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REGION 1

2006 SEP 19 AM 10: 07

Agilent Technologies
2850 Centerville Road
Wilmington, DE 19808

Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road,
King of Prussia, PA 19406

07-28762-026
03032988

Re: Letter of Commitment

September 18, 2006

Dear Sir or Madam,

The purpose of this letter is to inform the NRC of Agilent Technologies' commitment to corrective and preventative measures being taken in light of the vendor specification discrepancy identified in letters to the NRC dated August 10 and September 14, 2006 (copies included). A brief description of the issue leading to the amendment request of September 14 and the items that Agilent commits to in order to correct and prevent recurrence follow.

Description of issue:

During a 2004 audit, one of Agilent's Ni-63 sealed source vendors, QSA Global, Inc., was found to be manufacturing at a maximum activity specification that was different from the specification maintained in Agilent's historical engineering drawings, and the activity limit identified in the product introduction amendment request letter dated July 21, 1983. The audit was performed by a third party at the direction of the site's Procurement Department. The sealed sources provided by QSA Global Inc. are used to build Agilent ECD models 19233 and 19235 as described in the SS&D Registry NR-0348-D-109-B. As described in the letters dated August 10'th and September 14'th, Agilent's (originally Hewlett Packard's) maximum activity specification has always been 15 millicuries, but QSA Global has manufactured at a specification of 15 millicuries maximum with a tolerance of +20%, making the true possible maximum activity to be 18 millicuries. The Procurement Department initiated a supplier corrective action investigation attempting to identify the source of the problem but to no avail, due much to the length of time since the issue was first created.

Agilent has been notified by voice communication through Mr. Joe Nick of the NRC Region I office that the SS&D office has determined that the difference in maximum activity will not cause any significant performance change in the product nor present an increased customer exposure risk. Based

NMSS/RGN1 MATERIALS-002

on this information, Agilent determined to request an amendment to the affected registry to reflect the vendor's specification of 15 millicuries +20%, as shown in the enclosed amendment letter dated September 14, 2006.

Agilent commits to the following corrective and preventive measures:

1) Corrective Actions:

- Amend the affected SS&D registry (completed with submission of letter to Washington DC NRC office on September 14'th) to reflect the correct specification and manufacturing tolerance.

- Issue a Manufacturing Alert (internal communication form to stop parts manufacturing) to suspend manufacturing of the affected parts until the SS&D registry has been amended (copy enclosed).

- Amend Agilent Technologies, Inc,'s product engineering drawing to reflect the +20 maximum activity tolerance.

- Issue notification letters to all existing customers holding models 19233 (distributed to general license customers) and 19235 (distributed to specific license customers) identifying the situation and actions requested of them. Owners holding model 19235 will be requested to review their licenses and determine the need for license amendment due to the increased specification.

- Issue notification letters to all Agreement State and Regional NRC offices notifying those agencies of the issue and resolution.

- Review documents delivered to customers and correct any reference to incorrect specification.

2) Preventative Actions:

- Review other plating vendor's internal specifications vs. Agilent specs.

- Modify the Procurement Department inspection form used in vendor audits as follows:

  - Require evaluation of vendor and Agilent drawings to ensure specifications match. (see line item 14.4 in the enclosed document identified as *Audit of QSA Global for 19233-80545).*

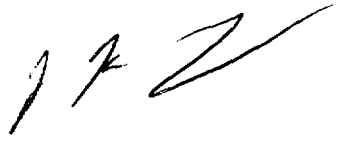
  - Add an action item line to pull together all action items resulting from the audit (ref. line item #16 in the same enclosed document.

- Hold post-vendor audit reviews to discuss audit results and findings. The RSO will be included in meetings.

Both corrective and preventative action items are expected to be completed or implemented as of October 15, 2006

Please contact the Radiation Safety Officer, David Bennett, at 302-633-8262 for further information.

Sincerely,



Keith Morgan
LFS/LSCA Environmental, Health, and Safety Manager

COPY

Agilent Technologies
2850 Centerville Road
Wilmington, DE 19808

Director
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, DC 20555

Re: Notice of error in Registry NR-0348-D-109-B

August 10, 2006

Dear Sir or Madam,

Agilent Technologies, Inc. has learned that the supplier of the models 19233 and 19235 electron capture detectors (ECDs), listed in the referenced registry above, may have manufactured some of the detectors to a maximum activity level that is above our specification, which was supplied to the NRC in the introductory amendment request dated July 21, 1983. The supplier, QSA Global Inc., has manufactured the ECD source to a maximum activity specification of 15 millicuries +20%, whereas Agilent Technologies, Inc.'s specification for maximum activity is 15 millicuries. QSA's maximum higher activity level has remained unbeknownst to HP/Agilent since the introduction of the two models above and was discovered during an audit of their operations. When questioned about the difference, QSA's response was that it was necessary for the higher manufacturing tolerance in order to provide HP/Agilent with a product that could meet our ion current specification. The QSA model used (model NBCK 4007) is identified in NRC registry NR-136-S-185-S.

We are in the midst of an investigation to identify both the cause of the situation and the direction in which Agilent and QSA both need to go in order to resolve the difference in specifications. We will notify you of the direction we take but wanted to notify your office of our situation, and the measures we have undertaken to date.

Please contact David S. Bennett (RSO) at 302-633-8262 if you have any questions.

Sincerely,

Keith Morgan
LFS/LSCA Environmental, Health, and Safety Manager

COPY

Agilent Technologies
2850 Centerville Road
Wilmington, DE 19808

Director
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, DC 20555

September 14, 2006,

Ref.: Amendment request to SS&D Registry NR-0348-D-109-B

Dear Director,

Agilent Technologies, Inc. requests an amendment to the above referenced registry to reflect a change of the maximum activity from 15 millicuries to 15 millicuries + 20%. As noted in a letter addressed to the NRC dated August 10, 2006 (copy enclosed), this change is necessary to properly reflect the tolerance Agilent's vendor has been working with since the introduction of the product line in 1983. Agilent was contacted by Mr. Joe Nick in the Region I office over the situation and has been working closely with that office since to address all concerns raised by the necessity of this amendment. Agilent will suspend shipments of the models of ECDs identified in the affected registry to customers by close of business of the date of this letter and will not resume shipment until the amendment is completed.

Agilent respectfully requests the expeditious processing of this amendment to the extent possible. The 19233/19235 product line currently is only being sold to replace spent units. New-unit shipments were discontinued some years ago. The ECD is a consumable product and has a typical life expectancy of between 5 and 10 years. Once customers develop a protocol using one of the devices, the customer is essentially locked in to its continued use and depends on Agilent for a fast turn around for replacement parts. Agilent provides devices into facilities and industries that include the EPA, FDA, food safety, military, Homeland Security, hospitals, and water testing and water treatment plants. The product is used for such critical applications as water purity by municipalities (pesticides), and hazardous chemicals testing by Homeland Security. Applications of Agilent ECDs can be found at
http://chemrel.business.agilent.com/scripts/LiteratureResults.asp?iprodinfotype=4&imod

el=19 and though the site references our current micro ECD, the applications are very similar.

Finally, Agilent would greatly appreciate notification of any decision to expedite this request, with any estimated time-line possible, in order to assist the sales and manufacturing operations to plan around the down time.

Please contact the Radiation Safety Officer, David Bennett, at 302-633-8262 for further information.

Sincerely,

Keith Morgan
LFS/LSCA Environmental, Health, and Safety Manager

c.c., NRC Region I Office
King of Prussia

Manufacturing Alert

Update Update + Close Print

Alert No. 951

Initiator: Gebreyesus, Retta (6338138)

Designate: Engel, Steve (6338709)

*** Material Handler Name:**
Gary Combs

OPEN

Opened: 09/13/2006 11:30 AM EDT
Last Updated: 09/13/2006 11:30 AM EDT

Change Time Zone

Select Hold Status

LFS Production Hold ☐ Click To Release
LFS Ship Hold ☐ Click To Release
LC-E Ship Hold ☐ Click To Release
LC-J Ship Hold ☐ Click To Release

Questions

	YES	??	NO
Is this a customer safety issue?	○	●	○
Have defective units been shipped to customer?	○	●	○
Have defective units been shipped to LC-A / E / J / AP?	○	●	○
Have defective units been shipped to Field Support Org?	○	●	○

Descriptions

Product Family: 6890 GC

* Product Numbers: Help — 5890, 4890 and 6890 standard ECD cells

* Problem Statement: (incl. names and dates)
Please add new entries to the top of the box.
Please start each entry with the date and your initials.

```
9/13/06 by Retta Gebreyesus
Following standard ECD cells are on ship hold until further notice.
19233-60576, 19235-60530, 19233-60536, 19233-60570, 19233-60770(Japan
only), 19233-60870(Japan only), G1533-60550, G1533-60570, G1533-60576,
G1533-60770(Japan only)
```

Action Plan: Help
Please add new entries to the top of the box.
Please start each entry with the date and your initials.

We are working to solve the problem.

Attachment Links: Help
Please add new entries to the top of the box.
Please start each entry with the date and your initials.
Please type in the hyperlink and give a brief description of it.

Root Cause Of Alert

* Reason: Material Specifications Issues (Specifications Inadequate, Incomplete, or In Error)
You must select a root cause reason before alert can be closed.

Comments:

LC A/E/J/AP Instructions

* Specific Part Numbers: Help
19233-60576, 19235-60530, 19233-60536, 19233-60570, 19233-60770(Japan only), 19233-60870(Japan only), G1533-60550, G1533-60570, G1533-60576 and G1533-60770(Japan only).
All the above parts numbers are on ship hold

Update MEA | Update + Close MEA
The Notification List Will Be Emailed About This Action - Click Here To View The List

Intranet

Agilent Restricted

Audit of QSA-Global for 19233-80545

Based on the HP Multinational Supplier Quality Audit

* - Denotes items which will be included in every audit per agreement with the NRC.

1. Company Organization

    1.7 To whom does the manager of Quality Assurance report?

    1.9 Is the supplier approved by other major customers?

    1.10 Is the supplier approved by the NRC?

3. Quality Management Organization

    *3.6 Have training needs been identified for each job function?

    *3.7 Has training been provided according to requirements?

    *3.8 Are there adequate training records?

    3.14 Does the supplier perform scheduled product & system audits to assure compliance to defined quality requirements?

4. Design Control

    *4.3 Are personnel qualifications adequate to assure product conformance to specifications?

5. Life Testing and Reliability

    5.1 Does the supplier have provisions for Life/Qualification testing ?

    5.2 Are samples life tested (current production parts stored for more than 6 months)?

    5.3 Is there a recording system for failures?

    5.4 Is there a formal system for investigating failures?

    5.5 Is there a formal feedback to design/customers?

7. Communication/Documentation Control & Work Movement

7.3 Is there an adequate and formal system for reviewing customer drawings, processes, change orders, etc.? Do the supplier and customer drawings match in every respect?

7.4 Are drawing/specification records maintained which reflect an adequate history of changes?

7.5 In the case of authorized subcontracting, does the supplier provide the sub-contractor with the appropriate specifications and standards?

7.6 Are the drawings/specifications/process instructions in use by Manufacturing and QC inspection current, legible, and with no unauthorized changes?

7.8 Is material handled correctly while in process?

7.9 Is material properly and adequately stored?

8. Purchased Material Control

*8.3 Has the supplier adequate controls to assure raw material conformance to specification by in-house testing or external labs?

*8.4 Does the supplier inspect or otherwise verify purchased parts/components prior to use?

8.5 If the supplier sub-contracts work to external sources, are there adequate controls to assure quality of the sub-contracted work?

8.7 Are adequate receiving inspection records maintained?

8.8 Are formal sampling plans in use and are they adequate?

8.9 Are gages/test equipment of adequate type and quantity for the work performed?

9. Measuring Equipment Control

*9.1 Are gages and test/inspection equipment, including customer owned gages and equipment maintained and adequately stored?

*9.3 Is calibration frequency for equipment and standards adequate?

9.5 Is calibration done in-house or is a contract calibration service retained?

10. Non-Conforming Material

*10.1 Is there a documented system with defined responsibilities for review and disposition of non-conforming material?

*10.3 Is non-conforming material segregated at all stages of production?

*10.5 Are there adequate corrective action programs implemented for the supplier's purchased material?

11. Manufacturing Technology

11.2 Are the supplier's processes flexible enough to handle reasonable increases or decreases in demand?

13. In-Process Controls

*13.6 Are inspection and process instructions adequate, controlled and available to respective personnel?

14. Final Verification

14.4 Are controlled customer drawings/specifications readily available and used at final test/verification? Do the supplier and customer drawings match in every respect?

14.7 Does the supplier have sufficient inspection/test equipment?

15. Packaging

15.1 Are there controlled special packaging instructions as required by customer's drawing?

15.4 Are packaging controls adequate to ensure proper parts protection up to delivery to the final destination?

15.5 Do the packaging requirements include provisions for indentification of special materials (ie radioactive)?

15.6 Does QC have the authority to stop the release of product?

15.7 Are secure storage areas used to prevent damage to products awaiting shipment?

*16. Action Item List resulting from the audit and Responsible Parties