

NIOWAVE, INC.

1012 North Walnut Street
Lansing, MI 48906
Phone: (517) 999-3475

October 20, 2023

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

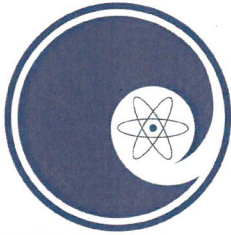
Attn: Mr. Frank Tran, Ms. Cassandra Frazier
Subj: Amendment 13 to license 21-35144-02

Dear Colleagues,
We request several changes to our 21-35144-02 license.

1. We are expanding our research partnerships to include the cancer-fighting possibilities of radon progeny. In order to take advantage of our existing radon-handling equipment on this license, we are requesting an increase to the radon possession limit. This will allow us to begin deliveries of radon progeny at quantities needed for clinical trials. This increase applies to Rn-222, Bi-214, and Pb-214 on our license. The proposed updated rows of Table 6.1 are shown below. The longer-lived progeny of radon (mass-210 series) will not grow appreciably due to their half-lives relative to radon. Therefore, the existing limits for those radioisotopes will not change.
Local shielding of the equipment used to handle the higher level of radon will be augmented to maintain existing dose estimates for workers and for the public; so there are no revisions to Appendix 10.1.
The radon will mostly be processed to contain the radon progeny. This will continue to limit the amount that is released. Due to the excessive exhaust ventilation of the NERD building the existing effluent release calculations of Appendix 10.2 will not change.

| ID | Isotope | Form | Activity | Usage |
|----|---------|------|----------|--------------------|
| AY | Rn-222 | Any | 2 Ci | Usage same as 9.G. |
| BB | Pb-214 | Any | 2 Ci | Usage same as 9.G. |
| BE | Bi-214 | Any | 2 Ci | Usage same as 9.G. |

2. We are pleased to inform you that Mr. Mike Zamiara is now our Chief Executive Officer and Dr. Grimm is our Founder and new Chief Science Officer. We also hired Mr. Adam Havey as Chief Operating Officer. Please see attached Appendix 7.2 for an updated organizational chart. This also includes an update to our list of Authorized users. We have removed Amanda Grimm and Valeriia Starovoitova as they are no longer with the company.



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3. We are providing updates to our decommissioning funding plan & cost estimate, certification of financial assurance, and trust agreement schedules in the attached package. The updated decommissioning cost estimate is \$327,017.35. Also, attached is a letter of acknowledgement and bank statement demonstrating this amount is present in our standby trust funded by cash.

The updates to the decommissioning funding plan & cost estimate are:

- Appendix C has been revised by updating the referenced salary data from the Bureau of Labor Statistics to the most recent available data. Additionally, the values used to account for fringe benefits and contractor profit & overhead costs were updated. This resulted in a small increase in salary data for the project manager, health physicist, supervisor, shipper, health physics technicians, radiation workers, and administrative support.
- Appendix D has been revised by updating the increased total hourly fee resulting from the updated referenced salary data. This resulted in a small increase in labor costs for the RAM Storage Vault, Radiochemistry Laboratory, Target Tunnels, and Radium Storage Area.
- No additional hours, costs, or areas have been added as the only changes to licensed materials is for isotopes with half-lives <120 days.

Thank you for your guidance and oversight throughout the amendment process.

Sincerely,

Michael Zamara
CEO

APPENDIX 7.2

Niowave's Organizational Structure

Executive Team

Figure 1 shows the most up to date organizational chart of Niowave's management. The Board of Directors provides high-level oversight for the company. The Executive Management team of Mike Zamiara as Chief Executive Officer (CEO), Terry Grimm as Founder & Chief Science Officer (CSO), Adam Havey as Chief Operating Officer (COO), and Jenevra Foley as Chief People Officer (CPO) provides strategic leadership and direction for the company.

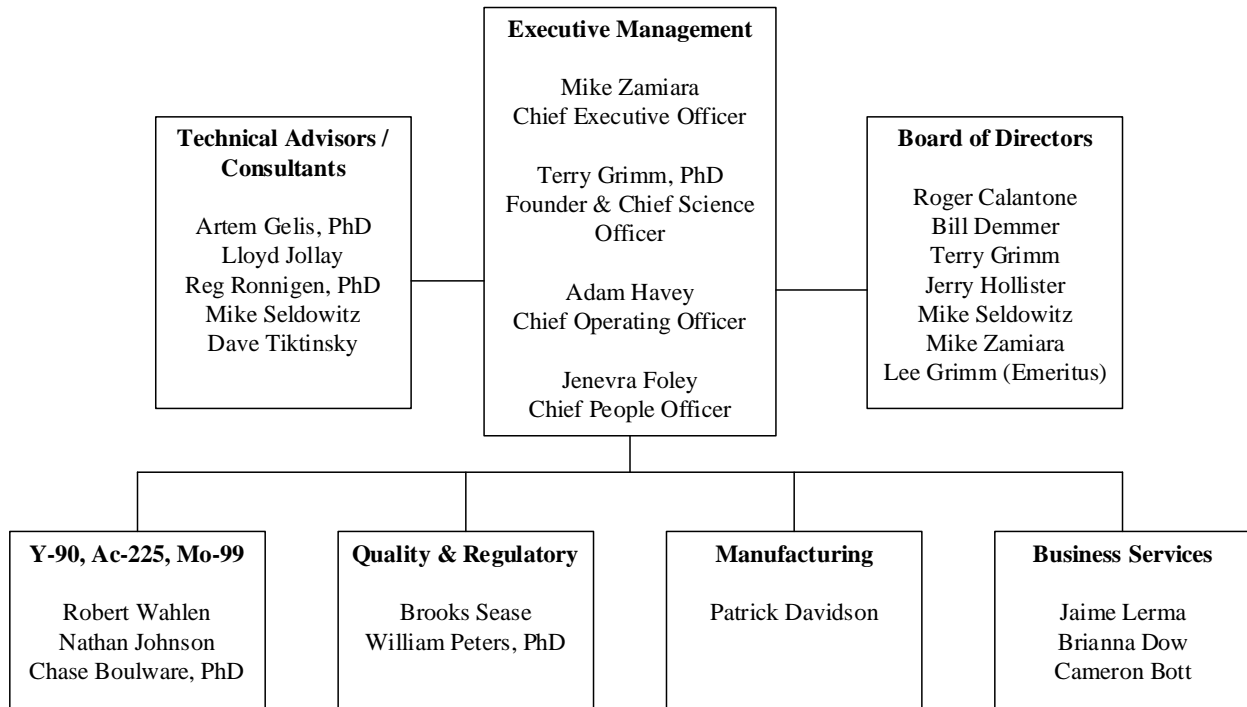


Figure 1. Niowave's Organization Chart

The company is divided into several branches: Business Services, Quality & Regulatory, Manufacturing, and the Radioisotope Programs: Yttrium-90 (Y-90), Actinium-225 (Ac-225), and Molybdenum-99 (Mo-99). The Radioisotope groups work to pursue radioisotope production utilizing Niowave's accelerators, radioisotope extraction, and radiopharmaceutical development.

APPENDIX 7.2

Radiation Safety Personnel

Figure 2 shows the current organizational chart of Niowave's Radiation Safety Program. This includes Niowave's Board of Directors, Radiation Safety Advisors, Executive Management, the RSO, and the Authorized Users. Niowave's Executive Team, has delegated the authority for the radiation safety program to Dr. William Peters as the RSO. Niowave also has Authorized Users (AUs) that work with the RSO to ensure licensed materials are used safely by radiation workers and according to regulatory requirements and license commitments.

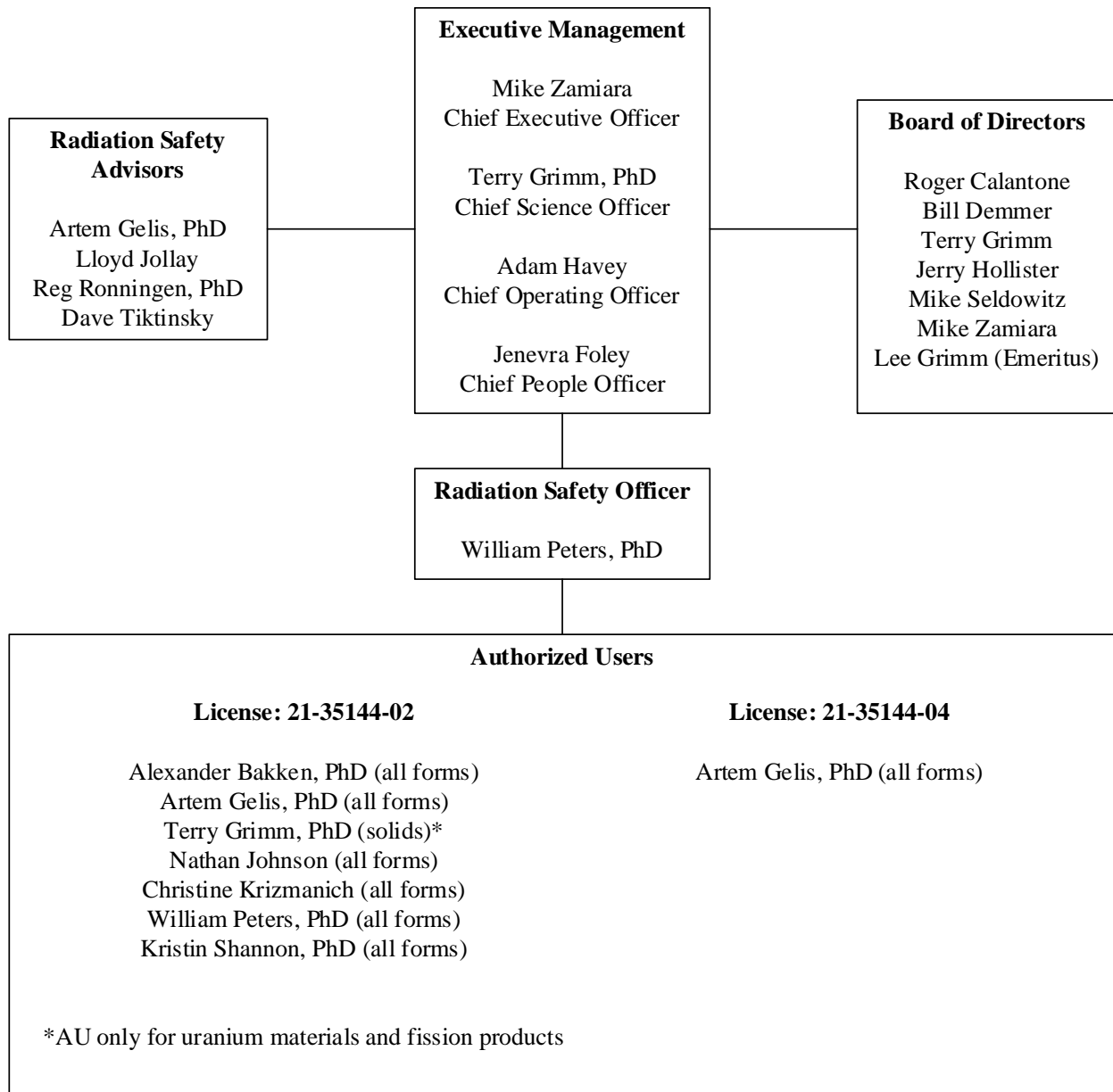


Figure 2. Organizational Chart of Niowave's Radiation Safety Program

Martha Pavon

From: Tammy Tomczak
Sent: Monday, October 23, 2023 1:43 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Amendment request for Niowave 21-35144-02
Attachments: 231023_Niowave_Amendment13_CoverLetter_signed.pdf; Appendix 7.2.pdf; 231016 FAD Package.pdf

Hi Martha 😊

For this one, can you please put the cover letter and appendix 7.2 together in one document (first accession number)?

Then can you put FAD Package in a separate document (second accession number)?

Thank you so much!!!

Tammy

From: Frank Tran <Frank.Tran@nrc.gov>
Sent: Monday, October 23, 2023 1:37 PM
To: Tammy Tomczak <Tammy.Tomczak@nrc.gov>
Cc: Bob Orlikowski <Robert.Orlikowski@nrc.gov>
Subject: FW: Amendment request for Niowave 21-35144-02

Hi Tammy,

Please process this as a new license amendment for Niowave. The “2310116 FAD Package.pdf” should be separated out as an additional information for the pending FA action. Let me know if you have any questions.

Thanks,

Frank

From: William Peters <peters@niowaveinc.com>
Sent: Monday, October 23, 2023 10:38 AM
To: Frank Tran <Frank.Tran@nrc.gov>
Cc: Cassandra Frazier <Cassandra.Frazier@nrc.gov>; Sandra Gubry <gubry@niowaveinc.com>
Subject: [External_Sender] Amendment request for Niowave 21-35144-02

Frank,

We have been growing and broadening our efforts here at Niowave. Please see attached documents for our amendment request for license 21-35144-02. This is mostly to increase our limit for radon at our NERD facility. We will be expanding our partnership with nearby institutions to develop a novel cancer-fighting drug from the short-lived radon progeny. We will not be increasing the limit of radium or other long-lived progeny. Please let me know if you have any questions or concerns.

Stay well,

-Bill

William A. Peters Ph.D.

Nuclear Physicist & RSO

Niowave, Inc.

Office: 517-999-3475

www.niowaveinc.com



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