

August 29, 2013

Bennett J. Lee  
Chief Executive Officer  
Eden Radioisotopes, LLC  
1508 Dartmouth Avenue, NE  
Albuquerque, NM 87106

SUBJECT: EDEN RADIOISOTOPES, LLC – ASSIGNMENT OF PROJECT NUMBER AND EXPLANATION OF BILLING

Dear Mr. Lee:

By letter dated May 20, 2013 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13144A083), Eden Radioisotopes, LLC (Eden), indicated its intent to submit applications to construct and operate a medical radioisotope production facility. Prior to the submittal of a construction permit application, Eden may engage in pre-application activities, such as public meetings and formal requests for interpretations of regulations. To facilitate these activities, U.S. Nuclear Regulatory Commission (NRC) staff has assigned Eden a project number. As such, Eden should reference Project No. 0802 (PROJ0802) in all future correspondence supporting pre-application licensing activities with the NRC. Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," Eden will be charged for the hours NRC staff apply to this project, beginning in the current fiscal quarter. Accordingly, NRC staff has assigned a billable technical assignment control (TAC) number (MF2286) to Eden's project. All NRC staff time devoted to pre-licensing activities, beyond an initial introductory presentation of technological and licensing concepts, conducted specifically in support of Eden's anticipated application for a construction permit, will be charged to this TAC number. However, recognizing the unique licensing considerations that medical radioisotope production facilities may pose, NRC staff will not charge Eden for time spent developing generic licensing infrastructure and guidance.

Following the receipt and acceptance of a construction permit application, Eden will be assigned a formal docket number. Specific licensing tasks will be assigned additional TAC numbers and Eden will be billed for the NRC staff's hours applied to those TAC numbers in accordance with 10 CFR Part 170. Following the issuance of an operating license, Eden will be billed, as applicable, an annual fee in accordance with 10 CFR Part 171, "Annual Fees for Reactor

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Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.”

Any questions regarding this matter may be addressed to me directly at 301-415-1524 or [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Sincerely,

***/RA/***

Steven Lynch, Project Manager  
Research and Test Reactors Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. PROJ0802

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Project No. PROJ0802

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**ADAMS Accession No. ML13234A467**

**NRR-106**

OFFICE	NRR/PRLB/PM	NRR/PROB/LA	NRR/PRLB/BC	NRR/PRLB/PM
NAME	SLynch	P Blechman	AAdams	SLynch
DATE	8/22/2013	8/26/2013	8/29/2013	8/29/2013

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