10-18-04

NRC FORM 567
(1-1999)

U.S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this rerquest AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER		REGION/LOCATION:
Int'l Isotopes, Inc.		☐ I ☐ II ☐ III ☐ IV ☐ HQ ☐ LFARB
TELEPHONE NUMBER: 800-699-3108	DATE:	TYPE OF ACTION REQUESTED *(Check as appropriate)*
NAME OF APPLICANT: John J. Miller		☐ SOURCE REVIEW ☐ AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S):		☐ DEVICE REVIEW
LETTER/APPLICATION DATE: 09/15/2004	LICENSE NUMBER(S):	☐ CUSTOM REVIEW

COMMENTS:
4137 Commerce Circle
Idaho Falls, ID 83401

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS	NUMBER ASSIGNED
Tony Kirkwood	INIS-SF-X.X-YY-AD, J, K, & L	05-04
DATE RECEIVED	**DATE ASSIGNED**	**DATE TO FEES**
10/18/2004	10/18/2004	10/18/2004

TYPE OF ACTION *(Indicate the number of each type)*

☑ COMMERCIAL DISTRIBUTION (FORMAL) ☐ USE BY A SINGLE APPLICANT (CUSTOM)

SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
☑ NEW	☐ NEW	☐ NEW	☐ NEW
☐ AMENDMENT	☐ AMENDMENT	☐ AMENDMENT	☐ AMENDMENT

☐ NO SAFETY EVALUATION REQUIRED
NO FEES REQUIRED

☐ LICENSING ACTION REQUIRED (IF KNOWN) ☐ YES ☐ NO

☐ OTHER *(Specify)*

	TOTAL NUMBER OF REVIEW HOURS	NOTES: Application for SS&D Evaluation & Registration I3-101504. Check 003568 sent in for $1800.00. Check sent to the lockbox 10/18/2004. ADAMS Package: ML042920400
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR FEE USE ONLY

TYPE OF FEE		FEE CATEGORY: ☐ 9A ☐ 9B ☐ 9C ☐ 9D	
AMOUNT RECEIVED	CHECK NUMBER	DATE OF CHECK	LOG
APPROVED BY			DATE OF RETURN
COMMENTS:			

F-1

International Isotopes Inc.
& International Isotopes Idaho Inc.

October 15, 2004

Mr. Timothy Harris
Section Chief
Mail Stop T-8FS
11555 Rockville Pike
Rockville, MD 20852

Subject: Application for Sealed Source and Device Evaluation and Registration I3-101504.

Dear Mr. Harris,

International Isotopes Inc. (I^3) is seeking to register Co-60 teletherapy source on the Nuclear Regulatory Commission's Sealed Source & Device Registry. Please find the enclosed Application for Safety Review I3-101504 along with a check for $1800.00 as required by 10 CFR 170.31, Category 9. C.

Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

Enclosures as stated

cc:
J. J. Miller file (JJM-2004-20)

4137 Commerce Circle, Idaho Falls, Idaho 83401
Phone: 208-524-5300, 800-699-3108 Fax: 208-524-1411
Website: www.intisoid.com

Enclosure 1
October 15, 2004

Application for Safety Review
I3-101504

SUMMARY DATA

Date: October 15, 2004

Sealed Source Type: Doubly encapsulated Co-60 Source Line Source

Models:
INIS-SF-X.X-YY-AD
INIS-SF-X.X-YY-J
INIS-SF-X.X-YY-K
INIS-SF-X.X-YY-L

Where:
X.X denotes the source diameter in centimeters
YY denotes the source length in centimeters
AD indicates a photon emitting teletherapy unit source
J indicates a Category I gamma irradiation source
K indicates a Category II gamma irradiation source
L indicates a Category III gamma irradiation source

Applicant:

International Isotopes Idaho Inc
4137 Commerce Circle
Idaho Falls, ID 83401
(Manufacturer/Distributor)

For further information, contact:
John J. Miller, CHP
Radiation Safety Officer
(208) 524-5300

Enclosure 1
October 15, 2004

Isotope and Maximum Activity:

Model Number	Isotope	Maximum Activity
INIS-SF-X.X-YY-AD	Co-60	[redacted]
INIS-SF-X.X-YY-J	Co-60	
INIS-SF-X.X-YY-K	Co-60	
INIS-SF-X.X-YY-L	Co-60	

Ex. 4

Leak Test Frequency: Six months.

(Not applicable to medical teletherapy applications per NUREG 1556 Vol. 3, Rev. 1)

Principal Uses: AD (Photon-emitting Teletherapy Units)
J (Gamma Irradiation Category I)
K (Gamma Irradiation Category II)
L (Gamma Irradiation Category III)

Custom Source: No

DESCRIPTIVE DATA

Description:

These sources consist of Co-60 as a metal or alloy in various physical geometries such as disks, cylinders and spheres. The Co-60 source material is doubly encapsulated in stainless steel housings. The open ends of both the inner and outer stainless steel housings will be seal welded. These sources are intended as replacement sources for use in medical teletherapy devices and gamma irradiators. For medical teletherapy applications, In accordance with 21 CFR § 892.5740 *Radionuclide teletherapy source,* these sources are categorized as a Class 1 device and are exempted from the premarket notification procedures in Subpart E of part 807 of Title 21.

Source dimension specifications are summarized in the following table:

Model INIS-SF-X.X-YY-Z	Max O.D. (in)	Min O.D. (in)	Max. Length (in)	Min. Length (in)
Outer Capsule	1.25±.0.01	0.375±.0.005	8.00±.0.01	2.00±.0.01
Inner Capsule	1.090±.0.005	0.225±.0.005	7.880±.0.005	1.335±.0.005

Note: The last digits of the model number (denoted by "X.X-YY") will identify the model number by dimensions. The first digits will identify the diameter of a specific model in centimeters rounded to the nearest decimal the last two digits will identify the length of a specific model in centimeters, rounded to the nearest whole number. The letter Z designates the source category.

For example a medical teletherapy source with a diameter of 2.75 cm and a length of 12.25 cm would be identified as model number INIS-SF-2.8-12-AD.

Labeling:

One end cap of each source is engraved with the active isotope (Co-60), source model and serial number. Refer to the INIS-SF-X.X-YY drawings included in Attachment 1.

In addition to the source, all shielded transportation containers will be conspicuously labeled with the isotope present, the nominal activity, the month and year of assay and bear the warning "CAUTION: RADIOACTIVE MATERIAL" along with the radioactive trefoil radiation symbol in magenta on a yellow background.

Safe handling instructions are included with the source.

Drawings: Refer to Attachment 1.

Conditions of Normal Use:
Under normal use conditions, a Model INIS-SF-X.X-YY-Z source would be placed into a heavily shielded device. The construction of these devices provides substantial radiation shielding and protects the source from physical damage as well. These devices are typically located in a protected environment such as a laboratory or medical clinic.

The useful life of the source is dependent on the 5.27 year half-life of Co-60 and is expected to be approximately 10 years.

Limitations And/Or Other Considerations Of Use:

1. The sources shall be distributed to persons specifically licensed or authorized to possess such a source in accordance with 10 CFR 35.600 or equivalent agreement or foreign agency equivalent.

2. Handling, storage, use, transfer and disposal of the sources will be determined by the licensing authority at a given location.

3. The sources shall not be subjected to conditions that exceed the test conditions identified in ANSI/HPS N43.6-1997 that pertain to a source with classification,

97E53424(4) or a bending force as described in ISO 2919:1999(E) for source with a length to diameter ratio greater than 15.

4. The probable effect of severe environmental conditions, such as accidents and fire, would be a minimal release of radioactivity since the cobalt metal is contained within a double stainless steel encapsulation.

5. This registration sheet and the information contained within the references shall not be changed without the written consent of the Nuclear Regulatory Commission.

HEALTH AND SAFETY DATA

Safety Analysis Summary:

The Co-60 Source designs described within this application have been proven capable to withstand the conditions of normal use. These sources will be used in a professional setting, installed in well maintained devices. Under conditions of normal use, the source will not be subjected to physical or environmental factors such as abrasion, corrosion, impact, puncture, or temperature/pressure extremes that would result in source failure.

The source designs meet the ANSI/HPS N43.6-1997 that pertain to a source with classification, 97E53424(4) and a bending force as described in ISO 2919:1999(E) for sources with a length to diameter ratio greater than 15.

Manufacturer's Safety Analysis of Sealed Source Review:

Environmental testing performed under the direction of International Isotopes Inc. showed that the INIS-SF-X-YY series design meets the performance classification ANSI 97E53424(4) per ANSI/HPS N43.6-1997 and ISO 2919:1999(E).

A copy of the test report and leak test results is contained in Attachment 2.

Bend Test:

A bend test was performed only on an INIS-SF-X.X-YY dummy source. The source used for the test was constructed with a diameter of 0.375 inches and a length of 8.0 inches. This is the smallest diameter and longest length allowed by the source design. This is considered to be the source dimensions that would be most susceptible to damage from a bend test.

A bending test apparatus was constructed as described in ISO 2919:1999(E).The testing apparatus was placed on a scale and a static force equal to 2000 N (102 kg) was applied to the Force Cylinder utilizing a press that was locked in position for the duration of the test. The static force was applied to the center of the source for 4 hours. It should be noted that ISO 2919:1999(E) did not provide guidance on the duration of the test. A time

of 4 hours was selected so that the bend test and subsequent inspections and tests for leakage could be accomplished during the course of a normal workday.

A copy of the test report and leak test results is contained in Attachment 2.

Radiation Profile:

Source activity will be limited to the maximum activity allowed for the device in which they will be installed. FDA (or Foreign Government Agency equivalent) approved teletherapy devices are so designed to limit the dose rate to the operator, patient and collocated persons to radiation exposures which have been deemed As Low As Reasonably Achievable. Radiation profiles will vary among different teletherapy devices. Sources will be transported in approved packages that limit the on contact package dose rates and transportation indexes to levels that coincide with Department of Transportation Regulations.

The dose profile for a[ ]teletherapy source, with a 1.26 cm radius and 3.39 cm length was determined using MicroShield 5.03. Radial and Axial dose rates at 5, 30 and 100 cm from the source where calculated and recorded below. Ex. 4

Distance (cm)	Axial		Radial	
5	3.72E+06	Rad/hr	3.87E+06	Rad/hr
30	1.63E+05	Rad/hr	1.66E+05	Rad/hr
100	1.52E+04	Rad/hr	1.60E+04	Rad/hr

The dose profile for a[ ]irradiator source, with a 1.38 cm radius and 5.74 cm length was determined using MicroShield 5.03. Radial and Axial dose rates at 5, 30 and 100 cm from the source where calculated and recorded below. Ex. 4

Distance (cm)	Axial		Radial	
5	1.47E+06	Rad/hr	1.86E+06	Rad/hr
30	7.88E+04	Rad/hr	8.39E+04	Rad/hr
100	7.95E+03	Rad/hr	8.11E+03	Rad/hr

A Technical Data Sheet will be included with each source or source set. This sheet will include the manufacturers Leak Test Results, Recommended Use and Storage, and Radiation Safety Recommendations.

Manufacturing and Distribution Controls:

International Isotopes Inc. (I^3) provides for design control, procurement control, process quality control and final quality assurance. I^3 has developed a Quality Assurance program

which has been verified to meet the standards of ANSI/AMSE NQA-1, a copy of the International Isotopes Inc. Quality System Description is included in Attachment 3. Periodic internal audits by I^3 quality assurance staff or consultants validates the effectiveness of the quality assurance program. In accordance with Title 21 §892.5740 *Radionuclide teletherapy source* medical teletherapy sources are exempt from the pre market notification procedures of Title 21 subpart E of part 870, subject to the limitations of §892.9 *Limitations of exemptions from section 510(k) of the Federal Food, Drug and Cosmetic Act.* I^3 is a registered manufacturer of Class I medical devices with the U.S. Food and Drug Administration, Registration Number 3034521 and participates in the National Institute of Standards and Technology/Nuclear Energy Institute's (NIST/NEI) Measurement Assurance Program for the radiopharmaceutical industry.

Sources distributed within the United States will only be transferred to persons licensed in accordance with 10 CFR Part 35 or equivalent agreement state regulations who possess an FDA (or equivalent foreign agency) approved teletherapy device that will accommodate the source set. Sources distributed to persons outside of the United States will be exported in accordance with 10 CFR § 110.23, *General license for the export of byproduct material* and any additional regulations imposed by Government of the country of import. Sources will not be distributed that exceed the maximum activity allowed for the device in which they will be installed.

ATTACHMENT 1

Source Drawings

ATTACHMENT 2

Testing
and
Leak Test Data

Report Date: 25 August 2004 Customer P.O.: 13-PO-2004-187

Test Period: 06 through 25 August 2004 Security Classification: NA

TEST REPORT

FOR

ENVIRONMENTAL TESTING OF VARIOUS TELETHERAPY 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:

Mary Webb, Technical Documentation Manager

QUALITY ASSURANCE:

Mike McCord, 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

27th day of August, 2004.

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

VIBRATION TEST SUMMARY

Test Start-Finish Dates: 06 August 2004

Responsible Test Technician: Don Hensley

1-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

1-2 TEST REQUIREMENTS WITH TOLERANCES

Perform 30 minutes of sinusoidal vibration consisting of 10-minute or longer cycles at a uniform rate from 25 to 500 to 25Hz at $5G_{pk}$ in both the longitudinal and transverse axes.

Tolerance:
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Sine Amplitude: ±10%; Frequency: ±2% or ±1 Hz (whichever is larger)

1-2.1 Test Specification:

ANSI/HPS N43.6-1997, Table 1 – Vibration, Class 2, and Section 7.5.2 (with customer clarifications)

1-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100006	Vibration Control System	Data Physics/ CH 1	DP550/DP430	6/22/2005
100032	Accelerometer	Endevco	7703A-50	11/30/2004
100118	Charge Amplifier	Endevco/ CH 1	104	11/20/2004
100122	Power Supply	Endevco	109	11/20/2004
100900	Power Amplifier	Ling Electronics	None	NA
100901	Vibration Exciter	Ling Electronics	B335	NA

The test items were strap mounted to the vibration exciter.

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 operating during the vibration testing.

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

Atmospheric Conditions: Temp (°C): 22 Relative Humidity (%): 46 Pressure: Site Ambient

Run #	Axis	End Time	Duration
1	Transverse	1044	Thirty (30) minutes
2	Longitudinal	1145	Thirty (30) minutes

One (1) representative plot was recorded for each run.

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

The vibration was performed using a rate of 1-octave/minute (about 8 minutes 39 seconds per cycle), as referenced in the quote, instead of the required rate referenced in the customer supplied specification.

1-5 ENVIRONMENTAL TEST DATA

Vibration plots are located after Figure 1-3. Note that the test technician inadvertently expressed the vibration tolerance on the plots as ±3dB instead of the much smaller ±10%. Nevertheless, no significant out of tolerance conditions occurred at ±10%.

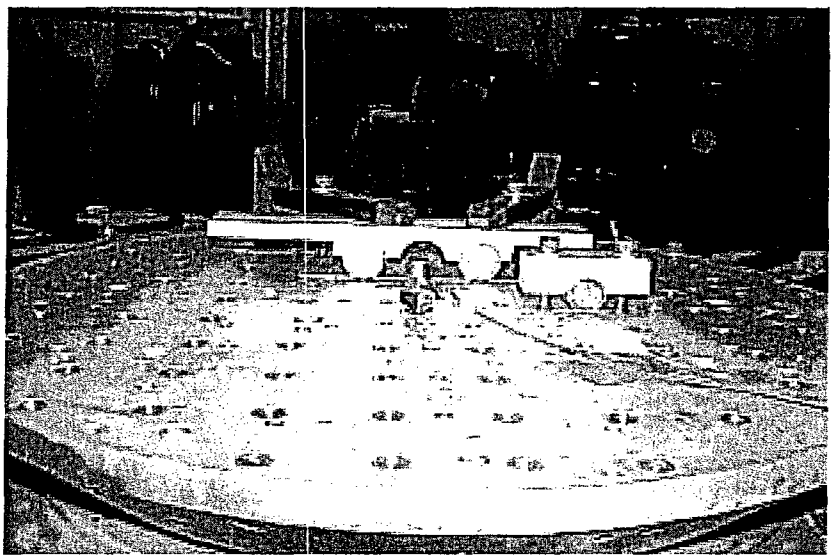


Figure 1-1. Test setup for transverse-axis vibration.

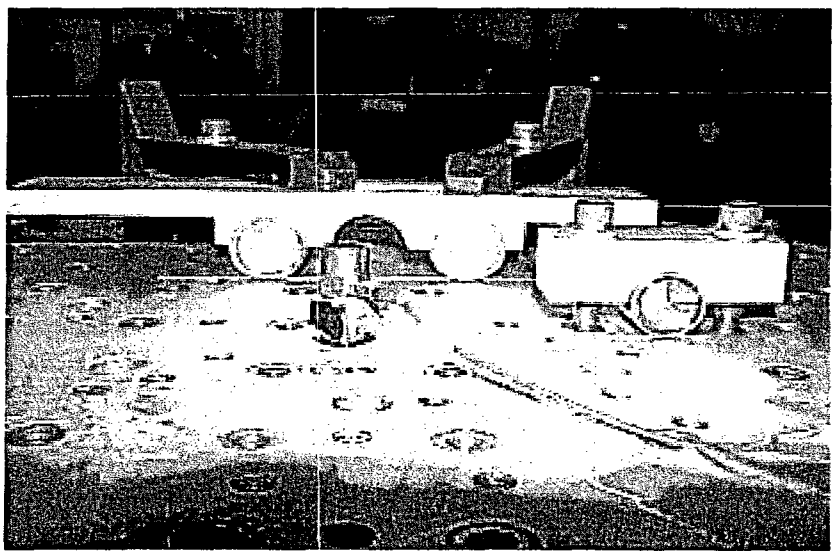


Figure 1-2. Test setup for transverse-axis vibration.

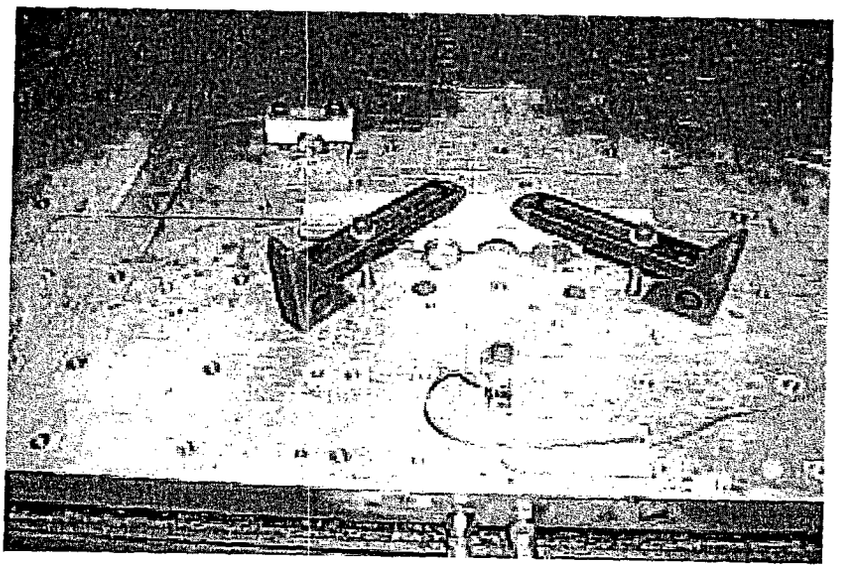
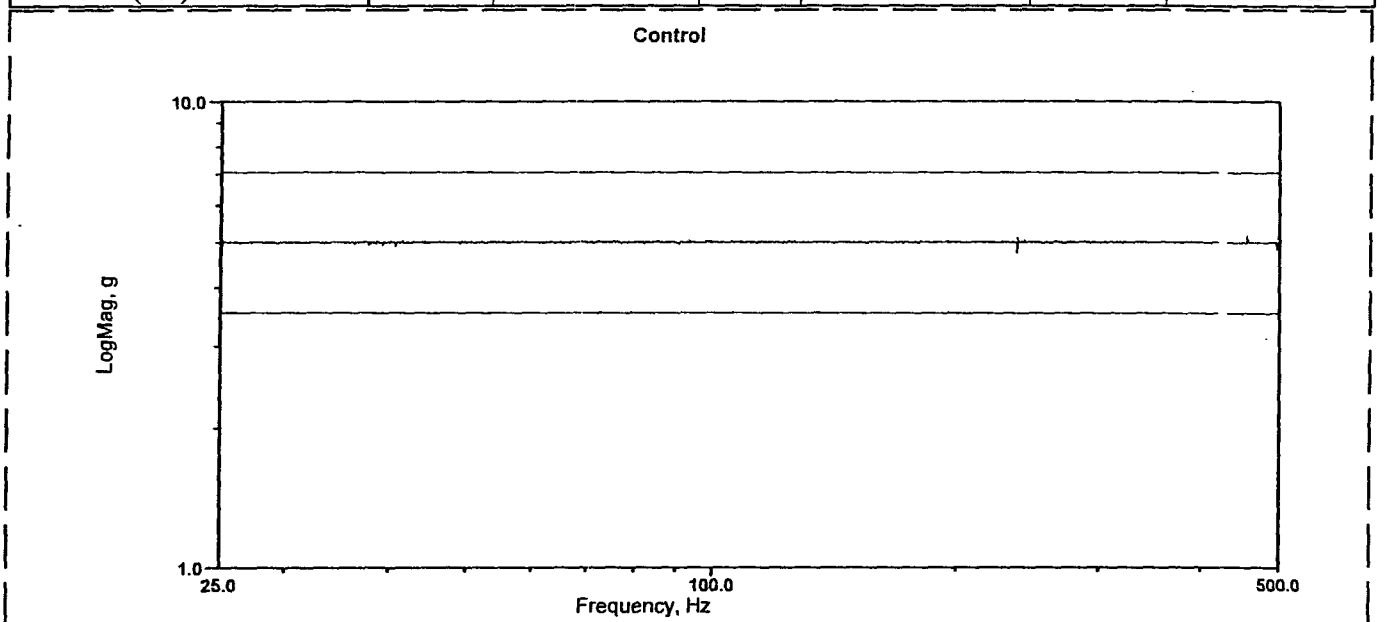
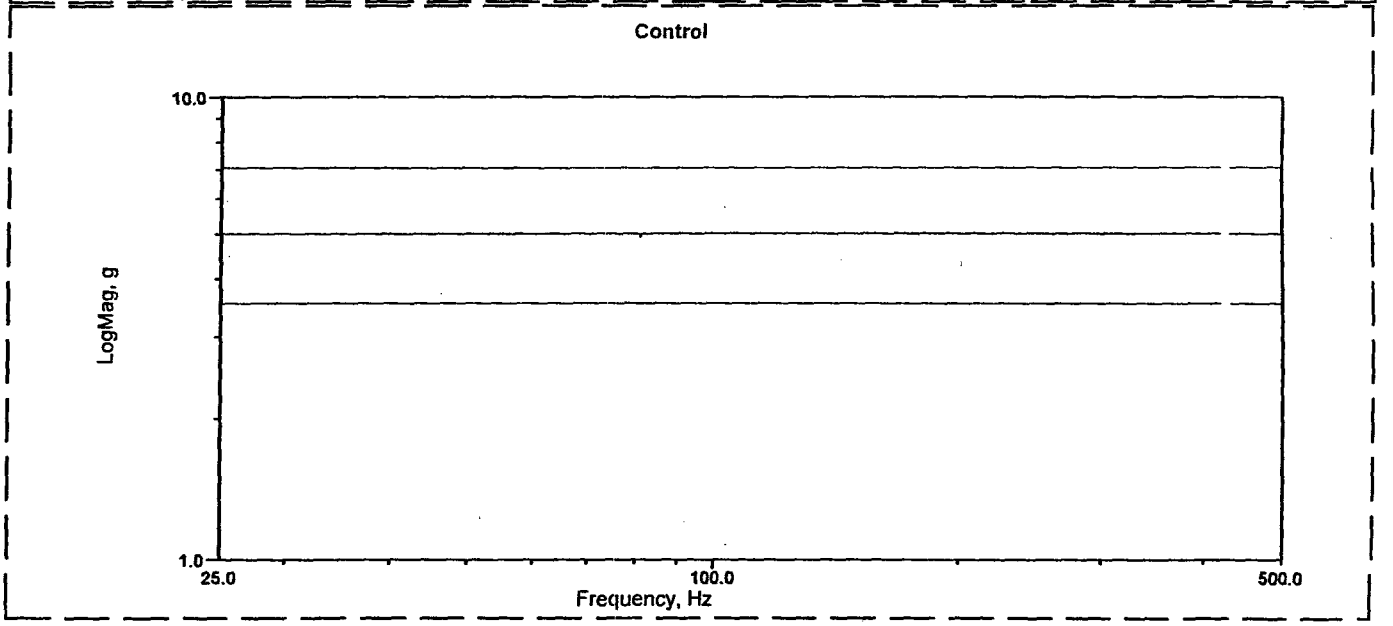


Figure 1-3. Test setup for longitudinal-axis vibration.

Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.				Job #:	04492
	Test Hardware:	Teletherapy Capsules (3 ea.) 1.01"OD (1 ea.), 1.21"OD (1 ea.) & 1.25"OD (1 ea.),				Run #:	1
						Axis:	Transverse
	Date:	8-06-04	Time:	1044		Duration:	30 minutes



Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.				Job #:	04492
	Test Hardware:	Teletherapy Capsules (3 ea.) 1.01"OD (1 ea.), 1.21"OD (1 ea.) & 1.25"OD (1 ea.),				Run #:	2
						Axis:	Longitudinal
	Date:	8-06-04	Time:	1145		Duration:	30-minutes



SECTION 2

PUNCTURE TEST SUMMARY

Test Start-Finish Dates: 09 August 2004

Responsible Test Technician: Don Hensley

2-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

2-2 TEST REQUIREMENTS WITH TOLERANCES

Drop a 50 gram impact tool (with rounded end impacting) 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, Table 1 – Puncture, Class 4, and Section 7.6.2 (with customer clarifications)

2-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100136	Scale	Setra	EL410D	9/16/2004
100207	Tape Measure (50 foot)	Lufkin	C-213w/Blank	Indefinite

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 operating during the puncture test.

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

Atmospheric Conditions: Temp (°C): 23 Relative Humidity (%): 48 Pressure: Site Ambient

Drop	Test Item	Drop Height	Time	Observation
1	1.01" OD	39.4 inches (1 meter)	0930	No visible anomaly
2	1.21" OD	39.4 inches (1 meter)	0935	No visible anomaly
3	1.25" OD	39.4 inches (1 meter)	0945	No visible anomaly

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).

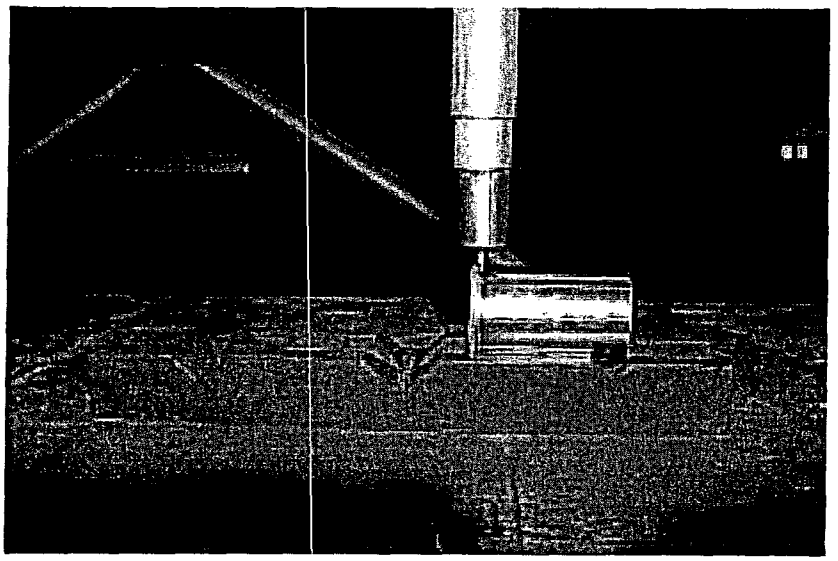


Figure 2-1. Test setup for puncture.

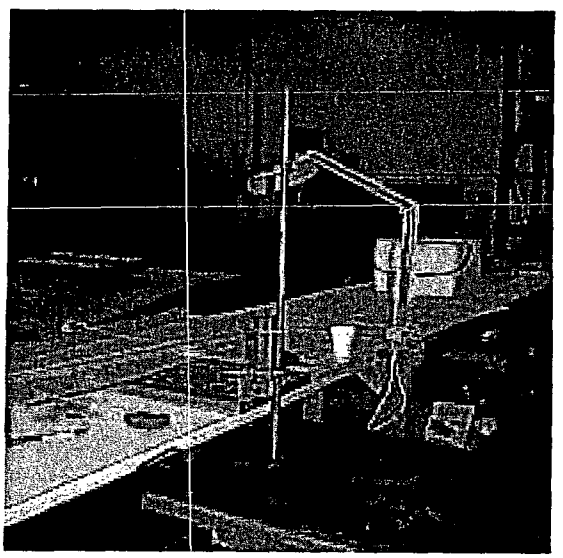


Figure 2-2. Test setup for puncture.

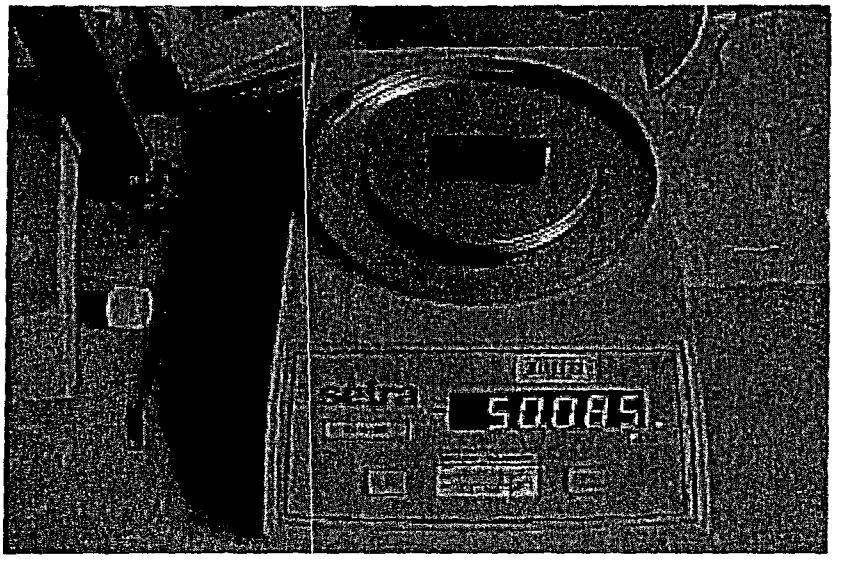


Figure 2-3. Weight of the impact tool for the puncture test.

SECTION 3

IMPACT TEST SUMMARY

Test Start-Finish Dates: 09 August 2004

Responsible Test Technician: Don Hensley

3-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

3-2 TEST REQUIREMENTS WITH TOLERANCES

Drop a 2,000 gram impact tool (with rounded end impacting) 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%

3-2.1 Test Specification:

ANSI/HPS N43.6-1997, Table 1 – Impact, Class 4, and Section 7.4.2 (with customer clarifications)

3-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100136	Scale	Setra	EL410D	9/16/2004
100207	Tape Measure (50 foot)	Lufkin	C-213w/Blank	Indefinite

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 operating during the impact test.

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

Atmospheric Conditions: Temp (°C): 23 Relative Humidity (%): 48 Pressure: Site Ambient

Drop	Test Item	Drop Height	Time	Observation
1	1.01" OD	39.4 inches (1 meter)	1110	No visible anomaly
2	1.21" OD	39.4 inches (1 meter)	1112	No visible anomaly
3	1.25" OD	39.4 inches (1 meter)	1114	No visible anomaly

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

None

3-5 ENVIRONMENTAL TEST DATA

Compliance verified through test setup and observation (reference photos).

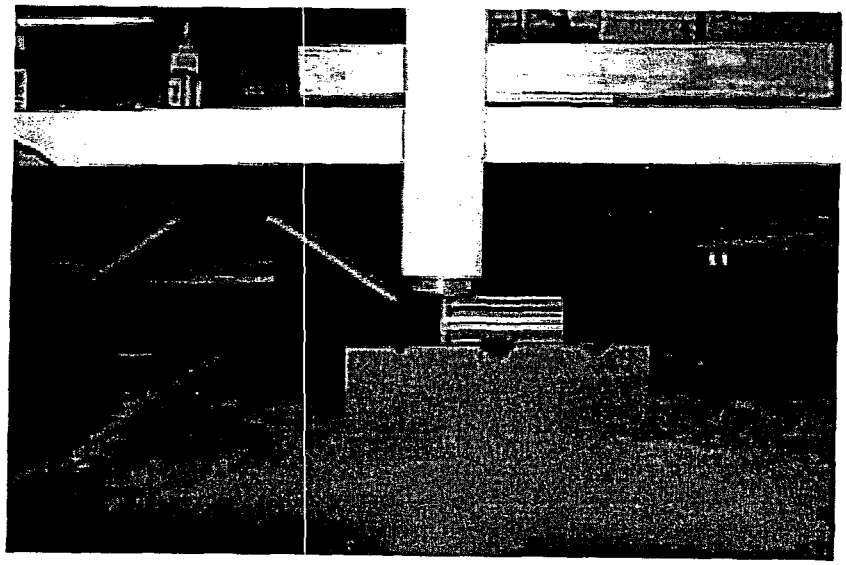


Figure 3-1. Test setup for impact.

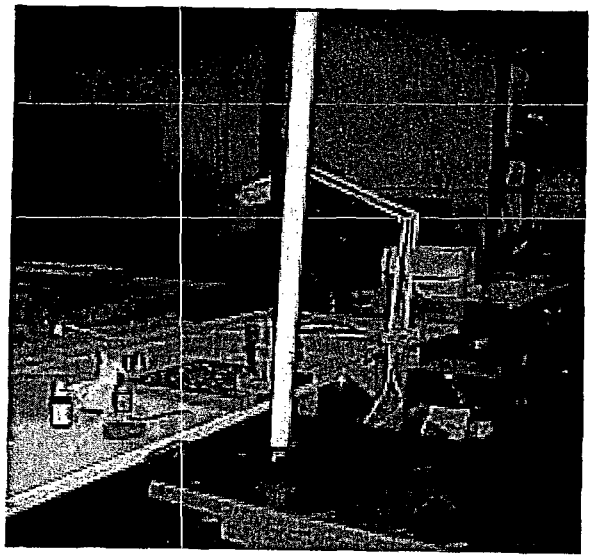


Figure 3-2. Test setup for impact.

Figure 3-3. Weight of the impact tool for the impact test.

SECTION 4

EXTERNAL PRESSURE TEST SUMMARY

Test Start-Finish Dates: 12 August 2004

Responsible Test Technician: Don Hensley

4-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

4-2 TEST REQUIREMENTS WITH TOLERANCES

Maintain 187.5 mmHg for five (5) minutes
Maintain 290 lb/in² (hydrostatic) for five (5) minutes
Maintain 187.5 mmHg for five (5) minutes
Maintain 290 lb/in² (hydrostatic) for five (5) minutes
Note: All pressures are absolute

4-2.1 Test Specification:

ANSI/HPS N43.6-1997, Table 1 – External Pressure, Class 3, and Section 7.3.2 (with customer clarifications)

4-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100052	Chart Recorder	Honeywell	DR450T-1110-0	12/20/2004
100252	Altitude Sensor	MKS Instruments	622A13TAE	8/13/2004
100264	Pressure Gauge	USG/AMETEK	None	4/29/2005
100301	Stop Watch	Oakton	220	7/20/2005
100979	Temp/Altitude Chamber	Thermotron	FA-96-CHM-705-705-81	NA

CHART RECORDER SETUP

Channel	Function	Type of sensor
1	Monitor chamber air temperature	100 Ω RTD
3	Monitor chamber pressure	Altitude sensor

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 operating during the pressure testing.

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

Atmospheric Conditions: Temp (°C): 23 Relative Humidity (%): 46 Pressure: 760.1 mmHg

Step #	Activity	End Time	Duration
1	Ramp to 187.5 mmHg	1342	10-minutes
2	Maintain 187.5 mmHg	1347	5-minutes
3	Ramp to laboratory ambient pressure	1357	10-minutes
4	Transfer to water filled pressure vessel	1410	13-minutes
5	Pressurize vessel with 290 PSIA	1411	1-minute
6	Maintain 290 PSIA	1416	5-minutes
7	Ramp to laboratory ambient pressure	1417	1-minute
8	Ramp to 187.5 mmHg	1426	10-minutes
9	Maintain 187.5 mmHg	1431	5-minutes
10	Ramp to laboratory ambient pressure	1441	10-minutes
11	Transfer to water filled pressure vessel	1501	20-minutes
12	Pressurize vessel with 290 PSIA	1502	1-minute
13	Maintain 290 PSIA	1507	5-minutes
14	Ramp to laboratory ambient pressure	1508	1-minute

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

None

4-5 ENVIRONMENTAL TEST DATA

Temperature and pressure data are located after Figure 4-4.

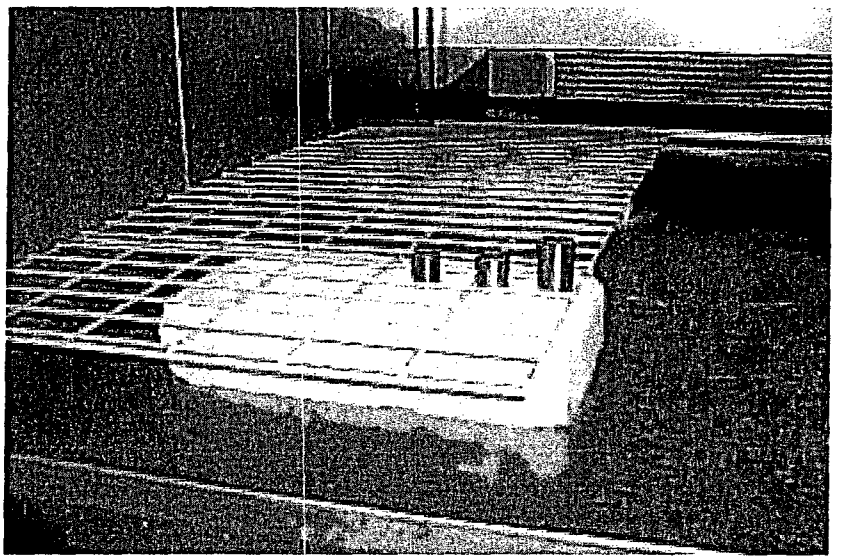


Figure 4-1. Test setup for external pressure (low).

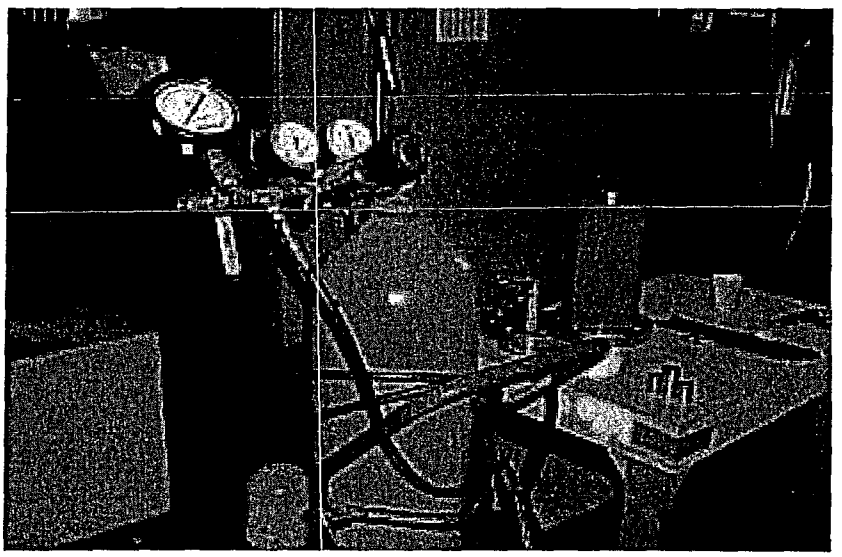


Figure 4-2. Test setup for external pressure (high).

Figure 4-3. Test setup for external pressure (high).

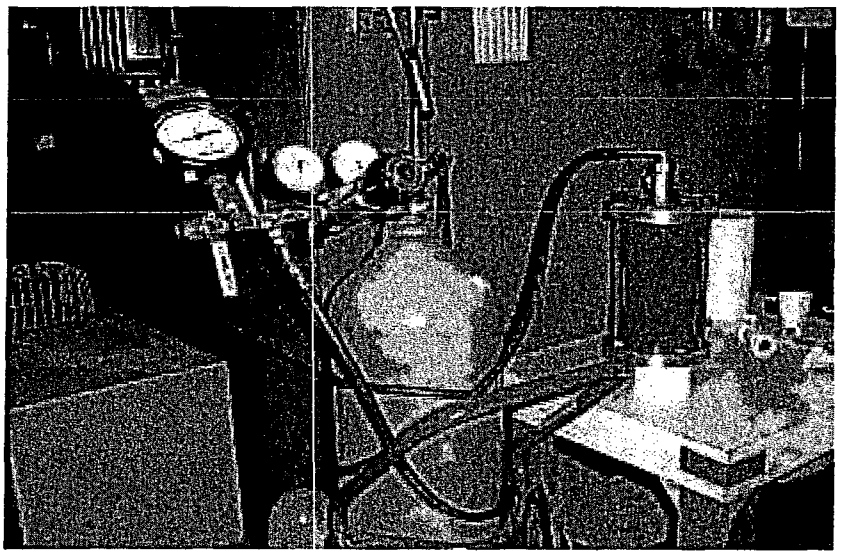
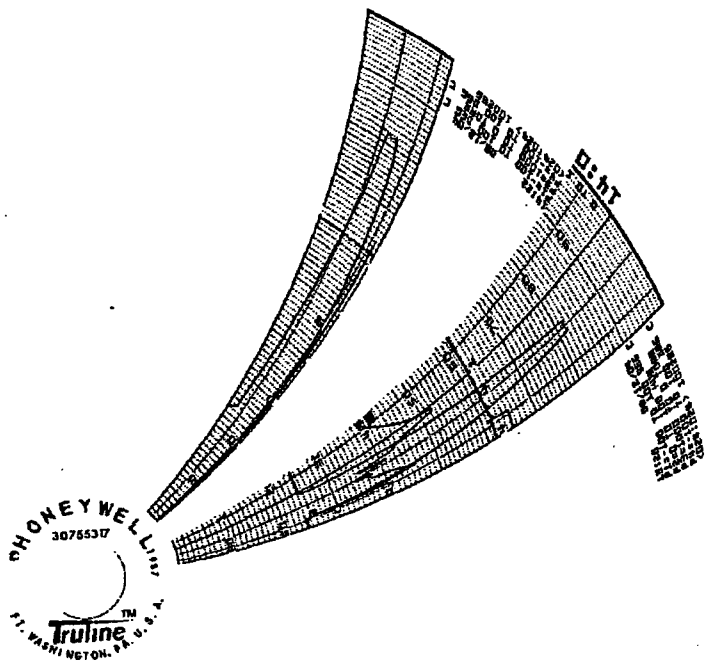


Figure 4-4. Test setup for external pressure (high).



JOB # 04492 DATE 3/12/04
CUSTOMER INTERNATIONAL ISOTOPES
TEST EXTERNAL PRESSURE (ALTITUDE)
TEST ITEM TELETHERAPY CAPSULES
P/N _____
S/N _____

SECTION 5

TEMPERATURE TEST SUMMARY

Test Start-Finish Dates: 13 through 18 August 2004

Responsible Test Technician: Don Hensley

5-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches (same test item used for vibration testing; used for second temperature shock test only)

5-2 TEST REQUIREMENTS WITH TOLERANCES

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

Temperature Shock:
Transfer to 800±50°C and maintain conditions for one (1) hour
Transfer to 20±2°C water at least 20 times the volume of the test item

5-2.1 Test Specification:

ANSI/HPS N43.6-1997, Table 1 – Temperature, Class 6, and Section 7.2.2 (with customer clarifications)

5-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100052	Chart Recorder (Cold)	Honeywell	DR450T-1110-0	12/20/2004
100074	Chart Recorder (Hot)	Honeywell	DR45AT-1111-0	10/3/2004
100102	Temperature Calibrator	Omega Eng.	OMNI-CAL IIA8	5/5/2005
100301	Stop Watch	Oakton	220	7/20/2005
100902	Temperature Chamber (Cold)	Cincinnati Sub Zero	Z-8-1-1-H/AC	NA
100935	Temperature Chamber (Hot)	Vulcan	3-130	NA

ID# 100052 (LOW TEMPERATURE) CHART RECORDER SETUP

Channel	Function	Type of sensor
1	Monitor chamber air temperature	100 Ω RTD

ID# 100074 (TEMPERATURE SHOCK) CHART RECORDER SETUP

Channel	Function	Type of sensor
1	Monitor chamber air temperature	K 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 operating during the temperature testing.

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

Atmospheric Conditions: Temp (°C): 23 Relative Humidity (%): 49 Pressure: Site Ambient

LOW TEMPERATURE
One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

Step #	Activity	Date	End Time	Duration
1	Ramp to -40°C	08/13/04	0828	45-minutes
2	Maintain -40°C	08/13/04	0848	20-minutes
3	Ramp to 23°C	08/13/04	1002	1-hour14-minutes

TEMPERATURE SHOCK
(PERFORMED WITH THE THREE ORIGINAL TEST ITEMS PRIOR TO RECEIVING THE CUSTOMER 08/18/04 1:17PM EMAIL)
One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

Step #	Activity	Date	End Time	Duration
1	Ramp to 800°C	08/18/04	1035	40-minutes
2	Maintain 800°C	08/18/04	1050	15-minutes
3	Transfer to water at 22°C	08/18/04	1050	<15-seconds

TEMPERATURE SHOCK
(PERFORMED WITH THE 1.25 INCHES OD VIBRATION TEST ITEM ONLY PER THE CUSTOMER 08/18/04 1:17PM EMAIL)

One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches (same test item used for vibration testing)

Step #	Test Item	Activity	Date	End Time	Duration
1	1.25" OD (vibration test item)	Ramp to 800°C	08/18/04	1353	37-minutes
2	1.25" OD (vibration test item)	Maintain 800°C	08/18/04	1453	1-hour
3	1.25" OD (vibration test item)	Ramp to 23° C	08/18/04	1535	42-minutes

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

None

5-5 ENVIRONMENTAL TEST DATA

Temperature data are located after Figure 5-3.

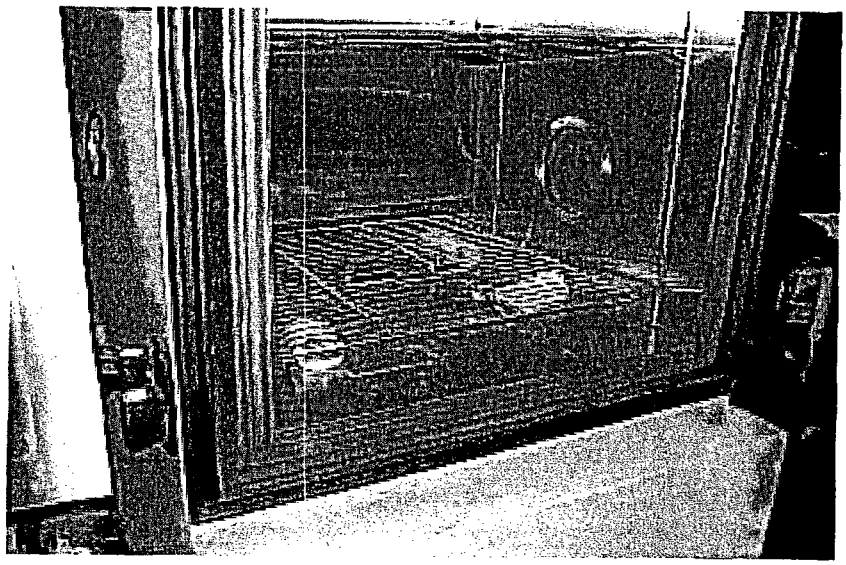


Figure 5-1. Test setup for low temperature.

Figure 5-2. Test setup for temperature shock.

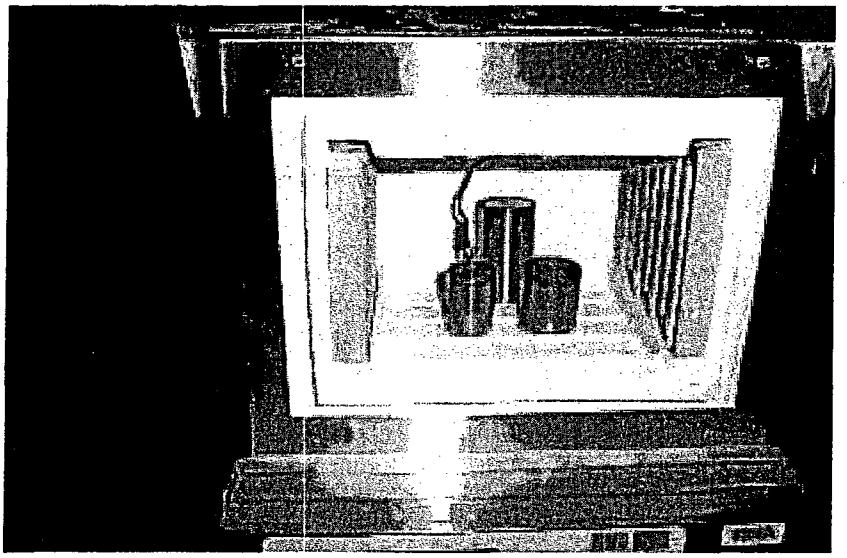
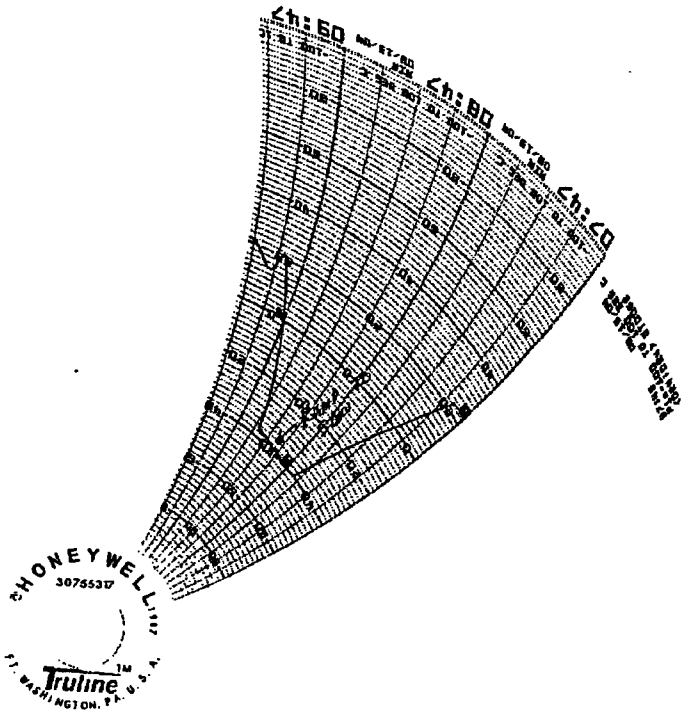
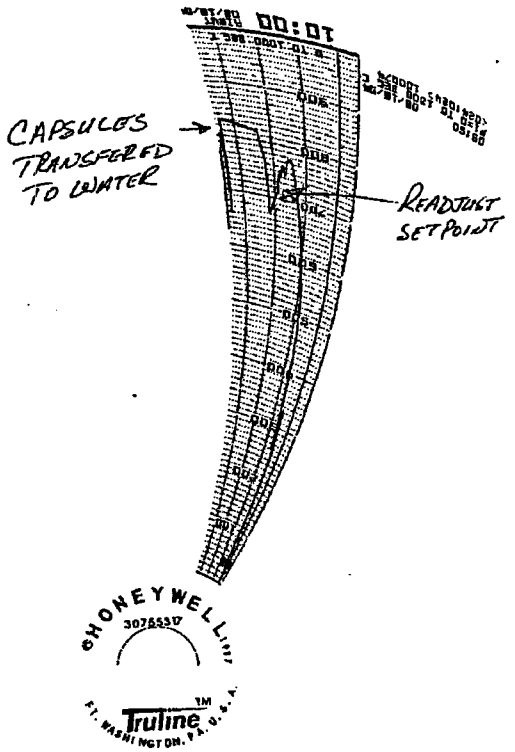


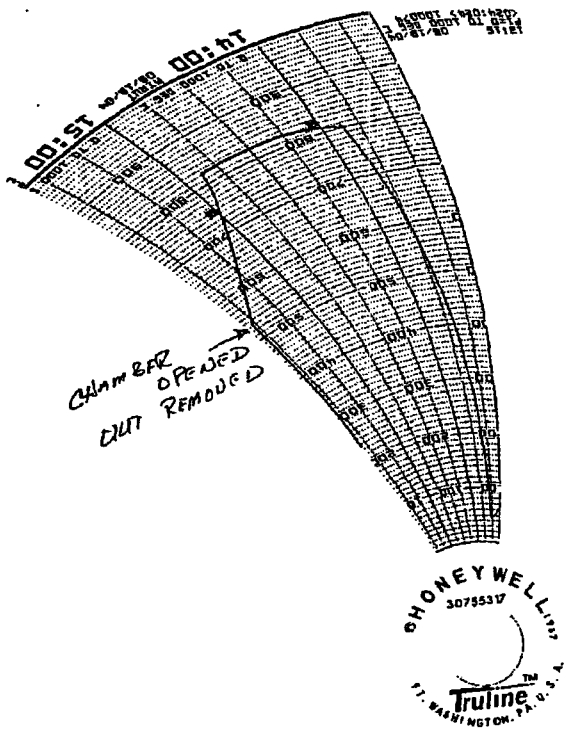
Figure 5-3. Test setup for high temperature (temperature shock).



JOB # 04492 DATE 8/13/04
CUSTOMER INTERNATIONAL ISOTOPES
TEST LOW TEMPERATURE
TEST ITEM TELETHERAPY CAPSULES
P/N
S/N



JOB # 04492 DATE 8/18/04
CUSTOMER INTERNATIONAL ISOTOPES
TEST THERMAL SHOCK
TEST ITEM TELETHERAPY CAPSULES
P/N
S/N



JOB # D4492 DATE 8/18/04
CUSTOMER INTERNATIONAL ISOTOPES
TEST HIGH TEMP (800°C)
TEST ITEM TELETHERAPY CAPSULE
P/N 1.250" O.D.

SECTION 6

VIBRATION (RETEST) TEST SUMMARY

Test Start-Finish Dates: 25 August 2004

Responsible Test Technician: Ross Blanco

6-1 TEST HARDWARE

One (1) Teletherapy Capsule, outside diameter measuring 1.01 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.21 inches
One (1) Teletherapy Capsule, outside diameter measuring 1.25 inches

Note: This is the same test hardware used in the previous vibration test.

6-2 TEST REQUIREMENTS WITH TOLERANCES

Perform 36 minutes of sinusoidal vibration consisting of 12-minute linear cycles from 25 to 500 to 25Hz at $5G_{pk}$ in both the longitudinal and transverse axes.

Tolerance:
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Sine Amplitude: ±10%; Frequency: ±2% or ±1 Hz (whichever is larger)

6-2.1 Test Specification:

Qualtest Change Order CO001: perform the sinusoidal vibration test using the proper cycling rate
Reference: ANSI/HPS N43.6-1997, Table 1 – Vibration, Class 2, and Section 7.5.2

6-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100002	Thermo/Hygrometer	Amprobe	TH-2	5/5/2005
100076	Torque Wrench	Proto	6369A	6/24/2005
100118	Charge Amplifier	Endevco/ CH 1	104	11/20/2004
100122	Power Supply	Endevco	109	11/20/2004
100208	Vibration Control System	Data Physics/ CH 1	DP550	2/4/2005
100222	Accelerometer	Endevco	7703A-50	2/3/2005
100927	Power Amplifier (transverse)	Ling Electronics	8096 SSPA	NA
100966	Vibration Exciter (transverse)	Ling Electronics	335A	NA
100974	Power Amplifier (longitudinal)	Ling Electronics	PP70/120 VC-1	NA

QTI #	Item	Manufacturer	Model Number	Calibration Due
100975	Vibration Exciter (longitudinal)	Ling Electronics	335A	NA

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 operating during the vibration testing.

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

Atmospheric Conditions: Temp (°C): 22 Relative Humidity (%): 57 Pressure: Site Ambient

Run #	Axis	End Time	Duration
1	Transverse	1047	Thirty-six (36) minutes
2	Longitudinal	1148	Thirty-six (36) minutes

One (1) representative plot was recorded for each run.

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

None

6-5 ENVIRONMENTAL TEST DATA

Vibration plots are located after Figure 6-2.

Figure 6-1. Test setup for transverse-axis vibration (retest).

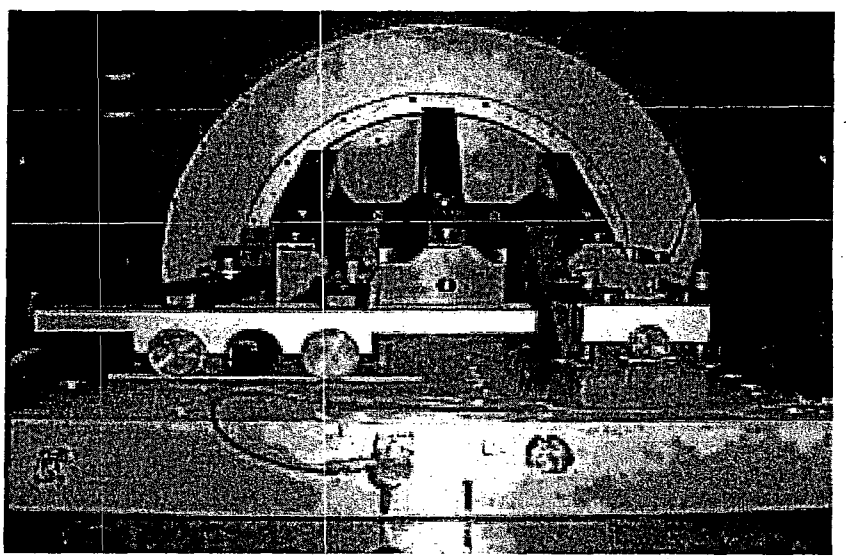
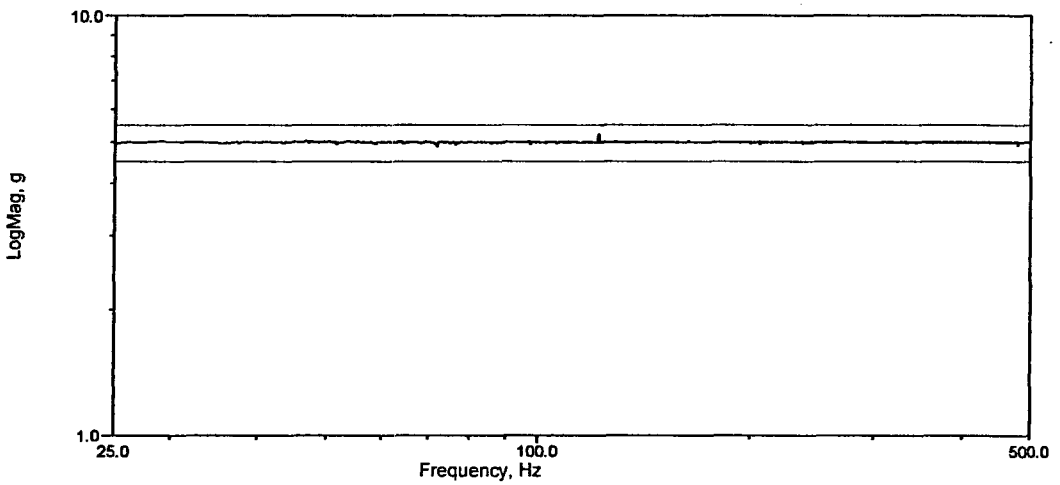


Figure 6-2. Test setup for longitudinal-axis vibration (retest).

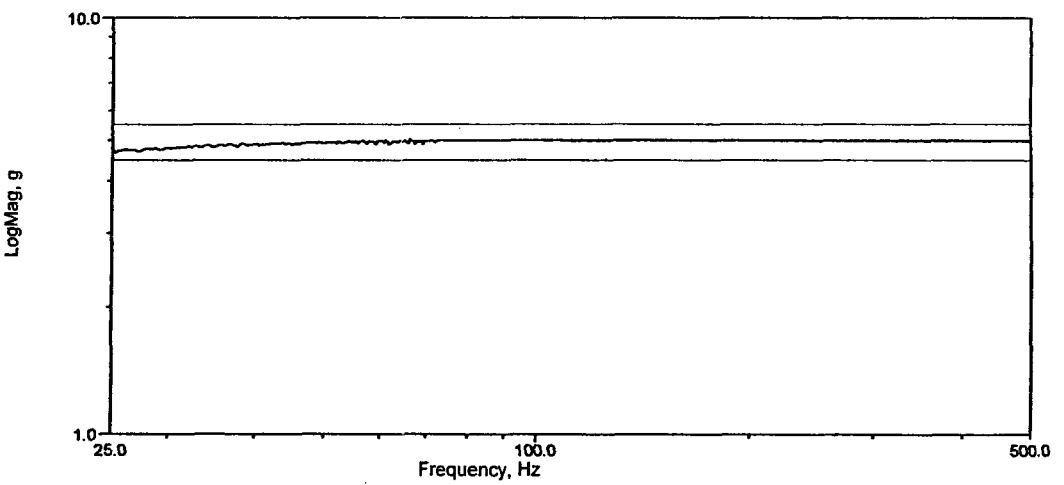
Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.			Job #:	04492
	Test Hardware:	Teletherapy Capsules (3 ea.) 1.01"OD (1 ea.), 1.21"OD (1 ea.) & 1.25"OD (1 ea.),			Run #:	1
					Axis:	Transverse
	Date:	8/25/04	Time:	1047	Duration:	36-minutes

Control



Qualtest, Inc. 5325 Old Winter Garden Road Orlando, Florida 32811 Tel. (407) 293-5844 Fax (407) 297-7376	Customer:	International Isotopes, Inc.			Job #:	04492
	Test Hardware:	Teletherapy Capsules (3 ea.) 1.01"OD (1 ea.), 1.21"OD (1 ea.) & 1.25"OD (1 ea.),			Run #:	2
					Axis:	Longitudinal
	Date:	8/25/04	Time:	1148	Duration:	36-minutes

Control



I³

International Isotopes Inc.

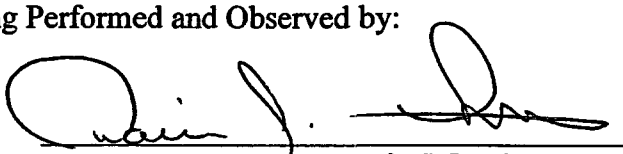
INIS-SF-XX-XX LEAK TEST RESULTS

After the environmental and bend tests were completed, dummy sources were leak tested using the Hot Liquid Bubble Test as described in ANSI/HPS N43.6-1997 Appendix A, section A.2.2.2.

A steel quart container was filled with water and heated to approximately 93°C. The water temperature was measured with a temperature probe calibrated to a NIST standard. A dummy source was then immersed in the water and observed for a period of two minutes. The water was then reheated and the temperature measured before another source was immersed. Results are described on the Table A as follows:

Source	Water Temperature	Immersion Time	Results/Comments
I3-SF-Sample #1 (subjected to temperature test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed
I3-SF-Sample #2 (subjected to pressure test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed
I3-SF-Sample #3 (subjected to impact test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed
I3-SF-Sample #4 (subjected to vibration test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed
I3-SF-Sample #5 (subjected to puncture test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed
I3-SF-Sample #5 (subjected to bend test)	93°C	2 minutes 15 seconds	No leakage/bubbles were observed

Leak Testing Performed and Observed by:



Darin J. Lords
International Isotopes Inc.QA

4137 Commerce Circle, Idaho Falls, Idaho 83401
208.524.5300 (Fax) 208.524.1411
1.800.699.3108

ATTACHMENT 3

International Isotopes Idaho Inc.
Quality System Description

Title:			
INTERNATIONAL ISOTOPES INC. QUALITY SYSTEM DESCRIPTION			
Quality Assurance Signature and Date:	Page:	Effective Date:	Superseded Date:
10/12/04	Page 1 of 4	10/04/04	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 I^3 Quality Management System is implemented through the quality plan and the standard operating procedures and associated worksheets, logs and forms.

I^3 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 I^3 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 I^3 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

I^3 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

I^3 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, I^3 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

I³ 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.