Tomczak, Tammy

From: Pelke, Patricia
Sent: Saturday, August 30, 2014 1:48 PM
To: Tomczak, Tammy
Cc: Null, Kevin
Subject: Fw: Updated Application
Attachments: NRC Accelerator Produced Radioisotopes Application (Episode III) 140829.pdf

Importance: High

Tammy - please process-in, resubmission of voided application assigned to Kevin. Please assign to Kevin (R2). Tks - Patty
Sent from Blackberry

From: Erik Maddock [mailto:maddock@niowaveinc.com]
Sent: Friday, August 29, 2014 05:01 PM Eastern Standard Time
To: Null, Kevin
Cc: Pelke, Patricia; Grimm, Terry <grimm@niowaveinc.com>; Starovoitova, Valeriia <valeriia@niowaveinc.com>
Subject: Updated Application

Mr. Null,
After meeting with Ms. Patricia Pelke in Washington DC on August 21st, we have made the following changes to the isotope production application we submitted this spring under Part 30 of Title X CFR. In particular we:

- Addressed the deficiencies identified in your email from July 23rd
- Added requests for licensing three more isotopes produced from stable targets: Mo-99, Zn-65, and Ag-110m
- Addressed financial assurance for decommissioning in the amount of $225,000 by way of a letter of credit

The attachment is a formal resubmission of this application for review. We look forward to working with you on any issues that might remain.

Regards,

Erik Maddock
Radiation Safety Officer
Niowave, Inc.
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(517) 756-8026 (mobile)
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Item 5: Radioactive Material

5.1. Unsealed Radioactive Material

The materials proposed for this license are phosphorus 32 (P-32) in solid form with a maximum possession limit of 10 mCi, scandium 46 (Sc-46) in solid form with a maximum possession limit of 10 mCi, scandium 47 (Sc-47) in solid form with a maximum possession limit of 10 mCi, manganese 56 (Mn-56) in solid form with a maximum possession limit of 10 mCi, zinc 65 (Zn-65) in solid form with a maximum possession limit of 10 mCi, copper 67 (Cu-67) in solid form with a maximum possession limit of 10 mCi, selenium 75 (Se-75) in solid form with a maximum possession limit of 10 mCi, yttrium 88 (Y-88) in solid form with a maximum possession limit of 10 mCi, yttrium 90 (Y-90) in solid form with a maximum possession limit of 10 mCi, molybdenum 99 (Mo-99) in solid form with a maximum possession limit of 10 mCi, technetium 99 (Tc-99) in solid form with a maximum possession limit of 10 mCi, technetium 99m (Tc-99m) in solid form with a maximum possession limit of 10 mCi, silver 110m (Ag-110m) in solid form with a maximum possession limit of 8 mCi, holmium 166 (Ho-166) in solid form with a maximum possession limit of 10 mCi, and gold 198 (Au-198) in solid form with a maximum possession limit of 10 mCi.

These isotopes will be produced using a superconducting electron linac. After undergoing bremsstrahlung conversion to x-rays, the beam will strike a high Z target that generate photon and neutron flux. When the target material is exposed to these fluxes, a photon or a neutron may be absorbed by the nucleus, thereby producing the proposed radioactive isotopes by either neutron capture or photonuclear reactions.

5.2. Financial Assurance and Recordkeeping for Decommissioning

5.2.1 Financial Assurance for Decommissioning

Certification of financial assurance for decommissioning (FAD) in the amount of $225,000 is required by this license. A letter of credit as required by NUREG-1757, Vol. 3, Rev. 1 will be provided to the NRC before Niowave produces any material under the proposed license.

5.2.2 Recordkeeping for Decommissioning

The following records will be maintained 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 licensed 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

With a growing need for radioisotopes, non-reactor based production will become vital to maintaining a commercial supply of manmade radioactive nuclides. Niowave proposes to begin production of seven specific radioisotopes for commercial distribution to authorized licensees.

6.2 Material Possession Limits

Radionuclides will be produced by an accelerator in accordance with applicable regulations. This material will be used in accordance with Table 6.1.

Table 6.1: Licensed material possession limits and uses.

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
P-32	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Sc-46	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Sc-47	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Mn-56	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Zn-65	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Cu-67	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Se-75	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Y-88	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Y-90	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.

Mo-99	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Tc-99	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Tc-99m	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Ag-110m	Unsealed solid	8 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Ho-166	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.
Au-198	Unsealed solid	10 mCi	Production of a radiochemical for transfer or distribution to authorized licensees.

Item 7: Training and Experience of Radiation Safety Officers

7.1 Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO)

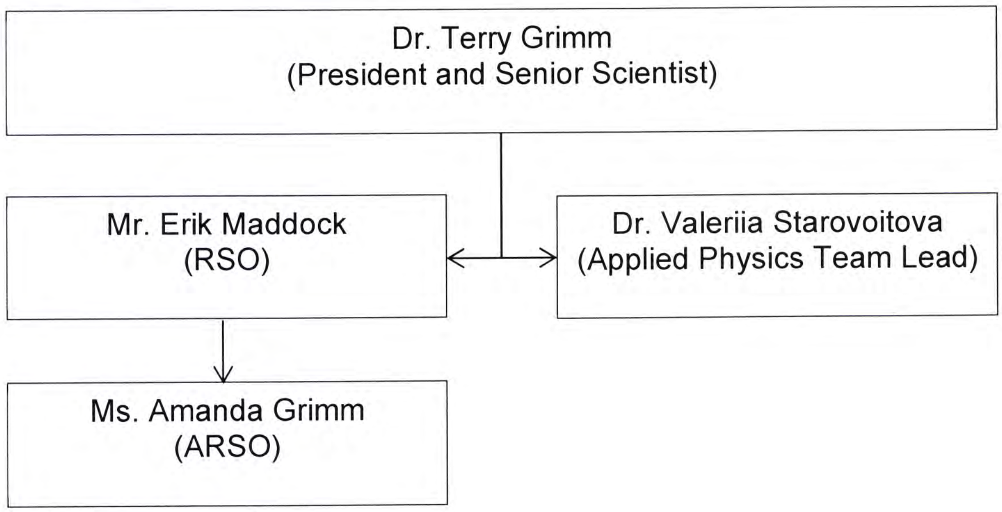

Figure 7.1: An organizational chart describing the management structure, reporting paths, and the flow of the authority between executive management and the RSO.

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, and the ARSO, Amanda Grimm, will be responsible for the radiation safety program and compliance with the Commission's regulations. The ARSO reports directly to the RSO. The RSO, ARSO, 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 hands-on 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 tasks at Niowave as the head 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.

Amanda Grimm is the Assistant Radiation Safety Officer at Niowave, Inc. She received her BSE degree in Materials Science and Engineering from the University of Michigan, Ann Arbor. The Materials Science Department uses chemistry and physics to understand how properties of materials depend on chemical bonding, atomic and molecular arrangements, crystal structures, and microstructures. Her undergraduate studies included a broad foundation in all classes of materials, including metals, polymers, ceramics, and materials used in the manufacture of solid-state electronic devices. She is currently in training for Assistant Radiation Safety Officer at Niowave, Inc.

7.2 Authorized Users

Four authorized users are proposed: the RSO, ARSO, 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 served at the Idaho Accelerator Center since 2007, 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.

7.3 Servicing, Maintenance and Repair

Niowave staff will be servicing and maintaining production linacs. Any worker who in the course of servicing a linac needs to be in a restricted area, or who needs to handle activated components involved in isotope production will have gone through the radiation worker training detailed in Item 8 below.

Niowave is primarily a linac manufacturer. All linac maintenance will be overseen by engineers responsible for the design and construction of the linac. The workers doing the servicing will be the same ones responsible for assembling the linac when new.

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

Niowave is currently licensed by the State of Michigan to operate several electron accelerators, including a 40 MeV, 100 kW linac. The outline of the current radiation safety training program given to Niowave's radiation workers is given 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 material when a license for possession was received from the NRC. At the start of this application process the curriculum was again updated to include neutron activated byproduct material and currently covers the following 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
- 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. For radiation workers, this training takes about 2 hours, with the time roughly equally split among all topics. It includes a ~15 minute tour of the restricted areas and other spaces relevant to radiation safety.

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. Both types of radiation safety training course is provided for new employees every quarter if needed.

Employees that have received previous training are required to attend a refresher radiation safety training course at least once a year. Retraining more frequent than annually will be performed as deemed necessary by the radiation safety team whenever there is a change in duties or the work environment affecting workers involved in isotope production.

Each employee's understanding of the material is assessed through a multiple-choice test given at the end of each training course. Passing grades are 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. Oral quiz results are recorded on the previously failed paper test.

Item 9: Facilities and Equipment

Licensed byproduct material will be produced at and shipped from Niowave's Walnut Street Headquarters, consisting of two adjacent buildings and located in Lansing, MI. The designated storage and shipping areas are in Niowave's Electron Research and Development (NERD) facility, which is a 14,000 ft^2 steel framed and walled structure, built on a concrete slab in 2012 (see Figure 9.1). The byproduct material ship will 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.

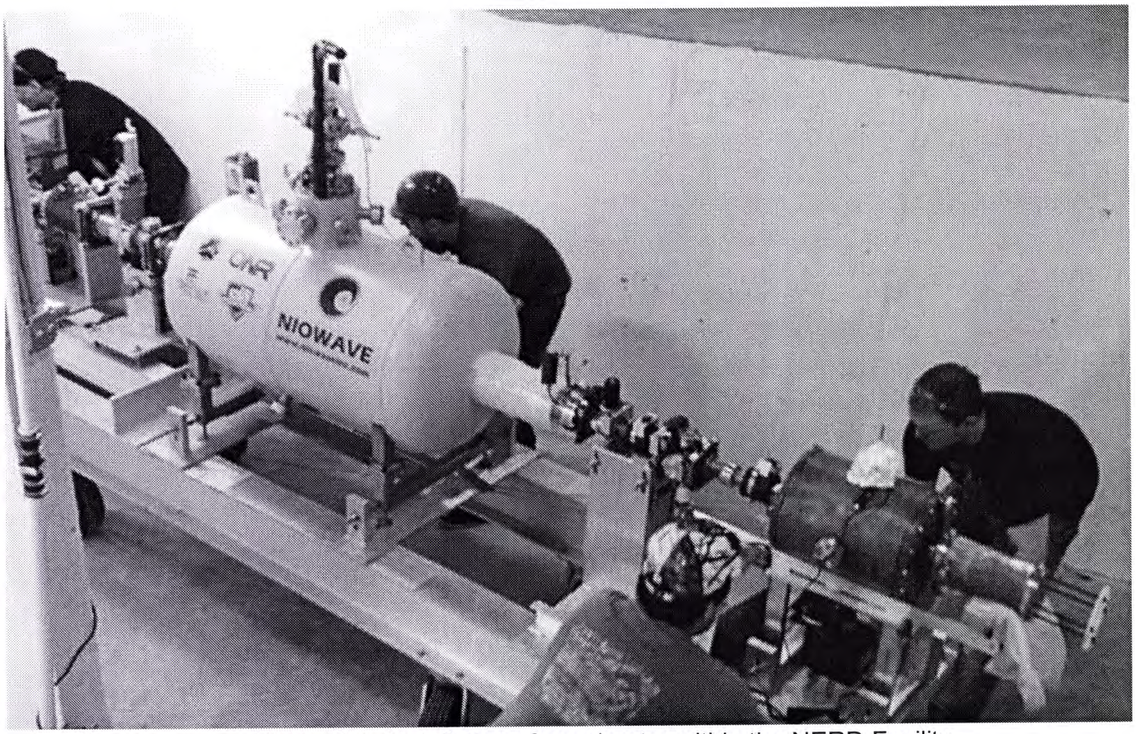

Figure 9.1: Installation of accelerator within the NERD Facility.

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, ARSO, and AUs having keys. The NERD building is locked when not in use, and security is continuously monitored by a burglar alarm service and video cameras after hours.

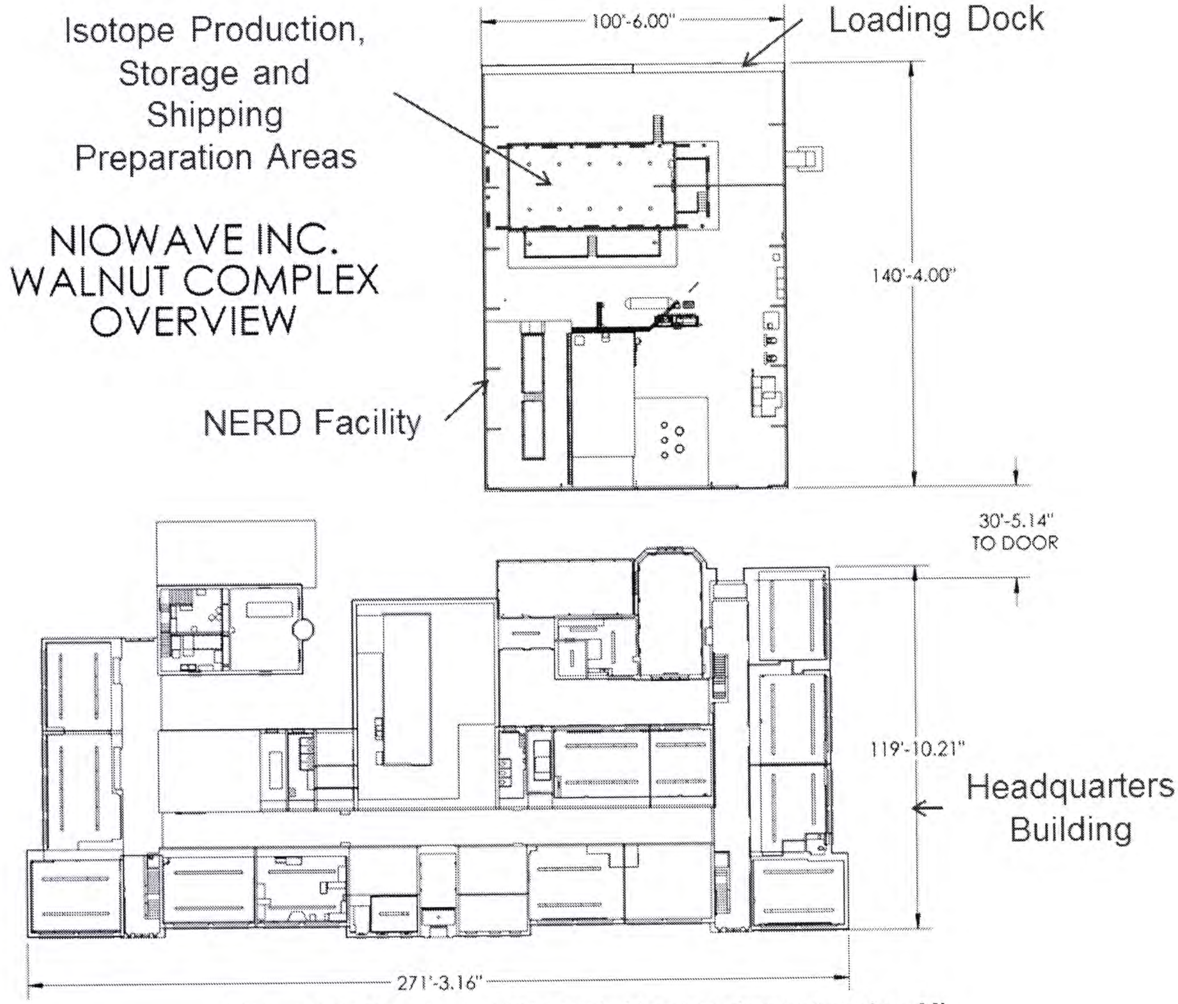

Figure 9.2: Overview of Niowave's Headquarters in Lansing, MI.

Niowave intends to use our superconducting linacs only for activation of stable isotopes in solid form. We will then transfer these activated targets to other license holders for their uses. Because radiochemistry will not be occurring on site, no hot-cells or synthesis units are planned for use under the proposed license. No radioactive liquids or gases will be produced under the proposed license. No particulates will be produced during activation and no air filtration will be necessary.

Once Niowave is licensed for isotope production, during the first test of the entire production system, a safety survey map will record all dose rates adjacent to the production site shielding. This map will be submitted to the NRC for review before production operations continue.

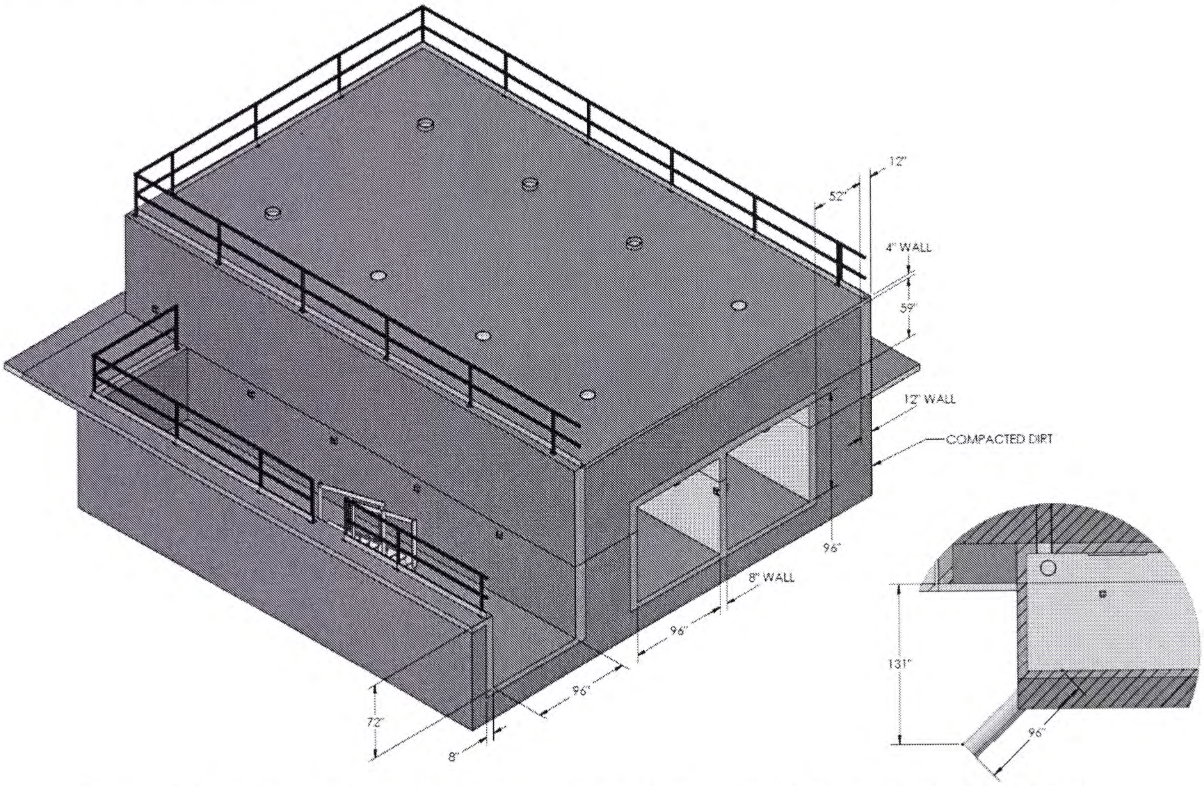

Figure 9.3: Shielded tunnels dimensions. Concrete is shown as gray and earth as brown.

Figure 9.4 is a diagram of the NERD heating and ventilation system. Ridge vents which open on overpressure are also installed in the building near the ceiling.

The shielded tunnels where the linac will do the production has a interlock consisting of a mechanical switch which suspends power to the accelerator when the entrance gate is opened. There also is an emergency stop button by the operating station where the area monitor dose rate display is located. Linac operators continuously monitor the entrance to the shielded enclosure via closed circuit camera.

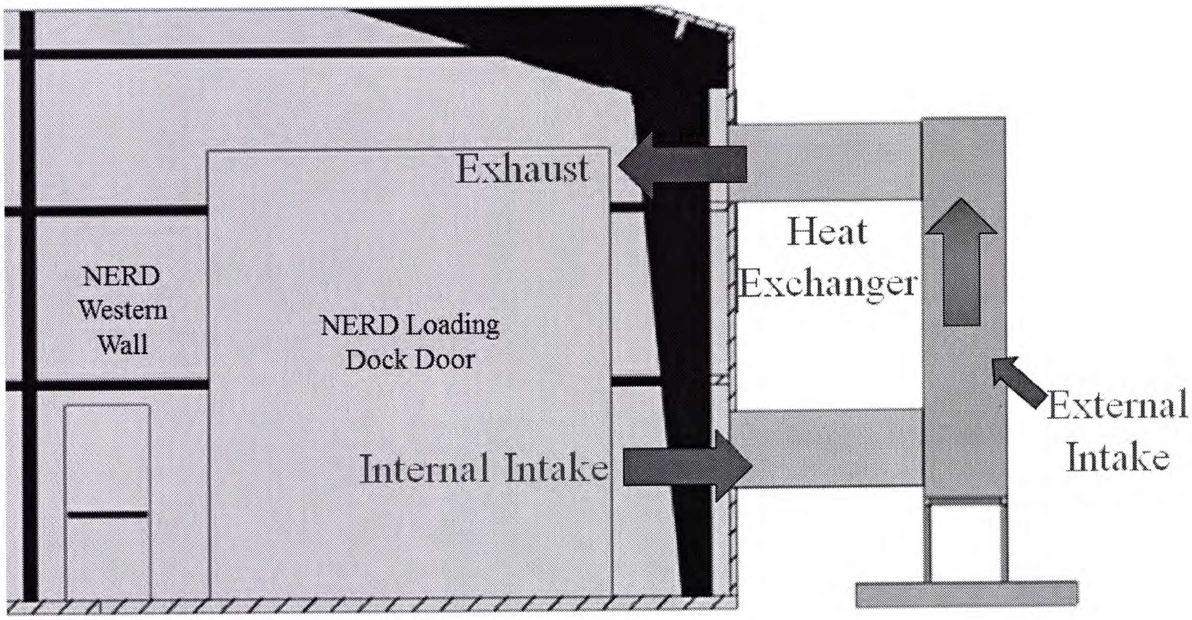

Figure 9.4: A cross section of the NERD facility showing the airflow thru the ventilation system as it is used in cold months. A majority the air flow is recirculated, while a minority is fresh air drawn from outside. In warmer months, cool, dry air is drawn into the building overnight, and the ventilation is secured during warm days. There is currently no air conditioning unit installed, but there is the capability to add that in the future.

Plans are in place for an upgrade to a comprehensive interlock system before isotope production begins. This includes a warning light visible within and at the entrance of the shielded enclosure which is illuminated only when the accelerator is producing radiation. An audible warning will sound within the tunnel and all adjacent areas at least 15 seconds before the creation of a high radiation area (i.e. dose rate ≥100 mrem/hr). In addition to the entrance gate interlock switch described above, there will be a time delayed arming switch located within the tunnels which will allow the arming of all interlocks and the making of radiation after 15 seconds. When radiation is being produced, operators will continuously monitor the entrance to the shielded enclosure via closed circuit camera See Figure 9.5 for an illustration of this system.

Non-permanent shielding will be added in the form of lead or concrete bricks, or poly sheeting, to keep the instantaneous dose rate at any accessible outer surface of the shielded enclosure to < 7 mrem/hr. This limit is required by Niowave's State of Michigan license for a Class A shielded enclosure. An area monitor ionization chamber will be placed in the highest radiation hotspot external to the shielding. This area monitor will trip the linac before the dose rate reaches 7 mrem/hr.

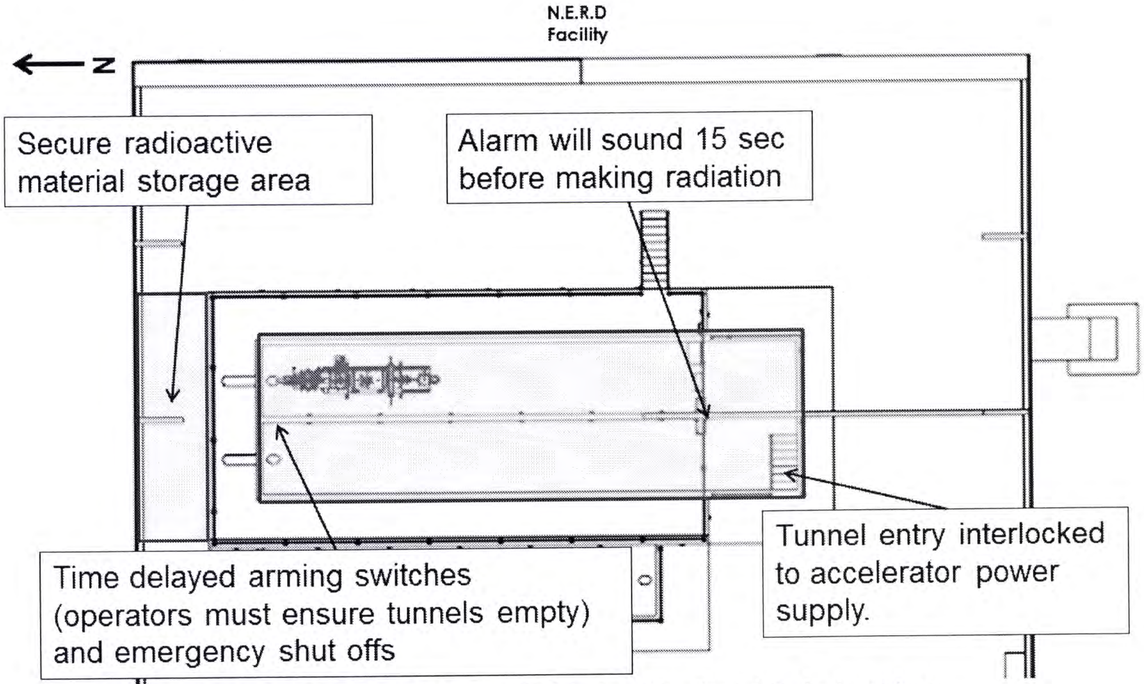

Figure 9.5: Overhead view with details of the linac interlock system.

Isotope production targets will be positioned for irradiation on a pneumatic rabbit or remotely operated cable system (still in development). No delivery piping is required. When necessary for worker safety, the activated target will be remotely moved into a pig for handling. The pig will be sufficiently shielded to reduce external dose rate to less than 2 mrem/hr on contact when it is removed from the enclosure for shipment, storage, or analysis. If storage is necessary, the target will remain inside the pig in Niowave's radiation storage area or within the tunnels until background radiation levels are less than 2 mrem/hr in the nearest unrestricted area upon its removal from the pig. Surveys of adjacent areas will be performed each time additional activity is add to the radioactive material storage area.

Item 10: Radiation Safety Program

10.1. Audit Program
No response is required.

10.2. Radiation Monitoring
Accelerator produced radionuclides generate a wide spectrum of radiation. Several types of detectors are needed to ensure radiation safety. Refer to Table 10.1 for Niowave's radiation monitoring instrumentation.

Table 10.1: Niowave Radiation Monitoring Instrumentation

Detector Make & Model	Detector Type	Radiation Monitored
Fluke 451P	Handheld survey meter	Gammas and x-rays
Ludlum Model 26	Geiger-Müller Frisker	Gammas and betas
Ludlum 357-9 & 45-9	Area monitor with ionization chamber	Gammas and x-rays
Ludlum Model 2241-4	Neutron detector	Neutron radiation
Ludlum Model 3000 with 43-92 Alpha Probe	Alpha Detector	Alpha radiation
Amptek Gamma-Rad	NaI scintillation detector	X-ray and gamma spectrum

Niowave will use instruments that meet the radiation monitoring instrument specifications published in Appendix I to NUREG-1556, Vol. 21, *Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator*. We reserve the right to upgrade our survey instruments as necessary.

10.3. Material Accountability
Niowave has developed and will 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 and control.
- Records of production, transfer, and disposal of licensed material are maintained.

We will conduct physical inventories of sealed sources of 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. No airborne release into worker breathing zones will occur during licensed operations.

10.5. Public Dose
No effluent or air emissions will be released during licensed operations.

10.6. Safe Handling of Radionuclides 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 and maintained 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; the licensee staff is provided training in the revised procedures prior to implementation; the changes are in compliance with NRC regulations and the license; and the changes do not degrade the effectiveness of the program.

During linac operations, emergency shutdown can be initiated by pressing the emergency shutdown button on the area monitor control panel.

10.7. Surveys and Leak Tests
We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in 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 non-transferred radioactive materials by decay-in-storage (DIS) for the isotopes we are specifically proposing to license that have a half-life of less than 120 days. All other 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 into nonradioactive waste streams.
- 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.

Figure 11.1 shows Niowave's designated radioactive material storage area. This area is within a locked enclosure and is in a building monitored when not occupied by a burglar alarm and video cameras. It is not accessible to workers, and only the RSO and ARSO will possess a key once licensed material is stored within.

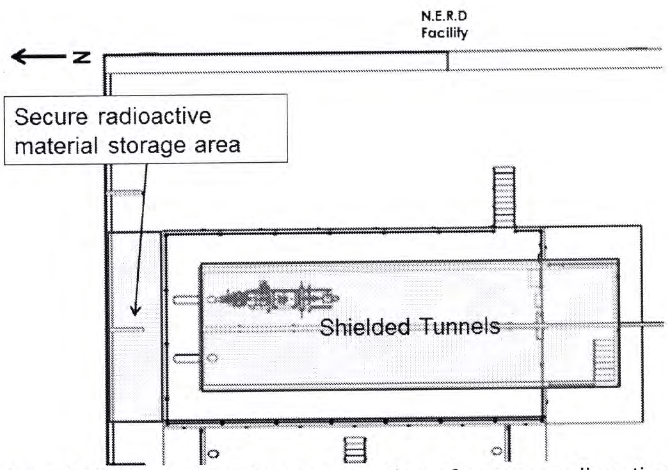

Figure 11.1: Overhead view of NERD facility showing location of secure radioactive material storage area.

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.
- Isotopes which are produced with a half-life longer than 65 days, but less than or equal to 120 days will be kept separately from isotopes produced which have 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.
- 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.