January 9, 2014

Mr. David Hoppy
EHS Manager, Eastern Region
Agilent Technologies
2850 Centerville Road
Wilmington, DE 19808

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, AGILENT TECHNOLOGIES LETTER DATED SEPTEMBER 13, 2013

Dear Mr. Hoppy:

This letter is in response to your letter dated September 13, 2013, requesting an amendment to change the current manufacturing facility location (Wilmington, DE) to China (Shanghai). In reviewing your request, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

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

If you have any questions, please contact me at Maria.Arribas-Colon@nrc.gov or (301) 415-6026.

Sincerely,

/RA/

Maria Arribas-Colon, Project Manager
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure: As stated

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NAME	MArribasColon	JJankovich	JJankovich for MKotzalas	MArribasColon
DATE	01/9/14	01/9/14	01/9/14	01/9/14

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Agilent Technologies Amendment Request dated September 13, 2013
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Agilent Technologies amendment request dated September 13, 2013, and determined that additional information is needed in regards to amend Registration Certificate NR-0388-D-111-B. In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556 Volume 3 titled "Applications for Sealed Source and Device Evaluation and Registration."

1. In your letter dated September 13, 2013, you stated: "The ECDs will be manufactured at ATS and distributed world-wide with the majority of US imports being transferred through Agilent's contracted distribution center in New Castle, DE. The distribution center is managed by Legacy Supply Chain Services, which is licensed under NRC licenses 07-31467-01 and 07-31467-02G to distribute generally licensed products. A smaller number of devices will be transferred to the Wilmington, DE site for the installation and final wipe for country of origin and other limited applications for distribution under licenses 07-28762-01 and 07-28762-02G." Please clarify the following:

   - Clearly delineate all the functions of Agilent Technologies, Inc. (located in Wilmington, DE) and Legacy Supply Chain Services (located in New Castle, DE).

   - Explain the following statement: "A smaller number of devices will be transferred to the Wilmington, DE site." Specifically, describe in detail why the transfer is performed, the condition of the devices to be transferred, the location the devices are coming from and explain what constitutes "installation," "final wipe for country of origin," and "limited application for distribution under licenses 07-28762-01 and 07-28762-02G."

   - Clearly state what differentiates the specific products that will be distributed from both facilities. Please note that License No. 07-31467-02G only authorizes Legacy Supply Chain Services to distribute only Device Model Number G2397A, which is one of the models listed in your Registration NR-0348-D-111-B.

2. In your letter you stated: "We wish to request permission to audit the manufacturing facility through the Agilent internal ISO 9001 process in lieu of sending a representative from the site." You also stated: "The QA program will ensure control over all activities applicable to the design, fabrication, inspection, testing, maintenance, modification, and distribution of the sealed device, which are listed in the Wilmington DE possession license." Please note that it is your responsibility as distributor to assess the China location QA/QC program performance in accordance with your QA/QC established procedures. Your must have an established program for assessing the QA/QC program in China, which includes and evaluation of the manufacturing process of your facility in China in accordance with your standards at a frequency necessary to assure quality assurance. You should also maintain records of such audits for future regulatory review in accordance with 10 CFR 110.53(b). Specifically, please describe the following:

   - How the QA/QC program of your Wilmington, DE, location was updated from the one submitted to NRC previously, to account for a manufacturing facility overseas. Please provide a copy of the QA program.

- How you will evaluate and audit the manufacturing process in China?

- Describe the scope of the periodic internal program audits to be performed by ATS's Radiation Safety Officer (Page 2, Bullet 2). Describe the scope of the annual program audits to be performed by ATS's Radiation Safety Officer (Page 2, Bullet 2).

- Describe the scope of the QA activity in your letter "to audit the manufacturing facility through the Agilent internal ISO 9001 process in lieu of sending a representative from the site." Particularly, please delineate the statements "through the Agilent interval ISO 9001 process" and "sending a representative from the site."

3. Please confirm the facility's exact name and location where the products are manufactured.

4. Specify the serial number of the last unit that was distributed by Agilent Technologies prior to the relocation. Please indicate how the records for these units will be kept.

5. Confirm that no changes were made to the products since its initial registration.

6. Confirm compliance, at the new manufacturing site, with all the commitments which had been previously submitted to the NRC and are currently listed in the References of Registration Certificate NR-0348-D-111-B.

7. Provide copies of the labels, which will be applied to the units manufactured in China. Is there a difference between the labels on the units which are distributed by Agilent from Agilent's Wilmington, DE, location and by Legacy Supply Chain Services from the New Castle, DE location?