UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

October 15, 2015

The Honorable Stephen G. Burns
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: REPORT ON THE SAFETY ASPECTS OF THE CONSTRUCTION PERMIT APPLICATION FOR SHINE MEDICAL TECHNOLOGIES, INC. MEDICAL ISOTOPE PRODUCTION FACILITY

Dear Chairman Burns:

During the 628th meeting of the Advisory Committee on Reactor Safeguards (ACRS), October 7-10, 2015, we completed our review of the construction permit application for the SHINE Medical Technologies, Inc. (SHINE) medical isotope production facility. We reviewed the Preliminary Safety Analysis Report (PSAR) submitted by SHINE and the draft final Safety Evaluation Report (SER) prepared by the NRC staff. Our Subcommittee on Radiation Protection and Nuclear Materials reviewed this matter during meetings on June 23-24, August 19, and September 22, 2015. During these reviews, we had the benefit of discussions with representatives of the NRC staff and SHINE. We also had the benefit of the documents referenced. This report fulfills the requirement of Section 182b of the Atomic Energy Act of 1954, as amended that ACRS shall review each application under Section 103 or Section 104b for a construction permit or an operating license for a facility.

RECOMMENDATION

The Construction Permit for the SHINE medical isotope production facility should be approved.

BACKGROUND

For the past two decades, the U.S. has relied on imported medical radioisotopes to perform approximately 50,000 medical procedures daily. The Energy Policy Act of 2005 called for a study of ways to ensure a reliable supply of medical isotopes and, furthermore, to do so without the use of highly enriched uranium (HEU). Global shortages of medical isotopes during 2009 and 2010 have underscored the need for prompt action to ensure a reliable domestic supply. The National Academy of Sciences' 2009 publication "Medical Isotope Production without Highly Enriched Uranium" encouraged the creation of a domestic supply of molybdenum-99 (^{99}Mo) that does not rely on use of HEU. Following this report, the National Nuclear Security Administration pledged financial support to accelerate the development of technology necessary to establish a domestic commercial supply of ^{99}Mo using processes that do not utilize HEU. SHINE was created in 2010 to pursue the production of medical isotopes from low-enriched uranium (LEU) based technology and address the weakness of the existing supply chain.

In 2011, SHINE notified the NRC of its intent to submit applications to construct and operate a unique medical isotope production facility. SHINE's facility would include an irradiation facility and a radioisotope production facility housed in a single building, and is proposed to be built in Janesville, Wisconsin. Wisconsin is an Agreement State.

The NRC staff recognized that the proposed irradiation units would not be nuclear reactors as defined in 10 CFR 50.2. These units do not meet the regulatory definition of a nuclear reactor, because they are not designed or used to produce nuclear fission in a self-sustained chain reaction (i.e., $k_{eff} \geq 1.0$). Therefore, the 10 CFR Part 50 regulations governing licensing of production and utilization facilities did not apply to SHINE's irradiation facility or irradiation units. The NRC staff issued a direct final rule amending the definition of utilization facility in 10 CFR 50.2 to include SHINE's proposed irradiation units. This rule was of particular applicability to SHINE and would not affect any other NRC licensees or applicants. The direct final rule and the companion proposed rule were codified on December 31, 2014. The NRC staff also published interim staff guidance (ISG) to augment NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," since the NUREG did not specifically address facilities, such as SHINE, which use homogeneous fuels.

On March 26, 2013, and May 31, 2013, SHINE submitted the required parts of a construction permit application. SHINE's application describes its proposed medical isotope production facility and provides a PSAR. The SHINE irradiation facility consists of eight irradiation units. Each irradiation unit uses an accelerator-driven neutron source to induce fission in LEU in a subcritical operating assembly. This is used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of ^{99}Mo and other fission products. The accelerator creates deuterium-tritium fusion reactions resulting in the formation of high-energy neutrons. The flux of neutrons into the target solution vessel is intensified in a neutron multiplier. The aqueous LEU solution undergoes subcritical fission of ^{235}U present in solution. Operation of the accelerator is needed to maintain the fission process. After irradiation, radioisotopes of interest are extracted by a chemical separation process in the radioisotope production facility of conventional design.

DISCUSSION

In accordance with the required licensing process for a construction permit, the applicant must provide a PSAR. As stated in the ISG for non-power reactor licensing, the PSAR is less detailed than that required for an operating license application. Of course, "less detailed" is not fully defined, but the application demonstrates knowledge of the requirements for the safety analysis and the kinds of accidents that ought to be of concern. We have identified many places where, while reasonable for the purposes of a construction permit, the analyses and assumptions are not supported well enough for an operating license. We document some of these in later paragraphs.

Process system chemical and radiological materials are not present during construction. Therefore, when we examine the application from a safety point of view, we must ask what activities during construction could affect chemical and radiological risk later, when the facility is

operating. That is, we seek issues that could create safety concerns in an operating facility, after the building is literally set in concrete. It could be difficult or impractical to correct these issues related to the configuration of the structure, once the buildings are in place. There have been instances in chemical processing plants (e.g., nuclear reprocessing facilities), where the completed facilities could not be operated after construction was complete, because of safety and operational problems that could not be resolved. In our review, we identified two such possibilities for SHINE—layup capability and analysis of aircraft crashes. Both have been addressed, such that we can recommend issuing the construction permit.

Nuclear chemical processing facilities need to have built-in capability to support layup following unexpected process interruptions. It must be possible to stop the process, safely remove materials within the system, clean the system, and place it in a safe condition for an extended period in a way that does not challenge the facility piping systems and chemical reactors. Using temporary, *ad hoc* processes to resolve process system failures may not be possible, could subject the operators and maintenance staff to unnecessary risks, and introduces possibilities for error. There are financial and worker risk issues. Under some circumstances, there may also be a public risk issue. Because of the significance of ^{99}Mo to medical procedures and the diminishing capacity at other sources, loss of the SHINE facility would also present an indirect health risk to the public.

There was no evidence in the applicant's PSAR or the draft SER that layup capability had been considered in the design. SHINE has submitted a letter indicating that they have twice the necessary capacity within the facility to store all target solution batches and that they will develop procedures to facilitate this process before operations. The staff has reviewed this submittal, found it sufficient, and is including the commitment for developing these procedures in its SER. The submittal does not demonstrate that an evaluation of possible system failures has been performed to ensure installed systems can address relevant failure modes. We expect that such analyses will be included in the integrated safety assessment.

For aircraft crashes, the protection of the facility depends on the as-built structure. All areas of the plant that contain safety-related systems and equipment are protected against damage from the identified design-basis aircraft impacts.

The SHINE facility handles fissile material, fission products, and hazardous process chemicals. The potential for their release is the focus of the accident analyses. SHINE employs confinement rather than a leak-tight containment structure. Confinement is achieved via a robust structure combined with engineered and tested cascading ventilation and filtration systems, and automatic isolation dampers actuated on high radiation levels. The design, construction, maintenance, and operation of the facility assure that the confinement protects workers and the public, and are key to the very low radiological consequences calculated in the PSAR. The facility meets 10 CFR 20 requirements.

The staff identified a number of issues where further technical and design information must be supplied in the Final Safety Analysis Report (FSAR) and where the applicant identifies necessary research and development. These issues are documented in Appendix A to the SER. In some cases the staff has proposed construction permit conditions, which must be resolved before construction is completed. They also identified regulatory commitments that must be addressed in the FSAR.

We reviewed important safety aspects of the SHINE application, including the site characteristics; the design of structures, systems, and components; radiation protection and waste management; conduct of operations and technical specifications; and accident analysis. We found the state of the PSAR adequate for the construction permit. Looking ahead to SHINE's future application for an operating license, we had questions related to criticality control and margin, adequacy of confinement, systems that provide support to safety-related systems, partial losses of electrical power, hydrogen generation and control, underwater maintenance issues, and possible "red oil" and acetohydroxamic acid reactions[1]. When the FSAR is submitted, assumptions should be justified and margins or uncertainties should be identified and quantified or bounded.

The staff demonstrated an ability to develop a practical licensing approach for a unique facility. We look forward to reviewing the application for an operating license.

Sincerely,

/RA/

John W. Stetkar
Chairman

REFERENCES

1. SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)
2. Final Draft SER (Package Accession No. ML15267A796)
3. SHINE PSAR, Rev 2, Chapters 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, and 14 (Package Accession Nos. ML15175A094 and ML15175A274)
4. SHINE RAI response dated: October 15, 2014 (ML14296A203); December 3, 2014 (ML14357A380, ML14357A381 and ML14357A382); February 6, 2015 (ML15043A443 and ML15043A397); March 23, 2015 (ML15092A371); April 10, 2015 (ML15120A254); May 1, 2015 (ML15131A483); May 14, 2015 (ML15147A284); May 20, 2015 (ML15140A734); September 2, 2015 (ML15247A067); September 15, 2015 (ML15259A024)
5. SHINE Emergency Plan (ML13269A379)
6. SHINE letter dated September 28, 2015, "SHINE-Definition of "Safety-Related Activities"" (ML15271A290)

[1] "Red oil" is an unstable compound of uncertain composition formed by interaction of organic liquids and nitric acid solutions in the solvent extraction processes. Red oil has been observed to decompose explosively in industrial-scale facilities. The exact reaction is unknown, but the conditions existing prior to these events have been documented. Acetohydroxamic acid is the common name for N-hydroxyacetamide [CAS Number 546-88-3]. It is used in the UREX process much as hydroxylamine is used in the PUREX process. Hydroxylamine has been implicated in several energetic industrial accidents. There is less operational experience with N-hydroxyacetamide.

7. SHINE letter dated September 28, 2015, “SHINE Strategy for Extended Plant Shutdowns” (ML15271A314)
8. U.S. Defense Nuclear Facilities Safety Board, Robinson et al, “Control of Red Oil Explosions in Defense Nuclear Facilities,” DNFSB/TECH-33, November 2003
9. Whipple, C., S.M. Larson, C. Atkins-Duffin, A.E. Boardman,T.J. Ruth, J. Vujic, R.G. Wymer, "Medical Isotope Production Without Highly Enriched Uranium”, Committee on Medical Isotope Production Without Highly Enriched Uranium, National Research Council, National Academy Press, Washington, 2009
10. Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, dated October 17, 2012
11. Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, dated October 17, 2012
12. Stephen Marschke, “Aircraft Crash Cutoff Probabilities for the SHINE Medical Facility,” Information Systems Laboratories, Inc., S. Cohen & Associates, Inc., prepared for the U.S. Nuclear Regulatory Commission, dated September 2015

7. SHINE letter dated September 28, 2015, “SHINE Strategy for Extended Plant Shutdowns” (ML15271A314)
8. U.S. Defense Nuclear Facilities Safety Board, Robinson et al, “Control of Red Oil Explosions in Defense Nuclear Facilities,” DNFSB/TECH-33, November 2003
9. Whipple, C., S.M. Larson, C. Atkins-Duffin, A.E. Boardman,T.J. Ruth, J. Vujic, R.G. Wymer, "Medical Isotope Production Without Highly Enriched Uranium”, Committee on Medical Isotope Production Without Highly Enriched Uranium, National Research Council, National Academy Press, Washington, 2009
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12. Stephen Marschke, “Aircraft Crash Cutoff Probabilities for the SHINE Medical Facility,” Information Systems Laboratories, Inc., S. Cohen & Associates, Inc., prepared for the U.S. Nuclear Regulatory Commission, dated September 2015

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