

November 4, 2010

MEMORANDUM TO: THOSE ON THE ENCLOSED LIST

SUBJECT: SUMMARY OF CATEGORY 1 MEETING WITH COQUÍ
RADIOPHARMACEUTICALS CORP TO DISCUSS THE
APPLICATION FOR A MEDICAL ISOTOPE PRODUCTION
FACILITY

On October 6, 2010, the U. S. Nuclear Regulatory Commission (NRC) staff met with Coquí Radiopharmaceuticals Corporation (Coquí) and other stakeholders at NRC headquarters to discuss the status of Coquí's application for a Medical Isotope Production Facility (MIPF). A portion of this meeting was closed to the public to discuss proprietary information. Enclosure 1 lists meeting attendees.

The NRC issued a public meeting notice on September 22, 2010. The notice, posted on the NRC's external (public) web page (Agencywide Documents Access and Management System (ADAMS) Accession No. ML102630033), included the meeting agenda, which NRC staff made available as a handout at the meeting.

Status of MIPF Application

During the meeting, Coquí provided the NRC with a status summary of their application for a MIPF. Coquí also announced INVAP as the designer and general contractor for their MIPF. According to plans presented at the meeting, two reactors, operating below 10 megawatts each, will occupy approximately a 98,000 square-foot facility. Additionally, the open pool type reactors will utilize a defense-in-depth approach to safety design.

To conclude their presentation, Coquí announced their intent to submit their MIPF application within the second quarter of calendar year (CY) 2011 and begin plant operation by CY 2014.

Questions and Comments

Following the presentation of the MIPF application status, NRC staff and Coquí engaged in a session of questions and comments.

Mary Jane Ross-Lee, Research and Test Reactors Projects Chief, asked Coquí whether they would seek a Class 103 or 104c operating license for their proposed facility. In response, Coquí indicated that they have not yet decided whether they will submit an application for a Class 103 or 104c operating license as they are in the process of reviewing and reevaluating their licensing approach based on NRC feedback provided by letter dated October 1, 2010 (ADAMS Accession No. ML1020205151) to questions posed in May 21, 2010 letter requesting pre-licensing guidance (ADAMS Accession No. ML101550454).

Additionally, Coquí informed the NRC that they had developed their licensing strategy, in part, based on the guidance provided in NUREG-1537; however, they also indicated that the guidance in this report did not completely fulfill their licensing needs. In response, the NRC acknowledged Coquí's unique licensing situation and indicated that interim guidance for reviewing their license application is in development. Until the interim guidance is completed, the NRC encouraged Coquí to consult NUREG-1520 and Title 10 of the *Code of Federal Regulations*, Part 70 to address safety and environmental impact at their proposed processing facility.

In response to a NRC staff inquiry regarding their interactions with the Food and Drug Administration (FDA), Coquí indicated that they will be working to gain FDA approval of their Molybdenum production based on the approach used by the Open Pool Australian Light-water (OPAL) reactor. Coquí went on to add that they are also consulting with groups such as the International Group on Research Reactors (IGORR) to stay informed on global happenings and developments in the Research and Test Reactor community.

/RA/

Marcus Voth, Project Manager
Research and Test Reactors Projects Branch
Division of Policy and Rulemaking
Office of Nuclear Regulatory Regulation

Enclosures: 1. Meeting Attendees
2. Presentation Slides

cc w/encl: See next page

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/RA/

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Division of Policy and Rulemaking
Office of Nuclear Regulatory Regulation

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2. Presentation Slides

cc w/encl: See next page

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ADAMS Accession No. PKG: ML103020016; MTG Notice: ML102630033; MTG Summary: ML103020021;
Slides: ML103020216 NRC-001

OFFICE	PRPB/SPM	PRPB/LA	PRPB/BC	PRPB/SPM
NAME	MVoth	GLappert	MRoss-Lee	MVoth
DATE	11/4/2010	11/4/2010	11/4/2010	11/4/2010

OFFICIAL RECORD COPY

LIST OF ATTENDEES

**CATEGORY 1 MEETING WITH COQUÍ RADIOPHARMACEUTICALS CORP TO DISCUSS
THE APPLICATION FOR A MEDICAL ISOTOPE PRODUCTION FACILITY**

WEDNESDAY, OCTOBER 6, 2010

1:00 PM EDT

<u>NAME</u>	<u>ORGANIZATION</u>
Carmen Irene Bigles	Coquí Radiopharmaceuticals
David Garrity	Coquí Radiopharmaceuticals
Joseph Brennan	Coquí Radiopharmaceuticals
Mark Geurts*	Coquí Radiopharmaceuticals
Alejandro Valderrábano-Wagner	Fiddler Gonzalez & Rodriguez, P.S.C.
Pablo Abbate	INVAP
Veronica Garea*	INVAP
Daniel Stenger	Hogan Lovells, US, LLP
Amy Roma	Hogan Lovells, US, LLP
Paul Sawyer	Louisiana Economic Development
Donald M. Pierson	Louisiana Economic Development
Allison Graves	Entergy Power
John Bolin*	General Atomics
Michelle Sanchez*	EWM Realtors
Katherine Smith	Embassy of Australia
Alex Sapountzis	NRC/NSIR/DSP
MaryJane Ross-Lee	NRC/NRR/DPR
Taylor Lichatz	NRC/NRR/DPR
Steve Lynch	NRC/NRR/DPR
Xiaosong Yin	NRC/NRR/DPR
John Adams	NRC/NRR/DPR
James McGovern	NRC/NRR/DPR
Al Adams	NRC/NRR/DPR
Ossy Font	NRC/NRR/DPR
Marcus Voth	NRC/NRR/DPR
Spyros Traiforos	NRC/NRR/DPR
Geoffrey Wertz*	NRC/NRR/DPR
Jonathan Ortega-Luciano	NRC/NRR/DE
Marilyn Diaz	NRC/NMSS/FCSS
Mary Adams	NRC/NMSS/FCSS
Christopher Hair	NRC/OGC
Cathy Kanatas	NRC/OGC

*Indicates Webinar participant

ENCLOSURE 1