



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 15, 2019

Terry Grimm, Ph.D.
President & Senior Scientist
Niowave, Inc.
1012 N. Walnut Street
Lansing, MI 48906-5061

Dear Dr. Grimm:

This refers to our telephone conference on February 12, 2019, between several members of the staff at Niowave, Inc. (Terry Grimm, Ph.D., President & Senior Scientist, Mike Zamara, Chief Financial Officer, William Peters, Ph.D., Radiation Safety Officer (RSO), and Amanda Grimm, Nuclear Engineer & Assistant RSO) and staff from the NRC Region III Materials Licensing Branch (Patricia Pelke, Chief, Materials Licensing Branch, Cassandra Frazier, Senior Health Physicist, and Frank Tran, Health Physicist) to discuss an electronic mail (email) submitted by your RSO, William Peters, Ph.D. on January 30, 2019, with an attached letter dated January 30, 2019. The letter included information in response to the items we identified in our letter dated January 24, 2019, which transmitted Amendment No. 07 to your NRC License No. 21-35144-02. We requested a conference call with Niowave, Inc. to discuss the information you planned to submit and asked you to highlight to us how the new information addressed the deficiencies previously identified in our review for Amendment No. 07 to your license.

In addition to the information submitted regarding the license, Dr. Peters sent another email later the same day (January 30, 2019) to notify Region III that Niowave, Inc. issued a press release dated January 28, 2019, which highlighted its radioisotope production activities. The press release included information which indicated that molybdenum-99 (Mo-99) was produced in large quantities and extracted from irradiated low enriched uranium. During our conference call, the NRC Region III staff stated that the information included in the press release did not align with the current licensed activities as specified in Amendment No. 07 to your NRC License No. 21-35144-02. The current license limits the extraction of no greater than 10 microcuries of Mo-99 from irradiated natural uranium.

Subsequent to our February 12, 2019 conference call, the Department of Energy (DOE) issued a press release dated February 20, 2019, announcing the US companies DOE would begin negotiations with for new cooperative agreement awards for production of Mo-99. Niowave, Inc. was included in the list of four US companies. As a result of this information, the NRC wants to gain a better understanding of the plans Niowave, Inc. has for its commercial operation in order to determine the appropriate licensing approach and regulatory process required. If the NRC determines that the Niowave, Inc. subcritical assembly should be licensed as a utilization facility under 10 CFR Part 50, a rulemaking would be needed.

During the conference call, the NRC Region III staff discussed several documents that provide useful information regarding the NRC regulatory process for applicants who plan to use low enrichment uranium in a subcritical assembly for the production of activated radioactive materials or fission products, including Mo-99. We have included links to several publically available reference documents submitted by SHINE for regulatory interpretation and the NRC's response related to the appropriate licensing approach for its proposed demonstration unit (note the letter only covers SHINE's proposed demonstration unit). A similar request (or requests) could provide Niowave, Inc. greater regulatory certainty regarding the appropriate licenses needed for each of its proposed phases of subcritical assembly operation. Niowave, Inc. may also find it beneficial to clarify the appropriate licenses needed for its processing facility (i.e., will Niowave, Inc. meet the definition of a production facility in any of their proposed phases of operation). The information in these documents will help you to better understand the NRC licensing and regulatory process involved for the use of special nuclear material and source material in the production of activated radioactive materials or fission products, including Mo-99 production on a commercial basis.

- SHINE Demonstration Unit Determination Cover Letter (<https://www.nrc.gov/docs/ML1714/ML17142A432.pdf>)
- SHINE Demonstration Project Enclosure (<https://www.nrc.gov/docs/ML1714/ML17142A433.pdf>)
- SHINE Demonstration Unit Request (<https://www.nrc.gov/docs/ML1707/ML17079A476.pdf>)
- SHINE Demonstration Unit Request Supplement (<https://www.nrc.gov/docs/ML1717/ML17173A013.pdf>)
- SECY-14-0061 – Enclosure 1 – Direct Final Rule: Definition of a Utilization Facility (<https://www.nrc.gov/docs/ML1405/ML14052A105.pdf>)
- SECY-14-0061 – Enclosure 2 – Proposed Rule: Definition of a Utilization Facility (<https://www.nrc.gov/docs/ML1405/ML14052A114.pdf>)
- SECY-14-0061 – Enclosure 5 – Environmental Assessment and Finding of No Significant Impact (<https://www.nrc.gov/docs/ML1405/ML14052A097.pdf>)
- SECY-14-0061 - Enclosure 6 - Regulatory Analysis for Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility (<https://www.nrc.gov/docs/ML1405/ML14052A115.pdf>)
- VR-SECY-14-0061: Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility (<https://www.nrc.gov/docs/ML1423/ML14238A188.pdf>)

If you have any questions or need any clarification regarding the documents listed above, please contact Steven Lynch, Project Manager, at 301-415-1524 or Steven.Lynch@nrc.gov. If you have any additional questions pertaining to your NRC license or this letter, please contact Frank Tran at 630-829-9623 or Frank.Tran@nrc.gov or Cassandra Frazier at 630-829-9830 or Cassandra.Frazier@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the

T. Grimm

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NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 21-35144-02
Docket No. 030-38770

Letter to Terry Grimm, Ph.D., From Patricia J. Pelke dated March 15, 2019.

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