



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

October 15, 2021

APPLICANT: Eden Radioisotopes, LLC

SUBJECT: SUMMARY OF AUGUST 4, 2021, MEETING WITH EDEN RADIOISOTOPES, LLC (EPID NO. L-2019-LLL-0027)

On August 4, 2021, a public observation meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of Eden Radioisotopes, LLC (Eden) via Microsoft Teams and an associated bridge line. The purpose of this meeting was to discuss environmental topics regarding Eden's proposed application for a construction permit (CP) to build a medical radioisotope production facility near Eunice, NM. The meeting notice and agenda, dated July 21, 2021, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML21202A455. Eden's presentations used in the meeting are also available in ADAMS at Accession No. ML21217A054. A list of meeting attendees is provided as an enclosure to this summary.

Eden representatives first provided a brief update on its planned schedule for completion and submission of its CP application. Eden informed the NRC staff that its current schedule is to submit the environmental report (ER) in the first quarter of the 2022 calendar year (CY) and the preliminary safety evaluation report (PSAR) no more than six months later. In the fourth quarter of CY2021, Eden plans to file the required exemption request for a two-part CP application submittal along with its Quality Assurance Program Description.

The basis for Eden's proposed submittal schedule is to mitigate the risk that the NRC's environmental review, conducted in accordance with the National Environmental Policy Act (NEPA), could become the critical path for the licensing review. Eden would also prefer to receive any requests for additional information (RAIs) in a staggered fashion and believes that initiation of the environmental review ahead of the safety review would help ensure that RAIs would be received in series rather than in parallel, which would be preferable to Eden from a resource perspective. The NRC staff explained that based on the information available about the project, it is highly unlikely the environmental review would take longer than the safety review. Eden noted that it would consider this feedback prior to submitting an exemption request.

Eden's presentation included a description of the proposed project and proposed location, highlighting the proximity of the project to other recent NRC licensing actions. Eden representatives explained the ER approach of citing to and incorporating previous agency environmental impact analyses rather than redoing these evaluations. Eden caveated that the relevant information would be included in their ER in a summary form in those instances where important supplemental information needed to be included.

The NRC staff's questions included how the ongoing design of the facility would be considered in the ER given the early submittal plans and the licensing approach for the hot cell area.

Eden confirmed that it did not plan to submit the ER until the facility design was sufficiently complete such that further changes to the design would not require a change to the design information in the ER. Eden also stated that it plans to request a license under Title 10 of the *Code of Federal Regulations*, Part 50, for a utilization and production facility for the hot cell area and would provide confirmation at a later date for its licensing plans for the target fabrication and assembly area. Regarding the use of incorporation by reference, NRC staff cautioned that the ER must provide the basis for how the incorporated material is relevant to construction and operation impacts from the project and that some types of information can change (e.g., listed protected species) and that Eden should be sure to confirm that the incorporated information is still accurate.

There was also discussion regarding the standard for preparing an Environmental Assessment (EA) over that which requires the preparation of an Environmental Impact Statement (EIS). Eden indicated that they believed an EA may be appropriate in their case since they believe that there would be no "large" environmental impacts associated with the construction and operation of their proposed facility. The staff informed Eden that the standard for preparing an EA is whether the agency can conclude that there are no "significant" impacts. Eden requested that the staff consider the preparation of an EA rather than assuming from the outset that the preparation of an EIS will be warranted. The staff responded that there will be a deliberative decision making process on the NEPA approach that will be publicly documented.

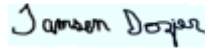
Eden representatives shared information regarding several public outreach efforts in the local community, including informal and informational meetings with schools, hospitals, and local fire and police departments. Eden reported that the public reaction to its project has been positive because of the nature of a medical isotope production facility.

Eden noted that it plans to coordinate additional pre-application meetings with the NRC regarding the environmental review, in addition to meetings for the safety review. The NRC noted that it would be particularly interested to learn about the status of Eden's efforts to obtain other necessary permits for the project, and Eden agreed to discuss those at the next meeting.

No members of the public requested an opportunity to ask questions or provide comment during the public participation portion of the meeting. The meeting was then adjourned.

Please direct any inquiries to me at 301-415.2272, or by electronic mail at Tamsen.Dozier@nrc.gov.

Sincerely,

Handwritten signature of Tamsen Dozier in blue ink.

Signed by Dozier, Tamsen  
on 10/15/21

Tamsen S. Dozier, Project Manager  
Environmental New Reactor Branch  
Division of Rulemaking, Environmental  
and Financial Support  
Office of Nuclear Material Safety  
and Safeguards

Project No. 99902077

Enclosure:  
As stated

cc:  
Mr. Chris Wagner, Chief Executive Officer  
Eden Radioisotopes, LLC  
520 Airport Dr. NW, Suite B5  
Albuquerque, NM 87110

SUBJECT: SUMMARY OF AUGUST 04, 2021, MEETING WITH EDEN RADIOISOTOPES,  
LLC (EPID NO. L-2019-LLL-0027) DATE: October 15, 2021

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ADAMS Accession Nos.: ML21202A455 Mtg. Notice

ML21217A054 Mtg. Slides

ML21265A365 Mtg. Summary

NRC-001

OFFICE	NMSS/REFS/PM*	NRR/DANU/PM*	NMSS/REFS/PM*
NAME	TDozier	MBalazik	RElliott
DATE	08/24/2021	09/09/2021	09/03/2021

OFFICIAL RECORD COPY

## LIST OF ATTENDEES

AUGUST 04, 2021, MEETING WITH EDEN RADIOISOTOPES, LLC

3:00 - 4:30P.M.

<u>Name</u>	<u>Organization</u>
Tami Dozier	U.S. Nuclear Regulatory Commission
Rob Elliott	U.S. Nuclear Regulatory Commission
Nancy Martinez	U.S. Nuclear Regulatory Commission
Kevin Folk	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Mary Casto	U.S. Nuclear Regulatory Commission
Jackson Goedjen	U.S. Nuclear Regulatory Commission
Duane Hardesty	U.S. Nuclear Regulatory Commission
Charles Kreuzberger	U.S. Nuclear Regulatory Commission
Steven Lynch	U.S. Nuclear Regulatory Commission
David Roth	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
Jim Saldarini	Eden Radioisotopes LLC
Bennett Lee	Eden Radioisotopes, LLC
Chris Wagner	Eden Radioisotopes, LLC
Paul Helmick	Eden Radioisotopes, LLC
Edward Parma	Eden Radioisotopes, LLC
Erin Wisler	Eden Radioisotopes LLC
Paul Schlavin	Eden Radioisotopes LLC
Michael Launi	Sargent & Lundy LLC
Frank Lear	Sargent & Lundy LLC
Maury Pressburger	Sargent & Lundy LLC
Paul Schlavin	Sargent & Lundy LLC
Kenneith Snell	Sargent & Lundy LLC
Michael Duffy	Sargent & Lundy LLC
Ryan Lighty	Morgan Lewis
Thomas Poindexter	Morgan Lewis
Lisa Matis	Tetra Tech
Daniel Ortiz	New Mexico Environment Department
Nicole Wallis	New Mexico Environment Department
Thomas Eiden	Atomic Alchemy Inc.

Enclosure