

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: April 27, 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, Chris Regan of the NRC provided opening remarks. Chris Regan stressed the importance of preapplication 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. ML22129A075). 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 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 an ultimate goal to produce up to 25 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 per subcritical assembly fission unit, 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 could house up to five separate Mo-99 generating units.

Following the slide presentation, Niowave responded to NRC questions and one question from a member of the public. Regarding the building structures, Niowave intends to use non-nuclear construction techniques. Facility construction will satisfy the state of Michigan's requirements and appropriately address the hazards identified in the Integrated Safety Analysis (ISA) for the facility. Regarding the National Environmental Policy Act analysis, the NRC suggested that Niowave request a focused pre-application meeting. When asked if an exemption from criticality monitoring will be requested, Niowave indicated that the determination for seeking an exemption had not been made. The NRC asked how far along Niowave was in conducting an ISA. Niowave indicated that they were being assisted in this regard by Y-12 of the Oak ridge National Lab through NNSA and that the ISA work is expected to ramp up in early summer 2022 with production of an early draft of the ISA by the end of summer 2022 depending on the analysis findings. NRC asked if Niowave was basing its decision to conduct an ISA on the amount of fissile material and the types of processes and facilities identified in Subpart H of 10 CFR Part 70 for which an ISA is required. Niowave indicated that they will take a closer look at the requirements in Subpart H of 10 CFR Part 70 to determine whether an ISA is required for its commercial Mo-99 facility or not.

PRINCIPAL CONTRIBUTOR
Yawar Faraz, NMSS/DFM/FFLB