



CONVERSATION RECORD

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Erik Maddock	DATE OF CONTACT 11/26/2014	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input type="checkbox"/> INCOMING	
E-MAIL ADDRESS maddock@niowaveinc.com	TELEPHONE NUMBER (517) 999-3475	<input type="checkbox"/> TELEPHONE <input type="checkbox"/> OUTGOING	
ORGANIZATION Niowave, Inc.	DOCKET NUMBER(S) 030-38770		
LICENSE NUMBER(S) 21-35144-02	CONTROL NUMBER(S) 584728		

SUBJECT  
Additional information required for application for new cyclotron-production license

SUMMARY AND ACTION REQUIRED (IF ANY)

1. Radioactive Material and Workload

A. Please identify incidentally activated products that will be produced during operation of the linac, and include the maximum quantities per radionuclide.

B. Describe the typical daily workload. Include the typical radionuclides and quantities produced each day. Also describe the workflow in the production of a radionuclide in detail beginning with installing a target in the linac, production and shipment of product, and ending with disposal of radioactive waste.

2. Decommissioning Financial Assurance

Please note that decommissioning financial assurance will need to be submitted for our review before we can issue the license.

3. Radiation Safety Officer and Assistant Radiation Safety Officer

Define the duties of the RSO and Assistant RSO. Refer to Appendix E in NUREG-1556, Volume 21. Confirm that the RSO is ultimately responsible for the radiation safety program, including any and all actions taken, or not taken, by the Assistant RSO.

4. Authorized Users

Submit more detail on the training and experience for Amanda Grimm to demonstrate that she is qualified to be an authorized user and handle licensed materials. Please refer to pages 8-16 and 8-17 of NUREG-1556, Volume 21, for the information that you will need to submit.

5. Maintenance

Item 7.3 of your application states that all maintenance involving the linac will be overseen by an engineer responsible for the design. Please define "overseen." Does this mean that maintenance may be performed by other employees, but under the physical presence of an engineer? Describe the types of

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## SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

maintenance that will be performed, and if it will involve potential exposure to activated targets or incidentally active materials in and around the machine.

## 6. Radiation Safety Training Program

- A. In the description of Niowave's Radiation Safety Training Program, a statement was made that the training lasts for 2 hours and that the amount of time spent on each of the 20 topics is relatively equal. This means that each topic receives about 6 minutes during the training session. We question the effectiveness of the training given the amount of material covered in the time provided. The time allotted for each topic appears minimal and may need to be increased.
- B. In your application it was stated that non-radiation workers receive training that is less comprehensive than the training provided for radiation workers. Describe the training program for non-radiation workers.
- C. On page 8 of your application, please explain what you mean by the following statement: "both types of radiation safety training courses are provided for new employees every quarter if needed." All new employees must be trained initially before being allowed to work with radioactive material, or near radioactive materials. Please commit to providing training to all new employees.
- D. Submit examples of tests that are provided to employees (both radiation and non-radiation workers) after they have completed their training.

## 7. Facilities and Equipment

- A. Please submit a facility diagram that clearly shows the location of the linac relative to areas surrounding the linac.
- B. Identify areas around the linac where incidentally activated radionuclides may be produced. Will there be incidentally activated products produced in the tunnel? Describe procedures that will be in place to control non-radiation worker exposure to incidentally produced radionuclides.
- C. You indicated that there is no radioactive air effluent produced as a result of production activities because Niowave only produces radiochemicals, and not radiopharmaceuticals that require chemical synthesis. Submit an evaluation, e.g., results of air sampling, to demonstrate that there is no radioactive air effluent created from operation of the linac. If there is any radioactive air effluent generated then you will need to describe equipment that is used to detect and analyze air effluent releases resulting from target interaction with the linac. Include the procedure that is used to calibrate the detection system, and describe how the results are analyzed to assure compliance with occupational or non-occupational dose limits, and the air effluent constraint limits specified in 10 CFR Part 20.

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

D. Describe how accelerator-produced product is removed from the linac and prepared for shipment. Include procedures and equipment that will be used to assure that the handling of product is performed safely and in accordance with ALARA principles. Include a description of personal protective equipment, remote handling tools, and dosimetry that will be used by staff who will be involved in the handling, processing, and shipment of product.

E. Submit your procedure and frequency for calibrating portable radiation monitoring instruments.

F. Describe how you will measure the activity of the radiochemicals that are produced in the linac to assure that you do not exceed possession limits on your license, and that you ship the correct quantity to your customers. Describe equipment that will be used, and the calibration procedure and the frequency at which calibration will be performed.

8. Waste Management

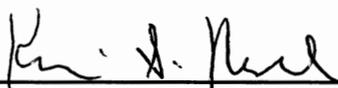
A. In the second and third bullets under item 11.1 of your application, please change the words "should" to "shall." Also, submit procedures that will be followed, and describe equipment that will be used for the safe handling of targets.

B. In the fifth and sixth bullets under item 11.2, please change the words "should" to "shall."

NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE



DATE OF SIGNATURE

11/26/14