[redacted]

From: "John J. Miller" <jjmiller@intisoid.com>
To: "'Jonathan Rivera'" <JXR4@nrc.gov>
Date: 07/07/2006 1:45:38 PM
Subject: RE: Acceptance review for Source Model Nos. INIS-SF-CS-**1J,** andINIS-SF-CS-2J.

Jonathan,

Not sure why the attachments where not with the letter. I am sending the missing ones electronically:

Attachment 2: Test report 5170.pdf

Attachment 1: The Cs-137 Source Capsules Drawing is Attachment 1. I may not be able to provide additional drawings. The basis for our sealed source is that we over encapsulate already existing sealed sources. We do not intend to construct a triply encapsulated source from individual components. We intend to take an existing sealed source manufactured under an existing SS&D. I explained this in the description, I established specific criteria in the application to qualify a source for over encapsulation, the first bullet is: "The source is marked with a Model and/or Serial number and can be linked to a specific Registry of Radioactive Sealed Sources and Devices Safety Evaluation of a Device", so any other drawing would depend on the source being over encapsulated. How the byproduct material is mounted in the source would be described in the original SS&D.

Attachment 3: I have attached an electronic copy of the QA Sys description. We developed this document to summarize the QA program. In the past we where providing copies of our entire QA manual and many reviewers thought that this was too much. If you would like a copy of our QA manual I can provide. Please let me know.

We do not have a "Certificate" that states our QA Program has been verified to meet the requirements of Verification of ANSI/AMSE NQA-1. We developed a Requirement Compliance Matrix for the 18 Basic Requirements of ANSI/AMSE NQA-1. This matrix cross references the NQA-1 requirements with sections and paragraphs in our QA manual. While the title is 18 Basic Requirements, the matrix is about 75 pages long. If you would like a hard copy of this matrix please let me know.

John Miller

-----Original Message-----
From: Jonathan Rivera [mailto:JXR4@nrc.gov]
Sent: Friday, July 07, 2006 9:31 AM
To: jjmiller@intisoid.com
Cc: John Jankovich; Traci Kime
Subject: Acceptance review for Source Model Nos. INIS-SF-CS-1J, andINIS-SF-CS-2J.

John J. Miller, CHP
Radiation Safety Officer
International Isotopes Idaho, Inc.

Dear Mr. Miller,

A-20

We have completed an acceptance review of your application, dated April 17, 2006, for the Sealed Source and Device Evaluation of Gamma Irradiator Source Model Nos. INIS-SF-CS-1J, and INIS-SF-CS-2J. However, the acceptance review found missing information. In order to proceed with the safety evaluation of the source, please provide the information indicated below. You may provide me the information via email, or to Attn: Jonathan Rivera, Mail Stop T-8F3, Division of Industrial and Medical Nuclear Safety, U.S. Nuclear Regulatory Commission, 11545 Rockville Pike, North Bethesda, MD 20852-2738.

Additional information needed:

1. On page 4 of 5 of your application, you stated "A copy of the test report...is contained in Attachment 2...." I was not able to find this attachment in the application package. Please provide a copy of this attachment.
2. On page 3 of 5 of your application, you stated "Drawings: Refer to Attachment 1." I was not able to find this attachment in the application package, however did find a one-page drawing titled "Cs-137 Source Capsules." Please confirm whether or not this drawing is Attachment 1. Please also provide additional drawings, with clearly labeled components, that indicate the mounting of the byproduct material into the capsules, as well as shows the triple encapsulation you mentioned on Page 2 of 5 of your application. Please ensure that the drawings include dimensions, tolerances, and units.
3. On page 5 of 5 of your application, you stated " a copy of the International Isotopes Inc. Quality System Description is included in Attachment 3." I was not able to find this attachment in your application. Please provide a copy of this attachment.
4. On page 5 of 5 of your application, you indicated that your Quality Assurance program has been verified to meet the standards of ANSI/AMSE NQA-1. Please provide a copy of the certificate that verifies this.

Thank you.

Jonathan Rivera
Materials Safety & Inspection Branch
U.S. Nuclear Regulatory Commission
Phone: (301) 415-5810
Email: jxr4@nrc.gov

Mail Envelope Properties (44AE9DA7.225 : 20 : 57893)

Subject:	RE: Acceptance review for Source Model Nos. INIS-SF-CS-1J, andINIS-SF-CS-2J.
Creation Date	07/07/2006 1:36:03 PM
From:	"John J. Miller" <jjmiller@intisoid.com>
Created By:	jjmiller@intisoid.com

Recipients
nrc.gov
TWGWPO03.HQGWDO01
JXR4 (Jonathan Rivera)

Post Office	**Route**
TWGWPO03.HQGWDO01	nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	4243	07/07/2006 1:36:03 PM
Test report 5170.pdf	1149776	
INIS_QA_Sys_description.pdf	5723023	
Mime.822	9411168	

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

Junk Mail Handling Evaluation Results
Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

Junk Mail settings when this message was delivered
Junk Mail handling disabled by User
Junk Mail handling disabled by Administrator
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled

Report Date: 23 March 2006 Customer P.O.: 13-PO-2006-29

Test Period: 03 through 10 March 2006 Security Classification: NA

TEST REPORT

FOR

ENVIRONMENTAL TESTING OF THE ¼ AND ½ INCH DIAMETER STAINLESS STEEL CAPSULES

TESTING PERFORMED BY:

QUALTEST, INC.
5325 Old Winter Garden Road
Orlando, Florida 32811-1520

Website: www.qualtest.com

FOR:

INTERNATIONAL ISOTOPES, INC.
4137 Commerce Circle
Idaho Falls, ID 83401

TEST REPORT PREPARED BY:

Ross Blanco, Documentation Manager

QUALITY ASSURANCE:

Ross Blanco, Deputy Quality Assurance Manager

"CQA Performed IAW One Book"

Not Required
Bill Kennedy, DCM Orlando QAS, S1002A

APPROVED BY:

Todd Scarborough, General Manager

being duly sworn, deposes and says that the information contained in this report is the result of complete and carefully conducted tests and is to the best of his knowledge true and correct in all respects. Subscribed and sworn to before me,

Susan Kingdon Fields, Notary Public in and for the State of Florida at large, this

24th day of March, 2006.

State of Florida, County of Orange

SUSAN KINGDON FIELDS
MY COMMISSION # DD 231223
EXPIRES: August 24, 2007
Bonded Thru Budget Notary Services

REPORT REVISION RECORD

REVISION	DESCRIPTION OF CHANGE
	INITIAL RELEASE

TABLE OF CONTENTS

Qualtest operates under the relevant quality system requirements of ISO-9001:2000 for providing environmental simulation services as recognized by TRC Registration Certificate #00018. This laboratory also maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #1805.01. However, the test results included in this report are not covered by the accreditation.

FOREWORD

The objective of this test program was to subject customer provided test hardware to environmental simulation in compliance with customer stated specifications, including any authorized modifications, deviations or concessions to the original requirements. Test hardware consisted of items identified in the appropriate sections of this report. In addition to test hardware identification, each section contains information that describes the associated test setup and performance, and the resulting data. Qualtest measuring instruments used in testing were calibrated according to the requirements of ANSI/NCSL Z540-1-1994 and are NIST traceable. Calibration records are on file and available for inspection by request. Because the test methods are well established and are qualitative or semi-quantitative in nature, Qualtest does not apply measurement uncertainty unless obligated by contract. Measured value related to the corresponding tolerance requirement is used to decide whether a test meets the requirements of the specification. Any test hardware operational setups and resulting evaluations or inspections performed by the customer are not included in this report, unless they were explicitly requested. While observations and/or specification compliance statements may be reported, no interpretations or opinions regarding customer product performance are intended. Unless otherwise indicated in the appropriate report section, all contract obligations were met and the test objective achieved.

SECTION 1

PUNCTURE TEST SUMMARY

Test Start-Finish Dates: 03 March 2006

Responsible Test Technician: Don Hensley

1-1 TEST HARDWARE

One (1) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 2
One (1) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 2

1-2 TEST REQUIREMENTS WITH TOLERANCES

Drop the customer supplied puncture tool (with rounded end impacting) backed by a custom fitted 1,000 gram weight, onto each test item from a height of one (1) meter. The point of impact will be from the side at the weld joint where the center of the puncture tool hits anywhere around the circumference of the weld where it meets the side.

Tolerance
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Drop Height: ±2.5%

1-2.1 Test Specification:

ANSI/HPS N43.6-1997, Section 7.6 Puncture test, Class 6, Table 1

1-3 TEST SETUP

TABLE 1-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100255	Scale	Setra	EL 4100S	8/30/2006
100420	Tape Measure (10 foot)	Starrett	CH12-10DME	Indefinite
100421	Dial Caliper	Aerospace	0	11/28/2005

TABLE 1-2: CUSTOMER FURNISHED FIXTURES AND SUPPORT EQUIPMENT

P/N	S/N	Nomenclature (description, model, manufacturer, etc)
NA	NA	Puncture Tool

1-4 TEST DESCRIPTION

1-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

1-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the puncture test.

1-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 21 Relative Humidity (%): 48 Pressure: Site ambient

TABLE 1-3: PUNCTURE TEST ACTIVITIES

Drop	Test Item	Drop Height	Time	Observation
1	¼ inch S/N 2	39.4 inches (1 meter)	1315	No damage
2	½ inch S/N 2	39.4 inches (1 meter)	1318	No damage

1-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

1-5 ENVIRONMENTAL TEST DATA

Compliance verified through test setup and observation (reference photos Figures 1-1 through 1-3).

Figure 1-1: Typical test setup for puncture.

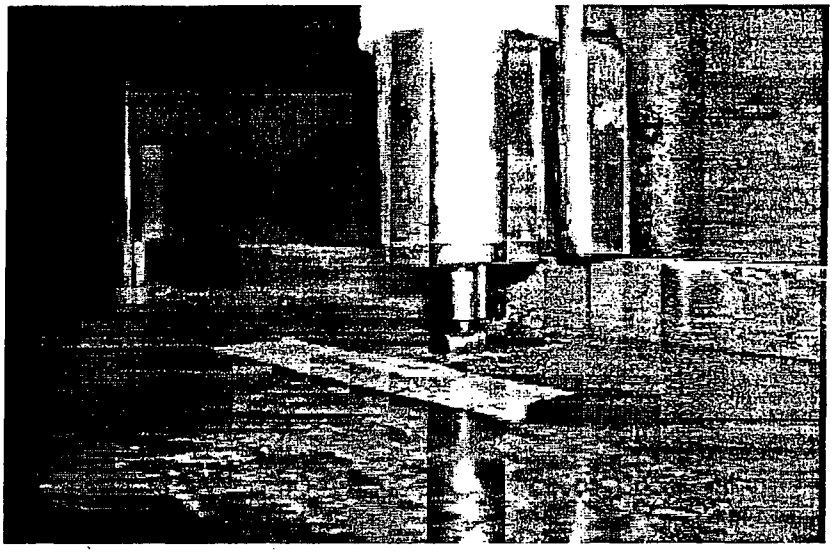


Figure 1-2: Test setup for Drop #1.

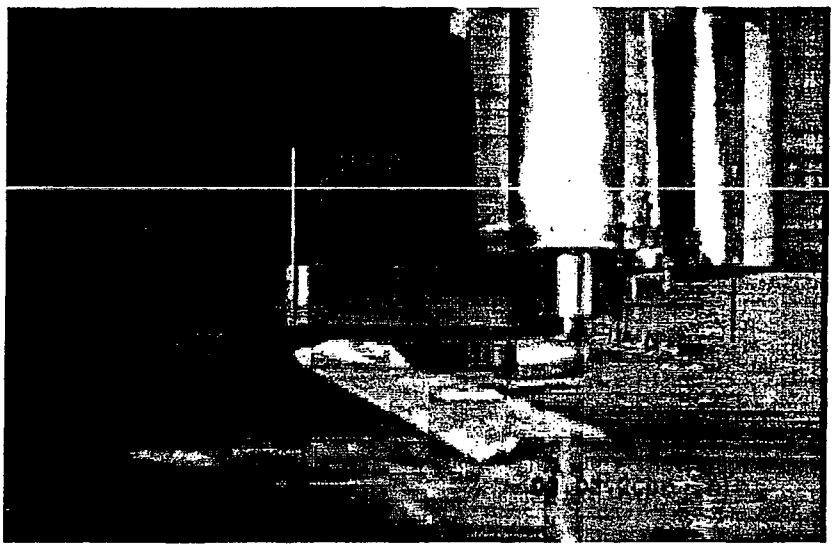


Figure 1-3: Test setup for Drop #2.

SECTION 2

IMPACT TEST SUMMARY

Test Start-Finish Dates: 03 March 2006

Responsible Test Technician: Don Hensley

2-1 TEST HARDWARE

One (1) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 3
One (1) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 3

2-2 TEST REQUIREMENTS WITH TOLERANCES

Drop the customer supplied impact tool (with rounded end impacting) backed by a custom fitted 5,000 gram weight, onto each test item from a height of one (1) meter. The point of impact will be from the side at the weld joint where the center of the impact tool hits anywhere around the circumference of the weld where it meets the side.

Tolerance
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Drop Height: ±2.5%

2-2.1 Test Specification:

ANSI/HPS N43.6-1997, Section 7.4 Impact test, Class 5, Table 1

2-3 TEST SETUP

TABLE 2-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100139	Scale	Fairbanks	FB1124/Morse	8/30/2006
100420	Tape Measure (10 foot)	Starrett	CH12-10DME	Indefinite
100421	Dial Caliper	Aerospace	0	11/28/2005

TABLE 2-2: CUSTOMER FURNISHED FIXTURES AND SUPPORT EQUIPMENT

P/N	S/N	Nomenclature (description, model, manufacturer, etc)
NA	NA	Impact Tool

2-4 TEST DESCRIPTION

2-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

2-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the impact test.

2-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 21 Relative Humidity (%): 48 Pressure: Site ambient

TABLE 2-3: IMPACT TEST ACTIVITIES

Drop	Test Item	Drop Height	Time	Observation
1	¼ inch S/N 3	39.4 inches (1 meter)	1340	No damage
2	½ inch S/N 3	39.4 inches (1 meter)	1351	No damage

2-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

2-5 ENVIRONMENTAL TEST DATA

Compliance verified through test setup and observation (reference photos Figures 2-1 through 2-3).

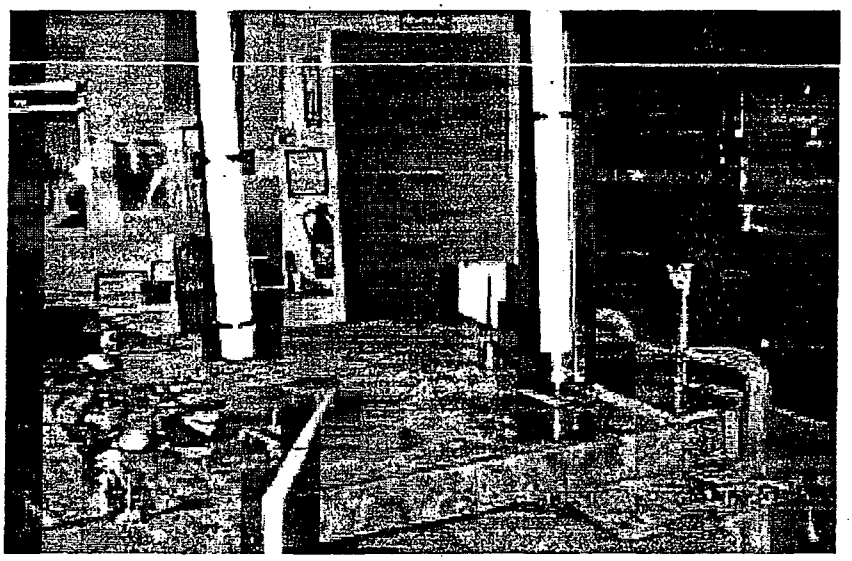


Figure 2-1: Typical test setup for impact.

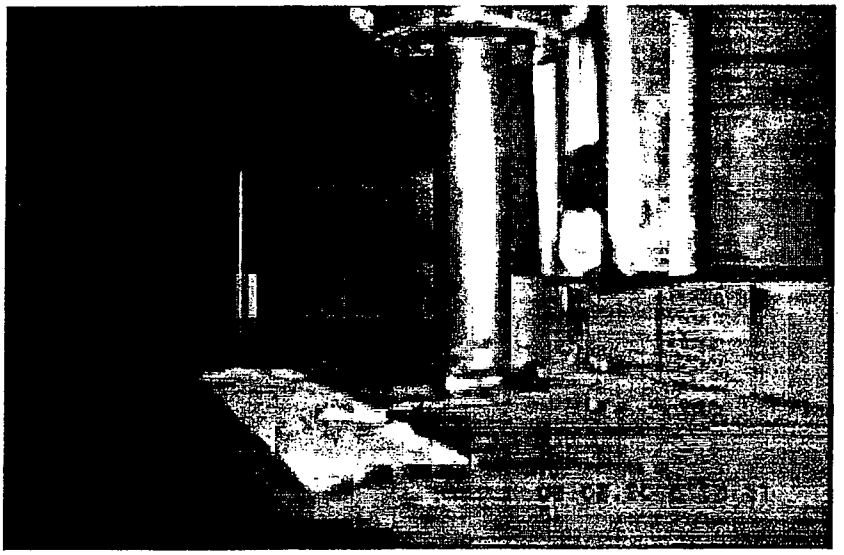


Figure 2-2: Test setup for Drop #1.

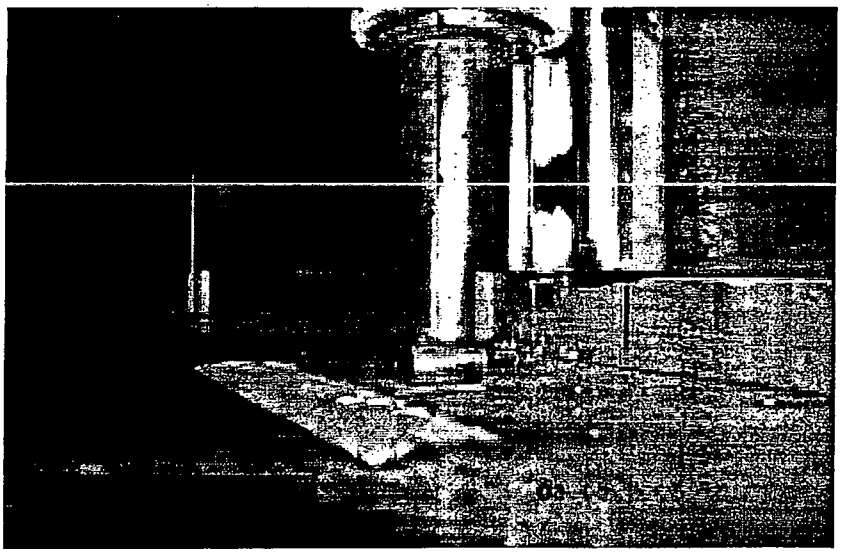


Figure 2-3: Test setup for Drop #2.

SECTION 3

EXTERNAL LOW PRESSURE TEST SUMMARY

Test Start-Finish Dates: 07 March 2006

Responsible Test Technician: Don Hensley

3-1 TEST HARDWARE

One (1) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 4
One (1) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 4

3-2 TEST REQUIREMENTS WITH TOLERANCES

Maintain 187.5 mmHg (187.5 Torr) for five (5) minutes
Maintain 290 PSIA hydrostatic for five (5) minutes
Maintain 187.5 mmHg (187.5 Torr) for five (5) minutes
Maintain 290 PSIA hydrostatic for five (5) minutes

3-2.1 Test Specification:

ANSI/HPS N43.6-1997, Section 7.3.2 External Pressure, Class 3, Table 1

3-3 TEST SETUP

TABLE 3-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100073	Chart Recorder	Honeywell	DR450T-2000-0	5/12/2006
100252	Altitude Sensor	MKS Instruments	622A13TAE	10/6/2006
100257	Pressure Gauge	Ashcroft	45 1379SS 04L	2/21/2007
100397	Stop Watch	Oakton	220	10/7/2006
100899	Temp/Altitude Chamber	Thermotron	F-4-CHA-1½-1½	NA
100904	Pressure Regulator	TESCOM	44-1125-24	NA

TABLE 3-2: CHART RECORDER SETUP

Channel	Function	Type of sensor
1	Monitor chamber air temperature	100 Ω RTD
4	Monitor chamber pressure	Capacitance Manometer

3-4 TEST DESCRIPTION

3-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

3-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the pressure testing.

3-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 20 Relative Humidity (%): 44 Pressure: Site ambient

TABLE 3-3: PRESSURE TEST ACTIVITIES

Step #	Activity	End Time	Duration
1	Ramped to 187.5 Torr	0746	17 minutes
2	Maintained 187.5 Torr	0751	5 minutes
3	Ramped to laboratory ambient pressure	0808	17 minutes
4	Transferred to water filled pressure vessel	0814	6 minutes
5	Pressurized vessel with 290 PSIA	0815	1 minute
6	Maintained 290 PSIA	0820	5 minutes
7	Ramped to laboratory ambient pressure	0821	1 minute
8	Ramped to 187.5 Torr	0853	17 minutes
9	Maintained 187.5 Torr	0858	5 minutes
10	Ramped to laboratory ambient pressure	0915	17 minutes
11	Transferred to water filled pressure vessel	0918	3 minutes
12	Pressurized vessel with 290 PSIA	0919	1 minute
13	Maintained 290 PSIA	0924	5 minutes
14	Ramped to laboratory ambient pressure	0925	1 minute

3-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

3-5 ENVIRONMENTAL TEST DATA

The pressure chart is located after Figure 3-3. Hydrostatic pressure compliance verified through test setup and observation (reference photos Figures 3-2 through 3-3).

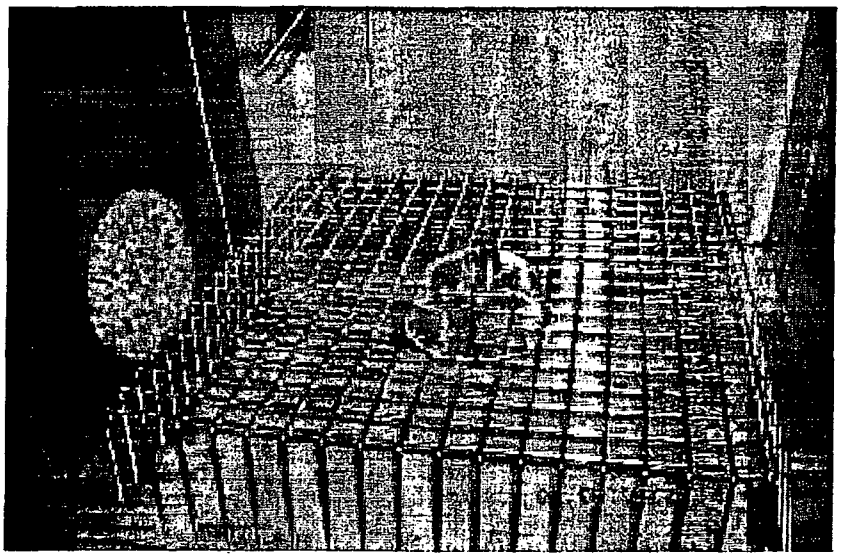


Figure 3-1: Test setup for external pressure.

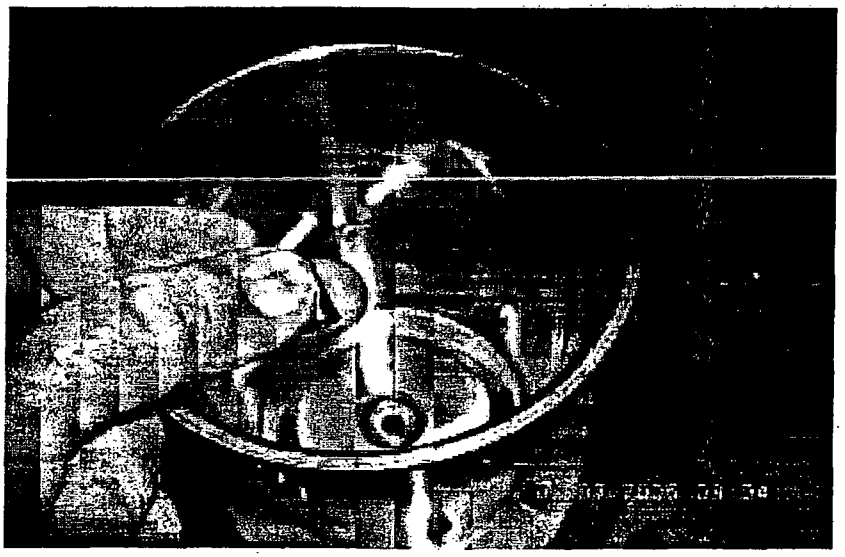


Figure 3-2: Test items being placed in pressure vessel for hydrostatic pressure.

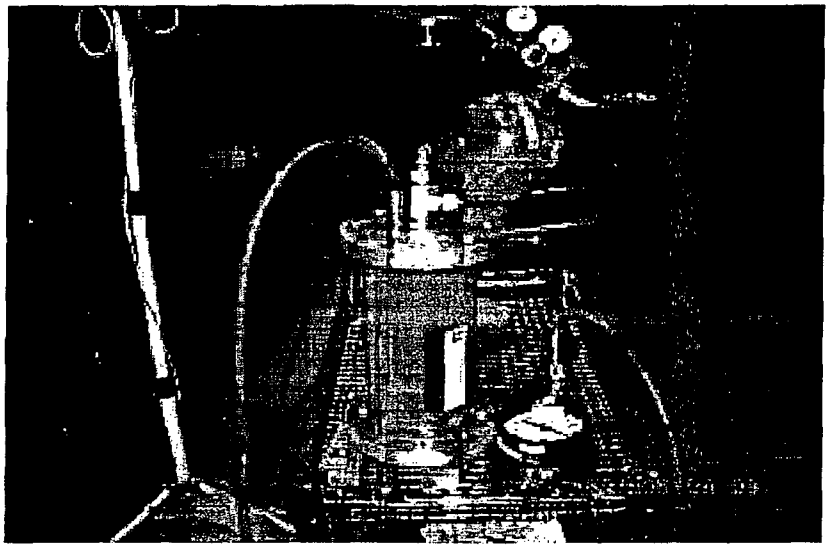
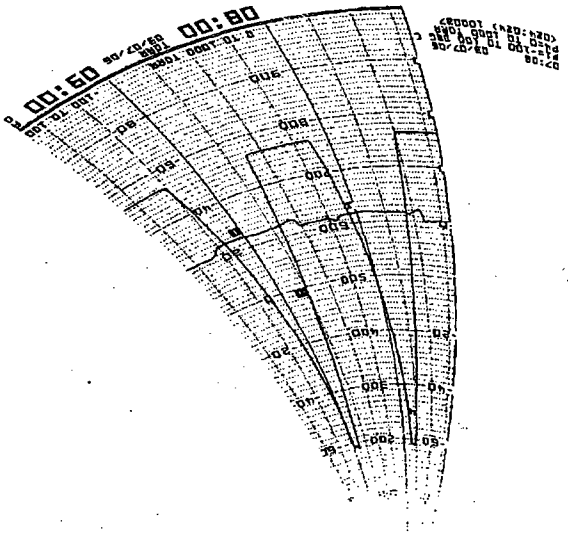


Figure 3-3: Test setup for hydrostatic pressure.



JOB # 05170 DATE 3/07/06
CUSTOMER INTERNATIONAL ISOTOPES
TEST EXTERNAL LOW PRESSURE
TEST ITEM TELETHERAPY CAPSULES
P/N _____
S/N 1/4" #4 & 1/2" #4

SECTION 4

VIBRATION TEST SUMMARY

Test Start-Finish Dates: 08 March 2006

Responsible Test Technician: Don Hensley

4-1 TEST HARDWARE

One (1) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 1
One (1) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 1

4-2 TEST REQUIREMENTS WITH TOLERANCES

Perform 90-minutes of sinusoidal vibration consisting of three 30-minute cycles from 25 to 2,000 to 25 Hz at a linear rate in the axial and radial axes:
25 to 80 Hz at 1.5 mm DA
80 to 2,000 Hz at $20G_{pk}$

Tolerance
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Sine Amplitude: ±10%; Frequency: < 25±0.5 Hz, ≥25 Hz ±2%

4-2.1 Test Specification:

ANSI/HPS N43.6-1997, Section 7.5 Vibration test, Class 4, Table 1

4-3 TEST SETUP

TABLE 4-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100116	Accelerometer	Endevco	2226C	4/21/2006
100119	Charge Amplifier	Endevco	104	11/14/2006
100122	Power Supply	Endevco	109	11/14/2006
100353	Vibration Control System	Dactron	Laser USB	2/28/2007
100956	Vibration Exciter	Ling Electronics	A300B	NA
100957	Power Amplifier	Unholtz-Dickie	MA130/HE130	NA

TABLE 4-2: ACCELEROMETER SETUP

Accelerometer ID	Charge Amp. ID/CH #	Controller CH #	Function	Location
100116	100119/CH #01	01	Control	Vibration Table

4-4 TEST DESCRIPTION

4-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

4-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the vibration test.

4-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 22 Relative Humidity (%): 42 Pressure: Site ambient

TABLE 4-3: VIBRATION TEST ACTIVITIES

Run #	Axis	End Time	Duration
1	Axial	1136	90 minutes
2	Radial	1224	90 minutes

4-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

4-5 ENVIRONMENTAL TEST DATA

The vibration plots are located after Figure 4-2.

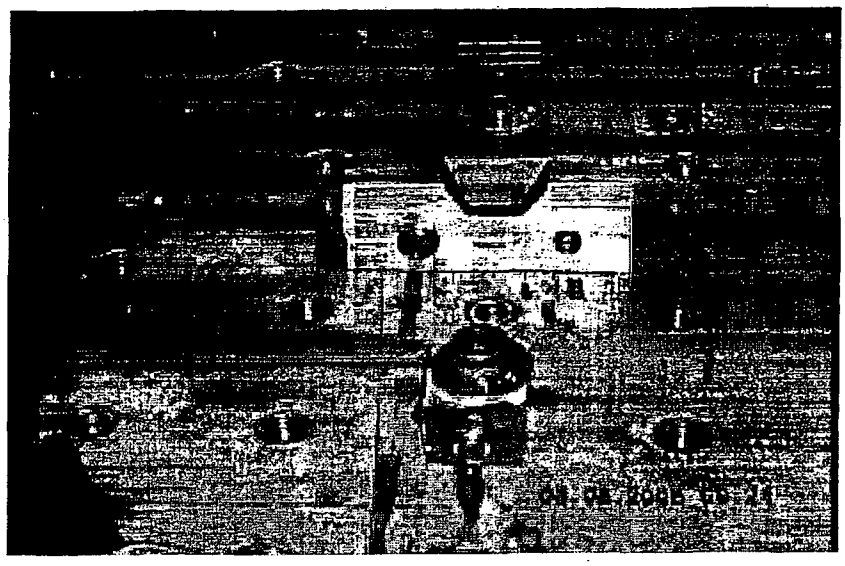


Figure 4-1: Test setup for axial-axis vibration.

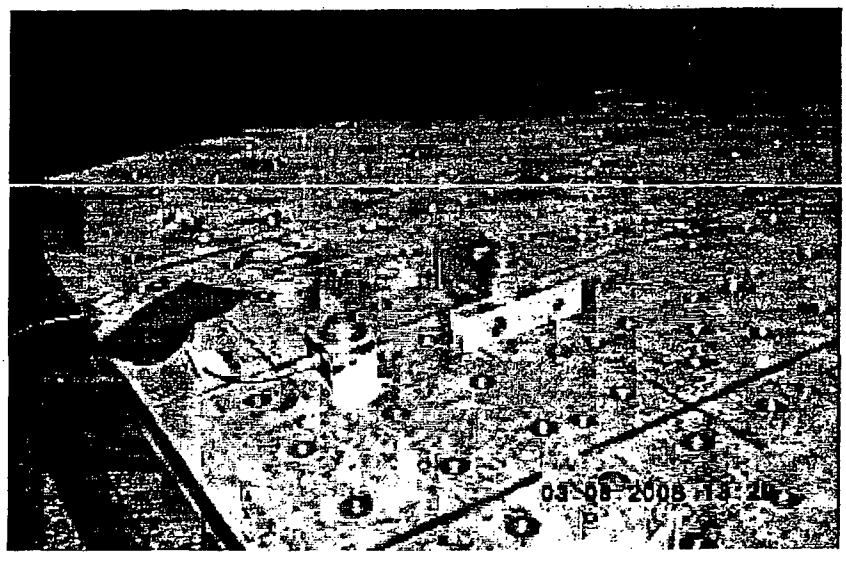
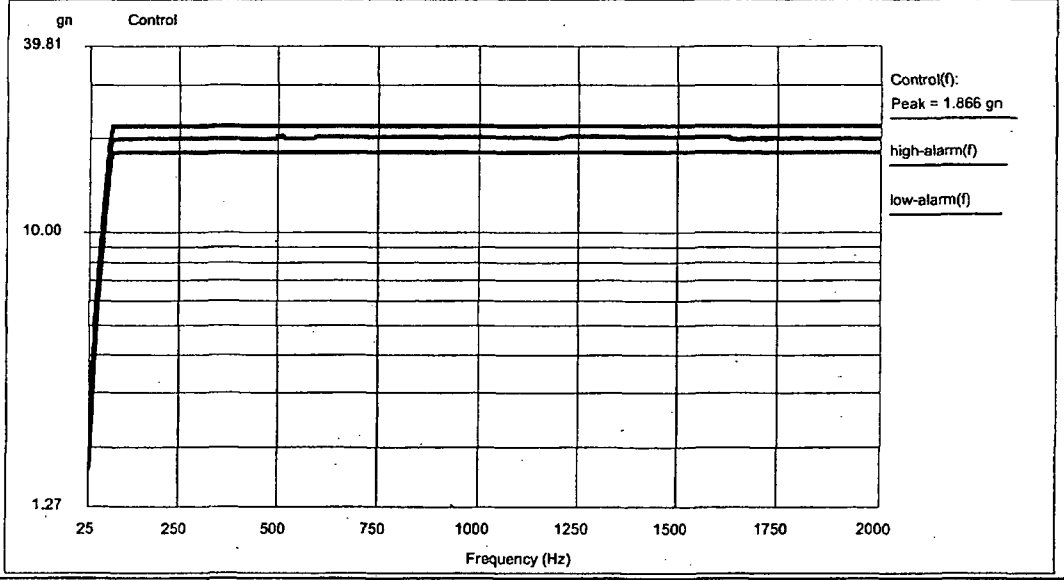
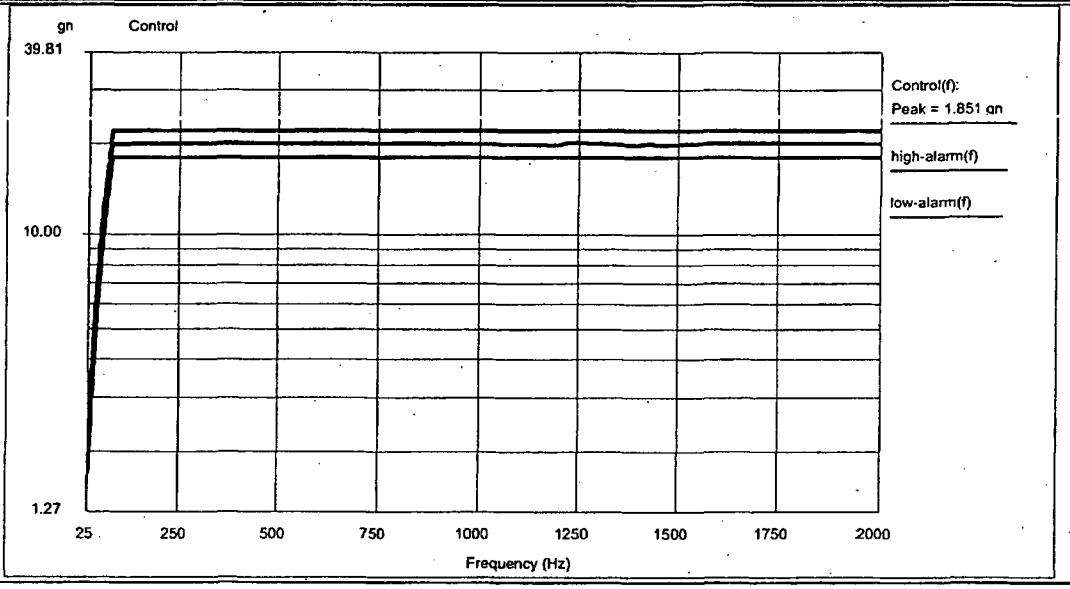


Figure 4-2: Test setup for radial-axis vibration.

Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.			Job #:	05170
	Test Hardware:	Stainless Steel Capsules (2 ea.)			Run #:	1
	P/N:	¼ inch OD. (1 ea.), ½ inch OD.(1 ea.)			Axis:	Axial
	S/N:	Marked #1			Duration:	90 minutes
	Date:	08 March 2006	Time:	1136		



Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.			Job #:	05170
	Test Hardware:	Stainless Steel Capsules (2 ea.)			Run #:	2
	P/N:	¼ inch OD. (1 ea.), ½ inch OD.(1 ea.)			Axis:	Radial
	S/N:	Marked #1			Duration:	90 minutes
	Date:	08 March 2006	Time:	1224		



SECTION 5

TEMPERATURE TEST SUMMARY

Test Start-Finish Dates: 09 through 10 March 2006

Responsible Test Technician: Don Hensley

5-1 TEST HARDWARE

One (1) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 1
One (1) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 1

5-2 TEST REQUIREMENTS WITH TOLERANCES

Low Temperature:
Maintain -40±2°C for at least twenty (20) minutes

Temperature Shock:
Transfer to 800±50°C and maintain conditions for at least one (1) hour
Transfer in fifteen-seconds or less to ≤ 20°C water at least 20 times the volume of the test item

5-2.1 Test Specification:

ANSI/HPS N43.6-1997, Section 7.2 Temperature test, Class 6, Table 1

5-3 TEST SETUP

TABLE 5-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100037	Chart Recorder	Honeywell	DR45AT-1111-0	6/7/2006
100102	Temperature Calibrator	Omega Eng.	OMNI-CAL IIA8	5/11/2006
100337	Chart Recorder	Honeywell	DR45AT	6/12/2006
100902	Temperature Chamber	Cincinnati Sub Zero	Z-8-1-1-H/AC	NA
100935	Temperature Chamber	Valcan	3-130	NA

TABLE 5-2: CHART RECORDER SETUP

Asset #	Channel	Function	Type of sensor
100037	1	Monitor chamber air temperature	100 Ω RTD
100937	4	Monitor chamber air temperature	K Type T/C

5-4 TEST DESCRIPTION

5-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

5-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the temperature testing.

5-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 21 Relative Humidity (%): 40 Pressure: Site ambient

TABLE 5-3: LOW TEMPERATURE TEST ACTIVITIES

Step #	Activity	Date	End Time	Duration
1	Ramped to -40°C	03/09/06	1112	30 minutes
2	Maintained -40°C	03/09/06	1132	20 minutes
3	Ramped to 23°C	03/09/06	1202	30 minutes

TABLE 5-4: TEMPERATURE SHOCK TEST ACTIVITIES

Step #	Activity	Date	End Time	Duration
1	Ramped to 800°C	03/10/06	0740	40 minutes
2	Maintained 800°C	03/10/06	0840	1 hour
3	Transferred to water at 20°C	03/10/06	0840	< 10 seconds

5-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

5-5 ENVIRONMENTAL TEST DATA

The temperature charts are located after Figure 5-3.

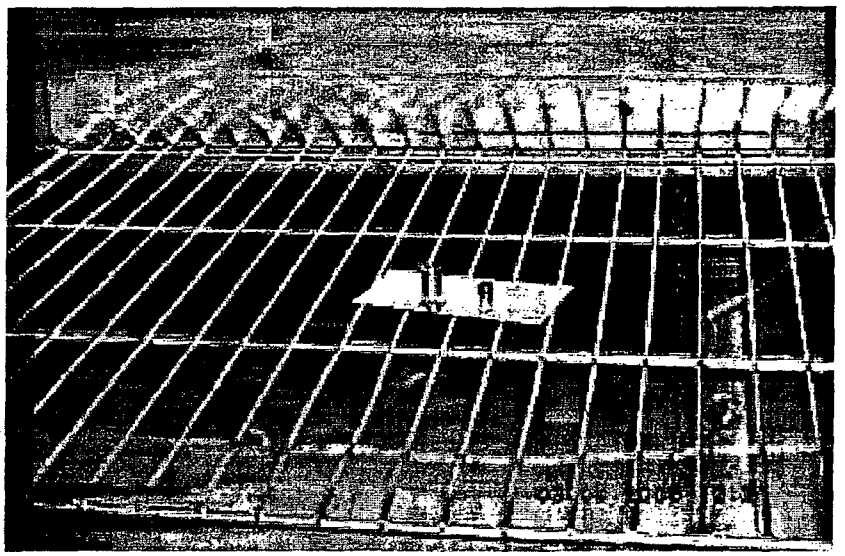


Figure 5-1: Test setup for low temperature.

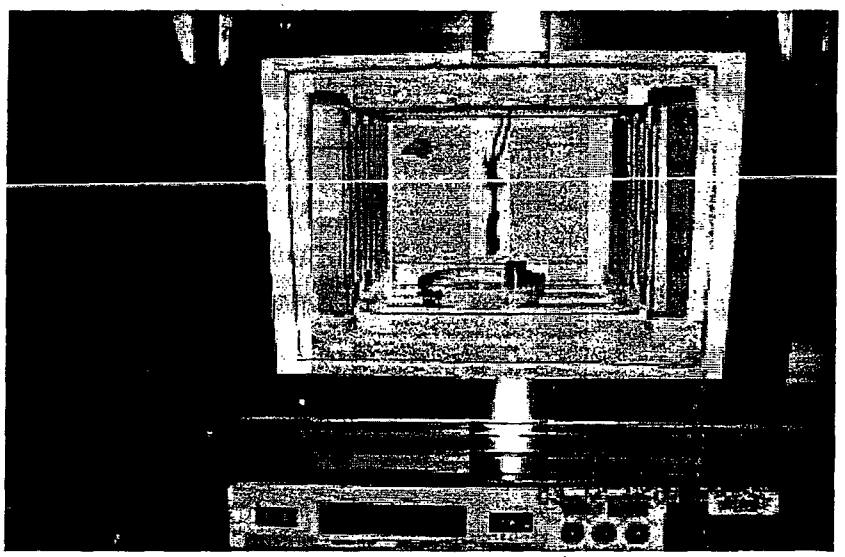


Figure 5-2: Test setup for temperature shock.

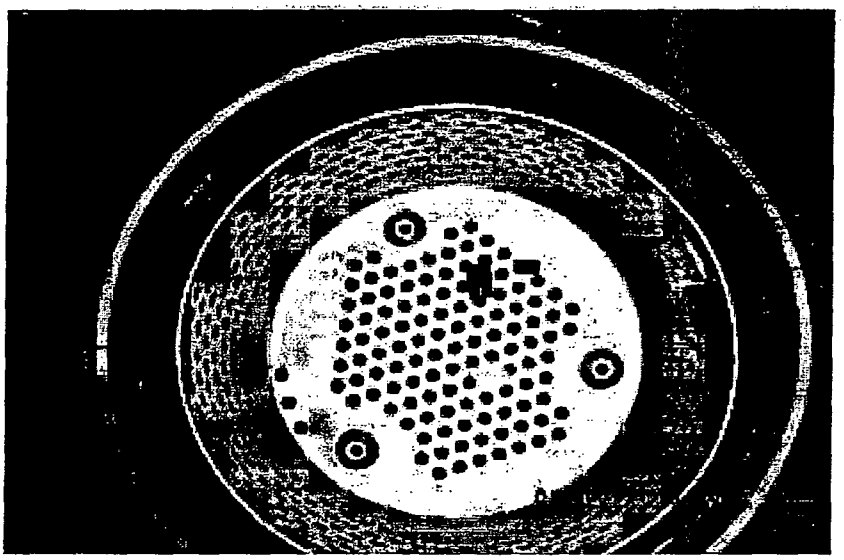
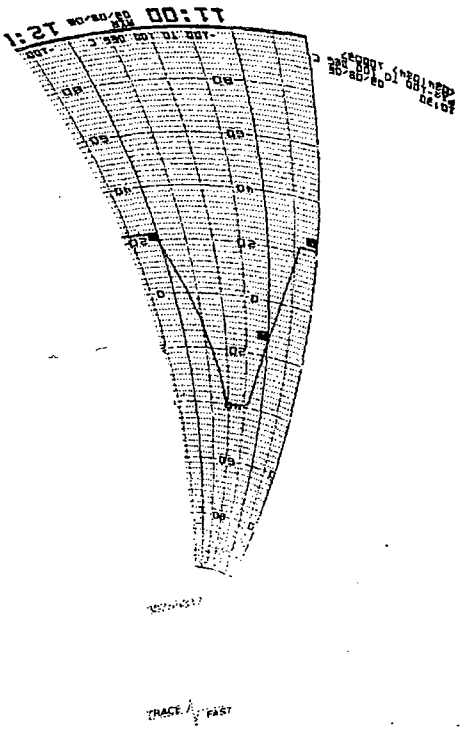
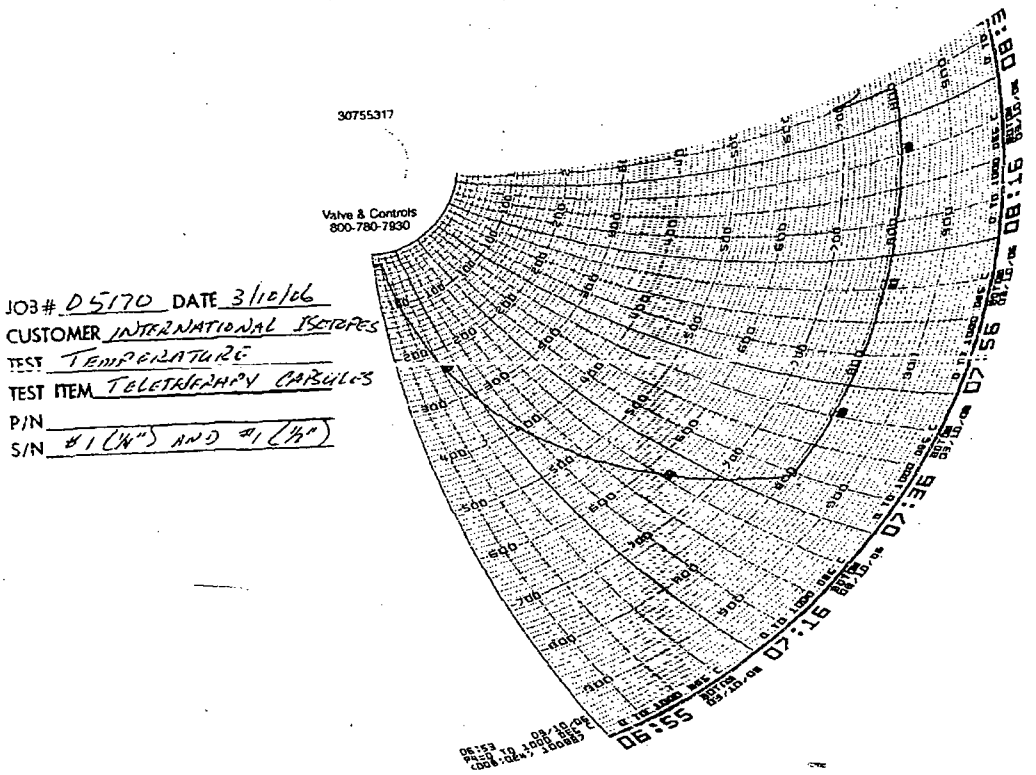


Figure 5-3: Test setup for temperature shock (in water container).



JOB # D5170 DATE 3/07/06
CUSTOMER INTERNATIONAL ISOTOPES
TEST TEMPERATURE
TEST ITEM TELETHERAPY CAPSULES
P/N
S/N #1 (¼") AND #1 (½")


30755317
Valve & Controls
800-780-7830
JOB# 05170 DATE 3/10/06
CUSTOMER INTERNATIONAL ISOTOPES
TEST TEMPERATURE
TEST ITEM TELETHERMOMETER CABLES
P/N
S/N #1 (¼") AND #1 (½")
08:15
07:56
07:36
07:16
06:55

SECTION 6

HOT LIQUID BUBBLE TEST SUMMARY

Test Start-Finish Dates: 10 March 2006

Responsible Test Technician: Don Hensley

6-1 TEST HARDWARE

Four (4) Stainless Steel Capsule, outside diameter measuring ¼ inches S/N 1 through 4
Four (4) Stainless Steel Capsule, outside diameter measuring ½ inches S/N 1 through 4

6-2 TEST REQUIREMENTS WITH TOLERANCES

Ensure that the test items are at ambient temperature and then immerse in 90 to 95°C water. Observe for bubble leaks over a period of at least two minutes.

Tolerance
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure

6-2.1 Test Specification:

ANSI/HPS N43.6-1997, Paragraph A.2.2.2

6-3 TEST SETUP

TABLE 6-1: QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/12/2006
100102	Temperature Calibrator	Omega Eng.	OMNI-CAL IIA8	5/11/2006

6-4 TEST DESCRIPTION

6-4.1 Non-Qualtest Personnel, Including Organization, Present for All or Part of the Test:

None

6-4.2 Powered/Operational State of the Hardware and by Whom:

The test items were not operated during the hot liquid bubble test.

6-4.3 Test Activities and Resulting Measurements from Observed/Recorded Data:

Atmospheric Conditions: Temp (°C): 21 Relative Humidity (%): 40 Pressure: Site ambient

TABLE 6-2: HOT LIQUID BUBBLE TEST ACTIVITIES

Run	Test Item	Time	Water Temperature	Duration	Observation
1	All	0912	92.0°C	3 minutes	No bubbles

6-4.4 Limitations or Departures from the Test Requirements and Authorizing Source:

None

6-5 ENVIRONMENTAL TEST DATA

Compliance verified through test setup and observation (reference photos Figures 6-1 through 6-2).

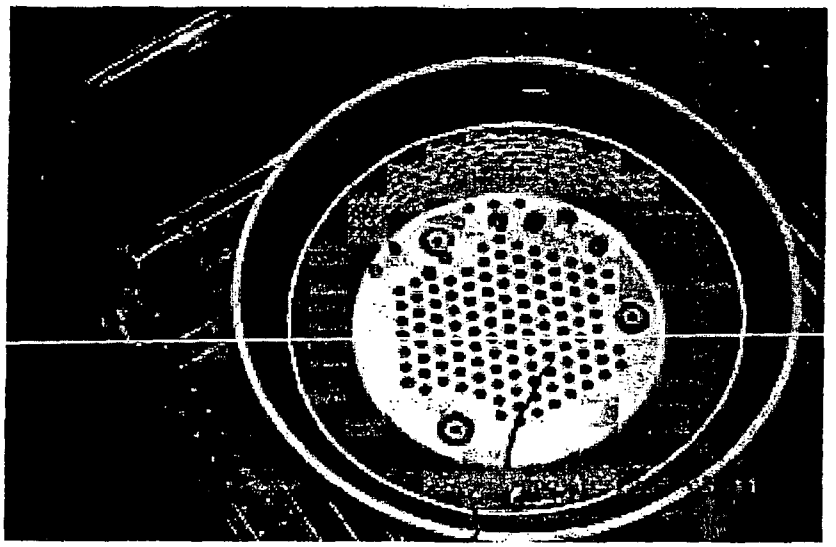


Figure 6-1: Test setup for hot liquid bubble.

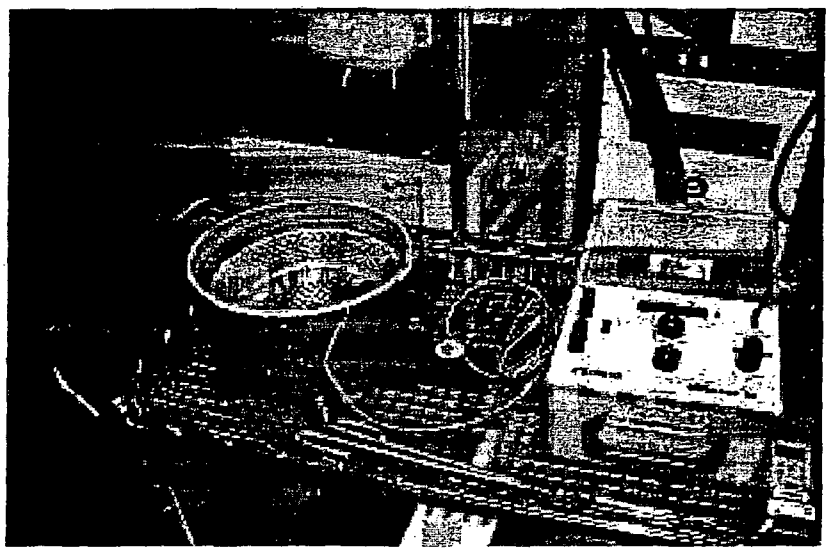


Figure 6-2: Test setup for hot liquid bubble.

Reference Qualtest P.O. #7560

ENCLOSURE I

ANSI/HPS N43.6-1997, SECTION 7.3 EXTERNAL PRESSURE TEST

TESTING PERFORMED BY:

ENVIRON LABORATORIES, LLC
9725 Girard Avenue South
Minneapolis, Minnesota 55431-2621

Phone: 952-888-7795; Fax: 952-888-6345

ABSTRACT

This Enclosure contains the ANSI/HPS N43.6-1997, Section 7.3 External Pressure test data provided by Environ Laboratories, LLC.

environ LABORATORIES LLC
9725 GIRARD AVENUE SOUTH
MINNEAPOLIS, MINNESOTA 55431-2621

ENGINEERING REPORT NO. 33831-1

EXTERNAL PRESSURE TEST

for

QUALTEST, INC.
5325 OLD WINTER GARDEN ROAD
ORLANDO, FL 32811

PREPARED BY:	John T. Pelkey Test Engineer
	John A. Beneke Test Engineer
APPROVED BY:	(Chris Kieser) FOR: Alan G. Thompson President

REVISION HISTORY

Revision	Total Number of Pages	Date	Description
--	7	6 March 2006	Original

PREPARED FOR:	TEST DATES:
QUALTEST, INC. 5325 OLD WINTER GARDEN ROAD ORLANDO, FL 32811 ATTN: Todd Scarborough	Start: 2/14/2006 Completion: 2/14/2006
	ENVIRON TEST NO.: 33831-1
	PURCHASE ORDER NO.: 7560
	PURCHASE DATE: 1/31/2006

EXTERNAL PRESSURE TEST

1.0 ABSTRACT

1.1 Object

Subject two (2) Stainless Steel Capsules to an External Pressure Test as described in Section 7.3 of test specification *ANSI/HPS N43.6-1997*.

1.2 Conclusions

Upon completion of the two pressure cycles, the two test units did not show any visual signs of damage.

2.0 UNIT(S) TESTED

SUPPLIED BY:	INTERNATIONAL ISOTOPES
DEVICE:	Stainless Steel Capsules
MODEL/PART NO.:	1 Stainless Steel Capsule 0.50 inch diameter by 0.75 inch long 1 Stainless Steel Capsule 0.25 inch diameter by 0.50 inch long
SERIAL NO.:	N/A

The results of this test apply only to the units identified in this Engineering Report by device identifier and model / part number, or serial number.

3.0 TEST REQUESTED

Subject two stainless steel capsules to an External Pressure Test as described in Section 7.3 of test specification *ANSI/HPS N43.6-1997*. Follow the test specification with one exception provided by Qualtest, Inc.: Do not weigh the test units before or after the test.

4.0 INSTRUMENTATION, PROCEDURE AND RESULTS

4.1 Instrumentation

All instrumentation is calibrated regularly by instruments directly traceable to the National Institute of Standards and Technology, and in accordance with MIL-I-45208A, ANSI/NCSL Z540-1-1994 and ISO/IEC 17025: 1999.

Equipment Number	Description	Manufacturer	Model Number	Last Calibration	Due Calibration	Range
400-025	Stopwatch	Radio Shack	63-5014	6/13/2005	6/13/2006	0 to 10 Hours
710-201	Pressure Gauge	Astra	W-75-1	10/27/2005	10/27/2006	0 to 75,000 PSIG

4.2 Procedure

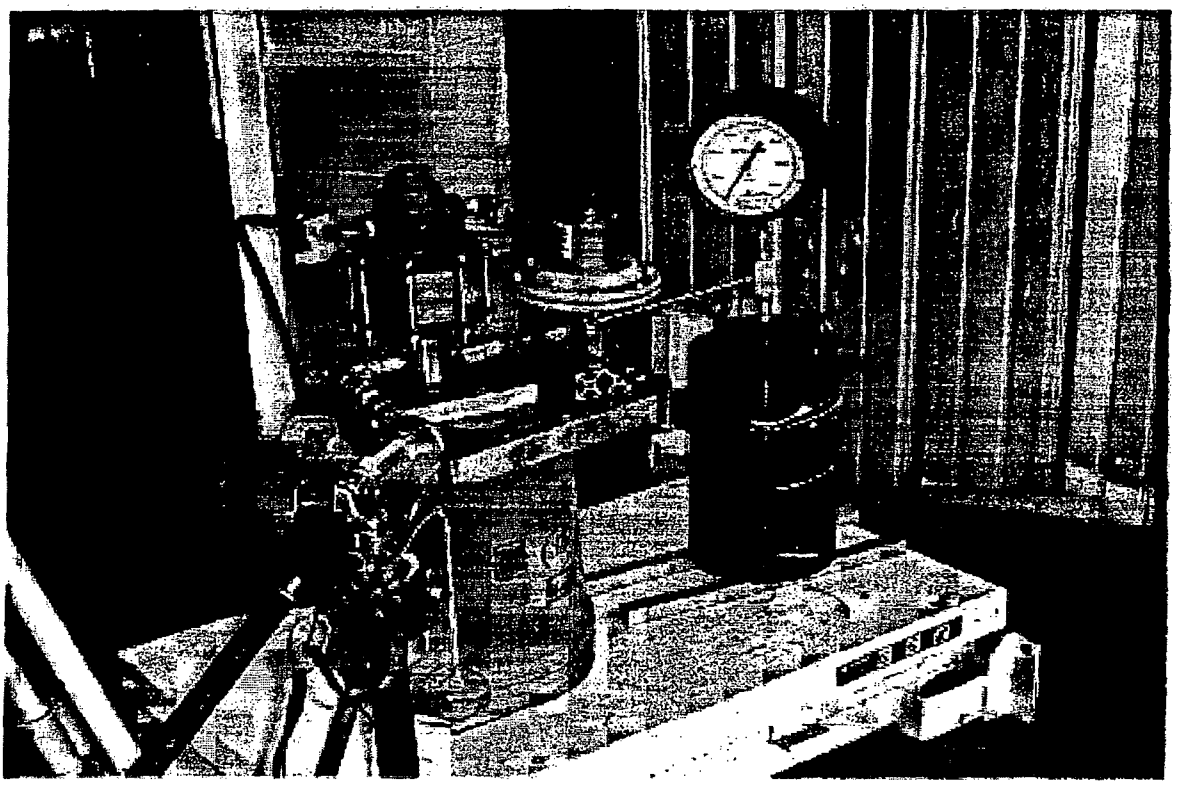
Both test units were placed in a high-pressure vessel which was sealed, filled with water, and bled of all air. The pressure in the vessel was slowly increased to between 24,656 PSIA and 27,121 PSIA, and held at this pressure for at least 5 minutes. The pressure was then returned to ambient conditions. Then, for a second cycle, the pressure in the vessel was slowly increased to between 24,656 PSIA and 27,121 PSIA, and held at this pressure for at least 5 minutes. The pressure was then relieved and the test units were visually inspected for damage. Lab ambient conditions for this testing was 74°F and 19% R.H.

4.3 Results

Upon completion of the two pressure cycles, the two test units did not show any visual signs of damage. Photograph No. 1 shows the test setup. Photograph Nos. 2 and 3 show post-test views of the test units. Table No. 1 provides detailed information on the test pressures and dwell times.

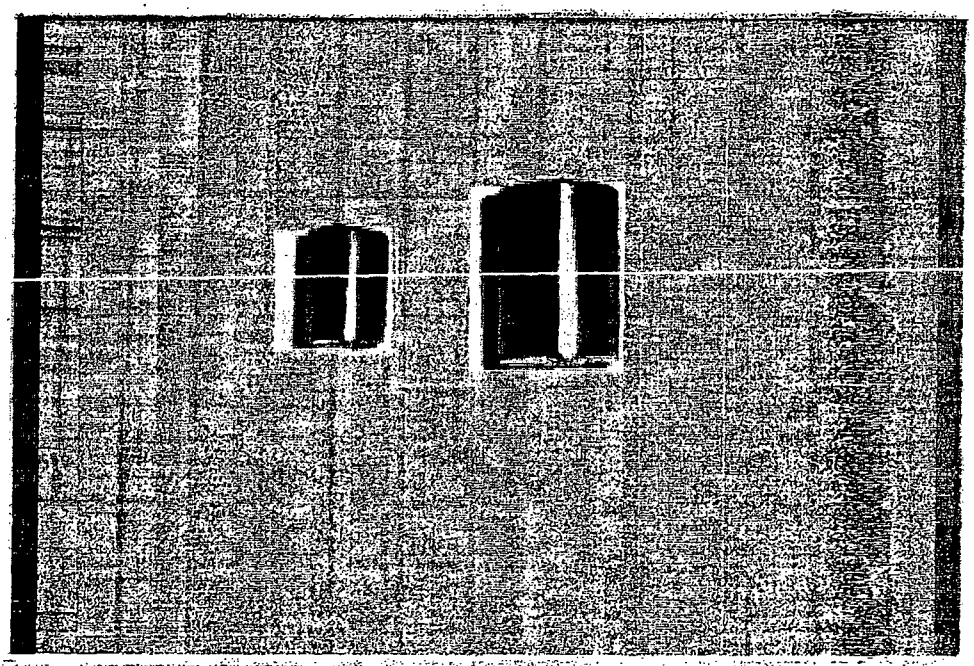
TABLE NO. 1: TEST PRESSURE CYCLES

Cycle	Pressure	Dwell Time
Pressure Cycle 1	26,500 PSIG	5 minutes 2 seconds
Ambient Cycle	14.7 PSIA (approximately)	3 minutes 0 seconds
Pressure Cycle 2	26,500 PSIG	5 minutes 1 seconds



Photograph No. 1: Test setup used to perform the test.

Photograph No. 2: Top view of the test units after the test.



Photograph No. 3: Side view of the test units after the test.

Title:			
INTERNATIONAL ISOTOPES INC. QUALITY SYSTEM DESCRIPTION			
Quality Assurance Signature and Date: 10/4/04	Page: Page 1 of 4	Effective Date: 10/04/04	Superseded Date: Original

I³ Quality Assurance Program Summary

I³ is committed to producing quality products meeting customer, regulatory and industry standards. To implement this policy, I³'s management has established a Quality Management System, based on ASME-NQA-1 and 21CFR 210, 211 and 21CFR 820, current Good Manufacturing Practices (cGMP).

I³ Organization

I³ maintains an effective organization to manage, perform and verify all work affecting the quality of products and services provided by the Company. I³ is managed by the President and Chief Executive Officer, who reports to the Chairman of the Board. Through the reporting Quality Assurance Manager, the President administers the operations that effect product quality. It is the responsibility of the President to ensure that I³ operates in compliance to the Quality Management System. It is the responsibility of the Quality Assurance Manager to ensure that the cGMP elements are incorporated into the Quality System and to assess and report its effectiveness to senior management.

Design Control

I³ maintains established procedures to control design activities, and to verify that the resulting design meets all specified requirements.

The design and development process includes the use of design inputs, design reviews and design outputs. Design verification activities are performed to evaluate the design against other similar proven designs or other competitive or benchmark standards. Design validation is performed to ensure that the final product meets defined user needs and specifications prior to shipping. Manufacturing and Quality must approve design changes.

Procurement Document Control

I³ requires that quality related materials and components used in the manufacturing, testing and packaging of the product be inspected and approved to pre-established specifications prior to use. In addition, these materials and components may only be purchased from approved suppliers. I³ has established purchasing specifications that define the requirements for purchased materials, release specifications, and sampling and testing procedures.

Document Control, Instructions, Procedures

The I³ Quality Management System is implemented through the quality plan and the standard operating procedures and associated worksheets, logs and forms.

I³ requires that QA approved specifications and procedures be prepared and followed for all work processes including planning, manufacturing, testing, holding, labeling, and packaging & distribution of products. As such the use, storage, inspection and maintenance of Type B packages utilized by I³ are governed by a QA approved package specific procedure. Revisions to these documents are strictly controlled and require that document revisions be approved by The I³ Quality Assurance Organization prior to issue. Records of document changes are maintained which include a description of the change and the justification for the change.

Identification & Control of Purchased Material, Parts & Components

I³ requires that quality related materials be inspected and approved to pre-established specifications prior to use. Upon receipt of quality related materials, the materials are quarantined until a receipt inspection is performed. Upon successful completion of the receipt inspection, the materials are labeled as accepted and stocked for use.

Control of Special Processes

All quality related work is performed under the direction of approved procedures. In this way, quality related "Special Process" functions are kept to a minimum. In the event that a special process evolution is required a one-time procedure is developed and approved by the Quality Assurance Manager.

Internal Inspection and Audits

I³ maintains an audit program to verify compliance and determine the effectiveness of the quality management system and to determine where corrective action is needed. In addition, I³ is routinely participates in external audits performed by customers to assure compliance with individual customer quality issues. Timely corrective action is taken to prevent reoccurrence of the same or a similar deficiency. Follow-up is performed to verify the effectiveness of any previously implemented corrective action. All audits are performed by qualified individuals.

Test Control & Control of Test and Measuring Equipment

I³ has established sound and appropriate specifications, sampling plans and test procedures to assure that materials, components and finished products conform to the appropriate quality standards. All finished products and appropriate components and materials are routinely inspected or tested to verify compliance with specifications. Only products that meet their predetermined specifications are released for distribution.

Equipment used for quality related measurements are routinely calibrated with NIST traceable standards.

Handling Storage and Shipping Control

I³ has established and implemented effective procedures that control the labeling, packaging and distribution of finished product. All labeling and packaging materials must meet specifications prior to use including specifications for radioactive materials. A qualified shipper trained in accordance with 49 CFR 72 subpart H, performs a final inspection of packages and labeling prior to shipment of the product.

Inspection, Test and Operating Status

Shipments of final products, are performed by qualified shippers trained in accordance with 49 CFR 72 subpart H. A checklist, generated for each package type is completed as the package is inspected for proper labeling and markings. Once completed, checklists are filed with other pertinent shipping documentation.

Nonconforming Materials, Parts or Components & Corrective Action

I³ requires that nonconforming materials, components, and final products be identified, documented, controlled, investigated, and dispositioned to ensure only products meeting approved specifications are distributed. Investigations are comprehensive and encompass similar products and other batches of product. The cause(s) of the nonconformance must be determined and corrective actions taken to prevent reoccurrence. Established procedures describe the requirements to identify, document, evaluate, segregate and allow for the disposition of product that does not meet specifications. The I³ Quality Assurance Organization verifies that all nonconforming material is identified and segregated from all other material and is properly dispositioned. The I³ Quality Assurance Organization conducts comprehensive investigations to determine causes and assignment of corrective actions that are designed to prevent reoccurrence.

Quality Assurance Records

I^3 has defined and implemented a record retention system that maintains all records and reports associated with the planning, manufacturing, testing, labeling and packaging, holding and distribution of final products. Records maintained also include records from audits and complaint handling activities. The system requires that the records be stored to facilitate retrieval.