May 20, 2015

SMT-2015-020
10 CFR 50.30

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

References: See Below

SHINE Medical Technologies, Inc. Application for Construction Permit
Response to Request for Additional Information 13a2.2-5

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI (References 1 and 2). The NRC staff determined that additional information was required to enable the staff's continued review of the SHINE construction permit application (Reference 3). SHINE responded to the NRC staff's requests via References (4) and (5). Via Reference (5), SHINE stated that a response to RAI 13a2.2-5 would be provided by June 12, 2015.

Enclosure 1 provides the SHINE response to RAI 13a2.2-5.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on May 20, 2015.

Very truly yours,

R. Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Administrator, Region III, USNRC
Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

References:
(1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
(2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)
(3) NRC letter to SHINE Medical Technologies, Inc., dated March 25, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15055A116)
(4) SHINE Medical Technologies, Inc. letter to NRC, dated April 10, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15120A248)
(5) SHINE Medical Technologies, Inc. letter to NRC, dated May 1, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15131A464)

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 13A2.2-5

The NRC staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 2 and 3). The following information is provided by SHINE in response to request for additional information (RAI) 13a2.2-5.

CHAPTER 13 – ACCIDENT ANALYSIS

Section 13a2.2 – Accident Analysis and Determination of Consequences

(Applies to RAIs 13a2.2-5 through 7)

> *The ISG Augmenting NUREG-1537, Part 2, Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category and that the mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, should be clearly stated.*

RAI 13a2.2-5

While SHINE's response to RAI 13a2.2-1 states that the basis for the internal dose conversion factors (DCFs) is International Commission on Radiological Protection Publication 30, "Limits for Intakes of Radionuclides by Workers," (ICRP 30) additional information is needed on this basis, as applied to offsite DCFs for members of the public, for the NRC staff to determine the adequacy of SHINE's radiological dose consequence analysis as part of its accident analysis.

Provide information supporting the acceptability of ICRP 30, which provides DCFs for adult workers, as the basis for calculating offsite doses to members of the public, including children.

SHINE Response

SHINE used International Commission on Radiation Protection (ICRP) Publication 30, *"Limits for Intakes of Radionuclides by Workers,"* (ICRP 30) to calculate dose to members of the public in the preliminary accident analysis because ICRP 30 forms part of the basis for 10 CFR 20, and there is no regulatory requirement to use any guidance other than ICRP 30. However, SHINE acknowledges that ICRP Publication 72, *"Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 5 Compilation of Ingestion and Inhalation Dose Coefficients,"* (ICRP 72) provides dose coefficients based on newer biokinetic models and data than ICRP 30. Therefore, during the detailed design process, SHINE will update the accident analysis calculations to use dose conversion factors (DCFs) from ICRP 72 and will calculate dose effects to ensure that the dose limits in 10 CFR 20.1301 are met.

SHINE has also prepared an analysis of the total effective dose equivalent (TEDE) to individual members of the public due to normal operational emissions, to demonstrate compliance with 10 CFR 20.1301, as well as 10 CFR 20.1101(d), using DCFs based on ICRP 30. This analysis was provided in the SHINE Response to RAI 11.1-9 (Reference 4).

SHINE also acknowledges that the use of ICRP 72 will provide more representative age-dependent dose estimates for the public for normal operation.

Therefore, SHINE will also perform normal operational dose calculations for the public using ICRP 72 DCFs during final design. The calculations will include age-dependent effects and potential ingestion pathways to demonstrate compliance with the regulations. As necessary, SHINE will provide additional engineered controls (e.g., crediting the Process Vessel Vent System (PVVS) acid gas scrubber, adding local charcoal or zeolite filters, using longer holdup times in the noble gas storage tanks) and/or refined source terms (e.g., more realistic iodine release fractions) to ensure that the resulting expected doses from normal operation meet the regulatory dose limits and dose constraints.

SHINE will ensure that a consistent methodology is applied to the final dose calculations. With the Final Safety Analysis Report (FSAR), SHINE will provide a description of the following:

- methodology used to derive the site-specific atmospheric dispersion and deposition (χ/Q and D/Q) values
- the evaluation of input parameters related to agricultural storage times, growing periods, and intake delays appropriate for the SHINE site
- selection and use of radioiodine partitioning factors applied in the calculations.
- applied DCFs for the appropriate iodine species
- dry and wet deposition effects
- source term assumptions and methodology
- final dose calculation results
- credited engineered controls

An Issues Management Report (IMR) has been issued to track the inclusion of this information in the FSAR.

Based on the above, it is acceptable to use ICRP 30 for calculating off-site doses to members of the public for purposes of obtaining the construction permit because the calculation results meet regulatory requirements, use codified methodologies, and SHINE will calculate doses to the public for normal operation and design basis accidents using ICRP 72 DCFs during final design.

References

(1) NRC letter to SHINE Medical Technologies, Inc., dated March 25, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15055A116)

(2) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)

(3) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)

(4) SHINE Medical Technologies, Inc. letter to NRC, dated March 23, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information 11.1-9 (ML15092A397)