From: Michael Balazik
To: Jeffrey Bartelme
Cc: Josh Borromeo; Holly Cruz
Subject: Request to Confirm Information FSAR Chapter 13, "Accident Analysis"
Date: Friday, October 28, 2022 11:36:00 AM

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), as supplemented, SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application 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 operating license application, questions have arisen for which confirmatory information is needed. The enclosed request for confirmatory information (RCI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical area of the SHINE operating license application covered by these RCIs is Chapter 13, "Accident Analysis."

It is requested that SHINE provide responses to the enclosed RCI within 30 days from the date of this letter. To facilitate a timely and complete response to the enclosed RCI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RCI response. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

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 confirmatory information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RCIs 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 301-415-2856, or by electronic mail at Michael.Balazik@nrc.gov.

OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR CONFIRMATORY 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 Accession No. ML19211C044), as supplemented, SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application 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 the SHINE operating license application, and the review of documents during the audit, questions have arisen for which confirmatory information is needed. This request for confirmatory information (RCI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RCI include the following:

- Chapter 13, "Accident Analysis"

Applicable Regulatory Requirements and Guidance Documents

Section 50.34, "Contents of applications; technical information," paragraph (b) of 10 CFR states, in part, that "[t]he final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole." Section 50.34, subparagraph (b)(4) of 10 CFR states, in part, that final analysis and evaluation of the design and performance of structures, systems, and components with the objective stated in paragraph (a)(4) of this section and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report.

RCI 13-1 For the accident-specific materials-at-risk described in SHINE FSAR Section 13a2.2, "Accident Analysis and Determination of Consequences," confirm the following the following information:

For the accident specific material-at-risk (MAR) for the maximum hypothetical accident, the analysis deterministically assumes that 25 percent of iodine in the TSV solution in initially within the TSV offgas system (TOGS). It is assumed that the iodine in solution is predominantly volatile and that aqueous to gas partitioning occurs rapidly, causing 100% of the iodine inventory to be released to TOGS post shutdown. SHINE conservatively assumes that 100% of the safety-basis MAR is released.

<u>RCI 13-2</u> For the identification of control volumes and leakage paths in SHINE FSAR Section 13a2.2, confirm the following information:

SHINE identified the control volumes, leakage paths, and heat sinks that define the model geometry. The control volumes used in the analysis include the source volume, the building volume, and the environment. Leakage paths are treated as junctions between the control volumes.

The analysis considers each part of the facility as a fixed volume that the material is free to disperse into. Dispersion within these volumes is assumed to be instantaneous. Each volume is connected by one or more junctions which allows flow in one direction at a volumetric flow rate, either pressure-driven or constant. Counter-current flow, or flow back into the previous control volume, is not considered in this calculation.

The SHINE-identified scenarios can be organized into four leak-path combinations which include: release location, initial confinement, secondary confinement, and release to environment. These leak-path combinations are:

1. Confinement by IU Cell or concrete cell -> IF building -> environment;
2. Confinement by glovebox -> IF building -> environment;
3. Confinement by hot cell -> RPF building -> environment; and
4. Confinement by concrete vault -> RPF building -> environment.

<u>RCI 13-3</u> For the derivation of iodine reduction factors in SHINE FSAR Section 13a2.2, confirm the following the following information:

SHINE utilized the following model and guidance to perform this analysis:

- Iodine partitioning was calculated using equations based on the definitions found in NUREG/CR-5950, "Iodine Evolution and pH Control."
- Bursting bubble aerosols are treated using a linear relationship between entrainment coefficients and the volumetric flow rate with entrainment coefficients consistent with the small amount of dissolved materials present in the target solution.
- Spray and free-fall aerosols use a constant airborne release fraction found in NUREG/CR-6410.
- Radiolysis was treated as either an instantaneous release of hydrogen or as entrainment with source generation based on decay power inputs for long-term problems.

All scenarios containing iodine use isotope reduction factors that account for

TOGS running during normal operations. Scenarios that are downstream from the IU cell take an additional removal factor of iodine due to the operation of the TOGS during the post-irradiation dump tank hold time.

SHINE calculation, CALC-2018-0048, Appendix B, "Justification for Treatment of Iodine," contains the justification for the removal factors that are utilized in this calculation as well as the isotope-specific reduction factors. The table below provides a list for each DBA scenarios which assumes iodine removal factors for the IU, the dump tank, or both.

Design-Basis Accident Scenarios Utilizing Iodine Removal Factors

Scenario Number	Irradiation Reduction Factor	Dump Tank Reduction Factor
1a	x	
1b	x	
3	x	
9a	x	x
9b	x	x
10	x	
11	x	x
12	x	x
14	x	x

RCI 13-4 For the quantification of leak rates between volumes in SHINE FSAR Section 13a2.2, confirm the following information:

SHINE defined leakage rates between volumes driven by pressure, gas density differences, and barometric breathing. The outcome of this sub-step as expressions for removal rates. The gas pressure in each volume is determined using a combination of conservation laws for mass and energy, temperature-dependent specific heats, and the ideal gas law. Pressure-driven flow through each junction was calculated using the standard compressible flow equation for pressure-driven flow. Pressure-driven flow through shielding cover plug gaps was calculated using the equation for plane Poiseuille flow. In the absence of pressure-driven flow, counter-current flow was assumed to be induced and was calculated based on the difference in pressure from one side of the cover plug to the other. There is no assumed flow from the IF to the RPF or vice versa; all material in the IF or RPF control volumes exits the SHINE facility to the environment.

RCI 13-5 For the quantification of removal mechanisms in SHINE FSAR 13a2.2, confirm the following information:

SHINE established expressions for removal rates of radionuclides. Specifically, iodine adsorption, non-volatile aerosol deposition, and removal by filters along flow paths. Removal by aerosol settling was evaluated using Stokes' law and the calculated equilibrium particle size for a hygroscopic particle. Consideration of removal by filters in the accident flow paths was done by assigning decontamination factors for noble gases, iodine, and aerosols to each filter. Removal due to barometric breathing was based on an analysis of the peak-to-peak magnitude of environmental pressure fluctuations. Eight years of pressure data were collected and analyzed to provide a bounding estimate of the barometric breathing flow rate for the facility.

RCI 13-6 For assessing meteorological conditions in SHINE FSAR Section 13a2.2, confirm the following:

The x/Q values are calculated for periods of 0-2 hours, 0-8 hours, 8-24 hours, 1-4 days, and 4-30 days following the effluent release.

The control room atmospheric dispersion x/Q values utilized in the SHINE accident analysis are reported in CALC-2018-0048 Rev. 6, Table 3-1, "95th Percentile Site Boundary x/Q values," are as follows:

Locations	Time Bin (hours)				
	0-2	2-8	8-24	24-96	96-720
Control Room Public x/Q Values (s/m^3)	1.40E-2	1.09E-2	4.61E-3	2.99E-3	2.33E-3

RCI 13-7 For operator radiological consequences assumptions in SHINE FSAR Section 13a.2.2, confirm the following:

The volume of the control room is conservatively estimated to be 350 m^3 based on the dimensions of the control room minus estimated sizes of the equipment in the control room. SHINE assumes no cross contamination from IF and RPF as the control room is not part of the radiologically control area. Therefore, the radionuclide flow path from the material at risk source to the control room is accident-dependent but generally flows to the environment to the facility ventilation system intake (FVZ4) using the control room atmospheric c/Q values. The facility ventilation zone four system is responsible for delivering air to the control room and many other rooms in the non-radiologically controlled area of the SHINE facility where approximately 20% of the FVZ4 inlet flow is delivered to the control room. The FVZ4 is assumed to continue running after all initiating events as it is not safety-related. Material that reaches the control room are assumed to instantaneously diffuses within the control room volume. The ventilation system is assumed to continue running after all initiating events for a period of 30 days. The breathing rate for control room operators is 3.50E-04 m^3/s based on those stated in RG 1.195 for the duration of the scenario. Control room occupancy factors are sourced from RG 1.195 item 4.2.6 as described below:

	Control Room Occupancy Factors		

	0-24 hours	24-96 hours	96-720 hours
Occupancy Factor	1.0	0.6	0.4

RCI 13-8 For public radiological consequences assumptions in SHINE FSAR Section 13a.2.2, confirm the following:

The public radiological consequences are computed by modeling the radionuclide flow path from the material at risk source to the environment in combination with the siting public atmospheric c/Q values over a 30-day period. The breathing rate for control room operators is 3.50E-04 m^3/s based on those stated in RG 1.195 for the duration of the scenario.

RCI 13-9 TS 5.5.1, "Nuclear Safety Program," states, in part, the following:

> *The safety program accomplishes these goals through development and maintenance of the accident analysis, identification of safety-related controls credited for the prevention or mitigation of accidents, and establishment of programmatic administrative controls to ensure reliability of the credited controls.*

Confirm that TS 5.5.1 will ensure that the SHINE Safety Analysis and its supporting documentation remain accurate and current, including prompt updates of the SHINE Safety Analysis and its supporting documentation when a change is made to the facility, operations, or FSAR descriptions.

Best Regards,

Michael Balazik
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