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P H A R M A Lifesaving Medical Isotopes

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Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

April 18, 2016

Re: Comments of Coquí RadioPharmaceuticals Corp. on NRC's Financial Qualifications for Reactor Licensing Draft Regulatory Basis Document (Docket ID NRC-2014-0161)

Coquí RadioPharmaceuticals Corp.'s ("Coquí") hereby submits comments to the U.S. Nuclear Regulatory Commission ("NRC") on the NRC's Financial Qualifications for Reactor Licensing Draft Regulatory Basis Document (Docket ID NRC-2014-0161) ("FQ Regulatory Basis"). While the comment period noted in the Federal Register notice for the FQ Regulatory Basis Document has expired, Coquí respectfully requests that the NRC consider these comments as it proceeds with the anticipated financial qualifications rulemaking for reactor applicants.

By way of background, Coquí is in the process of preparing an NRC construction permit application for a Medical Isotope Production Facility ("MIPF"), which would consist of two commercial non-power reactors (approximately 10 MW, which would not run simultaneously), a radioisotope processing facility, and a waste processing plant. This MIPF will be the first such facility in the United States and is designed to create a commercially scalable and reliable source of medical diagnostic and therapeutic radioisotopes. Coquí's facility will produce Molybdenum-99 (Mo-99). This critical material is the world's most widely used medical radioisotope, utilized in 80% of all nuclear medicine procedures. Annually over 18 million procedures in the United States utilize Mo-99. There is currently no domestic production source for this material. The U.S. government has recognized that establishing a U.S. production source for this critical life-saving isotope is a matter of national priority and in 2012 Congress passed the American Medical Isotope Production Act, which is incorporated into U.S. law at 42 U.S. C. § 2065, to promote the prompt development of facilities like the MIPF.

Coquí only recently became aware that the NRC was undertaking this financial qualifications ("FQ") rulemaking and that the NRC did not intend to include commercial non-power reactors within the scope of facilities for which the new rulemaking would apply. As set forth in Section 7.2.3 of the FQ Regulatory Basis Document, in relevant part and with emphasis added:

Non-power production and utilization facilities include all existing non-power reactors licensed under 10 CFR 50.21(a) and (c) and proposed production and utilization facilities licensed under 10 CFR 50.22 for the production of medical radioisotopes, such as molybdenum-99.

So far, no one has raised a concern with the NRC regarding the FQ requirements for non-power production and utilization facilities. It does not appear that applicants for this type of facility have had the same difficulty meeting current requirements for initial licensing that current merchant plant applicants are experiencing....Because it appears that the current requirements are working for this class of applicants, the NRC expects that this class of applicants will show they are financially qualified by demonstrating their availability of funds at the time of licensing. The NRC anticipates that some of the current requirements of Appendix C of 10 CFR Part 50 will be placed in guidance for this class of applicants.

As a commercial non-power reactor pre-applicant lining up project financing, Coquí respectfully disagrees with the NRC's position. Nuclear projects—whether power or non-power—are expensive to construct. From a private equity standpoint, only a limited number of investors have an appetite for nuclear projects, which makes access to capital more difficult than for non-nuclear projects. Long project times and regulatory uncertainty further dampen the risk appetite for potential investors. With that said, Coquí—like many of the merchant plant combined operating license (“COL”) projects—intends to finance its project using a traditional project finance model. While the current NRC FQ requirements require an applicant to line up financing before a license can be granted, under a project finance model, an applicant cannot line up the funds until a license has already been granted. This “chicken and egg” problem was first raised to the NRC's attention by then COL applicant and now COL holder, Nuclear Innovation North America, LLC (“NINA”), and the Nuclear Energy Institute (“NEI”). As the NRC summarized in the FQ Draft Regulatory Basis Document (at 2):

NINA and NEI stated it is difficult, if not impossible, for merchant plant COL applicants to secure project funding to meet FQ requirements in advance of initial license issuance. The failure of an applicant to meet FQ requirements would generally preclude the applicant from obtaining the COL.

This issue led to the NRC staff submitting SECY-13-0124, “Policy Options for Merchant (Non-Electric Utility) Plant Financial Qualifications,” dated November 22, 2013, to the Commission. In an April 24, 2014, Staff Requirements Memorandum on SECY-13-0124, the Commission approved the NRC staff's recommendation to conduct a rulemaking to amend the nuclear reactor FQ requirements in 10 CFR Part 50 to conform to 10 CFR Part 70 standards for fuel cycle facilities. As directed by the Commission, the proposed rulemaking would require the applicant to submit a plan for financing the construction and operation of the facility. The plan would demonstrate that the applicant has both a well-articulated understanding of the size of the project it is undertaking and the capacity to obtain the necessary financing when the applicant is ready to start construction. The rule would permit the NRC, when issuing a reactor license for applicants with 50 percent or less funding at the time of application, to include a license condition that would ensure funding is available prior to beginning construction, rather than at the time of license issuance. The NRC likewise applied this intended rulemaking policy in issuing NINA's COL for the STP 3 & 4 project.

Coquí does not agree with the NRC staff's position that a 10 MW reactor, like the MIPF, should be subject to a stricter financial qualification requirement than a large-scale nuclear power plant more than one hundred times the size of the MIPF. As an initial matter, there does not appear to be any sound reason to develop two different FQ tracks as the staff proposes—a less strict path for large scale

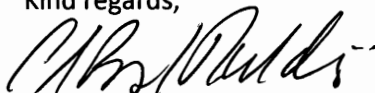
commercial reactors and a much stricter path for much smaller projects. If the staff's position lies in the fact that it has not heard an objection to this approach, then Coquí respectfully submits that this is likely because the NRC has been reviewing merchant plant COL applications for the last decade, and it was only during the course of this review did the FQ issue for merchant nuclear power plants arise—and that was in 2012—five years after NINA first submitted its COLA. For commercial non-power reactors, there have been so few of these types of applications over the years and only a couple in recent memory, that there likely has not yet been an opportunity for this issue to fully come to light during a licensing review. Along this line, Coquí further respectfully submits its objection to the staff's position that commercial non-power reactors should not be including in the NRC's present FQ rulemaking.

To the extent that the NRC believes that commercial non-power reactors are somehow not subject to the same "chicken and egg" project finance issue that NINA and other merchant plant applicants face, Coquí also respectfully submits that this is not correct. Like the NRC noted for merchant plants in the FQ Draft Regulatory Basis Document, Coquí must rely on "its own internal resources or third-party project finance investors" (at 2). Our project is an approximately \$500 million project. Few companies, if any, would have their own "internal resources" to finance a project of this size. Therefore, we intend to utilize the latter option. However, as with NINA, we would have difficulty meeting the NRC's present FQ requirements using our intended project finance model.

Moreover, the NRC staff does not state any safety reason to support its position that the FQ requirements for only large merchant plant applicants should be amended. As with the NRC's proposed approach to power reactors, a commercial non-power reactor applicant could submit a plan for financing the construction and operation of the facility that would demonstrate that the applicant has both a well-articulated understanding of the size of the project it is undertaking and the capacity to obtain the necessary financing when the applicant is ready to start construction. The NRC could also, when issuing a reactor license for applicants with 50 percent or less funding at the time of application, include a license condition that would ensure funding is available prior to beginning construction, rather than at the time of license issuance. That way, the NRC can ensure that post-license a project does not move forward until such time as sufficient funds are available to complete construction. If anything, this approach poses less risk than the proposed FQ approach for large nuclear power plants because our facility is so much smaller and construction costs are easier to manager.

Finally, Coquí would like to underscore the critical importance of the NRC licensing a facility like the MIPF. The facility will produce life-saving medical isotopes that are of critical importance in the U.S. The NRC should not keep arcane regulations that could impede our project development unless these regulations are supported by a sound safety or security concern. In this case, if the NRC determines that the proposed changes to the FQ requirements are sound regulatory changes for merchant power plants, then the NRC should also make the same determination for non-power plants.

Kind regards,



Carmen I. Bigles

Chief Executive Officer

Coquí RadioPharmaceuticals Corp.

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