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PRD J 0802

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

RE: REQUEST FOR EXEMPTION TO SUBMIT A CONSTRUCTION PERMIT APPLICATION IN TWO PARTS AS DESCRIBED IN 10 CFR 2.101 BY EDEN RADIOISOTOPES, LLC

The purpose of this letter is to request an exemption under 10 CFR 50.12 to submit a Construction Permit Application in two parts for the Eden Radioisotopes, LLC ("Eden") Isotope Production Facility (IPF). Eden believes that our request meets the requirements for an exemption under 10 Code of Federal Regulations (CFR) 50.12 because the requested exemption is authorized by law, does not present an undue risk to the public health and safety, will not endanger the common defense and security, and because special circumstances are present such that the exemption should be granted. Thus, the requested exemption would allow Eden to submit a Construction Permit Application for an IPF in two parts in accordance with the provisions of 10 CFR 2.101(a)(5).

For the first time since the late 1980s, the United States has the opportunity to produce a domestic, globally competitive source of molybdenum-99 (^{99}Mo). Eden intends to design and construct an IPF and intends to produce ^{99}Mo , the parent isotope of the most commonly used nuclear medicine imaging isotope, technetium-99m ($^{99\text{m}}\text{Tc}$) by 2023. Eden will build a full-scale facility that will produce up to the entire global demand for this product. The facility will include a reactor, hot cell processing facility, and possibly a fuel fabrication facility.

Proposed Exemption

Per the U.S. Nuclear Regulatory Commission (NRC) (Reference 1), Eden must apply for an exemption under 10 CFR 50.12 in order to submit its Construction Permit Application in two parts, as described in 10 CFR 2.101(a)(5). To submit a Construction Permit Application (per 10 CFR 50) in two parts [per 10 CFR 2.101(a)(5)], the proposed facility must be subject to 10 CFR 51.20(b) which identifies the types of actions that require an environmental impact statement (EIS). Construction and operation of a medical isotope production facility does not require an EIS under 10 CFR 51.20(b), therefore 10 CFR 2.101(a)(5) does not apply to such facilities (Reference 1).

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Although construction and operation of a medical isotope production facility does not require an EIS under 10 CFR 51.20(b), the Commission could determine that Eden's proposed action should be covered by an EIS. Early review of the Environmental Report would enable the Commission to make an earlier determination if an EIS, in accordance with 10 CFR 51.20(a)(2), is required. This early determination should be performed as soon as possible, which will allow Eden to realign resources and mitigate schedule impacts as a result of the expected longer review timeline associated with an EIS. If no EIS is required, a two-part application would facilitate potential earlier completion of the environmental review and ultimate issuance of the Construction Permit and construction of the Eden IPF.

10 CFR 50.12 states that the Commission may grant an exemption from requirements of the regulations provided that: 1) the exemption is authorized by law; 2) the exemption will not result in an undue risk to public health and safety; 3) the exemption is consistent with the common defense and security; and 4) special circumstances, as defined in 10 CFR 50.12(a)(2) are present.

As pertinent here, special circumstances are defined to include either: a) application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or b) the exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption.

The requested exemption to allow Eden to submit an application for a Construction Permit in two parts satisfies these requirements, as described below, including the two special circumstances listed above.

1. The requested exemption is authorized by law.

No law exists which precludes the activities covered by this exemption request. The Eden IPF will be licensed under Section 103 of the Atomic Energy Act of 1954 (AEA), 42 U.S.C. § 2133, as amended. Nothing in AEA § 103 prohibits the submittal of a Construction Permit Application for a Class 103 facility in multiple parts, nor does any other statute.

The NRC has promulgated 10 CFR 2.101(a)(5) to authorize certain types of Construction Permit applicants to submit their application in multiple parts, including Class 103 facilities under 10 CFR 50.22, confirming that this process is not prohibited by statute. As explained in Item 4 below, the regulatory history of 10 CFR 2.101(a)(5) suggests that the reason medical isotope production facilities have been omitted from this authorization is because the need for such an option has not previously arisen.

This exemption request does not change the quality or content of the Environmental Report or the PSAR and is administrative in nature. Therefore, the requested exemption is authorized by law.

2. The requested exemption does not present an undue risk to the public health and safety.

No risk to public health and safety is presented by the requested exemption. Eden will satisfy all of the substantive licensing criteria in 10 CFR 50 and 51 in its full Construction Permit Application. The NRC will have the necessary time to conduct a complete safety and environmental review of the Construction Permit Application, and the full right of public participation in the licensing process will be afforded in accordance with the Commission's regulations. The NRC will not issue the Construction Permit until it makes the requisite findings under both 10 CFR 50 and 51. Accordingly, granting the exemption will not interfere with the licensing or public participation process in any respect.

As explained in Item 4 below, if the exemption is approved and the Construction Permit ultimately granted, there will be significant benefits to the public health and safety.

3. The requested exemption will not endanger the common defense and security.

The NRC's substantive requirements for a Construction Permit will be fully met in Eden's application. The submittal of the application for a Construction Permit in two parts will in no way affect the security or safeguards features or programs at the facility at any point during construction or operation. Accordingly, the granting of the requested exemption is consistent with the common defense and security.

4. Special circumstances, as defined in 10 CFR 50.12(a)(2), are present. Eden feels that our request meets the special circumstances defined in 10 CFR 50.12(a)(2)(ii) and (iv).

- a) 10 CFR 50.12(a)(2)(ii) – Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.

The requested exemption meets these special circumstances because a strict application of 10 CFR 2.101(a)(5) would not serve the underlying purpose of the rule. The authorization to submit certain Construction Permit Application in two parts, up to six months apart, dates to 1974, when the Atomic Energy Commission (AEC) authorized the separate submittal of the PSAR and Environmental Report for nuclear power reactors under 10 CFR 2.101(a) and was later modified to link the authorization to submit a Construction Permit Application in multiple parts to facilities for which an EIS must be prepared, and this link was carried forward when 10 CFR 2.101(a)(5) was first promulgated in 1976. The current 10 CFR 2.101(a)(5) allows Construction Permit applicants to submit their application in two parts, but only when the application is for certain facilities where an EIS is required.

- b) 10 CFR 50.12(a)(2)(iv) – The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption.

In publishing the original 1974 rule authorizing, in 10 CFR 2.101(a), the submittal of the Construction Permit Application for nuclear power reactors in two parts, the AEC noted that at that time, there was “deep national concern over energy sources and supply,” and that the amendments were intended to “reduce the time required to bring on line nuclear power plants which satisfy all environmental and safety requirements.” Further, there was a public interest in “removing unnecessary obstacles” to the construction of needed power plants.

Eden’s requested exemption meets the special circumstances of 10 CFR 50.12(a)(2)(iv) because the granting of an exemption here is in the public interest. As previously noted, the demand for medical isotopes is a significant national public health and safety concern. This concern is similar to the AEC’s concerns regarding the need for nuclear power reactors at the time the two-part process was established.

Therefore, in accordance with the provisions of 10 CFR 50.12, Eden requests an exemption to allow submittal of a Construction Permit Application for an IPF in two parts in accordance with the provisions of 10 CFR 2.101(a)(5). These provisions state that one part of the submittal must include the environmental report required by 10 CFR 50.30(f), while the other part must include the PSAR required by 10 CFR 50.34(a).

Below presents the information that Eden proposed to include in each part of the Construction Permit Application:

- Construction Permit Application, Part 1:
 - Description and Safety Assessment of the site required by 10 CFR 50.34(a)(1)
 - Environmental Report required by 10 CFR 50.30(f)
 - Filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21
 - General information required by 10 CFR 50.33
 - Agreement limiting access to classified information required by 10 CFR 50.37
- Construction Permit Application, Part 2:
 - Remainder of PSAR required by 10 CFR 50.34(a)
 - Application will be submitted in accordance with requirements of 10 CFR 2.101(a)(5)

Based on the above, special circumstances are present that fully support the request for an exemption to submit a Construction Permit in two parts to be granted under 10 CFR 2.101. Approval of the Exemption Request is requested by August 1, 2019. This letter contains no new Regulatory Commitments and no revisions to existing Regulatory Commitments.



If you have any questions, please contact Dr. Richard Coats, Chief Technology Officer, on (505)-270-2629.

Sincerely,

Bennett J. Lee
Chief Executive Officer
Eden Radioisotopes, LLC

cc: Michael Balazik, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

References:

- 1) U.S. Nuclear Regulatory Commission Research and Test Reactor Licensing Branch (S.T. Lynch, M.H. Voth, and L.N. Tran), *Regulatory Preparations for Licensing Medical Radioisotope Production Facilities*, 2013, Rockville, MD