



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

February 9, 2022

Dr. William Peters  
Radiation Safety Officer  
Niowave, Inc.  
1012 North Walnut Street  
Lansing, Michigan 48906

SUBJECT: ACKNOWLEDGEMENT OF RECEIPT OF REGULATORY ENGAGEMENT  
PLAN FROM NIOWAVE FOR A MEDICAL ISOTOPES FACILITY LICENSED  
UNDER 10 CFR PART 70 (ENTERPRISE PROJECT IDENTIFICATION  
NUMBER: L-2022-LRM-0012)

Dear Dr. Peters:

By letter dated December 3, 2021 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML22011A315), Niowave, Inc. (Niowave) provided the Office of Nuclear Material Safety and Safeguards (NMSS) of the U.S. Nuclear Regulatory Commission (NRC) its regulatory engagement plan (REP) for production of Molybdenum-99 (Mo-99) and other medical isotopes at its facilities located in Lansing, Michigan.

The REP described Niowave's medical isotopes production program in three phases. Phase I involves ongoing laboratory scale activities licensed by the NRC's Region III office. Phase II, for which Niowave submitted an application to the NRC's Region III office on October 1, 2021 (ADAMS Accession No. ML21288A118, non-public), involves a pilot facility processing less than a critical mass of special nuclear material to produce Mo-99. Phase III involves a full-scale Mo-99 production facility. By letter dated January 12, 2022 (ADAMS Accession No. ML22012A443), however, Niowave withdrew the amendment request dated October 1, 2021, for its Phase II pilot medical isotopes facility. At that time, Niowave verbally informed the NRC that, as a result of the withdrawal of the Phase II application, Niowave, may need to revise its plans for submitting future license applications to the NRC. To aid in NRC planning, it would be helpful for you to submit to the NRC any revised plans for submitting future applications. In addition, since this will be a first-of-a-kind application under 10 CFR Part 70, it would help expedite NRC review if you identified the specific regulatory requirements and guidance you intend to follow in the areas of safety, safeguards, security, and environment, including any acceptance criteria you will be using to develop your application documents.

As requested in your December 3, 2021 REP, we support conducting pre-application discussions in which we can discuss your plans and schedule for submitting a license application for a Mo-99 production facility and the specific regulatory requirements and guidance, including any acceptance criteria you will be using to develop your application, as well as the proposed contents of your application. Such discussions should also facilitate your efforts in preparing a complete and high-quality application that the NRC can accept for technical review, as well as facilitate the NRC staff's understanding of the key safety,

safeguards, security, and environmental aspects of your facility. To make the discussions meaningful and efficient, providing the NRC an annotated outline of the application you intend to submit would also be very useful. It would also help facilitate discussions at future pre-application meetings if you could provide the items mentioned in the final two sentences of previous paragraph before the said meeting.

Niowave's project under NMSS has been assigned Docket Number 07007036. Your request for pre-application engagement has been assigned Enterprise Project Identification Number (EPID) L-2022-LRM-0012. Please reference this EPID number and Docket Number 07007036 in any future correspondence associated with this request.

In accordance with Title 10 of the *Code of Federal Regulations*, Section 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room, or from the Publicly Available Records component of the NRC's ADAMS. The ADAMS database is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>

If you have any questions regarding this communication, please contact me by telephone at 301-415-7220, or via e-mail at [Yawar.Faraz@nrc.gov](mailto:Yawar.Faraz@nrc.gov).

Sincerely,



Yawar H. Faraz, Senior Project Manager  
Fuel Facility Licensing Branch  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 70-7036

cc: Dr. Terry Grimm, Chief Executive Officer and Senior Scientist, Niowave  
M. Postman, National Nuclear Security Administration, Department of Energy

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**ADAMS Accession Number: ML22035A075**

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