



December 16, 2021

2021-SMT-0185
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)
 - (2) NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related to Operator Training and Requalification Program (EPID No. L-2019-NEW-0004)," dated October 22, 2021 (ML21280A338)
 - (3) SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated November 3, 2021 (ML21307A306)

SHINE Technologies, LLC Application for an Operating License
Response to Request for Additional Information

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. Via Reference 2, the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application. SHINE responded to a portion of the NRC staff's request for additional information (RAI) via Reference 3. Additionally, SHINE has determined that the SHINE Response to RAI OTR-5, provided via Reference 3, required revision.

Enclosure 1 provides the remaining SHINE response to the NRC staff's request for additional information (Reference 2).

Enclosure 2 provides Revision 1 of the SHINE Response to RAI OTR-5. Revision 1 supersedes the previously provided SHINE Response to RAI OTR-5, provided via Reference 3, in its entirety.

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

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I declare under the penalty of perjury that the foregoing is true and correct.
Executed on December 16, 2021.

Very truly yours,

DocuSigned by:

F52DB96989224FF...

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

Enclosures

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 RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Operator Training and Requalification

RAI OTR-3

Paragraph (e) of 10 CFR 55.53, "Conditions of licenses," requires, in order to maintain active status, a licensed operator to actively perform the functions for a specified number of hours per calendar quarter. Paragraph (f) of 10 CFR 55.53, requires, in order to restore active status, a licensed operator to perform a minimum amount of hours of licensed duties under the direction of another operator. While SHINE's application states that the requalification program describes the essential training required to maintain a license in active status, it does not discuss operator proficiency in sufficient detail.

Additionally, SHINE has described in Table 4-1 of its Licensed Operator Continuing Training Program that licensed operators are to perform four hours of licensed duties on a quarterly basis, consistent with the requirement for research and test reactors in 10 CFR 55.53(e). Additionally, SHINE states in Section 4, "Program Requirements," of its Licensed Operator Continuing Training Program that "[l]icensed operators and senior licensed operators who have not met the periodicity requirements for proficiency in Table 4-1 will perform a minimum of six hours of licensed duty under the direction of a qualified individual holding the same or higher-level license prior to being reinstated." This is consistent with the requirements for research and test reactors in 10 CFR 55.53(f)(2). However, SHINE is not a research reactor or a test reactor. As such, the research and test reactor provisions of 10 CFR 55.53(e) and (f)(2) are not applicable to SHINE.

- (a) Describe, in detail, how SHINE intends to implement this requirement to ensure operators can remain proficient and regain proficiency, including: an illustrative list of activities or duties, in addition to various examples of control manipulations, that are considered "actively performing the functions of an operator or senior operator."
- (b) Justify how the number of hours proposed for licensed operators to actively perform functions to maintain an active status or restore an active status, as described in the SHINE Licensed Operator Continuing Training Program, is in accordance with 10 CFR 55.53(e) and (f)(2), respectively. Alternatively, SHINE may consider requesting an exemption from

the NRC's regulations to require a different number of hours for licensed operators to maintain an active status or restore an active status.

This information is necessary for the NRC staff to determine that SHINE has established appropriate provisions to ensure the adequacy of training for licensed operators and senior operators consistent with 10 CFR 55.53.

SHINE Response

(a) Actively performing the duties of a licensed operator or senior licensed operator, during scheduled shift work, including reactivity manipulations, ensures that operators and senior operators remain proficient. Actively performing the duties of a licensed operator or senior licensed operator, under the direction of a qualified individual holding the same or higher-level license, during scheduled shift work, including reactivity manipulations, ensures that operators and senior operators regain proficiency. The following examples provide an illustrative list of activities or duties, including examples of control manipulations, that are considered actively performing the functions of an operator or senior operator:

- Placing target solution vessel (TSV) reactivity protection system (TRPS) channels in bypass or trip
- Placing engineered safety features actuation system (ESFAS) channels in bypass or trip
- Startup or shutdown of the TSV off-gas systems (TOGS)
- Authorizing the transfer of uranyl sulfate solution
- Authorizing work on a system, structure, or component covered by technical specifications
- Performing or supervising control manipulations
 - Filling or draining of a TSV with uranyl sulfate
 - Startup, shutdown, or adjustment of the neutron driver assembly system (NDAS) with uranyl sulfate solution present in the TSV

(b) SHINE has submitted a request for an exemption from the requirements of 10 CFR 55.53(e) and 10 CFR 55.53(f)(2) to modify the minimum number of hours required for licensed operators to maintain active status and restore active status (Reference 3). The SHINE Licensed Operator Continuing Training Program, OPS-01-03 currently specifies minimum hour requirements that are consistent with the exemption requested in Reference 3. Program OPS-01-03, Revision 2, is provided as Attachment 1 to Enclosure 2.

References

1. NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related to Operator Training and Requalification Program (EPID No. L-2019-NEW-0004)," dated October 22, 2021 (ML21280A338)
2. SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
3. SHINE Technologies, LLC letter to the NRC, "Request for Exemption from Licensed Operator Minimum Hours to Maintain Active Status and Minimum Hours to Restore Active Status," dated December 16, 2021.

ENCLOSURE 2

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

REVISION 1 OF SHINE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION OTR-5

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Technologies, LLC (SHINE) operating license application (Reference 2). SHINE responded to a portion of the NRC staff's request for additional information (RAI) via Reference 3. SHINE has determined that the SHINE Response to RAI OTR-5, provided via Reference 3, requires revision. Revision 1 of the SHINE Response to RAI OTR-5 is provided below. Revision 1 supersedes the previously provided SHINE Response to RAI OTR-5, provided via Reference 3, in its entirety.

Operator Training and Requalification

RAI OTR-5

Paragraph (a)(2) of 10 CFR 55.59 requires that each licensee shall "[p]ass a comprehensive requalification written examination and an annual operating test." Section 5.4, "Examinations," of ANSI/ANS 15.4-2016 describes how exams are to be administered.

The NRC staff could not identify who will be developing, administering, and grading exams in Section 5, "Examinations," of the SHINE Licensed Operator Continuing Training Program.

Update the SHINE Licensed Operator Continuing Training Program and Licensed Operator Initial Training Program, as appropriate, to describe how SHINE will ensure that the individual who develops, administers, and grades these exams is not indefinitely exempt from the requirements of taking a written examination and operating test themselves.

This information is necessary for the NRC staff to determine that SHINE has established appropriate examination requirements consistent with 10 CFR 55.59.

SHINE Response

SHINE has revised Section 5.3 of the Licensed Operator Continuing Training Program, OPS-01-03, to remove the discussion of exempting an individual from the requirements of taking a written examination and operating test. Program OPS-01-03, Revision 2, is provided as Attachment 1.

References

1. NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related to Operator Training and Requalification Program (EPID No. L-2019-NEW-0004)," dated October 22, 2021 (ML21280A338)
2. SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
3. SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated November 3, 2021 (ML21307A306)

**ENCLOSURE 2
ATTACHMENT 1**

SHINE TECHNOLOGIES, LLC

**SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

LICENSED OPERATOR CONTINUING TRAINING PROGRAM

REVISION LOG

Revision #	Description of Changes
0	This document supersedes and is a re-issue of 0300-09-02 Rev. 0. Document is being re-issued to conform with new procedure numbering standards and contains no content changes from 0300-09-02 Rev. 0.
1	Updated procedure for definition of training periodicities, notification requirements for operator license status, fitness for duty requirements and NRC exam development and administration.
2	Removed operator exemption for developing requalification exams.

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1 INTRODUCTION

1.1 Purpose

This program establishes a continuing training program for personnel performing, verifying, or managing licensed operator activities to ensure that suitable proficiency is achieved and maintained, satisfying the requirements of 10 CFR 55.59 and in accordance with ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors".

1.2 Scope

This program describes continuing training requirements for Operations Department licensed personnel to provide assurance that licensed operators maintain competence in all aspects of licensed activities.

Operations Department personnel may have additional training requirements (e.g., general employee, site access, radiation worker, emergency response, and criticality safety) not described in this program. Additional re-training requirements are identified and maintained in accordance with their respective programs and procedures.

1.3 Overview

The licensed operator continuing training program contains instructional requirements for licensed operators to operate and maintain the facility in a safe manner in all modes of operation and through all production activities.

Outcomes include:

- satisfactory completion of continuing training activities,
- a record of qualifications/certifications to ensure currency is maintained,
- adhering to the facility license,
- meeting or exceeding applicable regulations,
- maintaining production quality,
- conducting good manufacturing practices, and
- meeting the specific performance needs of the company.

This program is periodically evaluated and revised to reflect industry experience and to incorporate changes to the facility, procedures, regulations, and quality assurance requirements and, if determined by performance, reviewed by management for effectiveness.

Licensed operators will be enrolled into the licensed operator continuing training program within three (3) months after their operating license is issued by the Nuclear Regulatory Commission (NRC).

Document reviews will be conducted to ensure that licensed individuals are cognizant of all design, procedure, and license changes as appropriate.

2 DEFINITIONS

- 2.1 Annual Requalification Cycle:** Time period corresponding to a 12-month interval comprising half of a biennial requalification cycle per ANSI/ANS-15.4-2016 Section 6.2.
- 2.2 Biennial Requalification Cycle:** Time period corresponding to a 24-month interval that the requalification program is conducted in per ANSI/ANS-15.4-2016 Section 6.2. Each biennial requalification cycle is immediately followed by another 24- month cycle.
- 2.3 Controls**
- 1) Apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of an Irradiation Unit (IU).
 - 2) Apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear process of the facility in such a manner as to affect the protection of health and safety against radiation.
- 2.4 Graded Approach to Training:** A method of streamlining parts of the systematic approach to training (SAT) process, tying each of the five phases of SAT together in more efficient information management.
- 2.5 On-the Job Training:** Performance-based training (conducted in environment that replicates as much as possible the actual task conditions) through which trainees learn how to perform a task, and the task related knowledge and skills.
- 2.6 Quarterly:** Time period corresponding to a calendar quarter.
- 2.7 Simulation-Based Learning:** A technique to replace and amplify real experiences with guided ones, often “immersive” in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. Simulation-based learning may or may not include an actual simulation device.

3 RESPONSIBILITIES

3.1 Licensed and Senior Licensed Operators

1. Attend training and complete training requirements as assigned.
2. Be cognizant of their personal training and qualification status and act in accordance with processes, procedures and regulations.

3.2 Operations Manager

1. Responsible for the content of Operations Department training.
2. Assist the Training Manager as necessary to ensure that licensed operators participate in and complete the requirements of this program.
3. Schedule and conduct reviews of changes in the license, facility design and operating procedures to determine the effect of the change on the operations training programs.
4. Ensure proper operator medical program administration. Ensure changes in license status are enacted and proper notification of regulatory authority is accomplished. Determine licensed operator limitations or conditions of licenses related to medical issues.

3.3 Training Manager

1. Responsible for overall implementation of this program, including scheduling and administering training and examinations, and maintaining records.
2. Accountable for developing, implementing, and maintaining operations training programs.
3. Assist in the preparation of training material, examinations, and retraining lectures or tutoring sessions.
4. Review the graded examinations with the operators and schedule any retraining indicated by the examination results.
5. Determine remedial plans for operators not meeting training performance criteria.
6. Perform reviews and audits of program content.

3.4 Instructors, Mentors, and Implementers

1. Champion the processes and programs to which they are assigned and effectively communicate and enforce management expectations of each program.

4 PROGRAM REQUIREMENTS

Licensed operator continuing training, which encompasses requalification for licensed operators and senior licensed operators, provides the means to train individuals in the knowledge, skills, and abilities needed to maintain proficiency in conducting licensed activities. This program is developed using a Graded Approach to Training and fulfills regulatory requirements applicable to the individual's position and responsibility.

In general, and unless specifically stated otherwise, the licensed operator continuing training program and its topics are administered through instruction, self-study, on-the-job training and/or vendor supplied efforts over a period of not to exceed 24 months. Training is given in the venue and method that best promotes learning with a preference for performance-based efforts.

The content and the periodicity of program requirements are provided in Table 4-1.

Table 4-1 – Continuing Training Program Requirements

Continuing Training Program Requirements	Periodicity
Facility Design, Procedure, and License Changes	As Applicable
Training Lectures	Quarterly
Documentation of Proficiency - Four hours licensed duties	Quarterly
Abnormal and Emergency Procedure Reviews	Once per Annual Requalification Cycle
Reactivity Manipulations (10)	Once per Annual Requalification Cycle
Operating Test	Once per Annual Requalification Cycle
Medical Exams	See Section 4.1
Comprehensive Written Exam	Once per Biennial Requalification Cycle

Training completion for all sessions is mandatory. Session completion may be done via make-up training packages with the permission of the Operations Manager.

Periodic checks of competency may be administered throughout the continuing training cycle as necessary to assess the progress of the training.

Licensed operators and senior licensed operators who have not met the periodicity requirements for proficiency in Table 4-1 will perform a minimum of six hours of licensed duty under the direction of a qualified individual holding the same or higher-level license prior to being reinstated.

4.1 Medical Certification

Licensed personnel must meet the health requirements described in ANSI/ANS-15.4-2016, Section 7 to determine the physical condition and general health of the individual to perform licensed activities. A medical evaluation is required once every 2 years with the periodic examination being completed no later than the last day of the 12th month of the second year per ANSI/ANS-15.4-2016 Section 7.1.2..

4.2 Fitness for Duty

Licensed operators are required to adhere to fitness for duty requirements per ANSI/ANS-15.4-2016. SHINE's fitness for duty policy is described in the employee handbook.

4.3 Training Scope

The scope of licensed operator continuing training includes knowledge of topics listed in Attachment A. Sequence and methodology will be based upon training approach (e.g., self-study, classroom, mentoring, simulation).

The identified topics in Attachment A are based on the requirements of 10 CFR 55.41 and 10 CFR 55.45, modified for applicability to SHINE. The specific content of these sessions will be based on:

- Items identified as weaknesses in the training program or operator knowledge as determined by operating events, examination results and crew or individual performance gaps;
- Observations of operator performance;
- Facility modifications;
- Industry, operating experience, and initiatives; or
- Importance to safety as determined by Graded Approach to Training determination.

4.4 Change in Operator License Status

Any change in licensed personnel status must be communicated to the NRC within 30 days of the change in status per 10 CFR 50.74. Items requiring notification include:

- Permanent reassignment from the position for which SHINE has certified the need for a licensed operator or senior operator
- Termination of any operator or senior operator

- Permanent disability or illness

5 EXAMINATIONS

Demonstration of knowledge and proficiency is accomplished throughout the licensed operator training program. Evaluations and examinations preferentially include methods consistent with the training activity delivery method (i.e., a task performance in the field should be evaluated with an in-the-field performance metric).

5.1 Operating Evaluation

An annual operating evaluation is administered to each licensed operator and senior licensed operator. The evaluation requires that the individual demonstrate an understanding of and ability to perform the actions necessary to accomplish a broad sample of applicable items specified in 10 CFR 55.45(a) (1) through (13) inclusive to the extent applicable. The performance of tasks may be actual or simulated.

5.2 Biennial Written Examination

Biennial written examinations will be used to verify the operator's knowledge. Preplanned training sessions will be used to retrain those operators who demonstrate deficiencies in any part of the examination.

5.3 Development

Operating evaluations and biennial written examinations are developed by personnel designated by an ANS/ANSI-15.4-2016 Level 2 individual. The designated personnel work with the NRC to develop the exam.

5.4 Administration

All exams are open reference unless specifically identified during exam development.

The results of all exams including missed questions shall be reviewed with the operator to ensure proper understanding.

The acceptance criteria for all graded exams is 70% and all operators are required to complete each exam satisfactorily.

Evaluations and examinations are administered and graded by personnel designated by an ANS/ANSI 15.4-2016 Level 2 individual. The designated personnel work with the NRC to administer and grade the evaluations and examinations.

5.5 Remediation

A score on the written or other examination equal to or greater than 70% requires no additional training.

A score on the written exam of 65 – 69% will require retraining on those areas or topics where weakness or deficiencies are identified. This retraining and subsequent retesting must be completed within 60 days from the date on which the examination was administered. The candidate need not be removed from licensed duties subject to the evaluation of the Operations Manager or designee.

A score on the written exam of less than 65% requires that an evaluation be performed by the Operations Manager or designee within 30 days. The evaluation is to determine

the deficiencies required to be remediated. The individual shall be removed from licensed duties pending completion of any remedial training and subsequent retesting.

6 PROGRAM REVIEW AND EVALUATION

As part of ongoing requalification activities, training effectiveness will be determined throughout the continuing training cycle. Determinations of effectiveness will primarily be determined by operator performance and oversight of the Operations Department by management, training and supervisory personnel.

The licensed operator continuing training program is periodically evaluated and revised to reflect industry experience and to incorporate changes to the facility, procedures, regulations, and quality assurance requirements.

The licensed operator continuing training program is assessed by the Review and Audit Committee at least once every biennium, with an interval between assessments not to exceed 24 months.

7 RECORDS

7.1 Both programmatic and individual training records are retained in accordance with the SHINE records management program. Records will be stored in the electronic data management system and may be in the form of attendance sheets, proficiency logs, or other suitable forms. The required information may be contained in single or multiple records, or a combination thereof.

7.2 Programmatic records shall include:

- Retraining Schedule
- Training Material
- Procedure Reviews
- Operational and Written Exams
- Program Audits

7.3 Individual records shall include:

- Proficiency logs
- Reactivity manipulations
- Training sessions attended
- On-the-Job training and qualifications
- Operational exams
- Written exams, including the answers given and the results
- Performance deficiencies

7.4 Records of training and qualification of Operations Department personnel shall be maintained for the duration of the currently valid license.

8 REFERENCES

8.1 OPS-01-02, Licensed Operator Initial Training

8.2 2900-01-05, Systematic Approach to Training

8.3 ANSI/ANS 15.4 - 2016, "Selection and Training of Personnel for Research Reactors"

8.4 10 CFR 55.59, Requalification

ATTACHMENT A

Licensed Training Material (LO, SLO)

1. Nuclear theory and principles of operation (fundamentals of nuclear physics)
2. Design features (theory and principles of the radioisotope production process involving Special Nuclear Material (SNM), theory and principles of radioisotope extraction and purification process, criticality control features and management measures required for each process involving SNM)
3. Facility design including safety and emergency systems and applicable operating characteristics
4. Reactivity, alterations and control systems
5. Uranium handling
6. Shielding
7. Operating procedures and limits
8. Emergency and abnormal operating procedures
9. Radiation monitoring
10. Radiation control and safety
11. Handling and disposal of radioactive material
12. Authorizing changes
13. Technical Specifications
14. Other facility training as deemed applicable
15. Conditions of license (i.e., medical, proficiency, job observations)
16. Material needed based on performance deficiencies

Senior Licensed Training Material (SLO)

1. Conditions of facility license and limitations
2. Technical Specifications basis and operability
3. Procedures and authority to make changes
4. Radiation hazards
5. Assessment of facility conditions
6. Supervisory training
7. Emergency Plan
8. Security Plan