



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

January 18, 2017

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 request dated July 13, 2016 (ML16197A388) for NRC License Nos. 21-35145-01 and 21-35144-02 and the information provided during our licensing site visit on November 3 and 4, 2016 and our telephone conference on January 10, 2017. During the site visit, we discussed with you and your staff the deficiencies in the amendment requests and further discussed your new plan to produce xenon gas from irradiating low enrichment uranium (LEU) and molybdenum-99 from irradiating natural uranium. Based on the discussions, you agreed to void the amendment request dated July 13, 2016 and resubmit the amendment request in its entirety with updated and current information. Therefore, as discussed during our telephone conversation, the following information will need to be submitted:

NRC License No. 21-35145-01:

1) Radioactive Materials and Use:

Based on our telephone conversation, you stated that natural uranium and thorium-232 and all research and development activities authorized under this license will be transferred to the NRC License No. 21-35144-02. The only licensed material remaining on this license will be depleted uranium (DU) for storing, fabricating (cutting and machining) shielding and parts, and transferring to other authorized persons. Please confirm.

2) Radiation Safety Officer/Assistant Radiation Safety Officer:

In accordance with the information discussed during our site visit and the telephone conference, please confirm that the Assistant Radiation Safety Officer (ARSO) will perform assigned RSO tasks under the supervision of the RSO and that the RSO is ultimately responsible for the Radiation Safety Program.

3) Authorized Users:

a) You requested to add Ms. Amanda Grimm as an authorized user (AU) for this license. For hands-on experience with licensed materials, you indicated that Ms. Grimm performed two inventories and observed the machining of 550 grams of natural uranium into 28 pieces. Please provide additional information regarding the specific details of her training and experience related to the use of licensed materials, including the hands on activities related to cutting and machining DU.

Please note that, in accordance with the licensing guidance 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) During the telephone conference, you indicated that Ms. Kristin Gore did not have sufficient training and experiences to be qualified as an AU for the licensed material listed on this license; specifically, she has not used DU, including cutting and machining DU into shielding and parts. Therefore, you indicated that the request to name her as an AU on this license will be withdrawn. Please include this information in your response.

4) Radiation Safety Program:

- a) During the telephone discussion, you indicated that the leak test, if any, will be analyzed by persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, you indicated that the radiation survey instrument calibrations will be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. Please provide this revision to your procedures.
- b) Please provide the most current organizational chart.
- c) On page 6 of the attachment to the letter dated July 13, 2016, you stated that the Radiation Safety Program will be audited periodically and the results will be discussed with the management. NUREG-1556, Volume 21, Section 8.10.1, "Audit Program" suggests that 1) program audits should be conducted more frequently than annually if the licensee's activities involve the use of high-activity materials or frequent handling of intermediate activity materials, 2) the licensee should consider developing survey and audit schedules based on activity and use (e.g., high-use/activity areas may be audited monthly, moderate-use/activity areas may be audited quarterly), and 3) more frequent audits should be considered if the potential for overexposures exists. Based on your request to use readily dispersible source material, please provide the process for conducting the Radiation Safety Program audit, including the process to address any identified deficiencies.

NRC License No. 21-35144-02:

1) Radioactive Materials and Use:

- a) Please confirm that licensed materials including natural uranium and thorium-232 and all research and development activities authorized under NRC License No. 21-35145-01 will be transferred to this license.
- b) You indicated during the telephone conversation that you plan to increase the possession limit to 120 grams of LEU with enrichment in U-235 less than or equal to 10% by weight in solid form for research and development. You also indicated that

LEU will be irradiated and that each batch as a target for irradiating in the core will not exceed 100 grams of LEU and that xenon and other gases as fission products will be collected. Please provide the details of your plan, including the material, maximum possession limit, and the step-by-step process for producing xenon and other gases.

- c) You indicated that you will request the possession of natural uranium in readily dispersible form for research and development, including irradiating, dissolving, chemical processing, and transferring to other authorized persons. You stated that you will extract molybdenum-99 and other fission products from irradiated natural uranium. Please provide the details of your plan, including the material, maximum possession limit, and the step-by-step process for producing molybdenum-99.

2) Decommissioning Financial Assurance:

You provided a decommissioning funding plan cost estimate attached to the amendment request. However, the cost estimate did not include the decommissioning activities for all areas where requested licensed materials will be used (i.e., equipment and building materials that may contain activation products in the tunnel where LEU and natural uranium will be irradiated). Please provide a revision to the decommissioning funding plan cost estimate to address areas related to the use of the requested licensed materials.

3) Authorized Users:

- a) You requested authorization for Valeriia Starovoiatova, Ph.D., to be a user for the natural uranium in readily dispersible form. You indicated that Dr. Starovoiatova had worked with readily dispersible radioactive materials in the past. Please provide detailed information related to Dr. Starovoiatova's work with readily dispersible radioactive materials.
- b) You requested authorization for Amanda Grimm to be a user for all licensed material authorized on the license (including, LEU, natural uranium in readily dispersible form, etc.). You indicated that Ms. Grimm has used unirradiated depleted and natural uranium spiked with Mo-99 in her training at Argonne National Laboratory on several occasions in early 2016. Her training included diluting solid DU and natural uranium in nitric acid and performing the LEU Modified Cintichem (LMC) process on those materials. Additionally, you indicated that Ms. Grimm performed some tasks related to radiation safety under the RSO's supervision. Please provide additional information related to Ms. Grimm's training and experience with the use of the requested licensed material.
- c) You requested authorization for Kristin Gore to be a user for all licensed material authorized on the license (including, LEU, natural uranium in readily dispersible form, etc.). However, you did not provide any information regarding her training and experience related to the use of the radioactive materials listed on your license. During the conversation, you indicated that Ms. Gore did not meet the training and experience requirements and that you wish to withdraw the request to name her as a user. Please provide this information in your response.

Please note that, 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 (including adequate hands-on training) with the type and quantity of material that they propose to use.

4) Assistant Radiation Safety Officer:

In accordance with the information discussed during our site visit and the telephone conference, please confirm that the Assistant Radiation Safety Officer (ARSO) will perform assigned RSO tasks under the supervision of the RSO and that the RSO is ultimately responsible for the Radiation Safety Program.

5) Facilities and Equipment:

In letter dated January 19, 2016, received January 25, 2016, you indicated that you would like to possess a bulk quantity of LEU in solid form for storage only. In letter dated July 13, 2016, you revised your initial plan and requested to possess a readily dispersible form of LEU and to irradiate and chemically process irradiated LEU. During the telephone conversation on January 10, 2017, you provided that you will request the following:

- a) 120 grams of LEU with enriched U-235 less than or equal 10% in solid form for research and development, including irradiating and extracting xenon and others gases as fission products.
- b) Natural uranium in readily dispersible form for research and development, including irradiating, chemical processing, and extracting molybdenum-99 and other fission products.
- c) Upgrading the current fume hood and HEPA filter in the Radiochemistry Laboratory with a commercial fume hood and HEPA filter.

Based on your current plan, please provide a detailed description of the facilities and equipment associated with the use of requested materials (including, target, target rack, rods, piping system, collection tank, hold up tank, shielding, moderator, handling tools, etc.). 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) Radiation Safety Program:

- a) During the discussion, you indicated that the leak test, if any, will be analyzed by persons specifically licensed by the Commission or an Agreement State to perform

such services. In addition, you indicated that the radiation survey instrument calibrations will be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. Please provide this revision to your procedures.

- b) Please provide the most current organizational chart.
- c) On page 6 of the attachment to the letter dated July 13, 2016, you stated that the Radiation Safety Program will be audited periodically and the results will be discussed with management. NUREG-1556, Volume 21, Section 8.10.1, "Audit Program" suggests that: 1) program audits should be conducted more frequently than annually if the licensee's activities involve the use of high-activity materials or frequent handling of intermediate activity materials; 2) the licensee should consider developing survey and audit schedules based on activity and use (e.g., high-use/activity areas may be audited monthly, moderate-use/activity areas may be audited quarterly); and 3) more frequent audits should be considered if the potential for overexposures exists. Based on your request to use readily dispersible source material, please provide your process for conducting the Radiation Safety Program audits, including the process to address any identified deficiencies.

Please provide your written response to this letter by February 10, 2017. As discussed in our telephone conversation, please provide the response in its entirety (stand-alone) with no reference to information in previously submitted letters or applications. Your response must be dated and signed by an authorized person. 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 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 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