June 28, 2021

Dr. Gregory Piefer, Chief Executive Officer
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO STRUCTURAL ENGINEERING TOPICS (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), December 15, 2020 (ADAMS Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application (OLA) for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's OLA, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the OLA, and prepare a safety evaluation report. The specific chapters of the SHINE OLA covered by this RAI include Chapter 2, "Site Characteristics," and Chapter 3, "Design of Structures, Systems, and Components."

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this letter. In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application (OLA).

As the NRC staff continues its review of SHINE's OLA, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

Signed by Lynch, Steven
on 06/28/21

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

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure:
As stated

cc: See next page

cc:

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

Nathan Schleifer
General Counsel
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

Christopher Landers
Director, Office of Conversion
National Nuclear Security Administration,
NA 23
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept. of Materials Science and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO STRUCTURAL ENGINEERING TOPICS (EPID NO. L-2019-NEW-0004) DATED: JUNE 28, 2021

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REQUEST FOR ADDITIONAL INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), December 15, 2020 (ADAMS Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application (OLA) for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

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Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE OLA, which describes the SHINE irradiation facility, including the irradiation units, and radioisotope production facility (RPF), using the applicable regulations, as well as the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the "Final Interim Staff Guidance [ISG] 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 (ADAMS Accession No. ML12156A069), and "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 (ADAMS

Accession No. ML12156A075). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE OLA.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution." .

Chapter 3 – Design of Structures, Systems, and Components

SHINE FSAR Section 3.4, "Seismic Damage"

The following regulatory requirements and guidance are applicable to RAIs 3.4-18 through 3.4-22:

Section 50.34, "Contents of applications technical information," paragraph (b)(2) of 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components (SSCs) of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

The following considerations from NUREG-1537 are applicable to RAIs 3.4-18 through 3.4-22:

Chapter 3, "Design of Structures, Systems, and Components," of NUREG-1537, Part 1, and the corresponding ISG Augmenting NUREG-1537, state, in part that:

> The material presented [in the FSAR] **should** emphasize the safety and protective functions and related design features that help provide defense in depth against uncontrolled release of radioactive material. The bases for the design criteria for some of the systems discussed in this chapter may be developed in other chapters and should be appropriately cross referenced.
>
> [F]acility and system design **must** be based on defense-in-depth practices. Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges.…

The NRC staff evaluates the adequacy of design criteria for all SSCs that have been identified to perform an operational or safety function by using the guidance and acceptance criteria described in Chapter 3 of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2. Consistent with the guidance of Chapter 3 of NUREG-1537, all safety-related SSCs that could suffer effects of natural and "man-made" phenomena are reviewed and evaluated for adequacy such that there is a reasonable assurance that they would continue to perform their safety and protective functions so that, as noted in NUREG-1537, Part 1, a defense-in-depth "against uncontrolled release of radioactive material is maintained."

For RAIs 3.4-18 through 3.4-22, the NRC staff is requesting additional information to conclude the following, consistent with the evaluation findings in Section 3.4, "Seismic Damage," of NUREG-1537, Part 2:

- The SHINE facility has been designed to protect against seismic damage.

- There is reasonable assurance that the facility SSCs will perform the necessary safety functions described and analyzed in the SHINE FSAR.

- There is reasonable assurance that the consequences of credible seismic events at the facility are considered (or bounded) by the results of the accident analysis, ensuring acceptable protection of the public health and safety.

RAI 3.4-18 The SHINE OLA should include adequate information to describe the Facility Structure (FSTR), including its seismic isolation, if any, its safety-related SSCs, anchorage of its safety-related SSCs, or their ability to resist their own inertia to avert their collapse during design basis events. In its response to RAI 3.4-8 parts (2) and (3), SHINE did not provide sufficient design details regarding the construction of the FSTR as it relates to seismic damage necessary for the NRC staff to complete its evaluation. The overall description of the FSTR and its integration to safety and non-safety-related SSCs, the performance of which could affect the safety function of FSTR and related SSCs are essential for the NRC staff to reach a reasonable assurance safety determination.

The response to RAI 3.4-8 parts (2) and (3) did not summarize the FSTR construction materials used. It also did not include some aspects of its size, its height (minimum, maximum), and thickness of its outer shell (minimum, maximum). Additionally, the description and seismic qualification for some of the FSTR's SSCs, such as the integration of the RPF metal tanks to the FSTR, were not complete. Similarly, the response was not clear on the capacity of shield plugs to remain in place after a design basis event. The response also did not clarify whether an unsatisfactory performance of the non-safety related structures, such as the Exhaust Stack, FSTR partition walls, and the non-safety-related portion of the FSTR could affect the safety-related portion of FSTR and relevant SSCs during a design basis event.

This information is needed to confirm conservatism in the design of the FSTR and its SSCs to external hazards and to design basis events (e.g., seismic, aircraft impact, blast loads).

(a) Complete the description of the FSTR. State its height (minimum, maximum), the thickness (minimum, maximum) of its outer concrete shell (roof, walls, etc.). Identify the materials used for its construction and associated standards (e.g., Type II cement with concrete compressive strength (fc') of 4,000 pounds per square inch, rebar ASTM 706, structural steel ASTM A-36).

(b) For the non-safety-related exhaust stack, state its proximity to other safety-related structures (i.e., FSTR, nitrogen purge system (N2PS). Confirm that the failure of the exhaust stack would not affect the structural integrity of the aforementioned SSCs from external hazards and design basis events. If SHINE relies on the exhaust stack to remain in place or otherwise perform during a design basis event to prevent damage to safety-related SSCs, identify the industry standards to which it has been designed.

(c) For other non-safety-related structures or components of structures (including the non-safety-related portions of the FSTR and its internal partitions) not designed for seismic, aircraft impact, or blast loading effects, discuss how their potential failure/collapse would not impact safety-related SSCs and the defense-in-depth design characteristics of the FSTR.

(d) Describe the seismic isolation of the safety-related portion of the FSTR from its non-safety portion. If a gap was included, state its size, location, and its adequacy for seismic isolation of safety and non-safety-related portions of the FSTR.

(e) Discuss whether the supercell(s) are an integral part of the FSTR. If so, discuss its (their) anchorage. If not anchored, discuss its (their) integration to the FSTR and its safety-related SSCs.

(f) Clarify whether the prefabricated/precast concrete removable shield plugs (or cover plugs) are qualified to remain in place during a design basis event.

Following responses to the above requests (a) through (g), update the SHINE FSAR accordingly.

RAI 3.4-19 Section 3.4.5.1, "Aircraft Impact Analysis," of the SHINE OLA states that the FSTR has been designed consistent with DOE-STD-3014-2006, Appendix F of American Concrete Institute (ACI) 349-13, and Chapter NB of ANSI/AISC N690-12 for permissible ductility limits. It also states, in part, that "[t]o evaluate the capability of the structure to withstand impact from an aircraft, each wall that is subject to potential impact from an aircraft missile is evaluated. Figure 3.4-7 shows the openings in the building which are evaluated as missile barriers." The SHINE OLA further states that each FSTR wall that protects the safety-related SSCs was evaluated for impacts at its center and at critical locations near the edge of the wall panel.

In its response to RAI 3.4-11 regarding aircraft impact locations, SHINE stated that "[t]he structural screening and evaluation of the FSTR demonstrates that the building components meet the structural screening and evaluation guidelines at all [aircraft] impact locations and there is no safety-related equipment supported from the building in the vicinity of the postulated impact; therefore, the risk is deemed small and the results are documented."

It is not clear by limiting the analysis to postulated impacts at wall centers and at critical locations near the edge of each wall panel, the evaluation was adequate to assess other wall locations where safety-related SSCs (e.g., cranes) may be attached and the risk to be identified as "small." It is also not clear whether the postulated impact locations considered the structural adequacy of structural connections. Further, it is not clear what method of analysis SHINE has used for the aforementioned impact evaluations to assess wall deformation, cracking (if any), and risk so that the FSTR continues to maintain its structural integrity. In addition, it is not clear whether punching shear was implicitly evaluated as part of the perforation process consistent with DOE-STD-3014-2006 so that the risk to structural damage that could reduce facility's defense-in-depth is deemed to be small as well, and thus help terminate the analysis without consideration of fuel fires that may demand implementation of Appendix N4 to ANSI/AISC N690-12 for conformance of structural design to fires.

(a) Discuss how the localized structural evaluation at postulated impact locations can adequately represent the behavior at other wall critical locations where safety-related SSCs are attached, for example where crane runway systems are attached.

(b) Clarify whether the postulated impact locations at edge of each wall panel considered effects on structural connections.

(c) Discuss the method of analysis used and its conservatism in the screening and evaluation of wall deformations due to impact (including those at missile barrier locations identified in Figure 3.4-7 of the SHINE OLA), leading to the conclusion that the FSTR continues to maintain its structural integrity and its defense-in-depth with a risk level of concern deemed as "small." Include the basis for eliminating punching shear of the FSTR exterior walls.

Following responses to the above requests (a) through (c), update the SHINE FSAR accordingly.

RAI 3.4-20 Chapter 2 of SHINE OLA states, in part, that "[t]he ASCE standards provide minimum load requirements for the design of buildings and other structures that are subject to building code requirements…." Consistent with American Society of Civil Engineers (ASCE) 7-05, Section 2.5 and its commentary, the strength and stability of a structure shall be checked to ensure that it is capable of withstanding the effects of extraordinary (i.e., low-probability) events, such as fires, explosions, and vehicular impacts. Section 3.4.5.1 of the SHINE OLA states that the FSTR has been designed consistent with DOE-STD-3014-2006. The DOE-STD-3014-2006 discusses modes of impact and states that an "aircraft can crash into the structure either by skidding or by flying directly into it." SHINE determined that the Challenger 605 or Hawker 400 aircraft as the design basis aircraft for analyzing the postulated aircraft impacts. According to Table 2.2-12 of SHINE OLA the Southern Wisconsin Regional Airport (SWRA) has multiple runways one of which (runway 22) is less than a half a mile from the projected center of the SHINE facility. Given the proximity of the facility to SWRA runways, it may be possible to have an accidental skidding of an aircraft at the FSTR rooftop.

In RAI 3.4-16, the NRC staff requested SHINE to state whether the effects of traction in the design of the concrete roof and supporting steel truss (including stability of the compression flanges of the truss) for a postulated global response mode of impact with a horizontal velocity component, were considered. In its response SHINE stated, in part, that:

> Oblique or skidding impacts of the aircraft were not explicitly evaluated because a direct impact was determined to be controlling. This is because non-direct impacts would impart a portion of their energy perpendicular to the plane of wall or roof element (similar but less than the energy due to direct impact) and a portion into the plane of the wall or roof diaphragm, which is designed to be robust enough to distribute in-plane forces to adjacent supporting structural members. Non-direct impacts acting nearly in-plane with the impacted structural elements would likely glance off thereby imparting less overall energy to the structure.

The RAI response also states that the roof diaphragm is 12 inches thick and the truss is not designed to be composite with the roof and “any horizontal component of an aircraft strike would be dissipated through the roof diaphragm directly which is much stiffer against in-plane (horizontal) loading than the truss elements.” When discussing the non-safety-related portion of the FSTR, however, the SHINE OLA states, in part, that the “concrete on metal deck mezzanine slab and metal deck roof slab are diaphragms that transfer the lateral loads to a series of vertical brace systems.…”

It is not clear in the RAI response, how the soft fuselage could bounce off of a rigid surface unless the collision between the fuselage and the FSTR rooftop is perfectly elastic. In SHINE’s described perfectly elastic collision scenario, it is reasonable to conclude that the generated horizontal forces would be considerably less than those associated with a skidding aircraft across the FSTR roof top. It is also not clear whether the FSTR roof system relies completely on the 12-inch rigid concrete diaphragm for distribution of lateral seismic forces to shear walls or it is assisted by the metal deck roof slab for the transfer of lateral loads as well. In addition, it is not clear whether the analysis for seismic qualification of the FSTR adequately bounds the analysis for a skidding aircraft across the roof of the FSTR.

(a) Describe the safety-related portion of the FSTR roof system. Discuss whether the steel roof decking participates in the distribution of lateral forces to vertical elements. If not, state the reason.

(b) Clarify whether the seismically generated lateral forces at rooftop bound those of a skidding aircraft lateral forces and hence the analysis for seismic qualification of the FSTR bounds the analysis of a skidding aircraft across the roof top of the FSTR.

Following responses to the above requests (a) and (b), update the SHINE FSAR accordingly.

RAI 3.4-21 As noted in SHINE OLA and in SHINE’s response to RAI 3.4-13, the assessment of FSTR crane loads and loading combinations is consistent with the American Society for Mechanical Engineers (ASME) NOG-1, “Rules for Construction of Overhead and Gantry Cranes” (ASME, 2004). For civil/structural designs, however, typically local building codes reference such industry standards as the International Building Code (IBC), ASCE 7, or others, as applicable.

In that regard, in its response to RAI 3.4-13, SHINE describes the following:

- The RPF and irradiation facility (IF) cranes were evaluated using the deterministic approach of ASME NOG-1 with maximum potential crane load combinations considered, concluding that the design approach is conservative and "margin exists."

- ASME NOG-1 derived impactive (live) loads are less conservative than those provided in Section 4.9 of ASCE 7-05 and Section 1607 IBC for vertical and lateral loads. SHINE also stated that the impactive loads are approximately 10 percent of the seismic loads and stated, in part, that "[i]n light of the conservatism associated with the seismic loads and the magnitude of the difference between the impact and seismic loads, the slight difference in impact load factors is negligible."

In addition, SHINE stated that crane runway systems are not attached to exterior (FSTR) walls, and as such are sheltered from blast and aircraft impact loading.

As noted above, typical building codes for calculating crane loads follow industry codes and standards as those of ACI, ASCE, IBC, etc., as applicable. Accordingly, the following is not clear to the NRC staff:

- It is not clear what level of conservatism/margins there is in the SHINE structural facility design for crane loadings calculated based on ASME NOG-1 requirements versus those of the aforementioned building codes. It is also not clear whether the margins have been quantified for each (i.e., IF, RPF) of the crane runway systems and associated supports.

- It is not clear what building industry code or standard SHINE used to derive crane impactive loads. Typically, codes, such as ASCE or IBC, calculate the crane impactive loads based on percentage of a crane's lift capacity and its dead load. If SHINE based its crane impactive loads on seismic loads, it is not clear what was the basis for such determination. It is also not clear, whether the design methodology used resulted in a more conservative crane support system design when compared to that based on local and applicable civil/structural building code designs.

Further, it is not clear how the IF and RPF crane runway systems are supported in the FSTR. It is not clear whether they are attached to external walls and if so how. It is also not clear how the implemented crane runway system design isolates a crane from external forces/lateral loads (e.g., blast loads, aircraft impact), including base induced shear.

(a) Discuss whether the design margins have been quantified for each of the crane runway systems (i.e., IF, RPF) and if so, how conservative the design of the crane runway system (including its supports) is when calculating the necessary design crane loads based on ASME NOG-1.

(b) Provide the basis for using seismic loads as crane impactive loads. Clarify whether the loads evaluated based on building codes are less conservative than those derived from the discussed methodology.

(c) Describe the crane runway system including its supports for each of the FSTR cranes (i.e., IF, RPF) and how the design isolates the cranes from external forces including base induced shear.

Following responses to the above requests (a) through (c), update the SHINE FSAR accordingly.

RAI 3.4-22 In response to RAI 3.2-1 SHINE clarified that the N2PS structure performs, supports, and/or protects a safety function. SHINE also added Section 3.6, “Nitrogen Purge System Structure,” to the FSAR to describe the N2PS structure. SHINE FSAR Section 9b.6.2, “Nitrogen Purge System,” further describes the N2PS system.

SHINE FSAR Sections 3.6 and 9b.6.2 note that the N2PS piping and structure are seismically qualified; however, it is not clear that the supports are seismically qualified, specifically the nitrogen tube supports within the N2PS structure.

Clarify whether the N2PS supports are seismically qualified and identify what design code was used to design the supports. Update the appropriate FSAR section(s) to include this level of detail.