



August 9, 2013  
NWMI-LTR-007

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
11555 Rockville Pike  
Washington, DC 20555

PROJ 803

RE: REQUEST FOR EXEMPTION TO SUBMIT A CONSTRUCTION PERMIT APPLICATION IN TWO PARTS AS DESCRIBED IN 10 CFR 2.101 BY NORTHWEST MEDICAL ISOTOPES, LLC

The purpose of this letter is to request an exemption under 10 CFR 50.12 to submit a Construction Permit Application in two parts for the Northwest Medical Isotopes, LLC, (NWMI) radioisotope production facility (RPF). NWMI believes that our request meets the requirements for an exemption under 10 Code of Federal Regulations (CFR) 50.12 because the requested exemption is authorized by law, does not present an undue risk to the public health and safety, will not endanger the common defense and security, and because special circumstances are present such that the exemption should be granted. Thus, the requested exemption would allow NWMI to submit a Construction Permit Application for a RPF in two parts in accordance with the provisions of 10 CFR 2.101(a)(5).

For the first time since the late 1980s, the United States has the opportunity to produce a domestic, securable, and reliable source of molybdenum-99 ( $^{99}\text{Mo}$ ). NWMI intends to design and construct a RPF and intends to produce  $^{99}\text{Mo}$ , the parent isotope of the most commonly used nuclear medicine imaging isotope, technetium-99 ( $^{99\text{m}}\text{Tc}$ ) by 2016. NWMI will cost-effectively address the  $^{99}\text{Mo}$  market and provide approximately 50% of the  $^{99}\text{Mo}$  domestic need.  $^{99}\text{Mo}$  is created in nuclear reactors through the irradiation of low enriched uranium (LEU) targets. Once the LEU targets are irradiated, they are dissolved into solution and the  $^{99}\text{Mo}$  is then separated and purified.

#### **Proposed Exemption**

Per the U.S. Nuclear Regulatory Commission (NRC), NWMI must apply for an exemption under 10 CFR 50.12 in order to submit its Construction Permit Application in two parts.<sup>1,2</sup> To submit a Permit Construction Application (per 10 CFR 50) in two parts [per 10 CFR 2.101(a)(5)], the proposed facility must be subject to 10 CFR 51.20(b) which identifies the types of actions that require an environmental impact statement (EIS). NWMI believes that construction and operation of a RPF does not require an EIS under 10 CFR 51.20(b); therefore, 10 CFR 2.101(a)(5) does not apply to such facilities.

Submitting an application in two parts would allow the NRC to commence review of the Environmental Report (Chapter 19) and allow for an earlier determination as to whether an EIS is required, allowing a potential earlier completion of the environmental review and ultimate issuance of the Construction Permit and initiating construction of NWMI's RPF. NWMI believes that our request meets the requirements of 10 CFR 50.12 stating that the NRC may grant an exemption from requirements of the regulations provided that it meets the following requirements:

<sup>1</sup> U.S. Nuclear Regulatory Commission Research and Test Reactor Licensing Branch (S.T. Lynch, M.H. Voth, and L.N. Tran), *Regulatory Preparations for Licensing Medical Radioisotope Production Facilities*, 2013, Rockville, MD

<sup>2</sup> Letter from U.S. Nuclear Regulatory Commission (T.J. McGinty) to University of Missouri (R. Butler), December, 2012, *University of Missouri-Columbia – Clarification on the Application of 20 CFR 2.101(a)(5) to Proposed Medical Isotope Production Facilities Regarding Two-Part Construction Permit Application Submittals*, Rockville, MD

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1. *The requested exemption is authorized by law.* No law exists which precludes the activities covered by this exemption request. The NWMI RPF will be licensed under Section 103 of the Atomic Energy Act of 1954 (AEA), 42 U.S.C. § 2133, as amended. Nothing in AEA § 103 prohibits the submittal of a Construction Permit Application for a Class 103 facility in multiple parts, nor does any other statute. The NRC has promulgated 10 CFR 2.101(a)(5) to authorize certain types of Construction Permit applicants to submit their application in multiple parts, including Class 103 facilities under 10 CFR 50.22, confirming that this process is not prohibited by statute. As explained in item 4 below, the regulatory history of 10 CFR 2.101(a)(5) suggests that the reason medical isotope production facilities have been omitted from this authorization is because the need for such an option has not previously arisen. This exemption request does not change the quality or content of the Environmental Report or the PSAR, and is administrative in nature. Therefore, the requested exemption is authorized by law.
2. *The requested exemption does not present an undue risk to the public health and safety.* No risk to public health and safety is presented by the requested exemption. NWMI will satisfy all of the substantive licensing criteria in 10 CFR 50 and 51 in its full Construction Permit Application. The NRC will have the necessary time to conduct a complete environmental review and safety of the Construction Permit Application as well as the required NRC public participation. The NRC will not issue the Construction Permit until it makes the requisite findings under both 10 CFR 50 and 51. Accordingly, granting the exemption will not interfere with the licensing or public participation process in any respect.
3. *The requested exemption will not endanger the common defense and security.* The NRC's substantive requirements for a Construction Permit will be fully met in NWMI's application. The submittal of the application for a Construction Permit in two parts will in no way affect the security or safeguards features or programs at the facility at any point during construction or operation. Accordingly, the granting of the requested exemption is consistent with the common defense and security.
4. *Special circumstances, as defined in 10 CFR 50.12(a)(2), are present.* NWMI feels that our request meets the special circumstances defined in 10 CFR 50.12(a)(2)(ii) and (iv).

*10 CFR 50.12(a)(2)(ii) — Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.* The requested exemption meets these special circumstances because a strict application of 10 CFR 2.101(a)(5) would not serve the underlying purpose of the rule. The authorization to submit certain Construction Permit Applications in two parts, up to six months apart, dates to 1974, when the Atomic Energy Commission (AEC) authorized the separate submittal of the PSAR and environmental report for nuclear power reactors under 10 CFR 2.101(a) and was later modified to link the authorization to submit a Construction Permit Application in multiple parts to facilities for which an EIS must be prepared, and this link was carried forward when 10 CFR 2.101(a)(5) was first promulgated in 1976. The current 10 CFR 2.101(a)(5) allows Construction Permit applicants to submit their application in two parts, but only when the application is for certain facilities where an EIS is required.

*10 CFR 50.12(a)(2)(iv) — The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption.* In publishing the original 1974 rule authorizing, in 10 CFR 2.101(a), the submittal of Construction Permit Applications for nuclear power reactors in two parts, the AEC noted that at that time, there was "deep national concern over energy sources and supply," and that the amendments were intended to "reduce the time required to bring on line nuclear power plants which satisfy all environmental and safety requirements." Further, there was a public interest in "removing unnecessary obstacles" to the construction of needed power plants.



NWMI's requested exemption meets the special circumstances of 10 CFR 50.12(a)(2)(iv) because the granting of an exemption here is in the public interest. As previously noted, the demand for medical isotopes is a significant national public health and safety concern. This concern is similar to the AEC's concerns regarding the need for nuclear power reactors at the time the two-part process was established.

Therefore, in accordance with the provisions of 10 CFR 50.12, NWMI requests an exemption to allow submittal of a Construction Permit Application for a RPF in two parts in accordance with the provisions of 10 CFR 2.101(a)(5). These provisions state that one part of the submittal must include the environmental report required by 10 CFR 50.30(f), while the other part must include the PSAR required by 10 CFR 50.34(a).

Below presents the information that NWMI proposed to include in each part of the Construction Permit Application:

- Construction Permit Application, Part 1:
  - Description and Safety Assessment of the site required by 10 CFR 50.34(a)(1)
  - Environmental Report required by 10 CFR 50.30(f)
  - Filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21
  - General information required by 10 CFR 50.33
  - Agreement limiting access to classified information required by 10 CFR 50.37.
- Construction Permit Application, Part 2:
  - Remainder of PSAR required by 10 CFR 50.34(a)
  - Application will be submitted in accordance with requirements of 10 CFR 2.101(a)(5).

Based on the above, special circumstances are present that fully support the request for an exemption to submit a Construction Permit in two parts to be granted under 10 CFR 2.101. Approval of the Exemption Request is requested by October 10, 2013. This letter contains no new Regulatory Commitments and no revisions to existing Regulatory Commitments.

If you have any questions, please contact Ms. Carolyn Haass, Technical Program Director, on 509-430-6921.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicholas Fowler", is written over a horizontal line.

Nicholas Fowler  
Chief Executive Officer

cc: Steve Lynch, Project Manager,  
Research and Test Reactors Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation