



Agilent Technologies

2850 Centerville Road
Wilmington, DE 19808

April 12, 2017

U.S. Nuclear Regulatory Commission
Licensing Branch
Office of Federal and State Materials and Environmental Management Programs
ATTN: SSTR
Washington, DC 20555-0001

Ref.: Amendment request to Registry of Radioactive Sealed Sources and Devices NR-0348-D-111-B

To Whom It May Concern,

In 2014, Agilent Technologies, Inc. transferred its Electron Capture Detector (ECD) manufacturing operations from its Wilmington, DE location to its facility in Shanghai, China. Agilent has determined to return the ECD manufacturing operations to Wilmington, DE and the intent of this amendment request is to 1) have the Wilmington, DE site added back as a manufacturer to the above referenced registry, and 2) address a minor change to the QA program.

The address to be added to the current registry as a manufacturer is as follows:

Agilent Technologies, Inc.
2850 Centerville Road
Wilmington, DE, 19808
USA

The manufacturing function will be reinstalled in the exact same location as it was prior to the transfer to China with the same security measures as before.

Additionally, in a letter dated March 27, 2014, Agilent provided a comparison of the QA programs between its Wilmington, DE site and that planned for its Agilent Technologies Shanghai (ATS) site. A copy of that comparison is posted below. The QA program for the Wilmington site will be re-established as listed below with the following addition: Periodic third party certification ISO 9001 audits. ISO 9001 audit requirements are very similar to those identified in NUREG-1556, Vol. 3's Table G.1 "Checklist for Reviewing QA Programs."

Comparison of QA Programs

Wilmington, DE	ATS
Supplier certificates for source manufacture specification compliance	Supplier certificates for source manufacture specification compliance
Biennial auditing of the radioactive source vendor	Biennial auditing of the radioactive source vendor
Engineering control over specification drawings and manufacturing procedures	Engineering control over specification drawings and manufacturing procedures
Manufacturing procedures	Manufacturing procedures
Product test procedures	Product test procedures
Internal movement control procedures	Internal movement control procedures
Radiation measurement instrument control	Radiation measurement instrument control
RSO's quarterly radiation program review	RSO's quarterly radiation program review
RSO's annual radiation program review	RSO's annual radiation program review
Periodic radiation profiles on finished product	Periodic radiation profiles on finished product
	Biennial internal audits in line with NUREG-1556, Vol. 3, Appendix G, Table G.1
	Periodic third party certification ISO 9001 audits

The manufacturing operation transfer is expected to take place during the September to November 2017 timeframe, dependent upon the approval of this amendment request. As we do not have an exact date, we propose retaining the Shanghai location on the registry until the manufacturing process has been returned and then file for an amendment to have it removed. As there are multiple sealed source device model numbers impacted by the move, the site's RSO will record the first serial number of each model manufactured at the Wilmington location.

Please let me know if you have any questions or concerns regarding the supplied information in this amendment request.

Sincerely



David Hoppy, CHMM
EHS Manager, Eastern Region

C.c. David Bennett (RSO)