

Valentin-Rodriguez, Celimar

From: Valentin-Rodriguez, Celimar
Sent: Friday, September 26, 2014 10:07 AM
To: 'gary.shelton@smithsdetection.com'
Cc: Sepulveda, Lymari; Herrera, Tomas
Subject: NRC Request for Additional Information, Smiths Detection letter dated Aug 28, 2014

Good Morning Mr. Shelton,

This email is in response to your amendment request dated August 28, 2014. During the review of your application we found that additional information is needed for us to proceed with the amendment of your registration certificate NR-0163-D-102-E. Please provide the following information:

1. Please confirm that the quality assurance program Smiths Detection previously committed to in NR-0163-D-102-E will also include the new UK manufacturing location. Also, please confirm that the Smiths Detection QA program includes:
 - a. Full design conformity in accordance with the statements and commitments submitted in the application.
 - b. Leak tests for all units to 185 Bq (0.005 μ Ci).
 - c. Tests for proper orientation of all safety features in all units.
 - d. Verification that radiation levels for all units do not exceed maximum values stated in your application.

As stated in the last paragraph on page 10-17 of NUREG 1556, vol. 3, rev. 1, if a foreign manufacturer has an affiliate distributor in the United States, it is the distributor's responsibility to assess the manufacturer's QA/QC program performance in accordance with the manufacturer's established procedures, accepted standards, and/or guides.

Please submit the requested information within 30 days of the date of this email. If we do not receive a response with the complete information within 30 days of the date of this email, 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.

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