



November 3, 2021

2021-SMT-0157
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)

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.

Enclosure 1 provides the SHINE responses to the NRC staff's request for additional information (RAIs) with the exception of RAI OTR-3. The SHINE Response to RAI OTR-3 will be provided by December 21, 2021.

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 November 3, 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-1

Paragraph (c)(3)(iv) of 10 CFR 55.59 requires the requalification program to include on-the-job training such that each licensed operator reviews the contents of all abnormal and emergency procedures on a regularly scheduled basis.

While SHINE has identified the requirement for the reviews of abnormal and emergency procedure reviews on an annual basis in Table 4-1, "Continuing Training Program Requirements," of its Licensed Operator Continuing Training Program (ADAMS Accession No. ML19211C141), SHINE has not defined what time period constitutes annual periodicity. Further, SHINE has also not defined the periodicity for quarterly and biennial time periods set for other continuing training program requirements.

Update the SHINE Licensed Operator Continuing Training Program to define what constitutes periodicity for annual, quarterly, and biennial time periods for continuing training program requirements.

This information is necessary for the NRC staff to determine that SHINE has established an adequate periodicity of program requirements, as required by 10 CFR 55.59.

SHINE Response

SHINE has revised Section 2 of the Licensed Operator Continuing Training Program, OPS-01-03, to define annual requalification cycle time periods, biennial requalification cycle time periods, and quarterly time periods. SHINE has also revised the periodicity requirements in Table 4-1 of Program OPS-01-03 to align with the revised definitions. Program OPS-01-03, Revision 1, is provided as Attachment 1.

RAI OTR-2

Section 1.1, "Purpose," of SHINE's Licensed Operator Continuing Training Program states, in relevant part, that "[t]his 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."

Section 8, "Fitness for duty," of American National Standard Institute/American Nuclear Society (ANSI/ANS)-15.4-2016 describes elements of a drug and alcohol testing program to be incorporated into licensee training programs. The NRC staff could not identify any docketed information describing SHINE's approach to drug and alcohol testing.

Update the SHINE Licensed Operator Continuing Training Program and Licensed Operator Initial Training Program (ADAMS Accession No. ML19211C144), as appropriate, to describe the drug and alcohol testing program that will be implemented or utilized for licensed operators.

This information is necessary for the NRC staff to understand how SHINE is implementing its commitment to use ANSI/ANS-15.4-2016 and determine that SHINE meets the requirement of 10 CFR 50.34(b)(8) to include "[a] description and plans for implementation of an operator requalification program."

SHINE Response

SHINE has implemented a drug and alcohol testing program for licensed operators in accordance with 10 CFR 55.53(j) and consistent with the guidance of Section 8 of American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.4-2016, "Selection and Training of Personnel for Research Reactors" (Reference 3). SHINE has revised Section 5 of the Licensed Operator Initial Training Program, OPS-01-02, and Section 4.2 of the Licensed Operator Continuing Training Program, OPS-01-03, to describe the drug and alcohol testing program implemented for licensed operators. Program OPS-01-03, Revision 1, is provided as Attachment 1. Program OPS-01-02, Revision 1, is provided as Attachment 2.

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

The SHINE Response to RAI OTR-3 will be provided by December 21, 2021.

RAI OTR-4

The regulation, 10 CFR 50.74, “Notification of change in operator or senior operator status,” requires that each licensee notify the NRC within 30 days of a change in the status of a licensed operator or senior operator. The specific circumstances when a notification is required are (a) permanent reassignment from the position for which the licensee has certified the need for a licensed operator or senior operator under paragraph (a)(3) of 10 CFR 55.31, “How to Apply;” (b) termination of any operator or senior operator; (c) permanent disability or illness as described in 10 CFR 55.25, “Incapacitation because of disability or illness.”

While SHINE states that “[a]ny change in licensed personnel status must be communicated to the NRC within 30 days of the change in status” in Section 4.1, “Medical Certification,” of the Licensed Operator Continuing Training Program, it is unclear if this is only limited changes to medical status or covers the full scope of status changes requiring notification as identified in 10 CFR 50.74.

Revise the SHINE Licensed Operator Continuing Training Program to clarify that SHINE will provide notifications related to the change in status of a licensed operator or senior operator, as required by 10 CFR 50.74.

This information is necessary for the NRC staff to determine that SHINE has established appropriate provisions to provide notifications to the NRC as required by 10 CFR 50.74.

SHINE Response

SHINE has revised Section 4.4 of the Licensed Operator Continuing Training Program, OPS-01-03, to clarify that SHINE will provide notifications related to the change in status of

licensed personnel in accordance with 10 CFR 50.74. Program OPS-01-03, Revision 1, is provided as Attachment 1.

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 clarify how SHINE ensures that an individual who develops, administers, and grades requalification operating evaluations and written examinations is not indefinitely exempt from the requirements of taking a written examination and operating test. This exemption, identified in Section 6, “Requalification and Relicensing,” of American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.4-2016, “Selection and Training of Personnel for Research Reactors” (Reference 3), is not applicable to the Licensed Operator Initial Training Program. Program OPS-01-03, Revision 1, 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. American National Standards Institute/American Nuclear Society, “Selection and Training of Personnel for Research Reactors,” ANSI/ANS 15.4-2016, 2016

**ENCLOSURE 1
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. |

TABLE OF CONTENTS

1 Introduction 4
2 Definitions 5
3 Responsibilities 5
4 Program Requirements 6
5 Examinations 8
6 Program Review and Evaluation 9
7 Records 9
8 References 10
Attachment A 11

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.

If an individual involved in developing, administering, or reviewing the examinations/evaluations holds a license and is exempted from taking the examinations/evaluations as described in Section 6.6 of ANS/ANS-15.4-2016, this individual will not be allowed to be exempted from more than one examination/evaluation in a 36-month period.

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

**ENCLOSURE 1
ATTACHMENT 2**

SHINE TECHNOLOGIES, LLC

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

LICENSED OPERATOR INITIAL TRAINING PROGRAM

REVISION LOG

| Revision # | Description of Changes |
|-------------------|--|
| 0 | This document supersedes and is a re-issue of 0300-09-01 Rev. 0. Document is being re-issued to conform with new procedure numbering standards and contains no content changes from 0300-09-01 Rev. 0. |
| 1 | Corrected typographical error in Attachment A, added fitness for duty requirements, and added reference to Systematic Approach to Training procedure. |

TABLE OF CONTENTS

1 Introduction 4

2 Definitions 4

3 Responsibilities 5

4 Training 6

5 Medical Certification 7

6 Candidate Selection 8

7 Examinations 8

8 Training Review and Evaluation 9

9 Records 9

10 References 9

Attachment A 10

Attachment B 11

1 INTRODUCTION

1.1 Purpose

This program establishes and maintains an initial training program for personnel performing, verifying, or managing licensed operator activities to ensure that suitable proficiency is achieved.

1.2 Scope

This program describes personnel selection, initial training, qualification, and licensing for Operations Department personnel. This program complies with the applicable portions of 10 CFR Part 55 and follows the guidance of ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors".

All requirements in this program for licensed operator candidates or trainees are applicable to senior licensed operator candidates or trainees.

Licensed operators will be enrolled into the requalification program within three months after their operating license is issued. Continuing training requirements are described in program OPS-01-03, Licensed Operator Continuing Training Program.

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 training requirements are identified, administered, and maintained in accordance with their respective programs and procedures.

1.3 Overview

The Training Manager is responsible for the implementation of this program, with support from the Operations Department.

Training may be implemented by SHINE personnel, subject matter experts, contract staff, and vendor representatives. The Training Department also oversees and reviews/approves vendor courses and topics as applicable.

In general, all programs and topics are administered through instruction, self-study, on-the-job training or vendor supplied efforts. Training is given in the venue and method that best promotes learning with a preference for performance-based methods.

All training material selected is approved by Operations and Training prior to implementation.

All training material is correlated with approved procedures, which reflect current design changes and modifications.

2 DEFINITIONS

2.1 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.

- 2.2 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.
- 2.3 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
- 2.4 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 Operator Candidates / Trainees

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 and senior 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, maintaining records, and scheduling.
2. Accountable for developing, implementing, and maintaining operations training programs, including the analysis and identification of functional areas requiring training and the development of training objectives.
3. Accountable for developing, implementing, and maintaining instructions for the uniform development and use of training material.
4. Assist in the preparation of training material, examinations, and retraining lectures or tutoring sessions.
5. Review the graded examinations with the operators and schedule any retraining indicated by the examination results.
6. Determine remediation plans for operators not meeting performance criteria for operator training programs. 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 TRAINING

Licensed operator initial training, which encompasses initial qualification and training for licensed operators and senior licensed operators, provides the means to train individuals in the knowledge, skills, and abilities needed to perform and achieve proficiency in conducting licensed activities. This program is developed using a Graded Approach to Training, complying with respective regulatory requirements applicable to the individual's position and responsibility.

4.1 Program Requirements

The licensed operator initial training program meets the requirements of 10 CFR 55 and follows the guidance of ANSI/ANS-15.4-2016.

4.2 Analysis

Licensed operator candidates receive training in the topics listed in Attachment A.

Training efforts involved in actual manipulation of facility equipment are conducted under the cognizance of a licensed operator.

4.3 Reactivity Manipulations

Each licensed operator candidate will perform a minimum of five reactivity control manipulations with at least one startup and one shutdown of an IU.

Senior licensed operator candidates may receive credit for supervising and directing the performance of these activities, which will be considered as actual performance.

4.4 Exemptions

4.4.1 Experienced personnel can be considered for exemption from the knowledge and skills portion of initial training. Management review of an individual's prior training records and job performance history provides data for this exemption. This review should consist of the following, or equivalent processes:

- An objective, technical interview of the candidate to determine work experience, history, qualifications and training. This interview process validates resume history and may include contact with previous supervisor(s).
- A review of previous training records and job performance history to determine training received and work accomplished.

4.4.2 The following should be conducted to verify the candidate possesses adequate knowledge and skills.

- An examination or oral board based on learning objectives for the training being exempted. It is not necessary to test all learning objectives.
- An evaluation to verify proficiency of skills necessary to perform the tasks for which training is being exempted. This evaluation may be based on the candidate performing or having performed the task satisfactorily, or it may be a technical "walk-through" or "talk-through" of the tasks.

4.4.3 The Operations Manager shall determine whether the candidate may receive credit for a portion of the initial training program via exemption. Documentation related to the exemption (e.g., examination records, previous training records, etc.) and the results of the Operations Manager determination shall be retained in the candidate's training records.

4.5 Observation and Evaluation of Candidates

The Training Manager or designee should schedule periodic observations of the candidates and their training.

Oral Boards should be scheduled during initial training to assess candidate progress at points designated by the Training Manager.

Examinations shall be scheduled by the Training Manager or designee.

An NRC Exam Eligibility Review meeting shall be conducted for each candidate to determine if they will sit for the NRC License Exam.

4.6 Training Scope

The scope of licensee 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) and the individual's previous experience.

Training schedule overview is listed in Attachment B.

The depth of the training is based on the trainees' performance. Training or experience elsewhere may be substituted for fundamentals training.

4.7 Senior Licensed Operator Specific Training

Senior licensed individuals require additional qualifications. These individuals receive additional training addressing cognitive knowledge and application capabilities in activities where supervisory skills and abilities are required.

The scope of senior licensed operator specific 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) and the individual's previous experience. The depth of the training is based on the trainees' performance. The identified topics are based on the requirements of 10 CFR 55.43 modified for applicability to SHINE.

The topics fit into the following general categories:

- Supervisory Skills
- Administrative Requirements and Procedures
- Emergency Operations

5 MEDICAL CERTIFICATION AND FITNESS FOR DUTY

Licensed operator candidates will successfully complete a medical examination and evaluation prior to initial licensing.

Licensed operator medical requirements follow the standards established in ANSI/ANS-15.4-2016, Selection and Training of Personnel for Research Reactors.

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.

6 CANDIDATE SELECTION

Candidate selection will follow the guidelines established in ANSI/ANS-15.4-2016, Selection and Training of Personnel for Research Reactors. Additional selection criteria will be determined above and beyond the criteria listed and incorporated into individual job postings.

Operation Department supervisors shall have at least the qualifications required of personnel being supervised.

6.1 Licensed Operator

Candidate should have a high-school diploma or have successfully completed a General Education Development (GED) test. Individuals without a high-school diploma or GED are not excluded. Previous job-related experience or education is considered.

6.2 Senior Licensed Operator (Instant)

Candidate shall have a minimum of three years nuclear experience. A maximum of two years of full-time academic training may be substituted for two years of nuclear experience. Candidate shall have a high-school diploma or have successfully completed a GED test.

6.3 Senior Licensed Operator (Upgrade)

Candidate shall have a minimum of one year experience as a licensed operator at the SHINE facility or meet the selection requirements for a senior licensed operator (instant) candidate. Candidate shall have a high-school diploma or have successfully completed a GED test.

7 EXAMINATIONS

7.1 Methods

Demonstration of knowledge and proficiency is accomplished throughout the initial training program. Evaluation preferentially includes 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).

The initial training program uses written, oral, and on-the-job evaluation methods to determine competencies. Administration is conducted at key points throughout the progression of the course or after specific training activities. Periodic written exams may be administered to check operator cognition throughout the program.

7.2 Acceptance Criteria and Review

The acceptance criteria for all graded exams is 70% and all operators are required to complete each exam satisfactorily. Remediation training will be assigned if <70% and a reexamination exam given.

A score on any examination equal to or greater than 70% will require no formal remediation training.

The Training Manager or designee shall review the results of all exams including missed questions with the licensed operator candidates to ensure proper understanding.

8 TRAINING REVIEW AND EVALUATION

The Licensed Operator Initial Training 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 needed as determined by performance, by management for effectiveness.

Post training feedback is utilized during training and after each license class to make program improvements.

The Licensed Operator Initial Training Program is assessed at least once every three years by the Review and Audit Committee.

9 RECORDS

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.

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

9.1 Programmatic records should include:

- Training material
- Operational and written exams
- Program assessments

9.2 Individual records should include:

- On-the-Job training and qualifications (including reactivity manipulations)
- Operational and written exam scores
- Exemption documentation

10 REFERENCES

- 10.1** NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors
- 10.2** ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors
- 10.3** OPS-01-03, Licensed Operator Continuing Training Program
- 10.4** 2900-01-05, Systematic Approach to Training

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 Specification
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

ATTACHMENT B

Initial License Training Schedule Overview (Durations are Estimates)

| Training Course / Activity | Duration |
|---|----------|
| Fundamentals / Training | 6 Weeks |
| Administrative Requirements | 1 Week |
| Radiation Protection | 1 Week |
| Systems Training | 6 Weeks |
| Plant Evolutions | 6 Weeks |
| Pre-NRC Exam | 6 Weeks |
| Supervisory Training (Senior Licensed only) | 4 Weeks |