MEETING SUMMARY (OPEN SESSION)

Subject: Virtual Pre-Application Observation Public Meeting to Discuss Niowave Inc.'s Planned Medical Isotope Facility to be Licensed Under Title 10 of the *Code of Federal Regulations* Part 70

Date: November 2, 2022

Following participant introductions, Dr. Bill Peters of Niowave started the presentation (Agencywide Documents Access and Management System Accession No. ML22306A073).

Niowave described its facilities in Lansing, Michigan discussing its headquarters, warehouse, and research buildings. There is a second facility by East Lansing Airport. The commercial molybdenum-99 (Mo-99) facility to be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70 will be located adjacent to the airport facility.

Niowave currently is licensed by the U.S. Nuclear Regulatory Commission's (NRC's) Region III to produce radioisotopes through three different programs (i.e., Mo-99 program, reactor program, and Ac-225 program). The Mo-99 program uses a superconducting electron linear accelerator to irradiate uranium targets. The targets are chemically processed to extract volatiles and fission products and separate out the uranium. The second program involves extracting long-lived and short-lived radioisotopes from used fuel from decommissioned reactors. The Ac-225 program uses an electron linear accelerator and a radium target to generate Ac-225. Niowave's presentation focused on the planned commercial Mo-99 facility.

Niowave identified the regulatory agencies they are involved with including NRC Region III and the Food Drug Administration.

Niowave discussed its current quality system which implements 21 CFR 820 / ISO 13485:2016. Niowave is expanding its quality system to include:

1) practices for FDA approval, and
2) NUREG-1520 guidance for its planned commercial Mo-99 production activities.

Niowave described the superconducting electron linear accelerator and the uranium target assembly that it plans to use for its Mo-99 commercial facility. The uranium target assembly will sit between two linear accelerators. The electron beam power will be 200 kW. Neutron source intensity will be approximately 10^{15} neutrons/second. The uranium target assembly will have a neutron multiplicity factor (Keff) of less than 1.0 (Niowave will commit to a Keff of less than 0.95 for its commercial Mo-99 facility).

Niowave described its planned closed loop uranium cycle. With the uranium target assembly, the linear accelerator will cause a liquid-metal target to generate neutrons which will induce fission in the uranium in the target assembly. Using parallel processing lines, volatile elements (i.e., xenon and iodine) will be removed. A modified UREX process will be used to separate the rest of the fission products from uranium, neptunium, and plutonium. The uranium, neptunium and plutonium will be extracted together and fabricated into target assemblies for reuse.

Niowave provided photographs of the target dissolution, xenon and iodine extraction, UREX, target fabrication, and the uranium recovery processes.

Niowave presented a site overlay photo of the Mo-99 facility with a partial view of the airport.

Niowave indicated that they have a quality system in place referred to as QMS – Quality Management System which is consistent with the guidance in NUREG-1520.

Niowave presented a discussion on the organization and administration. Niowave has been working to address the acceptance criteria outlined in NUREG-1520. Regarding organization and administration portion of the application, Niowave will define the:

1) organizational structure,
2) management controls and communications across the organization,
3) roles, responsibilities, and authorities within the organization, and
4) commissioning plan and personnel supervising commissioning activities.

According to Niowave, Items 1 and 2 above have been completed. Regarding Item 3, Niowave has identified the roles and responsibilities for its current organization, but this may change as Niowave expands its safety and environmental protection programs. Regarding Item 4, Niowave is in the process of developing a commissioning plan.

Niowave summarized the key applicable requirements for safety management as follows:

1) 10 CFR 70, *Domestic Licensing of Special Nuclear Material*,
2) 10 CFR 70.61, *Performance Requirements*,
3) 10 CFR 70.62, *Safety Program and Integrated Safety Analysis*, and
4) 10 CFR 70.65, *Additional Content of Applications.*

Chapter 3 of NUREG-1520 states, “This chapter provides guidance for the NRC’s review of two types of information submitted by applicants:
(1) commitments regarding the applicant’s safety program including the ISA, pursuant to the requirements of 10 CFR 70.62, “Safety Program and Integrated Safety Analysis”
(2) ISA summaries submitted in accordance with 10 CFR 70.62(c)(3)(ii) and 10 CFR 70.65”

Niowave indicated that the following acceptance criteria will be applied for the safety program and integrated safety analysis (ISA):

1) applicant has established and maintains a safety program, which includes the performance of an ISA,
2) applicant has established and maintains an ISA program that complies with 10 CFR 70 (or procedures that define how ISA is performed, documented, reviewed, approved, and submitted to the NRC for review and approval),
3) applicant has performed ISA and prepared and submitted an ISA Summary to the NRC for approval,
4) ISA must demonstrate that credible high- and intermediate-consequence events meet the safety performance requirements of 10 CFR 70.61,
5) applicant has an established process for maintaining a current ISA and other safety program documentation when changes are made to the site, structures, processes, systems, equipment, components, computer programs, and/or activities of personnel, and
6) applicant has a process in place to update the ISA Summary at least once per year and submit a copy of the ISA Summary to the NRC for review on an annual basis.

Niowave discussed its plan to meet the safety program requirements by implementing the following actions:

1) move toward one integrated management system,
2) identify roles and responsibilities by incorporating and expanding the current health and safety (H&S) procedures into a formal health & safety management system,
3) identify specific H&S programs that will fall under the overall H&S management system,
4) expand existing and develop new supporting H&S documents, and
5) develop a training program to implement the improved H&S management system.

Niowave discussed its plan to conduct its ISA depicted in a flow chart. The plan can be characterized by the 5 following tasks:

1) establish a plan and procedures to meet ISA requirements,
2) define the ISA scope and methodologies,
3) identify and educate ISA teams,
4) perform and document ISA, and
5) prepare the ISA Summary and sumit it for NRC approval.

Niowave indicated that it plans to follow the Table 3.1 in NUREG-1520 to develop the ISA Summary.

The NRC staff asked why Niowave did not identify 10 CFR 70.64, “Requirements for new facilities or new processes at existing facilities,” which includes baseline design criteria, in the list of requirements that will be applied to perform an ISA? Niowave agreed that the requirements in 10 CFR 70.64 need to be applied that that omitting it from the list was an oversight on its part.

The NRC staff asked Niowave to discuss its qualifications and training program related to performing an ISA. Niowave indicated that this will be included in the closed session.

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