

Miller, Debra

From: Herrera, Tomas
Sent: Wednesday, June 07, 2017 7:15 AM
To: david_hoppy@agilent.com
Cc: david_bennett@agilent.com; Arribas-Colon, Maria
Subject: Request for Additional Information re: Amendment to NR-0348-D-111-B

Good Morning Mr. Hoppy,

We have reviewed Agilent Technologies amendment dated April 12, 2017. In order to complete our evaluation please address the questions listed below:

1. Please confirm that there are no changes to the devices or commitments made as part of the Sealed Source and Device Registration certificate NR-0348-D-111-B.
2. Your amendment request dated April 12, 2017, stated that Agilent Technologies will be re-establishing a quality assurance program for the Wilmington site. The amendment request references ISO 9001 certification. Please clarify whether the Wilmington site is ISO 9001 certified, if it is please provide a copy of Agilent's current certification. In addition, please confirm that Agilent Technologies quality assurance program will commit to the following:
 - There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials of construction, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling).
 - All units are leak tested to 185 Bq [0.005 μ Ci].
 - All units are tested for proper operation of all safety features.
 - All units are verified that the radiation levels do not exceed the maximum values stated in the application.

If the Wilmington site is not ISO 9001 certified, please provide a copy of Agilent Technologies quality assurance program. At a minimum, the QA program needs to ensure that (i) the materials of construction and the final assembly meet the design specifications; (ii) the final product is leak tested; (iii) a final radiation profile is performed; (iv) a test is performed that verifies that the product operates as intended, including all safety functions; and (v) a visual and mechanical inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.

3. The Sealed Source and Device Registration certificate NR-0348-D-111-B is a safety evaluation for Agilent Technologies electron capture detectors (ECD). The registration certificate does not authorize the manufacturing or distribution of the ECDs. Please confirm that Agilent Technologies will seek to amend its radioactive materials license issued by Region I to update these activities as necessary.

Please submit the requested information within 30 calendar days of the date of this e-mail. The information should be submitted in an official letter with proper signature we can accept the response as an attachment to an e-mail or via facsimile at 301-415-5955. If we do not receive 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 complete new request.

Please let me know if you have any questions.

Thank you,
Tomas Herrera

SSD Team Leader
U.S. NRC
NMSS/MSTR/MSLB
301-415-7138