Weaver, Deborah

From: Arribas-Colon, Maria
Sent: Monday, January 29, 2018 12:56 PM
To: John.Sgro@med.ge.com
Cc: Herrera, Tomas
Subject: Request for Additional Information: SS&D Certificates transfer from TX to US NRC: TX-1032-D-103-S and TX-1032-D-104-S

Good Afternoon Mr. Sgro,
The State of Texas recently notified the U.S. NRC of the need to transfer two registration certificates TX-1032-D-103-S and TX-1032-D-104-S from Texas to the NRC. We have reviewed the information provided by the State of Texas to transfer GE Healthcare Registrations Certificates TX-1032-D-103-S and TX-1032-D-104-S to NRC. In order for us to complete the transfer, we need the information below.

For Registration Certificate TX-1032-D-103-S

1. As part of the NRC's review to transfer the registration certificate from the State of Texas to the NRC, the NRC identified that three references were missing from the files transferred by the State of Texas. The State of Texas was unable to locate the references. For completeness purposes, please provide a copy GE Medical Systems letter dated September 14, 2006, electronic emails dated October 30, 2006 and November 9, 2006.

2. Please indicate if there are different designations for each of the models under the GE Discovery Series. We note that the registration certificate currently states: "It should be noted that individual units within the GE Discovery series may differ in the type and configuration of the detectors, the design of the operator's console, and some software features." For documentation purposes please explain the similarities and differences between the different types of units in the GE Discovery series.

3. The current registration certificate states that "Labels are rectangular in shape, approximately 40 mm x 50 mm (1.5 inches x 2.0 inches), and are attached with 3M#467 adhesive. Materials of construction for the labels are adhesive-backed Mylar/plastic and steel permanently attached to the outside covers with screws. Printing on the labels is underneath the Mylar cover, for added protection." Please confirm if this statement is accurate and clarify if the devices uses both steel and mylar/plastic labels, or if only one type of label is used.

For Registration Certificates TX-1032-D-103-S and TX-1032-D-104-S

4. In the label of your device the following text is cited: "As part of obtaining authorization for distribution, this device has been evaluated by the Bureau of Radiation Control, Texas Department of Health as Registry of Radioactive Sealed Sources and Devices Safety Evaluation TX-1032-D-103-S." Please note that your registration certificate will be now under the U.S. Regulatory Commission purview, therefore the text is not required In addition to the working current only the labels, the new labels must include the following statement, "The U.S. Nuclear Regulatory Commission has approved for distribution of the (name of the device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.00, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State." Please provide a new copy of the label without this text and provide a new label in accordance with 10 CFR 32.74(a)(3).

If you intend to submit the information to us via email, the information should be submitted in an official company letter as an attachment to an email. Please submit the requested information within 30 calendar days of the date of this email.

Thank you,
-María

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U.S. NUCLEAR REGULATORY COMMISSION

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