

15.0 FINANCIAL QUALIFICATIONS

Financial qualifications (FQs) establish whether an applicant is financially qualified to carry out the activities for which the permit or license is sought. If the application is for a construction permit, the applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle (here, low-enriched uranium (LEU)) costs.

This chapter of the safety evaluation report (SER) for the construction permit application of the Northwest Medical Isotopes, LLC (NWMI or the applicant) radioisotope production facility (RPF) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) review and evaluation of NWMI's FQs, as presented in Chapter 15.0, "Financial Qualifications," of the NWMI preliminary safety analysis report (PSAR), Revision 3 (Reference 60). As explained in SER Section 1.1.1, "Scope of Review," although NWMI states that it plans to conduct operations under separate licenses for both Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production And Utilization Facilities," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," activities within the RPF, the staff conclusions are limited to whether NWMI satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

15.1 Areas of Review

This SER Chapter provides the staff's evaluation of NWMI's FQs to construct its proposed RPF, as presented in NWMI PSAR Chapter 15.0, within which NWMI describes its financial ability to construct, operate, and decommission the NWMI RPF, and also provides information regarding foreign ownership, control, or domination (FOCD) and nuclear insurance and indemnity. Because NWMI PSAR Chapter 15.0 does not separate or distinguish between financial information related to 10 CFR Part 50 or 10 CFR Part 70 activities at the RPF, the staff's review evaluates the information provided for the entire RPF; however, as noted above, the staff conclusions are limited to whether NWMI satisfied the 10 CFR Part 50 requirements for the issuance of a construction permit.

Because NWMI proposes to construct a production facility and not a utilization facility, it does not have fuel cycle costs. However, the RPF will process LEU dissolved from irradiated targets. Therefore, the staff considered the cost of the LEU for the RPF in its first year of operation as part of this review.

The staff reviewed NWMI PSAR Section 15.1, "Financial Ability to Construct a Facility," against the applicable regulatory requirements at 10 CFR 50.33, "Contents of applications; general information," using regulatory guidance and standards to assess the sufficiency of the FQ of NWMI related to the construction of the proposed RPF. As part of this review, the staff evaluated information and discussions of NWMI's FQ, with special attention to the financial ability of the applicant to cover costs of construction. Areas of review for this section included estimates of construction costs, estimates of costs associated with the LEU used for targets, and the sources of funds to cover these costs. NWMI provided additional information related to its FQs to operate and decommission the NWMI RPF. This additional information is not required by 10 CFR 50.33(f)(1) for a construction permit applicant and is thus outside the scope of the FQs required for issuing a construction permit. Therefore, such information will be evaluated after NWMI submits an operating license (OL) application.

The staff reviewed NWMI PSAR Section 15.4, “Foreign Ownership, Control, or Domination,” against the applicable regulatory requirements at 10 CFR 50.38, “Ineligibility of certain applicants,” using regulatory guidance and standards to assess the sufficiency of NWMI’s application.

The staff reviewed NWMI PSAR Section 15.5, “Nuclear Insurance and Indemnity,” against the applicable regulatory requirements at 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements,” using regulatory guidance and standards to assess the sufficiency of NWMI’s application.

15.2 Summary of Application

NWMI PSAR Section 15.1 presents information related to NWMI’s financial ability to construct its proposed RPF, including the basis for NWMI’s conclusion that it possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated construction costs and related LEU costs. This section also provides budgetary estimates based on the preliminary design of the proposed NWMI RPF and states that NWMI has received committed sources of financing, including equity and debt, for a portion of its project.

NWMI PSAR Section 15.2, “Financial Ability to Safely Operate a Facility,” presents the basis for NWMI’s conclusion that it possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated operating costs for the period of the operating license. NWMI is anticipating to request an operating license with a period of 30 years. NWMI provides estimates for the total annual operating costs and expected revenues for each of the first 5 years of operation of the RPF from 2018 through 2022.

NWMI PSAR Section 15.3, “Financial Ability to Safely Decommission a Facility,” presents information indicating NWMI proposes to demonstrate how reasonable assurance will be provided that funds will be available to decommission the RPF.

NWMI PSAR Section 15.4, “Foreign Ownership, Control, or Domination,” presents information regarding the makeup of NWMI, from shareholders to board members.

NWMI PSAR Section 15.5, “Nuclear Insurance and Indemnity,” presents information indicating that NWMI is covered by the insurance and financial protection requirements of the Price-Anderson Act, pursuant to Section 170 of the Atomic Energy Act (AEA) of 1954, as amended.

15.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 15.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of NWMI’s FQ for the issuance of a construction permit under 10 CFR Part 50.

15.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of NWMI’s FQ are as follows:

- 10 CFR 50.33, “Contents of applications; general information.”

- 10 CFR 50.38, “Ineligibility of certain applicants.”
- 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR Part 50, Appendix C, “A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses.”

15.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its 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 10 CFR regulatory requirements, 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 [ISG] 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).

15.4 Review Procedures, Technical Evaluation, and Evaluation Findings

In order to demonstrate FQ, an applicant for a construction permit must submit estimates of the total construction costs of the RPF and related fuel cycle costs, must indicate the source(s) of funds to cover these costs, must demonstrate that the applicant is not ineligible to apply for a construction permit because of FOCD, and must address financial protection and indemnity. The staff performed an evaluation of the financial information presented in NWMI PSAR Chapter 15.0 to assess the sufficiency of NWMI’s FQ for the issuance of a construction permit against these requirements. The sufficiency of NWMI’s FQ information is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 15.3, “Regulatory Basis and Acceptance Criteria,” of this SER. The results of this technical evaluation are summarized in SER Section 15.5, “Summary and Conclusions.”

15.4.1 Financial Ability to Construct a Facility

The staff evaluated the sufficiency of NWMI's financial ability to cover construction costs of the RPF and related fuel cycle costs (i.e., LEU material costs), as described in NWMI PSAR Section 15.1 using the guidance and acceptance criteria from Section 15.1, "Financial Ability to Construct a Non-power Reactor," of NUREG-1537, Parts 1 and 2, and the ISG Augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 15.1, the staff evaluated the applicant's estimates of construction cost, including plant equipment and LEU material costs. The estimates provided in the PSAR are based on NWMI's proposed design of the RPF completed in May 2015.

Pursuant to 10 CFR 50.33(f)(1) and 10 CFR Part 50, Appendix C, Section I.A.1, "Estimate of construction costs," the applicant outlined the projected costs for the construction of the proposed medical isotope production facility.

According to the application, the estimate covers all components of the project, including engineering and construction equipment, materials, and labor. NWMI incorporated data from similar projects and a preliminary RPF time-cycle logistical study that includes data for labor requirements, materials, operations, and maintenance as the bases of the cost estimate. The estimate also used inputs based the project schedule and site conditions. Based on a detailed review of the cost to construct the facility and the supporting bases and assumptions, the staff finds that the applicant provided the total construction and LEU costs, as required by 50.33(f)(1), and a reasonable basis for the applicant's cost estimate.

As required by 10 CFR 50.33(f)(1) and (f)(4), the applicant must indicate the source(s) of funds to cover estimated construction costs and LEU (or special nuclear material) costs and, as a newly-formed entity, describe (a) its legal and financial relationships with its stockholders or owners, and (b) the stockholders' or owners' financial ability to meet any contractual obligations incurred or proposed to be incurred. As described in NWMI's PSAR Section 15.1, and General Information section of Part 1 of its application (Reference 67), NWMI is a limited liability corporation and a newly-formed entity that has established a wholly owned subsidiary for the RPF (which includes the production facility). Consistent with guidance in 10 CFR Part 50, Appendix C, II.A.2, "Source of construction funds," NWMI expects the source of funds for 100 percent of the construction costs to be debt financing. The applicant's reliance on debt financing through an established subsidiary is consistent with, and satisfies the criteria provided in 10 CFR Part 50, "Appendix C - A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses," II. "Applicants Which Are Newly Formed Entities." In addition, the applicant's ability to obtain equity financing and commitments for initial research and development, preliminary design, regulatory, and permitting cost projections, supports the conclusion that NWMI, through its subsidiary, has reasonable assurance of obtaining the funds necessary to cover estimated construction costs for this project.

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on NWMI's FQ for construction is reasonable and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 15.1, and the ISG Augmenting NUREG-1537, Part 2, Section 15.1, allowing the staff to make the following findings: (1) the applicant supplied financial information regarding construction and related fuel cycle costs (i.e., LEU material

costs) and the source of funds to cover these costs; and (2) there is reasonable assurance of the applicant obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs (i.e., LEU material costs).

Therefore, the staff concludes that NWMI's FQ for construction, as described in NWMI PSAR Section 15.1, meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

15.4.2 Financial Ability to Operate a Facility

In NWMI PSAR Section 15.2, the applicant addressed its financial ability to operate the proposed NWMI RPF. As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). The information NWMI provided related to its financial ability to operate the proposed NWMI RPF is outside the scope of FQs necessary for issuing a construction permit and, therefore, will be evaluated after NWMI submits an OL application.

15.4.3 Financial Ability to Decommission a Facility

In NWMI PSAR Section 15.3, the applicant addressed its financial ability to decommission the proposed NWMI RPF. As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). The information NWMI provided related to its financial ability to decommission the proposed NWMI RPF is outside the scope of the FQs necessary for issuing a construction permit and, therefore, will be evaluated after NWMI submits an OL application.

15.4.4 Foreign Ownership, Control, or Domination

The staff evaluated the sufficiency of NWMI's description of FOCD considerations, as presented in NWMI PSAR Section 15.4, using the regulations at 10 CFR 50.33(d) and 10 CFR 50.38 and guidance and acceptance criteria from Section 15.4, "Foreign Ownership, Control, or Domination (FOCD)," of the ISG Augmenting NUREG-1537, Parts 1 and 2. As stated in 10 CFR 50.38, any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.

Consistent with 10 CFR 50.33(d) and 10 CFR 50.38, along with the guidance in the ISG Augmenting NUREG-1537, the staff confirmed whether the application included a statement as to whether the applicant is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

The NWMI PSAR states that NWMI is a limited liability company formed under the laws of the state of Oregon with its headquarters located in Corvallis, Oregon. NWMI intends to construct and operate the NWMI RPF in Columbia, Missouri, at Discovery Ridge Research Park, which is owned and managed by the University of Missouri - Columbia. NWMI business operations are managed under the direction of a Board of Managers, consisting of six managers and two

executive officers, as well as through the officers of NWMI.¹ All managers and officers are citizens of the United States.

Furthermore, NWMI states that it is not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. In addition, NWMI is not acting as an agent or representative of another person in filing the construction permit application.

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on FOCD considerations is reasonable and satisfies the requirements of 10 CFR 50.33(d) and 10 CFR 50.38. Specifically, the staff finds that NWMI is not a citizen, national, or agent of a foreign country, or any corporation, or other entity, which the staff knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

Therefore, the staff concludes that NWMI's FOCD considerations, as described in NWMI PSAR Section 15.4, meet the applicable regulatory requirements and guidance for the issuance of a construction permit for the production facility in accordance with 10 CFR Part 50.

15.4.5 Nuclear Insurance and Indemnity

The staff evaluated the sufficiency of NWMI's nuclear insurance and indemnity considerations, as described in NWMI PSAR Section 15.5, using the guidance and acceptance criteria from Section 15.5, "Nuclear Insurance and Indemnity," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 170, "Indemnification and Limitation of Liability," of the AEA, as implemented in the regulations of 10 CFR Part 140, requires that a construction permit is conditioned such that an operating license will not be issued by the Commission unless NWMI submits proof of financial protection and executes an indemnity agreement.

As stated above, areas of review for FQ for a construction permit are estimates of construction and related fuel cycle costs and the sources of funds to cover these costs as required by 10 CFR 50.33(f)(1). At this time, NWMI has not requested a license to operate a 10 CFR Part 50 facility. The staff will evaluate information NWMI provides related to nuclear insurance and indemnity with respect to its 10 CFR Part 50 facility if NWMI submits an OL application.

15.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of NWMI FQ, as described in Chapter 15.0 of the NWMI PSAR, and finds that: (1) NWMI supplied financial information for construction and related LEU material costs, (2) there is reasonable assurance that NWMI can obtain the funds necessary to cover estimated construction and related LEU material costs, and (3) the financial status of the applicant regarding construction and related LEU material costs is in accordance with the requirements of 10 CFR 50.33(a) and (f) and Appendix C of 10 CFR Part 50. Therefore, NWMI meets all applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537. The staff also finds that NWMI is not subject to FOCD, as required by 10 CFR 50.38, and that NWMI provided sufficient information

¹ The names and addresses of the members of the NWMI Board of Managers are included in Part 2 of the construction permit application (Agencywide Documents Access and Management System Accession No. ML15210A112).

regarding nuclear indemnity and insurance for the purposes of a construction permit where no materials license is held.

Therefore, as required by 10 CFR 50.40(b), the staff concludes that NWMI demonstrated the requisite FQ to engage in the proposed activities for the issuance of a construction permit for a production facility in accordance with the regulations in 10 CFR Part 50.