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EDEN-NRC-2025-002

June 30, 2025

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Reference: Eden Radioisotopes, LLC
Eden Isotope Production Complex
Project/Docket No.: 99902077

Subject: Submittal of Regulatory Engagement Plan

Enclosed for your review is the Eden Radioisotopes, LLC ("Eden") Regulatory Engagement Plan (REP) for submittal of a License Application to construct the Eden Isotope Production Complex (EIPC).

The Eden REP is provided for NRC staff information and outlines plans for interaction with the NRC during licensing activities associated with the EIPC.

Eden plans to construct and operate the EIPC near Eunice, Lea County, New Mexico. The primary purpose of the proposed facility is to produce medical isotopes, primarily Molybdenum-99 and Lutetium-177, for medical imaging and radiotherapeutic purposes.

If you have any questions, please feel free to contact me or Mr. James Saldarini, Eden Licensing Director, at 240-344-5204 (jsaldarini@edenrad.com).

Sincerely,

Chris Wagner

Chris Wagner
Chief Executive Officer
Eden Radioisotopes, LLC

cc: Linh N. Tran, NRC (NRR/DANU/UNPL)

Enclosure: EIPC Regulatory Engagement Plan, Revision 0, June 2025

EDEN RADIOISOTOPES

Regulatory Engagement Plan for Submittal of a License Application to Construct the Eden Isotope Production Complex

Revision 0
June 2025

Signatures

	Name	Title	Signature
Prepared by:	James Saldarini	Licensing Director	JCSaldarini
Reviewed by:	Ed Parma	Chief Science Officer	Ed Parma
Approved by:	Chris Wagner	Chief Executive Officer	Chris Wagner

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1. Introduction

Eden Radioisotopes, LLC (Eden) plans to build a dedicated nuclear fission reactor and collocated hot cell processing facility to serve the medical radioisotope market. The facility will address the expected future shortfalls and supply constraints for several of these key radioisotopes, with initial focus on molybdenum-99 (Mo-99) and lutetium-177 (Lu-177). Recognizing the importance of Mo-99 and the challenges plaguing its consistent supply, the U.S. Department of Energy (DOE) invested in developing production alternatives. The design technology in Eden's facility includes Intellectual Property licensed from Sandia National Laboratories.

The purpose of this Regulatory Engagement Plan (REP) is to guide communications and anticipated interactions between Eden and the U.S. Nuclear Regulatory Commission (NRC) during the licensing pre-application phase of the Construction Permit Application (CPA) for a medical isotope production facility, called the Eden Isotope Production Complex (EIPC).

This REP identifies primary points of contact, describes the planned regulatory approach and tentative licensing submittal schedule, and provides a brief project overview in an effort to enhance on-going communication with the NRC. The applicable guidance in Nuclear Energy Institute document NEI 18-06, Guidelines for Development of a Regulatory Engagement Plan has been used to inform this REP.

2. Primary Points of Contact

The primary point of contact for written correspondence with the NRC is:

Chris Wagner, Chief Executive Officer
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The primary point of contact for regulatory engagement and coordination is:

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Eden Radioisotopes, LLC
9400 Holly Ave. NE, Suite 202
Albuquerque, NM 87122

Email: jsaldarini@edenrad.com
Phone: (240) 344-5204

The primary point of contact for technical matters is:

Ed Parma, Chief Science Officer
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3. Project Overview

Eden plans to construct and operate the EIPC in Lea County, New Mexico (NM), approximately 3 miles east of Eunice, NM, and 1.6 miles west of the Texas / NM, border. As stated previously, the primary purpose of the facility is to produce medical isotopes for medical imaging and radiotherapeutic purposes.

The facility consists of a small, non-power, open-pool reactor facility, a separation processing hot cell facility, a target fabrication facility, and a waste packaging, handling, and storage facility in addition to administrative and storage space. A site rendering of the EIPC is shown in Attachment 1 and the layout of the EIPC is shown in Attachment 2.

The principal structure within the EIPC is the Eden Medical Isotope Facility (EMIF). Within the EMIF, there is a Reactor Facility, and a collocated Hot Cell Facility. The Reactor Facility is a nuclear non-power reactor used to irradiate targets and it includes a high bay, reactor pool, and reactor control room. The Hot Cell Facility is the facility used to separate desired radioisotopes from irradiated targets and it includes the target processing high bay, target fabrication area, activation isotope production area, target processing canyon, and waste storage canyon. The EMIF is shown in Attachment 3.

The EIPC will produce Mo-99, iodine-131 (I-131), and xenon-133 (Xe-133) through the fission process and other isotopes, such as Lu-177, through neutron activation. The decay product of Mo-99, technetium-99m (Tc-99m), will be used for diagnostic medical procedures.

The Eden all-target reactor will be licensed to operate at a thermal power level of 1.8 megawatts (MW(t)), with a primary coolant temperature of around 100 degrees Fahrenheit (F) (38 degrees Celsius (C)) in an open pool. The reactor will operate continuously except for short downtime periods for withdrawal of irradiated targets for processing and placement of fresh targets into the core.

Key advantages of the EIPC can be summarized as follows:

- Proven technology recognized to produce isotopes at commercial scale (fission non-power reactor plus hot cell)
- Benefits from extensive reactor development and operational experience from Sandia National Laboratories.
- Small, single purpose, dedicated to medical isotope production
- Open pool system with natural circulation.
- Continuous, year-round operations
- Low-power (1.8 MW) and small footprint
- Design maintained within domain of NRC familiarity
- Eden targets are the reactor fuel and not an experiment. Results in efficiency of operation and a lower power level (greater safety margins) than designs that run targets as experiments
- Uses low-enriched uranium (LEU), produces no spent fuel, and recycles 90 percent of uranium for additional isotope production
- U.S. location to serve domestic market in timely fashion

4. Regulatory Approach

Eden plans to apply to the NRC to obtain a construction permit and subsequent operating license for a utilization and production facility under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Occurring within the 10 CFR Part 50 licensed facility will be several activities subject to 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material", and 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material".

Eden will apply for a Class 103 license per 10 CFR 50.22 (for commercial and industrial facilities) that includes license conditions for the receipt, possession, and use of source material under 10 CFR Part 40, byproduct material under 10 CFR Part 30, and special nuclear material under 10 CFR Part 70. The reactor also meets Section (3) of the definition of non-power reactor in 10 CFR Part 50, Section 2 (10 CFR 50.2). [NPUF Rule]

The Eden Construction Permit Application is being informed by the guidance in NUREG-1537, Part 1, and the Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors - Format and Content.

The strategic approach for the 10 CFR Part 50 license application process will also encompass activities regulated under different NRC requirements. These activities are intended to include at least the following partial list of applicable requirements: 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer Special Nuclear Material (SNM), 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct

Material," 10 CFR Part 20, "Protection Against Radiation," and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and related functions".

5. Pre-Application Engagement

5.1 Interactions

Eden's goal is to engage with the NRC early, often and at the appropriate level, seeking alignment with the NRC staff in key licensing positions and, based on feedback obtained from the NRC during the pre-application phase, submit a CPA that will be accepted for review by the NRC in a timely manner.

If during the license application preparation process, Eden determines that exemptions from regulatory requirements or deviations or exceptions from regulatory guidance are called for, Eden will promptly notify the NRC and initiate discussions with the appropriate NRC staff.

5.2 Project Management Discussions

Periodic nonpublic discussions between Eden and NRC project management are planned to be held throughout the pre-application submittal engagement period. These discussions may include participation by other members of the Eden Team, should questions be asked that warrant additional explanation. These discussions will typically be held with NRC project management to provide the NRC with nontechnical information, such as status reports, planning for future meetings, and schedule updates.

5.3 Public Meetings

Public meetings may be utilized for presentations related to the environmental review and selected technical discussions related to the licensing application submittal.

5.4 Pre-Application Readiness Assessments

A Pre-Application Readiness Assessment of the Draft Environmental Report was conducted by the NRC over the period March 12-March 29, 2024 and the NRC issued its summary report to Eden via letter on May 1, 2024 (ML24115A130).

Similarly, a Pre-Application Readiness Assessment of the Draft Preliminary Safety Analysis Report was conducted by the NRC over the period February 25-March 27, 2025, and the NRC issued its summary report to Eden via letter on May 15, 2025 (ML25115A140).

5.5 Key Features of the Eden Facility

- Facility designed to meet 100% USD Mo-99.
- Collocated Reactor Facility and Hot Cell Facility.
- All-target reactor uses LEU fuel in the form of annular targets.
- Reactor uses all of the fuel for Mo-99 processing – no driver elements.
- No spent fuel or greater than Class C waste generated.
- Reactor is a steady-state non-power reactor operating at 1.8 MWt, 24 hours per day.
- Reactor operates in a large open pool and is cooled by natural circulation flow.
- Reactor is controlled and operated in a very similar fashion as TRIGA-type reactors.
- Selected targets are removed and replaced in the core on a weekly basis.
- Irradiated targets are transferred underwater in a transfer canal to the Hot Cell Facility for processing.
- Target are disassembled and the LEU foil processed using the modified Cintichem process.
- LEU is separated from the fission product and transuranic waste using the UREX process.
- LEU is recycled back into targets or sent back to DOE as part of the ULTB program.
- Liquid waste is grouted in 55-Gal drums, staged for decay, and sent to a LLW site as Class C waste.

6. Preliminary Schedule For Issuance Of Construction Permit

Eden is currently in the process of establishing a detailed licensing schedule; however, for planning purposes, it is our present intent to submit the Eden CPA in the fourth quarter of CY2025. The regulatory timeline that Eden has assumed consists of the following major milestones:

Construction Permit Application Submitted	Q4 2025
NRC accepts the CPA for formal review (docketing)	Q1 2026
Construction Permit Issued	Q3 2027
Operating License Application Submitted	Q4 2027
Operating License Issued	Q3 2030
Commercial Operations	Q4 2030

7. References

Nuclear Energy Institute, NEI 18-06, Guidelines for Development of a Regulatory Engagement Plan

NUREG 1537, Part 1, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content, February 1996

Final 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 Homogenous Reactors, October 17, 2012

Eden Letter to the NRC dated August 7, 2023 (ML23230B208), Notice of Intent to Submit License Application

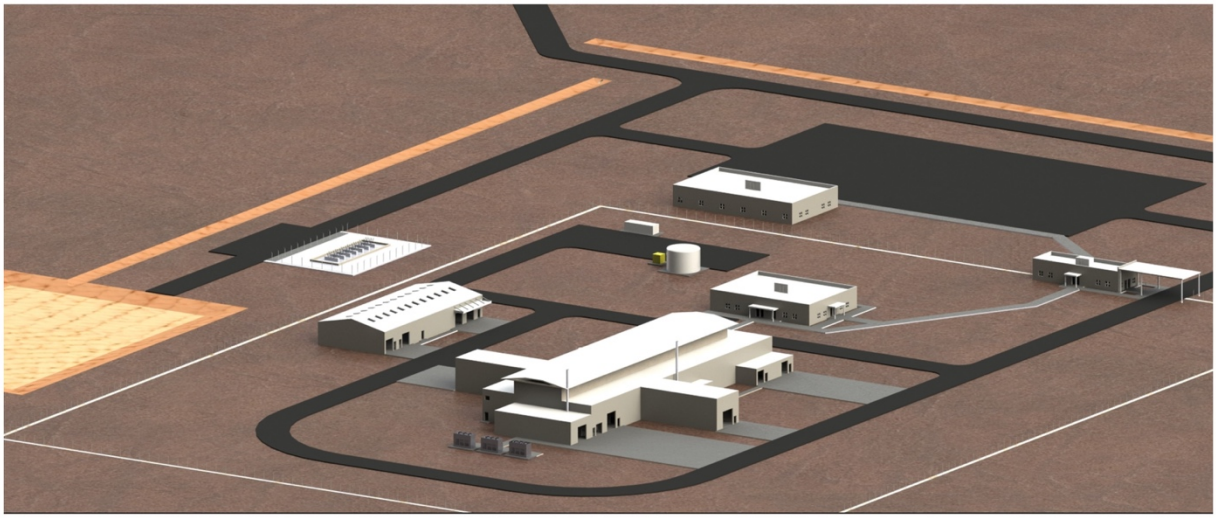
NRC Letter to Eden dated May 1, 2024 (Ml24115A130), Eden Radioisotopes, LLC – Preapplication Readiness Assessment Observations on Eden Draft Environmental Report for a Medical Isotope Production Facility (EPID L-2024-LRM-0033)

NRC Letter to Eden dated May15, 2025 (ML25115A140), 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)

8. Attachments

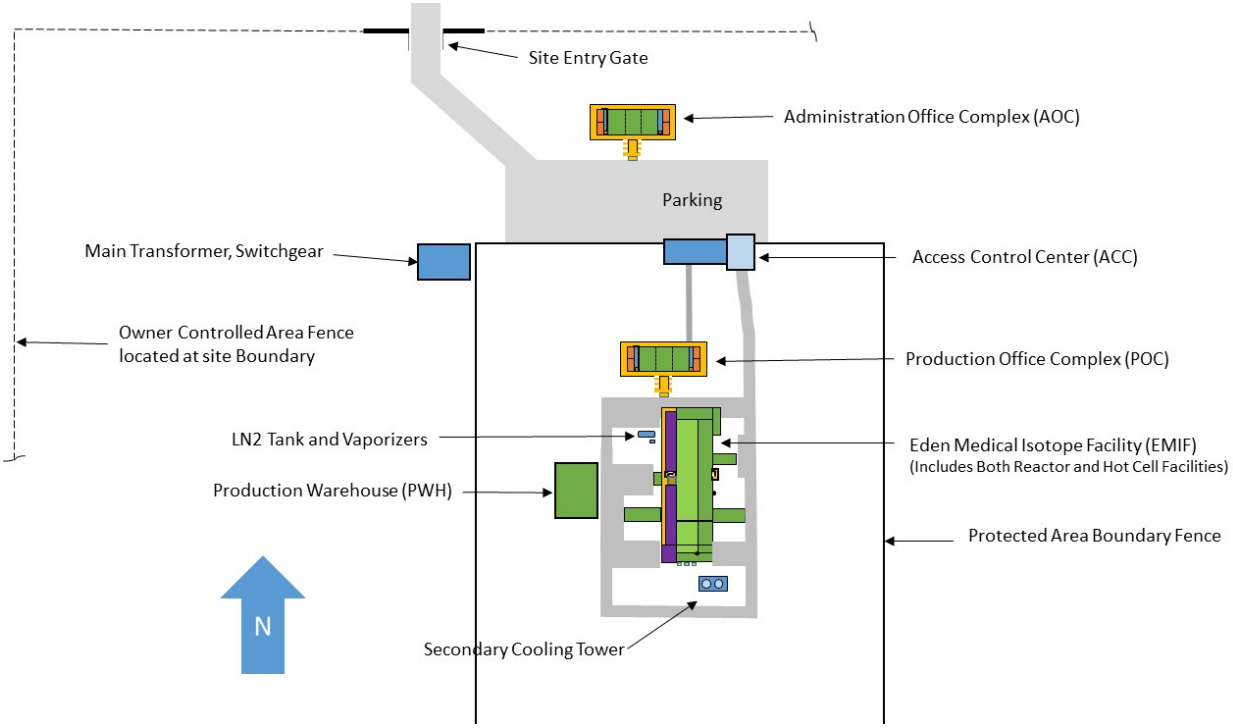
Attachment 1

Eden Isotope Production Complex Site Rendering

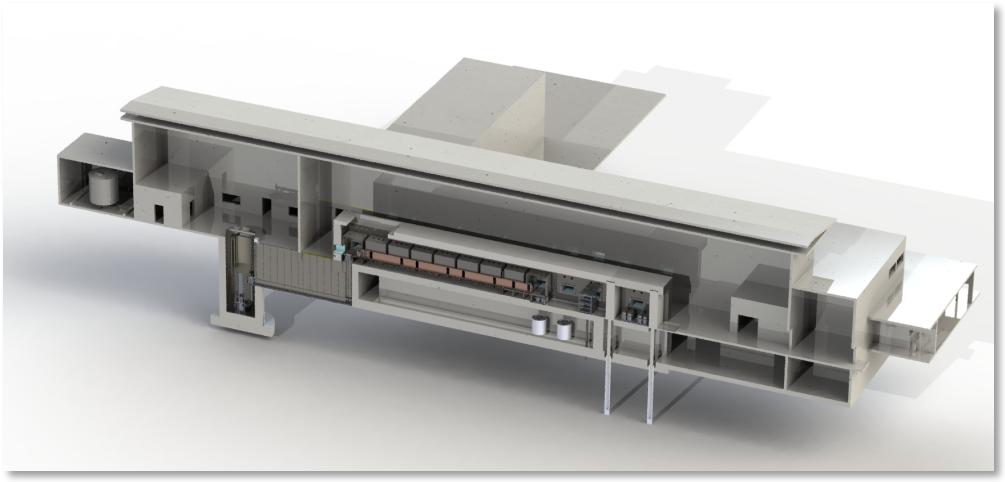


View Looking Northwest

Attachment 2
Eden Isotope Production Complex Layout



Attachment 3
Eden Medical Isotope Facility (EMIF) Plan Summary



- 76,000 square feet (6960 square meters) (largest building in complex)
- Reactor operations, target processing, and target fabrication
- Designed for 5,000 6-day Ci Mo-99 processing capacity (annual)
- Capable of producing neutron activation isotopes like Lu-177
- Reactor located near the bottom of a large cylindrical open pool (about 30 feet (9 meters) deep)
- Basement of Hot Cell Processing Facility contains shielded canyon for waste product storage and fission product decay, prior to transfer to a low-level radioactive waste disposal site
- Reactor and Hot Cell Processing Facility adjoined by underwater transfer canal