

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, DC 20555-0001

May 21, 2010

SUBJECT: Part I of the Proposed Licensing Strategy for Coquí Radiopharmaceuticals Corp.'s  
Medical Isotope Production Facility Pertaining to the Facility's License Class

During our recent discussions with the U.S. Nuclear Regulatory Commission (NRC), Coquí Radiopharmaceuticals Corp. (Coquí) informed the NRC that it intends to transmit a proposed licensing strategy document to the agency addressing Coquí's views on licensing the Medical Isotope Production Facility. Attached is the first part of the proposed licensing strategy for the NRC's review. Coquí intends to submit an additional licensing strategy document to the NRC in the near future. We respectfully request that the NRC review and provide comments, as requested, on the discussion contained in Enclosure (1).

Because Coquí considers some of the information contained in Enclosure (1) to be proprietary, Coquí requests that Enclosure (1) be withheld from public disclosure, pursuant to 10 CFR § 9.17(a)(4) and 10 CFR § 2.390. The proprietary information is identified in brackets in Enclosure (1). We have provided the necessary affidavit to support our request in Enclosure (3). We have provided an identical public version of the licensing strategy document, save for the redacted proprietary information, in Enclosure (2).

If you have questions or need additional information, please contact me at 787.993.2800 or by email at [cbigles@adioscancer.com](mailto:cbigles@adioscancer.com)

Sincerely,

Carmen I. Bigles  
President and Chief Executive Officer  
Coquí Radiopharmaceuticals Corp.

AD20  
NRR

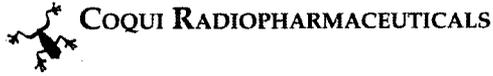
- Enclosure:
- (1) Part I of the Proposed Licensing Strategy for Coquí Radiopharmaceuticals Corp.'s Medical Isotope Production Facility Pertaining to the Facility's License Class **(Proprietary)**
  - (2) Part I of the Proposed Licensing Strategy for Coquí Radiopharmaceuticals Corp.'s Medical Isotope Production Facility Pertaining to the Facility's License Class **(Public Version)**
  - (3) 10 CFR 2.390 Affidavit of Carmen I. Bigles, President and Chief Executive Officer, Coquí Radiopharmaceuticals Corp.

Cc:

Mary Jane Ross-Lee, NRC  
Ossy Font, NRC  
Daniel F. Stenger, Hogan Lovells US LLP  
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**ENCLOSURE (3)**

**Affidavit of Carmen I. Bigles  
President and Chief Executive Officer  
Coquí Radiopharmaceuticals Corp.**



**COQUÍ RADIOPHARMACEUTICALS CORP.**

**10 CFR 2.390 AFFIDAVIT OF CARMEN I. BIGLES**

AFFIDAVIT

**I, Carmen I. Bigles, hereby affirm and state as follows:**

- (1) I am the President and Chief Executive Officer of Coquí Radiopharmaceuticals Corp. (Coquí), and I have been authorized to execute this affidavit on behalf of Coquí.
- (2) The bracketed information contained in Enclosure (1) is proprietary commercial information related to the proposed Medical Isotope Production Facility (MIPF) and Coquí's business. The proprietary information includes sensitive cost estimates that have been generated by or for Coquí. This information should be held in confidence by the NRC and withheld from public disclosure.
- (3) In making this application for withholding of proprietary information of which it is the owner, Coquí believes that the information qualifies for withholding under the exemption from disclosure set forth in the Freedom of Information Act ("FOIA"), 5 USC § 552(b)(4), the Trade Secrets Act, 18 USC § 1905, and NRC regulations 10 CFR §§ 9.17(a)(4) and 2.390(a)(4) for trade secrets and commercial information because:
  - i. This information is and has been held in confidence by Coquí.
  - ii. This information is of a type that is customarily held in confidence by Coquí, and there is a rational basis for doing so because the information includes sensitive business information pertaining to the costs of constructing and operating the MIPF.
  - iii. The information is being transmitted to the NRC voluntarily and in confidence.
  - iv. This information is not available in public sources and could not be gathered readily from other publicly available information.
  - v. Public disclosure of this information would create substantial harm to the competitive position of Coquí by disclosing the costs of constructing and operating the MIPF. Development and evaluation of this commercial information was achieved at, and disclosure could lead to additional, significant cost to Coquí.
  - vi. Public disclosure of the information sought to be withheld is likely to cause substantial harm to Coquí's competitive position and foreclose or reduce the availability of profit-making opportunities. The value of the information goes beyond the disclosure of actual information pertaining to Coquí's business, and includes substantial time and

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work towards developing the MIPF project, and represents significant efforts by Coquí and its associates.

- vii. Coquí's competitive advantage will be lost if its competitors are able to use Coquí's cost estimates to aid their own commercial activities. The value of this information to Coquí would be lost if the information were disclosed to the public. Making such information available to other entities without their having been required to undertake a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive Coquí of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment.



Carmen I. Bigles

Subscribed and sworn before me, a Notary Public, in and for the Commonwealth of Puerto Rico, this 21st day of May 2010.

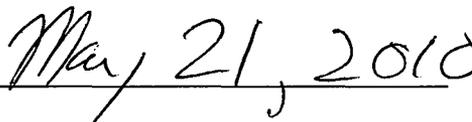
WITNESS my hand and Notarial Seal.

# 336





Notary Public



Date

**Public Version**

**ENCLOSURE (2)**

**Part I of the Proposed Licensing Strategy for Coquí  
Radiopharmaceuticals Corp.'s Medical Isotope Production Facility  
Pertaining to the Facility's License Class—*Public Version***

## Public Version

### Part I of the Proposed Licensing Strategy for Coquí Radiopharmaceuticals Corp.'s Medical Isotope Production Facility Pertaining to the Facility's License Class

On March 15, 2010, Coquí Radiopharmaceuticals Corp. (hereinafter "Coquí" or the "Company"), submitted a letter to the Nuclear Regulatory Commission (NRC) indicating that the Company intends to submit an application in December 2010 for a Medical Isotopes Production Facility (MIPF),<sup>5</sup> which will consist of two production reactors and a radioisotope processing plant for the production of molybdenum-99.<sup>6</sup> During an April 15, 2010 meeting with the NRC, Coquí informed the NRC that it intends to apply for a license for the MIPF under Section 104 of the Atomic Energy Act of 1954, as amended.<sup>7</sup> Coquí also stated its intent to submit a licensing strategy document during the pre-application phase for the NRC's review and comment. Coquí has broken down its licensing strategy into two documents. Part I, attached hereto in Enclosure (1), sets forth the Company's proposed licensing strategy pertaining to the MIPF's license class. Coquí intends to submit the remainder of its licensing strategy in the near future. In the meantime, Coquí respectfully requests that the NRC respond to the three questions contained below and provide responses to each question as the agency makes a determination on that particular issue.

a. Applicable Regulations

The NRC licenses non-power reactors as either Class 104 or Class 103 facilities as set forth in the agency's regulations at 10 CFR §§ 50.21 and 50.22, respectively. The implementing regulations for a Section 104 license have been promulgated by the NRC in 10 CFR § 50.21, which states (in relevant part):

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<sup>5</sup> Coquí's letter of intent refers to the MIPF as the "Medical Mo99 Production Complex"; however, Coquí has since changed the facility's name to the "Medical Isotopes Production Facility."

<sup>6</sup> For purposes of this discussion, all references to the MIPF herein refer solely to the reactor portion of the facility.

<sup>7</sup> Section 104 of the AEA, 42 USC § 2134, states (in relevant part):

a. The Commission is authorized to issue licenses to persons applying therefore for utilization facilities for use in medical therapy.

b. As provided for in subsection 102b., or 102c. [referring to facilities constructed or operated under the Cooperative Power Reactor Demonstration Program], or where specifically authorized by law, the Commission is authorized to issue licenses under this subsection to persons applying therefor for utilization and production facilities for industrial and commercial purposes.

c. The Commission is authorized to issue licenses to persons applying therefor for utilization and production facilities useful in the conduct of research and development activities of the types specified in section 31 and which are not facilities of the type specified in subsection 104b.

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A class 104 license will be issued, to an applicant who qualifies, for any one or more of the following: to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use.

(a) A utilization facility for use in medical therapy; or

...

(c) A production or utilization facility, which is useful in the conduct of research and development activities of the types specified in section 31 of the Act, and which is not a facility of the type specified in paragraph (b) of this section or in § 50.22.

As Coquí understands, if a non-power reactor does not meet the criteria for a Class 104 facility, then it would be licensed under 10 CFR § 50.22 as a Class 103 commercial non-power facility. Section 50.22 provides in this regard:

A class 103 license will be issued, to an applicant who qualifies, for any one or more of the following: To transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use a production or utilization facility for industrial or commercial purposes; *Provided, however, That in the case of a production or utilization facility which is useful in the conduct of research and development activities of the types specified in section 31 of the Act, such facility is deemed to be for industrial or commercial purposes if the facility is to be used so that more than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training.*

Underlined emphasis added.

### b. Questions for the NRC's Consideration

Coquí respectfully requests that the NRC confirm Coquí's understanding of the following three licensing issues:

1. The MIPF, as described herein, may appropriately be licensed as a Class 104c facility.
2. Alternatively, the MIPF, as described herein, may appropriately be licensed as a Class 104a facility.
3. In the event that the MIPF may not appropriately be licensed as a Class 104 facility, the MIPF may be licensed as a Class 103 commercial non-power reactor and Coquí may 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.

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Coquí requests that the NRC respond to each issue set forth above as it makes a determination, i.e., that the NRC provide its response for issues (1) through (3) separately, as necessary, as each response becomes complete.

c. Discussion of Licensing Issues

1. *Class 104c License*

Coquí believes that the MIPF can be licensed as a Class 104c facility. Currently all non-power reactors are licensed as Class 104 facilities and it appears, based on publicly available documents, that the NRC has licensed other similar research/commercial facilities as Class 104 facilities in the past.<sup>8</sup> In determining the difference between the Class 103 and Class 104 licenses, the NRC has provided the following guidance:

A non-power reactor may be considered a commercial reactor, as discussed in 10 CFR 50.22. If more than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training, the facility would be considered a commercial non-power reactor. Note that the key is not *where* funding comes from, but *the cost* of owning and operating the facility and *the percentage of the cost devoted* to commercial activities. It is possible for a non-power reactor to be involved in commercial activities that provide a large portion of the budget (e.g., 90 percent), but if the cost of conducting the commercial activity is less than 50 percent of the cost of owning and operating the facility, the facility may be licensed as a Class 104 facility. This arrangement allows facilities to use commercial activities to fund research and development. A commercial non-power reactor generally would be licensed as a Class 103 facility, in accordance with 10 CFR 50.22, and the licensing process would be similar to that for a power reactor .... The NRC staff determines whether an activity is a commercial activity on a case-by-case basis .... In the application, the applicant should discuss any specific activities it is involved in or plans to be involved in and should specify which are commercial activities and which are not. The applicant should show the percentage of cost devoted to commercial activities.

NUREG-1537 at 15-3 (underlined emphasis added).

As Coquí indicated during its April 15, 2010 meeting with the NRC, the Company intends to conduct research activities with the reactors. Based on the language in 10 CFR § 50.22 and the NRC guidance in NUREG-1537, if Coquí can establish that the cost of conducting the commercial activity for the reactor is

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<sup>8</sup> See, e.g., the Cintichem, Inc. reactor in Tuxedo, New York that generated isotopes for both commercial use and research from 1961 until it ceased operations in 1990. NRC Press Release No. 98-152, NRC Terminates Licenses at Request of Cintichem in Tuxedo, New York (Aug. 27, 1998).

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less than 50 percent of the cost of owning and operating the reactor, then the reactors may be licensed as a Class 104 facility under 10 CFR § 50.21.

In this regard, Coquí estimates that each of the identical twin reactors will cost [ ] to build. This estimate is derived from the cost estimate provided to us by the Company's selected contractor INVAP. Therefore the reactor portion of the facility is expected to cost a total of [ ] and will have a useful life of 40 years. Using a straight-line depreciation methodology, the cost of owning the reactor portion of the facility is [ ].

The staff necessary to run the reactor operations includes nuclear engineers, reactor operators, and electrical and mechanical technicians. Coquí estimates that the cost of the reactor operations personnel will be approximately [ ] per year, including payroll taxes and medical insurance. Other operating costs that must be considered are fuel burn-up, perquisites, decommissioning costs, maintenance, and utilities. The Company expects that the total cost of these attributable to reactor operations will be approximately an additional [ ].

Given the foregoing analysis, the Company therefore expects that the total annual cost of owning and operating the reactors will be [ ]. As previously stated, the Company intends to conduct a significant amount of research at this facility, as it will make reactor time available to various universities, the Puerto Rico Science Trust, and other companies that wish to conduct research at the facility. While the Company does not have any research agreements currently in place, by the time Coquí begins operations starting in December 2013, the Company expects to be able to generate revenues from such research activities well in excess of the [ ] that would be necessary for MIPF to qualify to be licensed under Class 104c.

Based on the foregoing, Coquí requests that the NRC make a determination that its facility may be licensed as a Class 104c facility.

### 2. *Class 104a License*

In the alternative, even if the facility did not qualify as a Class 104c facility, Coquí believes that, based on the language of 10 CFR § 50.21, the Company's reactors may qualify to be licensed as a Class 104a medical facility. Coquí recognizes that licensing its facility as a Class 104a medical therapy facility would mark a departure from existing NRC guidance, contained in NUREG-1537, which explains that for regulatory purposes, the NRC staff considers medical therapy at non-power reactors to require two components: (1) a medical use licensee authorized to use the neutron beam from the facility to irradiate patients and (2) the non-power reactor that provides the neutron beam. While Coquí's facility would not use the reactor itself for purposes of treating patients, the medical isotopes produced would be used for medical therapy. NUREG-1537 at 16-3.

As provided in 10 CFR 50.21, a "class 104 license will be issued, to an applicant who qualifies ... to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use ... a

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utilization facility for use in medical therapy....” Coquí believes that the MIPF is a utilization facility that produces, manufactures and sells in interstate commerce radioisotopes used in medical therapy. Such a reading appears to satisfy the plain meaning of the regulation, and thus Coquí believes that the MIPF can be licensed as a Class 104a facility. Further, the NRC has recognized that it has not had many opportunities over the years to examine the boundaries of Class 104a licenses, and thus the little precedent that exists in this area should not be dispositive. NUREG-1537 at 16-3.

The Coquí facility meets the definition of a utilization facility, which is defined in 10 CFR § 50.2 as “any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233.” The MIPF is designed for the production of medical isotopes and for research and therefore the reactor portion of the facility is classified as a “utilization facility.”

Based on the foregoing, Coquí requests that the NRC make a determination that its facility may be licensed as Class 104a facility.

### 3. *Class 103 Commercial Non-Power Reactor*

Coquí understands that if more than 50 percent of the annual cost of owning and operating the reactors is devoted to the production of materials for commercial activity, then the MIPF would be considered by the NRC to be a Class 103 facility, which should be licensed under 10 CFR § 50.22. In the event that Coquí does not meet the criteria for a Class 104 license, then the Company requests that the NRC make a determination that its reactors may be licensed as a Class 103 commercial non-power reactor and that Coquí can rely on NUREG-1537, to the extent applicable, as the appropriate licensing guidance and standard for preparing its application.

NUREG-1537 at xvi provides:

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.

Thus, it appears that during the development of the guidance document, the NRC understood that there may be commercial non-power reactors. 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 and that the potential hazards with fission product inventories are proportionately less than power reactors. Therefore, in comparison to power reactors, less prescriptive measures are appropriate for non-power reactors. Further, we believe the format and content for the license application for the facility should adhere to NUREG-1537, to the extent that it applies to the MIPF.

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This approach is consistent with recent NRC precedent. Coquí understands that the NRC recently made a determination that another molybdenum-99 production reactor could be licensed as a Class 103 commercial non-power reactor. Coquí further understands that the NRC indicated that the potential applicant could rely on NUREG-1537, to the extent applicable. See SECY-09-0101, Licensing of Babcock and Wilcox Medical Isotope Production System (July 9, 2009).

Based on the foregoing, in the event that the MIPF may not appropriately be licensed as a Class 104 facility, Coquí requests that the NRC make a determination that its facility may be licensed as a Class 103 commercial non-power reactor and that Coquí may rely on NUREG-1537, to the extent applicable, in preparing its application.