



March 12, 2018
NWMI-LTR-2018-001

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

PROJ0803

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

RE: SUPPLEMENTAL INFORMATION QUESTION – 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-2017-016 to U.S. Nuclear Regulatory Commission, “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” dated December 18, 2017 (ADAMS Accession No. ML13227A295)
2. U.S. Nuclear Regulatory Commission, NUREG-2209, *Environmental Impact Statement for Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility, Final Report*, dated May 31, 2017 (ADAMS Accession No. ML17130A862)
3. 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:

Per your email on February 15, 2018, Northwest Medical Isotopes, LLC (NWMI) is responding to your request for supplemental information on our request for an exemption from 10 CFR 70.21(f), “Filing” for the target fabrication portion of the NWMI Radioisotope Production Facility (RPF).

The purpose, background, discussion, and action for this letter is provided below.

Purpose: The purpose of this letter is to supplement the NWMI letter, NWMI-LTR-2017-016 (Reference 1), to the U.S. Nuclear Regulatory Commission (NRC) requesting approval of an exemption to waive the 9 months requirement for the NRC to complete an environmental review of the proposed 10 CFR 70 activities associated with the NWMI RPF prior to commencement of construction of the RPF 10 CFR 70 components.

Background: NWMI requested an exemption from 10 CFR 70.21(f) in December 2017 (Reference 1). The NRC staff determined that additional information was needed to make a final decision on this exemption request. Specifically, NWMI is requesting an exemption “to waiting at least 9 months prior to commencement of construction of the RPF 10 CFR 70 components (i.e., target fabrication).”

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The NRC previously conducted a comprehensive environmental review, including consideration of environmental impacts from proposed 10 CFR 70 activities, as part of our 10 CFR 50 Construction Permit Application review (Reference 2). When NWMI submits the Operating License Application for both the 10 CFR 50 and 10 CFR 70 portions of the RPF, the NRC staff will be able to complete an additional review of the Environmental Report required by 10CFR 70.21(f) for any significant new information.

Discussion: Attachment A provides additional detail on the exemption description, justification for the proposed exemption request, and NWMI's determination that the proposed exemption request is not significant.

Action: NWMI requests approval of this proposed exemption per 10 CFR 70.17, which is supported by the issuance of the Final EIS (NUREG-2209, ADAMS Accession No. ML17130A862) (Reference 2). There are no new regulatory commitments made within this submittal.

NWMI requests approval of this exemption by March 31, 2018 per NWMI-LTR-2017-016.

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

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury. Executed on March 12, 2018.

Sincerely,


Carolyn C. Haass
Chief Operating Officer

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

ATTACHMENT A

Exemption Request Pursuant to 10 CFR 70.17
from Requirement of 10 CFR 70.21(f)

Detailed Description, Justification for Change,
and Significance Determination

Detailed Description of Change

Pursuant to Title 10, *Code of Federal Regulations*, Part 70.17 (10 CFR 70.17), Northwest Medical Isotopes, LLC (NWMI) submitted an exemption request from the requirement of 10 CFR 70.21(f), “Filing,” for the 10 CFR 70 components of our Radioisotope Production Facility (RPF) (NWMI-2017-LTR-016¹). Specifically, this exemption request to forgo the submission of the Operating License Application (OLA) and associated Environmental Report at least 9 months prior to the commencement of construction will enable NWMI to initiate construction of the entire RPF, including 10 CFR 70 components (e.g., target fabrication), upon U.S. Nuclear Regulatory Commission (NRC) issuance of the 10 CFR 50 construction permit.

The NRC previously conducted a comprehensive environmental review, including consideration of environmental impacts from proposed 10 CFR 70 activities, as part of our 10 CFR 50 Construction Permit Application review. When NWMI submits the OLA for both the 10 CFR 50 and 10 CFR 70 portions of the RPF, the NRC staff will be able to review the Environmental Report required by 10 CFR 70.21(f) for any significant new information. Thus, the environmental review of the 10 CFR 70 portions of the RPF (i.e., target fabrication) would update the environmental review of 10 CFR 70 activities documented in the 10 CFR 50 Construction Permit environmental impact statement (EIS).²

Based on this Environmental Report, the NRC prepared an EIS 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 staff conducted an independent evaluation of the Environmental Report (ER), documented the information developed independently by the NRC staff on the potential impacts of the proposed action on the quality of human health and the environment, and identified reasonable alternatives to NWMI’s proposal.

Before development of the Draft EIS, the NRC 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),² addressed comments received and meets the requirements of 10 CFR 51.

Justification for Change

On December 18, 2017, NWMI submitted an exemption request from 10 CFR 70.21(f), specifically to forgo the requirement to submit the OLA and associated Environmental Report at least 9 months prior to the commencement of construction of the RPF, including 10 CFR 70 components (e.g., target fabrication).¹ This exemption request will enable NWMI to initiate construction of the entire RPF upon NRC issuance of the 10 CFR 50 construction permit.

¹ Northwest Medical Isotopes, LLC Letter NWMI-LTR-2017-016 to U.S. Nuclear Regulatory Commission, “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” dated December 18, 2017 (ADAMS Accession No. ML13227A295)

² NUREG-2209, *Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility, Final Report*, U.S. Nuclear Regulatory Commission, Washington, D.C., May 31, 2017 (ADAMS Accession No. ML17130A862).

10 CFR 70.17 allows the Commission, on its own initiative or at the request of NWMI, to grant exemptions from the requirements of 10 CFR 70, “as it determines are authorized by law and will not endanger life, or property, or the common defense and security, and are otherwise in the public interest.” The public record showing that NRC has previously granted exemption requests for other facilities to reschedule biennial emergency preparedness exercises confirms that this exemption request is authorized by law.

Granting this exemption request will not endanger life or property or the common defense and security of the facility since NWMI has not yet started construction or operation of the RPF. Additionally, there are no radiological hazards at the RPF site that require an active item relied on for safety (IROFS).

The proposed exemption request will not impact the design function, or method of performing or controlling design functions, structures, systems, and components, nor will the change decrease the effectiveness of any program since the OLA has not yet been submitted for the RPF. In addition, this proposed exemption request does not create any new accident initiators, new accident sequences, or result in an increase in the radiological or chemical consequences of accident scenarios. Therefore, the proposed exemption request does not adversely affect safety or the initiation of construction of the RPF. The OLA will be a combined application for both 10 CFR 50 and 10 CFR 70 components.

Finally, granting this exemption request is in the public interest because it allows for the construction of the RPF to support the domestic production of molybdenum-99 (⁹⁹Mo), which is a critical medical imaging agent needed to perform approximately 50,000 medical procedures daily in the United States. Global shortages of medical radioisotopes, especially ⁹⁹Mo, in the last decade have highlighted the need for prompt action to ensure a reliable domestic supply.

Significance Determination

NWMI is requesting the proposed exemption request to forgo the submission of the OLA and associated Environmental Report to the NRC at least 9 months prior to the commencement of construction, which will enable NWMI to initiate construction of the entire RPF, including 10 CFR 70 components (e.g., target fabrication), upon issuance of the 10 CFR 50 construction permit. This exemption request is based on the following:

1. **No significant changes to identified impacts in the EIS** – The proposed exemption request to forgo the 9-month review period prior to commencement of construction of the RPF, including 10 CFR 70 components, after the OLA is submitted does not make significant changes to any identified impacts in the NWMI RPF EIS.²

The NRC staff has already conducted a comprehensive environmental review, including consideration of environmental impacts from proposed 10 CFR 70 activities, as part of the NWMI 10 CFR 50 Construction Permit Application review. When NWMI submits the OLA for both the 10 CFR 50 and 10 CFR 70 portions of the RPF, the NRC staff will be able to again review the Environmental Report required by 10 CFR 70.21(f) for any significant new information.

Specifically, the NRC staff has determined 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” per 10 CFR 70.23(a)(7). 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, including the 10 CFR 70 components, can be initiated with the NRC approval of the NWMI 10 CFR 50 Construction Permit Application.

2. **No significant increase in the probability of occurrence or consequences of previously evaluated accidents** – The proposed exemption request will not change any accident scenario identified in the Integrated Safety Analysis Summary³ of the 10 CFR 50 Construction Permit Application or exceed the performance requirements of 10 CFR 70.61, since the RPF has not yet been constructed. Therefore, there is no significant increase in the probability of occurrence or consequences of the previously evaluated accidents. Prior to RPF operations, an OLA, including the Environmental Report and Final Safety Analysis report (FSAR), will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.
3. **No significant reduction in margins of safety** – NWMIL has not yet initiated construction or operation of the RPF; thus, material cannot be released by any credible event that would result in consequences that could exceed the performance requirements per 10 CFR 70.61. Therefore, the proposed exemption request does not decrease the margin of safety associated with any IROFS that are being credited to ensure the performance requirements of 10 CFR 70.61 are met. Prior to RPF operations, an OLA, including the Environmental Report and FSAR, will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.
4. **No significant decrease in the effectiveness of any programs or plans contained in the licensing documents** – The proposed exemption request will not decrease the overall level of security performance needed to protect against the loss or compromise of classified matter, control of classified storage areas or vaults, training of classifiers, or computer security; will not alter aspects of physical security or transportation of special nuclear material (SNM); and will not affect any other plant safety, safeguards, or security programs or any other programs or plans contained in the current license application and supporting documents. Therefore, the proposed exemption request will not decrease the effectiveness of any program or plan contained in such license application and supporting documents. In addition, the proposed exemption request does not change or represent a relaxation of a requirement of the Quality Assurance Program Description. Prior to RPF operations, an OLA, including the Environmental Report and FSAR, will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.
5. **The proposed changes do not result in undue risk to public health and safety, common defense and security, and the environment** – The proposed exemption request will not have an effect on plant boundary protection, documentation of patrols, performance of rounds, or training of protective force personnel. In addition, there is no likelihood that protected material or SNM will be accessible to unauthorized personnel since the RPF does not yet possess protected material or SNM. Therefore, based on the above, the proposed exemption request will not result in undue risk to public health and safety, the environment, or to the common defense and security of the RPF. Prior to RPF operations, an OLA, including the Environmental Report and FSAR, will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.
6. **There is no change in the type or significant increases in the amounts of any effluents that may be released offsite** – The proposed exemption request will not create new or unusual sources of hazardous substances, hazardous waste, or new waste streams that could be generated or used in unacceptable levels that exceed applicable regulatory requirements. Therefore, there is no change in the type or significant increases in the amounts of effluents that may be released offsite. Prior to RPF operations, an OLA, including the Environmental Report and FSAR, will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.

³ NWMIL-2015-SAFETY-002, *Radioisotope Production Facility Integrated Safety Analysis Summary*, Rev. 0, Northwest Medical Isotopes, LLC, Corvallis, Oregon, 2015.

7. **There is no significant increase in individual or cumulative occupational radiation exposure –** The proposed exemption request will not cause an increase in radiological or chemical releases beyond applicable regulatory limits nor will the proposed exemption request create any new or unusual sources of radioactive waste. Likewise, the proposed exemption request will not result in a significant increase in individual or cumulative occupational radiation exposure. Prior to RPF operations, an OLA, including the Environmental Report and FSAR, will be submitted to the NRC for the RPF, including both 10 CFR 50 and 10 CFR 70 components.
8. **There is no adverse impact on operations or decommissioning activities –** NWMI has not yet initiated construction of the RPF, so no operation or decommissioning activities are being pursued at this time; therefore, this exemption request has no adverse impact on RPF operations or decommissioning activities.