



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

May 15, 2025

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

**SUBJECT: EDEN RADIOISOTOPES, LLC – PRE-APPLICATION READINESS  
ASSESSMENT OBSERVATIONS ON EDEN DRAFT PRELIMINARY SAFETY  
ANALYSIS REPORT FOR A MEDICAL ISOTOPE PRODUCTION FACILITY  
(EPID L-2025-LRM-0009)**

Dear Mr. Wagner:

On February 25 – March 27, 2025, the U.S. Nuclear Regulatory Commission (NRC) staff conducted a pre-application readiness assessment (hereinafter “readiness assessment”) of the draft preliminary safety analysis report (PSAR) which Eden has prepared in support of its construction permit application for a medical isotope production facility.

The readiness assessment is not part of the NRC’s official acceptance review process. The staff performed the readiness assessment of Eden’s draft PSAR to understand the level of detail of the draft PSAR and identify any major issues or information gaps between the draft PSAR 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.

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

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) or Andrew Miller at (301) 415-1080, or via email at [Andrew.Miller@nrc.gov](mailto:Andrew.Miller@nrc.gov).

Sincerely,



Signed by Miller, Andrew  
on 05/15/25

Andrew J. Miller, Project Manager  
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:

Summary report on the pre-application audit  
of Eden Radioisotopes, LLC draft PSAR

cc w/enclosure: GovDelivery Subscribers

SUBJECT: EDEN RADIOISOTOPES, LLC – PRE-APPLICATION READINESS  
ASSESSMENT OBSERVATIONS ON EDEN DRAFT PRELIMINARY SAFETY  
ANALYSIS REPORT FOR A MEDICAL ISOTOPE PRODUCTION FACILITY  
(EPID L-2025-LRM-0009) DATED: MAY 15, 2025

**DISTRIBUTION:**

PUBLIC

RidsNrrDanu Resource

EHelvenston, NRR

JRady, NRR

LTran, NRR

MBalazik, NRR

NParker, NRR

DHardesty, NRR

BGallagher, NRR

AMiller, NRR

**ADAMS Accession No.: ML25115A140****NRC-106**

<b>OFFICE</b>	NRR/DANU/UNPL/PM	NRR/DANU/UNPL/LA	NRR/DANU/UNPL/TL
<b>NAME</b>	AMiller	NParker	MBalazik
<b>DATE</b>	4/30/2025	5/5/2025	5/7/2025
<b>OFFICE</b>	NRR/DANU/UNPL/ABC	NRR/DANU/UNPL/PM	
<b>NAME</b>	EHelvenston	AMiller	
<b>DATE</b>	5/13/2025	5/15/2025	

**OFFICIAL RECORD COPY**

# **SUMMARY REPORT ON THE PRE-APPLICATION AUDIT OF**

## **EDEN RADIOISOTOPES, LLC**

### **DRAFT PRELIMINARY SAFETY ANALYSIS REPORT**

**February 25 – March 27, 2025**

#### **1.0 BACKGROUND**

On February 25, 2025, through March 27, 2025, the U.S. Nuclear Regulatory Commission (NRC) staff conducted a pre-application readiness assessment (hereinafter “readiness assessment”) of the draft preliminary safety analysis report (PSAR) prepared by Eden Radioisotopes, LLC (Eden) in support of its anticipated construction permit (CP) application for the Eden Isotope Production Complex. The NRC staff conducted the readiness assessment in accordance with the audit plan provided to Eden on February 11, 2025 (Agencywide Documents Access and Management System Accession No. ML25045A016), and as requested by Eden in its letter dated January 17, 2025 (ML25017A058).

#### **2.0 AUDIT REGULATORY BASES**

The bases for the audit are the regulations at paragraph (a) of Title 10 of the Code of Federal Regulations (10 CFR) Section 50.34, “Contents of applications; technical information,” 10 CFR Section 50.35, “Issuance of construction permits,” 10 CFR Section 50.40, “Common standards,” and 10 CFR Section 50.50, “Issuance of licenses and construction permits.” The NRC staff also conducted the audit using the guidance in “Interim Staff Guidance [ISG] 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).

#### **3.0 AUDIT PURPOSE AND OBJECTIVES**

The purpose of this audit was to provide the NRC staff with an opportunity to assess the readiness of the draft PSAR before Eden formally submitted the CP application. This audit allowed the NRC staff to (1) identify any required information that is missing from the application, (2) identify technical or regulatory issues that may complicate the acceptance or technical reviews of the application, and (3) become familiar with the content of the application.

#### **4.0 SCOPE OF THE AUDIT AND AUDIT ACTIVITIES**

The readiness assessment focused on the following chapters of Eden’s draft PSAR:

- Draft PSAR chapter 1, “The Facility”
- Draft PSAR chapter 2, “Site Characteristics”
- Draft PSAR chapter 3, “Design of Structures, Systems and Component”
- Draft PSAR chapter 4a, “Reactor Description”
- Draft PSAR chapter 4b, “Radioisotope Production Facility Description”
- Draft PSAR chapter 5a, “Reactor Coolant System”
- Draft PSAR chapter 5b, “Radioisotope Production Facility Coolant System”

Enclosure

- Draft PSAR chapter 6a, "Reactor Engineered Safety Features"
- Draft PSAR chapter 6b, "Radioisotope Production Facility Engineered Safety Features"
- Draft PSAR chapter 7a, "Reactor I&C [Instrumentation and Control] Systems"
- Draft PSAR chapter 7b, "Radioisotope Production Facility I&C Systems"
- Draft PSAR chapter 8, "Reactor and Radioisotope Production Facility Electrical Power Systems"
- Draft PSAR chapter 9, "Reactor and Radioisotope Production Facility Auxiliary Systems"
- Draft PSAR chapter 10, "Experimental Facilities and Utilization"
- Draft PSAR chapter 11, "Radiation Protection Program & Waste Management"
- Draft PSAR chapter 12, "Conduct of Operations"
- Draft PSAR chapter 13a, "Reactor Accident Analysis"
- Draft PSAR chapter 13b, "Radioisotope Production Facility Accident Analysis"
- Draft PSAR chapter 14, "Technical Specification"
- Draft PSAR chapter 15, "Financial Qualifications"

The readiness assessment was conducted virtually using Eden's Electronic Reference Portal and communications via teleconference/video conference.

NRC staff audit team members included:

Edward Helvenston	Acting Branch Chief, Licensing
Linh Tran	Senior Project Manager (responsible for audit logistics)
Michael Balazik	Project Manager, Audit Lead (responsible for technical review)
Duane Hardesty	Senior Project Manager
Brooke Gallagher	Project Manager
Carol Dye	Geologist
Jason White	Physical Scientist (Meteorologist)
Hosung Ahn	Hydrologist
Jenise Thompson	Geologist
Sarah Tabatabai	Geophysicist
Luisette Candelario-Quintana	Civil Engineer
Se-Kwon Jung	Senior Civil Engineer
Nick Hansing	Mechanical Engineer
Santosh Bhatt	Senior Nuclear Engineer
Brandon Wise	Reactor System Engineer
Jo Ambrosini	Nuclear Engineer
Henry Wagage	Senior Safety and Plant Systems Engineer
Brian Lee	Senior Safety and Plant Systems Engineer
Brian Wagner	Reliability and Risk Analyst
Sheila Ray	Senior Electrical Engineer
Edward Stutzcage	Reactor Scientist (Radiation)
Glenn Tuttle	Material Control and Accounting Physical Inspection Analyst
Edward Robinson	Senior Emergency Preparedness Specialist
Langston Lewis	Reliability and Risk Analyst
James Hammelman	Senior Chemical Process Engineer
Shawn Harwell	Financial Analyst
Frankie Vega	Reactor Ops Engineer (Quality Assurance)
Norbert Carte	Senior Electronics Engineer

Andrew Miller  
Amitava Ghosh  
Charles Moulton  
Logan Crevelt  
Catie Szumski

Zee St. Hilaire  
Nicole Cortes  
Jennifer Beaton

Project Manager  
Physical Scientist (Hazards Analyst)  
Fire Protection Engineer  
Nuclear Process Engineer  
Nuclear Engineer, Nuclear Systems Performance  
(Training only)  
Nuclear Process Engineer (Training only)  
Chemical Safety Scientist (Training only)  
General Engineer (Training only)

The NRC staff did not acquire any documents during the audit.

## 5.0 SUMMARY OF OBSERVATIONS

The NRC staff's summary of observations listed below is based on the notes taken during the audit. The main purpose of the audit was to identify issues which could challenge potential acceptance of the PSAR when submitted and potential challenging regulatory or technical issues which may need additional documentation. In particular, the NRC staff noted:

Observations on potential acceptance review issues:

- Related to draft PSAR chapter 2, the NRC staff noted that details on the site characteristics, such as seismic hazard analysis inputs and results, design response spectrum, site response analysis inputs, and methodology, would be necessary for the NRC staff to evaluate the sufficiency of the facility design. The NRC staff's observation was based on 10 CFR 50.34(a)(1)(i), which states, in part, that the PSAR must include "A description and safety assessment of the site on which the facility is to be located, with appropriate attention to features affecting facility design." The NRC staff informed Eden of this concern during a teleconference on April 10, 2025.
- Related to draft PSAR chapter 2, the NRC staff noted that further details on the site characteristics, such as site-specific geotechnical information to demonstrate the stability of subsurface material and the stability of slopes, and an adequate basis on the application of nearby site data to Eden's specific site, would be necessary for the NRC staff to evaluate the stability of the facility structures. The NRC staff's observation was based on 10 CFR 50.34(a)(1)(i), which states, in part, that the PSAR must include "A description and safety assessment of the site on which the facility is to be located, with appropriate attention to features affecting facility design," and 10 CFR 50.34(a)(4), which states, in part, that the PSAR must include "A preliminary analysis of evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility, ... and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents." The NRC staff informed Eden of this concern during a teleconference on April 10, 2025.
- Related to draft PSAR chapter 13b, the NRC staff noted the need for further details on the integrated safety analysis (ISA) methodology, such as a clear definition of the term "credible" or an explanation of the deviation from the typically accepted definition of "credible" as stated in NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications" (ML15176A258). These details are necessary to ensure that all credible accident sequences with unacceptable risk are further evaluated to identify

potential structures, systems, and components (SSCs), engineered safety features (ESFs), and probable subjects of technical specifications (TSs) needed to prevent the occurrence or mitigate the consequences of accidents, and that all credible initiating events due to failure of SSCs, ESF, and probable subjects of TSs are identified and analyzed. The ISG Augmenting NUREG-1537, Part 1, provides guidance that the ISA methodology described in NUREG-1520 is an acceptable method for demonstrating adequate safety for a medical isotope production facility, e.g., Eden's proposed hot cell facility (HCF). If methods used are different than those described in the ISG, the application should provide a safety basis for the NRC staff to determine compliance with regulations. The NRC staff's observation was based on 10 CFR 50.34(a)(4), which states, in part, that the PSAR must include "A preliminary analysis of evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility, ... and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents." The NRC staff informed Eden of this concern during a teleconference on April 10, 2025.

General observations (the NRC staff does not consider these to be potential acceptance review issues but may seek additional information on specific related items as necessary if a CP application is accepted for review):

- There is general inconsistency between the reactor facility (RF) and HCF design criteria (DC) stated in chapter 3 of the draft PSAR and the remaining chapters of the draft PSAR that describe (or sometimes omit) the actual design implementation that corresponds to the specific SSCs. DC should be specified for each SSC that is assumed to perform an operational or safety function. Additionally, the design bases in the PSAR should include references to the applicable standards, guidance, and codes. For example,
  - RF DC-3 does not align with draft PSAR section 9a.3.2.2, which states the fire protection system does not perform safety-related functions. Draft PSAR table 3.5-1a categorizes the fire protection system as quality level (QL)-2 (i.e., not quality-related) but section 9a.3.1 states that the fire protection program protects SSCs to ensure safe shutdown is not prevented.
  - Draft PSAR section 7a.2.1.1 describes the DC applicable to the RF I&C systems using a bulleted list of DC numbers and names, and a summary description of how each DC is addressed in chapter 7. However, the descriptions appear to simply assert that the DC are met rather than providing descriptions of how the DC are met (i.e., providing design basis information).
- The NRC staff observed inconsistencies within and between draft PSAR chapters, such as core row designations in chapter 4, identification of limiting safety systems settings between chapter 7 and chapter 14, and I&C functions between chapter 5 and chapter 7.
- The NRC staff noted that there appears to be a lack of conservatism in the subcritical mass limit for the HCF in draft PSAR chapter 6b.
- The NRC staff noted certain values and content using the annotation "[TBD]" in draft PSAR chapter 7. This nomenclature was not used in any other chapters of the draft PSAR and it was not clear to the NRC staff if these annotations were intended to denote

information that would be provided in the final PSAR, information that would be provided in an operating license application, or something else.

- The NRC staff noted that the analysis performed in draft PSAR chapter 4 did not include or bound changes within the core over time. These effects include fuel burnup, mixed target batches, and boron depletion.
- The draft PSAR makes many references to similarities to equipment at facilities of similar design for which applications have previously been filed with the Commission. The draft PSAR states that “equipment is used in other research reactors” without sufficient detail to make any inference as to its suitability for use in the Eden I&C systems.
- Where I&C functions are credited in the safety analysis, an NRC reviewer must verify that all functions credited in the analysis are implemented in the I&C equipment design. An explicit cross reference of I&C function(s) to the analyses of associated limiting event(s) may help make the review more efficient.
- The PSAR should describe the systems and features designed to protect the RF and HCF from damage by fire and external hazards and discuss how the facility meets local fire and building codes. For PSAR references to the pertinent industry standards and PSAR citations of conformance to local building codes, it may be helpful to include specific clauses and criteria used for compliance.
- The NRC staff noted that analyses of potential pipeline hazards are not provided in draft PSAR chapter 2.

## 6.0 EXIT DISCUSSION

The NRC staff held a summary meeting with Eden on April 10, 2025. At the meeting, the NRC staff reiterated the purpose of the audit and discussed observations on potential acceptance issues and other general observations, as summarized above. At Eden’s request, the NRC staff and Eden held two additional meetings on April 30 and May 15, 2025, to further discuss the staff’s observations.

## 7.0 REQUESTS FOR ADDITIONAL INFORMATION RESULTING FROM AUDIT

The NRC staff did not use the formal request for additional information process as part of this audit. The NRC staff provided Eden questions and feedback during the audit, which Eden could consider and use to revise its PSAR prior to submittal of the CP application.

## 8.0 OPEN ITEMS AND PROPOSED CLOSURE PATHS

Not applicable. There are no open items as a result of this audit.