From:	Baklanov Sergey
To:	Sepulveda, Lymari
Cc:	Herrera, Tomas
Subject:	Re: Request for Additional Information
Date:	Monday, April 20, 2015 10:01:27 AM
Attachments:	ANT Response to NRC RAI150419 04.20.15.pdf

Dear Ms. Sepulveda

We are writing in response to your Request for Additional Information, dated 15 April 2015, with regard to our application for Sealed Source Registration of the ANT Model 1 brachytherapy source (please see attached letter).

We have also attached a revised version of the application body to incorporate the changes requested in your e-mail.

We have also attached the revised label drawing.

We trust this satisfactorily provides the additional information you require. Your prompt review of this request would be greatly appreciated. If we can provide any additional information, please contact me.

Sincerely,

Sergey Baklanov, Ph.D.

President

Advanced Nuclide Technologies
Phone: +1 267 2532271
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On Apr 15, 2015, at 4:25 PM, Sepulveda, Lymari wrote:

Mr. Sergey,

After reviewing your application, we found that further clarification is required in order to complete the safety evaluation of ANT Model 1 source. Please address the question listed below:

- In your letter dated December 29, 2014, page 4, states that " …a source certificate is provided with each source assembly." Please explain what the term "source assembly" represents.

- Please note that sources manufactured and distributed under 10 CFR 32.74 (3) or

equivalent Agreement State, should include in the label the following statement: "the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source) to persons licensed to use byproduct material identified in 35.400…" While this statement has been included in your source certificate, this statement needs to be incorporated in the label affixed to the source. Please provide a revised copy of the label containing the statement required by 10 CR 32.74 (3).

- In your letter dated December 29, 2015, you did not identify the method of sterilization or any limitations of use regarding how the sources will be sterilized. Please provide information on sterilization of the seeds and any limitations of use.

The information should be submitted in an official company letter via facsimile at 301-415-5955 or as an attachment to an e-mail.

Please submit the requested information within 30 days of the date of this e-mail. If we have not received complete information within 30 days of the date of this e-mail, we will considered your application as been abandoned by you. This is without the prejudice to the submission of a complete application.

Thanks,

Lymari Sepulveda
Mechanical Engineer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal, and Regulatory Programs
Office of Nuclear Material Safety and Safeguards