



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 30, 2022

EA-22-021

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

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

Dear Dr. Grimm:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted at your facility on Port Lansing Road, Lansing, Michigan, on January 18 and 19, 2022, with continued in-office review through March 24, 2022. The purpose of the inspection was to review activities performed under your NRC license and to evaluate the circumstances surrounding a January 5, 2022, notification that three of your employees had incurred doses above occupational limits for adults in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201(a)(2)(ii). The inspector discussed his preliminary inspection findings with you at an exit meeting on April 4, 2022, and the above-referenced inspection report was sent to you with our correspondence dated May 2, 2022.

In our May 2, 2022, letter, the NRC informed you that NRC staff had identified three apparent violations of NRC requirements and were considering them for escalated enforcement. On May 25, 2022, a partially public predecisional enforcement conference (PEC) was held in the NRC Region III offices in Lisle, Illinois, to discuss the causes, significance, and corrective actions taken relative to the apparent violations. Details of the PEC are found in Enclosure 1.

Based on the information developed during the inspection and the information you provided during the PEC, the NRC has determined that three escalated violations of NRC requirements occurred: (1) the failure to control the dose to the skin of any extremity to 50 rems or less, 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 that occupational doses would be as low as is reasonably achievable, as required by 10 CFR 20.1101(b). These violations are cited in the Notice of Violation (Notice) (Enclosure 2) and the circumstances surrounding them are described in detail in the inspection report.

These violations are safety significant because they resulted in actual consequences when three employees received doses to the skin of an extremity above regulatory limits, putting them at risk of acute radiation injury. These violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III (SLIII) problem. According to the NRC Enforcement Policy, a base civil penalty in the amount of \$16,000 is considered for a SLIII problem involving a large-scale materials user such as Niowave.

Because your facility has had no prior escalated enforcement action within the past two years, the next step in the NRC civil penalty assessment process is to consider whether credit is warranted for corrective action in accordance with Section 2.3.4 of the Enforcement Policy. According to information developed during the inspection, Niowave's first corrective action was to pause operations. On December 3, 2021, Niowave received dosimetry results for October 2021 that showed that two of four radiochemists working with Strontium-90 (Sr-90) had received extremity doses above regulatory limits for the year and three times their estimated doses. In response, Niowave immediately suspended radiological work with Sr-90. On December 14, 2021, Niowave received partial dosimetry results for November 2021 showing that one additional worker had received an extremity dose above regulatory limits for the year, after which it immediately suspended all radiological work company-wide. Niowave later confirmed that the three doses above regulatory limits were valid, and reported them to the NRC.

According to information provided at the PEC, Niowave's next corrective action was to establish an ad hoc radiation safety committee to perform a detailed evaluation of its processes involving Sr-90, which was completed the week of January 24, 2022. Niowave also refined a predictive dose estimating tool that considers isotope-specific source, type of shielding, distance, and time to estimate occupational dose to the whole body and to extremities. Niowave took steps to improve radiation monitoring, by switching to a more reliable dosimetry provider, requiring Sr-90 workers exchange ring badges weekly, incorporating live-finger dose monitoring, developing radiation work permits, and having the Director of Radioisotopes and Radiopharmaceuticals compare monitored doses to expected doses on a weekly basis. Niowave also implemented equipment enhancements including upgraded lead pigs; shielded, longer handles on tools for increased distance during material handling activities; and installation of additional fixed shielding throughout its processes. According to statements at the PEC, Niowave has also increased training for all radiation workers on general and isotope-specific topics, adjusted its internal action thresholds for dose to 50% of required dose limits, enhanced informational requirements to approve radiation work permits, and is actively recruiting for an additional health physicist. During the PEC, Niowave also clarified its plans to review its additional production lines to enhance radiological protection measures similar to those implemented on the production line associated with the exposure events.

The NRC determined that credit is warranted for corrective actions taken. Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SLIII problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved, additional planned corrective actions; and (3) the date when full compliance was achieved has already been adequately addressed in Inspection Report No. 07007031/2022001(DNMS) and during the May 25, 2022, PEC. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice of Violation (Enclosure 2).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made

available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b)) to support a request for withholding confidential commercial or financial information.

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement Officer of my staff at Diana.Betancourt-Roldan@nrc.gov.

Sincerely,



Signed by Shuaibi, Mohammed
on 06/30/22

Mohammed Shuaibi
Deputy Regional Administrator

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

Enclosures:

1. Summary of PEC
2. Notice of Violation

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

Letter to T. Grimm from Mohammed Shuaibi dated June 30, 2022

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07007031/2022001(DNMS) – NIOWAVE, INC.

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SUMMARY OF THE MAY 25, 2022, PREDECISIONAL ENFORCEMENT CONFERENCE
BETWEEN NIOWAVE, INC. AND THE U.S. NUCLEAR REGULATORY COMMISSION

On May 25, 2022, representatives of Niowave, Inc. met with NRC personnel in the Region III office in Lisle, Illinois, to discuss the three apparent violations identified in NRC Inspection Report Number 07007031/2022001(DNMS). The conference was held at the request of the NRC. The NRC presented a summary of the findings and the licensee agreed with the findings presented. The licensee provided a summary of its corrective actions in the public portion of the meeting, and a detailed review of its corrective actions and their effectiveness in the non-public portion; this detailed review included information that was considered business proprietary. During the non-public portion of the meeting, the NRC asked several questions of the licensee for clarification on the comprehensiveness of their corrective actions. The licensee provided satisfactory responses to these questions.

LIST OF ATTENDEES

NRC

Mohammed Shuaibi, Deputy Regional Administrator, Region III
Jared Heck, Deputy Director, Division of Nuclear Materials Safety, Region III
Shelbie Lewman, Acting Enforcement Officer, Region III
Russell Chazell, Acting Regional Counsel, Region III
Michael Kunowski, Chief, Materials Inspection Branch, Region III
Ryan Craffey, Senior Health Physicist, Materials Inspection Branch, Region III
Ken Lambert, Senior Enforcement Specialist, Region III
Susanne Woods, Senior Enforcement Specialist, Office of Enforcement
Robert Sun, Project Manager, Office of Nuclear Materials Safety and Safeguards
Susan Spicer, Allegations/Enforcement Specialist, Office of Enforcement
Sara Kirkwood, Senior Attorney, Office of General Counsel
Elizabeth Tindle-Engelmann, Health Physicist, Materials Inspection Branch, Region III
Andrew Panter, Student Intern, Materials Inspection Branch, Region III
Diana Betancourt-Roldan, Senior Resident Inspector (Incoming Enforcement Officer) Region III

NIOWAVE, INC.

Terry Grimm, PhD, Chief Executive Officer
Michael Zamiara, President and Chief Financial Officer
William Peters, PhD, Radiation Safety Officer
Robert Whalen, Director of Radioisotopes and Radiopharmaceuticals
Nathan Johnson, Director of Radioisotopes and Radiopharmaceuticals

NOTICE OF VIOLATION

Niowave, Inc.
Lansing, MI

Docket No. 070-07031
License No. 21-35144-04
EA-22-021

In a letter to the NRC dated January 5, 2022, Niowave reported three extremity overexposures among its employees for calendar year 2021. All three employees were radiochemists involved in validating and scaling up the Y-90 production process. All of this extremity exposure was received in the fall, beginning with a series of operations to aggregate, evaporate, and reconstitute 32 curies of Sr-90.

During an announced initial inspection conducted on January 18 and 19, 2022, with continued in-office review through March 24, 2022, violations of NRC regulations were identified.

Violation A

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 rem shallow-dose equivalent.

Contrary to the above, in 2021, Niowave did not control the occupational dose to the skin of any extremity of individual adults to annual dose limit of 50 rems shallow-dose equivalent. Specifically, three radiochemists received respectively 53.4, 89.2, and 97.4 rems shallow-dose equivalent to their hands during 2021.

Violation B

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 rem shallow-dose equivalent.

Contrary to the above, in 2021, Niowave did not perform adequate surveys to ensure compliance with the occupational dose limits of 10 CFR 20.1201(a)(2)(ii). Specifically, the licensee failed to correctly estimate and measure the exposures to the hands of four individuals who handled curie quantities of Sr-90 and Y-90, which resulted in three extremity overexposures.

Violation C

10 CFR 20.1101(b) requires each licensee to use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses that are as low as reasonably achievable (ALARA).

Contrary to the above, in 2021, Niowave did not use, to the extent practical, procedures and engineering controls to achieve occupational doses that are ALARA. Specifically, the licensee permitted an employee to work in close proximity to high specific activity material using procedures and engineering controls that were not adequate to prevent overexposures. As a result, between September and December 2021, the employee received a dose of 15.8 rem to the extremities.

This is a Severity Level III problem (Enforcement Policy Section 6.7c.1.).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 07007031/2022001(DNMS), your letter dated January 5, 2022, and the slides you presented during the May 25, 2022, PEC. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-22-021," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30TH day of June 2022