



April 13, 2022

2022-SMT-0046
10 CFR 50.30

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

References: (1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)

SHINE Technologies, LLC Application for an Operating License Supplement No. 21

Pursuant to 10 CFR Part 50.30, SHINE Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, Wisconsin via Reference 1. SHINE has determined that revisions to the technical specifications are necessary to address considerations discussed with the NRC Staff during a March 29, 2022 clarification call and to address identified administrative errors.

Enclosure 1 provides the Technical Specifications Change Summary, including a markup of affected technical specifications pages.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on April 13, 2022.

Very truly yours,

DocuSigned by:

F52DB96989224FF...

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE TECHNOLOGIES, LLC

**SHINE TECHNOLOGIES, LLC APPLICATION FOR AN
OPERATING LICENSE SUPPLEMENT NO. 21**

TECHNICAL SPECIFICATIONS CHANGE SUMMARY

| Summary Description of Changes | TS Impacts |
|--|-------------------|
| Administrative corrections, including correction of inconsistencies and typographical errors. | Section 5.3 |
| Update to clarify the applicability of the SHINE nuclear safety program. | Section 5.5.1 |
| Update to clarify the regulatory considerations of the SHINE configuration management program. | Section 5.5.4 |

A markup of the technical specifications (TS) changes is provided as Attachment 1.

**ENCLOSURE 1
ATTACHMENT 1**

SHINE TECHNOLOGIES, LLC

**SHINE TECHNOLOGIES, LLC APPLICATION FOR AN
OPERATING LICENSE SUPPLEMENT NO. 21**

TECHNICAL SPECIFICATIONS CHANGE SUMMARY

TECHNICAL SPECIFICATIONS MARKUP

- d. The SHINE Facility emergency plan and implementing procedures: at least once every other calendar year (interval between audits not to exceed 30 months);
 - e. The radiation protection plan: at least once per calendar year (interval between audits not to exceed 15 months);
 - f. The QAPD: at least once every other calendar year (interval between audits not to exceed 30 months);
 - g. The physical security plan: at least once every other calendar year (interval between audits not to exceed 30 months); and
 - h. The nuclear criticality safety program: at least once every third calendar year (interval between audits not to exceed 36 months).
2. Deficiencies identified during the audit will be entered into the Corrective Action Program. Deficiencies uncovered that affect nuclear safety shall immediately be reported to Level 1 management. A written report of the findings of the audit shall be submitted to Level 1 management and the review and audit committee members within three months after the audit has been completed.

5.3 Radiation Safety

The Radiation Protection Manager (RPM) shall be responsible for the implementation of the radiation protection program. The requirements of the radiation protection program are established by 10 CFR Part 20. The program shall use the guidelines of ANSI/ANS 15.11-~~1993~~2016, Radiation Protection at Research Reactor Facilities. Furthermore, SHINE is committed to ensuring that radiation exposures are ALARA and in maintaining ~~an~~an effective ALARA Program.

The radiation protection department is independent of facility operations. This independence ensures that the radiation protection department maintains its objectivity and is focused only on implementing sound radiation protection ~~principals~~principles necessary to achieve occupational doses and doses to members of the public that are ALARA.

Radiation protection staff maintain the ability to raise safety issues with the review and audit committee or executive management.

5.4 Procedures

1. Procedures for the operation and use of the SHINE Facility provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are written, reviewed, approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise.
2. The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation shall be in compliance with ANSI/ANS 15.1-2007.

significance of the consequences of error. The process for making changes and revisions to procedures is documented. A controlled copy of all operations procedures is maintained in the control room. Activities and tasks are performed in accordance with approved implementing procedures.

5.5 Programs

The following programs shall be established, implemented, and maintained.

5.5.1 Nuclear Safety Program

The SHINE nuclear safety program documents and describes the methods used to minimize the probability and consequences of accidents resulting in radiological or chemical release. The program applies a graded approach to the design and management of processes to assure plant safety through risk reduction and satisfaction of SHINE's performance goals. The safety program accomplishes these goals through development and maintenance of the accident analysis, identification of safety-related ~~structures, systems, and components (SSCs)~~controls credited for the prevention or mitigation of accidents~~mitigation~~, and establishment of programmatic administrative controls to ensure reliability of the credited ~~SSCs~~controls.

5.5.2 Training and Qualification

The SHINE training and qualification programs include initial and requalification training programs for Licensed Operators, which were developed to conform to the requirements of 10 CFR Part 55, as it pertains to non-power facilities, following the guidance contained in ANSI/ANS 15.4-2016, Selection and Training of Personnel for Research Reactors.

5.5.3 Radiation Protection

The SHINE radiation protection program is provided to protect the radiological health and safety of workers and the public. The program meets the requirements of 10 CFR 20, Subpart B, and is consistent with the guidance provided in ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities, and Regulatory Guide 8.2, Revision 1, Administrative Practices in Radiation Surveys and Monitoring. In addition, SHINE has established this program to maintain occupational radiation exposures and releases to the environment ALARA.

5.5.4 Configuration Management

The SHINE configuration management program provides oversight and control of design information, safety information, and records of modifications that might impact the ability of safety-related SSCs to perform their functions. The configuration management program is applied to all safety-related SSCs and is used to evaluate each change to the SHINE Facility for the potential to affect safety-related SSCs. The configuration management program is used to maintain consistency among the design requirements, the physical configuration and the facility documentation, and ensures changes are made in accordance with 10 CFR 50.59, ~~10 CFR 70.72~~, and the administrative controls and reviews specified by this program.

Table 5.5.4 lists controls derived from the accident analysis not otherwise included in Sections 3, 4, or 5 of the technical specifications. SHINE maintains these controls under the configuration management program and will not modify the characteristics of the items listed in Table 5.5.4 without prior NRC approval.