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Radiological Considerations Supporting the American Medical Isotope Producer Niowave

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September 2022
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EXECUTIVE SUMMARY

This report provides a summary of work performed by Savannah River National Laboratory (SRNL) during FY22 in support of Niowave, an American Medical Isotope Production (AMIP) facility.

SRNL served in a technical support role, funded by NA-231, supporting Niowave in the beginning of non-radiological functional testing of their airport facility in FY22. Through this agreement, SRNL provides Niowave access to subject matter experts (SMEs) for questions that may arise during the drafting of engineering plans, facility policies, and/or response procedures. This report summarizes discussions between SRNL and Niowave about guidance concerning issues with the floor of the hot cells, dispersible removable contamination (beta emitting fission product), hot cell operation specifically utilization of cameras or mirrors, and the process for removing contaminated waste from the hot cell.

Lessons learned and other various resources provided to Niowave by SRNL during FY22 are referenced in this report. This work was funded through NNSA’s Office of Material Management and Minimization, Conversion Office (NA-231).
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AMIP</td>
<td>American Medical Isotope Procedure</td>
</tr>
<tr>
<td>EPD</td>
<td>Electronic Personal Dosimeter</td>
</tr>
<tr>
<td>ERP</td>
<td>Emergency Response Plan</td>
</tr>
<tr>
<td>FDA</td>
<td>United States Food and Drug Administration</td>
</tr>
<tr>
<td>FY 22</td>
<td>Fiscal Year (October 1, 2021 – September 30, 2022)</td>
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<td>FY23</td>
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<tr>
<td>HEU</td>
<td>Highly Enriched Uranium</td>
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<td>Mo-99</td>
<td>Molybdenum-99</td>
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<td>NNSA</td>
<td>National Nuclear Security Administration</td>
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<tr>
<td>SRNL</td>
<td>Savannah River National Laboratory</td>
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<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
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<td>Tc-99</td>
<td>Technetium-99m</td>
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<tr>
<td>TRU</td>
<td>Transuranic</td>
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1.0 Introduction
Technetium-99 (Tc-99m) is an FDA approved radionuclide which is a critical component of diagnostic medical procedures. Tc-99m, a medical radioisotope, is vital for global cancer and heart disease detection. Tc-99m is produced via the decay of the short half-life isotope molybdenum-99 (Mo-99). Currently, the primary Mo-99 producers are located in Belgium, Netherlands, the Czech Republic, Poland, and South Africa[1].

The production of Mo-99 occurs by irradiating highly enriched uranium-235 targets in a nuclear reactor. The uranium-235 splits into at least two fission products of which six percent results as Mo-99[1]. To isolate the Mo-99, the target must undergo chemical separation. After separation, the Mo-99 can be shipped, actively decaying into the Tc-99m, to anywhere in the world. However, Mo-99 has a half-life of 66 hours and the decay product, Tc-99m, has an even shorter half-life of around six hours. This short half-life reduces the ability to stockpile material and requires that the entire supply be utilized within six days of production. In just the United States over 40,000 medical procedures are performed each day that require the use of Tc-99m[2]. Additionally, since Mo-99 production requires utilization of highly enriched uranium (HEU) targets for irradiation, proliferation concerns arise with the increased and widespread production utilizing HEU.

To address rising concerns associated with the production of Mo-99, Congress passed the American Medical Isotope Production Act of 2012, which scoped production that would be able to create a stable supply of medical isotopes for the United States[3]. The National Nuclear Safety Administration (NNSA) received direction to award five companies with a 50%/50% cost-shared agreement to develop viable production technology that would facilitate the concerns with Mo-99. Additionally, within the scope of this agreement, NNSA received direction to provide funding to Department of Energy National Laboratories who offer technical expertise and run experiments for American Medical Isotope Producers (AMIPs)[4]. Through this agreement and provided funding, SRNL has provided Niowave technical support across many different topics in FY22 as Niowave begins to establish facility considerations. Subject Matter Experts (SMEs) at SRNL have engaged with Niowave personnel to provide technical information related to processes and operations. This report covers discussions on hot cell floor contamination, hot cell operation dose rates, hot cell visual inspection, and hot cell trash, as well as several other topics of which information was requested by Niowave during FY22.

2.0 Personnel Dosimetry

2.1 Introduction
In October of 2021, Niowave and SRNL discussed issues with the floor of the hot cell and dispersible removable contamination (beta emitting fission product) in Niowave’s processing facilities. SRNL consulted with hot cell SMEs with the technical expertise required to appropriately address Niowave’s concerns.

2.2 Hot Cell Floor Contamination Discussion
- Niowave requested recommendations for cleaning hot cell environments to reduce overall background and removable contamination. Niowave was using isopropyl wipes at the time, but this was both time and labor intensive for relatively little decontamination.
  - SRNL hot cell expert informed Niowave that the exact decontaminating agent for the E-Wing shielded cells was unknown. However, the process for cleaning the environment involved several pressure washing attempts before entry was established within the cell with an acceptable dose rate, still prior to installing the coffer dams. To assist in decontamination, an electric pressure washer was modified to be remotely operated, which was coupled with a wet vacuum that was able to remove the liquid waste water from the cell. If utilizing a pressure washer for decontamination, SRNL hot cell SME suggested following up with a wet vacuum to remove the liquid waste water from the cell. Afterwards, the area and mop heads can be wiped clean, and a final rinse can be
performed. Even after several decontamination attempts, the dose was measurable in Rem/hr background.

- Additionally, SRNL hot cell experts reported great success with Contrad, which is a lab-approved decontamination agent. Contrad is a cleaning and disinfection agent, primarily for laboratory application, but also employed in medical and industrial applications. Another decontamination agent that was utilized was dilute (around 3 molar) nitric acid, which was reported to be very successful. The Contrad agent can be found at Decontamination Laboratories - the Contrad range of cleaning & disinfection agents, for laboratory, medical and industrial applications. Isopropyl wipes were also recommended by SRNL hot cell experts for decontamination implementation.

### 2.3 Hot Cell Operation Dose Rates Discussion

- In October of FY22, requested information on how SRNL monitors extremity and whole body dose rates during hot operations. Niowave at that time used the fingertip dosimetry and pocket dosimeters for daily estimation of worker dose and had the formal chest and ring badge for dosimetry records.

  - An SRNL SME was consulted for advice, reporting that for the vast majority of the operations, a standard issue TLD and finger rings were sufficient (<100 mrem/hr). However, if a worker needed to perform tasks in a higher radiation environment, or in a scenario for which the individual’s exposure is not adequately represented by the TLD worn on the upper torso, SRNL will provide “multi-pack” dosimetry. The multi-pack dosimetry will be worn in areas designated by the radiological protection division. These often include a dosimeter on a headband, armbands, thighs, ankles, and/or feet. The multi-pack dosimetry is returned to the radiological protection office at the end of the workday or at the completion of the job (whichever is sooner).

  - Additionally, a radiological control first-line manager reported that the multipack dosimetry is rarely used but are always available if needed. The need will depend on the job task/scope and radiation rates. Typically, for most of the jobs, the standard Laundauer TLD, finger ring dosimetry, and an electronic personal dosimeter (EPD) are sufficient.

### 3.0 Hot Cell “How-To”

#### 3.1 Introduction

In FY22, Niowave contacted SRNL concerning issues with hot cell operation specifically utilization of cameras or mirrors and the process for removing contaminated waste from the hot cell.

#### 3.2 Hot Cell Visual Inspection Discussion

- In October of FY22, Niowave requested information on whether SRNL utilized specific types of cameras or general mirror setups for their hot cells. This request was related to the scale up of processes as at the time, Niowave was still performing visual inspection using localized shielding, but knew that as the scale of production increased, so would dose rates.

  - SRNL policies do allow the utilization of cameras within the hot cells. After consulting with an SRNL hot cell block manager, it was reported that due to SRNL’s security posture, wireless (Wi-Fi, Bluetooth, etc.) cameras are prohibited, so SRNL is currently using some of the least expensive, wired (USB) cameras that are available. These cameras are not radiation hardened and do not have a zoom function but are relatively inexpensive so disposing of them is not cost prohibitive. There are also mirrors that can be picked up using the manipulator. The manager also mentioned that there are newer, high-tech solutions. Thus, a new facility without a strict security posture could easily incorporate higher-tech cameras (go-pro, etc.).
3.3 Hot Cell Trash Removal Discussion

- Niowave requested information on how to maintain negative pressure inside hot cell while bagging out trash and how many layers of bagging was used at each step.
  - SRNL hot cell expert reported that there is negative air flow in the cell blocks that is over 3600 ft³/min in the 6 cells in A-block. The negative air flow is 4600 ft³/min for the 10 cells in B-block. Each cell is about 550 ft³, which provides about 1.5 inches of water negative pressure.
  - Additionally, when SRNL bags out small amounts of trash, the trash is first cleaned/rinsed off, then the trash is placed within a zip-lock bag and passed out of a port or into a glove box before the trash is finally double bagged out of the port/glove box. SRNL’s F-area had a transfer draw that maintained containment and opened into a hood for removing samples/waste from the F-area cells.

- Niowave requested information on how to handle very hot trash in terms of decontaminating layers to get it clean (i.e. balancing external contamination vs worker exposure).
  - SRNL’s F-area used Contrad 70 detergent to clean plastic and glass by soaking, scrubbing, or sonicating, which is beneficial because the detergent completely rinses away. Absorbents (paper, rags, etc.) are essential to maintaining control of the detergent. Additionally, the work surfaces should be prepared so that the detergent can be rinsed into a sump or a drain with a filter/trap to catch solids.

- Niowave requested information on what the contamination levels required to pass each step of removal from hot cell are and whether they are even measured with high activity waste.
  - Hot cell SME recommended sharing the Transuranic Waste Procedure (Manual L1, Procedure 6.24[5]), which was approved for release and shared with Niowave.
  - In SRNL’s F-Area, waste was removed in 2-gallon plastic pails. These pails were typically decontaminated through chemical means (primarily to reduce dose rates). When the pails were removed from the hot cells, they were immediately double bagged in radiological bags and the exterior of the outermost bag was checked for residual contamination. These were kept to below SRNL Contamination Area levels, (i.e., <200 Alpha, <10,000 Beta/Gamma transferable contamination, and below 50 mrem for the whole body). The contamination levels of the pails inside the bags were never checked because the Radiological Bags would contain any contamination found on the pail. The waste stream was determined by the dose rates of the waste containers (B-12’s) that were sent to the SRNL burial ground.

- Niowave requested drawings or schematics of how trash gets out of high activity hot cells at SRNL.
  - SRNL SME recommended documents that went through the release of information process and were shared with Niowave in support of removal high activity trash from hot cells:
    - Cell 7 Old Liner 2021, Revision 0 (see Appendix, Attachment 6.1)
    - Cell Liner 8, Revision 0 (see Appendix, Attachment 6.2)
    - Old return duct in cell 9, Revision 0 (see Appendix, Attachment 6.3)
    - Removing containment box from cell and putting it in the Sealand container, Revision 0 (see Appendix, Attachment 6.4)
    - S5-7-628, Revision 11 (see Appendix, Attachment 6.5)
    - ST5-5841, Revision 2 (see Appendix, Attachment 6.6)
    - ST5-9802, Revision 5 (see Appendix, Attachment 6.7)
    - ST5-9862, Revision 1 (see Appendix, Attachment 6.8)
    - ST5-10115, Revision 4 (see Appendix, Attachment 6.9)
    - ST5-10129, Revision 1 (see Appendix, Attachment 6.10)
    - ST5-10221, Revision 1 (see Appendix, Attachment 6.11)
    - ST5-14398, Revision 18 (see Appendix, Attachment 6.12)
    - ST5-15032, Revision 1 (see Appendix, Attachment 6.13)
    - ST5-15385, Revision 12 (see Appendix, Attachment 6.14)
4.0 Conclusions and Future Work

SRNL has maintained their availability as a collaborative partner with Niowave throughout FY22, supporting activities to provide technical expertise, recommendations, and experience related to facility and operations. However, contact with Niowave was limited after the first quarter FY22 due to their business needs, including the redesign of their Mo-99 production process. SRNL's remaining activities were suspended for the remainder of the fiscal year and milestone deliverables were reallocated.

This work will continue into FY23 on a limited per request basis with technical support funding received by SRNL from NA-231 to further facilitate facility operation consultation work. Work performed in FY23 will emulate the work outlined in this report as Niowave continues buildout and testing of their airport facility and further design their final production facility.
5.0 References


5 - SRS Manual L1, Procedure 6-24, Revision 26, Transuranic Waste Procedure, available upon request

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  Marissa Reigel
  Bryan Foley

Niowave:
  Jenvra Foley
  Nathan Johnson
  Robert Wahlen
6.0 Appendix

Attachment 6.1: Cell 7 Old Liner 2021, Revision 0
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Cell 7 OLD LINER
5/2021

Ronald Blessing
Old return duct CELL 9

- Old return duct
- Reflectors
- Shield dampers
- Cell 9

Dimensions:
- 67.563'
- 10'
- 15'

Ronda Blessing 5/2021
Attachment 6.4: Removing containment box from cell and putting it in the Sealand container,
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Attachment 6.4: Removing containment box from cell and putting it in the Sealand container,
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leaning over the containment box
on to cradle cells 9 & 13
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