



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

March 6, 2024

Mr. Chris Wagner, Chief Executive Officer  
Eden Radioisotopes, LLC  
9400 Holly Ave. NE, Suite 202  
Albuquerque, NM 87122

SUBJECT: EDEN RADIOISOTOPES, LLC – ELECTRONIC REFERENCE PORTAL  
INFORMATION ACCESS AGREEMENT

Dear Mr. Wagner:

By letter dated August 7, 2023 (Agencywide Documents Access and Management System Accession No. ML23230B208), Eden Radioisotopes, LLC (Eden) informed the U.S. Nuclear Regulatory Commission (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.

To support pre-application interactions, Eden and the NRC staff discussed the use of an electronic reference portal that would provide authorized NRC staff and contractors with limited read-only access to certain materials owned by or under the control of Eden. Access to the electronic reference portal would require an NRC process (such as a regulatory audit) and the information therein would be treated as proprietary/business confidential information and would not be shared or copied. Pre-application engagement would be done in accordance with the NRC Office of Nuclear Reactor Regulation's Office Instruction LIC-116, "Preapplication Readiness Assessment" (ML20104B698).

The purpose of the electronic reference portal is to enhance the NRC's ability to timely and efficiently engage in pre-application activities and other regulatory responsibilities, as well as in the subsequent review of a construction permit application and an operating license application, by providing access to reference materials. If the NRC staff determines that information viewed or accessed via the electronic reference portal is necessary for formal evaluation or otherwise necessary to support the NRC staff's regulatory licensing responsibilities, the NRC staff will request that Eden formally submit such information in accordance with Title 10 of the *Code of Federal Regulations* Section 50.4, "Written communications."


The enclosed "Information Access Agreement" should be used as the only acknowledgement form for the authorized NRC staff's and contractors' access to the electronic reference portal. Any proposed modification or addition to the enclosed "Information Access Agreement" would require further review by the NRC. The NRC requests that Eden sign, date, and return the "Information Access Agreement" enclosed with this letter.

C. Wagner

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If you have any questions or comments about this matter, please contact Linh Tran at (301) 415-4103 or via email at [Linh.Tran@nrc.gov](mailto:Linh.Tran@nrc.gov)

Sincerely,

 Signed by Cruz, Holly  
on 03/06/24

Holly D. Cruz, Acting Chief  
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 No. 99902077

Enclosure:  
As stated

cc w/enclosures: GovDelivery Subscribers

SUBJECT: EDEN RADIOISOTOPES, LLC – ELECTRONIC REFERENCE PORTAL  
INFORMATION ACCESS AGREEMENT DATED: MARCH 5, 2024

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**NRR-106**

<b>OFFICE</b>	NRR/DANU/UNPL/PM	NRR/DANU/UNPL/LA	NRR/DANU/UNPL/ABC
<b>NAME</b>	LTran	NParker	HCruz
<b>DATE</b>	02/22/2024	02/22/2024	02/22/2024
<b>OFFICE</b>	OGC	NRR/DANU/ADD	NRR/DANU/UNPL/ABC
<b>NAME</b>	JWachutka	JBorromeo	HCruz
<b>DATE</b>	03/05/2024	03/05/2024	03/06/2024

**OFFICIAL RECORD COPY**

**INFORMATION ACCESS AGREEMENT BETWEEN**

**EDEN RADIOISOTOPES, LLC**

**AND**

**THE UNITED STATES NUCLEAR REGULATORY COMMISSION**

This agreement is made and effective on the 6th day of March, 2024 by and between the UNITED STATES NUCLEAR REGULATORY COMMISSION (“NRC”) and EDEN RADIOISOTOPES, LLC (“Eden”) (collectively “the Parties”) for the purpose of facilitating the NRC’s access to an electronic reference portal maintained by Eden, through which the NRC staff and contractors approved in accordance with section 1 (“the authorized NRC staff and contractors”) may access certain documents related to activities associated with the development of the Eden applications for a construction permit and an operating license for a medical isotope production facility.

Whereas Eden desires to enhance the NRC’s ability to timely and efficiently perform its regulatory licensing responsibilities with respect to activities associated with the Eden construction permit and operating license applications, including by providing the authorized NRC staff and contractors with access to certain documents owned by or under the control of Eden through an electronic reference portal so that the NRC may access such information in a timely manner; and

Whereas information accessed by the authorized NRC staff and contractors may consist of information considered by Eden to be trade secrets or privileged or confidential commercial and financial information (“Proprietary Information”); and

Whereas Eden is willing to make such Proprietary Information available to the authorized NRC staff and contractors for the purpose of promoting timely and efficient performance of the NRC’s regulatory licensing responsibilities with respect to activities associated with the Eden construction permit and operating license applications, subject to the terms and conditions set forth below.

The Parties mutually agree as follows:

**Terms:**

1. At no charge to the NRC, Eden agrees to maintain and make available to the authorized NRC staff and contractors an electronic reference portal in which Eden will provide access to documents relating to activities associated with the Eden construction permit and operating license applications, which may include Proprietary Information. Eden will provide the NRC with login credential access to the electronic reference portal. The Parties will separately agree upon a list of the authorized NRC staff and contractors permitted to use the login credential access. This list of authorized users will include only the NRC staff and contractors who have been determined to have a requisite need to access the electronic reference portal in furtherance of official duties in relation to regulatory licensing responsibilities with respect to activities associated with the Eden construction permit and operating license applications. This list of authorized users may be revised from time to time upon agreement of the Parties. The points of contact for the

Enclosure

Parties, for the purpose of agreeing upon the list of authorized users, are Eden's Licensing Manager (for Eden) and the NRC's Lead Project Manager for Eden (for the NRC).


2. The authorized NRC staff and contractors may use the electronic reference portal only to access Eden documents, including Proprietary Information, and only in furtherance of official duties and in accordance with any of Eden's reasonable policies and procedures governing access and use. The Parties expressly recognize that Eden reserves the right to revoke the NRC's access to the electronic reference portal at any time.
3. The electronic reference portal will be available to the authorized NRC staff and contractors through "read only" access with no capability to: (a) modify information on the electronic reference portal, (b) control the electronic reference portal application, or (c) print, save, or download information from the electronic reference portal. Use of snipping tools, screenshots, or taking photographs is prohibited.
4. The Parties expressly acknowledge that documents placed into the electronic reference portal and made available to the authorized NRC staff and contractors are owned by or under the control of Eden. The NRC does not consider documents placed in the electronic reference portal to constitute "agency records" for purposes of the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the NRC's implementing FOIA regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 9, "Public Records." The fact that Eden makes Proprietary Information available to the NRC as provided in this agreement shall not, in and of itself, be construed as a waiver of the proprietary nature of such Proprietary Information, or as an indication that such information residing within the electronic reference portal is not "owned by," "under the control of," or "in the possession of" Eden.
5. If the NRC determines that information viewed or accessed via the electronic reference portal is necessary for formal evaluation or otherwise necessary in support of the NRC's regulatory responsibilities with respect to activities associated with the Eden construction permit and operating license applications, the NRC will request that Eden formally submit such information in accordance with 10 CFR 50.4, "Written communications." Eden shall abide by the requirements in 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," paragraph (b) when submitting such information to the NRC if Eden seeks to have information contained within that correspondence withheld from public disclosure. If the NRC receives a FOIA request that encompasses records formally submitted by Eden to the NRC in accordance with the requirements of 10 CFR 2.390(b), such information shall be subject to disclosure only in accordance with the provisions of 10 CFR 9.19, "Segregation of exempt information and deletion of identifying details."
6. Information made available to the authorized NRC staff and contractors only through the electronic reference portal does not constitute "communications" as part of the NRC formal licensing, oversight, or enforcement functions with respect to the Eden construction permit and operating license applications pursuant to applicable regulations contained in 10 CFR. Eden is not required to submit an affidavit or mark documents in accordance with 10 CFR 2.390 when making them accessible through the electronic reference portal. Eden makes no warranty, guarantee, or representation as to the completeness or accuracy of information that the authorized NRC staff or contractors access through the electronic reference portal. The NRC requirements governing

completeness and accuracy of information apply to any information that Eden submits to the NRC in accordance with NRC regulations, or information that Eden is otherwise required to maintain or provide pursuant to statute, order, license, or regulation.

7. This Agreement may be modified at any time in writing signed by the Parties. Either party shall have the right, upon written notice to the other party, to terminate this Agreement, in whole or in part, at any time, without cost, penalty, or liability to any party.

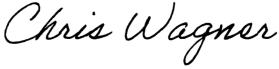
**IN WITNESS WHEREOF**, the undersigned have executed this Agreement.

**UNITED STATES NUCLEAR REGULATORY COMMISSION**

By:  Signed by Borrromeo, Joshua  
on 03/05/24  
Signature Date

**Joshua M. Borrromeo, Acting Deputy Director, Division of Advanced Reactors and Non-Power Production and Utilization Facilities**  
Printed Name and Title

**EDEN RADIOISOTOPES, LLC**

By:  March 6, 2024  
Signature Date

Chris Wagner, CEO  
Printed Name and Title