

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

August 26, 2020

APPLICANT: Eden Radioisotopes, LLC

SUBJECT: SUMMARY OF JULY 16, 2020, MEETING WITH EDEN RADIOISOTOPES, LLC (EPID NO. L-2019-LLL-0027)

On July 16, 2020, 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 licensing topics regarding Eden's proposed medical radioisotope project. The meeting notice and agenda, dated July 6, 2020, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML20188A224. Eden's presentations used in the meeting are also available in ADAMS at Accession No. ML20216A306. A list of meeting attendees is provided as an enclosure to this summary.

Eden first provided a brief update on its project status, including the target completion and submission of the final safety analysis report and the environmental report by October 1, 2020. Eden presented a change regarding the application format that would now include Part A, for the reactor activities, and Part B, for the hot cell and target activities. Eden stated that the new format would reduce redundancy in addressing the hot cell and the target fabrication facility.

Eden stated that it is pursuing the one-step licensing approach. The NRC staff confirmed that Eden continues to plan to submit a joint application for a construction permit and operating license under Title 10 of the *Code of the Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The NRC staff reiterated that if Eden is requesting a construction permit and operating license simultaneously, Eden would need to ensure that the application includes all necessary information to be reviewed by the NRC staff. The NRC staff also indicated that, if Eden submitted an application for a construction permit followed by an application for an operating license at a later date, Eden could use the provision provided in 10 CFR 50.35, "Issuance of Construction Permits," paragraph (c), which allows certain portions of the final design that are completed to be reviewed by the NRC prior to the submission of the operating license application.

Eden presented the outline of the content in its proposed Chapter 4A., "Reactor Description," of its application to illustrate the approach, level of detail, and analysis that will be included in the application.

During the portion of the meeting closed to the public, Eden went into proprietary-level detail related to the design of the reactor. Eden described the differences between driver and nominal targets, indicating a similar design with different design intents. Eden provided a summary of the design basis for the target elements and operational requirements that would be imposed. Eden also presented an overview of the reactor design including the reactor core, safety and control rods, reactor pool, and transfer canal.

The NRC staff expressed the need for additional pre-application meetings to understand the status of the development of various technical areas, which would be beneficial to both the NRC staff and Eden. Key topics of future meetings could include the licensing strategy, a pre-application readiness assessment, and an electronic reading room. Key technical areas could include target fabrication, thermal hydraulics, accident analysis, and the environmental report.

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

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

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ADAMS Accession Nos.: ML20188A224 Mtg. Notice ML20216A306 Mtg. Slides

	ML20231A776 Mtg. Summary *concurred via email				NRC-001
OFFICE	NRR/DANU/PM*	NRR/DANU/PM*	NRR/DANU/LA*	NRR/DANU/BC*	NRR/DANU/PM*
NAME	MKGavello	LTran	NParker	GCasto	LTran
DATE	8/20/2020	8/20/2020	8/20/2020	8/25/2020	8/26/2020

OFFICIAL RECORD COPY

LIST OF ATTENDEES

JULY 16, 2020, MEETING WITH EDEN RADIOISOTOPES, LLC

<u>1:00 P.M. -4:00 P.M.</u>

<u>Name</u>

Michael Balazik Antonio Barrett Tison Campbell Greg Casto Lisa Clark Phyllis Clark Jeremy Dean Tami Dozier Molly-Kate Gavello Jackson Goedien Edward Helvenston Steven Lynch Nancy Martinez Joseph McManus Brian Smith Joseph Staudenmeier Robert Taylor David Tiktinsky Linh Tran Elizabeth Reed Christopher Van Wert Jeremy Wachutka **Diana Woodyatt** Mitzi Young Bennett Lee Chris Wagner **Richard Coats Krvstal Harlow Edward Parma** Michael Raddatz Milton Vernon Paul Helmick Anthony Baca Alexander Adams **Edward Baker** Gerald Hilderbrand Mark Speck Mary Adams Rvan Lighty Thomas Poindexter **Rachel Houseman** Steven Miltenberger Jake Jackson

Organization

U.S. Nuclear Regulatory Commission Eden Radioisotopes, LLC Morgan Lewis Morgan Lewis SHINE Medical Technologies, LLC SHINE Medical Technologies, LLC **Representative Torres Small**