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EDEN-NRC-2025-001

January 17, 2025

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Reference: Eden Radioisotopes, LLC
Eden Isotope Production Complex Project/Docket No.: 99902077

Subject: Eden Isotope Production Complex
Request to Conduct an NRC Preapplication Readiness Assessment of the
Eden Draft PSAR

Enclosure: Eden Draft PSAR Preapplication Readiness Assessment Estimate

Dear Sir or Madam:

Eden Radioisotopes, LLC letter to the NRC dated August 7, 2023 (ADAMS Accession No. ML23230B208), informed the NRC of its intent to submit applications for a construction permit and an operating license for a medical isotope production facility called the Eden Isotope Production Complex.

The purpose of this letter is to request that the NRC conduct a high-level review of the Eden Draft Preliminary Safety Analysis Report (PSAR) to assess the sufficiency of this portion of the Eden License Application for docketing.

The Eden PSAR follows the format and content guidelines of NUREG-1537 and the associated Interim Staff Guidance (ISGs). Please see the enclosure for the Eden estimate of NRC staff review hours needed to conduct this review and publish their final report.

We request that the NRC safety review subject matter experts (SMEs) perform this high level review within their technical areas of responsibility. The desired outcome is to determine if the PSAR has areas where the NRC reviewer believes information is missing to the extent that would prevent docketing of the Eden License Application at the time of formal submittal.

It must be emphasized that the review being requested is not a technical review of the information being presented. Rather, as noted above, it is essentially a docketing “gap” assessment of the completeness of the PSAR relative to the guidelines of NUREG-1537 and the ISGs.

Eden PSAR Chapters will be posted in the Eden on-line reference portal for limited “read only” access, and will remain available to all authorized NRC reviewers until such time as the entire PSAR sufficiency review effort is completed. In addition, as PSAR Chapter reviews are completed, Eden requests that a short meeting be held to allow the NRC to discuss the results of their chapter review with Eden.

Eden has budgeted 260 hours for the NRC review under a 4-6 week schedule to start in mid-February 2025. An additional allowance has also been made for the final report preparation. Eden’s estimate for the NRC to conduct this audit and issue their final report is \$90,000.

If, prior to or during the course of this review, the Eden budget is deemed insufficient to complete the review, Eden SMEs will be available as requested by NRC to support this review.

If you have any questions, please feel free to contact me or Mr. James Saldarini, Eden Licensing Director, at 240-344-5204 (jsaldarini@edenrad.com).

Sincerely,

A handwritten signature in cursive script that reads "Chris Wagner".

Chris Wagner
Chief Executive Officer
Eden Radioisotopes, LLC

cc: Linh N. Tran, NRC (NRR/DANU/UNPL)

Eden Draft Preliminary Safety Analysis Report (PSAR)
Eden Hourly Estimate to Conduct a Preapplication Readiness Assessment

Chapter	Title	PSAR Content (pages, incl. figures)	NRC Audit Estimate (hours)
01	The Facility	25	8
02	Site Characteristics	202	20
03	Design of Structures, Systems and Component	106	18
04a	Reactor Description	130	18
04b	Radioisotope Production Facility Description	64	18
05a	Reactor Coolant System	48	8
05b	Radioisotope Production Facility Coolant System	54	8
06a	Reactor Engineered Safety Features	6	6
06b	Radioisotope Production Facility Engineered Safety Features	12	8
07a	Reactor I&C Systems	50	16
07b	Radioisotope Production Facility I&C Systems	38	16
08	Reactor and Radioisotope Production Facility Electrical Power Systems	18	10
09	Reactor and Radioisotope Production Facility Auxiliary Systems	60	16
10	Experimental Facilities and Utilization	NA	-
11	Radiation Protection Program & Waste Management	31	16
12	Conduct of Operations	66	16
13a	Reactor Accident Analysis	53	24
13b	Radioisotope Production Facility Accident Analysis	57	24
14	Technical Specification	18	8
15	Financial Qualifications	4	2
16	Other License Considerations	NA	-
17	Decommissioning	NA	-
18	Highly Enriched to Low-Enriched Conversion	NA	-
19	Environmental Report	NA	NA

Total Review Hours 260 x NRC Hourly Rate \$317/hour = \$82,420. Prepare/Issue Final Report. Total Estimate: \$90,000.