

October 6, 2014

Dr. Terry L. Grimm
President & Senior Scientist
Niowave, Inc.
1012 North Walnut Street
Lansing, MI 48906

SUBJECT: NIOWAVE, INC. – ASSIGNMENT OF PROJECT NUMBER AND EXPLANATION
OF BILLING AND FEES

Dear Dr. Grimm:

By letter dated August 27, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14246A115), Niowave, Inc. (Niowave), indicated its intent to submit license applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30 and 70, as appropriate, for the development and use of superconducting electron accelerator technology to produce molybdenum-99 (Mo-99). Based on the contents of this letter, the U.S. Nuclear Regulatory Commission (NRC) staff understands that Niowave intends to initially apply for a license in support of technology development to “demonstrate safe, reliable operations, and to benchmark simulations of Mo-99 production rates.” Following the submission of this initial application, the NRC staff understands that Niowave will submit a second application in support of licensing a commercial-scale facility for Mo-99 production.

Prior to the submittal of these applications, Niowave may engage in pre-application activities, such as public meetings and formal requests for interpretations of regulations. To facilitate these activities, NRC staff has assigned Niowave a project number. As such, Niowave should reference Project No. 0815 in all future correspondence supporting pre-application licensing activities with the NRC.

Pursuant to 10 CFR Part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended,” Niowave will be charged for the hours NRC staff apply to this project, beginning in the current fiscal quarter, as applicable. Accordingly, NRC staff has assigned a billable technical assignment control (TAC) number (MF4857) to Niowave’s project. All NRC staff time devoted to full-cost licensing activities, beyond an initial introductory presentation of technological and licensing concepts, conducted specifically in support of Niowave’s anticipated applications, will be charged to this TAC number. License applications, minor amendments, and device registrations not subject to full cost fees will be assessed charges according to the fee schedules provided in 10 CFR Part 170. Recognizing the unique licensing considerations that medical radioisotope production facilities may pose, NRC staff will not charge Niowave for time spent developing generic licensing infrastructure and guidance.

Each application will be assigned a formal docket number following its receipt and acceptance. Specific licensing tasks will be assigned additional TAC numbers, as applicable, and Niowave will be billed for the NRC staff’s hours applied to those TAC numbers, in accordance with 10 CFR Part 170.

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Following the issuance of each license, Niowave will be billed, as applicable, an annual fee in accordance with 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By The NRC."

Questions regarding Niowave's application for technology development and demonstration may be directed to Sandy Frazier at (630) 829-9830 or Cassandra.Frazier@nrc.gov.

Questions regarding Niowave's application for a commercial-scale Mo-99 production facility may be directed to Mary Adams at (301) 287-9146 or Mary.Adams@nrc.gov.

Questions regarding general Mo-99 program management may be directed to Steve Lynch at (301) 415-1524 or Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Steven Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 0815

T. Grimm

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Sincerely,

/RA/

Steven Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 0815

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NRR-106

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