



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 6, 2024

Mr. Chris Wagner, Chief Executive Officer  
Eden Radioisotopes, LLC  
9400 Holly Ave. NE, Suite 202  
Albuquerque, NM 87122

SUBJECT: EDEN RADIOISOTOPES, LLC - PREAPPLICATION READINESS ASSESSMENT  
ACTIVITIES AND AUDIT PLAN FOR EDEN DRAFT ENVIRONMENTAL REPORT  
FOR A MEDICAL ISOTOPE PRODUCTION FACILITY (EPID L-2024-LRM-0033)

Dear Mr. Wagner:

By letter dated August 7, 2023, Agencywide Documents Access and Management System Accession No. ML23230B208), Eden Radioisotopes, LLC (Eden) informed the U.S. Nuclear Regulatory Commission (NRC) of its intent to submit license applications for construction permit (CP) and operating license for a medical isotope production facility, called the Eden Isotope Production Complex. Eden has requested that the NRC staff conduct a preapplication readiness assessment (hereinafter "readiness assessment") of the draft environmental report (ER) which Eden has prepared in support of its CP application.

The readiness assessment is not part of the NRC's official acceptance review process. The readiness assessment of Eden's draft ER will allow the NRC staff to understand the level of detail and identify any major issues or information gaps between the draft ER and the technical content required to be included in the application submitted to the NRC. Therefore, the observations from the readiness assessment do not predetermine whether the application will be docketed. Audits of Eden's draft ER may be conducted using an applicant's electronic reference portal controlled by an applicant.

The enclosed readiness assessment plan provides the details and logistics of the readiness assessment activities.

If you have any questions or comments about this matter, please contact Linh Tran at (301) 415-4103, or via email at [Linh.Tran@nrc.gov](mailto:Linh.Tran@nrc.gov)

Sincerely,



Signed by Cruz, Holly  
on 03/06/24

Holly D. Cruz, Acting Chief  
Non-Power Production and Utilization Facility  
Licensing Branch  
Division of Advanced Reactors and Non-Power  
Production and Utilization Facilities  
Office of Nuclear Reactor Regulation

Project No. 99902077

Enclosure:  
As stated

cc: GovDelivery Subscribers

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 DATED: MARCH 6, 2024

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**ADAMS Accession No.: ML24065A500**

**NRC-106**

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<b>DATE</b>	3/6/2024	3/6/2024	

**OFFICIAL RECORD COPY**

**PREAPPLICATION READINESS ASSESSMENT PLAN  
EDEN DRAFT ENVIRONMENTAL REPORT  
MARCH 12- 29, 2024  
Docket No. 99902077**

**LOCATION**

The U.S. Nuclear Regulatory Commission (NRC) staff plans to conduct this readiness assessment audit virtually using Eden Radioisotopes, LLC (Eden) Electronic Reference Portal (ERP) and communicate via teleconference and/or video conference.

**PURPOSE**

Eden has requested that NRC environmental staff conduct a preapplication readiness assessment (hereinafter “readiness assessment”) of the draft environmental report (ER) which Eden has prepared in support of a future construction permit (CP) application.

The readiness assessment will allow the NRC staff to:

- Identify information gaps between the draft ER and the technical content required in the version of the report submitted to the NRC.
- Identify major technical or policy issues that may adversely impact a timely technical review of the application.

The observations from the readiness assessment will inform Eden in finalizing its CP application and will assist the NRC staff in planning NRC resources in preparation for the application review once the application is formally submitted.

**BACKGROUND**

By letter dated August 7, 2023 (Agencywide Documents Access and Management System Accession No. ML23230B208), Eden informed the NRC of its intent to submit license applications for a CP and operating license for a medical isotope production facility, called the Eden Isotope Production Complex. Eden has requested that the NRC staff conduct a readiness assessment of the draft ER which Eden has prepared in support of its CP application.

**SCOPE OF THE READINESS ASSESSMENT**

The below table shows the technical review areas to be covered in the readiness assessment and the responsible technical staff for each review area.

Technical Review Area and Related ER sections	Responsible Subject Matter Expert
Purpose and Need / Proposed Action / Cumulative Impacts Considerations / Overall Technical and Regulatory Approach (Deviation from Guidance, etc.)	Tami Dozier
Alternative Sites / Alternative Technologies / No Action Alternative / Comparison of Alternatives	Peyton Doub

Technical Review Area and Related ER sections	Responsible Subject Matter Expert
Land Use / Visual Impacts / Noise	Peyton Doub
Air Quality, Greenhouse Gas Emissions and Climate Change	Not identified
Geology and Water Resources	Dan Barnhurst
Ecological Resources / Consultations under Endangered Species Act	Peyton Doub
Cultural and Historic Resources / Consultations under National Historic Preservation Act / Tribal Engagement	Diana Diaz-Toro
Socioeconomics	Peyton Doub
Environmental Justice	Peyton Doub
Human Health, Nonradiological	Don Palmrose
Human Health, Radiological	Don Palmrose
Waste, Nonradiological	Don Palmrose
Waste, Radiological	Don Palmrose
Fuel Cycle	Don Palmrose
Transportation of Radiological Materials	Don Palmrose
Impacts from Postulated Accidents	Don Palmrose
Cost Benefit Discussion	Not identified

**INFORMATION AND OTHER MATERIAL NECESSARY FOR THE READINESS ASSESSMENT**

Eden will make available its draft ER on Eden’s ERP. The NRC staff will use Eden’s ERP to perform the readiness assessment. Access to the ERP is limited to specific NRC staff (e.g., based on NRC email addresses or the use of passwords which will only be assigned to NRC staff directly involved in the readiness assessment on a need-to-know basis), and documents in the ERP is read-only. The conditions associated with the ERP must be maintained throughout the review process. The NRC staff who should be granted access to the

portal are those listed in the “Readiness Assessment Review Team” section below. The NRC staff will provide a request to close the ERP at the conclusion of the audit.

### **READINESS ASSESSMENT REVIEW TEAM**

- Daniel Barnhurst, Branch Chief / Water Resources, Office of Nuclear Material Safety and Safeguards (NMSS)
- Diana Diaz-Toro, Historic and Cultural Resources, NMSS
- Peyton Doub, Alternatives / Ecological Resources / Land Use / Noise, NMSS
- Tami Dozier, Environmental Project Manager, NMSS
- Don Palmrose, Postulated Accidents / Human Health / Fuel Cycle, NMSS
- Michelle Rome, Branch Chief, NMSS
- Michael Balazik, Project Manager, Office of Nuclear Reactor Regulation (NRR)
- Holly Cruz, Acting Branch Chief, NRR
- Michelle Sutherland, Project Manager, NRR
- Linh Tran, Lead Project Manager, NRR

### **LOGISTICS**

The readiness assessment audit will be conducted during the period of March 12, 2024, through March 29, 2024. An entrance meeting is scheduled for Tuesday, March 12, 2024, from 3:00 PM - 3:30 PM to kick-off the audit. An exit meeting will be conducted at the conclusion of the audit.

The NRC staff will charge time for this assessment to the following fee-billable cost activity code number: Docket No. 99902077, EPID No. L-2024-LRM-0033.

### **SPECIAL REQUESTS**

All NRC review team members will observe appropriate handling and protection of proprietary or safeguards information, or both, throughout the readiness assessment. The NRC and Eden Electronic Reference Portal Information Access Agreement shall be reviewed by NRC review team members.

### **NRC REVIEW APPROACH**

The NRC staff will focus on identifying and documenting technical and regulatory gaps in the draft ER chapter/sections. These gaps, and other observations relevant to application quality and completeness will be compiled into a final readiness assessment report to Eden after all the sections have been examined.

The NRC staff will conduct a streamlined readiness assessment that includes the following aspects:

- This assessment will be conducted in accordance with NRR Office Instruction LIC-116, “Preapplication Readiness Assessment” (ML20104B698).
- The content of the ER will be informed by the Interim Staff Guidance Augmenting NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the

Licensing of Non-Power Reactors: Format and Content, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors” (ML12156A069).

- NRC Project Managers will provide regular status updates to NRC management and Eden, as needed.

#### **READINESS ASSESSMENT OBSERVATIONS**

The NRC staff will send the readiness assessment observations, including any identified technical concerns or major information gaps, to Eden in a publicly available report that will also summarize the scope of the readiness assessment. The NRC staff’s expectation is that Eden will consider the observations from the readiness assessment while finalizing its CP application.