

**COQUI RADIO PHARMACEUTICALS CORP.**  
**MEDICAL ISOTOPE PRODUCTION FACILITY**

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

December 19, 2013.

Project No.: PROJ0786

Subject: COQUI RADIO PHARMACEUTICALS, CORP. - PLANS FOR SUBMISSION  
OF APPLICATION FOR MEDICAL ISOTOPE PRODUCTION FACILITES

Coquí Radio Pharmaceuticals Corp. (Coquí) is providing the United States Nuclear Regulatory Commission (NRC) herein with an update on the status for the submittal of its applications.

If you have questions or need additional information, please contact me at my office 787-993-2800, or by email at [cbigles@coquipharma.com](mailto:cbigles@coquipharma.com).

Sincerely,



Carmen Irene Bigles  
Chief Executive Officer  
Coquí Radio Pharmaceuticals Corp.  
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Enclosure: (1) Coquí Radio Pharmaceuticals, Corp. Scheduling Update

Cc: Al Alexander, Senior Project Manager  
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NRR

## ENCLOSURE (1)

### Coquí Radio Pharmaceuticals Corp.

On May 24, 2013, Coquí submitted to the NRC information on the design, licensing, and scheduling for our proposed Medical Isotope Production Facility. Based on recent developments, we would like to provide an update to the information contained in that communication. As of September 2013, the company obtained partial financing. At this time we are completing the financing for the licensing which should be accomplished by February 2014.

In May 24, 2013 we update our May 24, 2013 letter.

#### *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 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 applications 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) 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 May 2014, its construction permit application in October 2014 or sooner, and operating license application in October 2016. The Preliminary Safety Analysis Report will follow NUREG-1537 acceptance criteria for non-power reactors. Based on conversations with the NRC staff, if Coquí's applications and supporting documents are submitted in accordance with the schedule discussed herein, it anticipates that the NRC will issue the requested construction permit by October 2015 and the requested operating license around October 2017.

(4) 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 an open pool type reactor, with MTR type fuel. The development of the specific features of this design, tailored for the purposes of this facility, is at the conceptual stage at this point, and it is based on previous designs by INVAP and on LEU proven technology.