

Kime, Traci

From: Valentin-Rodriguez, Celimar
Sent: Tuesday, September 29, 2015 10:48 AM
To: debra.bensen@elekta.com
Cc: Herrera, Tomas; Sepulveda, Lymari
Subject: NRC Request for Additional Information, Elekta Letter Dated September 1, 2015

Dear Ms. Bensen,

While reviewing the Elekta letter dated September 1, 2015, we found that we need additional information to complete our review of your proposed amendment to Registration Certificate NR-0497-S-113-S.

- The labels submitted with your letter do not reference the distributor's name and address in the U.S. Please provide a copy of the labels which identify Elekta as the distributor and include Elekta's address. In addition, the labels must be in accordance with 10 CFR 32.74(a)(3), which requires the following statement,

"The U.S. Nuclear Regulatory Commission has approved distribution of the (name of the source) to persons licensed to use byproduct material identified in 10 CFR 35.400."

Please submit the requested information within 30 days of the date of this e-mail. The information should be submitted in an official company letter as an attachment to an e-mail or via facsimile at 301-415-5955. If we do not receive a response with the complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a new request.

Thank you,

Celimar Valentin-Rodriguez, Ph.D.

General Engineer
U.S. Nuclear Regulatory Commission
NMSS/MSTR/MSLB

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✉ Celimar.Valentin-Rodriguez@nrc.gov