

MEETING SUMMARY (OPEN SESSION)

SUBJECT: Virtual Pre-Application Observation Public Meeting to Discuss Niowave Inc.'s Planned Medical Isotope Facility to be Licensed Under 10 CFR Part 70

DATE: September 21, 2022

Following introductions by the U.S. Nuclear Regulatory Commission (NRC), the Department of Energy's National Nuclear Security Administration (NNSA), and Niowave, Inc. (Niowave) staff listed in Enclosure 1, Yawar Faraz of the NRC provided opening remarks. Yawar Faraz stressed the importance of pre-application meetings and addressed the unique nature of Niowave's planned application for a medical isotope facility under 10 CFR Part 70. Dr. Bill Peters of Niowave, in his introductory remarks, indicated that Niowave anticipates requesting future pre-application meetings with a handful of participants to discuss specific subject areas.

Niowave then presented its slides (Agencywide Documents Access and Management System Accession No. ML22264A024). Niowave described its current operations licensed under NRC's Region III office and the State of Michigan, including production of strontium-90/yttrium-90 for cancer therapy, lutetium-177, and actinium-225 for alpha therapy. Niowave discussed the regulatory agencies that it will be working with including the State of Michigan, Department of Transportation, NRC, and the Food and Drug Administration. Niowave then described its proposed commercial facility to be licensed under 10 CFR Part 70 that will be used to primarily generate molybdenum-99 (Mo-99) with a goal to produce up to 5 percent of the domestic Mo-99 demand in the United States. The facility will include target irradiation in a subcritical uranium assembly fission unit, two superconducting electron linear accelerators, natural uranium target fabrication, irradiated target dissolution and extraction and capture of fission gasses including xenon and iodine, a modified UREX process to separate the uranium from the fission products, uranium recovery and conversion to U₃O₈ powder, and extraction of Mo-99 product from the fission product stream.

Niowave indicated that it was getting very good technical support from the NNSA via various national laboratories and university partners. Niowave then described the location of the Mo-99 commercial facility as being located adjacent to the international airport in Lansing, Michigan. According to Niowave, the facility will house one Mo-99 generating unit. Niowave discussed their licensing achievements, including work with Region III. Niowave then discussed their radiation protection program highlighting their radiation safety program. Niowave presented their security program and provided information on their biannual inventory, their two-layer security program, and their access authorization program. Lastly, Niowave presented their plans for scaling up to commercial scale. In closing, Niowave discussed their next steps and preparations they are making for the next public meetings with the NRC.

PRINCIPAL CONTRIBUTORS

Stephen Poy, NMSS/DFM

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