

 **Agilent Technologies**
Innovating the HP Way
2850 Centerville Road
Wilmington, DE 19808

Michelle Burgess
Materials Safety and Inspection branch,
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
Washington, DC 20555-0001

October 19, 2001

Re: Response to request for additional information

Dear Ms Burgess,

Our letter dated September 4, 2001 answered questions 2 through 4 from your request for further information to our amendment request of March 5, 2001. This letter provides responses to your remaining questions. Questions and responses are numbered to match the numbers of the items in your letter.

1. Your March 5 letter informs us that Agilent has not been conducting two tests during fabrication as specified in the registration certificate commitments. Please indicate when this practice started, and report the total number of ECDs involved.

Response:

Test 1 (Ionization current): After performing an examination of our records, we have determined the following:

- a) Ion current testing was performed in house on all models identified in certificates NR-348-D-106B, NR-348-D-801-S, NR-348-D-802-S, NR-348-D-803-S, and NR-348-D-804B as these models went out of production prior to the in-house ion current testing being terminated.
- b) Ion current testing was performed in house on models identified in registration NR-348-D-109-B until June of 1998. Since that time, we have shipped approximately 290 cells*.
- c) Ion current testing was performed in house on model G1533A identified in registration NR-348-D-111-B until June of 1998. Since that time, we have shipped approximately 60 cells*.

- d) Ion current testing has never been performed in house on models G2397A and G2398A of NR-348-D-111-B as the dimensions of the detector were incompatible with the dimensions of the ion current tester. There have been approximately 3570 detectors sold since start up in February of 1997*.
- e) Other models identified in NR-348-D-111-B (G1223A, G2310A, G2330A, G2404A, G2405A, G1224A, and G1536A) are either upper level numbers including models already covered or were never manufactured.

* Please note that our suppliers have historically performed ion current testing and provided results to us. Ref. question #6 below for detail.

Test 2 (Pesticide test): Please note that the amendment request dated March 5, 2001 should have indicated that of our three active certificates only NR-348-106-B and NR-348-D-109-B defined that pesticide testing would be performed on each ECD.

Though certificates -106-B and -109-B indicate pesticide testing to be performed on every ECD, an evaluation of the line item referencing the pesticide test reveals that the pesticide sample was only to be evaluated on "...the gas chromatography incorporating the electron capture detector to be shipped." This means that only ECDs shipped in gas chromatograph (GC) units (constituting approximately 1/3 of units sold) were identified in the certificates as being tested.

After a review of our QC process, we have determined that even this level of testing was never performed for every ECD shipped with a unit. One hundred percent pesticide testing was only done at start up of new models and then for only a limited number of units. The pesticide test has historically been performed on one ECD in a production GC unit once per week.

Archival record may be available for determination of starting date and number of all units tested but were not available as of the date of this letter. However, further evaluation by our engineering staff has determined that the test has no intrinsic value for determining radioactive leakage or activity and is not a valid part of the QA process from a radiation safety standpoint (see point #5 for further discussion.)

5. What is the purpose of the "analysis of a standard pesticide sample"? We need this information to determine whether this test is necessary.

Response: Manufacturing engineering has confirmed that the test is to determine (electron capture) detector sensitivity. It has nothing to do with measuring activity or leakage.

6. As a certificate holder for a custom source, via the NR-0348-D-106-S and NR-0348-D-109-S certificates, you are responsible for

ensuring that all commitments made regarding the design of the source are carried out. You requested that the "measurement of the ionization current" test be transferred to the source manufacturer. It is our understanding that the "measurement of the ionization current" is used to verify the activity of the cells. Please confirm or provide corrected information regarding the purpose of the test. In addition, if the test is used to confirm activity, please provide details regarding how this will be incorporated into your QA program's oversight of the manufacturer in order to ensure that no device exceeds the allowable activity. Regarding the NR-0348-D-111-S certificate, explain how Agilent ensures that all ECDs are distributed with the correct activity if this test is not performed by Agilent.

Response:

Certificates NR-0348-D-106-B and NR-0348-D-109-B:

- a) The purpose of the test, as properly interpreted by the NRC, is to measure or confirm activity. Any in-house ion current testing described in question #1 above was performed subsequent to that done by the supplier as part of their QA program.
- b) Certificate NR-348-D-106-B will be inactivated per an upcoming amendment request but historically, the supplier (Amersham Corporation) has performed ion current testing on 100% of product to a documented specification, providing record of the results with shipment.
- c) Certificate NR-0348-D-109-S describes models manufactured by AEA Technologies (previously Amersham Corporation) which, again, performs an ion current test on 100% of product to a documented specification providing record of the results with shipment.

Oversight of our sealed source suppliers will be ensured by means of physical audits of their plating operations. Audits will begin within six months of the date of this letter and will be performed as a part of our procurement organizations' ISO 9000 supplier review process on an annual basis. Supplier quality program audits will be typically performed against the following segments:

- Personnel qualifications
- Employee training
- Raw materials conformance
- Inspection of purchased parts/components prior to use
- Maintenance of test/inspection equipment
- Review of calibration histories and determination of calibration adequacy
- Control of non-conforming product
- In process controls (e.g. controlled written standards or procedures)

Certificate NR-0348-D-111-B includes models manufactured by two suppliers, AEA Technologies and Isotope Products Laboratories. Both suppliers provide results of their ion current tests and

both companies will be audited as defined in c). Furthermore, both suppliers are ISO 9000 certified, providing a controlled and documented quality system that undergoes both internal and external auditing to ensure compliance with procedures and ISO quality system requirements.

7. Your March 9 letter requests a change to "A careful visual inspection of new cells per documented sampling scheme." Please specify the scheme, and describe the visual inspection, or provide the test procedure.

Response:

The in house inspection scheme includes a visual inspection of 10% of new devices under a stereo-optic microscope at 10X magnification with 100% inspection under the same microscope if a failure is identified in the initial 10%. The documented criteria for rejection identifies that:

- a) There must be no discoloration, spotting or other visual discontinuities or effects that might indicate that the plating process was not in control.
- b) There must be no foreign material, films, or particles anywhere on the plated surface.
- c) There must be no flakes, bubbles, cracks, or voids anywhere on the plated surface.

Those devices failing the visual inspection are evaluated by support engineering and returned to the vendor.

The change in inspection frequency from 100% to this scheme was determined valid by our support engineering staff based on historical performance.

8. Your March 9 letter requested a reduction in the visual inspection of the plated surface of the ECDs, from 100% of the units to a sampling plan. Please confirm that the wipe and leak tests will still be performed on every cell.

Response:

Wipe and leak tests will still be performed on every cell. These are seen as critical to the product safety and quality.

9. Your March 5 letter informed us that Agilent is now ISO 9001 registered. Please indicate whether this is to the American or British standard. If you are indicating that you have begun manufacturing and distributing under this registration, please provide a copy of the ISO registration, and provide a listing of the sealed source and device registration certificates for which the ISO 9001 registered QA program applies. Please note that this would mean that you must continue to manufacture and distribute under an ISO 9001 registration, and change to that commitment would require an amendment to all registration certificates listed.

Response:

ISO 9001 is an international standard. The site has been qualified through Kema Registered Quality, Inc., which is accredited by the Dutch Council for Accreditation (RvA) as well as the Registrar Accreditation Board (RAB). A copy of the site's certificate is included.

The registration covers all currently active sealed source and device registration certificates as defined in the March 5, 2001 letter.

10. During our review, we noted that the QA plan in the file is dated October 3, 1990. Please indicate whether this is still a current version. If there is a more recent version, please provide a copy along with a list of items that have changed.

Response:

Following are the results of our review of the QA program that the NRC had on file as provided by Ms Traci Kime on September 19, 2001. Included please find a discussion of the NRC's file, QA components added since those provided, and a general overview of the current ECD QA program.

A. Discussion of the NRC's file:

- 1) Internal letter entitled "INSTRUCTIONS FOR ACQUIRING, OR AMENDING A RADIOACTIVE BYPRODUCT MATERIALS LICENSE FOR HEWLETT-PACKARD DETECTORS WITH RADIOACTIVE SOURCES". Per information in an enclosed letter dated August 8, 1977, new Tritium detectors have not been manufactured since 1975 and would have passed out of customer support in 1985. The information packet is obsolete.
- 2) Letter to the NRC dated September 20, 1979 (Application to manufacture and distribute ECD model 19303):

Response:

The ECD model 19303 was classified as obsolete and out of customer support on August 1, 1999. It was included in Registry NR-348-D-106-B, which we will request to be inactivated in a separate amendment letter. We saw no reference to a QA program in the letter as returned to Agilent on September 19, 2001.

- 3) Letter to the NRC dated July 21, 1983 (Request for safety evaluation of models 19233 and 19235):

Response:

ECD models 19233 and 19235 are covered in Registry NR-348-D-109-B. The following corrections or changes need to be made:

The QA program described in the application letter indicated that the control measures would include a careful visual inspection of the plated surface using a stereo microscope, measurement of the ionization current of the assembled detector cell, removable activity wipe test, and standard pesticide sample being analyzed with the gas chromatograph incorporating the electron capture detector to be shipped. The letter also indicated that only sealed sources would be allowed in the (GC) instrument final assembly of Production and only thermal testing of sealed devices would be allowed to verify the electrical circuits prior to shipment.

- The visual inspection has changed per response to question #7 above.
- The ionization measurement test has changed for models G2397A, G2398A, G2404A, and G2405A identified in certificate NR-348-D-111-B. Per the supplier, Isotope Products Laboratories, a sample of each lot is measured for radiation output using a GM and scaler. The lot sample must exhibit a uniformity of +/- 10% of the mean to show uniformity of the activity. Lots are sampled per ANSI-ASQC Z1.4-1993 Level III Single Normal. Products outside the +/- range are scrapped.
- There is no change to the required wipe test.
- The pesticide test has been changed per response to question #1 above.
- There has been no change to statements that only sealed sources would be allowed in the GC instrument final assembly and thermal testing used to verify electrical circuits prior to shipment. However, for clarification purposes, the thermal testing referenced is a functionality test in which the cell is heated only to reflect operating conditions for performing a detector electronic noise test. The test does not evaluate for ECD mechanical failure.

4) Letter to the NRC dated January 30, 1990 (Request for safety evaluation of models G1223A):

Response:

ECD model G1223A is covered in Registry NR-348-D-111-B. The following corrections or changes need to be made.

The QA program described in the application letter (line item #10) indicated that the control measures for each ECD would include microscopic examination of plating integrity and ionization measurement.

- The examination of plating integrity has changed per response to question #7 above.
- The ionization measurement has changed per response to question #6 above.

- 5) Letter to the NRC dated October 3, 1990 to complete a safety evaluation of a new electron capture detector:

Response:

Corrections or changes need to be made to the description of the generic quality assurance program for fabricated parts, the Hewlett-Packard Company Quality Manual and reference to the supplier's plating process.

- 1990 Component: Hewlett Packard Company, Avondale Division Quality Assurance Program for Fabricated Parts

2001 response: Responsibility for the process described in the 1990 letter has been transferred to the supplier of the non-plated source, American Manufacturing Technologies, Inc. (AMT) of Avondale, PA. Two changes need to be made to the document:

- Line 1.10, The sentence "Parts are only processed on equipment that have the process capability designated on engineering drawings" needs to be removed as there are no process capabilities defined on engineering drawings.
- Line 1.20, A sentence indicating that "These first article inspections may or may not be formal." is to be added to the line.

- 1990 Component: Corporate Quality Manual.

2001 Response: There is no Agilent Technologies Inc. equivalent corporate quality manual to date. The ISO 9001 Agilent Little Falls Site Quality Manual consists of the following site-wide quality system management procedures:

- 1.1 Requirements for Ship Release of Product Changes
- 1.2 Management Review Process
- 1.5 Quality Planning
- 3.1 Nonstandard Product Contract Process
- 3.2 Custom/Special Production: Newport Site
- 4.1 CAG (Consumables Analytical Group) Life Cycle
- 5.1 Document and Data Control Process, Local documents
- 5.2 Document Control Process, Corporate Issued Documents
- 5.3 Engineering Change Order Process
- 5.4 Document and Data Control: Newport Site
- 5.5 Production Test Specifications Control Procedure
- 6.1 Material Ordering and Release Procedure
- 6.2 Material Disruption Procedure
- 6.4 Product Discontinuance Process
- 7.1 Customer Supplied Product: Newport Site

- 10.2 Test Record Review and Release Authorization Procedure
- 10.3 Inspection and Testing: Newport Site
- 11.1 Equipment Calibration Process
- 11.3 Production Test Software Maintenance and Verification Procedure
- 12.1 Assembly / Test Status Identification Procedure
- 13.1 CAG Returns Process
- 13.2 Out of Tolerance Corrective Action Procedure
- 14.1 Corrective and Preventive Action
- 15.1 Material Handling Procedure
- 15.2 ESD Procedures
- 17.1 Internal Assessment Program
- 18.1 Training and Development Process

Due to the sensitivity of information contained within the documents listed above, full disclosure will require a confidential disclosure agreement and the documents will be made available only at an Agilent facility.

- 1990 Component: Reference to supplier plating process

2001 Response: As identified in our letter dated September 4, 2001, Amersham Corporation is now AEA Technologies. AEA's plating process is defined in their NRC Registry NR-136-S-185-S. The 1990 letter incorrectly referred to this as the "NBS Process".

Agilent's second supplier, Isotope Products Laboratory uses a plating process registered with the NRC (registry number unavailable as of date of this letter due to NRC registry web page shut down).

6) Drawings:

- DWG. NO. A-5950-3568-1 (Hot Lab Test Procedures), dated December 3, 1980 is obsolete and requirements identified in the document are defined in Drawing # A-19233-90570-1.
- DWG # A-19233-90570-1 (General Requirements), dated August 15, 1988 is current. Evaluation of the drawing does not define testing rates but only describes tests that can be performed.
- DWG # A-19233-90545-1 (ECD Sub Assembly Procedure) was converted to an ISO document, GCECD007 [General License Electron Capture Detector (ECD) Assembly]. A copy of the ISO document is available under the same confidential disclosure agreement restrictions as defined above for the site's Quality Manual

B. QA Components Added

1) Drawing B-G2397-80010 for Micro ECD (not included in drawings provided with September 19, 2001 letter). The drawing defines supplier manufacturing and test specifications for the ECD model G2397A's Ni-63 ring source assembly. QA specifications are defined on the drawing to include:

- Nominal activity requirement of 15 millicuries referenced to the source label date. Nominal activity tolerance is defined
- Requirement for source ionization current test and acceptance parameters
- Requirement for active source removable activity wipe and acceptance specification
- Requirement for visual evaluation under microscope

Again, due to the sensitivity of information contained within the documents listed above, full disclosure will require a confidential disclosure agreement and the documents will be made available only at an Agilent facility.

2) The following manufacturing procedures have been incorporated into the ECD process QA management program as a result of the site's becoming ISO 9000 certified:

- General License ECD Assembly
- Packard 1500 Calibration and Maintenance
- ECD Re-assembly
- Visual Inspection of Nickel-63 Plated Cells and Foils
- ECD Final Wipe Test & Six Month Wipe Process
- ECD Rebuilds Shipping Process
- ECD Initial Wipe Test
- Receiving Radioactive Sources
- ECD Heater/Senser Assembly Testing
- ECD 6890 Line Procedure
- Pressurization Leak Test for Electron Capture Detectors
- 6890 Manual Test
- 6890 VEE Test
- 6890 ECD Test
- 5890 ECD Test

Again, due to the sensitivity of information contained within the documents listed above, full disclosure will require a confidential disclosure agreement and the documents will be made available only at an Agilent facility.

C. General overview of the current ECD QA program

- Vendor qualification/re-qualification and tests (Ref. response to question #6 above for detail):
 - Nominal Activity
 - Source ionization current
 - Removable activity wipe of active source
 - visual evaluation under microscope
 - Initial qualification and re-qualification defined in response to question #6 above
 - Vendor audits

- In house:
 - Incoming wipe test of inactive surfaces (unsealed sources)
 - Test rate: Defined in response to question #7 above.
 - Sampling requirements defined in manufacturing procedure "ECD Initial Wipe Test"

 - Final wipe test of inactive surfaces (finished product)
 - Test rate: 100% of manufactured ECDs
 - Sampling procedure defined in manufacturing procedure "ECD Final Wipe Test & Six Month Wipe Process"

 - Pressure test
 - Test rate: 100% of manufactured ECDs
 - Sampling requirements defined in manufacturing procedure "Pressurization Leak Test for Electron Capture Detectors"

 - ECD Heater/Senser Assembly test (not for radiation control)
 - Test rate: 100% of manufactured ECDs
 - Sampling process defined in manufacturing procedure ECD Heater/Senser Assembly Testing procedure

 - ECD electrical circuit test (not for radiation control)
 - Test rate: 100% ECD accessories
 - Sampling requirements defined in manufacturing procedures 6890 ECD Test, 5890 ECD Test

 - ECD electrical circuit test (not for radiation control)
 - Test rate: 100% ECDs installed on production units, 100% accessories
 - Sampling requirements defined in manufacturing procedures 6890 Manual Test, 6890 VEE Test, 6890 ECD Test

 - Pesticide test (not for radiation control)
 - Test rate: One GC Production unit ECD pulled at random once per week
 - Sampling process defined in manufacturing procedure 6890 ECD Test.

11. Although your March 5 letter also lists your four inactive certificates, we do not see any requested changes to these certificates. Please verify that there are no changes requested, or identify the changes requested for your inactive certificates so that we may continue our review.

Response:

No changes are necessary for the inactive certificates. We will be filing an amendment to NR-348-D-106-B under separate amendment request.

In conclusion, regrettably, this company has made a number of changes to our program over the years without properly notifying the NRC. Having become aware of this on our own, we took action earlier this year to incorporate a review of our certificates into our annual radiation control program review and have communicated the necessity for proper notification to our manufacturing and engineering staff.

Please contact me at 302-633-8262 if you have any questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "David S. Bennett". The signature is written in a cursive style with a large initial "D" and "B".

David S. Bennett
RSO

Authorized to make commitments for Agilent Technologies, Inc.

CERTIFICATE

Number: 10014.04

The quality system of:

Agilent Technologies, Inc.
Chemical Analysis Group
Little Falls Site
Wilmington, Delaware

including its implementation, meets the requirements of the standard:

ISO 9001:1994

Scope:

The design, development and manufacture of analytical instrumentation and systems, chromatography columns and packing and the distribution of analytical instrument supplies.

Reports that form the basis of this certificate:

10014.04.P001, 10014.04.P002, 10014.04.C001, 10014.04.C002, 10014.04.CR01, 10014.04.S001 - S010
10014.04.CR02 up to including 10014.04.CR03

This certificate is valid until: February 1, 2003

Revised date: January 11, 2000

Issued for the first time: February 1, 1994



H. Pierre Salle

H. Pierre Salle
President
KEMA-Registered Quality, Inc.

The method of operation for quality system certification is defined in the ISO Regulations for Quality System Certification. Integral publication of this certificate and adjoining reports is allowed.

KEMA-REGISTERED QUALITY, INC.
4379 County Line Road
Chalfont, PA 18914
Phone (215) 822-4258 Fax: (215) 822-4285

ACCREDITED BY:

The Dutch Council for Accreditation (RvA)
The Registrar Accreditation Board (RAB)





**EXPRESS
MAIL**

UNITED STATES POSTAL SERVICE®

www.usps.com

AFFIX POSTAGE OR
CORPORATE ACCOUNT LABEL HERE.
ADHIERA AQUÍ EL FRANQUEO O SU
ETIQUETA DE CUENTA CORPORATIVA.
USO NACIONAL ÚNICAMENTE



EL818579264US



**POST OFFICE
TO ADDRESSEE**

customer block.

redd
01/24/02

ORIGIN (POSTAL USE ONLY)			DELIVERY (POSTAL USE ONLY)		
PO ZIP Code 17850	Day of Delivery <input type="checkbox"/> Next <input checked="" type="checkbox"/> Second	Flat Rate Envelope <input type="checkbox"/>	Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Date In 10/3/01	<input type="checkbox"/> 12 Noon <input checked="" type="checkbox"/> 3 PM	Postage \$ 12.45	Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Time In <input type="checkbox"/> AM <input checked="" type="checkbox"/> PM	Military <input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee	Delivery Date 1/18	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Weight 6 lbs	Int'l Alpha Country Code	GOD Fee	<input type="checkbox"/> WAIVER OF SIGNATURE (Domestic Only) Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.		
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Acceptance Clerk Initials H27	Insurance Fee	NO DELIVERY <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Customer Signature	
Total Postage & Fees \$ 27.24					

CUSTOMER USE ONLY
TO FILE A CLAIM FOR DAMAGE OR LOSS OF CONTENTS, YOU MUST PRESENT THE ARTICLE, CONTAINER, AND PACKAGING TO THE USPS FOR INSPECTION.

FROM: (PLEASE PRINT) AGILENT TECHNOLOGIES 2850 CENTERVILLE RD WILMINGTON DE 19809-1510	PHONE: (302) 637-7262	TO: (PLEASE PRINT) Michelle Burgess U.S. Nuclear Regulatory Commission Materials Safety & Inspection Branch Div. of Industrial & Med Nuclear Safety Office of Nuc. Material Safety & Safeguards Washington, DC 20555-0001	PHONE: (301) 415-5262
---	-----------------------	---	-----------------------

FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com



Addresssee Copy
Label 11-F August 2000

F U T

25