babcock & wilcox technical services group
2016 mt. athos road lynchburg, va 24505-5447 usa
phone 434.522.6000 fax 434.522.5450 www.babcock.com

October 3, 2008
Non-proprietary Version

R. William Borchardt, Executive Director of Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Licensing Process for a Medical Isotope Production System
Reference: 1) Letter from B&W (Cochran) to NRC (Klein) dated October 2, 2008
2) Letter from B&W to NRC dated December 13, 2007, Notice of Intent to Submit an Application to License and Operate a Medical Isotope Production System

Dear Mr. Borchardt:

In the above referenced letter dated December 13, 2007, Babcock and Wilcox (B&W) notified NRC of our intent to license and operate a Medical Isotopes Production System (MIPS) [ ] In a subsequent letter dated October 2, 2008, B&W advised the Commission we would be seeking pre-licensing decision on potential policy issues associated with MIPS. The purpose of this letter is to provide our understanding of the NRC regulations and propose a path forward on the licensing review of the MIPS.

The MIPS will be an aqueous homogeneous reactor (AHR) fueled with low enriched uranium. It will also include the associated extraction and purification system for the purpose of producing ^{99}Mo as a medical radioisotope. From a public policy perspective an AHR serving as a medical isotope production reactor will provide the US with a domestic source for this important medical radioisotope and will provide an important resource that would reduce nuclear proliferation concerns associated with the production of ^{99}Mo using highly enriched uranium.

The MIPS system could consist of up to four integrally operated AHRs operating at a maximum power of 200 kW each, resulting in a total power of less than 800 kW. The reactors will be fueled with low enriched liquid uranyl nitrate solution. The low enriched solution generates ^{99}Mo in the reactor during operation. The entire fuel solution is subsequently removed from the reactor and the ^{99}Mo chemically extracted in a co-located facility. Once the ^{99}Mo is removed, the fuel is returned to the reactor for subsequent operation.

B&W has had previous discussions with the NRC concerning potential licensing of the MIPS. During those discussions we identified that understanding the licensing process and establishing a predictable process was a key issue for the success of the project and indicated that we would pursue early clarification and resolution. The purpose of this letter is to provide our understanding of the regulations and propose a path forward on licensing where there was some potential uncertainty.

Our path forward proposes the following:

1. a single license for the MIPS (Reactor, Extraction and Purification Facility) that is issued under 10 CFR 50 with incorporation of other parts of 10 CFR as necessary
2. a NRC determination that the initial extraction portion of the facility will not be classified as a Production Facility
3. NRC agreement that the MIPS is a non-power reactor under 10 CFR 50, and
4. designation of the MIPS license as Class 103 under 10 CFR 50.23

Specifics of our proposal are discussed below.

1. Licensing Under 10 CFR 50

B&W recognizes that the MIPS is both a reactor and a chemical extraction and purification facility. The purpose of the extraction and purification is to remove ^{99}Mo from the fuel solution containing SNM. As such, close coordination between the Office of Nuclear Material Safety and Safeguards and the Office of Nuclear Reactor Regulation will be required. Since the chemical processing facility is integral to the reactor facility and will likely share components, such as confinement features, we propose a single license for the MIPS under 10 CFR 50 with incorporation of other necessary regulations into the Part 50 license. In relation to 10 CFR 70, B&W believes the safety basis of the non-reactor portion of the facility should conform to Subpart H and proposes that an Integrated Safety Assessment (ISA) be preformed and an ISA Summary for the non-reactor processing facility be submitted to supplement the Final Safety Analysis Report required by 10 CFR 50.

2. Determination that the MIPS is not a Production Facility

The first extraction step of the MIPS process will be to extract ^{99}Mo from the irradiated reactor fuel solution. This solution will then be returned to the reactor for subsequent irradiation and production of ^{99}Mo. It may also be necessary to periodically clean the fuel to remove fission products and possibly transuranic isotopes that could interfere with the ^{99}Mo extraction process if they are allowed to accumulate over long many irradiation cycles of the fuel.

A production facility is defined by 10 CFR 50 as follows:

> *Production facility means:*
>
> *(1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233; or*
>
> *(2) Any facility designed or used for the separation of the isotopes of plutonium, except laboratory scale facilities designed or used for experimental or analytical purposes only; or*
>
> *(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material, except (i) laboratory scale facilities designed or used for experimental or analytical purposes, (ii) facilities in which the only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U-235 and plutonium produced by the irradiation, if the material processed contains not more than 10^{-6} grams of plutonium per gram of U-235 and has fission product activity not in excess of 0.25 millicuries of fission products per gram of U-235, and (iii) facilities in which processing is conducted pursuant to a license issued under parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special nuclear material.*

The MIPS will not be a reactor specifically for formation of plutonium or uranium-233 nor will it be use for the separation of the isotopes of plutonium. Small amounts of plutonium will be generated and may be separated from the uranium fuel during the periodic cleaning process but the plutonium will not be separated from the fission products. In fact, at 800 kW the MIPS will only produce approximately 25 grams of plutonium each year.

The MIPS will, however, process irradiated materials containing special nuclear material that does not meet any of the 3 exceptions described in criteria (3) of the production facility definition in 10 CFR 50.

The Atomic Energy Act contains the following definition of a production facility:

> *The term "production facility" means (1) any equipment or device determined by rule of the Commission to be capable of the production of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public; or (2) any important component part especially designed for such equipment or device as determined by the Commission. Except with respect to the export of a uranium enrichment production*

facility, such term as used in Chapters 10 and 16 shall not include any equipment or device (or important component part especially designed for such equipment or device) capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

Based on the definition in the Atomic Energy Act and the intended use of the MIPS, B&W believes that it should not be considered a production facility. Moreover, it is not clear that there would be any benefit to be considering MIPS as a production facility since it is clearly a utilization facility.

3. Licensing of the MIPS Reactors as "Non-Power Reactor"

The MIPS will be comprised of up to four AHRs operated in an integrated system within a common confinement facility. The total power of each reactor will not exceed 200 kW thus the total system power will be less than 800 kW.

10 CFR 50.2 defines a *non-power reactor* as a research or test reactor licensed under 50.21(c) or 50.22 of this part for research and development. MIPS will not meet the criteria in 50.52 for research and development since more than 50 percent of the annual cost of owning and operating the facility will be devoted to the production of products for sale or commercial distribution.

10 CFR 100.3 defines a *power reactor* as nuclear reactor of a type described in 50.21(b) or 50.22 of this chapter designed to produce electrical or heat energy. MIPS will not be a power reactor as it is not designed to produce electrical or heat energy.

10 CFR 50.2 defines a *Testing facility* as a nuclear reactor which is of a type described in 50.21(c) licensed authorizing operation at:

(1) A thermal power level in excess of 10 megawatts; or
(2) A thermal power level in excess of 1 megawatt, if the reactor is to contain:
    (i) A circulating loop through the core in which the applicant proposes to conduct fuel experiments; or
    (ii) A liquid fuel loading; or
    (iii) An experimental facility in the core in excess of 16 square inches in cross-section.

10 CFR 50.21(c) applies to a facility intended for conducting research and development. MIPS has power levels below those of a testing facility and is not intended for the conduct of research and development therefore it is not a testing facility.

Based on these definitions, it appears that MIPS is left in a regulatory gap as this type of reactor was not envisioned when the regulations were developed. There is further discussion of this in NUREG 1537, Guidelines for Preparing and Reviewing

Applications for the Licensing of Non-power Reactors. The Introduction to Part 1 of the NUREG states in part,

> *Currently all non-power reactors are licensed as Class 104 facilities. However, NRC recognizes that a non-power reactor for commercial purposes could be licensed as a Class 103 facility, and thus, 10 CFR 50.22 contains criteria for judging if a non-power reactor is a Class 103 facility.*

This statement implies that, during development of NUREG 1537, it was understood that consideration as a non-power reactor is not exclusive to research and development and could be based on the power level of the facility. Further, the same section of NUREG 1537 discusses the fact that non-power reactors are licensed to operate at power levels several orders of magnitude below current power reactors with fission product inventories that are proportionately less than power reactors. Therefore, non-power reactors require less stringent and prescriptive measures to provide equivalent safety in comparison to power reactors. Also recognized is the fact that potential hazards vary widely among non-power reactors requiring regulations to be implemented in different ways within the non-power category.

Therefore, based on the above, B&W believes the MIPS should be licensed as a non-power reactor under 10 CFR 50. Further we believe the license format and content for the reactor should adhere to NUREG 1537 to the extent that it applies to the MIPS and that there is sufficient flexibility in the regulations that this can be done without a specific exemption to the definition of a non-power reactor in 10 CFR 50.2. If however, an exemption is required, B&W requests a pre-licensing determination that NRC would likely grant an exemption request to treat MIPS as a non-power reactor.

4. Reactor License Classification

Based on the criteria outlined in 10 CFR 50.22 and 50.23, we believe the MIPS should appropriately be licensed as a Class 103 utilization facility. We are aware that all existing non-power reactors are currently licensed as Class 104 however we believe the non-R&D nature of MIPS precludes licensing as Class 104. In addition, we do not believe the MIPS qualifies as a utilization facility for the use in medical therapy even though the products of MIPS are intended solely for use as a radiopharmaceutical in the medical industry.

As provided in the 10 CFR 2.105(c), B&W plans to submit the required documentation for the issuance of a combined Construction Permit and Operating License following the format of NUREG 1537.

Understanding a predictable licensing approach for MIPS is critical to the business plan for the facility. Absent predictability in the licensing process, it will be difficult for B&W to move forward with the project and to commit funding to design of the facility. Therefore, B&W requests that NRC review our proposed licensing approach and determine its acceptability.

If there are areas where our proposal is not acceptable, B&W requests NRC provide alternatives that will provide a clear and acceptable approach.

If you have any questions on this letter or need further information, please contact me at 434-522-6439 or Steve Schilthelm at 434-522-6243. We would also be pleased to meet with you at your convenience concerning this request.

Sincerely,

[signature on file with proprietary letter]

W.E. Reynolds,
MIPS Program Manager
Babcock and Wilcox Technical Services Group, Inc.

[Attachment: Affidavit for Withholding Information under 10 CFR 2.390] Not attached to non-proprietary version.

cc: Martin J. Virgilio, Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs

Bruce S. Mallett, Deputy Director for Reactor and Preparedness Programs

Michael F. Weber, Director, Office of Nuclear Material Safety and Safeguards

Eric J. Leeds, Director, Office of Nuclear Reactor Regulation