

12.4.10 Operator Training and Requalification

The NRC staff evaluated the sufficiency of the SHINE requalification training program, as described in SHINE FSAR 12.10, "Operator Training and Requalification Program," and Enclosure 12 to SHINE Medical Technologies, LLC, Application for an Operating License, "Licensed Operator Continuing Training Program" (ADAMS Accession No. ML19211C141), using the guidance and acceptance criteria from Section 12.10, "Operator Training and Requalification," in NUREG-1537, Parts 1 and 2 and in the ISG Augmenting NUREG-1537, Parts 1 and 2. During the NRC staff review, SHINE provided responses to requests for additional information (ADAMS Accession Nos. ML21307A306 and ML21350A191) and incorporated those responses in revisions to the requalification training program, where appropriate. The NRC staff reviewed Revision 2 (ADAMS Accession No. ML21350A191) of the program for this technical evaluation.

Additionally, SHINE submitted an initial training program, as described in SHINE FSAR 12.10 and Enclosure 13 to SHINE Medical Technologies, LLC, Application for an Operating License, "Licensed Operator Initial Training Program" (ADAMS Accession No. ML19211C144). However, the NRC staff verified that, for SHINE, there are no applicable regulatory requirements or guidance associated with an initial training program. The only regulatory requirements that exist for training and qualification of licensed personnel are contained in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel." None of the requirements in 10 CFR 50.120 will apply because SHINE will be a production and utilization facility licensed pursuant to 10 CFR Parts 50 and 70 and is not a nuclear power plant. Therefore, while the NRC staff can review the program against industry guidance committed to by SHINE and for conflicts with regulatory requirements, the NRC staff will not be rendering a sufficiency determination of the initial training program. During the NRC staff review, SHINE provided a revision to the initial training program along with the aforementioned responses to requests for additional information. The NRC staff reviewed Revision 1 (ADAMS Accession No. ML21307A306) of the program for this technical evaluation.

12.4.10.1 Licensed Operator Continuing Training Program

Under 10 CFR 50.34(b)(8), each applicant for a facility operating license must submit a description and plans for implementation of an operator requalification program that meets the requirements contained in 10 CFR 55.59. Accordingly, the SHINE continuing training program describes how the applicant's program for operators and senior operators will meet the requalification program requirements of 10 CFR 55.59. Additionally, the NRC staff notes that SHINE commits to following industry guidance in ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors," in Section 1.1, "Purpose" of the continuing training program and SHINE TS 5.1.4.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the continuing training program contains the purpose and scope, overview, applicability and effectiveness, evaluations, revisions, and reviews. The information provided in this chapter is mostly administrative in nature.

In Section 1.3, "Overview," the applicant states that licensed operators will be enrolled into the continuing training program within three (3) months after their operating license is issued. The NRC staff noted that there are no specific requirements in 10 CFR 55 and no guidance provided in ANSI/ANS-15.4-2016 related to timing of a newly licensed operator's enrollment in a

requalification program. Paragraph h of 10 CFR 55.53, “Conditions of Licenses,” only requires licensed operators and licensed senior operators to complete a requalification program as described by 10 CFR 55.53. Further, the NRC staff’s response to question 327 in NUREG-1262, “Answers to Questions at Public Meetings Regarding Implementation of Title 10, Code of Federal Regulations, Part 55 on Operators’ Licenses,” states that facilities have flexibility with implementation of requalification programs for operator licensing candidates as long as the training program meets the objectives of the requalification program. Therefore, the NRC staff determined that this enrollment timeframe is adequate and acceptable.

Based on its review, the NRC staff finds that the information provided in Chapter 1 to be acceptable because it adequately describes administrative elements and objectives of the program in sufficient detail for the NRC staff to review the rest of the program and is therefore sufficient for the issuance of an operating license.

Chapter 2 – Definitions

Chapter 2, “Definitions,” of the continuing training program describes terms having special meaning unique to the facility or were necessary to understand terms used in the program. Specifically, the following definitions were included: annual requalification cycle, biennial requalification cycle, controls, graded approach to training, on-the-job training, quarterly, and simulation-based training. Definitions related to time periods were added following an NRC staff request for additional information that asked for clarification and additional specificity to ensure the continuing training program met 10 CFR 55 regulatory requirements. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The applicant has proposed a definition for “annual requalification cycle,” which is the “[t]ime period corresponding to a 12-month interval comprising half of a biennial requalification cycle per ANSI/ANS-15.4-2016 Section 6.2.” The NRC staff determined that this definition conforms with requirements in 10 CFR 55 and consistent with the guidance in Section 6.2 of ANSI/ANS-15.4-2016. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “biennial requalification cycle,” which is the “[t]ime period corresponding to a 24-month interval that the requalification program is conducted in [sic] per ANSI/ANS-15.4-2016 Section 6.2. Each biennial requalification program is immediately followed by another 24-month cycle.” The NRC staff determined that this definition conforms with 10 CFR 55.59(c)(1), “Schedule,” meets the acceptance criteria for program duration contained in Section 12.10 of NUREG-1537, Part 2, and is consistent with the guidance in Section 6.2 of ANSI/ANS-15.4-2016. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “controls,” which are “[a]pparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the irradiation unit (IU).” One of the two definitions for “controls” required by 10 CFR 55.4, states that controls *when used with respect to a nuclear reactor* means apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the *reactor*. While SHINE’s IUs are considered utilization facilities, the IUs are not considered “nuclear reactors” since they are not “designed or used to sustain nuclear fission in a self-supporting chain reaction.” The NRC staff determined that this definition of “controls” is adequate and acceptable, because it is appropriate for the SHINE facility, where the IUs do not meet the definition of a “nuclear reactor.”

The applicant has incorporated a second definition of “controls” that appears in the regulations into the continuing training program. The second definition of “controls” required by 10 CFR 55.4, “Definitions,” states that controls *when used with respect to any other facility* means apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear processes of the facility in such a manner as to affect the protection of the health and safety against radiation. The NRC staff determined that the incorporation of the definition is acceptable because it is appropriate for the SHINE facility.

The applicant has proposed a definition for “graded approach to training” which is “[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.” The NRC staff verified that, for SHINE, there are no applicable regulatory requirements or guidance associated with this term or definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “on-the-job training” which is “[p]erformance-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.” 10 CFR 55.4 does not contain a definition for “on-the-job training.” 10 CFR 55.59(c)(3) requires that the requalification program must include on-the-job training. 10 CFR 55.59(c)(3)(i)-(v) provides specific types of on-the-job training that must be completed by licensed operators and licensed senior operators. ANSI/ANS-15.4-2016 defines “on-the-job training” as “a systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” and are not necessarily considered or constitute a requirement or recommendation. While the definition is different from industry guidance, the NRC staff did not identify specific challenges to accepting the continuing training program definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “quarterly” which is the “[t]ime period corresponding to a calendar quarter.” The NRC staff determined that this definition conforms with requirements in 10 CFR 55 and consistent with the guidance in Section 6.5 of ANSI/ANS-15.4-2016. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “simulation-based training” which is “[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.” 10 CFR 55.4 does not contain a standalone definition for “simulation-based training.” 10 CFR 55.59(c)(3)(v) states, in part, that [i]f the simulator or simulation device is used to administer operating tests for a facility, as provided in 10 CFR 55.45(b)(1), the device approved to meet the requirements of 10 CFR 55.45(b)(1) must be used for credit to be given for meeting the requirements of 10 CFR 55.59(c)(3)(i)(G)-(AA). 10 CFR 55.59(c)(4)(iv) states, in part, that [i]f a simulator is used in meeting the requirements of 10 CFR 55.59(c)(4)(iii), it must accurately reproduce the operating characteristics of the facility involved and the arrangement of the instrumentation and controls of the simulator must closely parallel that of the facility involved. The NRC staff note that SHINE has not submitted a request for approval of a simulator or simulation device at this

time. The NRC staff verified that, for SHINE, there is no applicable industry guidance associated with this term or definition. While the definition provides SHINE with the future flexibility of incorporating a simulation device, the NRC staff did not identify specific challenges to accepting the continuing training program definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

Based on its review, the NRC staff finds the terms and definitions meet the applicable regulatory requirements and acceptance criteria, are appropriate for the SHINE facility, and is therefore sufficient for the issuance of an operating license.

Chapter 3 – Responsibilities

Chapter 3, “Responsibilities,” of the continuing training program contains program-applicable positions and position responsibilities. The information provided in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information provided in Chapter 3 to be acceptable because it adequately describes responsibilities of those individuals involved in the continuing training program in sufficient detail for the NRC staff to review the rest of the program and is therefore sufficient for the issuance of an operating license.

Chapter 4 – Program Requirements

Chapter 4, “Program Requirements,” of the continuing training program contains several different categories of requalification requirements. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(2), “Lectures,” the requalification program must include preplanned lectures on a regular and continuing basis throughout the license period in those areas where operator and senior operator written examinations and facility experience indicate that emphasis in scope and depth of coverage is needed. 10 CFR 55.59(c)(2)(i)-(xi) provides a list of subjects. In Table 4-1, “Continuing Training Program Requirements,” of the continuing training program, the applicant states that training lectures will be performed on a quarterly periodicity. In Section 4.3, “Training Scope,” of the continuing training program, the applicant states that licensing operator continuing training includes knowledge of topics listed in Attachment A to the program, which are modified for applicability to SHINE. The applicant also states that the specific content of the training sessions will be based on a number of items that can be considered facility operating experience. The NRC staff determined that this conforms with 10 CFR 55.59(c)(2), “Lectures,” and meets the acceptance criteria for preplanned lectures contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3), “On-the-job training,” paragraph (i), the requalification program must include on-the-job training so that each licensed operator of a utilization facility manipulates the plant controls and each licensed senior operator either manipulates the controls or directs the activities of individuals during plant control manipulations during the term of the licensed operator’s or senior operator’s license that are applicable to the plant design and involve reactivity control manipulations. In Chapter 4 of the continuing training program, the applicant states that the licensing operator continuing training program will be administered, in part, through on-the-job training. In Table 4-1 of the continuing training program, the applicant states that ten (10) reactivity manipulations will be performed once per annual requalification cycle. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(i) and meets the

acceptance criteria for control manipulations contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3), paragraph (ii), the requalification program must include on-job-training so that each licensed operator and senior operator has demonstrated satisfactory understanding of the operation of the apparatus and mechanisms associated with the control manipulations in 10 CFR 55.59(c)(3)(i), applicable to the facility, and knows the operating procedures in each area for which the operator or senior operator is licensed. In Section 4.3 of the continuing training program, the applicant states that the scope of licensed operator continuing training includes knowledge of topics listed in Attachment A. In Attachment A, the applicant states that licensed training material includes facility design and operating procedures. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(ii) and meets the acceptance criteria for control manipulations contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3), paragraph (iii), the requalification program must include on-the-job training so that each licensed operator and senior operator is cognizant of facility design changes, procedure changes, and facility license changes. In Section 1.3, "Overview," of the continuing training program, the applicant states that document reviews will be conducted to ensure that licensed individuals are cognizant of all design, procedure, and license changes, as appropriate. In Table 4-1 of the continuing training program, the applicant states that facility design, procedure, and license changes will be performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iii) and meets the acceptance criteria for control manipulations contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3), paragraph (iv), the requalification program must include on-the-job training so that each licensed operator and senior operator reviews the contents of all abnormal and emergency procedures on a regularly scheduled basis. In Table 4-1 of the continuing training program, the applicant states that abnormal and emergency procedure reviews will be performed once per annual qualification cycle. Additionally, as discussed previously, document reviews related to any procedure changes are performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iv) and meets the acceptance criteria for control manipulations contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3), paragraph (v), a simulator may be used in meeting the requirements of paragraphs (c)(3)(i) and (c)(3)(ii). The applicant has not provided any additional information on the use of a simulator or simulation device. Additionally, as discussed previously, the NRC staff noted that the applicant has not submitted a request for approval of a simulator or simulation device.

Under 10 CFR 55.59(c)(4), "Evaluation," paragraph (iii), the requalification program must include systematic observation and evaluation of the performance and competency of licensed operators and senior operators by supervisors and/or training staff members, including evaluation of actions taken or to be taken during actual or simulated abnormal and emergency procedures. In Section 4.3 of the continuing training program, the applicant stated that specific content of training sessions will be based on observations of operator performance and items identified as weaknesses in the training program or operator knowledge as determined by operating events, examination results, and crew or individual performance gaps. In Section 4.3 of the continuing training program, the applicant stated, in relevant part, that the scope of

training includes knowledge of topics in Attachment A and sequence and methodology will be based upon training approach (e.g., simulation). The NRC staff noted that, in Attachment A, the applicant's list of licensed training material and senior licensed training material includes emergency and abnormal operating procedures, conditions of license (i.e., job observations), and emergency plan. Further, in Chapter 6, "Program Review and Evaluation," of the continuing training program, the applicant states that training effectiveness will be determined through the continuing training cycle based on operator performance and oversight of the Operations Department by management, training, and supervisory personnel. The NRC staff determined that the program implementation of systematic observations and evaluations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iii) and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(iv), the requalification program must include simulation of emergency or abnormal conditions that may be accomplished by using the control panel of the facility involved or by using a simulator. In Section 4.3 of the continuing training program, the applicant stated, in relevant part, that the scope of training includes knowledge of topics in Attachment A and sequence and methodology will be based upon training approach (e.g., simulation). The NRC staff noted that, in Attachment A, the applicant's list of licensed training material and senior licensed training material includes emergency and abnormal operating procedures, conditions of license (i.e., job observations), and emergency plan. In Section 4.3 of the continuing training program, the applicant stated that specific content of training sessions will be based on observations of operator performance and items identified as weaknesses in the training program or operator knowledge as determined by operating events, examination results, and crew or individual performance gaps. As the NRC staff evaluated above, the applicant proposed a definition for "simulation-based training" which is "[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." Additionally, as discussed previously, the NRC staff noted that the applicant has not submitted a request for approval of a simulator or simulation device. The NRC staff determined that the program implementation of simulation of emergency or abnormal conditions conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iv) and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Chapter 4 of the continuing training program included additional items specific to Part 55 license requirements for operators and senior operators. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.53(e), to maintain a license in active status, a licensed operator or licensed senior operator is required to actively perform licensed duties for a specified number of hours per calendar quarter. Under 10 CFR 55.53(f), to restore a license back to active status, a licensed operator or licensed senior operator is required to perform a minimum number of hours of licensed duties under the direction of another operator. In Table 4-1 of the continuing training program, the applicant stated 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, in Chapter 4 of the continuing training program, the applicant stated 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. Following an NRC staff request for additional information, the applicant submitted an exemption request (ADAMS Accession No. ML21350A190) from the requirements of 10 CFR 55.53(e) and 10 CFR 55.53(f) to modify the minimum number of hours required for licensed operators maintain active status and restore active status. The NRC staff review of that exemption request is ongoing.

Under 10 CFR 55.22 and 10 CFR 55.53(i), a licensed operator or licensed senior operator is required to have a medical examination by a physician every two years (i.e., biennially). In Section 4.1 of the continuing training program, the applicant states that a medical evaluation is required every 2 years with the periodic examination being completed no later than the last day of the 12th month of the second year in accordance with Section 7.1.2 of ANSI/ANS-15.4-2016. The NRC staff noted that this reflects that the medical examination must be completed within a two-year period of time from the date of the initial or previous medical examination that is not extendable by an additional grace period. The NRC staff determined that the program implementation of medical evaluations for licensed operators and licensed senior operators conforms with 10 CFR 55.22 and 10 CFR 55.53(i) and, therefore, is adequate and acceptable.

Section 8, “Fitness for Duty,” of ANSI/ANS-15.4-2016, describes elements of a program or policy that shall be established to assure that licensed individuals are fit to perform licensed duties. Additionally, ANSI/ANS-15.4-2016 provides that all licensed personnel shall adhere to the established policy or program including drug testing if required. The NRC staff noted that 10 CFR 55.53(j) also requires, in relevant part, that licensed operators and licensed senior operators shall not use, possess, or sell any illegal drugs and shall not perform activities authorized by their license while under the influence of alcohol or any prescription, over-the-counter, or illegal substances that could adversely affect their ability to safely and competently perform licensed duties. Information related to fitness for duty was added following an NRC staff request for additional information to ensure the continuing training program was consistent with SHINE’s 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.” In response to the request, the applicant stated that they have implemented a drug and alcohol testing program for licensed operators that is consistent with requirements of 10 CFR 55.53(j) and consistent with the guidance of Section 8 of ANSI/ANS-15.4-2016. In Section 4.2 of the continuing training program, the applicant states that licensed operators are required to adhere to fitness for duty requirements as described in the SHINE employee handbook. The NRC staff determined that this conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Under 10 CFR 50.74, each Part 50 licensee is required to notify the NRC within 30 days of a change in licensed operator or licensed senior operator status. In Section 4.4 of the continuing training program, the applicant states that the changes in operator status, as outlined in 10 CFR 50.74, will be communicated to the NRC within 30 days. The NRC staff determined that this conforms with 10 CFR 50.74 and, therefore, is adequate and acceptable.

Based on its review, the NRC staff finds the program requirements meet the applicable regulatory requirements and acceptance criteria, are appropriate for the SHINE facility, and is therefore sufficient for the issuance of an operating license.

Chapter 5 – Examinations

Chapter 5, “Examinations,” of the continuing training program contains requalification requirements related to evaluations. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, comprehensive requalification written examinations which determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. Under 10 CFR 55.59(c)(4)(ii), the requalification program must include written examinations which determine licensed operators’ and licensed senior operators’ knowledge of subjects covered in the program and provide a basis for evaluating their knowledge of abnormal and emergency procedures. 10 CFR 55.59(a)(2)(i) requires that the written examination will sample the items specified in 10 CFR 55.41 and 10 CFR 55.43, to the extent applicable to the facility, the licensee, and any limitation of the license under 10 CFR 55.53(c). In Section 5.2 of the continuing training program, the applicant states that biennial written examinations will be used to verify the operator’s knowledge and preplanned training sessions will be used to retrain those operators who demonstrate deficiencies in any part of the examination. In Section 4.3 of the continuing training program, the applicant states that the scope of training includes the identified topics in Attachment A of the continuing training program, which are based, in relevant part, on the requirements of 10 CFR 55.41, modified for applicability to SHINE. The NRC staff noted that, in Attachment A of the continuing training program, the applicant provided a list of licensed training material applicable to both licensed operators and licensed senior operators that is consistent with the topics in 10 CFR 55.41, to the extent applicable to SHINE. The NRC staff noted that, in Attachment A of the continuing training program, the applicant provided a list of senior licensed training material applicable to licensed senior operators that is consistent with the topics in 10 CFR 55.43, to the extent applicable to SHINE. The NRC staff determined that the program implementation of written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i), 10 CFR 55.59(c)(4)(ii), and 10 CFR 55.59(a)(2)(i) and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, annual operating tests which determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. 10 CFR 55.59(a)(2)(i) requires that the operating test will require the operator or senior operator to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a comprehensive sample of items specified in 10 CFR 55.45(a)(2) through (13) inclusive to the extent applicable to the facility. In Section 5.1 of the continuing training program, the applicant states that an annual operating evaluation is administered to each licensed operator and licensed senior operator consisting of a broad sample of applicable items specified in 10 CFR 55.45(a)(1) through (13) inclusive to the extent applicable. In Section 4.3 of the continuing training program, the applicant stated the scope of training includes the identified topics in Attachment A of the continuing training program, which are based, in relevant part, on the requirements of 10 CFR 55.45, modified for applicability to SHINE. The NRC staff noted that, in Attachment A of the continuing training program, the applicant provided a list of licensed and senior licensed training material topics applicable to licensed operators and licensed senior operators that is consistent with the topical areas of the specified actions outlined in 10 CFR 55.45, to the extent applicable to SHINE. The NRC staff determined that the program implementation of annual operating tests conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i) and 10 CFR 55.59(a)(2)(i) and meets the

acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(v), the requalification program must include provisions for each licensed operator and licensed senior operator to participate in an accelerated requalification program where performance evaluations conducted pursuant to 10 CFR 55.59(c)(4)(i) through (iv) clearly indicate the need. Section 6.3, "Evaluation and retraining," of ANSI/ANS-15.4-2016, describes the scoring criteria that are to be used for requalification. In Section 5.5 of the continuing training program, the applicant outlined provisions for accelerated requalification if performance evaluations indicated the need. Specifically, in Sections 5.4 and 5.5 of the continuing training program, the applicant discussed acceptance criteria for all graded exams, operator status during retraining, performance evaluation and retraining time frames, determination of retraining content, and acceptance criteria to complete retraining. The NRC staff determined that the program implementation of written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(v), conforms with SHINE's commitment to use ANSI/ANS-15.4-2016, and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Based on its review, the NRC staff finds the implementation of examinations meet the applicable regulatory requirements and acceptance criteria, are appropriate for the SHINE facility, and is therefore sufficient for the issuance of an operating license.

Chapter 6 – Program Review and Evaluation

Chapter 6, "Program Review and Evaluation," of the continuing training program contains information on programmatic evaluation. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

The forward of ANSI/ANS-15.4-2016 provides that administrative and organizational requirements and structures, including reviews and audits, are found in companion standard ANSI/ANS-15.1-2007 (R2013), "The Development of Technical Specifications for Research Reactors." Section 6.2.4, "Audit Function," of ANSI/ANS-15.1-2007 (R2013), describes the review and audit functions that are to be established, which include, in relevant part, audits for the retraining and requalification program for the operating staff to be conducted at least once every other calendar year with the interval between audits not to exceed 30 months. In Technical Specification 6.2.4, the applicant has proposed to incorporate this audit requirement as it appears in ANSI/ANS-15.1-2007 (R2013). However, in Section 6 of the continuing training program, the applicant stated that the program will be assessed at least once every biennium (i.e., 2-year period), with an interval between assessments not to exceed 24 months. The NRC staff verified that, for SHINE, there are no applicable regulatory requirements associated with timeliness for conducting reviews or audits, just that reviews and audits are included as administrative controls in technical specifications [10 CFR 50.36(c)(5)]. Regardless of the potential confusion that could be introduced by the differences in audit grace periods, the NRC staff determined that this conforms with SHINE's commitment to use ANSI/ANS-15.4-2016 and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Based on its review, the NRC staff finds that the implementation of reviews and evaluations is consistent with industry guidance, meets acceptance criteria in regulatory guidance, and is therefore sufficient for the issuance of an operating license.

Chapter 7 – Records

Chapter 7, “Records,” of the continuing training program contains requalification requirements related to recordkeeping. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(5), “Records,” the types and retention period of requalification program documentation are specified. In Sections 7.1, 7.2, and 7.3 of the continuing training program, the applicant provided information on the record storage system, record formats, and an illustrative list of the programmatic and individual records that will be retained. In Section 7.4 of the continuing training program, the applicant stated that records of training and qualification of Operations Department personnel shall be maintained for the duration of the currently valid license. In Technical Specification 5.9.2, the applicant stated that records of meeting and audit reports of the review and audit group will be maintained for a period of at least five years. In Technical Specification 5.9.3, the applicant stated that records of retraining and requalification of operations personnel who are licensed pursuant to 10 CFR Part 55 shall be maintained at all times while the individual is employed or until license is renewed. The NRC staff determined that the program implementation of written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(5), conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016, and meets the acceptance criteria contained in Section 12.10 of NUREG-1537, Part 2. Therefore, the NRC staff determined that this is adequate and acceptable.

Based on its review, the NRC staff finds the implementation of recordkeeping meets the applicable regulatory requirements and acceptance criteria, are appropriate for the SHINE facility, and is therefore sufficient for the issuance of an operating license.

Conclusion

The NRC staff have reviewed the SHINE Licensed Operator Continuing Training Program. The NRC staff have determined the program is in accordance with the applicable regulations for requalification contained in 10 CFR 55.59, meets acceptance criteria in NUREG-1537, and consistent with the guidance contained in industry standard ANSI/ANS-15.4-2016. Therefore, the NRC staff have concluded that this program provides reasonable assurance that requalification for licensed operators and licensed senior operators will be carried out in a manner that assures knowledge, skills, and proficiency will be maintained and is sufficient for the issuance of an operating license.

12.4.10.2 Licensed Operator Initial Training Program

The initial training program for SHINE describes how the applicant’s program will prepare operator and senior operator trainees for licensure under 10 CFR Part 55. Additionally, the NRC staff notes that SHINE commits to following industry guidance in ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors,” in Section 1.2, “Scope” of the continuing training program and SHINE TS 5.1.4.

Chapter 1 – Introduction

Chapter 1, “Introduction,” of the initial training program contains the purpose and scope, overview, applicability and effectiveness, evaluations, revisions, and reviews. The information

provided in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information provided in Chapter 1 adequately describes administrative elements and objectives of the program in sufficient detail for the NRC staff to review the rest of the program.

Chapter 2 – Definitions

Chapter 2, “Definitions,” of the initial training program describes terms having special meaning unique to the facility or were necessary to understand terms used in the program. Specifically, the following definitions were included: controls, graded approach to training, on-the-job training, and simulation-based training. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The applicant has proposed a definition for “controls,” which are “[a]pparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the irradiation unit (IU).” One of the two definitions for “controls” required by 10 CFR 55.4, states that controls *when used with respect to a nuclear reactor* means apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the *reactor*. While SHINE’s IUs are considered utilization facilities, the IUs are not considered “nuclear reactors” since they are not “designed or used to sustain nuclear fission in a self-supporting chain reaction.” The NRC staff determined that this definition of “controls” is adequate and acceptable, because it is appropriate for the SHINE facility, where the IUs do not meet the definition of a “nuclear reactor.”

The applicant has incorporated a second definition of “controls” that appears in the regulations into the initial training program. The second definition of “controls” required by 10 CFR 55.4, “Definitions,” states that controls *when used with respect to any other facility* means apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear processes of the facility in such a manner as to affect the protection of the health and safety against radiation. The NRC staff determined that the incorporation of the definition is appropriate and acceptable because it is appropriate for the SHINE facility.

The applicant has proposed a definition for “graded approach to training” which is “[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.” The NRC staff verified that, for SHINE, there are no applicable regulatory requirements or guidance associated with this term or definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “on-the-job training” which is “[p]erformance-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.” 10 CFR 55.4 does not contain a standalone definition for “on-the-job training.” ANSI/ANS-15.4-2016 defines “on-the-job training” as “a systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” and are not necessarily considered or constitute a requirement or recommendation. While the definition is different from industry guidance, the NRC staff did not identify specific challenges to accepting the continuing training program definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The applicant has proposed a definition for “simulation-based training” which is “[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.” 10 CFR 55.4 does not contain a standalone definition for “simulation-based training.” 10 CFR 55.4 contains a definition for “simulation facility” and 10 CFR 55.46 contains requirements for Commission acceptance of a plant-referenced simulator used for performing control manipulations that affect reactivity to establish eligibility for an operator’s license as described in 10 CFR 55.31(a)(5). The NRC staff note that SHINE has not submitted a request for approval of a simulator or simulation device at this time. The NRC staff verified that, for SHINE, there is no applicable industry guidance associated with this term or definition. While the definition provides SHINE with the future flexibility of incorporating a simulation device, the NRC staff did not identify specific challenges to accepting the initial training program definition. Therefore, the NRC staff determined that this definition is adequate and acceptable.

Based on its review, the NRC staff finds the terms and definitions do not cause conflict with regulatory requirements, conforms with industry guidance, and are appropriate for the SHINE facility.

Chapter 3 – Responsibilities

Chapter 3, “Responsibilities,” of the initial training program contains program-applicable positions and position responsibilities. The information provided in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information provided in Chapter 3 adequately describes responsibilities of those individuals involved in the initial training program in sufficient detail for the NRC staff to review the rest of the program.

Chapter 4 – Training

Chapter 4, “Training,” of the initial training program contains information related to program implementation. The NRC staff reviewed this chapter for conformance with regulatory requirements and consistency with guidance, as applicable.

In Section 4.1, “Program Requirements,” of the initial training program, the applicant states that the program meets regulatory requirements and follows industry guidance. The NRC staff verified that this conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016.

In Section 4.2, “Analysis,” of the initial training program, the applicant states that trainees manipulating the controls shall do so only under the direct supervision of a licensed operator. The NRC staff verified that this supervision of a trainee is consistent with the regulatory requirements in 10 CFR 55.13, “General Exemption,” and conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016.

In Section 4.3, “Reactivity Manipulations,” of the initial training program, the applicant states that each licensed operator candidate will perform a minimum of five reactivity control manipulations with at least one startup and one shutdown of an IU. The NRC staff verified that this is consistent with the regulatory requirements in paragraph (a)(5) of 10 CFR 55.31, “How to apply.” In Section 4.3, the applicant also states that each senior licensed operator candidate may receive credit for supervising and directing the performance of these activities, which will be considered as actual performance. Without reviewing an actual application for a senior operator, the NRC staff could not determine if this provision in the initial training program would

be entirely consistent with the regulatory requirements in 10 CFR 55.31(a)(5). The NRC staff specifically noted that credit is given to licensed operators applying for a senior operator license if they are certifying that they have operated the controls of the facility as a licensed operator. Additionally, if not consistent with the regulatory requirements, an applicant may seek a specific exemption under 10 CFR 55.11. The NRC staff verified that this conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

In Section 4.4, "Exemptions," of the initial training program, the applicant provides a process to account for previous experience and training. The NRC staff note that the use of the word "exemption" by the applicant is specific to the initial training program and does not appear to be synonymous with a request for a specific exemption in accordance with 10 CFR 55.11 or a waiver in accordance with 10 CFR 55.47. The NRC staff verified that the use of a process to account for previous experience and training conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

In Section 4.5, "Observation and Evaluation of Candidates," of the initial training program, the applicant provides that candidates will be evaluated through observations, oral boards, examinations, and an NRC exam eligibility review. The NRC staff verified that the candidate evaluation process conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

In Section 4.6, "Training Scope," of the initial training program, the applicant provides training topics and training schedule overview and states that depth of training is based on trainee performance and experience. The NRC staff verified that the training topics in Attachment A are consistent with the areas covered in 10 CFR 55.41, 55.43, and 55.45, to the extent applicable to SHINE. The NRC staff verified that training scope conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

In Section 4.7, "Senior Licensed Operator Specific Training," of the initial training program, the applicant provides information on the additional training consistent with the appropriate knowledge, skills, and abilities for that position. The NRC staff verified that the development of position-specific training conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

Based on its review, the NRC staff finds the information related to program implementation will not likely conflict with regulatory requirements, conforms with industry guidance, and are appropriate for the SHINE facility.

Chapter 5 – Medical Certification and Fitness for Duty

Chapter 5, "Medical Certification and Fitness for Duty," of the initial training program contains commitments to performing medicals and incorporating fitness for duty in accordance with ANSI/ANS-15.4-2016. The information provided in this chapter does not contain specific details and is administrative in nature. Based on its review, the NRC staff finds that the information provided in Chapter 5 does not conflict with regulatory requirements and conforms with SHINE's commitment to use ANSI/ANS-15.4-2016.

Chapter 6 – Candidate Selection

Chapter 6, "Candidate Selection," of the initial training program contains information related to personnel selection and qualifications. The NRC staff reviewed this chapter for conformance with regulatory requirements and consistency with guidance, as applicable.

In Section 6.1, “Licensed Operator,” Section 6.2, “Senior Licensed Operator (Instant),” and Section 6.3, “Senior Licensed Operator (Upgrade),” of the initial training program, the applicant provides position-specific qualification criteria. The NRC staff verified that these qualifications conform with SHINE’s commitment to use ANSI/ANS-15.4-2016.

The NRC staff note, in Section 6.3, the applicant states that senior operator upgrade candidates shall have a minimum of one year experience as a licensed operator at the SHINE facility. However, the initial training program does not contain a similar experience requirement for senior operator instant candidates. The NRC staff verified that this inconsistency does not conflict with regulatory requirements or guidance and conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016.

Based on its review, the NRC staff finds that the information provided in Chapter 6 does not conflict with regulatory requirements and conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016.

Chapter 7 - Examinations

Chapter 7, “Examinations,” of the initial training program contains information on methods, acceptance criteria, and review of written, oral, and on-the-job evaluations performed with trainees. The information provided in this chapter contains administrative and general information. Based on its review, the NRC staff finds that the information provided in Chapter 7 does not conflict with regulatory requirements and conforms with SHINE’s commitment to use ANSI/ANS-15.4-2016.

Chapter 8 – Training Review and Evaluations

Chapter 8, “Training Review and Evaluations,” of the initial training program contains information on periodic program review. The information provided in this chapter contains administrative and general information. Based on its review, the NRC staff finds that the information provided in Chapter 8 does not conflict with regulatory requirements and conforms with SHINE’s commitment to use ANSI/ANS 15.4-2016.

Chapter 9 - Records

Chapter 9, “Records,” of the initial training program contains information on recordkeeping. The information provided in this chapter contains administrative and general information. Based on its review, the NRC staff finds that the information provided in Chapter 9 does not conflict with regulatory requirements and conforms with SHINE’s commitment to use ANSI/ANS 15.4-2016.

Conclusion

The NRC staff have reviewed the SHINE Licensed Operator Initial Training Program. The NRC staff determined that the program is consistent with the guidance contained in industry standard ANSI/ANS-15.4-2016.