June 2, 2020

2020-SMT-0046
10 CFR 21.7

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) U.S. Nuclear Regulatory Commission letter to SHINE Medical Technologies, LLC, dated July 1, 2019, "SHINE Medical Technologies, LLC – Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID No. L-2018-LLM-0154)" (ML19162A024)
(2) U.S. Nuclear Regulatory Commission, "Final Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance"," August 2015 (ML15152A457)

Request for Exemption from Definition of Commercial Grade Item, Basic Component, Critical Characteristic, Dedication, and Dedicating Entity

SHINE Medical Technologies, LLC (SHINE) is the holder of a Construction Permit, issued pursuant to 10 CFR Part 50 (Reference 1), for the construction of a medical isotope production facility in Janesville, WI. SHINE has begun construction of the SHINE facility; however, as noted by the NRC staff in Reference (2), the regulations in 10 CFR 21.3 do not provide sufficient flexibility regarding commercial grade dedication to 10 CFR Part 50 non-power reactor licensees (among other licensees) for nuclear construction in this era of reduced quality suppliers.

Pursuant to 10 CFR 21.7, SHINE hereby requests an exemption from 10 CFR 21.3 to modify the definitions of "commercial grade item," "basic component," "critical characteristic," "dedication," and "dedicating entity." The requested exemption will allow SHINE to procure components for construction of the SHINE facility. Allowing SHINE to use the same flexibility for commercial grade dedication as is allowed in 10 CFR 21.3 for power reactor licensees will not adversely affect public health and safety.

The evaluation provided in Enclosure 1 identifies the specific requirements in the regulation for which an exemption is requested and concludes that modifications of the definitions contained in 10 CFR 21.3 are authorized by law, will not endanger life, property, or the common defense and security, and are in the public interest.

Following NRC approval of the exemption request, SHINE will revise the Quality Assurance Program Description (QAPD) to reflect the commitments made in this exemption request prior to implementing the exemption. More specifically, the revised QAPD will (1) reflect the definitions of "commercial grade item," "basic component," "critical characteristics," "dedicating entity," and "dedication," applicable to the SHINE facility and the procurement of equipment and services therefor, and (2) implement a commercial grade item procurement strategy and dedication process in which SHINE or its approved sub-contractor will assume full responsibility as the

dedicating entity in cases where SHINE or its approved sub-contractor, as appropriate, applies the commercial grade item procurement strategy.

Enclosure 1 provides the SHINE exemption request to certain definitions provided in 10 CFR 21.3. SHINE respectfully requests that NRC approve this exemption request by July 30, 2020 to allow SHINE to continue the procurement of long lead-time components, which is currently proceeding at-risk pending the approval of the requested exemption, in order to meet the SHINE facility construction schedule.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

Very truly yours,

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
SHINE General Counsel

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, LLC

REQUEST FOR EXEMPTION FROM DEFINITION OF COMMERCIAL GRADE ITEM, BASIC COMPONENT, CRITICAL CHARACTERISTIC, DEDICATION, AND DEDICATING ENTITY

Background

SHINE Medical Technologies, LLC (SHINE) is the holder of a Construction Permit, issued pursuant to 10 CFR Part 50 (Reference 1), for the construction of eight utilization facilities and one production facility designed for the production of medical radioisotopes. SHINE has begun construction of the medical isotope production facility in Janesville, WI. As a part of that effort, SHINE is planning for the procurement of long lead-time components and desires to use the commercial grade dedication process for certain unique components. In accordance with 10 CFR 21.31, "Procurement Documents," each procurement document for a basic component must specify that the provisions of 10 CFR Part 21 apply. 10 CFR 21.21(a) requires each supplier of a basic component (unless exempted) to adopt procedures to evaluate deviations and failures to comply and to notify the NRC of deviations and failures to comply that are associated with a substantial safety hazard. 10 CFR 21.7 exempts suppliers of commercial grade items.

The definition of "commercial grade item" in 10 CFR 21.3 applicable to facilities and activities licensed pursuant to 10 CFR Part 50 (other than nuclear power plants) provides that a "commercial grade" item is: (i) not subject to design or specification requirements that are unique to those facilities or activities; (ii) used in applications other than those facilities or activities; and (iii) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description.

Parts (i) and (iii) are unnecessarily restrictive for defining commercial grade items. This definition of a commercial grade item for Part 50 facilities (other than nuclear power plants) greatly complicates - and in many cases prohibits - the procurement of certain components to support the design, construction, and safe operation of the SHINE facility. Due to the first-of-its-kind nature of the SHINE facility, numerous components will be subject to unique design or specification requirements, based upon their safety functions for their intended applications.

In addition, and more generally, many manufacturers and suppliers of equipment needed to construct the SHINE facility (including foreign suppliers) do not have a quality assurance program which meets a quality assurance standard endorsed by the NRC (e.g., ANSI/ANS-15.8-1995 (Reference 2)) because of the high cost of maintaining and implementing such a program as compared to the relatively small revenue generated by selling certain equipment to non-power production and utilization facilities currently under construction or in operation in the United States. Additionally, these manufacturers and suppliers do not have the evaluation and notification processes in place that would satisfy the requirements of 10 CFR Part 21.

For example, SHINE will need to procure tritium purification system (TPS) components (e.g., thermal cycling adsorption process [TCAP] columns, cryopumps) and the supercell. The TPS components and supercell perform safety functions to prevent or mitigate accidents in the

SHINE safety analysis. The design and specification requirements of the TPS components and supercell are unique to the SHINE facility; this equipment is not available in manufacturer's published product descriptions. The TPS components and supercell are only available from a limited number of specialized suppliers and the suppliers SHINE has chosen to procure this equipment from do not maintain quality assurance programs which meet a standard endorsed by the NRC (e.g., ANSI/ANS-15.8-1995). The prospective suppliers for TPS components and supercell do not maintain evaluation and notification processes that would satisfy the requirements of 10 CFR Part 21.

In 1995, in response to a petition filed on behalf of operators of nuclear power plants, the Commission determined that the definition of "commercial grade item" was unnecessarily restrictive and resulted in very limited use of the commercial grade item designation. To provide added flexibility in using commercial grade items for safety-related service, the Commission adopted a new definition of "commercial grade item" for nuclear power plants. The amended definition added flexibility only for nuclear power plants and did not change the requirements applicable to other facilities and activities. The NRC began to consider a rulemaking in 2011 to assess the desirability of revising 10 CFR 21.3 to apply a similar standard to non-reactor licensees; however, that effort was discontinued in April 2016 as part of the Project AIM rebaselining.

SHINE is requesting an exemption from certain definitions of 10 CFR 21.3, "Definitions," that are consistent with the added flexibility given to nuclear power plants and to support procurement of long lead-time components for the SHINE facility. Procurement of these long lead-time components by SHINE are progressing at risk, consistent with the SHINE facility construction schedule. SHINE desires to use the commercial grade dedication process for certain unique components for the SHINE facility in a fiscally prudent manner and in an effort to not delay construction of the SHINE facility.

Since 2008, the NRC has approved several exemption requests submitted by fuel cycle facility applicants and licensees because of their inability to effectively design and construct new enrichment and fuel fabrication facilities absent that exemption. The requested exemption is similar to the exemptions approved by the NRC for Shaw AREVA MOX Services (Reference 3), for Louisiana Energy Services, LLC (Reference 4), for AREVA Enrichment Services, LLC (Reference 5), and for General Electric-Hitachi Global Laser Enrichment, LLC (Reference 6).

Specific Exemption Request

In accordance with 10 CFR 21.7, "Exemptions," SHINE requests NRC approval of an exemption from the requirements of 10 CFR 21.3, "Definitions," for "commercial grade item," "basic component," "critical characteristics," "dedication," and "dedicating entity."

Upon approval of the exemption request, SHINE will revise the Quality Assurance Program Description (QAPD) to define "commercial grade item," "basic component," "critical characteristic," "dedication," and "dedicating entity" as described below. The below definitions are analogous to those approved by the NRC in the safety evaluation report for Louisiana Energy Services, LLC (Reference 4). Implementation of the below definitions establishes an equivalent standard for the dedication of commercial grade items to those components which SHINE procures as basic components.

- *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 revised QAPD would provide the same added flexibility in procuring commercial grade items for safety-related structures, systems, and components as the Commission provided for nuclear power plant licensees when it amended the definition of “commercial grade item” in September 1995 (Reference 7). SHINE will implement a commercial grade item procurement strategy and dedication process, in which SHINE or its approved sub-contractor will be responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process.

The ability to employ these proposed definitions would provide SHINE with increased flexibility to apply the commercial grade item procurement strategy for equipment procurements where

the equipment would not meet the definition applicable for Part 50 licensees (other than nuclear power plants). This flexibility is particularly necessary in situations in which few or no suppliers are available with a quality assurance program which meets a quality assurance standard endorsed by the NRC and Part 21 procedures. The proposed definitions for "commercial grade item," "basic component," "critical characteristic," "dedication," and "dedicating entity" would remove unnecessary restrictions and allow SHINE to employ an equally controlled and safe approach to item procurement.

The Requested Exemption is Authorized By Law

The NRC has the authority under the Atomic Energy Act to grant exemptions from its regulations if doing so would not violate the requirements of law. No law exists that precludes the activities covered by this exemption request. The provisions of 10 CFR 21.3, "Definitions," were adopted at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt the specific provisions from which SHINE seeks an exemption. The NRC may determine that alternative means are adequate to provide reasonable assurance of safety.

The Requested Exemption Will Not Endanger Life, Property, or the Common Defense and Security

In adopting the revised definition of "commercial grade item" for nuclear power plants in 1995, the Commission 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 (Reference 7). Similarly, Regulatory Guide 2.5, Revision 1 (Reference 8), provides that "general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in ANSI/ANS-15.8-1995 provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of Applications; Technical Information." As a result, implementation of a similar procurement process by SHINE under Part 50 also will not endanger life, property, or the common defense and security.

The Requested Exemption is in the Public Interest

NRC approval of the requested exemption is in the public interest because it will allow SHINE to implement a controlled and safe approach to item procurement that will support the construction of the SHINE facility in a timely and cost efficient manner. Additionally, timely 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. NRC denial of the requested exemption is not in the public interest because it will result in increased cost, delayed completion of the SHINE facility, and the associated economic losses, all without any safety benefit.

Therefore, granting the requested exemption is in the public interest.

Conclusion

The use of commercial grade items by SHINE, which are properly dedicated, would be equivalent to those which would be manufactured under a quality assurance program which meets the requirements of ANSI/ANS-15.8-1995. SHINE is committing to revise its QAPD and

to apply this exemption in our commercial grade item procurement strategy. Further, the requested exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest.

Since the provisions of 10 CFR 21.7 are satisfied, the requested exemption should be granted. Approval of the exemption is requested by July 30, 2020 to continue the procurement of long lead-time components, which is currently proceeding at-risk pending the approval of the requested exemption, in order to meet the SHINE facility construction schedule.

Commitments

SHINE makes the following commitments if the requested exemption is approved:

1. Upon approval, SHINE will revise the QAPD to specify the SHINE-specific definitions for "commercial grade item," "basic component," "critical characteristics," "dedication," and "dedicating entity," based on the definitions presented in this exemption request.

2. Upon approval, SHINE will 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.

References

1. U.S. Nuclear Regulatory Commission letter to SHINE Medical Technologies, LLC, dated July 1, 2019, "SHINE Medical Technologies, LLC – Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID No. L-2018-LLM-0154)" (ML19162A024)

2. American National Standards Institute/American Nuclear Society, "Quality Assurance Program Requirements for Research Reactors," ANSI/ANS-15.8-1995 (R2013), La Grange Park, IL

3. U.S. Nuclear Regulatory Commission letter to Shaw Areva MOX Services, dated March 20, 2008, "Request for an Exemption from 10 CFR Part 21.3 "Commercial Grade Item"" (ML080030393)

4. U.S. Nuclear Regulatory Commission letter to Louisiana Energy Services, LLC, dated February 11, 2009, "Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License" (ML083400454)

5. U.S. Nuclear Regulatory Commission letter to AREVA Enrichment Services, LLC, dated July 28,2010, "Approval of AREVA Enrichment Services' Part 21 Exemption Request (TAC L32744)" (ML110310794)

6. U.S. Nuclear Regulatory Commission letter to General Electric-Hitachi Global Laser Enrichment LLC, dated September 25, 2012, "License for the General Electric-Hitachi Global Laser Enrichment Commercial Facility" (ML12248A316)

7. U.S. Nuclear Regulatory Commission, “Procurement of Commercial Grade Items by Nuclear Power Plant Licensees,” Federal Register, Vol. 60, No. 181, September 19, 1995, pp. 48369-48374

8. U.S. Nuclear Regulatory Commission, “Quality Assurance Program Requirements for Research and Test Reactors,” Regulatory Guide 2.5, Revision 1, June 2010 (ML093520099)