[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-608; NRC-2021-0090]

SHINE Medical Technologies, LLC

SHINE Medical Isotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to a June 2, 2020, request from SHINE Medical Technologies, LLC from certain NRC regulations related to commercial grade dedication of equipment.

DATES: The exemption was issued on April 30, 2021.

ADDRESSES: Please refer to Docket ID **NRC-2021-0090** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to https://www.regulations.gov and search for Docket ID **NRC-2021-0090**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; e-mail: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number

for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **Attention:** The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via e-mail at pdr.resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Lynch, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-1524, e-mail: Steven.Lynch@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: May 5, 2021.

For the Nuclear Regulatory Commission.

/RA/

Steven T. Lynch, Senior Project Manager,
Non-Power Production and Utilization
Facility Licensing Branch,
Division of Advanced Reactors and
Non-Power Production and Utilization
Facilities,
Office of Nuclear Reactor Regulation.

Attachment – Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50-608

SHINE Medical Technologies, LLC

SHINE Medical Isotope Production Facility

I. Background and Request

SHINE Medical Technologies, LLC (SHINE) is the holder of a construction permit issued February 29, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16041A471), which authorizes SHINE to construct the SHINE Medical Isotope Production Facility (SHINE facility) in Janesville, Wisconsin, and is currently under construction. As authorized by the construction permit, the SHINE facility will house an irradiation facility and radioisotope production facility. The irradiation facility will consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in title 10 of the *Code of Federal Regulations* (10 CFR) 50.2, "Definitions," and supporting structures, systems, and components (SSCs) for the irradiation of low enriched uranium. The radioisotope production facility would consist of hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2, and associated SSCs for the processing of irradiated material and extraction and purification of medical radioisotopes. The irradiation facility and radioisotope production facility are collectively referred to as the SHINE Medical Isotope Production Facility (or SHINE facility). SHINE submitted an application for an operating license on July 17, 2019, which the U.S. Nuclear Regulatory Commission (NRC) staff accepted for docketing as indicated in a *Federal Register* (FR) notice published on October 15, 2019 (84 FR 55187). Issuance of the operating license

would authorize the applicant to operate the SHINE facility for a 30-year period.

By letter dated June 2, 2020 (ADAMS Accession No. ML20154K754), SHINE requested an exemption from certain requirements of 10 CFR 21.3, “Definitions,” related to commercial grade dedication of equipment. Specifically, SHINE requested an exemption from the requirements in 10 CFR 21.3 for the definitions of “commercial grade item,” “basic component,” “critical characteristic,” “dedication,” and “dedicating entity.” SHINE proposed definitions that SHINE seeks permission to use in lieu of the current 10 CFR 21.3 definitions for the five terms listed, including the same “commercial grade item” definition that 10 CFR 21.3 requires for nuclear power plants. Approval of this exemption would provide SHINE the flexibility to procure facility-specific and other components for the construction of the SHINE facility.

SHINE is planning for the procurement of long lead-time components for the SHINE facility and wants to use the commercial grade dedication process for certain unique components.

The definition of “commercial grade item” required by 10 CFR 21.3, for a 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” facility (other than a nuclear power plant), states that a commercial grade item means an item that is: “(i) [n]ot subject to design or specification requirements that are unique to those facilities or activities; (ii) [u]sed in applications other than those facilities or activities; and (iii) [t]o be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer’s published description.” In its exemption request, SHINE states that this required definition of commercial grade item restricts SHINE’s ability to use commercial grade dedication of safety-related SSCs. SHINE also states that items (i) and (iii) stated above, are unnecessarily restrictive for defining commercial grade items. Furthermore, items (i) and (iii) stated above complicate and, in many cases, prohibit the

procurement of certain components to support the design and construction of the SHINE Facility.

SHINE states that its proposed definitions for the five terms identified above would allow SHINE to employ an equally controlled and safe approach to item procurement. Additionally, SHINE stated that the proposed definitions will increase the flexibility to apply a commercial grade item procurement strategy for equipment procurements (1) to equipment that would not meet the 10 CFR 21.3 definition applicable to 10 CFR Part 50 licensees that are not nuclear power plant licensees; and (2) in situations in which few or no suppliers are available with a quality assurance program that meets a quality assurance standard endorsed by the NRC and 10 CFR Part 21, "Reporting of Defects and Noncompliance," procedures.

SHINE further stated that in 1995, in response to a petition filed on behalf of nuclear power plant operators, the NRC determined that the definition of "commercial grade item" was unnecessarily restrictive and resulted in very limited use of the commercial grade item designation used by power plant licensees. As a result, the NRC revised 10 CFR Part 21 to provide licensees added flexibility in procuring commercial grade items for safety-related services for nuclear power plants. See Statement of Considerations (SOC), *Federal Register*, Volume 60, page 48369 (September 19, 1995).

If the exemption were granted, SHINE committed to "revise the commercial grade dedication process to ensure SHINE or its approved sub-contractor assumes full responsibility as the dedicating entity in cases where SHINE or its approved sub-contractor applies the commercial grade item procurement strategy, for compliance with identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process and performs the dedication process."

SHINE also committed that, prior to implementing the above commercial grade procurement strategy and dedication process, it will revise its Quality Assurance Program Description (QAPD) to reflect the commitments made in the exemption request dated June 2, 2020.

II. Discussion

Pursuant to 10 CFR 21.7, "Exemptions," upon application of any interested person or on its own initiative, the Commission may grant such exemptions from the requirements of 10 CFR Part 21 as it determines are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest. The exemption SHINE seeks would allow SHINE to use different definitions for five terms defined in 10 CFR 21.3, thereby providing SHINE the flexibility to implement item procurement for facility-specific and other components in support of the construction of the SHINE facility.

The NRC staff reviewed the information SHINE provided as well as similar exemptions granted to Shaw AREVA MOX Services (ADAMS Accession No. ML080030393), Louisiana Energy Services, LLC (ADAMS Accession No. ML083400454), and AREVA Enrichment Services, LLC (ADAMS Accession No. ML110310794). As part of its review, the NRC staff noted that the SOC stated that the commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under a 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," quality assurance program. NRC regulations do not require SHINE, a licensee authorized to construct eight non-reactor utilization facilities and one production facility, to have a 10 CFR Part 50, Appendix B, quality assurance program. However, the NRC staff

reviewed the SHINE QAPD using American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, “Quality Assurance Program Requirements for Research Reactors,” as endorsed by Regulatory Guide 2.5, Revision 1, “Quality Assurance Program Requirements for Research and Test Reactors” (ADAMS Accession No. ML093520099). The NRC staff found the SHINE QAPD acceptable for the design and construction of the proposed SHINE facility in NUREG-2198, “Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility” (ADAMS Accession No. ML16229A140), which supported the issuance of the SHINE construction permit. In its exemption request, SHINE stated that in all cases the applicable provisions of the ANSI/ANS-15.8-1995 will be used to conduct the dedication process. If the exemption is granted, SHINE committed to revising its QAPD to specify the following definitions of commercial grade item, basic component, critical characteristics, dedicating entity, and dedication (in lieu of the 10 CFR 21.3 definitions):

- *Commercial grade item:* A commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).
- *Basic component:* A basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee or activity subject to the regulations in 10 CFR Part 21 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or

license issued by the Commission would create a substantial safety hazard. In all cases, basic components include safety-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

- *Critical characteristics:* Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.
- *Dedication:* Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under an ANSI/ANS-15.8-1995 quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of ANSI/ANS-15.8-1995. The process is considered complete when the item is designated for use as a basic component.
- *Dedicating entity:* Dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the

item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where the Licensee applies the commercial grade item procurement strategy and performs the dedication process, the Licensee would assume full responsibility as the dedicating entity.

The NRC staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Therefore, the NRC finds that the requested exemption is authorized by law.

The NRC staff determined that the requested exemption will not endanger life or property or the common defense and security. In adopting the revised definition of "commercial grade item" for nuclear power plants in 1995, the NRC determined that a commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or similar item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. While SHINE does not maintain a 10 CFR Part 50 Appendix B, quality assurance program, the NRC staff reviewed the SHINE QAPD using ANSI/ANS-15.8-1995, as endorsed by Regulatory Guide 2.5. The NRC staff found the SHINE QAPD acceptable for the design and construction of the proposed SHINE facility with the issuance of NUREG-2198. Additionally, in the current version of the SHINE QAPD (ADAMS Accession No. ML20105A316), SHINE defines safety-related SSCs as "those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the

consequences of such accidents." The NRC staff approved of SHINE's use of a custom-definition of safety-related SSCs in NUREG-2198 because the 10 CFR 50.2 definition of "safety-related structures, systems, and components" did not apply to a facility that was not a power reactor and the custom definition was appropriate for the SHINE facility. The NRC staff similarly concludes that the definitions that SHINE proposes to use (in lieu of the those required by 10 CFR 21.3) are similar to those previously approved at other facilities and are appropriate for the SHINE facility, which has SSCs with unique design or specification requirements based on their intended safety function. Accordingly, the revision of the QAPD to incorporate the proposed definitions and the assumption by SHINE (or its approved sub-contractor) of full responsibility as the dedicating entity are appropriate to support procurement of certain unique items because they will provide a controlled and safe approach for item procurement for the construction of the first-of-its-kind SHINE facility. Therefore, the NRC finds that the requested exemption does not endanger life or property or the common defense and security.

The NRC staff determined that the requested exemption is in the public interest. The requested exemption would allow SHINE to implement a controlled and safe approach to item procurement for the construction of the SHINE facility. Additionally, consistent with the American Medical Isotopes Production Act of 2012 (42 U.S.C. 2065), construction of the SHINE facility supports the establishment of a domestically-produced commercial supply of molybdenum-99, which is in the interest of public health. Therefore, the NRC finds that the requested exemption is in the public interest.

III. Environmental Considerations

The granting of this exemption is categorically excluded under 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions

eligible for categorical exclusion or otherwise not requiring environmental review," paragraph (c)(25), and there are no special circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(I), that the requirements from which the exemption is sought involve other requirements of an administrative, managerial, or organizational nature. The NRC staff also determined that approval of this exemption involves no significant hazards consideration because authorizing the use of the specified definitions that differ from those in 10 CFR 21.3 does not authorize any physical changes to the facility or any of its safety systems, does not change any of the assumptions or limits used in SHINE's safety analyses, does not introduce any new failure modes, and allows procurement of commercial grade items, which if properly dedicated, will have comparable safety functions. As a result, there is no significant increase in the probability or consequences of an accident previously evaluated, there is no creation of the possibility of a new or different kind of accident from any accident previously evaluated, and there is no significant reduction in a margin of safety.

In addition, because the SHINE facility is under construction and an operating license has not been issued, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite because the exemption does not affect any effluent release limits as provided in SHINE's technical specifications or by the regulations in 10 CFR Part 20, "Standards for Protection Against Radiation." There is no significant increase in individual or cumulative public or occupational radiation exposure because the exemption does not affect the limits on the release of any radioactive material or the limits provided in 10 CFR Part 20 for radiation exposure to workers or members of the public. There is no significant construction impact because the exemption does not involve any changes to a construction permit.

There is no significant increase in the potential for or consequences from radiological accidents because the exemption does not alter any of the assumptions or limits in SHINE's safety analysis. Therefore, the NRC has determined that granting the exemption would not individually or cumulatively have a significant effect on the human environment.

IV. Conclusions

Based on its review, the NRC staff finds that the use of the SHINE-proposed definitions of commercial grade item, basic component, critical characteristics, dedication, and dedicating entity do not adversely affect public health and safety. Therefore, the use of commercial grade items by SHINE, which are properly dedicated, is acceptable. Further, the NRC staff considered the requirements of 10 CFR 21.7 and finds that granting this exemption from certain 10 CFR 21.3 definitions is authorized by law and will not endanger life or property or the common defense and security, and is otherwise in the public's interest. Therefore, the NRC grants the exemption from 10 CFR 21.3 definitions of commercial grade item, basic component, critical characteristics, dedicating entity, and dedication, subject to the condition that (1) SHINE revise its QAPD consistent with the alternate definitions stated above and prior to assuming full responsibility as the dedicating entity or otherwise implementing its commercial grade procurement strategy and dedication process, and (2) SHINE shall submit the revised QAPD to the NRC consistent with the 10 CFR 50.34(b)(6)(ii) requirement to include managerial and administrative controls to be used to assure safe

operation of the facility as part of the final safety analysis report for an operating license application.

This exemption is effective upon issuance.

Dated at Rockville, Maryland this 30th day of April 2021.

For the Nuclear Regulatory Commission.

/RA/

Brian W. Smith, Deputy Director,
Division of Advanced Reactors and Non-Power,
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Office of Nuclear Reactor Regulation.