Review and Analysis

In Section 10.6 of the TR (RER,2022a) the applicant committed to the development and implementation of standard operating and emergency procedures to address routine activities to keep occupational exposures ALARA. These procedures will document the processes for safe use, security and emergencies related to the generation, use receipt or offsite shipment of licensed materials. The applicant also committed to the use of radiation work permits for situations where potentially significant radiation exposure to personnel can occur and standard operating procedures do not exist. Procedures will be revised only if changes are approved in writing by the Safety and Environmental Review Panel (SERP), comply with NRC regulations and the license, and do not degrade the effectiveness of the RPP. Employees will be trained on the procedures or any procedure revisions. The applicant provided several areas where procedures will be developed. These areas include, but are not limited to, contamination controls, external monitoring, airborne radiation monitoring, airborne effluents, and radiation surveys (including surface contamination levels). The commitments to use SOPs and RWPs to identify hazards and implement radiological controls to minimize doses to personnel are tied to the license as LC 17 and LC 18.

Evaluation Findings

The NRC staff finds that the applicant's proposed program for development and use of standard operating procedures to support safe use of radioactive material and respond to emergency situations, in terms of development, documentation, and implementation are sufficient to meet the intent of the requirements of 10 CFR 19.11(a)(3); 10 CFR 20.1406, 10 CFR 20.1801, 10 CFR 20.1802, and 10 CFR 20.1902–1905 because they are consistent with NRC guidance; and are therefore acceptable. The use of SOPs and RWP to identify hazards and implement appropriate radiological controls to minimize dose are detailed in LC 17 and LC 18. SERP requirements are detailed in LCs 15 and LC 16.

12.0 Surveys and Leak Tests

Regulatory Requirements

Section 8.10.7 (Surveys and Leak Tests) of NUREG-1556, Volume 12 Revision 1 (NRC, 2018), the relevant regulatory requirements for the NRC staff's review of an applicant's proposed use of surveys associated with the licensed activities. For purposes of this source material application, the relevant regulatory requirements are 10 CFR 20.1501 (General – Surveys and Monitoring), §20.2103 (Records of Surveys); and 10 CFR 40.63 (Tests).

Regulatory Acceptance Criteria

The applicant's description of the proposed use of surveys associated with its licensed activities was reviewed for compliance with 10 CFR 20.1501(a), 20.1501(b), 20.2103(b), and 10 CFR 40.63 by comparing it to the recommended information to be submitted in Section 8.10.7 and Appendix M of NUREG-1556, Volume 12 Revision 1 (NRC, 2018).

Staff Review and Analysis

Unless otherwise stated, the information reviewed in this section is from information, data, and maps submitted by the applicant (RER, 2022a, 2022b, 2022c).

12.1 Routine Radiological Surveys

The applicant provided a summary of proposed routine radiological surveys and monitoring in Table 18 of the TR (RER, 2022a). Proposed facility surveys include ambient radiation levels, contamination surveys, occupational external dose and air monitoring, and airborne effluent releases.

12.2 Contamination Surveys

The applicant proposed daily contamination surveys of process areas in the Main Process Facility, routine personnel contamination surveys and monthly contamination surveys of office and gate areas.

The NRC staff finds the proposed contamination surveys consistent with the recommendation in NUREG-1556, Volume 12 Revision 1, Section 8.10.7, and therefore acceptable.

12.3 Occupational Monitoring

For occupational external dose monitoring, the applicant described its approach for issuing a personal dosimeter for any worker onsite for five days or greater. This time period was derived based on the applicant's dose estimates.

For occupational internal exposure monitoring, the applicant will monitor the breathing zone of workers, take air samples in process areas, and use radon track-etch detectors. In addition, as

recommended in RG 8.25 (NRC, 1992a), the applicant will take airflow patterns into account when planning operational air monitoring.

The NRC staff find the proposed occupational surveys consistent with the recommendation in NUREG-1556, Volume 12 Revision 1, Section 8.10.7, and therefore acceptable.

12.4 Monitoring for Public Dose

The NRC staff addressed surveys for determining compliance with public dose limits in this SER in Section 10 (Public Dose) and will not repeat that information in this section.

12.5 Monitoring airborne effluent releases.

The applicant discussed where it would monitor for possible effluent releases from the PUG/sample storage facility and the Main Process Facility. Proposed monitoring included monitoring for radon and particulate emissions.

In response to an RSI (NRC, 2022b), the applicant identified that the high-efficiency particulate air (HEPA) ventilation associated with the Main Process Facility would not have the potential for radiological releases and would not be monitored for airborne effluent releases (RER, 2022c). RSI-5(3) (NRC, 2022b) requested, in part, that the applicant should "state the purpose and the associated acceptance criteria to accomplish this purpose for each proposed emission control device."

In Section 9.2.2 of the TR (RER, 2022a), the applicant stated:

> The Main Process Facility is designed to be a zero-emission facility. All process emissions will be collected and neutralized in appropriate scrubber systems before discharge. The Main Process Facility scrubber and bulk chemical storage scrubber will be in the designated scrubber area, which will be a 10ft x 10ft area on the south side of the processing facility. Within the Main Process Facility, all process equipment other than the calciner will be vented through the main scrubber system. The calciner will have its own, dedicated local scrubber system. The building heating, ventilation, air conditioning (HVAC) system will also have a HEPA filtration system.
>
> The general, HEPA filtered ventilation system for the Main Process Facility, indicated in the Auxiliary Plant on the east side of the processing facility…is not anticipated to have any potential radiological effluent releases or monitoring.

NRC staff evaluating the airborne effluent monitoring system requested clarification of the purpose of the HEPA ventilation in RAIs (NRC 2023). In its response to the RAI (RER, 2023b), the applicant indicated the HEPA filtration system is provided as a best practice for general facility ventilation and is not intended to capture direct process emissions. Process emissions are designed to be routed through the scrubbers as detailed above.

WDEQ Air Quality Division reviewed the potential emissions from the facility and determined "the temporary REE Demonstration Plant to be insignificant in emission rate and ambient air quality impact" A copy of this determination with the listed equipment (dust suppression and

scrubbers) is provided in Appendix I to the Environmental Report (RER,2002a). In Section 10.7 of the TR (RER,2022a) the applicant committed to meeting the monitoring requirements specified in the WDEQ Air Quality Permit as well as monitoring of work areas during operations.

Based on the commitments made in Section 10.7 of the TR, the NRC staff determined the monitoring for airborne effluents to be sufficient to address NRC and the State's concerns.

12.6 Surface Contamination Levels

Personnel, equipment and items, unrestricted areas

The applicant proposed acceptable levels of surface contamination at its facility and provided the values in Table 17 of the TR (RER, 2022a). The proposed levels of surface contamination will be used in the applicant's RPP for monitoring personnel, releasing material for unrestricted use, and surveys of the facility. According to the applicant, the proposed values in Table 11 (below) are the most restrictive surface contamination values listed in Table M-2 of Appendix M to NUREG-1556 Volume 12 Revision 1.

Use	Value	Average	Maximum	Removable
Personnel monitoring, surveys of unrestricted areas, and releasing equipment and items for unrestricted use	Alpha surface radioactivity (dpm 100 cm^{-2})	100	300	20
	Beta surface radioactivity (dpm 100 cm^{-2})	5,000	15,000	1,000
Surveys of restricted areas	Alpha surface radioactivity (dpm 100 cm^{-2})	220,000	660,000	44,000

Note: It will be conservatively assumed that all measured alpha radiation is attributable to radionuclides in the most restrictive category of Table M-2 of Appendix M to NUREG–1556, Volume 12 (NRC 2000).

dpm 100 cm^{-2} – decays per minute per 100 square centimeters

Table 11. Proposed acceptable surface contamination levels [from Table 17. (RER, 2022a)]

The NRC staff evaluated the proposed values in Table 11 against Table M-2 of Appendix M to NUREG-1556, Volume 12, Revision 1. In addition, the NRC staff reviewed a previous comparison of acceptable levels of surface contamination in various NRC guidance documents and in use elsewhere (See Table 12 below). Regulatory Guide (RG) 8.23 (NRC, 1981) was withdrawn in 2018, but the NRC staff finds the previous guidance in withdrawn RG 8.23 useful for comparison purposes.

Loose Surface Contamination Limits (dpm/100 cm²)_						
	RG 8.21	**RG 8.23**	**RG 8.24 (U only)**	**US Navy Ra Sites**	**DOE**	**RG 8.30**
Skin	ALARA (No detectable)	220 (Decon if detectable)	0	No detectable	No detectable (Decon if detectable)	1000
Personal Clothing	22	220	200	No detectable	No detectable	1000 (5000 for soles of shoes)
Restricted Area Surfaces	U-nat: 220,000, Ra-226: 22,000 **NOTE:** These values are for use with protective clothing	220	5000			220,000
Unrestricted Area Surfaces	U-nat: 22 Ra-226: 22	22	200			1000

Table 12. Comparison of acceptable levels of surface contamination (adapted from NRC, 2009).

12.7 Alpha Emitters

For alpha surface radioactivity for personnel monitoring, the NRC staff finds the proposed surface contamination levels in Table 11 acceptable because Ra-226 will be present at the facility, and no isotopic analyses will be performed by the applicant. Surface contamination levels other than the Ra-226 levels in Table 11 could be determined on a sum of fractions basis if isotopic analyses were performed at the facility. The applicant stated that if it wants to use different values for surface contamination levels other than the Ra-226 values it will submit a request for NRC review.

However, the applicant did not specify how the surface contamination levels would be applied to personnel monitoring. It is typical to use removable surface contamination levels when monitoring personnel for contamination.

In its response to the NRC's RAIs (NRC, 2023) the applicant committed to adopting NRC's recommended limits. The surface contamination levels as they are applied to monitoring personnel for contamination are documented in Table 12 (above). The levels in Table 12 will replace the values proposed by the applicant in Table 17 of the applicant's TR (RER, 2022a).

12.8 Beta-gamma Emitters

The NRC staff evaluated Table M-2 of Appendix M to NUREG-1556 Volume 12, Revision 1 (see Table 13 below) against the applicant's statement that the proposed acceptable surface contamination levels in Table 12 are the most restrictive surface contamination values for beta-gamma emitting nuclides.

Table M–2. Acceptable Surface Contamination Levels for Equipment			
Nuclide[1]	**Average[2,3,6]**	**Maximum[2,4,6]**	**Removable[2,5,6]**
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm^2 [5,000 dpm/100 cm^2]	250 Bq/100 cm^2 [15,000 dpm/100 cm^2]	16.7 Bq/100 cm^2 [1,000 dpm/100 cm^2]
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm^2 [100 dpm/100 cm^2]	5.0 Bq/100 cm^2 [300 dpm/100 cm^2]	0.3 Bq/100 cm^2 [20 dpm/100 cm^2]
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm^2 [1,000 dpm/100 cm^2]	50.0 Bq/100 cm^2 [3,000 dpm/100 cm^2]	3.3 Bq/100 cm^2 [200 dpm/100 cm^2]

Table 13. Acceptable surface contamination levels for equipment [excerpted from Table M-2 in NUREG-1556, Volume 12, Revision 1 (NRC, 2018)]

As Table 13 demonstrates, there are lower values for surface contamination levels for thorium isotopes than the uranium isotope values (5,000/15,000/1,000 dpm/100cm^2) proposed by the applicant in Table 11. According to a previous NRC staff interpretation of thorium surface decontamination limits (NRC, 1992b), the thorium isotope values (1,000/3,000/200 dpm/100 cm^2) surface contamination levels should apply to beta-gamma measurements.

As was the case with the alpha surface contamination levels, the applicant did not specify how the surface contamination levels would be applied to personnel monitoring.

The surface contamination levels proposed by the applicant as discussed above were part of the NRC's RAIs (NRC 2023). In its response to the RAI (RER 2023b) the applicant committed to using the NRC recommended thorium isotope value limits and revised the surface contamination levels as shown in Table 14, below.

Use	**Surface Radioactivity Type**	**Average [a]**	**Maximum**	**Removabl**
		dpm 100 cm^{-2}	dpm 100 cm^{-2}	dpm 100 cm^{-2}
Personnel monitoring	Alpha	Not monitored	220	Not monitored
Surveys of unrestricted areas, release of equipment and items for unrestricted use	Alpha	1,000	3,000	200
	Beta	1,000	3,000	200
Surveys of restricted areas	Alpha	Not monitored	22,000	Not monitored

[a] Average will be over any 1 square meter area.
dpm 100 cm^{-2} – decays per minute per 100 square centimeters

Table 14. Revised surface contamination levels in response to RAI (RER, 2023b) [replacing Table 17 from the applicant's TR (RER 2022a)]

12.9 Restricted Areas

The applicant provided its proposed acceptable surface contamination levels for restricted areas in Table 11. According to the applicant, the proposed values (are based on the guidance in Section 2.5 of RG 8.30 (NRC, 2002)). The NRC staff notes that the guidance in Section 2.5 of RG 8.30 addresses uranium ore and natural uranium concentrates and does not evaluate all the materials that will be present at the applicant's facility.

The applicant proposed average, maximum, and removable surface contamination levels for restricted areas. However, the guidance in Section 2.5 of RG 8.30 provides a single value (220,000 dpm/100 cm^2) to apply throughout a restricted area with no distinction between surface areas. The applicant did not discuss how it derived the proposed value for a maximum acceptable surface contamination level for restricted areas. Therefore, it was not clear what criteria the applicant used to derive a maximum value of 660,000 dpm/100 cm^2 in Table 11 for restricted areas.

In its response to the NRC's RAIs (NRC, 2023), the applicant adopted NRC's recommended value of 22,000 dpm/100 cm^2 average alpha for restricted area surveys. This value is 10% of the recommended limit in RG 8.30, Revision 1 Section 2.5 (NRC 2002) for uranium radionuclides and is consistent with the technical basis recommendation of using 10 percent of the uranium values for thorium levels (Wrixon et al 1979) identified in the NRC's RAI. Table 14 above reflects this change from the applicant's TR and will replace Table 17 in the applicant's TR (RER, 2022a).

12.10 General Survey Records

The applicant discussed records associated with various surveys in Section 10.10.1 of the TR (RER, 2022a). The NRC staff reviewed the types of records proposed by the applicant and the length of time the records would be maintained.

The NRC staff finds that the applicant's proposed recordkeeping program for surveys meets the requirements in 10 CFR 20.2103(a) and (b) due to the applicant's commitment to ensure the records meeting the requirements of 10 CFR 20.1501 and 10 CFR 40.63.

12.11 Decommissioning Records

The applicant described its plan for decommissioning the facility in Appendix B [Decommissioning Funding Plan (DFP)] to the TR (RER, 2022a). The applicant stated that it will retain records of information that could have a material effect on the ultimate costs of decommissioning until the license terminates, in accordance with 10 CFR 40.36(f). The following are examples of records the applicant will retain under this commitment:

- Spills or other contamination that cause contaminants to remain following cleanup efforts.
- As built drawings of structures, equipment, and modifications thereto where radioactive contamination exists (e.g., from the use or storage of such materials).
- Original and modified cost estimates of decommissioning; and

- Original and modified decommissioning funding instruments and supporting documentation.

The NRC staff finds that the applicant's proposed recordkeeping program for decommissioning meets the requirements in 10 CFR 20.1501(a) and (b) because the survey records will be maintained in accordance with 10 CFR 40.36(f) and the applicant made a commitment in its Decommissioning Funding Plan to maintain records in accordance with 10 CFR 40.36(f).

12.13 Leak Tests

Although section 8.10.7 of NUREG-1556, Volume 12, Revision 1 specifically identifies leak tests as an area for review consistent with 10 CFR Parts 32, §34, §35, §36,and §39 none of these requirements apply to the applicant's operations. The only sources identified by the applicant are calibration sources for its radiation instrument program. The NRC staff evaluated commercial NIST- traceable calibration sources and identified that the activities are approximately 0.1 microcuries or less.[5] According to the guidance in NUREG-1556, Volume 12, Revision 1, leak tests are typically not required for these types of sources. Therefore, leak tests are not required and were not reviewed as part of this SER.

Evaluation Findings

The NRC staff finds that the applicant's description of its Survey program, in terms of development, documentation, and implementation, is thorough, complete, and consistent with guidance and therefore, meets the requirements of 10 CFR 20.1501(a), and (b), 10 CFR 20.2103(b), and 10 CFR 40.63 and is therefore acceptable.

13.0 Maintenance

Regulatory Requirements

Section 8.10.8 (Maintenance) of NUREG-1556, Volume 12, Revision 1 (NRC, 2018), identifies the relevant regulatory requirements for the NRC staff's review of the applicant's proposed plans for maintenance of equipment and facilities. For purposes of this source materials license, the relevant regulatory requirements are 10 CFR 20.1101(Radiation Protection Programs; 10 CFR 40.41(e) (Terms and Conditions of Licenses).

Regulatory Acceptance Criteria

In order to meet the regulatory requirements in this area, the maintenance of devices and facilities should be planned and carried out as frequently, as needed, using ALARA principles. Individuals performing maintenance should be trained in
the procedures they implement. Procedures should be written to account for the skills of the

[5] See, for example, https://www.ezag.com/fileadmin/user_upload/isotopes/isotopes/Isotrak/isotrak-pdf/Product_literature/EZIPL/EZIP_catalogue_reference_and_calibration_sources.pdf

implementing personnel. Ordinarily, individuals handling unshielded materials should have approximately 40 hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Staff Review and Analysis

The applicant committed to the development of SOPs for routine maintenance activities. For non-routine maintenance activities not covered by SOPs, the applicant committed to using radiation work permits. Furthermore, the applicant acknowledges that routine maintenance of process equipment and facilities is integral to keeping exposures ALARA. Because the SOPs were not developed and available for NRC review, the applicant proposed license conditions that would require the use of SOPS or RWPs to identify radiological hazards and implement controls to keep exposures ALARA. These license conditions are documented in the license as LC 17 (SOPs) and LC 18 (RWPs).

Evaluation Findings

NRC staff has determined that the maintenance program as described in the TR, and as required by license conditions LC 17 and LC 18, is consistent with NRC's guidance in this area and, therefore, sufficient to the meet the requirements of 10 CFR 20.1101 and 10 CFR 40.41(e).

14.0 Transportation

Regulatory Requirements

Section 8.10.9 (Transportation) of NUREG-1556, Volume 12 Revision 1 (NRC, 2018), identifies the relevant regulatory requirements for the NRC staff's review of the applicant's proposed methods for transportation of licensed material. For purposes of this source materials license, the relevant regulatory requirements are 10 CFR 20.1101 (Radiation Protection Programs); 10 CFR Part 20, Appendix G (Requirements for Transfer of Low Level Radioactive Waste intended for Disposal); 10 CFR Part 37 (Subpart D- Physical Protection in Transit); 10 CFR 40.51 (Transfer of Source and Byproduct Material); 10 CFR 40.61 (Records) ;10 CFR 71.5 (Transportation of Licensed Material); 10 CFR 71.12 (Specific Exemptions); 10 CFR 71.13 (Exemptions for Physicians); 10 CFR 71.14 (Exemptions for Low Level Materials); 10 CFR 71.37 (Quality Assurance); 10 CFR 71.38 (Renewal of a Certificate of Compliance or a Quality Assurance Program Approval);10 CFR 71.47 (External Radiation Standards for All Packages); 10 CFR 71.87 (Routine Determinations), Subpart H of 10 CFR Part 71 (Quality Assurance); 49 CFR Parts 171-178 (U.S. Department of Transportation)

Regulatory Acceptance Criteria

In order to satisfy the NRC requirements in this area, applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

While potentially applicable to source material applications, the NRC staff determined that Part 37 does not apply to this particular applicant's proposed operations. The only isotope produced at the demonstration plant that is regulated under 10 CFR Part 37 is Ra-226. Based on Table 8 in Appendix F to the Environmental Report (RER, 2022a), there will be a total of 0.034 Ci of Ra-226 processed during the entire Demonstration Project. This is significantly less than the amount required for classification as Category 2 (10.8 Ci), and thus, less than an amount that would require compliance with 10 CFR Part 37.

Staff Review and Analysis

NRC staff determined that this section will be evaluated against the criteria in 10 CFR 20.1101; 10 CFR Part 20, Appendix G; 10 CFR 40.51; 10 CFR 40.61; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71.47; 10 CFR 71.87, Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178

In the application, the applicant committed to complying with all applicable NRC and DOT requirements associated with packaging and transportation of radioactive materials and the development of SOPs to describe the packaging and transportation requirements for shipments, contamination surveys of packages, package labelling and vehicle placarding, and preparation of shipment manifests. The applicant specifically prohibits the vehicles transporting materials to and from the Demonstration Plant from entering the restricted area.

Evaluation and Findings

The NRC staff finds the proposed package and transportation program with the required SOPs and the commitment to comply with all applicable NRC and DOT requirements to be consistent with NRC guidance and regulations, and therefore, acceptable.

15.0 Waste Management

Regulatory Requirements

Section 8.11 of NUREG-1556 Volume 12, Revision 1, identifies the relevant regulatory requirements associated with waste management. For purposes of this source materials license, the relevant regulatory requirements are: 10 CFR 20.1301 (Dose Limits of Individual Members of the Public); 10 CFR 20.1904 (Labeling Containers); 10 CFR Part 20, Subpart K (Waste Disposal); 10 CFR Part 20, Appendices B (Annual Limits on Intake and Derived Air Concentrations) and G (Requirements for Transfer of Low Level Radioactive Waste intended for Disposal); 10 CFR 37.11(c)(General Provisions – Specific Exemptions); 10 CFR 40.61 (Records).

Regulatory Acceptance Criteria

The NRC staff determined that 10 CFR 37.11(c) is not applicable to this license because, as previously explained, the application does not involve Category 1 and 2 material implicating 10 CFR Part 37. Additionally, the NRC staff determined that 10 CFR 61.52 is not applicable as the applicant intends to treat all waste streams and send them offsite for disposal.

The requirements of 10 CFR 20.1301 are related to public dose and are discussed Section 10 (Public Dose) of this SER and will not be repeated here. The requirements of 10 CFR 20.1904 related to labelling of radioactive materials and posting of areas where radioactive materials are in use is addressed in Sections 9 (Occupational Dose) and 14 (Transportation) of this SER and will not be addressed in this section.

In order to meet the relevant regulatory requirements in this area, radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Staff Review and Analysis

In Section 9.1.5 of the applicant's TR (2022a) the applicant identified four waste streams, two solid waste streams and two liquid waste streams. These waste streams are expected to have a mixture of chemical and radiological components. Radiological components include thorium, uranium, radium, actinium, and protactinium. Chemical components include acids, chlorides, oxides, and heavy metals. All four waste streams are considered radioactive waste streams by the applicant. The liquid waste streams will be mixed to form a sludge and then neutralized by the addition of burnt lime to reduce radioactivity concentrations. The solid waste streams will be neutralized by the addition of burnt lime and then combined with the liquid waste streams. Once the liquid and solid waste streams are combined bentonite clay will be added to stabilize the waste for shipment. (Bentonite clay has high cation exchange capacity and high absorption properties). The bentonite mixture will then be transferred to a roll off bin and stored until it can be shipped offsite to a licensed disposal site. Per the applicant's Technical Report, the waste will contain nearly 100 percent of the radioactive material.

The organic process material used will be recycled within the process, or in the case of an upset condition, transferred to a portable tanker trailer within the restricted area and analyzed for reuse or disposal. Organic waste found to have trace amounts of thorium will be conditioned and mixed with the other radioactive wastes for disposal. Non-radioactive organic waste will be disposed of at a local hydrocarbon treatment facility.

Section 9.2.2 of the TR (RER, 2022a) indicates the Main Processing Facility is designed to be a zero-emissions facility and that all process emissions will be collected and neutralized in an appropriate scrubber system before discharge. Within the Main Processing Facility, all process equipment other than the calciner will be vented through the main scrubber system. The calciner will have its own scrubber.

Evaluation Findings

The NRC staff finds that the applicant's proposed waste management program for decommissioning meets the requirements in, 10 CFR 20.1904, 10 CFR Part 20, Subpart K, 10 CFR Part 20, Appendices B and G, and 10 CFR 40.61 because the applicant intends to treat, stabilize, and ship all radioactive waste offsite for disposal.

16.0 Conclusion

The NRC staff has determined based on the information discussed in the previous sections that issuance of the source materials license, including the conditions added to the license, for the pilot project complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (The Act), and the Commission's regulations. Based on NRC staff's review, as documented in this SER, the determination was made that issuance of this license will not be inimical to the common defense and security or to the health and safety of the public. The applicant's license application meets the relevant regulatory requirements and recommended guidance as identified in NUREG-1556 Volume 12 Revision 1. Because not all of the programs supporting the operations were developed and available for review, the NRC staff has added a condition to the license requiring that the applicant's commitments outlined in the application are verified by NRC staff in a pre-operational inspection. Specifically, the licensee must verify completion of the following commitments in the pre-operational inspection:

- Public dose must be confirmed to bound the new locations added in response to RAI 1,
- The proposed AUs must complete the required training and qualifications committed to in Section 7.4 of the TR,
- The applicant must complete the development, implementation, and maintenance of SOPs for ensuring accountability of licensed materials and other SOPs associated with occupational exposure records, routine surveys, leak tests, disposal and receipt surveys, and conduct of physical inventories for all radioactive source material received and possessed under the license.
- The applicant must complete development and implementation of a multiple alpha source calibration protocol that will cover the range of alphas present in the process rather than relying on the single point calibration protocol originally proposed using Po-210.
- The applicant must submit the financial assurance certification as described in Appendix B to the TR, and the applicant must support a pre-operational inspection by NRC inspection staff that verifies the above items are complete.

17.0 References

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NRC, 2023 Letter from B. Bolz, NRC, to R. Scott, Rare Element Resources, Inc., NRC staff Request for Additional Safety Information for the Rare Element Resources Application for a Source Material License, March 2023, ML23068A307.

RER, 2022a. Rare Element Resources, Rare Earth Element Separation and Processing Demonstration Project Application for Source Material Possession License – Resubmittal in Response to Request for Supplemental Information (RSI), September 2022, ML22256A319. (Cover letter, TR and ER)

RER, 2022b. Rare Element Resources - Rare Earth Element Separation and Processing Demonstration Project Application for Source Material Possession License - Resubmittal in Response to Request for Supplemental Information, September 2022, ML22258A148 (nonpublic).

RER, 2022c. Rare Element Resources, Rare Earth Element Separation and Processing Demonstration Project Application for Source Material License – Response to Request for Supplemental Information August 26, 2022, ML22238A107

RER 2022d. Rare Element Resources, Rare Earth Element Separation and Processing Demonstration Project Application for Source Material Possession License – Response to Request for Additional Information, December 2022, ML2233B028 (nonpublic).

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