



January 4, 2010

Chairman Gregory B. Jaczko
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Regulatory Process for a Molybdenum Manufacturing System based on an Accelerator

Advanced Medical Isotopes Corporation (AMIC), a company engaged in production and distribution of medical isotopes, is considering the submittal of an application to license a Molybdenum (Mo-99) Manufacturing System (MMS). There are approximately 300,000 medical-imaging tests that are prescribed by doctors in the United States each week. These medical-imaging tests rely on technetium-99m which is a radioactive isotope produced from Mo-99. As you are aware, there is no domestic source for Mo-99, and the North American facility in Canada is not currently operating. There is a significant worldwide shortage of Mo-99. Thus, it is imperative for companies like AMIC that is interested in building domestic facilities for Mo-99 production to understand NRC licensing requirements.

The AMIC facility would be based on the use of an accelerator and not a reactor. The accelerator would be used to generate photons from a tungsten target that would in turn strike the deuterons in a solution of heavy water to produce neutrons that would interact with low level enriched U-235 in the uranyl nitrate to promote fission thereby producing the Mo-99. The purpose of this letter is to provide NRC our understanding of the NRC regulations and propose a path forward on the licensing review of the MMS. Confirmation from the NRC on the path forward is necessary as part of our decision making to go forward on this project and to prepare an application.

The MMS is a four step system made up of 1) the accelerator, 2) reaction vessel, 3) Mo-99 separation activity, and 4) Mo-99 purification. Other aspects of the facility would include uranium recycle/solution clean up and waste management activities. From a jurisdictional perspective, we would expect that the state where the facility is located would regulate the accelerator, NRC would regulate the reaction vessel and Mo-99 separation in light of the quantity of special nuclear material involved, and the Mo-99 purification being a byproduct material activity would be regulated by the NRC unless the facility was located in an Agreement State.

Reaction Vessel Is Not A Reactor

In our view, the reaction vessel where the fission occurs would be regulated under Part 70 because there would be more than 350 grams of special nuclear material with low-enriched uranium (less than 20%). The vessel containing the uranyl nitrate/ heavy water solution would consist of a small vessel lined with a

moderator-reflector. The target for the electron beam would be located outside the tank. Based on the design and experimental data for the reaction vessel volume, uranium mass, and the moderator/reflector, K effective will not exceed one and there will not be a sustained fission reaction. Fission ceases if the accelerator is turned off. Consequently, since the reaction vessel is “not designed or used to sustain nuclear fission in a self-supporting chain reaction” nor is it capable to do so, it is not a “nuclear reactor” as defined by 10 CFR 50.2. Our application will provide the details to support these statements.

Please confirm that if we demonstrate that there will not be a self sustained fission reaction, that the reaction vessel will be regulated under Part 70.

Mo-99 Separation Activity Is Not A Production Facility

In our view, the separation activity should be regulated under Part 70. We recognize that the NRC informed B&W by letter dated October 13, 2009, that the separation activity at its proposed MIPS facility would be considered a production facility as B&W did not provide a compelling case to the contrary. Under the Atomic Energy Act a production facility is a facility capable of production of SNM 1) in such quantities to be significant to the common defense and security or 2) in such manner to affect the health and safety of the public. Part 50 defines a production facility as a facility used for processing irradiated material with three exceptions. The separation activity at the MMS facility will not be producing a significant amount of SNM, i.e., less than 1E-5 grams of plutonium per gram of U-235, so it is not clear why this activity which is not designed to produce SNM should be considered a production facility under Part 50 especially since it will not be processing irradiated reactor fuel. In addition, it is not clear why processing irradiated material necessarily meets the Atomic Energy Act definition of a production facility. Given that the NRC exempts some processing of irradiated material from its definition of production facility, we believe the separation activity at the MMS that does not involve processing irradiated fuel should also be exempted.

More importantly, for the Cintichem facility, the only precedent that we are aware of concerning processing of irradiate material for Mo-99 production, NRC licensed the separation activity as an SNM facility under Part 70 (Cintichem license SNM-639). Specifically authorized activities under SNM-639 included performing chemical separation of radioactive isotopes from irradiated targets containing SNM. To our knowledge, it was not considered to be a production facility under the Atomic Energy Act. Treating the MMS' separation activity as an SNM facility rather than a production facility would result in a more efficient and timely licensing process as the Atomic Energy Act requirements for a production facility, e.g., a two step licensing process, technical specifications, licensed operators, and ACRS review, is not required. Having a more efficient and timely process that does not compromise safety is consistent with the October 9, 2009 SRM on SECY 09-0101 and will help expedite licensing of a facility to meet the worldwide shortage of Mo-99.

Thus, in our view the MMS facility which has no reactor component should not be considered a production facility and should be licensed under Part 70 similar to Cintichem. Please confirm whether NRC will license the MMS separation activity as an SNM facility under Part 70 rather than a production facility under Part 50.

If MMS Is A Production Facility, It Should Be Exempted From Part 50

If NRC is of the view that the separation activity for the MMS facility, since it processes irradiated material, is a production facility, and thus it is regulated under Part 50, then it is our view that the MMS' separation activities should be exempted from Part 50 and regulated under Part 70 for the reasons provided below.

Part 50 addresses reactors and to a limited extent fuel reprocessing facilities. However, Part 50 does not define reprocessing. It does not specifically address separation technology. In fact, in the six areas within Part 50 where the term "reprocessing" is used, i.e., §§50.30, 50.34, 50.36, 50.54, Appendix B, and Appendix F), it is modified by the word "fuel." We found no references to reprocessing not associated with reactor fuel and, as noted above, the MMS facility not being a reactor has no reactor fuel to process. To our knowledge, Part 50 has never been applied to a separation activity not associated with reactor fuel reprocessing. In addition, Part 50 does not have a design basis for a reprocessing facility. In fact, in 1970 a footnote was added to 10 CFR 50.34 stating that a design bases for chemical reprocessing plants would be established but they never were. It would likely be a major effort to develop design basis requirements using a Part 50, Appendix A approach for separation activities. Part 50 does not address the hazards of a chemical processing which is the focus of a separation facility. Over time 10 CFR Part 50 has evolved into a regulation to ensure safety of light water reactors and non-power reactors. The technology used in separation is not similar to reactor technology. In Cintichem, the only applicable precedent that we are aware of as we noted above, NRC did not apply Part 50 to its separation activity.

It is also recognized that Part 50 has not been applied for more than 30 years to a reprocessing licensing case. NRC recognizes that Part 50 would need to be modified to apply it to reprocessing. In fact, the NRC staff stated in SECY-06-0066, Regulatory and Resource Implications of a DOE Spent Nuclear Fuel Recycling Program (March 22, 2006), that:

Part 50 is focused on LWR design and technology and would have limited applicability to commercial reprocessing facility design and technology. That is, the design and operational safety issues associated with a commercial reprocessing facility would be very different from design and operational safety issues associated with an LWR. The current Part 50 regulations would not necessarily address all commercial reprocessing facility safety issues and, conversely, are likely to contain requirements that are not applicable to a reprocessing facility. The application of the whole of Part 50 to the licensing of a commercial reprocessing facility would present significant challenges to the applicant and to the NRC. If Part 50 is used to license a commercial reprocessing facility, the regulations would have to be reviewed to determine which apply, which do not apply, and which may partially apply. Additional requirements would also need to be established to address reprocessing facility-specific design and safety issues.

Moreover, in SECY-08-0134, Regulatory Structure for Spent Fuel Reprocessing (September 12, 2008), the NRC staff expressed the view that "it would not be effective or efficient to revise Part 50 to license reprocessing facilities." The NRC staff further stated in SECY-08-0134 that:

[T]he existing Part 70 currently regulates many different types of fuel cycle facilities. 10 CFR 70 provides a model of a regulation capable of licensing several different types of facilities, yet adequately ensures safe facility operation. As such, the staff believes that it is possible to either include a new subpart to Part 70 that would provide new regulatory requirements for reprocessing

facilities, or create a new Part specific for reprocessing. These new regulations could be capable of licensing aqueous separation techniques, as well as any potential pyroprocessing techniques.

We agree with the NRC staff observations on Part 70. Part 70 with its performance base integrated analysis approach is a better fit for licensing of the separation activities of the MMS facility. It closely aligns with the risks of the facility and possession of an SNM inventory. The risks associated with this facility, e.g., criticality, chemical exposure, and radiological exposure, are routinely addressed with the Part 70 licensing process. The public health and safety would be protected under Part 70. Importantly, unlike with Part 50, this protection would be provided without the need for a new rulemaking.

We considered proposing to the NRC that it apply Part 50, but with a Part 70 type review for MMS' separation activity. However, a Part 50 license for the separation activity with an associated Part 70 like license review would be cumbersome, may require exemptions, may take time for the NRR staff to learn, and would add no public health and safety benefit.

Therefore, we propose that NRC exempt the MMS from Part 50 pursuant to 10 CFR 50.12. 10 CFR 50.12, "Specific Exemptions," states that the NRC may grant exemptions from the requirements of the regulations in 10 CFR Part 50 upon application by any interested person or upon its own initiative if three conditions are met. The three conditions of 10 CFR 50.12 (a)(1) are: (1) the exemption is authorized by law; (2) the exemption will not present an undue risk to the public health and safety; and (3) the exemption is consistent with the common defense and security. In addition, 10 CFR 50.12(a)(2) provides that the NRC will not consider granting an exemption unless special circumstances are present.

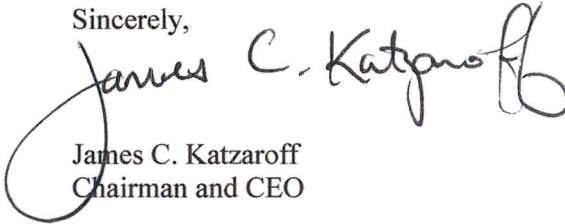
The NRC has the authority under the Atomic Energy Act to grant exemptions from its regulations if doing so would not violate the requirements of law. No law exists that precludes the activities covered by this exemption request. In fact, NRC licensed Cintichem's separation activities under Part 70. If MMS is a production facility, there may need to be several additional requirements added to Part 70, but these can be added as conditions of the exemptions such as the need for technical specifications and the use of a two-part licensing process. In our view, this exemption would be authorized by law. The provisions of Part 70 will provide assurance that the public health and safety will be protected. In our view, this exemption would not present an undue risk to the public health and safety. Similarly, the provisions of Part 70 will provide assurance that the common defense and security will be protected. In our view, this exemption would be consistent with the common defense and security.

Consistent with the provisions of 10 CFR 50.12(a)(2)(ii) special circumstances exist as application of Part 50 would not serve the underlying purpose of the rule in that Part 50 primarily addresses reactors and to a lesser extent fuel reprocessing and not the separation technology proposed for MMS. As noted above, Part 50 focuses on reactor design and technology, and has no design criteria for production facilities. For the risks associated with this facility, public health and safety is best assured by exempting the separation portion of the facility from the regulatory requirements of 10 CFR Part 50 and regulating it under Part 70. See SECY-06-066 and SECY-08-0134. The Part 70 process has existing guidance with known standards for the staff and applicant and be transparent to the public. Use of Part 70 would be consistent with the only known precedent for Mo-99 production (Cintichem license SNM-639). Importantly, use of Part 70 with known guidance and standards would provide for a more efficient process consistent with the direction in the October 9, 2009 SRM on SECY-09-0101. The regulatory efficiency on using Part 70 with its likely improvement in licensing time is in the public interest in light of the national isotope shortage.

Therefore, in our view, the Commission should exempt the MMS from Part 50 and regulate it under Part 70 either by its own motion or based on this request. Please confirm as to whether NRC will exempt the separation activity of the MMS from Part 50 and apply Part 70 to this facility should an application be submitted.

If you need any additional information, please contact Mike Korenko at 509-551-9281. We would be pleased to meet with the appropriate NRC staff concerning this request at their earliest convenience.

Sincerely,

A handwritten signature in black ink that reads "James C. Katzaroff". The signature is written in a cursive style with a large, looping initial "J".

James C. Katzaroff
Chairman and CEO

cc:

Commissioner Klein
Commissioner Svinicki
R. William Borchardt, EDO
Stephen G. Burns, OGC
Michel F. Weber, NMSS
Eric J. Leeds, NRR
Timothy J. McGinty, NRR
Mary Jane Ross-Lee, NRR