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Subject: SHINE Accident Analysis and Criticality Safety Audit Topics
Date: Wednesday, June 17, 2020 4:57:00 PM
Attachments: [SHINE Accident Analysis and Criticality Control Audit Topics.pdf](#)

Jeff,

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), and March 27, 2020 (ADAMS Accession No. ML20105A295), 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, questions have arisen related to SHINE's accident analysis and criticality safety program for which additional information is needed to determine that there is reasonable assurance of adequate protection of public health and safety and that applicable regulatory requirements are met. The topics below identify areas where additional information is needed for the NRC staff to continue its review of the SHINE accident analysis and criticality safety program may become formal requests for additional information following the regulatory audit.

As part of its review, the NRC staff has prepared audit topics related to SHINE's accident analysis and criticality safety program, which are included as an attachment to this e-mail. In addition to these audit questions, the NRC staff is seeking specific documentation to be uploaded to its electronic reading room to support the audit of the PODCATS workbook (Mathcad document) and the following documents where SHINEs applied the five factor formula as: $A_i(C_i) = (M_i) \times (D_i) \times (R_i) \times (L_i)$

where:

- $A_i()$ = airborne source term for nuclide i
- (M_i) = material at risk for nuclide i
- (D_i) = damage ratio, assumed to be 1.0
- (R_i) = airborne release fraction for nuclide i
- (L_i) = leak path factor for nuclide i

Requested SHINE Source Documents:

MAR:

- SHINE Medical Technologies, "CALC-2018-0010 Rev. 2, 'Bounding Fission Product Inventories and Source Terms'," 2018:
 - CALC-2018-0010_R2_Source1b-Target_Solution_NoExtraction.xlsx
 - CALC-2018-0010_R2_Source2-TOGS_Iodine.xlsx", "CALC-2018-0010_R2_Source3and4-TOGS_KrXe_andDPs.xlsx"

- CALC-2018-0010_R2_Source1a-Target_Solution.xlsx
- CALC-2018-0010_R2_Source7-ExtColmEluate.xlsx
- CALC-2018-0010_R2_Source12-PVVS_IodineRPF.xlsx
- CALC-2018-0010_R2_Source1a-Target_Solution.xlsx
- CALC-2018-0010_R2_Source3and4-TOGS_KrXe_andDPs.xlsx
- CALC-2018-0010_R2_Source1b-Target_Solution_NoExtraction.xlsx

DR: Not applicable.

ARF:

- Fauske & Associates, LLC, "FAI/19-0035 Rev. 1, "Leak Path Factor Analysis for the SHINE Facility

LPF:

- Fauske & Associates, LLC, "FAI/19-0035 Rev. 1, "Leak Path Factor Analysis for the SHINE Facility

To prevent the inadvertent release of sensitive information, the NRC staff requests that SHINE review these RAIs to ensure that no proprietary information has been included. Should SHINE identify any proprietary information, contact Steven Lynch within the next ten days.

Following the completion of SHINE's review or after ten days, whichever comes first, the documents uploaded to BOX and associated e-mail correspondence will be added to ADAMS. Proprietary information within these documents will be withheld from public disclosure pursuant to Title 10 of the Code of Federal Regulations 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Documents that do not contain proprietary information will be made publicly available.

The NRC staff also requests that SHINE propose a date or dates to discuss these audit topics, including when specific reference documents or calculations may be available.

Please contact me with any questions.

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