



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

July 21, 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 April 21, 2017 (ML17114A407) for NRC License No. 21-35144-02. Based on the review of your application, we will need the following additional information.

1) Radioactive Materials and Use:

- a) Your license is currently authorized for activation products which are the result of the irradiation process. However, you did not address the activation products in the application. Specifically, Table 6.1 did not list the activation products. Please provide information about the activation products that you will generate.
- b) You requested to produce, extract, and transfer actinides, which are fission products from irradiated LEU, to other specific licenses. Please provide information to demonstrate that your facility will not be a "Production facility" as defined in 10 CFR 50.2.
- c) In Figure 1 of the Appendix 6.7, you provided that uranium recovery is one step in your work process (Step 5.6). Please provide information to demonstrate that your facility will not be a "Production facility" as defined in 10 CFR 50.2.

2) Facilities and Equipment:

- a) Please provide information to demonstrate that K_{eff} will be maintained at less than or equal to 0.43.
- b) Please confirm that you will provide an amendment request and be approved by the NRC before you perform any modifications to the UTA which may alter its operation parameters or provide an alternative response.
- c) Please confirm that instruments (HPGe and NaI detectors), that are used to quantify the radioactive material, will be used and calibrated in accordance with national recognized standards or the manufacturer's instructions.
- d) Please address the activation gases (i.e., Ar-41 and N-16) during and after the irradiation, including the maximum activities that will be generated, the gases escaping from the tunnel, and the radiation dose to non-radiation workers in the NERD building.

- e) With regard to the Spectroscopy Laboratory's ventilation system, the effluent release point (stack's end) is low and close to the residential area; therefore, based on the building wake effect, the effluent release plume is around the release area. Therefore, the concentration at the release point should meet 10 CFR Part 20 effluent release limit. Please note that the equation (2) in Appendix 10.2 did not consider the building wake effect (stack height less than 2.5 times of the building height). Please revise the public dose calculation and provide the estimate annual activities of noble gas and iodine released to the fume hood upon opening the rods and during dissolution of irradiated pellets.
- f) In Page 15, it is stated that the licensee will perform air monitoring in the tunnel for the first 5 times for each new operation protocol. However, there was not a quality assurance program to address any periodic air monitoring (monthly, quarterly, etc.) to ensure that the performance of the operations is maintained. Please provide your quality assurance program.

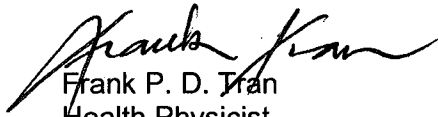
3) Authorized user:

In Item 10.7, "Safe Handling of Radionuclides and Emergency Procedures", you stated that the Radiation Safety Officer (RSO), Assistant RSO (ARSO) or an authorized user will supervise all handling of radioactive material. Based on your license, the licensed materials are only authorized to use by or under the supervision of listed authorized users. Please confirm that licensed material shall only be used by or under the supervision of authorized users (AU). Please note that, the AU's responsibility is to ensure that radioactive materials are used safely and in accordance with the regulatory requirements. The AU is also responsible to ensure that the procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA. An AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material.

The above deficiencies were discussed with your Radiation Safety Officer, Dr. Valeria Starovoirova, on July 21, 2017. Please provide your written response to this letter by August 21, 2017. 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 No. 21-35144-02
Docket No. 030-38770