



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 24, 2016

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

Dear Dr. Grimm:

This refers to your amendment requests dated January 19, 2016 (ML16025A084) for NRC License No. 21-35145-01 and January 19, 2015, received on January 25, 2016 (ML16025A091) for NRC License No. 21-35144-02, the licensing meeting with your company representatives on May 10, 2016, and our telephone conference on June 22, 2016. Based on the information you provided in the amendment requests and discussed during the licensing meeting and telephone conference, we determined that the following additional information is needed to complete our review:

NRC License No. 21-35145-01:

1) Radioactive Materials and Use:

This is in regards to your current authorization to conduct research and development activities involving the use of natural uranium and thorium-232. During the meeting, it was discussed that all research and development activities should be authorized on one license (NRC License No. 21-35144-02). Based on the discussion, please provide a revised description of the proposed use of licensed materials for NRC License No. 21-25144-01. This description should include the licensed materials to be transferred to NRC License No. 21-35144-02, and the licensed materials that should remain on the license (manufacturing and distribution of shielding material).

2) Radiation Safety Officer/Assistant Radiation Safety Officer:

Please provide a detailed description of the roles and responsibilities for the Assistant Radiation Safety Officer (ARSO) based on the scope of activities proposed under this license. Also, clarify that the Radiation Safety Officer (RSO) is ultimately responsible for the Radiation Safety Program.

3) Radiation Safety Program:

Based on the change in RSO, please update and provide a revision for Item 7, "Training and Experience of Radiation Safety Officers"; Item 8, "Training for Individuals Working In or Frequenting Restricted Areas"; and Figure 7.1 "An Organizational Chart" in the letter dated January 19, 2016.

NRC License No. 21-35144-02:1) Radioactive Materials and Use:

- a) This is in regards to your current authorization to conduct research and development activities involving the use of natural uranium and thorium-232. It was discussed during the meeting that all research and development activities should be authorized on one license (NRC License No. 21-35144-02). Based on the discussion, please provide a revised description of the proposed use of licensed materials for License No. 21-25145-02. This description should include the licensed materials to be transferred from the License No. 21-25145-01 license.
- b) You requested the use of low-enriched uranium (LEU) up to 700 grams with enriched uranium-235 up to 19.99% by weight. Based on the information you provided during the May 10, 2016, licensing meeting you indicated that you will generate a small amount of plutonium as a fission product from the use of LEU. In accordance with 10 CFR 70.24(a), "Criticality accident requirements", the possession of any combination of fissile material (uranium-235, uranium-233, and/or plutonium) is limited to 450 grams. In addition, you provided that beryllium will be used around the LEU core as a reflector. In accordance with 10 CFR 70.24(a), if massive moderators or reflectors made of beryllium are present, the LEU possession limit will be further reduced. During the meeting, you also stated that Niowave may reduce the requested quantity of LEU to 200 to 500 grams with enriched uranium-235 up to 10% by weight. Therefore, based on the type of moderators or reflectors used and the amount of plutonium produced, please specify the amount of requested LEU and maximum percentage of enriched U-235.
- c) In your amendment request dated January 19, 2015, received on January 25, 2016, you stated that the increase of the possession limits for the LEU will support your goals to "finalize procurement of larger quantities of LEU with a commercial vendor and implement an LEU stewardship program for bulk quantities, including safe storage, materials accounting, and assay verification." Please clarify this statement and provide a detailed description for each specified goal.

2) Decommissioning Financial Assurance:

You provided a decommissioning funding plan cost estimate which was included in your letter dated January 19, 2015, received on January 25, 2016. However, you have not addressed the decommissioning activities associated with the use of the requested licensed materials (natural uranium in a readily dispersible form and a large increase in the amount of LEU), and the addition of the new facility – Radiochemistry Laboratory. Please provide a revision to the decommissioning funding plan cost estimate to address these activities.

3) Authorized Users:

- a) Please provide the names of each proposed authorized user (AU) for the use of natural uranium in readily dispersible form and include his/her training and experiences related to this use. In accordance with the guidance from NUREG-1556, Volume 7, Section 8.7.2, AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination. Specifically, AUs must demonstrate training and experience with the type and quantity of material that they propose to use.
- b) You requested to name Ms. Amanda Grimm as an AU for the licensed material listed on your license. Please provide additional information regarding her training and experience with hands-on use of licensed material (the amount of training and experience needed is based on the types, form, quantity and the use of radioactive materials on the license).

4) Assistant Radiation Safety Officer:

- a) Please provide a detailed description of the roles and responsibilities for the ARSO based on the scope of activities proposed under this license. Also, clarify that the RSO is ultimately responsible for the Radiation Safety Program.
- b) In your letter, you requested to name Mr. Stephen Barnard as an ARSO. Please provide additional information regarding his training and experience with hands-on use of licensed material (the amount of training and experience needed is based on the types, form, quantity and the use of radioactive material listed on the license).

5) Facilities and Equipment:

This is in reference to the information provide during the licensing meeting regarding your request to use licensed material in readily dispersible form and the addition of a new radiochemistry laboratory where licensed material will be used. Please provide a detailed description of the facilities and equipment associated with the use of natural uranium in readily dispersible form and the radiochemistry laboratory. Based on NUREG-1556, Volume 7, Section 8.9, this description should include the area(s) assigned for the receipt, storage, security, preparation and measurement of radioactive materials. Diagrams should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For your references, additional guidance regarding facilities and equipment are in NUREG-1556, Volume 7, Appendix K.

6) Materials Control and Accountability:

- a) This is in regards to your request for possession of LEU with a quantity (700 grams) that is approaching the limit specified in 10 CFR 70.24, "Criticality accident requirements".

Please describe your methodology to control the inventory so that the possession limit will not exceed the threshold set forth in 10 CFR 70.24(a).

- b) Condition 9 in your license specifies the maximum possession limit for each listed licensed material. However, Section 10.3, "Material Accountability", in your letter said "Niowave commits to take a physical inventory of all licensed material received and possessed every six months. Such inventory will be done to assure that Niowave does not exceed possession limits as defined in our proposed license application ..." Based on our understanding, it appears that Niowave will verify that its possession limits have been exceeded at six months interval only. Please clarify and describe the material control and accountability procedure used by Niowave to assure that on a continual basis the licensed possession limits will not be exceeded.

7) Radiation Safety Program:

Based on the change in RSO, please update and provide a revision for Item 7, "Training and Experience of Radiation Safety Officers"; Item 8, "Training for Individuals Working In or Frequenting Restricted Areas"; and Figure 7.1 "An Organizational Chart" in the letter dated January 19, 2015, received January 25, 2016.

8) Additional Information Discussed:

This is in reference to information provided by Mr. Yawar Faraz of the Nuclear Material Safety and Safeguards (NMSS) in NRC Headquarters during the licensing meeting on May 10, 2016, via telephone. As discussed by Mr. Faraz, Niowave will fall under the 10 CFR Part 70 requirements and be managed and licensed by the NRC Headquarters Office if the requested possession limit for LEU, with enriched U-235 less than 20% by weight, exceeds 700 grams. Mr. Faraz stated that Niowave should review NUREG-1513, "Integrated Safety Analysis Guidance Document" to prepare an Integrated Safety Analysis report whenever it plans to request an amount exceeding 700 grams. In addition, Mr. Faraz provided that if Niowave plans to extract plutonium as a fission product from irradiated LEU, Niowave should review NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications", Revision 1 and provide the NRC Headquarters with information specified in this guidance.

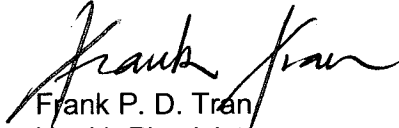
Additionally, in accordance with Mr. Steven Lynch of Nuclear Reactor Regulations (NRR) in NRC Headquarters who participated in the licensing meeting on May 10, 2016, via telephone, Niowave may have to apply for a license in accordance with 10 CFR Part 50 if Niowave plans to have more than 100 grams of LEU in each batch as a target in the core that will be irradiated.

Please be mindful of the licensing requirements if you plan to make changes to the possession limit of the LEU or scope of use authorized on the license.

Based on a discussion with you and your staff via telephone on June 22, 2016, you stated that Niowave will provide a response in writing by July 25, 2016. Please address the matters discussed above in the response. The response must be dated and signed by an authorized personnel. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact Cassandra Frazier at 630-829-9830 or Frank Tran at 630-829-9630.

In accordance with Title 10 Code of Federal Regulations 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,


Frank P. D. Tran
Health Physicist
Materials Licensing Branch

License Nos. 21-35145-01 and 21-35144-02
Docket Nos. 040-38369 and 030-38770