



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

November 13, 2019

LICENSEE: Eden Radioisotopes, LLC

SUBJECT: SUMMARY OF OCTOBER 8, 2019, MEETING WITH EDEN RADIOISOTOPES, LLC (EPID NO. L-2019-LLL-0027)

On October 8, 2019, a Category 1 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of Eden Radioisotopes, LLC (Eden) via teleconference. The purpose of this meeting was to discuss the ongoing development and design of Eden's proposed medical radioisotope production project. The meeting notice and agenda, dated September 27, 2019, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML19270F870. Eden's presentation used in the meeting is also available in ADAMS at Accession No. ML19283B737. A list of meeting attendees is provided as an enclosure to this summary.

Eden presented a facility overview and its proposed licensing path and schedule for its radioisotope production project. Eden plans to submit a joint application for a construction permit and operating license for its reactor facility under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and a separate license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," for its hot cell and target fabrication facility. Eden also stated it plans to submit the environmental report with the 10 CFR Part 50 joint application and the information in the report would address the activities of all facilities. Eden indicated the reactor and hot cell facilities will share a target transfer pool and have a separating boundary. Eden expects to submit an application for the reactor facility license in June 2020 and an application for the hot cell facility in January 2021.

Eden then discussed the key documents needed for a 10 CFR Part 50 joint application for a construction permit and operating license. The NRC staff informed Eden that a joint application for a construction permit and operating license is expected to contain all the information required to be submitted with an operating license application including the final design of the facility, general and financial information, the final safety analysis report, technical specifications, the emergency plan, the physical security plan, and the operator qualification and requalification plan.

Eden inquired about the process for facility changes during operation and presented its proposed facility changes. The NRC staff stated the regulations for changes to a facility are provided in 10 CFR 50.59, "Changes, tests and experiments," for the reactor facility and 10 CFR 70.72, "Facility changes and change process," for the hot cell and target fabrication facility.

Eden described its processing line in more detail to provide clarification on the amount of uranium-235 (U-235) in each batch. Eden stated that each batch will have up to four targets equaling less than 100 grams of U-235 total in the batch. Eden then stated that there could be up to four batches processed at one time, each in a separate processing line. The NRC staff

informed Eden that Eden could submit a request for written interpretation of the definition of production facility, as used in 10 CFR 50.2, "Definitions," to determine whether its hot cell facility should be licensed under 10 CFR Part 50 or 10 CFR Part 70. The request should also describe Eden's basis for concluding that its hot cell facility could be licensed under 10 CFR Part 70.

Eden then discussed a range of solutions for its target qualification. Eden plans to request additional pre-application meetings to continue discussing its proposed project.

Please direct any inquiries to Linh Tran at 301-415-4103 or 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

Enclosure:
As stated

cc: w/enclosure:

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

SUBJECT: SUMMARY OF OCTOBER 8, 2019, MEETING WITH EDEN RADIOISOTOPES, LLC. (EPID NO. L-2019-LLL-0027) DATED NOVEMBER 13, 2019

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ADAMS Accession Nos.: ML19311C636 Package
ML19270F870 Mtg. Notice
ML19311C690 Mtg. Summary
ML19283B737 Slides *concurring via email NRC-001

OFFICE	NRR/DANU/UNPL/PM*	NRR/DANU/UNPL/PM	NRR/DANU/UNPL/LA*	NRR/DANU/UNPL/BC	NRR/DANU/UNPL/PM
NAME	MGavello	LTran	NParker	GCasto	LTran
DATE	11/8/19	11/12/19	11/8/19	11/12/19	11/13/19

OFFICIAL RECORD COPY

LIST OF ATTENDEES

OCTOBER 8, 2019, MEETING WITH EDEN RADIOISOTOPES, LLC.

10:00 A.M. - 12:30 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
John Monninger	U.S. Nuclear Regulatory Commission
Greg Casto	U.S. Nuclear Regulatory Commission
Joseph McManus	U.S. Nuclear Regulatory Commission
Alexander Adams	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
David Tiktinsky	U.S. Nuclear Regulatory Commission
Robert Schaaf	U.S. Nuclear Regulatory Commission
Steven Lynch	U.S. Nuclear Regulatory Commission
Lisa Clark	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
Nancy Martinez	U.S. Nuclear Regulatory Commission
Lynnea Wilkins	U.S. Nuclear Regulatory Commission
Ed Parma	Eden Radioisotopes, LLC
Paul Helmick	Eden Radioisotopes, LLC
Bennett Lee	Eden Radioisotopes, LLC
Dick Coats	Eden Radioisotopes, LLC
Milton Vernon	Eden Radioisotopes, LLC
Jessica Bridges	Eden Radioisotopes, LLC
John Garcia	Eden Radioisotopes, LLC
Joe Laprad	SHINE Medical Technologies, Inc.
Jordan Hill	Atomic Alchemy
Thomas Eiden	Atomic Alchemy
John Stang	RadWaste Monitor

Enclosure