SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

PUBLIC VERSION

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 RAI 6b.3-23 and RAI 6b.3-26 (Reference 1).

CHAPTER 6 – ENGINEERED SAFETY FEATURES

Section 6b.3 – Nuclear Criticality Control

(Applies to RAIs 6b.3-23 through 30)

> *As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."*
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> *As stated in the ISG Augmenting NUREG-1537, Chapter 13, the NRC staff has determined that the use of integrated safety analysis (ISA) methodologies as described in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR Section 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility.*
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> *Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in this ISG, the term "performance requirements," when referencing 10 CFR Part 70, Subpart H, is not intended to mean that the performance requirements of Subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.*

RAI 6b.3-23

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical" and that "NCS [nuclear criticality safety]

limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety."

For example, the applicant could commit to base the safety limits on validated calculation methods. These methods should be industry-accepted and peer-reviewed. Also, the applicant should commit to ensuring that methods used to develop NCS limits will be validated to confirm that they are used within acceptable ranges and that the applicant used both appropriate assumptions and acceptable computer codes.

In response to RAI 6b.3-1b, SHINE submitted a general validation report and a project-specific validation report, which provided the methods and assumptions used to determine that nuclear criticality safety criteria are met at the SHINE facility. Staff reviewed these reports and has determined that additional information is needed to determine that the methods used to validate NCS safety criteria are acceptable and that SHINE used both appropriate assumptions and acceptable computer codes.

a. *The general validation report appears to be an off-the-shelf report, dated 2007. As described in ANSI/ANS-8.24, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," verification and validation should be performed using the same operating systems, software, and hardware that will be used for performing evaluations and placing systems under configuration control.*

   Provide additional information describing how the general validation report uses appropriate methods to validate NCS safety criteria, including information on the operating systems, software, and hardware used to perform evaluations and place systems under configuration control.

b. *As described in NUREG-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology," prior to the initiation of validation activities, the operating conditions and parameters for which the validation is to apply must first be identified.*

   For both the general and project-specific validation reports, describe the area of applicability with respect to the actual operations and describe the applicability of the benchmark experiments to these operations.

c. *As described in NUREG-6698, the statistical results from the bias trends are used to establish safety limits. Both the general and project-specific validation reports are missing an evaluation of trends in the bias data, which may impact potential bias estimates.*

   For both the general and project-specific validation reports, provide an evaluation of the trends in the bias data, describing potential impacts on the bias impacts.

d. *The validation of two different libraries for different materials, introduces the possibility of human error in selecting a library for the evaluation (i.e., picking the wrong library).*

   Provide the methods SHINE uses to guard against the selection of the incorrect library for validation.

e. *The project-specific validation report utilizes only a limited number of experiments to evaluate the bias and estimate uncertainty. For example, only four experiments were listed for the most applicable enrichment. Additionally, modeled results were compared with calculated results, as opposed to only with experimental data.*

Explain why only a limited number of experiments are sufficient to evaluate bias and estimate uncertainty. Additionally, explain why modeled results were compared with calculated results, as opposed to only with experimental data.

SHINE Response

a. SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1.

   The information on the operating systems, software, and hardware used to perform evaluations and place systems under configuration control is provided in Sections 1.1 and 2 of the validation report. When computer hardware or software is upgraded, a re-verification of the installation is performed by running tests that provide assurance that the computer program continues to produce correct results. The validation is performed using the same operating systems, software, and hardware that will be used for performing evaluations.

b. SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1.

   Section 6 of the validation report describes the area of applicability with respect to actual operations. Section 4 of the validation report describes the applicability of the benchmark experiments to actual operations.

c. SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1.

   Section 5 of the validation report evaluates the trends in the bias data and the impacts of those trends.

d. SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1.

   The validation report was performed in accordance with Atkins Nuclear Solutions (Atkins) Quality Assurance (QA) Program and Engineering procedures, which ensure the correct software library is selected for use. The Engineering procedure for design analysis calculations require the preparer list the inputs, including library and input files, and the reviewers shall check that inputs were correctly selected for use in the calculation.

   The Atkins nuclear criticality safety evaluation procedure requires the calculations be performed using a validated computer code and the correct cross section library.

e. SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1.

   The updated validation report examines 140 benchmark experiments. As described in the validation report, this number of experiments is sufficient to evaluate bias and estimate uncertainty.

   As shown in the validation report, the modeled results are only compared to experimental data.

RAI 6b.3-26

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that the reviewer should determine "whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality."

In response to RAI 6b.3-4, SHINE states it intends to utilize a subcritical margin of 0.05 with additional considerations for uncertainty in the validation and modeling. In addition, SHINE states in multiple places in the PSAR that processes will be maintained to a $k_{eff} \leq 0.95$ *(assuming a subcritical margin of 0.05).*

The NRC staff's review of SHINE's response to RAI 6b.3-1, which requested the applicant's validation report and NCS reference manual, found that there was insufficient benchmarking of the code against experiments utilizing the materials and enrichments expected in SHINE's processes. For this reason, the proposed subcritical margin of 0.05 is not sufficient to adequately address the uncertainty associated with the neutron interactions of these process materials. The subcritical margin of 0.05, which SHINE quoted from NUREG-1520, was intended for facilities with enrichment less than five percent utilizing well established processes and for which there is significant experience and data. In contrast, the SHINE facility will be a first-of-a-kind facility using materials not normally utilized and of an enrichment up to 20 percent.

Provide additional information describing how SHINE will sufficiently benchmark against experiments utilizing the materials and enrichments expected to be used in SHINE facility processes for its proposed margin of subcriticality, or propose a new margin of subcriticality that appropriately takes into account materials and enrichment.

SHINE Response

SHINE has updated the validation report for nuclear criticality safety applications. The updated validation report is provided in Attachment 1. The updated validation report supersedes the previous validation reports provided as Attachments 10 and 11 to Enclosure 1 of Reference (4) and Enclosure 1 of Reference (5). The validation was performed in accordance with ANSI/ANS-8.24-2007 (Reference 6).

The new validation examines 140 benchmark experiments. NUREG/CR-6698 (Reference 7) provides no minimum number of experiments to produce a rational validation; however, NUREG/CR-6698 states that examining less than 10 experiments should be accompanied by a technical basis supporting the rationale for acceptability of the validation results.

All materials and processes within the SHINE facility are established technology and benchmarking against experiments using sufficiently similar materials and enrichments as expected to be used in the SHINE facility is performed within the attached validation report.. The validation report documents the ability to predict k_{eff} accurately for the SHINE processes. Therefore, it is judged that the subcritical margin of 0.05 is acceptable. The attached validation provides sufficient benchmarks against experiments using the materials and enrichments expected to be used in the SHINE facility for the proposed margin of subcriticality.

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 December 3, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14356A527)

(5) SHINE Medical Technologies, Inc. letter to NRC, dated April 1, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Submittal of NSA-DAC-SHN-13-02, Revision 1 (ML15091A749)

(6) American National Standards Institute/American Nuclear Society, “Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations,” ANSI/ANS-8.24-2007 (R2012), La Grange Park, IL

(7) U.S. Nuclear Regulatory Commission, “Guide for Validation of Nuclear Criticality Safety Calculational Methodology,” NUREG/CR-6698, January 2001(ML050250061)