

October 1, 2010

Mrs. Carmen Bigles, President and CEO
Coqui Radiopharmaceuticals Corp.
P.O. Box 958
Bayamon, P.R. 00960-0958

SUBJECT: COQUI RADIOPHARMACEUTICALS CORPORATION – U.S. NUCLEAR
REGULATORY COMMISSION RESPONSE TO PART I OF THE PROPOSED
LICENSING STRATEGY RE: MEDICAL ISOTOPE PRODUCTION FACILITY'S
LICENSE CLASS

Dear Mrs. Bigles:

The U.S. Nuclear Regulatory Commission (NRC) is writing in response to your letter dated May 21, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML101550454), in which Coqui Radiopharmaceuticals Corporation (Coqui) seeks pre-licensing guidance from the NRC on potential policy questions associated with licensing Coqui's proposed Medical Isotope Production Facility (MIPF).¹ In your letter, you state that the purpose of the letter was to propose a licensing strategy addressing Coqui's views on licensing the MIPF. In particular, you requested a response from the NRC to the following three licensing questions:

1. May the MIPF be licensed as a Class 104c facility?

NRC Response to Question 1:

The NRC agrees with Coqui's understanding of NUREG-1537 Chapter 15.2 and Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.22 which covers the 50 percent annual cost threshold which differentiates Class 104c and Class 103 facilities. Coqui must provide grounds in their complete license application that will justify accepting and reviewing the application as one for a Class 104c facility.

2. Alternatively, may the MIPF be licenses as a Class 104a facility?

NRC Response to Question 2:

The NRC does not agree with Coqui that the MIPF, as currently presented, could be licensed as a Class 104a facility.

¹

The letter indicated that for purposes of this discussion, MIPF was the reactor portion of the facility only. Notably, the proposed facility will also have a radioisotope processing plant. A separate analysis is required to determine the appropriate licensing of the radioisotope processing plant.

Section 104a of the Atomic Energy Act of 1954, as amended (AEA), relates to utilization facilities administering medical therapy. 10 CFR Section 50.21(a) also specifies that a Class 104a license will be issued if a utilization facility is used in medical therapy.

NUREG-1537 explains that the authors of the AEA saw a use for special nuclear material in medical therapy. In order to qualify as a Class 104a facility, patients would be irradiated by the neutron beam generated from the non-power reactor. Coqui has not provided any documentation explaining how the utilization facility would be used directly in medical therapy. The only NRC licensed 104a utilization facility, Massachusetts Institute of Technology's Nuclear Research Reactor, uses the reactor to deliver a neutron beam directly to the patient for therapeutic purposes.

In contrast, Coqui has presented plans to fission low enriched uranium to produce molybdenum-99 (Mo-99), a byproduct material, which will be processed and distributed for eventual use for medical diagnostic purposes. This would not meet the definition of "medical therapy" as contemplated by the AEA.

3. In the event that the MIPF may not appropriately be licensed as a Class 104 facility, may the MIPF be licensed as a Class 103 commercial non-power reactor and may Coqui rely on NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" (NUREG-1537), to the extent applicable, in preparing its application?

NRC Response to Question 3:

The NRC agrees that the MIPF may be licensed as a Class 103 commercial non-power reactor.² The NRC also agrees with Coqui's understanding of using NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" in preparing a Class 103 commercial non-power license application. Coqui can also reference the NRC's response to Babcock and Wilcox's Medical Isotope Production System pre-licensing letter dated October 13, 2009 (ADAMS Accession Number ML092090423), for Class 103 licensing guidance.

² While the MIPF can appropriately be licensed as a Class (i.e., Section) 103 commercial non-power reactor, 10 CFR Part 52 applies only to Section 103 power reactors. Therefore, absent an order, a combined construction permit and operating license is not authorized under 10 CFR Part 52 for the proposed MIPF.

C. Bigles

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Please contact Ossy Font (301-415-2490) of my staff if you have any questions regarding the NRC's responses to Coqui's proposed licensing strategy.

Sincerely,

/RA/

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

C. Bigles

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Please contact Ossy Font (301-415-2490) of my staff if you have any questions regarding the NRC's responses to Coqui's proposed licensing strategy.

Sincerely,

Timothy J. McGinty, Director
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