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NRC FORM 313 (03-2013)

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NIOWAVE, INC 1012 North Walnut Street Lansing, MI 48906 Phone: (517) 999-3475 Fax: (517) 999-3626 www.niowaveinc.com

16 June, 2014

NRC Region III Office 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

Subj: Application for a License to Accelerator Produce and Commercially Distribute Mo-99 from Low Enriched Uranium of Less than Critical Mass

Good day,

The American Medical Isotope Production Act of 2012 establishes a program to support the production on Mo-99 by domestic, non-federal entities, and requires the phase-out of highly enriched uranium fuel over a period of seven years. Currently, all of the country's medical needs for Mo-99 are being met by imports from reactors located in Canada and Europe, and are produced mainly from highly enriched uranium. Niowave has developed a radioisotope production method using our superconducting electron linear accelerator technology to generate Mo-99 from a low enriched uranium target via photon and neutron induced fission.

Enclosed is Niowave's application to produce and commercially distribute Mo-99 from our headquarters in Lansing, Michigan. The application is written to allow production of enough Mo-99, along with its decay daughter Tc-99m, to meet the needs of the North American market. Initially, only a small amount of low enriched uranium will be requested as target material, but we expect to increase that amount through the amendment process as we perfect and expand our production techniques.

Niowave has been licensed by the State of Michigan since 2010 to operate ionizing radiation producing superconducting linacs. Our current license allows Niowave to operate with electron beam energies up to 40 MeV, well above the photonuclear activation threshold. Niowave has assembled a talented and experienced team to ensure safe and efficient operation of all radiation producing equipment, as well as handling all resulting activated materials. Much of the attached application builds directly on the successful radiation safety program we have instituted to meet state regulations, as well as to meet NRC requirements for previously requested additional licensing to possess and distribute source material, and to use our accelerators to produce several short lived radioisotopes.

We look forward to continuing our work with the Commission to complete our licensing processes.

Sincerely.

Dr. Terry L. Grimm President and Senior Scientist

Item 5: Radioactive Material

5.1. Unsealed Radioactive Material

The byproduct materials proposed for license are molybdenum 99 (Mo-99) in solid form with a maximum possession limit of 40,000 Ci, technetium 99m (Tc-99m) in solid form with a maximum possession limit of 27,100 Ci, and technetium 99 (Tc-99) in solid form with a maximum possession limit of 10 mCi. The special nuclear material (SNM) proposed for license is low enriched uranium (LEU) in solid form where the U-235 enrichment is less than 20% by weight and with a maximum possession limit for the contained U-235 of 4.545 grams.

5.2. Financial Assurance and Recordkeeping for Decommissioning

5.2.1 Financial Assurance for Decommissioning

No financial assurance for decommissioning is required. Tc-99 is kept below the limits of USC Title 10 §30.35 and U-235 is kept below the limits of USC Title 10 §70.25. Mo-99 and Tc-99m are short lived, with half-lives of 66.7 hours and 6.03 hours respectively.

5.2.2 Recordkeeping for Decommissioning

The following records will be maintained without limitations until the license is transferred to another party, or to the NRC following the termination of the license:

- Records of spills or other unusual occurrences involving the spread of contamination, including known nuclides, quantities, forms, and concentrations. These records need not be maintained if the contamination was completely cleaned up.
- As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored. This includes any inaccessible locations which might become contaminated.
- Beginning at the issuance of the license, and updated every two years thereafter, a single document that contains:
 - A list of all areas currently or formerly designated as restricted areas;
 - All areas (if any) outside of restricted areas where spills or unusual occurrences involving the spread of contamination have taken place;
 - All areas (if any) where waste is buried;
 - All areas (if any) outside of restricted areas that contain material such that, if the proposed license expired, would either require the area to be decontaminated prior to decommissioning, or an approval of an application for disposal to be issued.

Item 6: Purpose for Which Licensed Materials Will Be Produced

6.1. Purpose for License

The Mo-99 market in the United States is estimated to be \$3 billion annually, with most of the production occurring in Canada and Europe. In addition to the current practice of using weapon's grade enriched uranium for production, the lack of a domestic supply led Congress to pass the American Medical Isotope Production Act in fiscal year 2013. This legislation establishes a program to support the production of Mo-99 by non-federal entities while phasing out the use of high-enrichment uranium within 7 years. This license will allow Niowave to take a step toward fulfilling the goals of this act.

6.2 Material Possession Limits

Mo-99 will be produced from LEU by an accelerator in agreement with all applicable regulations. These materials will be used in accordance with Table 6.1.

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
U-235	Unsealed solid dispersed in LEU	4.545 g (10 μCi)	Target material to be transmutated into Mo-99 by accelerator induced nuclear fission
Mo-99	Unsealed solid	40,000 Ci	Transferred to licensed radio-pharmacies for separation and use to produce Tc-99
Tc-99m	Unsealed solid	27,100 Ci	Daughter nuclide of Mo-99 decay; used in nuclear medicine
Тс-99	Unsealed solid	10 mCi	Daughter nuclide of Mo-99 and Tc-99m decay
Any other byproduct material	Activation products	Possession incident to the transmutation process	To be transferred along with the Mo-99 and Tc-99 for separation by licensed radio- pharmacies.

Table 6.1: Licensed material possession limits and uses

Item 7: Training and Experience of Radiation Safety Officers

7.1 Radiation Safety Officer (RSO)



Figure 7.1: An organizational chart describing the management structure, reporting paths, and the flow of the authority between executive management and the RSO

Figure 7.1 shows an organizational chart of Niowave's radiation safety team. Niowave's Senior Scientist, Dr. Terry Grimm, is responsible for all aspects of safety at Niowave, Inc. Dr. Grimm has delegated the authority for the radiation safety program to the RSO, but maintains oversight of the program. The RSO, Erik Maddock, will be responsible for the radiation safety program and compliance with the Commission's regulations. The RSO, and Senior Scientist are all qualified to be Authorized Users (AUs) as is Dr. Valeriia Starovoitova, Applied Physics Group Lead. The RSO will be delegated by senior management with sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material.

Erik Maddock is the current Niowave, Inc. Radiation Safety Officer. He obtained his MS degree in Radiological Physics from Wayne State University's Medical Physics Graduate program. During graduate school, he worked with medical radioisotopes including Mo-99, F-18, and high specific activity brachytherapy Cs-137 and Co-60 sources. Before attending graduate school, Mr. Maddock worked in the navy submarine fleet for three years as a nuclear trained naval officer. His training includes six months of classroom instruction in radiological controls from the Navy Nuclear Power Training Command in Goose Creek, SC. After power school he completed six months of handson training covering all aspects of nuclear power plant radiation safety including spill response, decontamination, and record keeping at the MARF plant in Ballston Spa, NY. His navy training covered the following subjects: radiation protection principles, characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, biological hazards of exposure to radiation, and hands-on use of radioactive materials. His understanding of the radiological sciences is further confirmed by his certification from passing the Part 1 Exam of the American Board of Radiology Therapeutic Medical Physics. His duties at Niowave as the RSO include providing radiation safety training to all employees, establishing written safety guidelines and rules for tests in which radiation will be produced, and conducting radiation dose surveys.

7.2 Authorized Users

In addition to the RSO two other authorized users are proposed: Dr. Terry Grimm, the President and Senior Scientist at Niowave, and Dr. Valeriia Starovoitova, Applied Physics Group Lead. Both Dr. Grimm and Dr. Starovoitova have significant experience working with radioactive material and are qualified to be authorized users.

Dr. Terry Grimm has over 25 years of experience in accelerator research with both the Department of Energy and Department of Defense. Prior to founding Niowave, he was a senior physicist and adjunct professor at Michigan State University's National Superconducting Cyclotron Laboratory for 13 years. He received his PhD from the Massachusetts Institute of Technology in Applied Plasma Physics and Nuclear Engineering.

Dr. Starovoitova has over 10 years of experience in nuclear physics. She received her BS degree from St. Petersburg State University and her PhD from Purdue University. Prior to joining Niowave, Dr. Starovoitova had worked at the Idaho Accelerator Center starting in 2009, first as a Postdoctoral Researcher, and later as a Research Assistant Professor. During these years she was involved in several applied nuclear physics projects, in particular photonuclear production of isotopes, nuclear waste transmutation, and photon activation analysis. In 2013 she joined Niowave to head the Applied Physics department.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

Niowave is currently licensed by the State of Michigan to operate electron accelerators up to 40 MeV beam energy and 100 kW beam power. The outline of the current radiation safety training program given to Niowave's radiation workers is shown below. This training was initially structured to cover material related to safely operating radiation producing machinery, but was expanded to deal with radioactive material as the threshold energy for photonuclear activation was exceeded by accelerator output. The radioactive material curriculum was again updated to include source and neutron activated byproduct material when license applications were submitted to the NRC. At the start of this application process the curriculum was again updated to include special nuclear material and fission products. Below is a current list of training topics:

- Radiation Safety Regulations
- Types of Radiation
- Ionizing Radiation
- Radiation Sources
- Units of Radioactivity, Exposure, and Dose
- Half-life of Radioactive Materials
- Biological Effects of Radiation
- Sources of Exposure to Radiation
- Types of Radiation Exposure
- Individual Dose Limits
- ALARA Principle
- Dose Reduction Practices
- Monitoring the External Exposure
- Monitoring the Internal Exposure
- Records and Reports
- Safety Procedures
- Accelerator Produced Radioactivity and Radioactive Material
- Fission Produced Radioactivity and Radioactive Material
- Security of Radioactive Material
- Radiation Emergency
- Niowave Building: Areas and Postings

Radiation safety courses are taught by the RSO, Erik Maddock. See Item 7 (above) for his qualifications.

Radiation workers at Niowave are classified as employees that are allowed to work in restricted areas, which are environments that may have radiation levels higher than that allowed to the general public. Non-radiation workers are classified as employees not allowed in restricted areas. All Niowave employees, including radiation and non-radiation workers receive training on radiation safety; however, training for non-radiation workers is less comprehensive than the radiation worker training. A radiation safety training course is provided for new employees every quarter. Employees that have

received previous training are required to attend a refresher radiation safety training course once a year.

Each employee's understanding of the material is assessed through a multiple-choice test given at the end of each training course. Passing grades is 80% for radiation workers, and 70% for non-radiation workers. If the employee does not answer a sufficient number of test questions correctly, then the RSO reviews the material related to the incorrect answers with the employee, and an oral upgrade quiz is administered by the RSO. To streamline documentation, the oral quiz results are recorded on the previously failed paper test.

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Item 9: Facilities and Equipment

Licensed SNM material will be stored and used at Niowave's Walnut Street Headquarters, which consists of two adjacent buildings and located in Lansing, MI. Licensed byproduct material will be produced at and shipped from the same location. The designated storage and shipping areas are in Niowave's Electron Research and Development (NERD) facility, which is a 14,000 ft² steel framed and walled structure, built on a concrete slab in 2012 (see Figure 9.1). The byproduct material will ship from the NERD loading dock, (labeled in Figure 9.2). Preparation for shipping will be in the tunnels (labeled in Figure 9.2). The floor of the tunnels is 6' below grade and it is shielded as shown in Figure 9.3.



Figure 9.1: Installation of accelerator within the NERD Facility

Once they contain radioactive material, the tunnels will be marked as a restricted area. Access to the tunnels will be limited to trained radiation workers. Restricted areas will be locked up when not in use, with only the RSO, and AUs having keys. The NERD building is locked when not in use, and security is continuously monitored by a burglar alarm service after hours.

Each LEU target will be encapsulated in a non-reactive, low neutron cross section metal (e.g. niobium) cladding. In the event a cladding rupture resulting in the of escape of fission product gasses, primarily Xe-135, a vent fan of at least 300 SCFM, similar to what is used in residential radon mitigation systems, with an intake at the floor of the tunnel and an exhaust pipe at the ceiling, will prevent the pooling of radioactive gasses in the tunnel.

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Figure 9.2: Overview of Niowave's Headquarters in Lansing, MI



Figure 9.3: Shielded tunnels dimensions

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Item 10: Radiation Safety Program

10.1. Audit Program

No response is required.

10.2. Radiation Monitoring

Accelerator induced fission generates a wide spectrum of radioactive products. Several types of detectors are needed to ensure radiation safety. Refer to Table 10.1 for Niowave's radiation monitoring instrumentation.

Detector Make &	Detector Type	Radiation Monitored
Model		
Fluke 451P	Handheld survey meter	Gammas and x-rays
Ludlum Model 26	Geiger-Müller Frisker	Alphas, gammas and betas
Ludlum 357-9 & 45-9	Area monitor with ionization chamber	Gammas and x-rays
Ludlum Model 2241-4	Neutron detector	Fast and thermal neutrons
Amptek Gamma-Rad	Nal scintillation detector	X-ray and gamma spectrum

Table 10.1: Niowave Radiation Monitoring Instrumentation

Niowave will use instruments that meet the radiation monitoring instrument specifications published in Appendix H to NUREG-1556, Vols. 17, *Program-Specific Guidance About Special Nuclear Material of Less Than a Critical Mass* dated November 2000 and Appendix I to NUREG-1556, 21 *Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator.* We reserve the right to upgrade our survey instruments as necessary.

10.3. Material Accountability

Prior to receipt of licensed material, Niowave will developed, implement and maintain written procedures for licensed material accountability and control to ensure that:

- License possession limits are not exceeded,
- Licensed material is secured from unauthorized access or removal,
- Licensed material is maintained under constant surveillance or control,

Records of production, transfer, and disposal of licensed material are maintained.

We will conduct physical inventories of all licensed material at intervals not to exceed 6 months.

10.4. Occupational Dose

We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, and 10 CFR 20.2106, as applicable.

10.5. Public Dose

No response required.

10.6. Operating and Emergency Procedures

Procedures for safe handling of radionuclides and emergencies will be developed and documented before receipt of licensed materials. These procedures will be implemented after appropriate staff is trained. This training will occur before receipt of licensed materials. Procedures will be revised only if:

- The changes are reviewed and approved by the licensee management and the RSO in writing,
- Licensee staff is provided training in the revised procedures prior to implementation,
- The changes are in compliance with NRC regulations and the license,
- The changes do not degrade the effectiveness of the program.

10.7. Surveys and Leak Tests

Niowave will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix K to NUREG-1556, Vol. 17 and Appendix M to NUREG-1556, Vol. 21.

10.8. Maintenance

No response required.

10.9. Transportation

No response required.

10.10. Minimization of Contamination

See 5.1, Item 9, 10.6, 10.7, and Item 11.

Item 11: Waste Management

Niowave plans to dispose of short lived (half-life of less than 120 days) non-transferred radioactive materials by decay-in-storage (DIS). Low-level radioactive waste will be disposed of via transfer to an authorized, licensed recipient, such as Waste Control Specialists, LLC in Andrews, Texas.

11.1 General Waste Management Procedures

The following procedures shall be observed when dealing with radioactive waste:

- All radioactivity labels must be defaced or removed before disposal as nonradioactive waste.
- Nonradioactive waste, including uncontaminated packaging of radioactive material, should never be mixed with radioactive waste.
- Radioactive waste should not be created unnecessarily. The RSO or ARSO should occasionally monitor the handling of radioactive material to ensure that needless waste is not being created. All new procedures should be scrutinized to ensure the same.
- Cost, occupational and public exposure to radiation, and any other hazards which are properties of the material (e.g. toxicity, carcinogenicity, flammability, etc.) shall be considered when choosing a disposal method.
- The full scope of waste handling procedures from the source of the waste to the waste storage areas, and eventual disposal will be taught to all radiation workers.
- All non-radiation workers will be instructed as to how to avoid unauthorized contact with and disposal of radioactive material.

11.2 DIS Procedures

The following procedures shall be observed when disposing of waste via DIS:

- Only waste with a physical half-life of 120 days or less may be disposed of by DIS.
- Waste with a half-life longer than 65 days, but less than or equal to 120 days should be segregated at its source from waste which has a half-life less than or equal to 65 days.
- Waste shall be stored in suitable containers marked with the isotope(s) contained therein. The container should provide adequate shielding (if needed) and the material it is constructed from should be chemically compatible with the waste it contains. Liquid and solid waste shall be stored in separate containers.
- Full containers shall be sealed with identifiable labels.
 - The label shall contain the date when the container was sealed, the longest lived radionuclide in the container, total activity, and the initials of the person (RSO, ARSO, or AU) who sealed the container.
 - After being sealed, the container may then be transferred to the DIS area.
 When large quantities are held for DIS, potential measurable radiation exists even after 10 half-lives.

- Prior to disposing as ordinary trash after 10 half-lives of the longest lived isotope within, each container should be checked as follows:
 - Remove any shielding from around the container (if necessary).
 - Survey the contents of the container in a low background setting.
 - If the survey readings are indistinguishable from background readings, the material may be disposed of as trash after removing or defacing any radiation labels.
 - If the surface reading is still above background, return the container to the DIS area and notify the RSO or ARSO.
- Before disposing in the trash, record the date when the container was sealed, the disposal date, they type of material, and which instrument was used in the Radioactive Material Log. The person performing the survey should then initial the record.

