

September 29, 2014

MEMORANDUM TO: Alexander Adams, Chief  
Research and Test Reactors Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

FROM: Steven T. Lynch, Project Manager */RA/*  
Research and Test Reactors Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF AUGUST 21, 2014, MEETING WITH NIOWAVE INC. TO  
DISCUSS THE POTENTIAL APPLICATION FOR A MEDICAL  
RADIOISOTOPE PRODUCTION FACILITY

On August 21, 2014, a Category 1 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of Niowave Inc. (Niowave) at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The purpose of the meeting was for Niowave to provide NRC staff with more information on topics relating to its proposed production of molybdenum-99 (Mo-99) using a superconducting electron linear particle accelerator (linac). Specifically, Niowave presented on features of its technology, Mo-99 production rates, and its anticipated licensing strategy. A portion of this meeting was closed to the public to discuss proprietary information related to the specifics of design and operation of Niowave's proposed medical radioisotope production technology. A list of the attendees at this meeting is enclosed.

The NRC staff opened the meeting by providing Niowave a discussion on the importance of engagement and open communication with the NRC during the development of license applications. These qualities are important to developing a high-quality application that the NRC staff will be able to review in a timely and efficient manner. NRC staff expressed its eagerness to both better understand Niowave's proposed methodology for producing Mo-99 and to discuss the NRC's applicable application process. Furthermore, the NRC staff stated that its goal for the meeting was for Niowave to leave with a clear understanding of the next steps it should take to successfully develop an application for NRC review.

Niowave's presentation (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14231A946) began with an introduction of its key personnel before moving into an overview of superconducting linacs. This overview covered topics such as commercial uses of superconducting electron linacs, linac systems and subsystems, accelerating and multi-spoke cavities, power sources, and liquid metal converters. Following this discussion, Niowave covered its plans to produce Mo-99 from uranium fission. This included announcement of Niowave's plans to eventually produce Mo-99 at four to five facilities capable of producing about nine kilocuries each week. Molybdenum-99 will be recovered from the uranium targets through dissolution with nitric acid and processed in standard technetium-99m generators in the existing medical radioisotope supply chain.

Niowave's public presentation concluded with a high-level discussion on its plans for licensing its proposed 60,000 square-foot facility. Niowave has three phases planned for its proposed Mo-99 production. The first phase will demonstrate technology feasibility, producing up to 900 curies of Mo-99 per week. Phase two will demonstrate full scale production at a single facility, producing up to 9,000 curies of Mo-99 each week. And finally, in phase three, full scale production will expand production capabilities up to 36,000 curies per week among four to five facilities. Niowave believes that all of its licensing could be covered under the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30. Following this discussion, NRC staff encouraged Niowave to review the applicability of the licensing requirements of 10 CFR Parts 51 and 70 for applicability to Niowave's proposed design.

A portion of this meeting was closed to the public to discuss proprietary details of those discussion topics that could not be completely addressed in the open portion of the meeting.

There were no comments from members of the public at this meeting.

Please direct any inquiries to Steven Lynch at 301-415-1524 or [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Project No. 0815

Enclosure:  
List of Attendees

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Project No. 0815

Enclosure:  
List of Attendees

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Lansing, MI 48906

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LIST OF ATTENDEES

AUGUST 21, 2014, MEETING WITH NIOWAVE, INC.

| <u>Name</u>           | <u>Organization</u>                      |
|-----------------------|--|
| Valeriia Starovoitova | Niowave Inc.                             |
| Erik Maddock          | Niowave Inc.                             |
| Terry Grimm           | Niowave Inc.                             |
| Dan Cronin            | University of Florida Training Reactor   |
| Mary Adams            | U.S. Nuclear Regulatory Commission (NRC) |
| Steve Lynch           | NRC                                      |
| Linh Tran             | NRC                                      |
| Robert Hoffman        | NRC                                      |
| Nancy Martinez        | NRC                                      |
| Alex Sapountzis       | NRC                                      |
| Maria Guardiola       | NRC                                      |
| William Schuster      | NRC                                      |
| Mitzi Young           | NRC                                      |
| Larry Harris          | NRC                                      |
| Eben Allen            | NRC                                      |
| Elizabeth Smiroldo    | NRC                                      |
| Donna-Beth Howe       | NRC                                      |
| Cassandra Frazier     | NRC                                      |
| Carl Weber            | NRC                                      |
| Patricia Pelke        | NRC                                      |
| Meena Khanna          | NRC                                      |
| Lisa London           | NRC                                      |
| Timothy Sippel        | NRC                                      |
| Glenn Tuttle          | NRC                                      |
| Greg Chapman          | NRC                                      |
| Ossy Font             | NRC                                      |
| Bob Lukes             | NRC                                      |
| Alexander Adams       | NRC                                      |

ENCLOSURE