

Tiktinsky, David

From: Tiktinsky, David
Sent: Thursday, February 15, 2018 11:20 AM
To: Carolyn Haass (carolyn.haass@nwmedicalisotopes.com)
Cc: Balazik, Michael
Subject: Follow-up on discussion of NWMI exemption request
Attachments: Summary of phone call between NRC and NWMI on 2 06 18 rev 4.docx; centrus exemption request incoming cl.pdf; centrus incoming request justification.pdf; centrus exemption cl.docx; centrus exemption enc.docx

I have enclosed a summary of our discussion from last week with regard to your Part 70 exemption request. I am also enclosing a recent Part 70 exemption so that you can see what was sent in and the documentation the NRC needed to prepare. Please let Mike or I know if you have any questions.

Summary of phone call between NRC and NWMI on 2/6/18 with respect to NWMI's exemption request dated December 18, 2018. The subject request related to an exemption from 10 CFR 70.21(f), "Filing" for the target fabrication facility.

During the phone call, the NRC staff informed NWMI that additional information, in the form of a supplement to, or a withdrawal and resubmittal of their December 18, 2017 exemption request was needed, prior to the staff being able to accept the submittal for docketing. The following is a summary of the supplemental information items that the staff discussed with NWMI.

- a. The scope of the exemption request with respect to 10 CFR 70.21(f) is not clear. Specifically, because the exemption request refers to a number of regulatory requirements, it is not clear whether NWMI intends to request relief from only from the 9-month waiting period to begin construction. The staff stated that the exemption request needs to explicitly state which regulatory requirements from which NWMI is requesting relief.
- b. The exemption request references 10 CFR 50.12 which is not relevant to requesting an exemption under Part 70. The standard for granting an exemption to Part 70 requirements is set forth in 10 CFR 70.17.
- c. Any exemption request should provide the reasons and a justification for the exemption request, specifically addressing a) why NWMI believes the exemption request is authorized by law; b) why, if granted, it would not endanger life or property or the common defense and security; and c) why it is in the public interest as stated in 10 CFR 70.17, "Specific exemptions".
- d. The exemption request stated that the 10 CFR 70.23(a)(7) requirements for the target fabrication facility (i.e., an NRC determination) are met based on the conclusions in the EIS. If this is a basis for the exemption request, NWMI should explain the basis for this conclusion given that the EIS for the Part 50 production facility, in Chapter 6, "Conclusion" refers only to the Part 50 construction permit, stating: "This environmental impact statement (EIS) contains the environmental review of the Northwest Medical Isotopes, LLC (NWMI), application for a construction permit under Title 10 of the Code of Federal Regulations (10 CFR) Part 50 that would allow construction of the NWMI medical radioisotope production facility (NWMI facility) at the Discovery Ridge site in Columbia, Missouri"

The staff requested that NWMI provide the requested information within two weeks. NWMI stated that it plans on submitting the information within that timeframe. The staff also agreed to provide NWMI with additional examples of Part 70 exemptions.