


United States Nuclear Regulatory Commission Official Hearing Exhibit		
In the Matter of:	NORTHWEST MEDICAL ISOTOPES, LLC (Medical Radioisotope Production Facility)	
	<b>Commission Mandatory Hearing</b>	
	Docket #: 05000609	Identified: 1/23/2018
	Exhibit #: NWMI-010-MA-CM01	Withdrawn:
	Admitted: 1/23/2018	Stricken:
	Rejected:	
Other:		

Exhibit NWMI-010

December 18, 2017  
NWMI-LTR-2017-016

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

Mr. Michael Balazik  
Research and Test Reactors Branch A  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

RE: EXEMPTION REQUEST PURSUANT TO 10 CFR 70.17, FROM REQUIREMENT OF 10 CFR 70  
21(F), "*FILING*," FOR NORTHWEST MEDICAL ISOTOPES, LLC RADIOISOTOPE  
PRODUCTION FACILITY

**References:**

1. Northwest Medical Isotopes, LLC Letter NWMI-LTR-007 to U.S. Nuclear Regulatory Commission, "Request for Exemption to Submit a Construction Permit Application in Two Parts as Described In 10 CFR 2.101," dated August 9, 2013 (ADAMS Accession No. ML13227A295)
2. U.S. Nuclear Regulatory Commission Letter to Northwest Medical Isotopes, LLC, "Acceptance Letter for Northwest Medical Isotopes, LLC Regarding Request for Exemption from the Requirements of 10 CFR 2.101(a)," dated August 22, 2013 (ADAMS Accession No. ML13238A034)
3. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2015-003 to U.S. Nuclear Regulatory Commission, "NRC Project No. 0803 – Northwest Medical Isotopes, LLC, Submittal Part 1 Construction Permit Application for a Radioisotope Production Facility...", dated February 5, 2015, (ADAMS Accession No. ML15086A262, ML15210A123, ML15210A128, ML15210A129, and ML15210A131)
4. U.S. Nuclear Regulatory Commission Letter to Northwest Medical Isotopes, LLC, "Northwest Medical Isotopes, LLC – Acceptance for Docketing of Part One of The Application for Construction Permit (TAC No. MF6135)," dated June 1, 2015 (ADAMS Accession No. ML15125A048)
5. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2015-006 to U.S. Nuclear Regulatory Commission, "NRC Project No. 0803 – Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility," dated July 20, 2015 (ADAMS Accession No. ML15210A114 and Package ML15210A182)
6. U.S. Nuclear Regulatory Commission, NUREG-2209, *Final Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility*, dated May 31, 2017 (ADAMS Accession No. ML17130A862)
7. Northwest Medical Isotopes, LLC Letter to U.S. Nuclear Regulatory Commission, "Docket No. 50-609, Northwest Medical Isotopes, LLC, Transmittal of Revision 3 of Chapters 1.0 through 18.0 of NWMI-2013-021, *Construction Permit Application for Radioisotope Production*," dated September 8, 2017 (ADAMS Accession No. ML17257A019)
8. U.S. Nuclear Regulatory Commission, *Safety Evaluation Report Related to the Northwest Medical Isotope, LLC Construction Permit Application for a Production Facility*, Docket No. 50-609, dated November 2017 (ADAMS Accession No. ML17310A368)

Dear Mr. Balazik:

Pursuant to Title 10, *Code of Federal Regulations*, Part 70.17 (10 CFR 70.17), Northwest Medical Isotopes, LLC (NWMI) submits this exemption request from the requirement of 10 CFR 70.21(f), “Filing,” for the NWMI Radioisotope Production Facility (RPF).

*(f) An application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.*

Below is the basis for this exemption request.

NWMI applied to the U.S. Nuclear Regulatory Commission (NRC) to obtain a license for a production facility under 10 CFR 50, “Domestic Licensing of Production and Utilization Facilities.” The 10 CFR 50 license application for the RPF is being prepared following the guidance in NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*. The NRC has determined that a radioisotope separation and processing facility, which also conducts separation of special nuclear material (SNM), will be considered a production facility and as such, will be subject to licensing under 10 CFR 50.

Additional RPF operational activities are subject to other NRC regulations, including 10 CFR 70, “Domestic Licensing of Special Nuclear Material,” to receive, possess, use, and transfer SNM, and 10 CFR 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” to process and transport <sup>99</sup>Mo for medical applications. RPF operations will also include the fabrication of LEU targets, which will be licensed under 10 CFR 70 (applied for under a separate license application submittal). These targets will be shipped to NWMI’s network of research or test reactors for irradiation (considered a connected action) and returned to the RPF for processing. Any byproduct materials produced or extracted in the RPF will be licensed under 10 CFR 30.

NWMI was granted an exemption from certain requirements of 10 CFR 2.101(a)(5), “Filing of Application,” by the Commission to submit our construction permit application in two parts (References 1 and 2). This exemption was published in the Federal Register (FR) on October 24, 2013 (78 FR 63501).

NWMI submitted Part One of a two-part application for a construction permit on February 5, 2015 (Reference 3), to allow the construction of the RPF in Columbia, Missouri. The NRC acknowledged receipt of Part One of the application for a construction permit under 10 CFR 50 in a notice published in the FR on April 21, 2015 (80 FR 22227). A notice of docketing was published in the FR on June 8, 2015 (80 FR 32418) (ADAMS Accession No. ML15125A048) (Reference 4).

In accordance with Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. [United States Code] § 4332(2)(C)) and implementing NRC regulations in 10 CFR 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” the NRC prepared a EIS. The NRC conducted an independent evaluation of the Part One construction permit application, and information developed independently by the NRC staff of the potential impacts of the proposed action on the quality of the human environment and reasonable alternatives to NWMI’s proposal.

Before development of the Draft EIS, the staff published a notice of intent to prepare an EIS and invited the public to provide information relevant to the environmental review at a scoping meeting held on December 8, 2015, in Columbia, Missouri. The NRC also provided opportunities for governmental and general public participation during the public comment period and meeting on December 6, 2016, in Columbia, Missouri, on the Draft EIS, and used publicly available guidance in the development of its Final EIS. The Final EIS, published as NUREG-2209, *Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes*

*Radioisotope Production Facility*, on May 31, 2017 (ADAMS Accession No. ML17130A862) (Reference 6), addressed comments received and meets the requirements of 10 CFR 51.

NWMI submitted Part Two of the construction permit application on July 20, 2015 (ADAMS Accession No. ML15210A114) which provided the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a) (Reference 5). NWMI updated the Part Two construction permit application, which incorporated all responses to NRC requests for additional information, and submitted the revised application on September 8, 2017 (ADAMS Accession No. ML17257A019) (Reference 7). The NRC issued their final Safety Evaluation Report for the NWMI RPF construction permit application in November 2017 (ADAMS Accession No. ML17310A368) (Reference 8).

NWMI intends to submit one integrated Operating Licensing Application (OLA) for the entire RPF which will cover both 10 CFR 50 and 10 CFR 70 activities. This OLA will be submitted to the NRC in 3<sup>rd</sup> quarter of 2018.

NRC's proposed action in the NUREG-2209 (page xxi and xxii) was the following:

*The proposed Federal action is for the NRC to decide whether to issue a construction permit under 10 CFR Part 50 that would allow construction of the NWMI medical radioisotope production facility. If the NRC were to issue a construction permit, NWMI could build the proposed facility at the 7.4-acre (3-hectare) Discovery Ridge site, in Boone County, Columbia, Missouri. The NWMI process would involve fabricating low-enriched uranium (LEU) targets, shipping targets to university research reactors, irradiating LEU targets at university research reactors, returning targets to NWMI, LEU target dissolution, and molybdenum-99 (Mo-99) recovery and purification.*

In addition, NRC's recommendation in NUREG-2209 (page xxiv) was the following:

*After weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, the NRC staff's recommendation, unless safety issues mandate otherwise, is the issuance of a construction permit to NWMI.*

Thus, pursuant to 10 CFR 50.12, NWMI is requesting an exemption from 10 CFR 70.21(f) due the following environmental activities being completed for the RPF regardless of which NRC regulatory license is required to be obtained (e.g., 10 CFR 50, 10 CFR 70).

- NWMI submitted the required documents under 10 CFR 51, Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)" (e.g., Environmental Report, Site Characteristics) (ADAMS Accession No. ML15086A262) (Reference 3)
- NRC published the Final EIS for NWMI's RPF on May 31, 2017 (NUREG-2209, ADAMS Accession No. ML17130A862) (Reference 6).

This exemption request from 10 CFR 70.21(f) will enable NWMI to initiate construction of the RPF, including 10 CFR 70 components (e.g., target fabrication), upon authorization of our 10 CFR 50 construction permit application. Specifically, the exemption will allow NWMI to initiate construction of 10 CFR 70 components without waiting 9 months after submission of the required Environmental Report (ER), since the ER was covered under the NRC environmental review for the 10 CFR 50 construction permit application. In addition, 10 CFR 70.23(a)(7) requirements are met, as the NRC, through the final EIS, determined that NWMI RPF activities (including target fabrication) will not "affect the quality of the environment after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives." The NRC action called for the issuance of the proposed license under 10 CFR 50, without any conditions to protect environmental values. Thus, commencement of RPF construction can be initiated with the approval of NWMI's 10 CFR 50 construction permit application.

NWMI requests approval of this proposed exemption since it "will not endanger life or property or the common defense and security and are otherwise in the public interest" per 10 CFR 70.17 which is supported by the issuance of the Final EIS (NUREG-2209, ADAMS Accession No. ML17130A862) (Reference 6). In addition,

NWMI requests approval of this exemption by March 31, 2018 to support initiation of RPF construction in late second quarter 2018.

There are no new regulatory commitments made within this submittal.

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury.  
Executed on December 20, 2017.

If you have questions, I can be reached at (509) 430-6921 or carolyn.haass@nwmedicalisotopes.com.

Sincerely,

A handwritten signature in cursive script that reads "Carolyn C. Haass". The signature is written in dark ink on a white background.

Carolyn C. Haass  
Chief Operating Officer

cc: Mr. Alexander Adams, Office of Nuclear Reactor Regulation  
Mr. David Drucker, Office of Nuclear Reactor Regulation  
Mr. David Tiktinsky, Office of Nuclear Material Safety and Safeguards