October 15, 2021

2021-SMT-0134
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 Human Factors Engineering and Conduct of Operations (EPID No. L-2019-NEW-0004)," dated September 23, 2021 (ML21253A234)

SHINE Technologies, LLC Application for an Operating License
Supplement No. 10 and 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 Final Safety Analysis Report (FSAR) Change Summary, identifying changes to the SHINE FSAR not related to the SHINE responses to the NRC staff's request for additional information.

Enclosure 2 provides the SHINE responses to the NRC staff's request for additional information.

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 October 15, 2021.

Very truly yours,

DocuSigned by:
Jim Costedio
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 SUPPLEMENT NO. 10 AND RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

FINAL SAFETY ANALYSIS REPORT CHANGE SUMMARY

Summary Description of Changes	FSAR Impacts
Update to the organizational structure affecting titles, responsibilities, and reporting relationships. Section 5.1, Figure 5.1.1, and Section 5.2, of the technical specifications have also been revised to incorporate these organizational structure changes.	Section 11.1, Section 11.2, Figure 11.1-3, Section 12.1, Section 12.2, and Figure 12.1-1
Update to audit activities to include nuclear criticality safety program audit requirements, consistent with Section 5.2 of the technical specifications and the SHINE Response to RAI 6b.3-18 (Reference 1).	Section 12.2

Final Safety Analysis Report (FSAR) and technical specifications mark-ups related to the SHINE Technologies, LLC (SHINE) responses to requests for additional information are provided as Attachment 1 and Attachment 2, respectively, to Enclosure 2. FSAR mark-ups associated with the above FSAR changes are included with those mark-ups provided as Attachment 1 to Enclosure 2. Conforming technical specification mark-ups associated with the above FSAR changes are included with those mark-ups provided as Attachment 2 to Enclosure 2.

References:

1. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Operating License Application Supplement No. 5 and Response to Request for Additional Information,” dated December 10, 2020 (ML20357A084)

ENCLOSURE 2

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE SUPPLEMENT NO. 10 AND 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.

Human Factors Engineering

RAI HFE-1

SHINE FSAR Chapter 7, "Instrumentation and Control Systems," Section 7.1.5, "Control Console and Displays," states, in part, that "SHINE uses human factors engineering principles to facilitate the safe…performance of operations…and to ensure the implementation of operator interfaces…are standardized across vendors." Specifically, the SHINE FSAR contains the following characterizations related to the role of operators at the SHINE facility:

- "The main control board, PICS [process integrated control system]and NDAS [neutron driver assembly system] operator workstations, and supervisor workstation are not credited with performing safety functions and only assisting operators in performance of normal operations or diverse actuations to the safety systems." (SHINE FSAR Section 7.6, "Control Console and Display Instruments")

- "Manual actuations are not required to ensure adequate safety of the facility…" (SHINE FSAR Section 7.6.1.1, "Main Control Board")

- "There are no time constrained operator-required responses" (SHINE FSAR Section 7.6.2.2.3, "General I&C Requirements")

- "Operator action inside the facility is not required to stabilize accident conditions." (SHINE FSAR Section 13a2.2, "Accident Analysis and Determination of Consequences")

- "…safe shutdown conditions can be achieved without operator actions." (SHINE FSAR Section 13b.2.3, "External Events")

- "Appropriate preventative or mitigative controls were identified to reduce the overall risk of the evaluated scenarios to within acceptable limits." (SHINE FSAR Section 13b.1.2, "Accident Initiating Events")

- “Radiological consequences of criticality accidents are not included in the accident analysis because of preventative controls being used to ensure criticality events are highly unlikely.” (SHINE FSAR Section 13b.1.2.4, “RPF Inadvertent Nuclear Criticality”)

While the SHINE FSAR presents a number of individual statements of related to an operator’s role in ensuring safety at the SHINE facility, this information is not presented in a cohesive, comprehensive manner for the NRC staff to conduct a risk-informed, graded, and appropriately scoped review of SHINE’s HFE considerations.

(a) Revise the SHINE FSAR to explain, in a consolidated manner, the operator role in the SHINE facility safety as it pertains to both Irradiation Facility and Radioisotope Production Facility operations.

(b) Revise the SHINE FSAR to explain, in a comprehensive manner, how this operator role in facility safety is supported by human factors engineering.

This information is necessary for the NRC staff to fully understand the role of the operator in ensuring the safe operation of the SHINE facility and that SHINE has comprehensively identified all safety-significant aspects of facility operations for which HFE considerations are warranted. Specifically, this information will support the NRC staff in finding that, consistent with 10 CFR 50.57(a)(3), “[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…”

SHINE Response

(a) The role of the operator in the SHINE facility is to perform the manual actions required to safely and efficiently manufacture medical isotopes. Licensed operators stationed in the facility control room use the human interface systems described in Sections 7.3 and 7.6 of the FSAR to input commands to fill target solution vessels with target solution, start the irradiation processes, make adjustments to the neutron driver operating parameters during irradiation, stop the irradiation process, and transfer target solution from an irradiation unit to the supercell. Operators in the facility control room also input commands to control the transfer of target solution and radioactive waste between sub-grade tanks in the radioisotope production facility and to the radioactive liquid waste solidification system. Licensed operators input commands from the facility control room to control and maintain the operation of other systems within the facility that are provided with remote control capabilities as described in Section 7.3 of the FSAR.

Non-licensed operators stationed outside the control room prepare target solution from solid uranium and perform manual operations at the supercell to import materials and reagents, extract and purify Mo-99 product, and export packaged products, samples and waste. Non-licensed operators also perform actions necessary to control and maintain the operation of the tritium purification system, the radioactive liquid waste solidification system, building heating, ventilation, and air conditioning (HVAC) and cooling water systems, and other systems within the facility that are provided local control capabilities as described in Section 7.3 of the FSAR.

Within the SHINE Safety Analysis (SSA), certain operator actions are credited to prevent or mitigate specific accident sequences. These credited operator actions (i.e., specific administrative controls [SACs]) occur during routine activities within the facility. There are no postulated accident sequences that credit operator action to mitigate the consequences of

the event after initiation of the event. Should an initiating event of a postulated accident sequence occur, operator actions provide a defense-in-depth, nonsafety-related, diverse means of actuating components.

(b) The operator role in facility safety is supported by human factors engineering (HFE) via implementation of the SHINE HFE Program. The HFE Program ensures the control room and human system interfaces conform to specific style guidance via the use of a checklist. The checklist is used to verify that the intent of the HFE design guidelines is met and that the physical installation of systems and components complies with the HFE design guidelines. The operator role in facility safety is also supported by procedure development and training programs as described in the SHINE Response to RAI HFE-6.

SHINE has revised Subsection 12.1.3 of the FSAR to clarify the role of the facility operators. SHINE has revised Subsection 7.6.3.3 of the FSAR to clarify that HFE principles are incorporated via the implementation of the HFE Program. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

RAI HFE-2

SHINE FSAR Section 7.4.2.2.14, "Human Factors," describes, in part, that "[h]uman factors is a design consideration for development of the TRPS. *Changes to the design throughout the lifecycle process include human factors considerations"* (emphasis added). SHINE FSAR Section 7.5.2.2.14, "Human Factors," similarly addresses HFE considerations for the engineered safety features actuation system (ESFAS).

NUREG-1537, Part 2, Section 7.6, "Control Console and Display Systems," contains, in part, the following acceptance criteria:

- "The outputs and display devices showing reactor nuclear status should be readily observable by the operator while positioned at the reactor control and manual protection systems."

- "Other controls and displays of important parameters that the operator should monitor to keep parameters within a limiting value, and those which can affect the reactivity of the core should be readily accessible and understandable to the reactor operator."

- "Annunciators or alarms on the control console should clearly show the status of systems such as operating systems, interlocks… ESF initiation, radiation fields and concentration, and confinement or containment status."

The information provided in the SHINE FSAR describes how human factors is considered during the design and verification processes of SHINE's safety-related instrumentation and control (I&C) systems (i.e., the target solution vessel (TSV) reactivity protection system (TRPS) and ESFAS), however, it is unclear how it will be ensured that human factors considerations will be addressed for subsequent modifications to safety-related I&C systems once the SHINE facility is in operation. Failure to consider human factors during the operation of the SHINE facility may allow for the introduction of new human error modes which may, in turn, affect safety.

(a) Revise the SHINE FSAR to describe how it will be ensured that changes to the TRPS and ESFAS design throughout the lifecycle of the SHINE facility will include human factors considerations.

(b) Revise the SHINE FSAR to describe how HFE-related discrepancies that occur during human-system interface design, installation, and modification will be tracked and evaluated.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation finding in Sections 7.6 NUREG-1537, Part 2: "[t]he applicant has shown that all nuclear and process parameters important to safe and effective operation…will be displayed at the control console. The display devices for these parameters are easily understood and readily observable by an operator positioned at the reactor controls. The control console design and operator interface are sufficient to promote safe reactor operation."

SHINE Response

(a) Changes to the target solution vessel (TSV) reactivity protection system (TRPS) and engineered safety feature actuation system (ESFAS) design throughout the lifecycle of the SHINE facility will include human factors considerations via implementation of the SHINE HFE Program. The HFE Program ensures the control room and human system interfaces conform to specific style guidance via the use of a checklist, both during the design phase and after equipment has been installed in the facility. The checklist is used to verify that the intent of the HFE design guidelines are met and that the physical installation of systems and components complies with the HFE design guidelines.

(b) HFE-related discrepancies that occur during human system interface design, installation, and modification will be tracked and evaluated within Issues Management Reports (i.e., the SHINE corrective action program).

SHINE has revised Subsection 7.6.3.3 of the FSAR to clarify that changes to the TRPS and ESFAS design will include human factors considerations, and that identified discrepancies will be tracked and evaluated within the corrective action program. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

RAI HFE-3

Several SHINE FSAR sections (e.g., SHINE FSAR Sections 7.3.1.3.11, "Target Solution Vessel Reactivity Protection System and Engineered Safety Features Actuation System," 7.6.4.2, "Alarms," 7.6.1.5, "Other Control Room Interface Equipment," and 7.6.2.2.8, "Annunciators") discuss alarms associated with systems such as TRPS, ESFAS, PICS, the criticality accident alarm system, and fire protection. These sections provide descriptions, in part, of the visible indications associated with these alarms.

NUREG-1537, Part 2, Section 7.6 contains, in part, the following acceptance criterion:

- "Annunciators or alarms on the control console should clearly show the status of systems such as operating systems, interlocks… ESF initiation, radiation fields and concentration, and confinement or containment status."

As part of its review of SHINE's annunciators and alarms, the NRC staff also considered Section 4.2.3-2, "Unacknowledged Alarm Indication," of NUREG-0700, which sates, in part that "[u]nacknowledged alarms should be indicated both by visual (e.g., flashing) and audible means."

While the provided descriptions of Human Systems Interface (HSIs) indicate that alarms are visible to operators, no other information has been provided regarding whether the alarms are also audible. Human factors design principles, such as those discussed above from NUREG-0700, suggest that important alarms should be audible so that they will reliably call operator attention to them as needed. In contrast, using only visual alarms could increase the probability of alarms going unnoticed should an operator happen to not be oriented in a direction where the visual alarm can be observed when it occurs. This has the potential to delay operators from noticing safety-significant conditions that warrant attention.

(a) Revise the SHINE FSAR to describe how it will be ensured that audible alarm sounds are generated in order to alert operators to safety-significant conditions.

(b) Clarify how the audibility of alarms is addressed by SHINE's HFE principles.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation findings in Sections 7.6 NUREG-1537, Part 2:

- "The applicant has shown that all nuclear and process parameters important to safe and effective operation…will be displayed at the control console. The display devices for these parameters are easily understood and readily observable by an operator positioned at the reactor controls. The control console design and operator interface are sufficient to promote safe reactor operation."

- "The annunciator and alarm panels on the control console give assurance of the operability of systems important to adequate and safe reactor operation…"

SHINE Response

(a) Audible alarm sounds are generated, in order to alert operators to safety-significant conditions, by the configurable stacklights mounted above the main control board in the control room. The stacklights provide audible and visual alarm indication. Individual stacklight segments are programmed to represent each irradiation unit (IU) and a general segment for non-IU alarming. At a minimum, the following conditions will cause an audible alarm:
    - ESFAS actuation
    - TRPS actuation
    - High radiation or contamination levels
    - Loss of electrical power
    - Improper transfer of target solution

(b) The stacklight system is part of the control room design and will therefore be evaluated with

respect to human factors engineering design guidelines. This evaluation is performed as part of initial installation, as well as during future modifications that may be required.

SHINE has revised Subsection 7.6.4.2 of the FSAR to describe control room audible alarms. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

RAI HFE-4

SHINE FSAR Section 12.3, "Procedures," states, in part, that "[p]rocedures for the operation and use of the SHINE facility provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. These procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise." Additionally, it is stated that "[t]he extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error…. Activities and tasks are performed in accordance with approved implementing procedures."

NUREG-1537, Part 2, Section 12.3, "Procedures," contains, in part, the following acceptance criteria:

- "The applicant should propose a minimum list of procedural topics as given in ANSI/ANS 15.1-1990." (The NRC staff notes that SHINE is using ANSI/ANS 15.1-2007.)

- "The applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval."

The categories of procedures described within the SHINE FSAR do not appear to address abnormal and emergency operations. Safe facility operation requires that operations personnel have procedural guidance available to address abnormalities and emergency situations that may occur. For example, it may be necessary to have procedures for addressing manual actuations of the TRPS and ESFAS when warranted by facility conditions, including when required as a means of diversity and defense-in-depth.

(a) Revise the SHINE FSAR to include the establishment and summary of both abnormal and emergency operating procedures for the SHINE facility.

(b) Clarify what means will be used to verify and validate procedures, including those associated with abnormal and emergency operations. As part of this, describe how it will be verified and validated that the SHINE facility design will support the implementation of procedures for manual operator actuations of TRPS and ESFAS.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation finding in Section 12.3 of NUREG-1537, Part 2: "The applicant has proposed a set of required procedures that is appropriate to operation of the facility as proposed in the SAR and is acceptable to the staff."

SHINE Response

(a) SHINE has established processes for developing abnormal and emergency operating procedures. Abnormal procedures cover facility operation under abnormal conditions, which may include operation with certain equipment or systems out of service or operating at a reduced capacity. Emergency operating procedures address facility emergencies and are intended to ensure the facility is placed in a safe and stable condition as part of casualty response (e.g., shut down or isolate processes prior to the actuation of safety systems if adverse trends are identified [as a defense-in-depth function], verify that safety systems have actuated appropriately, or take other actions to facilitate recovery from the event).

(b) Verification and validation of operating procedures, including abnormal and emergency operating procedures (e.g., procedures for manual operator actuations of TRPS and ESFAS, as applicable), is accomplished in accordance with established processes. Verification and validation are performed prior to the issuance of a new procedure or major procedure revision. Verification and validation are normally accomplished by a procedure walkthrough in the facility; however, the specific method of verification and validation are at the discretion of the Operations Manager (e.g., a tabletop discussion in lieu of a walkthrough).

SHINE has revised Section 12.3 of the FSAR and Section 5.4 of the technical specifications to describe the establishment of abnormal and emergency operating procedures and the verification and validation of procedures. A mark-up of the FSAR incorporating these changes is provided as Attachment 1. A markup of the technical specifications incorporating these changes is provided as Attachment 2.

RAI HFE-5

SHINE FSAR section 12.1.3, “Staffing,” states, in part, that “[t]he minimum staffing when the SHINE facility is not secured shall be:

(a) A senior licensed operator present in the facility,

(b) A second senior licensed operator or licensed operator present in the control room, and

(c) An additional designated person present at the facility able to carry out prescribed written instructions.”

Additionally, the SHINE Technical Specifications Section 5.1.3, “Facility Staffing Required,” states the following:

1. The minimum staffing when the facility is not secured shall be:
    a. A Senior Licensed Operator present in the facility,
    b. A second Senior Licensed Operator or Licensed Operator present in the control room, and
    c. An additional designated person present at the facility able to carry out prescribed written instructions.

Unexpected absence of any of the minimum staffing positions for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.

NUREG-1537, Part 2, Section 12.1, “Organization,” contains, in part, the following acceptance criteria:

- “The applicant should discuss the staffing at the reactor facility for various reactor modes, especially when the reactor is not secure. At a minimum, the staffing requirements shall meet the requirements of 10 CFR 50.54…”

The SHINE staffing model described in the SHINE FSAR and in the SHINE Technical Specifications appears to be similar to that which would be implemented at a non-power reactor. However, unlike a non-power reactor where an operator is responsible for a single reactor, the SHINE facility operations would involve managing the operations of eight irradiation units and the Radioisotope Production Facility. The workload associated with operation of the eight irradiation units is likely to be quite different than operating a single nonpower reactor. SHINE’s basis for the described staffing model is unclear and needs to be supported in order to demonstrate that the scope of operations can be accommodated by the available staffing.

Additionally, the allowance provided in Technical Specification Section 5.1.3 for unexpected absences would potentially permit the Facility Control Room to be unattended for up to 2 hours during facility operations. Allowing the Facility Control Room to remain unstaffed in this manner would not support implementation of manual TRPS and ESFAS actuations for diversity and defense-and-depth.

(a) Clarify how the number and qualifications of operations personnel for the full range of SHINE facility conditions and tasks was determined, as well as how it will be ensured that the operational tasks (under normal, abnormal, and emergency conditions), facility maintenance, facility surveillance, and testing will be supported by this staffing model. Update the FSAR, as necessary.

(b) Explain how the Technical Specifications will ensure that the provisions of Section 5.1.3 of Technical Specifications will not result in the Facility Control Room being unstaffed by a licensed operator at any time while the SHINE facility is not secured (regardless of any allowance made for unplanned absences), such that the capability for the timely implementation of defense-in-depth actions will be maintained. Update the Technical Specifications, as necessary.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), “[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…”. Specifically, the information requested is necessary to support the following evaluation finding in Section 12.1 of NUREG-1537, Part 2: “The applicant has described facility staffing requirements that demonstrate its ability to safely operate the facility and protect the health and safety of the staff and the public. The staffing meets the requirements of the regulations.”

SHINE Response

(a) The minimum staffing model presented in Subsection 12.1.3 of the FSAR and Section 5.1.3 of the technical specifications is the minimum staffing required when the facility is not secured. The minimum staffing model is acceptable for periods of low activity and is not intended to be the typical staffing model for the full range of facility operations and workloads. The staffing level required to perform the full range of scheduled tasks (e.g., operational tasks, facility maintenance, facility surveillance, testing) varies dependent on length and complexity of the scheduled tasks. The staffing level and qualifications of operations personnel present at the facility, in excess of the minimum staffing requirements, is at the discretion of the on-shift Shift Supervisor.

(b) SHINE has revised Subsection 12.1.3 of the FSAR and Section 5.1.3 of the technical specifications to clarify the minimum staffing requirements, ensuring that the facility control room is not unstaffed at any time while the SHINE facility is not secured. A markup of the FSAR incorporating these changes is provided as Attachment 1. A markup of the technical specifications incorporating these changes is provided as Attachment 2.

RAI HFE-6

SHINE FSAR Section 13b.1.2 states, in part, that "[a]ppropriate preventative or mitigative controls were identified to reduce the overall risk of the evaluated accident scenarios to within acceptable limits." Additionally, SHINE FSAR Section 13b.1.2.4 states, in part, that the "[r]adiological consequences of criticality accidents are not included in the accident analysis because preventative controls are used to ensure criticality events are highly unlikely."

Section 13b, "Radioisotope Production Facility Accident Analyses," of the ISG Augmenting NUREG-1537, Part 2, states, in part, that an application may be found acceptable "if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property." The acceptance criteria within this section include the following:

- "For a radioisotope production facility, the results of the accident analysis should demonstrate adequate safety by either meeting the performance requirements described in 10 CFR 70.61 or propose and justify alternate performance criteria that the NRC staff determines to demonstrate adequate safety."

- "NUREG-1520, Section 3.4, provides additional criteria for adherence to the safety program and ISA performance."

NUREG-1520, Section 3.4.3.1, "Safety Program and Integrated Safety Analysis Commitments," describes, in part, that human factors engineering is generically applicable to safety controls and should generally be part of the safety program. Furthermore, it is stated that "[h]uman factors practices should be incorporated into the applicant's safety program sufficiently to ensure that… management measures perform their functions…" In addition to the HFE-related acceptance criteria presented in Section 3.4, "Acceptance Criteria," of NUREG-1520 the NRC staff notes the general methodology presented within NUREG-1520 Chapter 3, Appendix E, "Human Factors Engineering for Personnel Activities," would constitute an appropriate approach for justifying the reliability of administrative controls.

NUREG-1520 Chapter 3, Appendix E, describes the acceptance criteria that are associated with HFE within this context. These acceptance criteria include the following:

Section G – “Procedure Development”

> The applicant’s procedure development for personnel activities should incorporate HFE principles and criteria, along with all other design requirements, to develop procedures that are technically accurate, comprehensive, explicit, easy to use, and validated consistent with the acceptance criteria in this Standard Review Plan. Because procedures are considered an essential component of the HSI design, they should be derived from the same design process and analyses as the other components of the HSI (for example, displays, controls, operator aids) and subject to the same evaluation processes. Procedures to support the personnel activity may include generic technical guidance, plant and system operations, abnormal and emergency operations, tests (for example, preoperational, startup, and surveillance), and alarm response.

Section H – “Training Program Development”

> The applicant’s training program development should address all personnel activities. The training program development indicates how the knowledge and skill requirements of personnel will be evaluated, how the training program development will be coordinated with the other activities of the HFE design process, and how the training program will be implemented in an effective manner consistent with human factors principles and practices.
>
> The training program development should address the areas of review and acceptance criteria described in Chapter 11 of this SRP and should result in a training program that provides personnel with qualifications commensurate with their activities.

The SHINE application describes, in part, the use of administrative controls and how they are used to reduce the risk of certain accidents. However, it is unclear how the application, in an integrated and holistic manner, covers the use human factors engineering to reduce the risk of certain accidents. An example of an issue identified by the NRC staff within this area is that SHINE FSAR does not address the training of non-licensed personnel on administrative controls or the verification and validation of procedures containing those controls. This is of concern because the reliability of administrative controls can be affected by human factors engineering considerations. Given the preventative and mitigative nature of these controls, there is the potential to adversely impact the risk associated with certain accident sequences. NUREG-1520, Appendix E, describes how HFE can be applied in a comprehensive manner to ensure that management measures perform their functions. While not a regulatory requirement, the use of the methodology in NUREG-1520, Appendix E, would be an acceptable means of addressing parts (a) through (c) below.

(a) Describe how SHINE’s approach to management measures and administrative controls incorporates HFE in an integrated manner.

(b) Describe how the procedures used to implement administrative controls (e.g. Specific Administrative Controls) will be verified and validated such that the assumptions made about the reliability of these controls in the safety analysis is supported.

(c) Describe how non-licensed facility personnel will be trained on the implementation of administrative controls such that the assumptions made about the reliability of these controls in the safety analysis is supported.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following determination in Section 13b.1 of NUREG-1537, Part 2: "The applicant has identified designated engineered and administrative [controls] necessary to provide preventive or mitigative measures that give reasonable assurance that the facility will operate in a safe manner."

SHINE Response

(a) The administrative controls credited within the SSA are Specific Administrative Controls (SACs). The SACs are safety-related controls, as defined in the SSA, and are incorporated into procedures. SHINE programmatic administrative controls (i.e., management measures), such as procedure development and training, are not addressed by the SHINE HFE Program; however, SHINE programmatic administrative controls ensure that operators are trained and provided with procedures as needed to ensure the reliability of SACs.

The licensed operator training program ensures that individuals are trained in the knowledge, skills, and abilities needed to perform and achieve proficiency in conducting licensed activities. The licensed operator training program, as well as the non-licensed operator training program, use a systematic approach to training (SAT). The implementation and evaluation of these training programs include self-study, classroom, mentoring, and simulation, consistent with the guidance of American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.4-2016, Selection and Training of Personnel for Research Reactors (Reference 3). This method of training ensures operators are prepared to fulfill their required duties as they relate to facility safety and the implementation of SACs. Operator training is further described in Section 12.10 of the FSAR.

Procedures are written and reviewed by operations personnel in accordance with the SHINE operating procedure development process. Additionally, procedures that include SACs are reviewed by the Review and Audit Committee (RAC). The RAC is further described in Section 12.2 of the FSAR. Following these review processes, procedures are verified and validated as described in the SHINE Response to RAI HFE-4 prior to procedure issuance for use within the facility. Procedures that implement SACs (i.e., specific actions credited to ensure facility safety) are verified and validated to be technically accurate, comprehensive, explicit, and easy to use through these processes. Procedures are further described in Section 12.3 of the FSAR.

(b) The procedures used to implement SACs are verified and validated, such that the assumptions made about the reliability of SACs in the SSA is supported, as described in the SHINE Response to RAI HFE-4 and the SHINE Response to RAI HFE-6.a.

(c) The SAT process, as described in the SHINE Response to RAI HFE-6.a, is used to provide training for non-licensed facility personnel. SACs that are performed by non-licensed facility personnel will be identified and evaluated through the SAT process. Changes to the SSA, changes to existing training, or the addition of new training requirements, are evaluated using the SAT process.

RAI HFE-7

Section 13a2, “Aqueous Homogeneous Reactor Accident Analyses,” of the ISG Augmenting NUREG-1537 states, in part, that the application should demonstrate “that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences.”

Section 13b of the ISG Augmenting NUREG-1537 further states that “NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.”

In Section 2.1 in the SHINE Safety Analysis (SSA), SHINE states that it uses guidance from NUREG-1520 to implement a risk index method which includes assigning failure indices to the safety-related administrative controls cited in Appendices A and B of the SSA. The methodology applies failure indices based on Tables 2.3.4-1, 2.3.4-2, and 2.3.4-3. These tables match Tables A-9, A-10, and A-11 in NUREG-1520, which are part of an example application of a risk index method of likelihood evaluation. Data, such as operating experience, should be applied to determine the failure indices. Furthermore, NUREG-1520 states that in the absence of sufficiently detailed information about the factors that influence the failure likelihoods, appropriate conservatism should be used in assigning indices (e.g., using the highest index in the range).

Given that SHINE is a first-of-a-kind facility and in the process of developing training and procedures for many of the safety-related administrative controls, describe the processes and references (e.g., SSA team review or WSRC-TR-93-581, “Savannah River Site Human Error Data Base Development for Nonreactor Nuclear Facilities”) SHINE uses to justify the current failure likelihoods. Include descriptions of the periodic audits, reviews, or analyses that will be performed to verify the selection of failure indices for and intended functionality of safety-related administrative controls, as described in the SSA.

The NRC staff is requesting this information to evaluate SHINE’s accident analysis methodology and determine whether that methodology demonstrates that SHINE has considered all potential accidents and adequately evaluated their consequences. This evaluation is needed for the NRC staff to find reasonable assurance that SHINE:

- Has adequately described the SHINE facility, including those analyses and evaluations that show that safety functions will be accomplished; and

- Can conduct the activities in its application without endangering the health and safety of the public.

SHINE Response

The processes used to justify the failure likelihoods for accident scenarios are described in the SSA. The assignment of failure likelihoods, including those for administrative controls, relies on the engineering judgement of the SSA team.

The failure likelihoods assigned to SACs (i.e., human actions) and human-caused initiating events are consistent with the guidance provided in Table 2.4-2 of the SSA, where an enhanced SAC or a SAC for routine planned operations is assigned a probability of failure on demand of 10^{-2} to 10^{-3} (i.e., a failure probability index number [FPIN] of -2 or -3), while a SAC that must be performed in response to a rare unplanned demand is assigned a probability of failure of 10^{-1} to 10^{-2} (i.e., an FPIN of -1 or -2). To ensure conservatism, consistent with the guidance in NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications" (Reference 4), SHINE uses the higher index in these ranges when assigning FPINs to SACs and human-caused initiating events (i.e., an FPIN of -2 is assigned to an enhanced SAC or a SAC for routine planned operations and an FPIN of -1 is assigned to a SAC that must be performed in response to a rare unplanned demand).

The SHINE nuclear safety program, which controls the development and maintenance of the SSA, requires an audit of the SSA at least once every three years. This audit is an evaluation of the overall effectiveness of the SSA, including review of SHINE operating experience and the effect it may have on both the failure indices for human actions and the intended functionality of safety-related administrative controls.

RAI HFE-8

In SHINE FSAR Table 3.1-3, "SHINE Design Criteria," SHINE establishes the following design criterion that is relevant to its human factors engineering program:

> Criterion 6 – Control Room
>
> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The scope of SHINE Design Criterion 6 is limited to only the irradiation units. However, SHINE FSAR Section 7.1.1, "Process Integrated Control System," describes the PICS as providing monitoring and control of the various processes throughout the SHINE facility. The PICS is described as being used to control and monitor facility systems and components, including those in both the irradiation facility and in the radioisotope production facility. The functions of the PICS discussed include enabling the operator to perform irradiation cycles, transfer target solution to and from the irradiation units (as well as throughout the RPF), and interface with the tritium purification system, processes in the supercell, waste handling operations, and the auxiliary systems. Thus, it appears that the scope of operations performed from the control room is broader than just irradiation unit operations and extends to the overall irradiation facility and radioisotope production facility as well. It is unclear if the scope of SHINE Design Criterion 6 is appropriate based upon the nature and operations of the SHINE facility.

Clarify SHINE's basis for limiting the scope of SHINE Design Criterion 6 to only the irradiation units and how this limited scope is consistent with ensuring the safe operation of the overall facility.

This information is necessary for the NRC staff to determine that SHINE has developed an adequate set of principal design criteria for the SHINE facility, as required by 10 CFR 50.34(a) and (b).

SHINE Response

The SHINE Design Criteria are based on the General Design Criteria (GDC) for nuclear power plants provided in Appendix A to 10 CFR Part 50. Specifically, SHINE Design Criterion 6 was developed from GDC 19 regarding nuclear power plant control rooms. The scope of GDC 19 is limited to the "nuclear power unit," which is defined in Appendix A to 10 CFR Part 50 as "a nuclear power reactor and associated equipment necessary for electric power generation and includes those structures, systems, and components required to provide reasonable assurance the facility can be operated without undue risk to the health and safety of the public." An irradiation unit is the closest analog to a nuclear power reactor for the SHINE facility when establishing a SHINE Design Criterion based on GDC 19.

The scope of SHINE Design Criteria 6 does not limit the scope of control room functions that are incorporated into the design of the facility, as described in the FSAR. While the irradiation units are specifically mentioned in SHINE Design Criterion 6, the facility control room allows for operation of the systems and components contained within the irradiation facility (IF) and radioisotope production facility (RPF) within the main production facility, inclusive of the irradiation units. In addition to the control stations in the facility control room, there are local control stations outside of the control room that allow for local control of the target solution preparation system, radioactive liquid waste immobilization system, supercell, and tritium purification system. The full scope of control systems and human system interfaces, within the facility control room and local control stations, ensures the SHINE facility can be operated safely.

Conduct of Operations

RAI 12-1

Paragraphs (b)(6)(i) and (ii) of 10 CFR 50.34 require that an applicant's FSAR include information regarding the "applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements" and "managerial and administrative controls used to assure safe operation."

The acceptance criteria in Section 12.2 of NUREG-1537, Part 2, state, in part, that "[t]he applicant should discuss the composition of the review and audit committee… The committee members should represent a broad spectrum of expertise (e.g., nuclear engineering, electrical engineering, mechanical engineering, and radiation protection); the exact composition of the committee will vary from facility to facility. Committee members should be appointed by the highest level of upper management. It is also desirable to have members on the committee who are not employed by the reactor owners."

SHINE FSAR Section 12.2.1, "Composition and Qualification," states that "[t]he qualifications for the review and audit committee members shall include a broad spectrum of technical, operations, and managerial expertise. Non-SHINE employees may be appointed as committee members at the discretion of the COO [Chief Operating Officer]." However, it is not clear what qualifications members of the review and audit committee will have or how SHINE will determine what circumstances it will be necessary to appoint non-SHINE employees to the committee.

Update the FSAR to include additional detail on the types of technical, operations, and managerial expertise that will be represented on the SHINE review and audit committee. Additionally, update the FSAR to describe the circumstances when a non-SHINE individual be appointed as a committee member.

This information is necessary for the NRC staff for the NRC staff to make the following evaluation finding in Section 12.2 of NUREG-1537, Part 2: "The applicant has proposed a review and audit function for the…facility. The committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes persons from outside the university (or corporation)."

SHINE Response

The minimum qualification for assignment to the review and audit committee is expert level knowledge and experience in a relevant subject area. Committee member assignments are based on an evaluation of each individual's technical, operational, and managerial expertise as it pertains to the subject areas of the committee's oversight role. At minimum, the committee will include members with expertise in facility operations, engineering, and radiation protection. The overall committee membership is selected to provide a broad spectrum of expertise.

Subject areas of the committee's oversight role are described in Subsections 12.2.3 and 12.2.4 of the FSAR.

The assignment of individuals from outside the SHINE organization is permissible and desirable, especially in cases where expert knowledge or experience not present within the SHINE organization is provided by outside individuals. Assignment of non-SHINE employees to

the committee will be necessary in circumstances when the required expertise to perform an activity is not available from SHINE employees (e.g., to perform an audit of an area where the only personnel with expertise in that area are immediately responsible for that area).

SHINE has revised Subsection 12.2.1 of the FSAR to provide additional detail on the types of expertise represented on the review and audit committee and to describe the circumstances when a non-SHINE employee will be assigned to the committee. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

RAI 12-2

Paragraphs (b)(6)(i) and (ii) of 10 CFR 50.34 require that an applicant's FSAR include information regarding the "applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements" and "managerial and administrative controls used to assure safe operation."

SHINE FSAR Section 12.2.2, "Charter and Rules," describes the charter and rules for the SHINE review and audit committee. This section states that "…approval of minutes shall happen in a timely manner."

The acceptance criteria in Section 12.2 of NUREG-1537, Part 2, state that "minutes of committee meetings should be approved and distributed within three months after the meeting." However, it is not clear what constitutes a timely manner for approval and distribution of the minutes of review and audit committee meeting minutes.

Update the SHINE FSAR to define what constitutes a timely manner for approval and distribution of the minutes of review and audit committee meeting minutes.

This information is necessary for the NRC staff for the NRC staff to make the following evaluation finding in Section 12.2 of NUREG-1537, Part 2: "The review and audit committee has proposed a charter and rules that describe the number of times the committee meets, the way the committee conducts business, the requirements for a quorum when voting, and the way the committee distributes its reports and reviews to the applicant."

SHINE Response

SHINE has revised Subsection 12.2.2 of the FSAR to define the timeliness requirement for the for approval and distribution of review and audit committee meeting minutes. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

References

1. NRC letter to SHINE Medical Technologies, LLC, “SHINE Medical Technologies, LLC – Request for Additional Information Related to Human Factors Engineering and Conduct of Operations (EPID No. L-2019-NEW-0004),” dated September 23, 2021 (ML21253A234)

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

4. U.S. Nuclear Regulatory Commission, “Standard Review Plan for Fuel Cycle Facilities License Applications,” NUREG-1520, Revision 2, June 2015

ENCLOSURE 2
ATTACHMENT 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE
SUPPLEMENT NO. 10 AND RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

FINAL SAFETY ANALYSIS REPORT CHANGES
(MARK-UP)

15 pages follow

7.6.3.2 Operating Conditions

The operator workstations and the main control board are designed to operate in the normal environmental conditions of the facility control room, presented in Table 7.2-2. The main control board equipment is designed to operate in the transient environmental conditions listed in Table 7.2-2 for a minimum of two hours after initiation of a protective action resulting from a design basis event.

In the event of a loss of ventilation to the facility control room, the environment within the facility control room is calculated to remain below 120ºF after two hours. This result is based on the following assumptions:

- Initial facility control room temperature: 75ºF
- Outdoor air temperature: 102.6ºF
- Facility control room occupancy: 10
- Facility control room equipment load: 29 kW

The resultant temperature is within the temperature indicated in Table 7.2-2 for at least two hours, which is sufficient time to ensure that safety-related equipment is able to perform its safety function if required. Therefore, no safety-related ventilation or cooling systems are required to ensure the safety-related I&C systems located in the control room can continue to perform their safety function as required.

7.6.3.3 Human Factors

The design of the facility control room, display screens, and operator interfaces incorporates human factors engineering principles via the implementation of the human factors engineering program. The layout of screens presenting the same set of information at multiple locations is identical for each (i.e., PICS operator workstation, supervisor workstation, local control station, or main control board). The displays and controls are generally grouped by system to aid the operator in the recognition and operation of the controls.

The supervisor workstation is placed and arranged so that the supervisor has a visual of both operator workstations, the displays that the operators are working from, and the main control board. Operator workstations are oriented such that the main control board static display screens are directly in front of the operator workstation.

The manual actuation push buttons are located directly below the static display screens so that the operator can be directly monitoring the variables important to the safe operation of the facility when the manual actuation is performed. The use of selector switch and push buttons in the same product line ensures consistency in look and function. These push buttons also include a positive position indication and a protective guard to prevent inadvertent actuation.

As described in Subsections 7.4.2.2.14 and 7.5.2.2.14, human factors is a design consideration for TRPS and ESFAS. Modifications to safety-related I&C systems after the SHINE facility is in operation include human factors considerations. Issues related to human factors are identified and tracked to resolution using the corrective action program.

Also included in displayed variables at the PICS operator workstation displays, the following variables used in determining and assessing the magnitude of radioactive material release are provided for display at the operator workstations:

- Stack release monitor emissions
- Carbon delay bed effluent monitor emissions
- Radiological ventilation zone 1 (RVZ1) radiologically control area (RCA) exhaust radiation detectors emissions
- Radiological ventilation zone 2 (RVZ2) RCA exhaust radiation detectors emissions

Radiation monitoring information is conveyed from the radiation monitoring instruments described in Section 7.7 to the PICS and displayed in the facility control room. Radiation monitoring information is available on demand at the operator workstations.

Display values on each PICS display screen are automatically updated as more current data becomes available. Each PICS display screen presented on the operator workstation has a title or header and unique identification to distinguish each display page.

The maintenance workstation provides diagnostic information received from the ESFAS and TRPS on system status to be used as a test interface.

Limited function local displays, including radiation monitoring information, are also provided in the irradiation facility (IF) and radioisotope production facility (RPF) at select locations (Subsection 7.6.1.6).

7.6.4.2 Alarms

Alarms are integrated into the PICS display systems. The operator workstations provide detailed visual alarms to the operator to represent unfavorable status of the facility systems. Indications at the operator workstation are provided as visual feedback as well as visual features to indicate that systems are operating properly.

Indication of alarms present is also provided for each IU and for the facility process systems at the main control board. Configurable stacklights are mounted above the main control board to provide audible and visual alarm indication. Alarms are provided to inform the operator of off-normal operating system status, interlocks, engineered safety feature initiations, confinement status, and radiation fields and concentration. Alarms are evaluated with respect to human factors engineering design guidelines. This evaluation is performed as part of initial installation and future modifications.

Alarms for facility systems are further described in Subsection 7.3.2.

7.6.4.3 Controls

Manual controls are provided on both of the PICS operator workstations, via input to the PICS, and on the main control board.

Manual controls for the safety-related TRPS and ESAFS protective functions are located at the main control board. Nonsafety manual push buttons that provide a diverse actuation to the automatically generated safety actuations are located directly below the static display screens for

~~Chief Operating Officer~~Diagnostics General Manager

The ~~Chief Operating Officer~~Diagnostics General Manager (~~COO~~DGM) reports to the CEO and is responsible for ~~overall company~~diagnostics division operations.

Vice President Regulatory Affairs & Quality

The Vice President Regulatory Affairs & Quality reports to the CEO and is responsible for licensing and quality activities.

Quality Manager

The Quality Manager reports to the Vice President Regulatory Affairs & Quality and is responsible for assuring compliance with regulatory requirements and procedures.

~~Plant Manager~~Director of Plant Operations

The ~~Plant Manager~~Director of Plant Operations (DPO) is responsible for operation of the facility~~, including~~. The DPO reports to the DGM.

Director of Corporate Support

The Director of Corporate Support (DCS) is responsible for the protection of personnel from radiation exposure resulting from facility operations and materials, and for compliance with applicable NRC regulations and the facility license. The ~~Plant Manager~~DCS designates the authority to approve procedures related to personnel radiation protection to the Radiation Protection Manager in accordance with the guidance provided in ANSI/ANS-15.1-2007 (ANSI/ANS, 2007). The ~~Plant Manager~~DCS reports to the ~~COO~~DGM.

Radiation Protection Manager

The Radiation Protection Manager is responsible for implementing the radiation protection program. The Radiation Protection Manager reports directly to the ~~Plant Manager~~DCS, independent from facility operations. The Radiation Protection Manager has direct access to executive management for matters involving radiation protection. The Radiation Protection Manager and radiation protection personnel are responsible for:

- Establishing the radiation protection program.
- Generating and maintaining procedures associated with the program.
- Ensuring that ALARA is incorporated into procedures and practiced by personnel, including stopping work when unsafe practices are identified.
- Ensuring the efficacy of the program is reviewed and audited for compliance with NRC and other governmental regulations and applicable regulatory guides.
- Modifying the program based upon experience, facility history, regulatory updates, and changes to guidance documents.
- Adequately staffing the Radiation Protection Department to implement the radiation protection program.
- Ensuring that the occupational radiation exposure dose limits of 10 CFR 20 are not exceeded under normal operations.

- Instructed of their responsibility to report promptly to the facility management any condition which may cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and radioactive material.
- Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material.
- Advised of the various notifications and reports to individuals that a worker may request in accordance with 10 CFR 19.13.

Workers who perform or supervise the shipment of radioactive materials are trained and qualified in accordance with 49 CFR 172, Subpart H, in accordance with 10 CFR 71.5.

The radiation protection training program takes into consideration a worker's normally assigned work activities. Abnormal situations involving exposure to radiation and radioactive material, that can reasonably be expected to occur during the life of the facility, are also evaluated and factored into the training. The extent of these instructions is commensurate with the potential radiological health protection problems present in the workplace.

Retraining of personnel previously trained is performed for radiological, chemical, industrial, and criticality safety at least annually. The retraining program also includes procedure changes and updating and changes in required skills. Changes to training are implemented, when required, due to incidents potentially compromising safety or if changes are made to the facility or processes.

Records of training are maintained in accordance with the SHINE records management system.

Facility training programs are established in accordance with Subsection 12.1.4. The radiation protection sections of the training program are evaluated at least annually. The program content is reviewed to ensure it remains current and adequate to ensure worker safety.

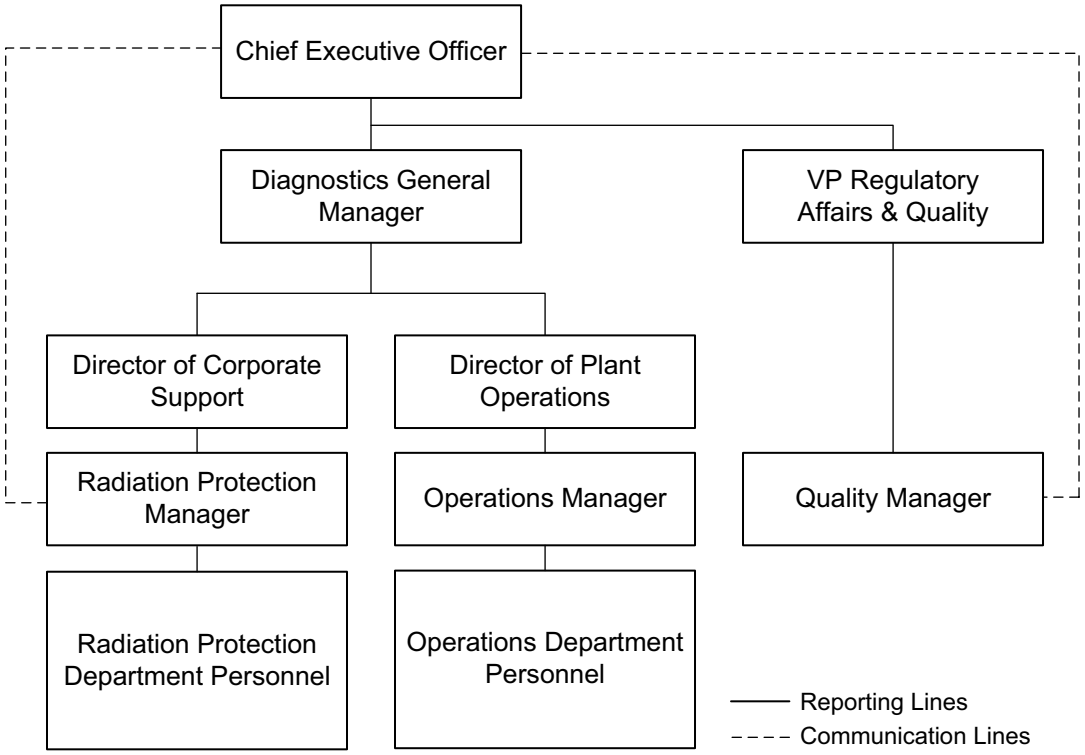
11.1.2.1.7 Radiation Safety Audits

Radiation safety audits are conducted, at a minimum, on an annual basis for the purpose of reviewing all functional elements of the radiation protection program to meet the requirement of 10 CFR 20.1101(c). The audit activity is led by a member of the Review and Audit Committee, or other designated independent individual, with the knowledge and experience to perform the activity. The audits provide sufficient information to assess:

- Compliance with NRC regulations
- Compliance with the terms and conditions of the license
- Occupational doses and doses to members of the public for ALARA compliance
- Maintenance of radiation protection program required records

Deficiencies identified during the audit are addressed through the corrective action program. The results of the radiation safety audits are provided to the Radiation Safety Committee, the ~~COO~~DGM and the CEO for review. Section 12.2 provides additional details of audit activities.

Figure 11.1-3 – Radiation Protection Organization



11.2 RADIOACTIVE WASTE MANAGEMENT

SHINE produces medical isotopes by the fission of low enriched uranium (LEU) driven by accelerator-produced neutrons. Several irradiation and processing steps create liquid, gaseous, or solid radioactive waste materials. This section describes the management program, controls, and disposal pathways established to ensure proper identification, classification, control, processing (as required), and packaging, for each anticipated radioactive waste stream generated by the SHINE facility. SHINE is committed to comply with all applicable local and national regulations for managing radioactive wastes.

SHINE will comply with the following federal regulations related to radioactive wastes:

- 10 CFR 20, Standards for Protection Against Radiation
- 10 CFR 61, Licensing Requirements for Land Disposal of Radioactive Waste
- 10 CFR 71, Packaging and Transportation of Radioactive Material
- 40 CFR, Chapter I, Subchapter F, Radiation Protection Programs
- 40 CFR, Chapter I, Subchapter I, Solid Wastes
- 49 CFR, Chapter I, Subchapter C, Hazardous Materials Regulations

SHINE is regulated by the NRC. The State of Wisconsin regulates radioactive waste once it leaves the SHINE facility and is transported. SHINE complies with Wisconsin regulations relating to the transportation and disposal of hazardous waste per Wisconsin Administrative Code Chapter NR 662. The State of Wisconsin implements the U.S. Department of Transportation (DOT) radioactive waste transportation regulations.

Radioactive wastes are prepared for shipment in approved shipping containers and shipped off-site using common or contract carriers in compliance with DOT regulations (49 CFR) and 10 CFR 20, 10 CFR 61 and 10 CFR 71, as applicable.

SHINE complies with the waste acceptance criteria (WAC) of the selected licensed disposal facilities, including any local or state regulations specified in those criteria. The State of Wisconsin is in the Midwest Interstate Low-Level Radioactive Waste Compact. Waste disposal sites available for this compact include:

- Energy*Solutions* in Clive, UT
- Waste Control Specialists (WCS) in Andrews, TX

Section 11.1 describes the program and procedures for controlling and assessing radioactive exposures associated with radioactive sources, including radioactive waste streams.

11.2.1 RADIOACTIVE WASTE MANAGEMENT PROGRAM

The Radioactive Waste Management Program is coordinated with the Radiation Protection Program under the ~~Plant Manager~~Director of Corporate Support (DCS). The goal of the Radioactive Waste Management Program is to minimize waste generation, minimize exposure of personnel, and to protect the general public and environment. The authority, duties, and responsibilities of personnel in the waste management organization are prescribed in the Radioactive Waste Management Program document.

11.2.1.1 ~~Plant Manager~~Director of Corporate Support

The ~~Plant Manager~~Director of Corporate Support (DCS) reports to the ~~Chief Operating Officer~~Diagnostics General Manager (DGM). The ~~Plant Manager has overall responsibility for the safe operation of the SHINE facility and~~DCS is responsible for ensuring the protection of personnel from radiation exposure resulting from processing, handling, and storing radioactive material and waste. The ~~Plant Manager~~DCS's responsibilities are to:

- Assign responsibility and delegates commensurate authority to implement the Radioactive Waste Management Program.
- Provide waste management staff appropriate to the scope of operations and experienced in waste management operations.
- Ensure that the waste management self-assessment program is implemented.
- Ensure compliance with applicable federal and state regulations, and facility license conditions.
- Approve changes to the facility Process Control Program.

11.2.1.2 Radiation Protection Manager

The Radiation Protection Manager reports to the ~~Plant Manager~~DCS. The Radiation Protection Manager is responsible for establishing and maintaining the Radioactive Waste Management Program. The Radiation Protection Department maintains organizational independence from the Operations Department. The Radiation Protection Manager and Radiation Protection staff responsibilities are to:

- Develop waste management procedures for the processing, packaging and shipment of radioactive waste from the facility.
- Ensure that the concept of ALARA is incorporated into the Radioactive Waste Management Program procedures and is practiced by personnel.
- Process radioactive waste generated at the facility.
- Provide technical input to the design of equipment and processes.
- Perform radiological analysis tasks supporting the Radioactive Waste Management Program.
- Provide technical input to the Radioactive Waste Management Program training program.
- Maintain contractual relationships with waste disposal sites, waste processing facilities, and radioactive waste carriers.
- Maintain working knowledge of waste disposal acceptance criteria, regulations, standards and guides.
- Conduct self-assessments of radioactive waste management practices and compliance with procedures.

11.2.1.3 Training Manager

The Training Manager reports to the ~~Plant Manager~~DCS and is responsible for implementation of the Radioactive Waste Management Program training as described in the Radiation Protection Program. The Training Manager has the following responsibilities:

- Develops the waste management training and qualification program in accordance with facility procedures and ensuring compliance with 49 CFR 172, Subpart H, Training.

CHAPTER 12 – CONDUCT OF OPERATIONS

12.1 ORGANIZATION

This section describes the SHINE organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The SHINE organizational structure implements a conduct of operations philosophy of working in a formalized, disciplined manner to achieve operational excellence, which emphasizes safety in every aspect of plant operations. The organizational aspects of the radiation protection (RP) program (RPP), the production facility safety program, staffing, and selection and training of personnel will also be discussed in this section.

12.1.1 STRUCTURE

Responsibility for the safe operation of the SHINE facility shall be with the chain of command established in the SHINE operational organization chart provided in Figure 12.1-1. The individuals at the various management levels, in addition to having responsibility for the policies and operation of the SHINE facility, shall be responsible for safeguarding the public and facility personnel from undue radiation exposures and for adhering to the requirements of the operating license and technical specifications.

SHINE management functional levels and assignments of responsibility are described below:

- Level 1: Individuals responsible for the medical isotope facility license
- Level 2: Individuals responsible for the facility operation
- Level 3: Individuals responsible for day-to-day operation or shift
- Level 4: Operating staff

Alternates may perform the functions required in the absence of the normal designee.

Facility operators (i.e., senior licensed operators, licensed operators, and field operators) (Level 4) report directly to the shift supervisors (Level 3). The ~~RP Manager reports directly to the Plant Manager and has~~personnel performing the radiation safety function have communication lines with the ~~Operations Manager~~shift supervisors and executive management. The shift supervisors report directly to the Operations Manager (OM) (Level 2). The O~~perations M~~anager reports to the Director of Plant ~~Manager~~Operations (DPO) (Level 2). The review and audit committee is chaired by the ~~Chief Operating Officer~~Diagnostics General Manager (~~COO~~DGM) or designee and has communication lines with the ~~Plant Manager~~DPO and executive management. The ~~Plant Manager~~DPO reports to the ~~COO~~DGM (Level 1). The ~~COO~~DGM reports to the Chief Executive Officer (CEO) (Level 1).

12.1.2 RESPONSIBILITY

12.1.2.1 SHINE Medical Technologies, LLC

SHINE Medical Technologies, LLC is the entity with legal responsibility for holding the facility operating license.

12.1.2.2 Chief Executive Officer (CEO)

The CEO is responsible for the overall design, management, and technical leadership of the company and is also responsible for all technical and administrative support activities provided by SHINE. The CEO reports to the Board of Directors with respect to all matters.

12.1.2.3 ~~Chief Operating Officer~~Diagnostics General Manager (~~COO~~DGM)

The ~~COO~~DGM is responsible for operational aspects of the ~~company~~division including safety, management, and training. The ~~COO~~DGM is also responsible for matters regarding environment, safety, and health. The ~~COO~~DGM delegates sufficient responsibility and authority to direct reports that ensures appropriate controls have been established and for verifying that activities have been correctly performed. The ~~COO~~DGM encourages managers and employees to identify problems and initiate, recommend, or provide corrective action, and ensures corrective action implementation. The ~~COO~~DGM reports to the CEO.

12.1.2.4 Director of Plant ~~Manager~~Operations (~~PM~~DPO)

The ~~PM~~DPO is responsible for the operation and management of the SHINE facility. ~~The PM is also responsible for establishing and managing the required training programs to support the organization, and for establishing and maintaining the programs and systems to ensure protection of the company's assets.~~ The ~~PM~~DPO reports to the ~~COO~~DGM.

12.1.2.5 Operations Manager (OM)

The OM is responsible for safe, reliable, and efficient plant operations within the constraints of the operating license and regulatory requirements. This position is also responsible for the development and implementation of appropriate operational controls in accordance with the Quality Assurance Program Description (QAPD). The OM reports to the ~~PM~~DPO.

12.1.2.6 Shift Supervisors

The shift supervisors are senior licensed operators and are responsible for the safe day-to-day operation of the facility. The shift supervisors report to the OM.

12.1.2.7 Senior Licensed Operators, Licensed Operators, and Field Operators

Senior licensed operators, licensed operators, and field operators are responsible for conforming to applicable rules, regulations, and procedures for operation of the facility. Senior licensed operators are responsible for safe and efficient operation of a portion of the facility when designated by the shift supervisor. Senior licensed operators and licensed operators are responsible for maintaining senior licensed operator and licensed operator status, respectively. Field operators are non-licensed operations personnel. Senior licensed operators, licensed operators, and field operators report to shift supervisors.

12.1.2.8 Radiation ~~Protection Manager (RPM)~~Safety Function

The ~~RPM~~radiation protection organization fulfills the radiation safety function and is responsible for establishing and implementing the RPP, monitoring worker doses, and the calibration and

quality assurance of health physics instrumentation. The ~~RPM reports to the PM~~radiation protection organization is described in Subsection 11.1.2.1.1.

12.1.2.9 Review and Audit Committee

The review and audit committee is responsible for the independent review and audit of the safety aspects of the SHINE facility operations. The review and audit committee is described in Section 12.2.

12.1.3 STAFFING

SHINE provides sufficient resources in personnel and materials to safely conduct operations.

(1) The minimum staffing when the facility is not secured shall be:
   (a) A senior licensed operator present in the facility,
   (b) A second senior licensed operator or licensed operator present in the control room, and
   (c) An additional designated person present at the facility able to carry out prescribed written instructions.

   Unexpected absence of ~~any of~~ the ~~minimum staffing~~ positions described in (1)(a) or (1)(c) for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.
(2) A list of facility personnel by name and telephone number shall be readily available in the control room for use by the operator. The list shall include:
   (a) Management personnel,
   (b) Radiation safety personnel, and
   (c) Other operations personnel.

Staffing requirements are included in the technical specifications.

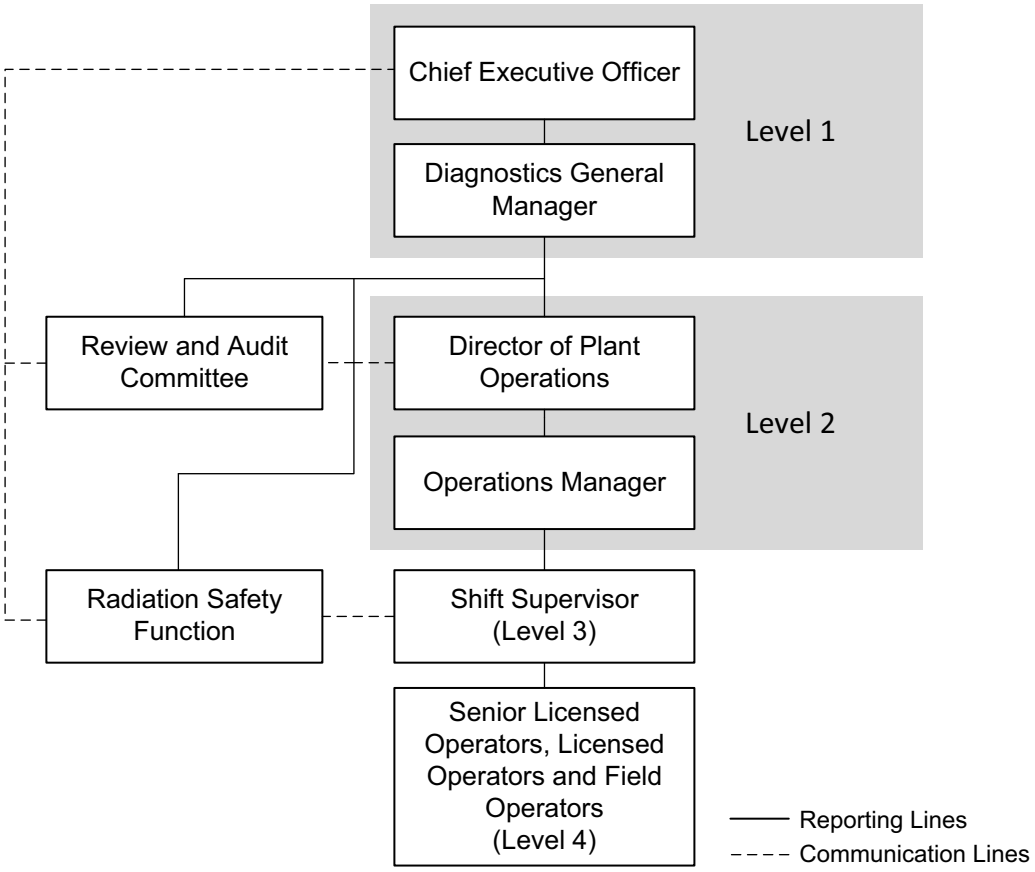
The role of the operator in the SHINE facility is to perform the manual actions required to safely and efficiently manufacture medical isotopes. There are no postulated accident sequences that credit operator action to mitigate the consequences of the event after initiation of the event. Should an initiating event of a postulated accident sequence occur, operator actions provide a defense-in-depth, nonsafety-related, diverse means of actuating components.

12.1.4 SELECTION AND TRAINING OF PERSONNEL

SHINE establishes and maintains training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) reports to the ~~PM~~Director of Corporate Support (DCS) and is responsible for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. American National Standards Institute/ American Nuclear Society (ANSI/ANS) 15.4-2016 is used in the selection and training of personnel (ANSI/ANS, 2016a). Records of personnel training and qualification are maintained.

In general, operations personnel have the combination of academic training, job-related experience, health, and skills commensurate with their level of responsibility that provides reasonable assurance that decisions and actions during normal and abnormal conditions are

Figure 12.1-1 – SHINE Operational Organization Chart



12.2 REVIEW AND AUDIT ACTIVITIES

The ~~Chief Operating Officer~~Diagnostics General Manager (~~COO~~DGM) establishes the review and audit committee and ensures that the appropriate technical expertise is available for review and audit activities. The ~~COO~~DGM holds approval authority for review and audit activities. Independent audits of the SHINE facility are conducted periodically.

The review and audit committee will interact with facility management through the dissemination of meeting minutes and meeting reports. SHINE will submit a written report or minutes of the findings and recommendations of the review group to Level 1 management and the review and audit group members in a timely manner after the review has been completed. SHINE will immediately report deficiencies uncovered that affect nuclear safety to Level 1 management.

12.2.1 COMPOSITION AND QUALIFICATIONS

The review and audit committee shall have the appropriate expertise and experience such that members provide the SHINE management an independent assessment of the operation. The ~~COO~~DGM or designee chairs the review and audit committee and appoints additional members. The minimum number of the members shall be three. The qualifications for the review and audit committee members shall include a broad spectrum of technical, operational, and managerial expertise. At a minimum, the committee shall include members with expertise in facility operations, engineering, and radiation protection. Non-SHINE employees may be appointed as committee members, at the discretion of the ~~COO~~chair. Assignment of non-SHINE employees to the committee will be necessary in circumstances when the required expertise to perform an activity is not available from SHINE employees (e.g., to perform an audit of an area where the only personnel with expertise in that area are immediately responsible for that area).

12.2.2 CHARTER AND RULES

The charter for the review and audit committee requires at least one meeting per year, with a quorum being a minimum of 50 percent of committee members where the operating staff does not constitute a majority. Dissemination, review, and approval of minutes shall ~~happen in a timely manner~~occur within three months. The review and audit committee charter shall include provisions for the use of subgroups. Committee reports and reviews shall be distributed by memorandum to Level 1 management and other management as designated in the charter. Voting may be conducted at the meeting or by polling members with a majority required for approval.

12.2.3 REVIEW FUNCTION

At a minimum, the following items shall be reviewed:

- Determinations that proposed changes in equipment, systems, test, or procedures are allowed without prior authorization by the responsible authority (e.g., 10 CFR 50.59 safety reviews);
- All new procedures and major revisions having safety significance;
- Proposed changes in facility equipment or systems having safety significance;
- Proposed changes in technical specifications or license;
- Violations of technical specifications or license;
- Violations of internal procedures or instructions having safety significance;

- Operating abnormalities having safety significance;
- Reportable occurrences; and
- Audit/Assessment reports.

Upon completion of a review, a written report of any findings and recommendations of the review and audit committee shall be provided to SHINE executive management.

12.2.4 AUDIT FUNCTION

The audit function will include selective (but comprehensive) examination of operating records, logs, and other documents. Discussions with personnel and observation of operations will be used as appropriate. In no case will the individual immediately responsible for the area perform an audit in that area. SHINE will work to establish relationships with other entities to participate in audits of the facility. The following items will be audited:

- Facility operations for conformance to the technical specifications and applicable license conditions (including organization and responsibilities, training, operations, procedures, logs and records, health physics, technical specification compliance, and surveillances): at least once per calendar year (interval between audits not to exceed 15 months).
- The retraining and requalification program for the operating staff: at least once every other calendar year (interval between audits not to exceed 30 months).
- The results of action taken to correct those deficiencies that may occur in the SHINE facility equipment, systems, structures, or methods of operations that affect nuclear safety: at least once per calendar year (interval between audits not to exceed 15 months).
- The SHINE facility emergency plan and implementing procedures: at least once every other calendar year (interval between audits not to exceed 30 months).
- The radiation protection plan: at least once per calendar year (interval between audits not to exceed 15 months).
- The quality assurance program description: at least once every other calendar year (interval between audits not to exceed 30 months).
- The physical security plan: at least once every other calendar year (interval between audits not to exceed 30 months).
- The nuclear criticality safety program: at least once every third calendar year (interval between audits not to exceed 36 months).

Deficiencies identified during the audit will be entered into the corrective action program. Deficiencies uncovered that affect nuclear safety shall immediately be reported to Level 1 management. A written report of the findings of the audit shall be submitted to Level 1 management and the review and audit committee members within three months after the audit has been completed.

12.3 PROCEDURES

Procedures for the operation and use of the SHINE facility provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct and the wording and format are clear and concise.

The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation is in compliance with American National Standards institute/ American Nuclear Society (ANSI/ANS) 15.1-2007 (ANSI/ANS, 2007a).

SHINE will prepare, review, and approve written procedures for the following basic topics:

1. startup, operation, and shutdown of the irradiation unit (IU);
2. target solution fill, draining, and movement within the main production facility;
3. maintenance of major components of systems that may have an effect on nuclear safety;
4. surveillance checks, calibrations and inspections required by the technical specifications;
5. personnel radiation protection, consistent with applicable regulatory guidance. The procedures shall include management commitment and programs to maintain exposures and releases as low as reasonably achievable in accordance with applicable guidance;
6. administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;
7. implementation of required plans (e.g., emergency, security); and
8. use, receipt, and transfer of byproduct material.

The specific procedures within these topic areas are developed in accordance with Section 2.5 of the SHINE Quality Assurance Program Description (QAPD).

SHINE shall review and approve written procedures prior to initiating any of the activities listed above. The procedures shall be reviewed by the SHINE review and audit committee and approved by Level 2 management or designated alternates, and such reviews and approvals shall be documented in a timely manner.

Substantive changes to procedures related to the activities listed above shall be made effective only after documented review by the SHINE review and audit committee and approval by Level 2 management or designated alternates. Minor modifications to the original procedure that do not change their original intent may be made by Level 3 management or higher, but the modifications must be approved by Level 2 or designated alternates. Temporary deviations from the procedures may be made by a senior licensed operator or higher individual present, in order to accommodate special or unusual circumstances or conditions. Such deviations shall be documented and reported within 24 hours or the next working day to Level 2 management or designated alternates. Review and approval of procedural changes shall be documented in a timely manner, in accordance with the SHINE document control procedure.

Revisions to the procedures for the operation and use of the SHINE facility are initiated and tracked through the document control processes. Following preparation, procedure revisions

receive a technical review, which will include a screening for 10 CFR 50.59 applicability and are then reviewed and approved as described above.

Prior to a new or revised procedure being issued for use, the procedure is verified and validated to ensure it will accomplish its intended purpose.

The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures is documented. A controlled copy of all operations procedures is maintained in the control room. Activities and tasks are performed in accordance with approved implementing procedures.

ENCLOSURE 2
ATTACHMENT 2

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE
SUPPLEMENT NO. 10 AND RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

TECHNICAL SPECIFICATIONS CHANGES
(MARK-UP)

8 pages follow

5.0 Administrative Controls

5.1 Organization

5.1.1 Structure

This section describes the SHINE organizational structure, functional responsibilities, and levels of authority. The levels employed are adapted from the definitions from ANSI/ANS 15.1-2007:

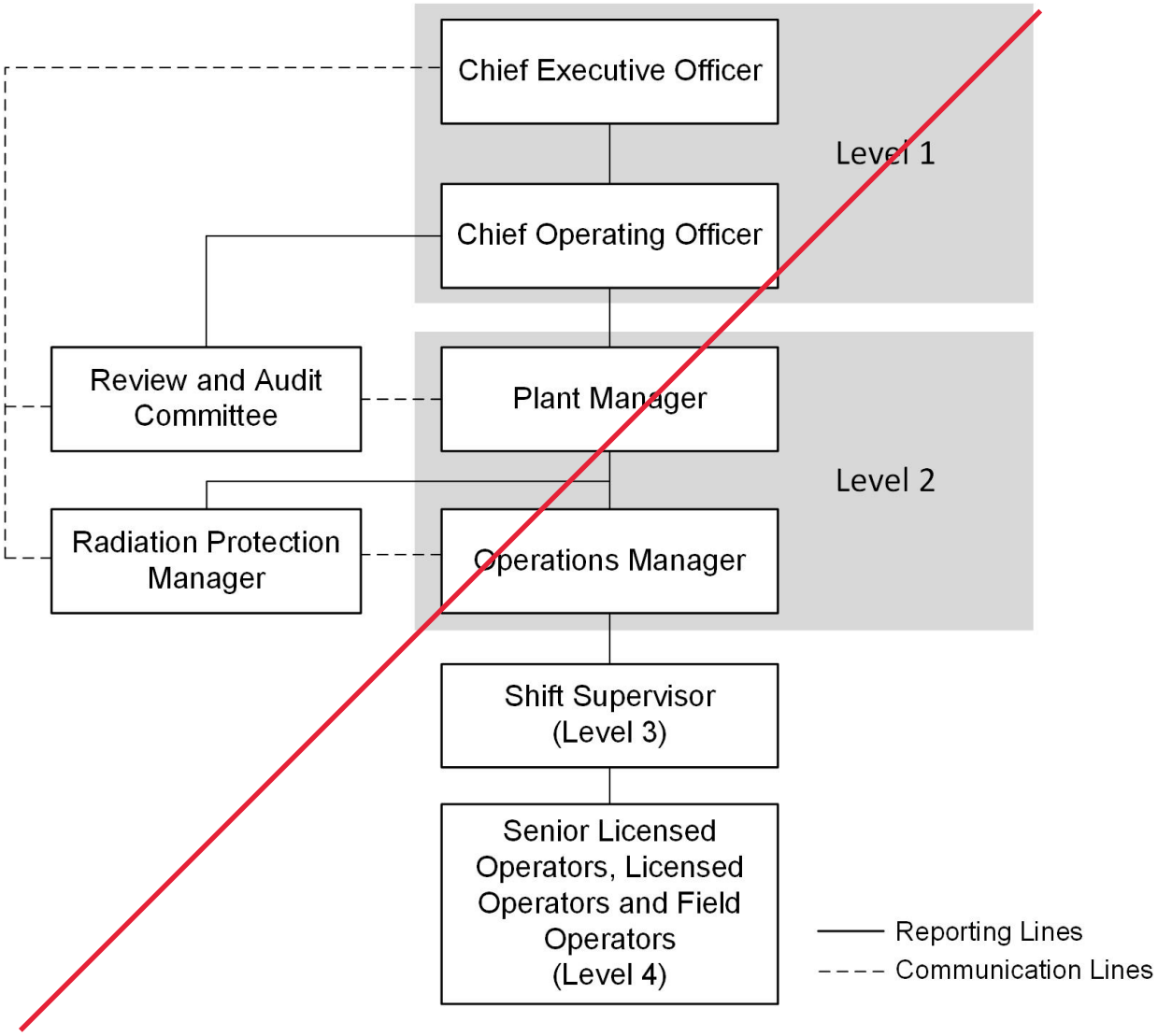
- Level 1: Individuals responsible for the SHINE Facility License;
- Level 2: Individuals responsible for SHINE Facility operation;
- Level 3: Individuals responsible for day-to-day operation or shift;
- Level 4: Operating staff.

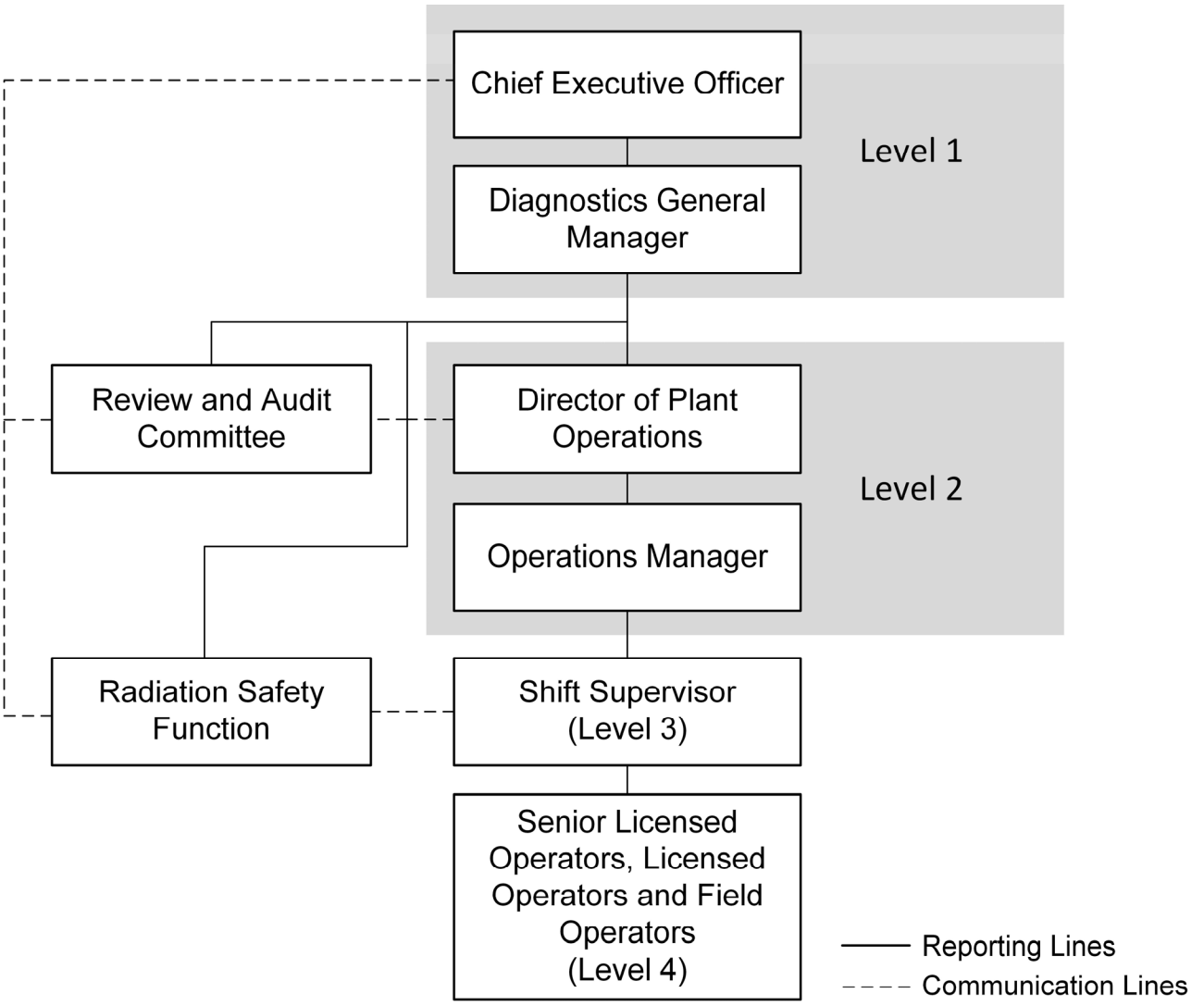
Alternates may perform the functions required in the absence of the normal designee.

The management for operation of the SHINE Facility shall consist of the organizational elements described below and shown in Figure 5.1.1:

1. Chief Executive Officer (CEO) - Level 1
2. ~~Chief Operating Officer (COO)~~Diagnostics General Manager - Level 1 Alternate
3. ~~Plant Manager~~Director of Plant Operations (~~PM~~DPO) - Level 2
4. Operations Manager (OM) - Level 2 Alternate
5. Shift Supervisors - Level 3
6. Senior Licensed Operators, Licensed Operators, and Field Operators - Level 4
7. Radiation ~~Protection Manager (RPM)~~Safety Function
8. Review and Audit Committee (RAC)

Figure 5.1.1 SHINE Operational Organization Chart





5.1.2 Responsibility

Responsibility for the safe operation of the SHINE Facility shall be with the chain of command established in Figure 5.1.1. Individuals at the various management levels shall be responsible for the policies and operation of the SHINE Facility, for safeguarding the public and facility personnel from undue radiation exposures, and for adhering to all requirements of the License and technical specifications.

1. The CEO is responsible for the overall design, management, and technical leadership of the company and is also responsible for all technical and administrative support activities provided by SHINE. The CEO reports to the Board of Directors with respect to all matters.

2. The ~~COO~~DGM is responsible for operational aspects of the ~~company~~division including safety, management, and training. The ~~COO~~DGM is also responsible for matters regarding environment, safety, and health. The ~~COO~~DGM delegates sufficient responsibility and authority to direct reports that ensures appropriate controls have been established and for verifying that activities have been correctly performed. The ~~COO~~DGM has the overall responsibility for any

programs that are established to ensure appropriate control of measures pertaining to safety, operability, and maintenance of the facility. The ~~COO~~DGM encourages managers and employees to identify problems and initiate, recommend, or provide corrective action, and ensures corrective action implementation. The ~~COO~~DGM reports to the CEO.

3. The ~~PM~~DPO is responsible for the operation and management of the SHINE Facility. The DPO reports to the DGM.

~~3. The PM is also responsible for establishing and managing the required training programs to support the organization, and for establishing and maintaining the programs and systems to ensure protection of the company's assets. The PM reports to the COO.~~

4. The OM is responsible for safe, reliable, and efficient plant operations within the constraints of the operating License and regulatory requirements. This position is also responsible for the development and implementation of appropriate operational controls in accordance with the QAPD. The OM reports to the ~~PM~~DPO.

5. The Shift Supervisors are responsible for the safe day-to-day operation of the facility. The Shift Supervisors report to the OM.

6. Senior Licensed Operators, Licensed Operators, and Field Operators are responsible for conforming to applicable rules, regulations, and procedures for operation of the facility. Senior Licensed Operators are responsible for safe and efficient operation of a portion of the facility when designated by the Shift Supervisor. Senior Licensed Operators and Licensed Operators are responsible for maintaining Senior Licensed Operator and Licensed Operator status, respectively. Field Operators are non-licensed operations personnel. Senior Licensed Operators, Licensed Operators, and Field Operators report to Shift Supervisors.

7. The ~~RPM~~radiation protection organization fulfills the radiation safety function and is responsible for establishing and implementing the RPP, monitoring worker doses, and the calibration and quality assurance of health physics instrumentation. ~~The RPM reports to the PM~~The radiation protection organization is described in FSAR Subsection 11.1.2.1.1.

8. The RAC is responsible for the independent review and audit of the safety aspects of the SHINE Facility operations. The RAC duties, authorities, and responsibilities are described in FSAR Section 12.2.

5.1.3 Facility Staffing Required

1. The minimum staffing when the facility is not Secured shall be:

   a. A Senior Licensed Operator present in the facility,

   b. A second Senior Licensed Operator or Licensed Operator present in the control room, and

   c. An additional designated person present at the facility able to carry out prescribed written instructions.

   Unexpected absence of ~~any of the minimum staffing positions~~the positions described in 5.1.3.1.a or 5.1.3.1.c for as long as two hours to accommodate a

personal emergency may be acceptable provided immediate action is taken to obtain a replacement.

2. A list of facility personnel by name and telephone number shall be readily available in the control room for use by the operators. The list shall include:

   a. Management personnel,

   b. Radiation safety personnel, and

   c. Other operations personnel.

5.1.4 Selection and Training of Personnel

SHINE establishes and maintains training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) reports to the ~~PM~~Director of Corporate Support (DCS) and is responsible for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. ANSI/ANS 15.4-2016 is used in the selection and training of personnel and compliance is maintained with 10 CFR Part 55. Records of personnel training and qualification are maintained.

In general, personnel have the combination of academic training, job-related experience, health, and skills commensurate with their level of responsibility that provides reasonable assurance that decisions and actions during normal and abnormal conditions are such that the facility is operated in a safe manner.

Additional information is detailed in FSAR Subsection 12.1.4.

5.2 Review and Audit

The ~~COO~~DGM establishes the RAC and ensures that the appropriate technical expertise is available for review and audit activities. The ~~COO~~DGM holds approval authority for review and audit activities. Independent audits of the SHINE Facility are conducted periodically.

The RAC will interact with facility management through the dissemination of meeting minutes and meeting reports.

5.2.1 Composition and Qualifications

The RAC shall have the appropriate expertise and experience such that members provide the SHINE management an independent assessment of the operation. The ~~COO~~DGM (or designee) shall be the chair of the RAC and shall appoint additional members. The minimum number of the members shall be three. The qualifications for the RAC members shall include a broad spectrum of technical, operational, and managerial expertise. At a minimum, the committee shall include members with expertise in facility operations, engineering, and radiation protection. Non-SHINE employees may be appointed as committee members, at the discretion of the ~~COO~~chair. Assignment of non-SHINE employees to the committee will be necessary in circumstances when the required expertise to perform an activity is not available from SHINE employees (e.g., to perform an audit of an area where the only personnel with expertise in that area are immediately responsible for that area).

5.2.2 Charter and Rules

The charter for the RAC requires at least one meeting per year, with a quorum being a minimum of 50 percent of committee members where the operating staff does not constitute a majority. Dissemination, review, and approval of minutes shall ~~happen in a timely manner~~occur within three months. The RAC charter shall include provisions for the use of subgroups. Committee reports and reviews shall be distributed by memorandum to Level 1 management and other management as designated in the charter. Voting may be conducted at the meeting or by polling members with a majority required for approval.

5.2.3 Review Function

1. At a minimum, the following items shall be reviewed:
    a. Determinations that proposed changes in equipment, systems, tests, or procedures are allowed without prior authorization by the responsible authority (e.g., 10 CFR 50.59 safety reviews);
    b. All new procedures and major revisions thereto having safety significance;
    c. Proposed changes in facility equipment or systems having safety significance;
    d. Proposed changes in technical specifications or License;
    e. Violations of technical specifications or License;
    f. Violations of internal procedures or instructions having safety significance;
    g. Operating abnormalities having safety significance;
    h. Reportable occurrences; and
    i. Audit/Assessment reports
2. A written report or minutes of the findings and recommendations of the RAC shall be submitted to Level 1 and the RAC group members in a timely manner after any review has been completed.

5.2.4 Audit Function

1. The audit function shall include selective (but comprehensive) examination of operating records, logs, and other documents. Discussions with personnel and observation of operations will be used as appropriate. In no case shall the individual immediately responsible for the area perform an audit in that area. SHINE will work to establish relationships with other entities to participate in audits of the facility. The following items shall be audited:
    a. Facility operations for conformance to the technical specifications and applicable License conditions (including organization and responsibilities, training, operations, procedures, logs and records, health physics, technical specification compliance, and surveillances): at least once per calendar year (interval between audits not to exceed 15 months);
    b. The retraining and requalification program for the operating staff: at least once every other calendar year (interval between audits not to exceed 30 months);

c. The results of action taken to correct those deficiencies that may occur in the production facility equipment, systems, structures, or methods of operations that affect nuclear safety: at least once per calendar year (interval between audits not to exceed 15 months);

d. The SHINE Facility emergency plan and implementing procedures: at least once every other calendar year (interval between audits not to exceed 30 months);

e. The radiation protection plan: at least once per calendar year (interval between audits not to exceed 15 months);

f. The QAPD: at least once every other calendar year (interval between audits not to exceed 30 months);

g. The physical security plan: at least once every other calendar year (interval between audits not to exceed 30 months); and

h. The nuclear criticality safety program: at least once every third calendar year (interval between audits not to exceed 36 months).

2. Deficiencies identified during the audit will be entered into the Corrective Action Program. Deficiencies uncovered that affect nuclear safety shall immediately be reported to Level 1 management. A written report of the findings of the audit shall be submitted to Level 1 management and the review and audit committee members within three months after the audit has been completed.

5.3 Radiation Safety

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

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

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

5.4 Procedures

1. Procedures for the operation and use of the SHINE Facility provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are written, reviewed, approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise.

8. Prior to a new or revised procedure being issued for use, the procedure is verified and validated to ensure it will accomplish its intended purpose.

~~8.~~9. The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures is documented. A controlled copy of all operations procedures is maintained in the control room. Activities and tasks are performed in accordance with approved implementing procedures.