



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 17, 2003

MEMORANDUM TO: Marissa Bailey, Section Leader
Materials Safety and Inspection Branch, IMNS

FROM: Tomas Herrera */RA/*
Materials Safety and Inspection Branch, IMNS

SUBJECT: SUMMARY OF MEETING WITH AGILENT
TECHNOLOGIES, INC., NOVEMBER 6, 2003

Representatives of Agilent Technologies, Inc., requested a meeting with NRC staff on November 6, 2003, to seek assistance in the clarification of the ISO 2919 for the prototype testing of sealed radioactive sources. The meeting was a pre-application meeting for an amendment to the Sealed Source and Device certificate NR-0348-D-111-B.

The meeting addressed the following issues:

- the request to grandfather current models to ISO 2919 equivalence;
- the interpretation of ISO 2919 section 6.1 General Requirements;
- the interpretation of ISO 2919 prototype testing requirements, particularly the External Pressure test;
- the Agilent representatives stated that only an internal pressure test was performed because the conditions in which the devices are used do not require them to be in an environment with an increased external pressure.

The NRC participants outlined to the Agilent Technologies, Inc. representatives

- their interpretations of ISO 2919 sections 6.1 General Requirements and the prototype testing requirements;
- the need for Agilent Technologies, Inc., to present the results of the prototype testing, engineering analysis, and/or operational history of the product to verify that the devices meet the ISO 2919 guidelines;
- that the ISO 2919 requirements were clear in regards to External Pressure, an External Pressure test or engineering analysis will need to be conducted to see how the device would respond to an increased external pressure.

A copy of Agilent Technologies, Inc.'s, discussion points, comparison table, and a letter to the NRC dated April 9, 1996 are attached.

Attachments: As stated

Participants:

NRC Staff:

Marissa Bailey
John Jankovich
Jonathan Rivera
Tomas Herrera

Agilent Technologies, Inc.:

David Bennett
Wayne Hunter

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DATE	11/17/03		11/14/03			

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NRC Visit for 11/6/03

Ref: Amendment to Registry:

NR-0348-D-111-B

- G1223A (now obsolete) Original test data provided Jan 30, 1990 but same as 19233/19235
- G1533A (now obsolete) Based on model G1223A
- G2310A Based on G1533A
- G2330A Based on G1533A
- G2397A Original test data provided April 9, 1996
- G2398A Original test data provided April 9, 1996
- G2404A Original test data provided April 9, 1996
- G2405A Original test data provided April 9, 1996
- G1224A Now obsolete
- G1536A

Points for Discussion:

- Request to grandfather current models (limited to those on NR-0348-D-111-B) to ISO 2919 equivalence with the direction that we will comply with ISO 2919 specifics for future models; and, if not, what are the minimum issues we have to address.
- Interpretation of ISO2919 section 6.1 (General requirements).
 - ISO: All sealed sources shall be tested after manufacture to ensure freedom from surface contamination.
Agilent's interpretation: Set for 7 days and perform existing removable activity wipe test
 - ISO: All sealed sources shall be tested after manufacture to ensure from freedom from leakage.
Agilent's interpretation: Check for leakage through existing pressure test
 - ISO: All sealed sources shall be measured after manufacture to determine their radiation output.
Agilent's interpretation: This is similar to the first requirement and should be met by the same removable activity wipe test.
 - ISO: The content activity of all sealed sources shall be estimated.
Agilent's interpretation: This is currently done and identified on our customer certificate (identified as 13.2 nominal activity on each 15mCi cell).
- Request for definition of the term "specimen" under ISO 2919 Section 6.1 (General requirements)

- Continuing with Section 6.1, request interpretation of “sealed sources shall be subjected, as specified herein, to the tests described in clause 7.A”. Does the NRC interpret this to require physical performance of testing under 7.1 or can we rely on a periodic engineering review of the vendors, materials, and processes applicable to the vendors and Agilent.
- Request evaluation of increasing Temperature classification in Table 4 “Sealed Sources Performance Requirements for Typical Usage” from class 3 to class 4.

Materials for review:

- Copy of original amendment request
- Copy of original registry
- Copies of QC test procedures
 - Wipe
 - Pressure
- Copy of ANSI N542
- Copy of ISO 2919
- Copy of ISO 9978
- Comparison of standards

ISO 2919/ANSI N542 Comparison

	ISO 2929 2919	ANSI N542	Performed by HP (Now Agilent)	Comments
Validation Tests**	Temperature (Table 2, Class 3) - 40 ⁰ C for 20 min. + 180 ⁰ C for 1 hour	Temperature (Table 1, Class 3) Same specifications as ISO 2919	<ol style="list-style-type: none"> 1. Reduced temperature to - 40⁰ C for 20 minutes 2. Elevated temperature to 800⁰ C for 1 hour 	Exceeds ANSI and ISO for Class 3
	External Pressure (Table 2, Class 2) Test in pressure chamber 25 kN/m ² abs. (3.6 lb/in ²) to atmospheric. Low pressure test in air. High pressure test in H ₂ O.	External Pressure (Table 1, Class 2) Test in pressure chamber 25 KPA abs. to atmospheric. Low pressure in air. High pressure test in H ₂ O	Internal pressure test Tested with helium at 60 lb/in ² for 30 sec. Observed pressure drop. No loss of test gas detected.	Needs evaluation for ISO status

* Note: All validation tests based on Sealed Source classification requirements for typical usage of Ion generators (Table 4 ISO 2919 and ANSI N542)

	ISO 2919	ANSI N542	Agilent	Comments
	Impact (Table 2, Class 2) 50 gm from 1 meter one time.		340 gm from 1 meter one time	Exceeds ISO for Class 2
	Vibration Class 1 (no test)	Vibration Class 1 (no test)	N/A	N/A
	Puncture Class 1 (no test)	Puncture Class 1 (no test)	N/A	N/A
	1) Visual loss of integrity 2) Leak (wipe) test from ISO 9978 after 7 day wait. Spec: < 5 nCi.	1) Visual loss of integrity 2) Leak test, no wait. Spec: < 5 nCi.	1) Loss of visual integrity 2) Leak test, no wait. Spec: < 5 nCi.	Meets ANSI, needs evaluation for ISO status.

	ISO 2919	ANSI N542	Agilent	Comments
Production Control	Freedom from surface contamination per ISO 9978 5.3	Implied as Leak Test Results in Appendix B, B6 (Certification)	Final wipe test	Meets ANSI, needs evaluation for ISO status
	Freedom from leakage per ISO 9978 sections 5 (radioactive means) or 6 (non-radioactive means)	Not mentioned in Appendix B (Quality Assurance And Control)	Internal Pressure Test	Exceeds ANSI, needs evaluation for ISO status
Periodic Inspections	Temperature test	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status
	External pressure test	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status
	Impact test	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status

	ISO 2919	ANSI N542	Agilent	Comments
	Vibration test (N/A)	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status
	Puncture (N/A)	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status
	Bending test (N/A)	Not found in standard	Proposed annual engineering evaluation	Exceeds ANSI, needs evaluation for ISO status
Additional:				

Hewlett-Packard Company
Little Falls Site
2850 Centerville Rd.
Wilmington, DE 19808

April 9, 1996

CERTIFIED

US Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Attention: Mr. Steve Baggett
Washington, D.C. 20555

Models: G 2397A
G 2398A
G 2404A
G 2405A

**Re: New Electron Capture Detector Models G2397A, G2398A, G2404A, and G2405A
(License # 07-28762-01) and Amendment to Certificate of Registry NR-348-D-111-B**

Dear Mr. Baggett,

Please accept this letter as authorization to add a new Electron Capture Detector (ECD) to our current Certificate of Registry (NR-348-D-111-B).

Externally this new ECD is almost identical to our existing ECDs, but internally it is very different. It still contain up to 15 mCi of Ni63, but instead of being plated like our current ECDs the radioactive material is plated on a thin nickel cylinder on both the internal and the external surfaces. The cylinder is then press-fitted into the stainless steel lower body (for all practical purposes the cylinder is fitted inside the lower body permanently). In our current ECDs the radioactive material is plated directly on the lower body. The upper body then attaches to the lower body with the same tamper-proof screws used in our current ECDs. The geometry of the radioactive surface will also be different, our current ECD is cone shaped and the new ECD will be cylindrical.

This tubular insert will be manufactured by Dupont Merck Pharmaceutical of N. Billerica, MA and their plating process is licensed by the NRC, see attached.

For the following reasons we feel the new ECD will be much safer than existing ECDs:

1. The radioactive material is located deeper in the stainless steel lower body which makes it safer to handle.
2. The chromatographic column is not allowed to enter the cell as it is stopped by the mixing fused silica liner. This keeps the column farther away from the radioactive surface (safer operation).

3. The stainless steel anode is also kept away from the radioactive surface by the ceramic flow guide (safer operation). The ceramic flow guide is supported by a stainless steel wavy washer. Both the ceramic flow guide and the wavy washer are located outside the radioactive compartment.

4. In the new ECD, the radioactive surface area is much smaller (one sixth that of our current ECD).

We are currently in the process of having an isodose survey prepared for this new ECD, but we feel this is probably unnecessary because we strongly believe that the new isodose survey will be significantly lower than the results for our existing ECDs. For your reference I have attached a copy of an isodose survey for our current ECDs, because of the new geometry of the new source, because it is located much deeper in the body than our previous ECD, and because the new source is plated on both sides.

We have performed the following tests (see attached data sheets) on the detector:

- Drop Test
- Impact Test
- Pressure Test
- Elevated Temperature Test
- Freeze Test

Because the body of the detector is very similar to our existing ECD, and because the plating process is licensed by the NRC, I did not think a full test program would be necessary. If you feel any additional testing is required please do not hesitate to contact me.

The four model numbers being submitted are all identical from a radiation perspective, with the only difference being mounting and connections for different types of gas chromatographs. The model breakdown is as follows:

G2397A	6890 Gas Chromatograph with EPC	<i>configuration G2397A w/special sample for Japan</i>
G2398A	6890 Gas Chromatograph without EPC	<i>Product improper configuration</i>
G2404A	5890 Gas Chromatograph with EPC	<i>Product Never Released</i>
G2405A	5890 Gas Chromatograph without EPC	<i>Product Never Released for target</i>

Thank you for your assistance in these matters. If should you require any additional information, please do not hesitate to contact me at (302)633-8120.

(A) G2398A:G2397A conf. 1 with Japan sample

Sincerely yours,


Brian Donnelly

Judy Sherman (8565)

*(1) G2397A will have 2 configurations
Normal configuration: standard rest of world (std wipe, std sample)
Japan configuration: ...*

Product: Micro ECD, G2397ATested By: B DonnellyDate Tested: 3/28/96Equipment Used: Scale Asset #2-732Calibration Date: 12/3/95Impact TestMETHOD:

The detector body was placed on a flat steel surface, with a surface large enough to accommodate the detector and with a minimum mass of 10 kilograms. Then a steel hammer weighing 340 grams with a flat striking surface, 25 mm in diameter, with its edge rounded to a radius of 3 mm was dropped from a height of 1m, measured between the highest point of the detector body and the base of the hammer in the release position. The hammer was then dropped onto the source at it's most vulnerable point. At the completion of the test the detector is visually inspected and then wipe tested.

RESULTS:

Serial #	Initial Wipe Results (DPMs)			Wipe Results after Impact Test (DPMs)			Comments from Visual Inspection, after Impact Test
	Body	Inlet	Vent	Body	Inlet	Vent	
LP11	32.6	90.6	26.1	148.7	110.0	29.4	OK
LP12	22.9	139.5	39.0	35.8	64.8	34.3	OK
LP13	35.8	87.4	34.7	16.5	16.5	34.7	OK

Technician's Notes: _____

Product: Micro ECD, G2397ATested By: B. DonnellyDate Tested: 3/28/96Equipment Used: Ruler

Calibration Date: _____

Drop TestMETHOD:

The ECDs were dropped from a height of 1.5m onto a flat steel surface with a minimum mass of 500 grams. This test was performed on two samples and repeated 10 times. At the completion of the test the detectors were visually inspected and then wipe tested.

RESULTS:

Serial #	Initial Wipe Results (DPMs)			Wipe Results after Drop Test (DPMs)			Comments from Visual Inspection, after Drop Test
	Body	Inlet	Vent	Body	Inlet	Vent	
LP11	55.2	39.0	51.9	32.6	90.6	26.1	
LP12	58.4	48.7	122.9	22.9	139.5	39.0	
LP13	84.2	84.2	42.3	35.8	87.4	34.7	

Technician's Notes: _____

Product: Micro ECD, G2397ATested By: B DonnellyDate Tested: 3/28/96Equipment Used: ThermoLyne FB1300Calibration Date: 2/1/96

Elevated Temperature Test

METHOD:

The detector was placed in an oven with a volume of at least 5 times the volume of the detector. The oven temperature was then increased to 800C with a maximum ramp time of 70 minutes. The temperature was maintained at 800C for a minimum of 60 minutes. At the completion of the test the detector is visually inspected and then wipe tested.

RESULTS:

Serial #	Initial Wipe Results (DPMs)			Wipe Results after Temperature Test (DPMs)			Comments from Visual Inspection
	Body	Inlet	Vent	Body	Inlet	Vent	
LP11	148.7	110.0	29.4	32.7	65.0	13.4	Black, burnt

Technician's Notes: _____

Product: Micro ECD, G2397ATested By: B. DannellyDate Tested: 4/2/96Equipment Used: Thermotron Model 1520Calibration Date: 12/10/95Freeze TestMETHOD:

The detector was placed in an chamber with a volume of at least 5 times the volume of the detector. The chamber temperature was then decreased to -40C with a maximum ramp time of 30 minutes. The temperature was maintained at -40C for a minimum of 20 minutes. At the completion of the test the detector is visually inspected and then wipe tested.

RESULTS:

Serial #	Initial Wipe Results (DPMs)			Wipe Results after Freeze Test (DPMs)			Comments from Visual Inspection
	Body	Inlet	Vent	Body	Inlet	Vent	
LP12	60.2	44.0	18.2	66.6	206.6	29.5	OK
LP13	50.0	39.2	19.7	56.9	260.2	98.9	OK

Technician's Notes: _____

Product: Micro ECD, G2397A



Tested By: B Donnelly

Date Tested: 4/2/96

Equipment Used: Pressure Gauge

Calibration Date: _____

High Pressure Test

METHOD:

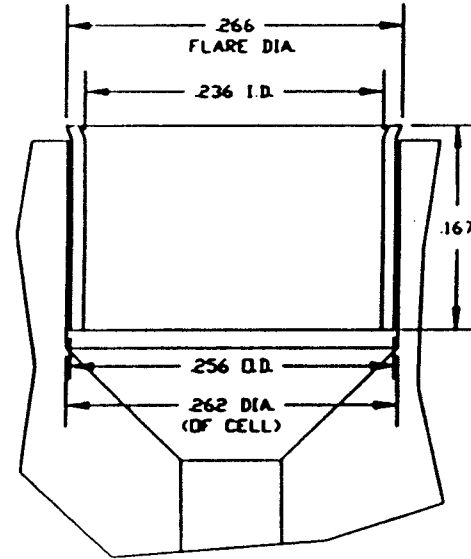
The detector was pressure tested with up to 60 psig of Helium connected to the cell entrance. The vent tube/purge gas tubing was plugged with swagelock fittings. This pressure was maintained for 30 minutes and then the pressure was removed and then the test was repeated. During testing no pressure loss was observed. The ECD is near atmospheric pressure during normal use. At the completion of the test the detector is visually inspected and then wipe tested.

RESULTS:

Serial #	Initial Wipe Results (DPMs)			Wipe Results after Pressur Test (DPMs)			Comments from Visual Inspection
	Body	Inlet	Vent	Body	Inlet	Vent	
LP12	35.8	64.8	34.3	60.2	44.0	18.2	OK
LP13	16.5	16.5	34.7	50.0	39.2	19.7	OK

Technician's Notes: _____

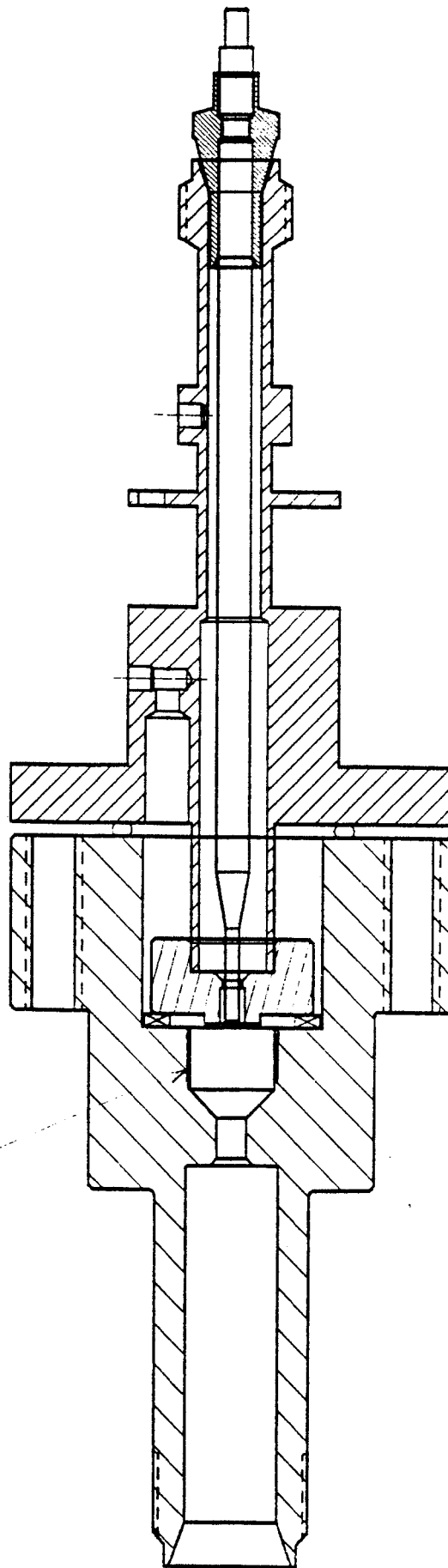
REVISIONS				
REV.	DESCRIPTION	BY	DATE	APPROVED



TUBE FLARING DETAIL

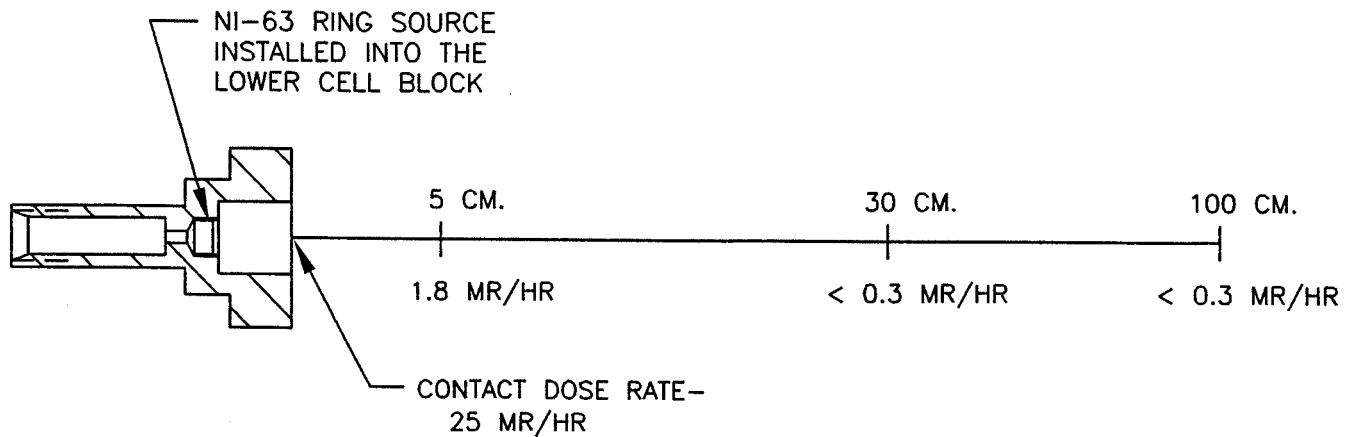
REV. NO.	DATE	PART OR IDENTIFYING NO.	DESCRIPTION	BY

FROM ASSEMBLY NOT ASSEMBLY	APPROV. DATE, P. NO.	DU PONT MERCK TELEPHONE: DATES: DATE JAN : 1940 CHECKED JAN : 1940 APPROVED PRICE : 1.75 QUANTITY : 30 QTY SOLD DTL. OF	DU PONT MERCK PHARMACEUTICAL CO.	B DTL. NO. REC.

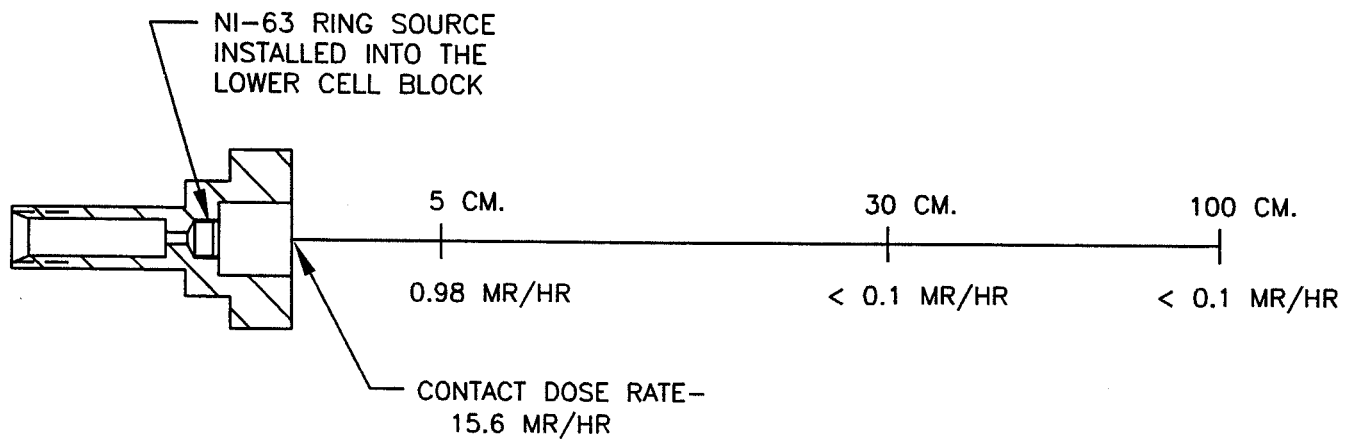


Pressed-in
radioactive ring

NER-004P NI-63 RING SOURCE DOSE RATE REPORT



BETA (SHALLOW) DOSE RATES



GAMMA (DEEP) DOSE RATES

NOTES

1. Source used: NER-004P 15 mCi Ni-63 on 4/96.
2. Beta dose rate measurements are performed with 'Landauer' Type G film badges having 7 milligrams/square centimeter filter. Minimum detectable dose rate is 0.3 mR/hour.
3. Gamma dose rate measurements are performed with 'Landauer' Type G film badges having 300 milligrams/square centimeter filter. Minimum detectable dose rate is 0.1 mR/hour.