

14.0 TECHNICAL SPECIFICATIONS

The principal purpose of the technical specifications (TSs) is to maintain system performance and safe operation. This is accomplished by addressing limiting or enveloping conditions of design and operation ensuring that emphasis is placed on the safety of the public, the facility staff, and the environment. TSs are typically derived from the facility descriptions and safety considerations contained in the safety analysis report (SAR).

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the probable subjects of TSs for the NWMI production facility, as presented in preliminary safety analysis report (PSAR) Chapter 14.0, Revision 3, "Technical Specifications," as supplemented by responses to requests for additional information (RAIs). As explained in SER Section 1.1, "Introduction," the NWMI application generally refers to the entire proposed building as the radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the RPF area where NWMI states that it plans to conduct Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing Of Production and Utilization Facilities," activities (and which encompasses most of the proposed building) as "the NWMI production facility" or "the facility" and the separate RPF area where NWMI states that it plans to conduct 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," activities as "the target fabrication area." The staff reviewed the entire application to understand the interface between and impact on the production facility activities from the target fabrication area activities, but its conclusions are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

14.1 Areas of Review

NWMI PSAR Chapter 14.0 describes the process by which the NWMI production facility TSs will be developed and written. NWMI did not develop TSs for the construction permit application, but states that it will provide these as part of its operating license (OL) application.

The staff reviewed NWMI PSAR Chapter 14.0 against applicable regulatory requirements using appropriate regulatory guidance and standards, to assess the sufficiency of NWMI's discussion of its preliminary TS methodology for the NWMI production facility for the purposes of issuance of a construction permit. Consistent with 10 CFR Part 50, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items which NWMI determined to be probable subjects of TSs for the facility, with special attention given to those items which may significantly influence the final design.

14.2 Summary of Application

As stated above and described in NWMI PSAR Chapter 14.0, the purpose of the TSs is to maintain system performance and safe operation emphasizing the safety of the public, the facility staff, and the environment.

NWMI PSAR Chapter 14.0 states that the format and content of the TSs for the NWMI production facility will be based on the guidance provided in American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.1-2007, (Reference 43) "The Development

of Technical Specifications for Research Reactors,” NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,” (Reference 8) and the “Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” (Reference 10). NWMI PSAR Chapter 14.0 also states that the TSs will be consistent with 10 CFR 50.34, “Contents of applications; technical information,” and will address the applicable paragraphs of 10 CFR Part 50.36, “Technical specifications.” Finally, the NWMI PSAR states that the TSs will be written in consideration of the differences between the NWMI production facility and either power or research reactors, such as that the NWMI production facility has items relied on for safety (IROFS) that the TSs will need to reflect. The NWMI production facility integrated safety analysis (ISA) process identified systems, structures, and components (SSCs) that are defined as IROFS, and the importance of these SSCs will need to be reflected in the TSs included in the OL application, in accordance with 10 CFR 50.36. Each IROFS will need to be examined and will likely become the subject of a limiting condition of operation (LCO) TS. The development of each IROFS into a TS will involve identifying the most appropriate specification to ensure operability, as well as corresponding surveillance periodicity for the specification.

NWMI PSAR Chapter 14.0 also states that the proposed TSs will form a comprehensive set of parameters to ensure that normal NWMI production facility operations will not result in off-site radiation exposures in excess of the guidelines in 10 CFR Part 20, “Standards for Protection against Radiation,” and also reasonably ensure that the facility will function as analyzed in the OL application. Adherence to the TSs will limit the likelihood of malfunctions and mitigate the consequences to the public of off-normal or accident events.

NWMI PSAR Chapter 14.0, Table 14-1, “Potential Technical Specifications,” lists items or variables that may be probable subjects of TSs for the NWMI production facility. This table includes systems and components for prevention of inadvertent criticalities, and the prevention or mitigation of events that may cause radiological or chemical exposures to the workers and the public with respect to the requirements of 10 CFR 70.61, “Performance requirements.” The table also identifies items which NWMI states will significantly influence the final design of the NWMI production facility. NWMI PSAR Chapter 14.0 further states that NWMI will submit formal TSs with the OL application as required by 10 CFR 50.36.

14.3 Regulatory Basis and Acceptance Criteria

Pursuant to 10 CFR 50.36(b), TSs, which are derived from the analyses and evaluations included in the SAR, are required to be included in each 10 CFR Part 50 license authorizing operation of a production facility. TSs are not required to be submitted with a 10 CFR Part 50 construction permit application, but pursuant to 10 CFR 50.34(a), a 10 CFR Part 50 construction permit application shall include an identification and justification of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probably subjects of TSs for the facility, with special attention given to those items which may significantly influence the final design.

The staff reviewed NWMI PSAR Chapter 14.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary TS methodology for the NWMI production facility for the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, “Issuance of construction permits,” a

construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

- (1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).
- (3) Safety features or components, if any, which require research and development have been described and identified by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
- (4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (Reference 10) and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (Reference 11). The staff's review in Chapter 2.0, "Site Characteristics," of this SER evaluated the geography and demography of the site; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the construction permit will not be inimical to public health and safety.

14.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the staff's evaluation of the NWMI production facility TS are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

14.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9).
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 10).
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that 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 safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, ANSI/ANS standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is based on the technical judgment of the

reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References" of this SER.

14.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the TS methodology presented in NWMI PSAR Chapter 14.0 to assess the sufficiency of the preliminary TS methodology for the NWMI production facility for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the NWMI production facility's TS methodology is determined by ensuring that the design and performance of the TS methodology meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 14.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in SER Section 14.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the TSs may be adequately described as probable subjects. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility based on the applicant's TS methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the NWMI production facility does not constitute approval of the safety of any design feature or specification. Such approval, if granted, will be after an evaluation of the final design of, and proposed TSs for, the NWMI production facility, as described in the FSAR as part of NWMI's OL application.

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which NWMI determined, as the result of its preliminary safety analysis and evaluation, to be probable subjects of TSs for the NWMI production facility, with special attention given to those items which may significantly influence the final design.

Consistent with the review procedures of NUREG-1537, Part 2, Chapter 14, "Technical Specifications," and the ISG Augmenting NUREG-1537, Part 2, Section 14b, "Radioisotope Production Facility Technical Specifications," the staff confirmed that NWMI states that TSs and bases will be determined, as appropriate, based on the IROFS that were derived from the ISA and are supported by appropriate references to PSAR analyses and statements. As discussed in SER Section 14.2, "Summary of Application," NWMI PSAR Chapter 14.0 states that the NWMI facility ISA process identified SSCs that are defined as IROFS. NWMI PSAR Chapter 14.0 further states that the importance of these SSCs will also need to be reflected in the TSs, that each IROFS will need to be examined and likely translated into an LCO TS, and that this translation will involve identifying the most appropriate LCO TSs to ensure operability of the SSCs, as well as a corresponding surveillance periodicity for each LCO TS. NWMI PSAR Chapter 14.0 also states that some IROFS could potentially become design features TSs requiring certain SSCs.

In SER Section 6.4.6, "Probable Subjects of Technical Specifications," the staff evaluates probable topics of TSs on criticality control and finds them acceptable.

In SER Section 7.4.7, "Probable Subjects of Technical Specifications," the staff evaluates probable topics of TSs on the criticality accident alarm system and finds them acceptable.

In SER Section 8.4.3, “Probable Subjects of Technical Specifications,” the staff finds that the applicant’s identification and justification for the uninterruptable power supply being the probable subject of a TS acceptable because of its required safety function to provide electrical power to engineering safety features, emergency lighting, radiation monitoring, and shutdown instrumentation and control during a loss of normal emergency power.

NWMI PSAR Chapter 13.0 provides detail on NWMI’s ISA process used to identify IROFS. The staff reviewed NWMI’s ISA process in Chapter 13.0 of this SER.

NWMI PSAR Chapter 14.0, Table 14-1 lists items or variables that may be probable subjects of TSs. This table includes SSCs for prevention of inadvertent criticalities and the prevention or mitigation of events that may cause radiological or chemical exposures to the workers and the public with respect to the requirements of 10 CFR 70.61. In the table, NWMI also identified items or variables which it states will significantly influence the final design of the facility, including uranium mass limits on batches, samples, and approved containers; spacing requirements on targets and containers with special nuclear material; floor and sump designs; hot cell liquid confinement; process tank size and spacing; air pressure differential between zones; ventilation system filtration; hot cell shield thickness and integrity; the hot cell secondary confinement boundary; and the stack height.

The PSAR also provided an outline for the TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, design features (including a site and facility description), LCOs, limiting safety system settings, safety limits, and surveillance requirements. In response to RAI 14.0-1 (Reference 31), NWMI stated that TSs on items involved with preventing release of radioactive materials routinely or in the event of an accident are planned for inclusion in sections of the FSAR that address LCOs and surveillance/maintenance as part of the OL application. The staff is tracking this issue in Appendix A, “Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments,” of this SER. The staff will perform a detailed review of the complete TSs for the NWMI production facility as part of its review of the NWMI OL application.

Based on the information provided in NWMI PSAR Chapter 14.0, as well as other chapters of the NWMI PSAR, the staff finds that NWMI has provided an identification and justification for the selection of those variables, conditions, or other items which are determined as the result of NWMI’s preliminary safety analysis and evaluation to be probable subjects of TSs, with special attention given to those items which may influence the final design, in accordance with 10 CFR 50.34(a)(5), and that NWMI’s identification and justification of the proposed TSs methodology is sufficient for the issuance of a construction permit. The staff also finds NWMI has stated that it will provide TSs for the proposed NWMI production facility with its OL, and the staff finds that this is acceptable, because 10 CFR 50.36(b) requires that operating licenses includes TSs, but 10 CFR 50.34(a) does not require TSs to be submitted with a construction permit application. Therefore, based on the above, the staff concludes that NWMI meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

14.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility’s TS, as described in NWMI PSAR Chapter 14.0 and other relevant chapters of the NWMI PSAR, and finds that the preliminary TS methodology meets all applicable regulatory requirements and

acceptance criteria in NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2. Based on these findings, the staff concludes the following regarding the issuance of a construction permit in accordance with 10 CFR Part 50:

- (1) NWMI has described the proposed design of the production facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) Such further technical or design information as may be required to complete the safety analysis of the NWMI production facility TSS, and which can reasonably be left for later consideration, will be supplied in the FSAR.
- (3) There is reasonable assurance that (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.