



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

March 9, 2020

APPLICANT: Eden Radioisotopes, LLC

SUBJECT: SUMMARY OF JANUARY 30, 2020, MEETING WITH EDEN RADIOISOTOPES, LLC (EPID NO. L-2019-LLL-0027)

On January 30, 2020, a Category 1 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of Eden Radioisotopes, LLC (Eden) at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville Maryland. The purpose of this meeting was to discuss licensing topics regarding Eden's proposed medical radioisotope project. The meeting notice and agenda, dated January 17, 2020, are available in the Agencywide Documents Access and Management System at Accession No ML20017A281. A list of meeting attendees is provided as an Enclosure 1 to this summary. No presentation was made at the meeting, however, a list of topics discussed is provided in Enclosure 2.

Eden first shared a brief update on its project status, including plans to request additional pre-application meetings to discuss proprietary information related to the designs and key technical areas. Eden discussed its interpretation of the definition of *production facility* in Title 10 of the *Code of the Federal Regulations* (10 CFR) 50.2, "Definitions." Specifically, Eden discussed paragraphs (3)(ii) and (3)(iii) of the *production facility* definition and how its interpretation could affect Eden's licensing path. Eden then discussed the possibility of submitting an application under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," for its proposed reactor, target processing, and target fabrication. Eden stated that this licensing approach could provide consistency and operational flexibility throughout the facility.

The NRC staff discussed historical precedence of licensing under 10 CFR Part 50 and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The NRC staff also indicated that 10 CFR 50.31, "Combining applications," allows for an applicant to combine in one several applications for different kinds of licenses under 10 CFR Part 50, and 10 CFR 50.52, "Combining licenses," states that the Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately. The NRC staff informed Eden that it could submit a request for written interpretation of the definition of *production facility*, as used in 10 CFR 50.2, to provide for a stable licensing process for its project. Eden then discussed approaches to performing accident and hazard analyses.

Three members of the public participated in this meeting but provided no comments. Please direct any inquiries to me at 301-415-4103, or by electronic mail at Linh.Tran@nrc.gov.

/RA/

Linh Tran, Senior 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/Docket No. 99902077

Enclosures:
As stated

cc: w/enclosures:

Mr. Bennett Lee, CEO/Co-Founder
Eden Radioisotopes, LLC
6100 Indian School Road NE
Suite 125
Albuquerque, NM 87110

SUBJECT: SUMMARY OF JANUARY 30, 2020, MEETING WITH EDEN RADIOISOTOPES, LLC. (EPID NO. L-2019-LLL-0027) DATED: MARCH 20, 2020

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OFFICE	NRR/DANU/UNPL/PM	NRR/DANU/UNPL/PM	NRR/DANU/UNPL/LA*
NAME	MGavello	LTran	NParker
DATE	3/9/2020	3/9/2020	3/9/2020
OFFICE	NRR/DANU/UNPL/BC	NRR/DANU/UNPL/PM	
NAME	GCasto	LTran	
DATE	3/9/2020	3/9/2020	

OFFICIAL RECORD COPY

LIST OF ATTENDEES

JANUARY 30, 2020, MEETING WITH EDEN RADIOISOTOPES, LLC.

1:00 P.M. - 4:00 P.M.

<u>Name</u>	<u>Organization</u>
Linh Tran	U.S. Nuclear Regulatory Commission
Molly-Kate Gavello	U.S. Nuclear Regulatory Commission
Brian Smith	U.S. Nuclear Regulatory Commission
Greg Casto	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Robert Schaaf	U.S. Nuclear Regulatory Commission
Steven Lynch	U.S. Nuclear Regulatory Commission
Yawar Faraz	U.S. Nuclear Regulatory Commission
Reginald Augustus	U.S. Nuclear Regulatory Commission
Mary Woods	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Ed Parma	Eden Radioisotopes, LLC
Bennett Lee	Eden Radioisotopes, LLC
Dick Coats	Eden Radioisotopes, LLC
Milton Vernon	Eden Radioisotopes, LLC
Paul Helmick	Eden Radioisotopes, LLC
Ryan Lighty	Morgan Lewis
Thomas Eiden	Atomic Alchemy
Jordan Hill	Atomic Alchemy
Joe Laprad	SHINE Medical Technologies, LLC

Discussion Topics for Eden Meeting
January 30, 2020

- Schedule/Status Update
- Production facility definition (hot cell facility, target fabrication facility)
- Potential Licensing under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 (all three)
 - o Final Safety Analysis Report/One-step licensing for 10 CFR Part 50
 - o Maximum Hypothetical Accident vs. Independent Safety Analysis methodologies
 - o Including Target Fabrication activities in “B” chapters as a subsection