amic
ADVANCED MEDICAL ISOTOPE CORPORATION

03/01/2010

Michael F. Weber
Director
Office of Nuclear Materials, Safety, and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Weber:

Subject: February 12, 2010 Meeting on Potential Application for a Mo-99 Manufacturing System

We appreciated the opportunity to meet with you on February 12, 2010, to discuss the Advanced Medical Isotope Corporation (AMIC) concept for a Molybdenum (Mo-99) Manufacturing System (MMS). As we mentioned, AMIC is giving serious consideration to submitting an application to the NRC for licensing its MMS. However, before submitting an application, as we discussed, AMIC needs to understand the NRC licensing requirements for Mo-99 production.

Since the MMS does not involve a reactor, AMIC noted its preference that our facility be licensed under Part 70 and not Part 50. Part 70 will result in the more timely development and processing of an application with no compromise of safety; resulting in our Nation having a more rapid access to domestic Molybdenum 99 to help alleviate the current shortage of technetium-99. To supplement our explanation as to the advantages of Part 70 over Part 50, we have attached a more complete explanation for your review.

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 matter at their earliest convenience.

cc:Bruce Mallet, DEDO
Eric J. Leeds, NRR
Timothy J. McGinty, NRR
Mary Jane Ross-Lee, NRR
Stephen G. Burns, OGC
Attachment: a/s

Sincerely,

James C. Katzaroff

James C. Katzaroff
CEO
Advanced Medical Isotope Corporation

8131 West Grandridge Blvd Suite 101 · Kennewick, WA 99336 · (509) 736-4000 · (509) 736-4007 fax
www.isotopeworld.com

Part 50 or Part 70

Advantages of 10 CFR Part 70

But for the definition of a "production facility" in Part 50, this facility would be licensed under Part 70. If this facility is exempted from the Part 50 definition of a "production facility," under Part 70 there would not need to have a separate construction permit and operating license proceeding. It would be a one step licensing process with the potential for only one adjudicatory hearing. In addition, neither technical specifications nor licensed operators are required under Part 70. It is important to note that the last time the NRC licensed an Isotope production facility for purposes of producing Molybdenum-99, NRC licensed it under Part 70 and not Part 50. Cintichem SNM-639.

The risks posed by the facility are more closely aligned to the risks associated with a Part 70 facility which handles special nuclear material. That is the operator must be sensitive to and capable of preventing an upset condition which could cause an inadvertent criticality, an unintended chemical reaction or release, or the release of radiological material. The provisions of Subpart H 10 CFR Part 70 were specifically intended to address these sorts of risks in a facility which handles special nuclear material. The performance criteria contained in this section of the regulation have been developed to protect the worker and the public from the potential hazards of a facility licensed to handle or use special nuclear material and the safety program and the integrated safety analysis described in Section 70.62 of this regulation provide a cost effective methodology for evaluating the facility's risks and designing and implementing a safety program to ensure that the hazards are adequately addressed and that the health and safety of the public are not compromised. As a risk informed flexible regulation, 10 CFR Part 70 more readily lends itself to unique technologies. The regulation allows the applicant to develop a safety program that is graded which allows the management measures that are to be applied to be graded commensurate with the reduction of risk attributable to the item to which the measure applies. An integrated safety analysis which is a part of the safety program required by 10 CFR Part 70 is specifically designed to have the appropriate detail for the complexity of the process to which it is applied. Thus an inherently simple process can have a less complex ISA which is commensurate with the risk which the process poses. In summary, public health and safety is best assured under the provisions of the 10 CFR Part 70 regulation and the application of this regulation is both more cost effective and more flexible which allows the regulation to more closely match the complexity and the risk of the process which is being regulated.

Use of the Part 70 approach has the advantage that NMSS is familiar with the Part 70 approach and being a risk informed regulation is directly applicable to a variety of facilities including the one proposed by AMIC. There is known guidance and standards that will facilitate preparation and review of the application.

Finally, a Part 70 license for the separation phase would be easily combined with the Part 70 license for the reaction vessel.

Disadvantages of 10 CFR Part 50

The application of 10 CFR Part 50 to this technology would not serve the underlying purpose of the rule which addresses reactors and fuel reprocessing facilities. This regulation as implemented over time has evolved into a rather specific regulation for the licensing of light water moderated and cooled reactors. As such the regulation focuses on the light water reactor design and technology and the regulation has few provisions which would apply directly to this facility which is being designed to produce accelerator induced molybdenum. The regulation has no design criteria for production facilities. As a result the agency would need to incorporate additional appropriate provisions to the 10 CRFR Part 50 regulation to address the regulatory requirements for public health and safety which are already incorporated into the safety program process contained in 10 CFR Part 70, and using the review techniques imposed by this developed regulatory surrogate, craft a regulatory review process which could achieve the needed safety oversight for this facility under the provisions of 10 CFR Part 50. The result would likely be more cumbersome, more expensive and less certain than simply applying the best regulation for this technology, 10 CFR Part 70, in the first place. From a practical view it will take additional time to sort out the positions of NRR and NMSS that would need to be combined into a single license. A process will need to be developed for licensing licensed operators and the establishment of technical specifications. From a procedural aspect, there will need to be two licenses issued, a construction permit and an operating license. In addition there will be one mandatory hearing at the construction permit stage and one opportunity for a hearing at the operating license stage. In light of the procedural requirements under Part 50 and the guidance and standards that will need to be devolved, licensing under Part 50 will likely take more time than Part 70.

Conclusion

In sum, we believe that the use of Part 70 rather than Part 50 will result in the more timely development and processing of our application with no compromise of safety. This will result in our Nation having a more rapid access to domestic Molybdenum 99.