

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

September 7, 2018

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

Dear Dr. Grimm:

This refers to your letter dated March 2, 2018 (ML18064A260) requesting an amendment for NRC License No. 21-35144-02. We reviewed the letter and conducted a licensing site visit at your facility in Lansing, Michigan on May 31, 2018 to evaluate your proposed equipment, facilities and licensed activities associated with the request. We determined that the proposed facilities and equipment had not been completely constructed and tested. On June 25, 2018, we discussed the deficiencies identified during our site visit with you and sent a request for additional information dated June 26, 2018. You provided letters dated June 29, 2018 (ML18183A306) and July 17, 2018 (ML18199A455) in response to our request. On August 28, 2018, we conducted a second site visit to your company to assess your completed facility, equipment, proposed licensed activities, and the radiation safety program. Based on the review of your information provided, discussions with your staff and our observations during the site visit, we will need the following additional information.

- You proposed that you will make modifications to the ventilation system for the glove box. Specifically, you will move the outlet of valve V-G11 to the section before or after valve V-F3. Please note that: i) your air monitoring system is currently operating and calculating using the ratio of the air flow through the air monitor instrument and the air flow in the main pipe that takes suction from the fume hood and ii) the intake for the air monitoring should be placed where the air is well mixed. Please provide an updated ventilation system diagram and information about the changes to the ventilation system.
- 2. Provide an update to the calculations of the effluent release using the most conservative approach and include the details of your assumptions.
- 3. Provide an update of the company organizational chart.
- Provide information regarding the methodology you will use to quantify licensed materials, including the correction factors and their efficiencies for different geometries and densities.
- 5. You stated that the current Radiation Safety Officer (RSO), Dr. Valeriia Starovoitova, is currently abroad for family related matters and will not be available to provide day to day oversight and management of the company's radiation safety program. Please provide information regarding the company's short term (three to six months) and long term plans for the RSO. You expressed that you may seek a new RSO for your license. Please note that the NRC guidance regarding the RSO's training and experience and

his/her duties and responsibility is discussed in NUREG-1556, Volume 7, Revision 1, Section 8.7.1 and Appendix E, respectively. An electronic copy of NUREG-1556, Volume 7, Revision 1 could be found on the NRC's web page at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/.

Please provide your written response to this letter by September 30, 2018. Your response must be dated and signed by an authorized person. To facilitate proper mail handling in our office, please refer to Mail Control No. 608427 in your response. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact Frank Tran at 630-829-9630 or frank.tran@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 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,

ank P. D. Tran

Health Physicist Materials Licensing Branch

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