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

May 24, 2013

Project No.: PROJ0786

Subject: NRC REGULATORY ISSUE SUMMARY 2013-03, PRE-APPLICATION COMMUNICATION AND SCHEDULING FOR MEDICAL RADIOISOTOPE FACILITIES INTENDING TO PRODUCE MOLYBDENUM-99

Coquí Radio Pharmaceuticals Corp. (Coquí) is providing the Nuclear Regulatory Commission (NRC) herein the voluntary answers to the questions set forth in the above-mentioned April 24, 2013 communication. If you have question or need additional information, please contact me by telephone at 787-685-5046 or by email at cbigles@coquipharma.com.

Sincerely,

Carmen Irene Bigles
Chief Executive Officer / President
Coquí RadioPharmaceuticals Corp.

Enclosure: As stated

Cc: Al Alexander, Senior Project Manager
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Board of Directors of Coquí RadioPharmaceuticals Corp.
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ENCLOSURE (1)

Coquí RadioPharmaceuticals Corp.

Design and Licensing Submittal Information

(1) How many applications will be submitted to the NRC? What NRC licensing actions will the application(s) request? What will be the content of the application(s)?

Coquí RadioPharmaceuticals Corporation (Coquí) anticipates that it will submit applications for both a construction permit and an operating license in a single submittal per 10 CFR 2.105(c) for a Medical Isotope Production Facility (MIPF), which will consist of two production reactors and a radioisotope processing plant for the production of molybdenum-99. Coquí intends to submit its Environmental Report for the requested licenses prior to submitting its license application.

(2) Under which part(s) of 10 CFR will the application(s) request licenses? In particular, will license applications be submitted under 10 CFR Part 50 for consideration as a production or utilization facility or under 10 CFR Part 70 as a processing facility? Will an exemption from any part of the regulations be sought?

Coquí's application will be submitted pursuant to 10 CFR Part 50. At this point, Coquí does not anticipate the need to request any exemptions from any part of the NRC regulations when it submits its applications. Coquí will also request a radioactive materials license, which will be requested in its Part 50 reactor license applications.

(3) What consideration, if any, has been given to the applicability of other parts of 10 CFR to the application(s)? For example, a license for possession of byproduct material may be necessary in accordance with 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Coquí will also request authority to possess and use the necessary radioactive materials at the facility when it submits its Part 50 reactor license applications.

(4) When (month and year) will the NRC receive the application(s) for review? Please provide the licensing milestones that have been established for the development, submission, and review of the application(s).

Coquí intends to submit its Environmental Report in November 2013 and its construction permit and operating license applications in a single submittal in March 2014. The Preliminary Safety Analysis Report will follow NUREG 1537 acceptance criteria for non-power reactors. The submission date for the application is subject to timely and successful placement of external funds and receipt of all board of director's approvals. Based on conversations with the NRC staff, Coquí anticipates that the NRC will issue the requested construction permit in March 2015 and the requested operating license in October 2016.

(5) Has a site been selected for each facility described in the application(s)? If so, please describe it.

University of Florida has allocated a site in Alachua, Florida for the MIPF. In a December 7, 2012 communication to the NRC, Coquí provided the NRC with the site assessment for this location.

(6) What design will be used for each facility? What is the current status of the development of the design(s) (i.e., conceptual, preliminary, or final)? Please provide a schedule for completing the design(s).

The Coquí reactor is an INVAP reactor design. INVAP is the reactor designer and the general contractor for the MIPF. The INVAP reactor design is conceptual, the development of the preliminary design supporting the Preliminary Safety Assessment is associated with the availability of external funds.

(7) Are vendors or consultants assisting in preparing the application(s)? If so, please describe their roles and responsibilities in the design and licensing activities.

INVAP is the reactor designer and general contractor for the project. Gresham Smith & Partners domestic design firm. Coquí has also engaged the law firm of Hogan Lovells to provide nuclear regulatory licensing counsel.

White Papers and Technical or Topical Reports

(1) Are there current plans to submit white papers or technical or topical reports related to design features, policy resolution, or technical issues for review and approval? If so, please describe and provide a schedule for submitting the anticipated report(s).

In May 2010, Coquí submitted a first licensing strategy document to the NRC about what class of license Coquí intends to apply for. In June 2012, Coquí submitted a second licensing strategy document to the NRC, which provided for the NRC staff's review a Safety and Licensing Plan for the technical portions of the applications that Coquí prepared with INVAP. Coquí does not anticipate that it will submit any more white papers.