



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

May 1, 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
OBSERVATIONS ON EDEN DRAFT ENVIRONMENTAL REPORT FOR A
MEDICAL ISOTOPE PRODUCTION FACILITY (EPID L-2024-LRM-0033)**

Dear Mr. Wagner:

On March 12 – March 29, 2024, U.S. Nuclear Regulatory Commission (NRC) staff from the Office of Nuclear Reactor Regulation and the Office of Nuclear Material Safety and Safeguards conducted a preapplication readiness assessment (hereinafter “readiness assessment”) of the draft environmental report (ER) which Eden Radioisotopes, LLC (Eden) has prepared in support of its anticipated construction permit application for the Eden Isotope Production Complex. The readiness assessment plan used to conduct the assessment can be found in Agencywide Documents Access and Management System under Accession No. ML24065A500.

The readiness assessment is not part of the NRC’s official acceptance review process. The NRC staff performed the readiness assessment to understand the level of detail of Eden’s draft ER and to identify any major issues or information gaps between Eden’s draft ER and the technical content required to be included in the final ER. Therefore, the observations from the readiness assessment do not pre-determine whether the application will be docketed. Furthermore, Eden did not request, and the NRC did not perform a readiness assessment of the draft preliminary safety analysis, at this time.

The enclosed document provides the NRC staff observations of the Eden’s draft ER. Please consider these observations when finalizing your ER.

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

Sincerely,

A handwritten signature in black ink, appearing to be 'JB' or similar, written over a horizontal line.

Bowen, Jeremy signing on behalf
of Shams, Mohamed
on 05/01/24

Mohamed K. Shams, Director
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: MAY 1, 2024

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ADAMS Accession No.: ML24115A130**NRR-106**

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NAME	DBarnhurst	HCruz	MShams (JBowen for)
DATE	04/29/2024	04/29/2024	05/01/2024

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NRC STAFF OBSERVATIONS REPORT
PREAPPLICATION READINESS ASSESSMENT OF DRAFT ENVIRONMENTAL REPORT
EDEN ISOTOPE PRODUCTION COMPLEX CONSTRUCTION PERMIT APPLICATION
DOCKET NO. 99902077

Introduction

On March 12 – March 29, 2024, U.S. Nuclear Regulatory Commission (NRC) staff from the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Material Safety and Safeguards conducted a preapplication readiness assessment (hereinafter “readiness assessment”) of the draft environmental report (ER) which Eden Radioisotopes, LLC (Eden) has prepared in support of its anticipated construction permit (CP) application for the Eden Isotope Production Complex (EIPC). The NRC staff conducted the readiness assessment in accordance with the NRR’s office instruction, LIC-116, “Pre-application Readiness Assessment” (Agencywide Documents Access and Management System under Accession No. ML20104B698). The readiness assessment was conducted virtually using Eden Electronic Reference Portal and communicated via teleconference/video conference. The NRC staff’s use of the electronic portal is described in an NRC letter to Eden dated March 6, 2024 (ML24053A016). The NRC staff’s readiness assessment follows earlier preapplication discussions with Eden, most notable for the environmental review which was a public meeting held on August 4, 2021 (ML21265A364).

Assessment Approach

The readiness assessment plan used to conduct the assessment was issued to Eden on March 6, 2024 (ML24065A500). As stated in the readiness assessment plan, the primary objective of the readiness assessment was to allow NRC staff to identify information gaps between the draft ER and the technical content required in the version of the report that would be submitted to the NRC and to identify any technical or policy issues that may adversely impact a timely technical review of the application. While readiness assessments provide valuable insights for the NRC staff and prospective applicants regarding a preliminary version of an application, the readiness assessment is not part of the NRC’s official acceptance review process and is not intended to determine whether the associated CP application will be acceptable for docketing. A readiness assessment is not a formal comprehensive review and additional issues could be identified during the NRC staff’s formal review process.

After a kickoff meeting held with Eden on March 12, 2024, and familiarization with the discussions from the August 4, 2021, public meeting mentioned above, the NRC staff examined Eden’s draft ER via the electronic portal using the guidance provided in Interim Staff Guidance (ISG) Augmenting NUREG-1537, “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). On March 29, 2024, the NRC staff shared the observations listed in the next section with Eden representatives.

Enclosure

General Observations

The NRC staff did not identify any issues with the draft ER that would indicate Eden would not be able to meet its proposed schedule for submittal as part of the CP application. The NRC team took note that Eden had completed archaeological surveys to identify potential historic properties to support the anticipated NRC staff's review under the National Historic Preservation Act (NHPA), submitted survey reports to the State Historical Preservation Officer (SHPO), and reached out to Tribes potentially interested in the project.

Table 1, "NRC Staff Observations of Eden Draft Environmental Report," describes NRC staff's observations in a few resource areas that it believes Eden could address prior to submitting its application. Addressing the NRC staff observations would improve the efficiency and schedule predictability of its review when the ER is submitted with the CP application.

While the team did not identify any issues with the draft ER that would indicate Eden would not be able to meet its proposed schedule for submittal as part of the CP application, it is possible that additional issues may be identified during the detailed acceptance review of the CP application.

Table 1 - NRC Staff Observations of Eden Draft Environmental Report

Item No.	Draft ER Section Number	Resource Area	Observation	Regulatory Basis
1	19.3.6 and Appendix A	Historic and Cultural Resources	The applicant states that a 100 percent, intensive cultural resource survey was conducted in 2020 within the Area of Potential Effect. The consultation letters to the New Mexico (NM) SHPO and Tribes referenced the 2020 survey report as well as a 2022 amended report. Additionally, the applicant references a cultural resource survey conducted in the area where the offsite utility corridor would be located. In conjunction with the ER, the applicant should submit all cultural resource survey reports used to identify and evaluate effects of the proposed construction, operation, and decommissioning of the facility.	NHPA section 106
2	19.3.6	Historic and Cultural Resources	The cultural resource survey reports should consider whether any information should be redacted consistent with Section 800.11(c) of Title 36 of the <i>Code of Federal Regulations</i> (CFR) and section 304 of the NHPA. Thus, a redacted and a non-redacted version of the reports would be beneficial and facilitate the NRC staff's National Environmental Policy Act and NHPA section 106 reviews.	NHPA section 106
3	19.3.6 and 19.4.6	Historic and Cultural Resources	By providing the applicable cultural resource survey reports with the ER, the applicant would also provide the following information: <ul style="list-style-type: none"> • Maps showing the extent of the survey, and/or the area of potential effect, the proposed project activities and known historic properties listed or eligible for listing in the National Register of Historic Places; • A description of the survey techniques used to conduct the survey, including consideration of State survey standards and guidelines; and • Qualifications of the surveyors, including consideration of State requirements. 	NHPA section 106

Item No.	Draft ER Section Number	Resource Area	Observation	Regulatory Basis
4	19.3.6	Historic and Cultural Resources	The ER should also discuss the methods and surveyor's qualifications used during the cultural resource survey to identify Traditional Cultural Properties and properties of significance to Tribes.	NHPA section 106
5	19.5.2.1.1.1	Alternatives	The ER should provide more explanation as to why the siting effort (range of alternative sites) was limited to central and eastern NM.	ISG Augmenting 1537 section 19.5.2
6	19.5.2.1	Alternatives	The ER should include a map showing alternative sites selected for detailed evaluation. Ideally the ER would have figures showing the boundaries and major features of each site.	ISG Augmenting 1537 section 19.5.2
7	19.4.4.2.2	Water Resources	Per section 19.3.4.2.2, the NRC staff understand that water for EIPC operations would be supplied by the Eunice public water supply system and would be within total capacity for the system (section 19.3.4.2.3). EIPC usage would result in a slight increase in in the daily average use, which is below the total capacity of the system. It is not clear in the draft ER whether the impacts of the increased rate of pumping on the High Plains Aquifer (including uses and users) have been considered. The ER should include recent studies or reports evaluating the impacts of pumping at the total capacity.	ISG Augmenting 1537 sections 19.3.4 and 19.4.4
8	19.4.2.2	Noise	The ER should include the noise attenuation calculations that underlie the conclusions in this section.	ISG Augmenting 1537 section 19.4.2
9	19.3.1.1.1	Land Use	The ER should include information on current ownership of the site.	ISG Augmenting 1537 section 19.3.1
10	19.4.2.1.1	Air Quality	Regardless of whether the site is in attainment or not, a new emissions source requires a review under the Clean Air Act (CAA). Eden would be required to provide this information to the State of NM to be granted a permit or a waiver. That information should be included in the ER.	CAA (40 CFR 52.1620) NM Administrative Code 20.2.73