



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

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

**APR 12 2017**

Valeria Starovoitova, Ph.D.  
Radiation Safety Officer  
Niowave, Inc.  
1012 North Walnut Street  
Lansing, MI 48906-5061

Dear Dr. Starovoitova:

Enclosed is Amendment No. 03 to your NRC Material License No. 21-35144-02 in accordance with your request.

Please note that in accordance with current NRC policy, we updated License Condition No. 13 regarding the limitation for distributing licensed materials, License Condition No. 14 regarding the requirement for sealed source leak tests, License Condition No. 15 regarding the requirement to maintain the sealed source integrity, and License Condition No. 17 regarding the decommissioning financial assurance requirement. We also added License Condition No. 18 regarding the sealed sources inventory requirement.

Additionally, your license format was changed based on our new licensing process system.

Please note that we have not added low enriched uranium (LEU) in solid form, natural uranium in readily dispersible form, and their activation or fission products to the license as requested in the letter dated January 20, 2017, because we did not have sufficient information regarding the facilities, equipment, and procedures related to the use of those materials. In addition, we have not added any new users to the license because we have not received sufficient information regarding the training and experience for the proposed users. As discussed in a telephone conversation on April 3 and 5, 2017, we will need the following additional information specific to facilities, equipment, procedures, and authorized users in order to continue our review of your request.

1. You requested the use of LEU for research and development involving the irradiating and processing of its fission/activation products. Please provide the most current information regarding the facilities and equipment, and the procedures for the safe use of licensed material. These procedures should include the step-by-step process and information specific to radiation safety practices before, during, and after handling licensed materials.
2. Also, you requested the possession of natural uranium in readily dispersible form for research and development, including irradiating, processing, and transferring licensed materials to other authorized persons. Please provide the most current information regarding the facilities and equipment, and the procedures for the safe use of licensed material. These procedures should include the step-by-step process and information

specific to radiation safety practices before, during, and after handling licensed materials.

3. Based on the information provided on April 3, 2017, your facilities have been upgraded with a new commercial graded fume hood, HEPA filter, and the stack. Please re-evaluate the effluent released in accordance with 10 CFR 20.1101, 20.1701, and 20.1702, and provide information as described in NUREG-1556, Volume 7, Appendix K, "Facilities and Equipment Consideration" and Appendix Q, "Radiation Safety Survey Topics". Please refer to Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors" for evaluation method acceptable to NRC for compliance with the constraint on air emissions to the environment.

In addition, please clarify the following:

- NUREG-1556, Volume 12, Appendix P states that an area was found with 100 dpm/100 cm<sup>2</sup> of alpha emitter removable contamination should be considered contaminated; however, the Appendix 6.3, page 2 of your submission said an area with 1000 dpm/100 cm<sup>2</sup> or greater of removable alpha contamination will be considered contaminated.
  - It appeared that the total quarterly doses that were estimated on page 3 of Appendix 10.1 were incorrect.
  - 10 CFR 20.1301(a)(2) requires the licensee to limit the dose to the individual member of the public in an unrestricted area to less than or equal to 2 mrem per any one hour. In addition, 10 CFR 20.1101(d) requires the licensee to limit the total effective dose equivalent to the individual member of the public to less than or equal to 10 mrem. However, you considered only one factor, 2 mrem per any one hour, in your emission evaluation in Appendix 10.2.
  - In Appendix 10.4, you stated that you will verify if the Niowave's clients are authorized for the licensed materials before the transferring by checking their licenses in the NRC's ADAMS database only.
4. With regard to the licensed material users, you requested authorization for Terry Grimm, Ph.D., to be a user for licensed materials in readily dispersible form. However, you did not provide adequate information regarding his training and experience related to the use of radioactive materials in readily dispersible form. Please provide additional information related to Dr. Grimm's work experiences involved the handling of readily dispersible radioactive materials.
  5. This is in regards to your request to authorize Ms. Amanda Grimm to be an authorized user for all licensed materials, including the following physical forms: solid, liquid, gas, and readily dispersible. Based on the provided information, we determined that the training and experience for Ms. Grimm is insufficient. Specifically, Ms. Grimm has not demonstrated that she had adequate hands on experience with requested licensed materials. Therefore, we have not listed her as an authorized user on the license.


Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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

Enclosure: Amendment No. 03