

12.9 Quality Assurance

The NRC staff evaluated the sufficiency of the SHINE Quality Assurance Program Description (QAPD) Revision 18 (ADAMS Accession No. ML21301A131), by reviewing how the relevant requirements of 10 CFR 50.34(b)(6)(ii) were satisfied and by using the guidance and acceptance criteria from Section 12.9, "Quality Assurance," of NUREG-1537, Part 2. NUREG-1537, Part 2 provides a basis for the NRC staff's review of the QA program that is based on ANSI/ANS-15.8-1995 (R2013), as endorsed in RG 2.5 Revision 1.

As part of the review of SHINE's application for construction permit, the NRC staff approved SHINE's QAPD, Revision 7. The NRC staff's evaluation for SHINE's construction permit application is documented in NUREG-2189, "Safety Evaluation Report – Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility" (ADAMS Accession No. ML16229A140). For the operating license application, the NRC staff reviewed up to Revision 18 of the QAPD.

SHINE's revised QAPD from Revision 8 to Revision 18 to includes the following changes:

- QAPD revision log was added that provides the history of changes.
- Section 1.3, "Definitions," was revised to add 10 CFR Part 21.3 definitions related to commercial grade dedication of equipment, deleted the definition of safety-related structure, system, or component (SSC) and replaced it with the definition of safety-related items.
- Section 2.1, "Organization," was revised with roles and responsibilities changes that were administrative improvements.
- Section 3, "Facility Operations," was added to include a description of the operational quality assurance program.
- Enclosure 1, "Shine Functional Organization Chart," was revised to make it consistent with the information provided in Section 1.3 of the QAPD.
- Enclosure 2, "Graded Approach to Quality," was revised by deleting the definition of Quality Level-3.
- Enclosure 3, "Procedure that Implement the QAPD," was revised to include 5 implementing procedure numbers and their titles for SHINE and its contractor, Baker.
- Enclosure 3 was revised to identify additional procedures and to update procedure numbers and titles of SHINE's implementing procedures.

The NRC staff reviewed Section 1.3 where SHINE added definitions associated with commercial grade dedication of equipment. Specifically, the following definitions were added: basic component, commercial grade item, critical characteristics, dedication, and dedicating entity. The NRC staff review and approval of these SHINE specific definitions (in lieu of those required by 10 CFR 21.3) is documented in NRC Safety Assessment, dated April 30, 2021 (ADAMS Accession No. ML21076A519). Based on this review, the NRC staff concluded that the use of the SHINE-proposed definitions of commercial grade item, basic component, critical characteristics, dedication, and dedicating entity do not adversely affect public health and safety. Therefore, the use of commercial grade items by SHINE, which are properly dedicated, is acceptable. Further, the NRC staff considered the requirements of 10 CFR 21.7 and finds that granting this exemption from certain 10 CFR 21.3 definitions is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public's interest.

The NRC staff reviewed the addition of these definitions in Revision 18 of the QAPD and confirmed that these were the same as the definitions previously approved by the NRC in the safety assessment referenced above. Therefore, the NRC staff determined that SHINE's inclusion of definitions related to commercial grade dedication of equipment is adequate and acceptable.

Further, the NRC staff reviewed Section 1.3 where SHINE replaced the NRC's previously approved definition of 'safety-related system, structure or component' (SSC), with a definition of 'safety-related items,' consistent with the definition in ANSI/ANS 15.8-1995 (R2013), which the NRC has endorsed in RG 2.5, Revision 1. The NRC staff noted that the modified definition of safety-related items explicitly addresses items whose intended function is to prevent accidents that could cause undue risk to health and safety of workers and the public. While the revised definition no longer contains explicit thresholds in determining the acceptability of the consequences of a postulated event, SHINE has retained similar safety criteria for the classification of physical SSCs in the licensing basis, described in Section 3.1, "Design Criteria," of Chapter 3, "Design of Structures, Systems and Components," of the FSAR.

Based on its review, the NRC staff determined that SHINE's deletion of the definition of safety related SSC and replacing it with the definition of safety-related items is adequate and acceptable, because this definition is appropriate for the SHINE facility, which does not meet the definition of a 'power reactor,' and is consistent with the ANSI/ANS-15.8-1995 (R2013) which the NRC has endorsed in RG 2.5, Revision 1.

The NRC staff reviewed Section 2.1 where SHINE made the following administrative changes to reflect organizational changes which included: removing role of the Chief Financial Officer , removing role of the Director of Engineering Support and Auxiliary Systems and replacing it with the Engineering Support Manager , deleting Chief Operating Officer , adding Diagnostics General Manager , deleting Plant Manager, adding Director of Plant Operations , and adding Director of Corporate Support. Further changes include replacing the role of Director of Process Engineering with the role of Vice President of Engineering (VPE), and the VPE role reporting to the Chief Executive Officer, and the Director of Engineering Support and Auxiliary Systems reporting to the VPE; modifying the programmatic responsibility for Document Control and Records Management from the Director of Engineering Support to the Chief Operating Officer. Enclosure 1, "SHINE Functional Organizational Chart" of the QAPD was updated to reflect the administrative title changes. In addition, Enclosure 3, "Procedures that Implement the QAPD," was revised to identify additional procedures and update procedure numbers and titles of SHINE implementing procedures.

On the basis of its review, the NRC staff determined that SHINE's organizational changes are acceptable, as the changes represent administrative improvements with organizational revisions that continue to maintain persons and organizations performing quality assurance functions having the requisite authority and organizational freedom. The NRC staff determined that SHINE's modifications to Enclosure 3 are acceptable and additions are consistent with commitments made in previous revisions of the QAPD. The NRC staff noted that implementing procedures have been added to all activities included in Section 2 of the QAPD except for "Control of Special Processes." SHINE committed to develop an implementing procedure for this activity prior to the issuance of the operating license. The adequacy of the implementing procedures will be reviewed as part of the NRC staff's inspection of SHINE's implementation of the QAP.

The NRC staff notes that SHINE has not made any changes to Sections 2.2 through 2.18 of the QAPD. The NRC staff evaluation of Sections 2.2 through 2.18 of the QAPD is documented in a previous safety evaluation report (ML Accession No. ML15288A076) as part of their review of SHINE's construction permit application.

Section 3 of the SHINE QAPD describes the elements of a QA program for conduct of operations at the SHINE facility. The SHINE QAPD also establishes that some requirements of the QA program for operations may be found in other documents, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications, and the Radiation Protection Program, and would not be duplicated in the QA program. The NRC staff noted that there is no specific requirement to place these programs, plans or technical specifications in the QA program. SHINE has established their facility operations QA program based on ANSI/ANSI-15.8-1995 (R2013).

The NRC staff evaluated the sufficiency of the SHINE QA program controls for the conduct of operations at the SHINE facility, against applicable regulatory requirements using regulatory guidance and standards. On the basis of its review, the NRC staff has determined that the level of SHINE's commitment to establish a QA program for conduct of facility operations is adequate and supports acceptable criteria provided in Section 12.9 of NUREG -1537, Part 2, allowing the NRC staff to make a finding that the applicant's commitments to develop and conduct quality assurance activities provide reasonable assurance that the SHINE quality assurance program for the conduct of facility operations will comply with applicable requirements and is consistent with ANSI/ANS-15.8-1995 (R2013) guidance, endorsed in RG 2.5 Revision 1.

In Section 4, "Applicability to Existing Facilities," of the QAPD, SHINE stated that, "the SHINE facility will be a newly constructed facility and this section does not apply." The NRC staff determined that since SHINE facility will be a new facility, therefore, this section of the QAPD does not apply to SHINE facility.

In Section 5, "Decommissioning," of the QAPD, SHINE stated that this section would be updated at a later date. The NRC staff has deferred the review of this section until the receipt of an FSAR supporting a decommissioning application. Following receipt of the SHINE FSAR, the NRC staff will confirm that this issue has been resolved.

Based on the evaluation of SHINE QAPD, Revision 18, described in Subsection 12.9, "Quality Assurance," of Chapter 12, "Conduct of Operations," in SHINE's FSAR, the NRC staff determined that the QA program for operating license application follows the guidance contained within and conforms to the acceptance criteria of Section 12.9 of NUREG-1537, Part 2, and ANSI/ANS-15.8-1995 (R2013), endorsed by the NRC in RG 2.5, Revision 1. The NRC staff concludes that the SHINE QAPD, Revision 18, which includes all revisions after Revision 7, complies with the applicable program requirements of 10 CFR 50.34(b)(6)(ii) for the QA program used for the design, fabrication, construction, and operation of the SHINE facility.