UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 2, 2022

EA-22-021

Terry Grimm, Ph.D.
Chief Executive Officer
Niowave, Inc.
1012 N. Walnut St.
Lansing, MI 48906

SUBJECT: NRC INSPECTION REPORT NO. 07007031/2022001(DNMS) – NIOWAVE, INC.

Dear Dr. Grimm:

On January 18 and 19, 2022, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at your facility on Port Lansing Road in Lansing, Michigan, with continued in-office review through March 24, 2022. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The inspection and in-office review also included an evaluation of the circumstances surrounding a report dated January 5, 2022, notifying the NRC of three doses above the occupational limits for adults in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(2)(ii). The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the NRC rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, three apparent violations of NRC requirements were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations concerned: (1) the failure to control the dose to the skin of any extremity to 50 rems or less, with three examples, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(2)(ii); (2) the failure to perform adequate surveys to ensure compliance with the annual occupational dose limits in 10 CFR 20.1201(a)(2)(ii), as required by 10 CFR 20.1501(a); and (3) the failure to implement procedures and engineering controls that were adequate to ensure occupational doses would be as low as is reasonably achievable (ALARA), as required by 10 CFR 20.1101(b).

Mr. Ryan Craffey of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with Dr. William Peters of your staff at the inspection exit meeting on April 4, 2022.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. Before the NRC makes its enforcement decision, a pre-decisional enforcement conference (PEC) to discuss the apparent violation(s) has been scheduled for Wednesday, May 25, 2022, at 1:00 p.m. at the U. S. Nuclear Regulatory Commission Region III Office, located at 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4352. This conference will be open to public observation in accordance with Section 2.4 of the NRC Enforcement Policy.

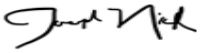
The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation(s).

Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with the NRC's "Rules of Practice" in 10 CFR 2.390, a copy of this letter, its enclosure, and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Craffey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655.

Sincerely,



Nick, Joseph signing on behalf
of Brock, Kathryn
on 04/27/22

Kathryn M. Brock, Acting Director
Division of Nuclear Materials Safety

Docket No. 070-07031
License No. 21-35144-04

Enclosure: Inspection Report No.
07007031/2022001(DNMS)

cc w/encl: Dr. William Peters, Radiation
Safety Officer
State of Michigan

Letter to Dr. Terry Grimm from Kathryn M. Brock, dated May 2, 2022.

SUBJECT: NRC INSPECTION REPORT NO. 07007031/2022001(DNMS) – NIOWAVE, INC.

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	070-07031
License No.	21-35144-04
Report No.	07007031/2022001(DNMS)
EA No./NMED No.	EA-22-021
Licensee:	Niowave, Inc.
Facility:	2450 Port Lansing Road Lansing, MI
Inspection Dates:	January 18-19, 2022 In-office review through March 24, 2022
Exit Meeting Date:	April 4, 2022
Inspector:	Ryan Craffey, Senior Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Niowave, Inc.
NRC Inspection Report 07007031/2022001(DNMS)

This was an announced initial inspection of activities performed under U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-35144-04. The licensee, Niowave, Inc., was authorized to use special nuclear material and byproduct material at a facility in Lansing, Michigan. The inspection included a review of activities performed at this facility as well as an evaluation of the circumstances surrounding a report dated January 5, 2022, notifying the NRC of three doses above the occupational limits for adults in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(2)(ii).

As a result of this inspection, the NRC determined that three apparent violations of regulatory requirements occurred: (1) the failure to control the dose to the skin of any extremity to 50 rems or less, with three examples, as required by 10 CFR 20.1201(a)(2)(ii); (2) the failure to perform adequate surveys to ensure compliance with the annual occupational dose limits in 10 CFR 20.1201(a)(2)(ii), as required by 10 CFR 20.1501(a); and (3) the failure to implement procedures and engineering controls that were adequate to ensure occupational doses would be as low as is reasonably achievable, as required by 10 CFR 20.1101(b).

The circumstances surrounding the event and the apparent violations, as well as a discussion of the root causes, contributing factors, and the licensee's corrective actions, are discussed in more detail in the following report.

REPORT DETAILS

1 Program Overview and Inspection History

Niowave, Inc. is an accelerator and radionuclide manufacturer in Lansing, Michigan, authorized by Special Nuclear Material (SNM) license 21-35144-04 issued on January 20, 2021, to possess and use gram quantities of SNM scrap (used nuclear fuel) and other stock materials at a facility on Port Lansing Road in Lansing, Michigan to extract daughter products via radiochemical processing for transfer to licensed persons. At the time of the inspection, the licensee had not yet taken possession of any SNM scrap; instead, it possessed curie quantities of strontium-90 and radium-226 under the license for research and development and radiochemical processing to supply manufacturers of medical devices and radiopharmaceuticals.

The licensee was headquartered at a facility on Walnut Street in Lansing, Michigan, where additional activities involving byproduct and source material were performed under separate NRC licenses (21-35145-01 and 21-35144-02).

This was the initial inspection of activities under license 21-35144-04. An on-site pre-licensing site visit was performed on October 22, 2020, with additional remote and in-office review through January 11, 2021.

2 Report of Doses Above Regulatory Limits

2.1 Inspection Scope

The inspector visited the licensee's facility in Lansing, interviewed involved staff and management, and reviewed a selection of records to obtain a detailed understanding of the circumstances surrounding a report dated January 5, 2022, of extremity doses above regulatory limits and to evaluate the licensee's response.

2.2 Sequence of Events

In March and September 2021, the licensee received a total of 32 curies of strontium-90 (Sr-90) salts with the intention of performing radiochemical operations on this material to extract a daughter product, yttrium-90 (Y-90). In September 2021, four radiochemists began a series of operations in a negative-pressure glovebox to aggregate, evaporate, and reconstitute the Sr-90, and continued to work with this high specific activity material (on the order of curies per milliliter) through early December to optimize and validate the radiochemistry process for extracting Y-90.

On December 3, 2021, the licensee received personnel monitoring results for the month of October 2021 (delayed due to issues at their dosimetry provider) showing that two of the four radiochemists had received between 30 and 40 rems of shallow dose to the extremities (hands), a factor of three higher than the licensee had estimated using prior calculations and real-time extremity monitoring. The next day, the licensee sent in the radiochemistry staff's November badges for rush processing. On December 13, the licensee received personnel monitoring results for the other two radiochemists. One received 97.4 rems of shallow dose to the hands in 2021, with 87.1 rems received in the month of November alone. Two days later, the licensee received personnel monitoring

results for first two radiochemists, and found that they received 53.4 and 89.2 rems of shallow dose to the hands in 2021, respectively. All three individuals received between 1.0 and 1.1 rems of deep dose to the whole body for the calendar year.

Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin of any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.

The licensee's failure to control the occupational dose to the skin of the hands of three individual adults to an annual dose limit of 50 rems shallow-dose equivalent is an apparent violation of 10 CFR 20.1201(a)(2)(ii).

2.3 Licensee's Response and Corrective Actions

On December 3, 2021, upon receiving the unexpectedly high personnel monitoring results for October 2021, the licensee suspended all radiological work with Sr-90. On December 14, upon receiving the first monitoring results for November 2021 which included one annual dose above regulatory limits, the licensee suspended all radiological work company-wide. As of January 19, 2022, the licensee had yet to resume radiological work with Sr-90 until it identified a clear path to reducing total extremity dose from an estimated 10 rems per Y-90 production run under previous conditions to a target of 1.5 rems per run.

Shortly after receiving the delayed monitoring results, the licensee switched dosimetry providers and stated that it planned to monitor staff involved in the Y-90 production process with badges exchanged every two weeks once this work resumes. The licensee also reduced its administrative limit for annual exposure from 80 percent to 50 percent of regulatory limits.

The licensee entered the incidence of high doses into a formal corrective action program that the U.S. Food and Drug Administration requires for medical device manufacturers (the NRC does not require a formal corrective action program for this licensee). As of January 28, 2022, the licensee had completed the investigation phase of the program, including a review of all records and video recordings of past work. The licensee concluded from this review that none of the doses were the result of a loss of control of licensed material, but rather the result of controlled routine operations.

Using insights from the investigation, the licensee revised its training for employees involved in radiological work. The licensee formalized instruction on specific tasks and hazards that was previously provided on the job by mentors and, as of January 28, 2022, had already provided multiple sessions of this training with the stated aim of providing more structured education and more consistent content and messaging to all participating staff. The licensee intends to provide refresher training on these topics at a frequency that it has yet to determine.

The licensee also stated that it intended to recruit and hire a health physicist to help oversee planning and execution of operations involving licensed material. The licensee stated that it would require 5 to 10 years of experience working with curie-quantities of radioactive material and hoped to hire such an individual within 30 to 90 days of January 19, 2022. The licensee also stated that it planned to hire two or more additional staff for Y-90 production work to spread extremity dose out amongst a larger cohort.

Following suspension of all radiological work, the licensee established an ad hoc Radiation Safety Committee (RSC) to review and approve radiological work on a case-by-case basis. The licensee stated that it planned to develop this ad hoc committee into a formal RSC which would meet quarterly to independently review the radiation safety program and the Radiation Safety Officer's implementation of it. As of January 28, 2022, the licensee had drafted a charter for the RSC and planned to submit it for management review soon.

2.4 Notifications and Reporting

In a letter to the NRC dated January 5, 2022, the licensee notified the agency of three extremity doses above the regulatory limits in 10 CFR 20.1201(a)(2)(ii), as required by 10 CFR 20.2203(a)(2)(i). The letter described the extent of exposure of all three individuals to radioactive material including estimates of each individual's dose, the levels of radiation and concentrations of radioactive material involved, the causes of the elevated dose rates, and the corrective steps taken and planned to ensure against recurrence.

The licensee concluded that since the doses above regulatory limits were not the result of a loss of control of licensed material, but rather the result of controlled routine operations, the doses did not require reporting per 10 CFR 20.2202(b)(1)(iii).

The inspector reviewed the circumstances of the doses and found no reason to disagree with the licensee's conclusion. Therefore, the inspector determined that the licensee reported the doses above regulatory limits as required, and that the licensee's written report contained all required information.

2.5 Conclusions

The inspector determined that an apparent violation of 10 CFR 20.1201(a)(2)(ii) occurred for the failure to control the dose to the skin of any extremity to 50 rems or less to three employees in calendar year 2021.

3 NRC Assessment of Doses Above Regulatory Limits

3.1 Inspection Scope

The inspector visited the licensee's facility in Lansing, interviewed involved staff and management, and reviewed a selection of records to obtain a detailed understanding of the circumstances surrounding a report of extremity doses above regulatory limits and to evaluate the licensee's response.

3.2 Assessment and Findings

A. Adequacy of Surveys

Prior to commencing radiological work with Sr-90, the licensee performed Monte Carlo N-Particle (MCNP) dose calculations for various geometries to estimate the doses that staff would receive while performing work in the glovebox. Staff used these initial estimates to anticipate their dose prior to beginning each evolution.

During the work itself, the licensee provided each employee with a whole-body badge and ring badge, and used area monitors outside the glovebox, a high-range handheld ion chamber inside the glovebox, and a JCS Nuclear Solutions ED3 electronic fingertip dosimeter with D4 probe to measure real-time beta exposure.

Considering the highly variable beta and bremsstrahlung x-ray fields present in the glovebox, the employees relied primarily on the electronic fingertip dosimeter to determine dose. Relying on the manufacturer's specifications on measuring beta dose, the licensee instructed staff to multiply readings on the dosimeter display by three to determine their extremity dose after each evolution.

Exposure readings from the real-time monitor at first appeared to be consistent with the initial estimates from MCNP. However, after receiving the reports of three exposures above regulatory limits, the inspector determined that the licensee's estimates and surveys were both incorrect.

The estimates did not account for all sources of dose; for example, they did not include handling quality control (QC) sample planchettes outside of the glovebox or remediating contamination, which in one case involved a measured dose rate of 94 rems per hour (94 rems/hr).

The surveys, on the other hand, were inaccurate on several accounts: (1) individuals continued to receive significant extremity dose even when not working in the glovebox and wearing the fingertip dosimeter, such as when handling QC sample planchettes; (2) individuals sometimes wore the fingertip dosimeter and their ring badge on opposite hands; and (3) the licensee used a conversion factor given by the manufacturer of the electronic fingertip dosimeter that was not accurate for the conditions of use.

The licensee interpreted the manufacturer's statement that the dosimeter's response to Sr-90 and Y-90 in equilibrium (Sr/Y) was "0.31 of true beta dose" to mean that employees should multiply the monitor's reading by three to determine their total extremity exposure. However, when the licensee later measured a Sr/Y calibration source with the fingertip dosimeter, they found that the true dose was greater than indicated on the dosimeter by a factor of nine for that configuration, rather than a factor of three.

At the time of the inspection, the licensee had not determined why the manufacturer's conversion factor was inaccurate. However, the inspector noted that, per the manufacturer's specifications, the dosimeter responded only to bremsstrahlung x-rays between 33 and 60 kiloelectron-Volts, and moreover responded only to dose rates under 10 rems/hr. Radiation fields in excess of both were common occurrences during Y-90 radiological work.

10 CFR 20.1501(a) requires, in part, that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

10 CFR 20.1003 defines *survey* as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and presence of radioactive material or other sources of radiation.

10 CFR 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin of any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.

The licensee's failure to make or cause to be made surveys adequate to ensure compliance with 10 CFR 20.1201(a)(2)(ii) is an apparent violation of 10 CFR 20.1501(a).

As corrective action, the licensee performed a detailed evaluation of the Y-90 production process and identified all "hot moments" in the process in which staff received significant dose including those where material was handled outside of the glovebox.

The licensee purchased two additional real-time fingertip dosimeters and began a study using its Sr/Y source to independently determine dose correction factors across a range of radiation fields and a variety of geometries to determine true dose with these instruments more accurately.

B. ALARA Practices

During a review of the licensee's engineering and procedural controls for controlling exposure to radiation from Sr-90 radiological work, several deficiencies were noted:

- Staff performed the radiological work by hand in a glovebox with only partial lead and plexiglass shielding against dose rates upwards of 100 rems/hr. The licensee's exposure calculations in its application dated May 18, 2020, indicated that four inches of lead shielding would be used. Although this was in the context of a different radiochemical process involving SNM scrap, in a February 21, 2021, request to increase Sr-90 and Y-90 possession limits, the licensee stated that "the engineering controls, handling tools, and shielding designs remain adequate to manage the worker dose within the existing estimates." However, only the following shielding was implemented, which was not sufficient under the circumstances to prevent shallow dose exposures above regulatory limits:

  - The vials of Sr-90 and/or Y-90 were shielded by a plexiglass vial holder inside a 2-inch-thick lead pig
  - The resin column was shielded by a 2-inch lead half-cylinder
  - Two movable plates combining approximately ½-inch of lead and ½-inch of plexiglass were hung vertically in front of the radiochemistry process and moved into place when practical

- Staff remediated high specific activity contamination by hand. They used lead-doped gloves that provided shielding but drastically increased overall exposure time as the gloves were extremely cumbersome.

- QC planchettes with significant activity were routinely moved around the production area by hand without any shielding or long-handled tools.

- There were no engineering or procedural controls to prevent inadvertent boiling of Sr-90 nitrate left on a hot plate inside the glovebox, which on two occasions resulted in contaminated condensation inside the glovebox where staff's extremities were subject to shallow-dose exposure.

- There were no engineering or procedural controls to minimize contamination from the opening of Sr-90 vials, the septa of which burst on two occasions, resulting in contamination inside the glovebox where staff's extremities were subject to shallow-dose exposure.

As a result of these deficiencies, in addition to the three exposures above regulatory limits mentioned already, a fourth radiochemist who worked in close proximity to high specific activity material received a relatively high and unexpected dose of 15.8 rems to the extremities from September to mid-December 2021.

Title 10 CFR 20.1101(b) states that licensees shall use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

The licensee's the failure to implement procedures and engineering controls that were adequate to ensure occupational doses would be ALARA is an apparent violation of 10 CFR 20.1101(b).

As part of the licensee's investigation into the doses above regulatory limits mentioned in Section 2.3, the licensee performed a detailed evaluation of the Y-90 production process. The licensee identified 15 "hot moments" in the process on which to focus dose reduction efforts. The licensee completed this evaluation the week of January 24, 2022, and thereafter began implementing process improvements including, but not limited to a new manifold design, new custom long-handled tools, additional shielding for QC sample planchettes, new limitations on handling these planchettes, requiring both the fingertip dosimeter and ring badge to be worn on the same hand, and a new waste container.

C. Root Causes and Contributing Factors

The direct cause of all three doses above regulatory limits was the handling and use of curie-quantities of Sr-90 and Y-90 in a glove box without adequately accounting for the high dose rates from the beta and bremsstrahlung x-ray radiation emitted by these radioisotopes.

The inspector completed both a "five whys" table and a barrier analysis to consider root and contributing causes of the apparent violations.

The root cause of the apparent violation of 10 CFR 20.1201(a)(2)(ii) was determined to be an inadequate evaluation and mitigation of exposure risk in the planning and execution phases of Sr-90 radiological work. Lack of health physics experience and

the perception of production pressures were contributing factors. The root cause of the violation for 10 CFR 20.1501(a) was determined to be a lack of attention to detail in the assessment of real-time monitoring results. Lack of health physics experience and delayed dosimetry results were contributing factors. The root cause of the violation of 10 CFR 20.1101(b) was determined to be a lack of health physics expertise.

3.3 Conclusions

The inspector identified apparent violations of 10 CFR 20.1501(a) for the failure to perform adequate surveys to ensure compliance with the annual occupational dose limits in 10 CFR 20.1201(a)(2)(ii), and of 10 CFR 20.1101(b) for inadequate procedures and engineering controls which resulted in occupational doses that were not ALARA.

3 Radiation Safety Program

3.1 Inspection Scope

The inspector visited the licensee's facility in Lansing, interviewed staff and management, and reviewed a selection of records related to the licensee's radiation safety program to evaluate the initial conduct of licensed activities.

3.2 Observations and Findings

The inspector confirmed that the facility in Lansing matched the description in its application dated May 18, 2020, and in additional information dated September 28, 2020, and January 5, 2021. All areas of the facility were adequately posted, and all licensed material was adequately secured.

The inspector observed demonstrations of activities conducted under the license, discussed waste handling procedures, and performed independent and confirmatory surveys of the facility. The inspector found no exposures in unrestricted areas above regulatory limits to members of the public and found all staff interviewed to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records, including those for receipt of licensed material, material accountability and physical inventories, area surveys, air effluent monitoring, and initial and refresher training.

3.3 Conclusions

The inspector had no findings in this area.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on April 4, 2022. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

Matt Burba – Chief Operating Officer
Terry Grimm, Ph.D. – Chief Executive Officer, Senior Scientist
Sandy Gubry – Regulatory Compliance Coordinator
Nathan Johnson – Co-Manager, Radioisotopes / Radiopharma
William Peters, Ph.D. – Radiation Safety Officer
Brooks Sease –Manager, Quality Department
Robert Wahlen – Co-Manager, Radioisotopes / Radiopharma
Michael Zamiara – President, Chief Financial Officer

Attended exit meeting on April 4, 2022

INSPECTION PROCEDURES USED

IP 87103 – Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87125 – Materials Processor/Manufacturer Programs
IP 87126 – Industrial/Academic/Research Programs