

**ENCLOSURE 12**

**SHINE MEDICAL TECHNOLOGIES, LLC**

**SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE**

**LICENSED OPERATOR CONTINUING TRAINING PROGRAM**

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## **1 INTRODUCTION**

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### **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**

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### **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**

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### **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<br>- Four hours licensed duties | Quarterly     |
| Abnormal and Emergency Procedure Reviews                     | Annually      |
| Reactivity Manipulations (10)                                | Annually      |
| Operating Test   | Annually      |
| Medical Exams  | Biennially    |
| Comprehensive Written Exam                                   | Biennially    |

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 24 months.

Any change in licensed personnel status must be communicated to the NRC within 30 days of the change in status.

#### **4.2 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.

### **5 EXAMINATIONS**

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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 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.

#### **5.4 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**

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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**

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**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**

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**8.1** 0300-09-01, Licensed Operator Initial Training

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

**8.3** 10 CFR 55.59, Requalification



**ATTACHMENT A**

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**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, critical 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