

June 7, 2010

Mr. James C. Katzaroff, Chairman and Chief Executive Officer
Advanced Medical Isotope Corporation
8131 W. Grandridge Blvd, #101
Kennewick, WA 99336

SUBJECT: REGULATORY PROCESS FOR A MOLYBDENUM MANUFACTURING
SYSTEM BASED ON AN ACCELERATOR

Dear Mr. Katzaroff:

The U.S. Nuclear Regulatory Commission (NRC) is writing in response to your letter dated January 4, 2010, in which Advanced Medical Isotopes Corporation (AMIC) seeks prelicensing guidance from the NRC on potential policy issues associated with licensing AMIC's Molybdenum Manufacturing System (MMS). In your letter, you state that the purpose of the letter was to provide the NRC with AMIC's understanding of the NRC regulations and to propose a path forward on the licensing review of the MMS, a four-step system consisting of an accelerator, a reaction vessel, molybdenum (Mo)-99 separation activity, and Mo-99 purification. Other aspects of the facility would include uranium recycle/solution cleanup and waste management activities.

Furthermore, your letter stated that AMIC expects that the State where the facility is located would regulate the accelerator, that the NRC would regulate the reaction vessel and the Mo-99 separation activity in light of the quantity of special nuclear material (SNM) involved, and the NRC would regulate Mo-99 purification as a byproduct material activity, unless the facility was located in an Agreement State.

Your January 4, 2010, letter indicated that confirmation from the NRC on the path forward was necessary as part of AMIC's decisionmaking to proceed with this project and submit an application. In particular, AMIC sought confirmation from the NRC on the following prelicensing issues to which the NRC provides these responses:

1. Confirm that if AMIC demonstrates that there will not be a self-sustained fission reaction, the reaction vessel will be regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material."

NRC Response to Issue 1: The NRC agrees that if designed and operated as AMIC proposes, this reaction vessel does not meet the definition of a nuclear reactor in 10 CFR 50.2, "Definitions." Further, the reaction vessel does not meet the definition of a production facility in 10 CFR 50.2. Therefore, it is possible for the reaction vessel to be regulated under 10 CFR Part 70.

2. Confirm whether the NRC will license the MMS separation activity as an SNM facility under 10 CFR Part 70 rather than as a production facility under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

NRC Response to Issue 2: Although AMIC contends that the Commission should not require the separation activity to be licensed as a production facility, based on preliminary information provided by AMIC, it appears that AMIC's proposed separation activity for the MMS falls under the current 10 CFR Part 50 definition of production facility. Accordingly, AMIC must seek an exemption from licensing the proposed separation activity under 10 CFR Part 50. If the exemption were granted, the separation activity could be licensed under 10 CFR Part 70.¹

3. Confirm whether NRC will exempt the separation activity of the MMS from 10 CFR Part 50 and apply 10 CFR Part 70 to regulate this facility "should an application be submitted."

NRC Response to Issue 3: 10 CFR 50.12, "Specific Exemptions," contains the criteria that the Commission considers when determining whether to grant exemptions from the requirements of 10 CFR Part 50. To be granted an exemption, AMIC must show that the exemption is authorized by law, does not present an undue risk to the public health and safety, and is consistent with the common defense and security. Further, AMIC must demonstrate that special circumstances, as defined in 10 CFR 50.12(a)(2), exist. Whether the NRC will exempt AMIC's separation activity for the MMS from 10 CFR Part 50 and instead regulate it under 10 CFR Part 70 will depend on the NRC's review of a complete exemption request that contains compelling arguments demonstrating to the NRC staff that the requirements in 10 CFR 50.12(a)(1) and (a)(2) are fully met.

Please contact me or Marcus H. Voth (301-415-1210) of my staff if you have any questions regarding the NRC's responses to AMIC's proposed path forward.

Sincerely,

/RA/

Timothy J. McGinty, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

¹ If however, the proposed separation activity meets the exception in the definition of production facility found at 50.2(3)(iii), than an exemption would not be necessary.

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