

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

June 23, 2010

SUBJECT: Part 2 of the Proposed Licensing Plan for Coquí Radiopharmaceuticals Corp.'s Medical Isotope Production Facility Pertaining to the Safety and License Strategy for the MIPF and Certain Questions for the NRC

During our April 2010 discussions with the U.S. Nuclear Regulatory Commission (NRC), Coquí Radiopharmaceuticals Corp. (Coquí) informed the NRC that it would transmit a licensing plan document to the agency addressing Coquí's views on the licensing of the proposed Medical Isotope Production Facility (MIPF). On May 21, 2010, Coquí transmitted to the NRC Part 1 of the Proposed Licensing Strategy for Coquí Radiopharmaceuticals Corp.'s Medical Isotope Production Facility Pertaining to the Facility's License Class. Herein, Coquí provides the NRC with its second submission pertaining to the licensing of the MIPF. In Enclosure (1), which is considered proprietary, Coquí provides its Safety and Licensing Plan for the NRC Staff's information. In Enclosure (2), Coquí sets forth certain specific questions on important issues related to the NRC's licensing standards and processes for which Coquí requests NRC responses. The NRC's responses to these questions will assist Coquí in determining the best path forward for the project.

Because Coquí considers the information contained in Enclosure (1) to be proprietary, Coquí requests that Enclosure (1) be withheld in its entirety from public disclosure, pursuant to 10 CFR § 9.17(a)(4) and 10 CFR § 2.390. We have provided the necessary affidavit to support our request in Enclosure (3). Upon the removal of Enclosure (1), this document and its attachments may be made public.

We look forward to the NRC's responses to the licensing questions set forth in Enclosure (2). We would appreciate the Staff's responses by July 30, 2010 or earlier if possible, and are prepared to work with the Staff to facilitate its review as necessary. If you have questions or need additional information, please contact me at 787.993.2800 or by email at cbigles@coquipharma.com.

Sincerely,



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

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- Enclosure:
- (1) Safety and Licensing Plan (**Proprietary**)
 - (2) Certain Questions for the NRC Pertaining to the Safety and Licensing Plan
 - (3) 10 CFR 2.390 Affidavit of Carmen I. Bigles, President and Chief Executive Officer, Coquí Radiopharmaceuticals Corp.

Cc:

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ENCLOSURE (2)

**Certain Questions for the NRC Pertaining to the
Safety and Licensing Plan**

Certain Questions for the NRC Pertaining to the Safety and Licensing Plan

1) *Safety Criteria.* In Section 7.2 of the of the Safety and Licensing Plan (Plan), at page 14, Coquí Radiopharmaceuticals Corp. (Coquí) provides that safety criteria will be specified for all structures, systems, and components (SSCs) important to safety. Dose, dose rate and radionuclide concentration limits will be established, and the analysis of the design will demonstrate compliance with these limits. As per NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, Part 1, at pg. 6-5, dose acceptance criteria will be adopted as follows:

nnnn) Dose limits for normal operation for staff and the public: as presented in 10 C.F.R. 20.1201 and 10 C.F.R. 20.1301

oooo) Dose limits for Maximum Hypothetical Accident :

(v) Staff: 50 mSv whole body, 300 mSv thyroid

(vi) Public: 5 mSv whole body, 30 mSv thyroid

Please confirm whether this approach to specifying safety criteria is acceptable to the NRC.

2) *Safety Assessment.*

A. Safety Assessment Analyses List. Section 9 of the Plan, at page 15, provides a list of analyses that will be included in the Safety Assessment for the Medical Isotope Production Facility (MIPF), including the following:

pppp) Comprehensive list of postulated initiating events;

qqqq) Design basis accidents analysis;

iv. Reactors: Plant analysis; and

v. RPP (Radioisotope Processing Plant): Systems behavior and consequence analysis;

vi. WMP (Waste Management Plant): Systems behavior and consequence analysis;

rrrr) Human factors assessment;

ssss) Beyond design basis accident analysis; and

tttt) Dose assessment for maximum hypothetical accident.

Please comment on this list and indicate whether the list is comprehensive or whether the NRC believes there are additional important tasks or analyses that should be included in the Safety Assessment.

B. Design Basis Accidents. Section 9.1.2 of the of the Plan, at page 17, provides that the acceptance criteria for design basis accidents (DBA) in the Reactors facility will be no damage to the core or molybdenum targets. For purposes of the design and licensing basis for the MIPF, a DBA is defined as an initiating event combined with a single failure in the system performing the most significant safety function. Multiple failures will not be considered within the design basis.

Please confirm whether this approach is acceptable to the NRC.

3) *NRC Inspection of the Construction and Testing of Safety-Related Systems, Structures, and Components.* In Section 5.4 of the Plan, at page 9-10, Coquí notes that the NRC may want to witness the construction and testing of safety-related SSCs. In coordination with the NRC, Coquí will agree to hold on these construction and testing activities as necessary to allow the NRC to conduct desired inspections. At this stage of the project, Coquí envisions that the NRC may wish to witness the construction and testing of the following SSCs:

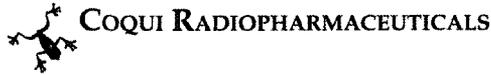
- a) Reactor Building
- b) Reactor Block
- c) Fuel
- d) Reactor Protection System
- e) Reactor Shutdown System
- f) Reactor Pool
- g) Flap valves
- h) Systems related to confinement reconfiguration in emergency mode
- i) Hot cells in the RPP
- j) Ventilation system in the RPP

Each SSC will have a Specific Inspection and Test Plan (SITP) that will be prepared according to the project's Quality Assurance Management Plan. While the SITP may not be ready before the application of the application early 2011 , the SITP will be prepared and approved prior to the construction stage.

In order to ensure that Coquí has all the necessary SITPs prepared, please comment on this approach, including whether the list of safety-related SSCs is comprehensive or whether the Staff believes additional SSCs should be included.

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 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 business information created 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 U.S.C. Section 552(b)(4), the Trade Secrets Act, 18 U.S.C. Section 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 Coquí's proposed 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 certain business decisions Coquí has made or is considering and the analysis that went behind those decisions. 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 potential business, and includes substantial time and work towards developing the MIPF project, and represents significant efforts by Coquí and its associates. The research, development, engineering, and analytical costs comprise a substantial investment of time and money by Coquí. The precise value of the information is difficult to quantify, but clearly is substantial.
 - vii. Coquí's competitive advantage will be lost if its competitors are able to use the results of Coquí's activities 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

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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 24 day of June 2010.

WITNESS my hand and Notarial Seal.





Notary Public

Perpetual

Date