(7)

International Isotopes Inc.

& International Isotopes Idaho Inc.

March 2, 2005

Mr. Tomas Herrera
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Additional Information to Support Application for Safety Review, I3-101504, SSD Case 05-04

Dear Mr. Herrera,

Thank you for the timely review and beneficial comments to International Isotopes Inc.'s application to register teletherapy and gamma irradiation sources dated October 15, 2004. I have included International Isotopes Inc.'s (INIS) response along with the NRC's comments below:

1. Licensing:

   1.1. Your current NRC license, 11-2768-01, authorizes I^3 to possess[ ]of unsealed cobalt-60. Please note that you must amend your license with NRC's Region IV office to reflect the amounts of cobalt-60 that will be at your facility.

   Ex. 4

   I^3 Response:

   An application to amend our license to accommodate source manufacturing and increase our cobalt possession limit to[ ]of cobalt in any form was submitted to the NRC Region IV on January 14, 2005. The NRC has conducted a pre-licensing visit to our facility on January 12, 2005, Amendment 10 to our current license was issued March 1.

   Ex. 4

   1.2. Please note that the licensed material listed in the State of Texas, sealed source and device registration certificate TX-1153-S-102-S will have to be registered with the NRC now that International Isotopes Inc is located in the State of Idaho, a non-agreement state. Please note that the NRC will issue a new certificate for the byproduct material listed in that certificate.

   I^3 Response:

   The issuance of a new certificate is noted and considered appropriate.

J-2

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

1.3 A user leak test will be required for the teletherapy sources.

I^3 Response:

The Safety Evaluation will stipulate a leak test at a frequency of 6 months.

2. Descriptions/Constructions:

2.1. Please specify the material used for the end caps.

I^3 Response:

The end caps as well as the inner and outer housings will be constructed of Type 304 stainless steel. The source capsule drawings have been updated to indicate material type and thickness (Reference Attachment 2)

2.2. Attachment 1 of your application contains two drawings, one for a double welded cap design the other for a single welded cap design. Please explain any differences between the two and the intended use for each design. Please also describe how the single welded design will be fabricated; specifically address the issue of how you will fabricate the capsule and assure that the specified wall thickness of 0.045 inches is maintained.

I^3 Response:

The single and double welded cap designs are considered equivalent in strength and are interchangeable. The option to use a single or double welded cap was based upon the capsule fabrication process that will allow for use of either pipe or solid bar stock as a starting material for capsule fabrication. When using a single welded cap design the capsule is bored to match the inside dimension and to result in a bottom end wall thickness of 0.025. When using a double welded cap design the end caps measure 0.045 inches thick. INIS will have a vendor fabricate the source capsules and end caps in accordance with the INIS Quality Assurance program. INIS has a Specifications Document (Reference Attachment 1) that will be used to complete dimensional inspection and acceptance of 100% of the fabricated source capsules

2.3. The application specified that the principal use of the "L" series sources will be for Category III gamma irradiation (page 2 of 6). Category III irradiators are self-contained wet source storage irradiators (ref. ANSI N43.10-2001). But the application in the section "Conditions of Normal Use" stated that the sources are to be "used in a protected environment such as a laboratory or medical clinic" (page 3 of 6). Please clarify the discrepancy.

I^3 Response:

The intent of the statement was to make the reviewer aware that the sources installed in Category III irradiators would not normally be subjected to the elements during their normal

course of use. The statement would have been better written as: "These devices are typically located in a protected environment such as a laboratory, medical clinic, or irradiator facility".

3. Prototype Testing:

3.1. The application requested registration of sources with dimensions that range from a diameter of 0.225 to 1.25 inches and lengths of 1.335 to 8.00 inches. However, the prototypes that where subjected to the ANSI 43.6 classification tests were in the range of diameters from 1.01 to 1.25 inches, with the length not specified. Please provide information that demonstrates that the prototype tests represent the full range of possible source configurations, regarding dimensions as well as the single welded and double welded designs.

I^3 Response:

In all, seventeen source prototypes were used for the prototype testing. Sixteen prototypes were used for the puncture, pressure, impact, vibration and temperature tests and one was use for the bend test. For each test, sources considered to be most susceptible to damage for that test were used. For example, a prototype with the largest allowed diameter was used for impact test and a prototype with the smallest allowed diameter and longest allowed length was used for the bend test. Single welded sources were used for the puncture, pressure, impact, vibration and temperature tests. By using a source with both a welded end and a machined end, the performance of the two configurations under identical circumstances could be compared. This allowed comparison of the welded end to the machined end for each source tested. A double welded source was used for the bend test. Although a larger number of single welded sources were tested, by testing seventeen prototype sources, a significant number of welds were also tested. Although the prototype tests do not "*represent the full range of possible source configurations, regarding dimensions as well as the single welded and double welded designs*" I^3 is confident that the prototype testing results can be equally applied throughout the specified range of dimensions and configuration because the material (Type 304 Stainless Steel) and welding method utilized are consistent for all source configurations and the source configuration most susceptible to failure was tested.

The following table provides the dimensions of the prototypes used for the respective tests.

Test	Diameter	Length
Impact, Vibration, Temperature, Puncture, Pressure (single weld)	1.21 in	1.50 in
Impact, Vibration, Temperature, Puncture, Pressure (single weld)	1.25 in	2.425 in
Impact, Vibration, Temperature, Puncture, Pressure (single weld)	1.01 in	1.50 in
Bend (double weld)	0.375 in	8.00 in

3.2. On page 4 of your application under Manufacturer's Safety Analysis of Sealed Source Review you stated that the INIS-SF-X-YY series deign meets the performance classification ANSI 97E53424 per ANSI/HPS N43.6-1997 that is the highest classification for irradiator sources but a Medical Teletherapy source requires a level 5

impact test. Please provide prototype tests for a level 5 impact test of [sic] justify why the current test is acceptable for teletherapy sources.

I^3 Response:

This was an oversight by I^3. Per ANSI/HPS N43.6-1997 the impact test should have been completed at a level 5. This testing has been satisfactorily completed and test results are included (Reference Attachment 3).

3.3. On page 4 of your application stated that a "static force equal to 2000 N (102 kg) was applied to the Force Cylinder utilizing a press that locked in position for the duration of the test", for the bend test. Please clarify what amount of force was used: 1000 N (102 kg) or 2000 N (204 kg)?

I^3 Response:

The bend test was performed with a force equal to 1000 N (102 kg). The prototype source was retested at a static force equal to 2000 N (204 kg). Test results are enclosed (Reference Attachment 3).

3.4. Please specify the design used for prototype testing; i.e. the double welded or single welded cap.

I^3 Response:

The bend test was performed with a double welded cap. Typically, very small diameter stainless steel cylinders are provided as a tube with both ends open, thus the use of the double welded cap. All other prototype tests where performed with the single welded cap so that both the weld end and machined end could be compared for the same test.

4. Quality Assurance and Control:

4.1. Please review the provisions of the applicable guidance NUREG 1556, Vol 3. Rev. 1, under Section 10.7 that outline the quality assurance and quality control requirements. Under Test Control & Control on Test and Measuring Equipment" on page 3 of Attachment 3 of your application, you state that all finished products and appropriate components and materials are routinely inspected to verify compliance. Please describe the inspections and tests you perform, such as leak tests, sampling methods, and design conformity checks, on the sources prior to distribution.

I^3 Response:

All incoming parts shall be receipt inspected for proper dimensions and materials. INIS uses a Specifications Document (Reference Attcahment 1) to prescribe and control this process. INIS then uses a Operating Procedure (Reference Attachment 4) to provide Quality Assurnace for the actual capsule fabrication process. This fabrication procedure controls the cobalt measurement/loading, capsule welding requirements, and post fabrication leak tests

and wipe tests. INIS will utilize a formal welder and leak test qualification program for capsule fabrication.

4.2. One page 2 of your application, you state that the open ends of the steel housings will be seal welded. Please state the weld testing acceptance criteria that I^3 will use.

I^3 Response:

INIS will use the Cobalt Source Fabrication Operations Procedure (Reference aAttachment 4) to control the welder qualification, welding, and leak testing. The Welding set up used in this document is identical to the process used to weld the prototype sources for testing. Source welding is performed by qualified welders. A weld is considered acceptable when performed by qualified individuals in accordance with the weld specifications established in the procedure, and after the source passess the leak test. Copies of the welder qualificaiton sheet, welder settings sheet (Reference Attachment 5) are enclosed for review.

5. Accompanying Documentation:

Please describe the information that is provided to the user of the sources to safely operate and maintain them. This includes instructions for operation, maintenance, calibration, damage and failure, specific warnings, leak tests, and radiaiton surveys.

I^3 Response:

Each source will include a Sealed Source Calibration, Contamination and leak Test Certificate and a decay chart specific to the source. If required by local regulations, the State of Texas for example, a copy of the SS&D will also be provided. INIS will not be providing maintenance, operation or emergency action procedures because those procedures are provided by the device OEM and are specific for the devise the source is instralled in. INIS will provide required Emergency response information for shipping in accordance with Title 49 CFR §172 Subpart G Emergency Response Information. A copy of Guide 163, Radioactive Materials, (Low to High Levels of Radiation) 2004 Emergecny Response Guidebook will be included with each shipment and is enclosed for your review (Reference Attachemnt 6)

6. Servicing:

Please provide a list of services, if any, that International Isotopes Inc., will provide to specific licensees.

I^3 Response:

INIS will load sources into End User provided transportation packages for shipment to the End User facility. Installation of the sealed source should be performed in accordance with the device manufacturer instructions and is the responsibility of the End User. On a case-by-

case basis, INIS may accept Co-60 sources for recycle that have decayed beyond their useful life.

7. Meeting January 25, 2004 10:00 AM One White Flint North Building Room 09B6

During the above referenced meeting the issue was raised that International Isotopes Inc. selected Type 304 stainless steel as the material utilized for construction of the sources. 10 CFR 36.21(a)(4) references the use of Type 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools. This criterion is applicable to the Category III irradiators. A comparison between Type 316 and Type 304 stainless steel did reveal some differences in the corrosion resistance of the two alloys in some applications. However, their performance in air or in an environment characteristic of an irradiator pool (i.e. low conductivity water) is nearly identical. A table comparing the corrosion resistance of various metals in fluid environments is as follows:

Comparison of Common Engineering Metals in Various Fluid Environments

Corrosion Resistance [1]Good [2]Be Careful [3]Not Useable												
Fluid	Metal											
	Carbon Steel	Cast Iron	302 and 304 Stainless Steel	316 Stainless Steel	Bronze	Durimet	Monel	Hasteloy B	Hasteloy C	Titanium	Cobalt base alloy 6	416 Stainless Steel
Gasoline	1	1	1	1	1	1	1	1	1	1	1	1
Glucose	1	1	1	1	1	1	1	1	1	1	1	1
Hydrogen peroxide		1	1	1	3	1	1	2	2	1		2
Methanol	1	1	1	1	1	1	1	1	1	1	1	1
Milk	3	3	1	1	1	1	1	1	1	1	1	3
Petroleum oils	1	1	1	1	1	1	1	1	1	1	1	1
Sodium chloride	3	3	2	2	1	1	1	1	1	1	1	2
Turpentine	2	2	1	1	1	1	2	1	1	1	1	1
Vinegar	3	3	1	1	2	1	1	1	1		1	3
Water, steam boiler feeding system	2	3	1	1	3	1	1	1	1	1	1	2
Water, distilled	1	1	1	1	1	1	1	1	1	1	1	2
Water, sea	2	2	2	2	1	1	1	1	1	1	1	3
Whiskey	3	3	1	1	1	1	2	1	1	1	1	3

This chart was abridged from information available at http://www.engineeringtoolbox.com

"L" grades of stainless steel (304L & 316L) contain lower percentages of carbon in the alloy. These grades are specifically designed to prevent or minimize the precipitation of

carbide at temperatures between 800 and 1600°C. The high temperature test for these sources was 800°C, therefore these sources are not designed for use in this temperature range and the "L" grade provides no added benefit.

In addition to the above I would like to increase the maximum activity for the teletherapy sources, model INIS-SF-X.X-YY-AD this would change the dose profile as follows:

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

Attachments

1. Source Capsule Acceptance Specification Document
2. Revised Source Capsule Drawings
3. Impact Test Results
4. Copy of I4-OP-52, *Co-60 Source Loading Procedure*
5. Welder Qualificaiton Sheet, Welder Settings Sheet
6. 2004 Emergecny Response Guidebook, Guide 163

cc JJM Letter File JJM-2005-03

Attachment 1

Source Capsule Acceptance Specification Document

TITLE:		Number:	Effective Date:
Purchase Specification for INIS-XX-YY-Z Special Form		I4-SD-016	2/15/05
PRI:		Page:	Superceded Date:
Steve Laflin		Page 1 of 2	Original
PRI Signature and Date:	Document Control Signature and Date:	Quality Assurance Signature and Date:	
3.1.05	Linda Sherman 2/1/05	2/17/05	

1.0 Physical Specifications

1.1 Material shall be 304 Stainless Steel

1.2 Sidewall shall be 0.045 ± 0.005 inches thick.

1.3 Welded caps shall be 0.045 ± 0.005 inches thick

1.4 For "Single Welded Cap Design" sources, the bottom shall be 0.025 ± 0.005 inches thick.

1.5 The outer capsule shall have a maximum length of 8.00 ± 0.05 inches and a minimum length of 0.375 ± 0.005 inches.

1.6 The inner capsule shall have a maximum length of 7.75 ± 0.05 inches and a minimum length of 0.19 ± 0.05 inches.

2.0 Biological Specifications

2.1 None.

3.0 Chemical Specifications

3.1 None

4.0 Radiological Specifications

4.1 None

5.0 Mechanical Specifications

5.1 None.

6.0 Documentation

6.1 A specific drawing shall be generated for each capsule size to be manufactured.

6.2 A Certified Mill Test Report is required for all materials used in fabrication of these capsules.

6.3 Upon receipt and successful completion of the receipt inspection, each lot shall be issued a Quality Release Form (Form –I4-52).

7.0 Receipt Inspection Requirements

7.1 Perform a 100% receipt inspection of all capsules and caps. Verify all dimensions.

8.0 Approved Vendors

8.1 R&D Assembly and Machine

527 South Utah Ave
Idaho Falls, Idaho 83401
208-529-8723

8.2 ACCRA Machine
1220 North 825 East
Shelley, Idaho 83274

Attachment 2

Revised Source Capsule Drawings

Attachment 3

Impact Test Results

Report Date: 24 February 2005 Customer P.O.: 13-PO-2005-26

Test Period: 11 through 23 February 2005 Security Classification: NA

TEST REPORT

FOR

ENVIRONMENTAL TESTING OF THE 3" TELETHERAPY CAPSULE

AND THE 8" TELETHERAPY CAPSULE

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

2nd day of March, 2005.

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

IMPACT TEST SUMMARY

Test Start-Finish Dates: 11 February 2005

Responsible Test Technician: Don Hensley

1-1 TEST HARDWARE

One (1) unmarked Teletherapy Capsule, measuring 3 inches

1-2 TEST REQUIREMENTS WITH TOLERANCES

Drop the rounded end of a 4,990-gram (11-lb) impact tool onto the test item from a height of one (1) meter. Impact the test item anywhere around the circumference where the weld joint meets the side.

Tolerance:
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Drop Height: ±2.5%; Force: ±1%

1-2.1 Test Specification:

Customer RFQ fax dated 01/25/05 11:47, Table 1, Class 5, Impact Test

1-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100207	Tape Measure (50 foot)	Lufkin	C-213w/Blank	Indefinite
100255	Scale	Setra	EL 4100S	9/1/2005
100315	Thermo/Hygrometer	Mannix	SAM990DW	10/13/2005

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 item was not operating during the impact test.

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

Atmospheric Conditions: Temp (°C): 20 Relative Humidity (%): 34 Pressure: Site Ambient

Drop	Drop Height	Time	Observation
1	39.4 inches (1 meter)	1127	No visible 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)

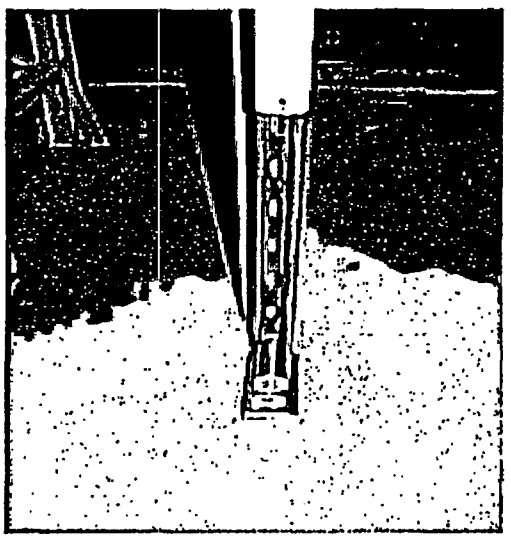

Figure 1-1. Test setup for impact.

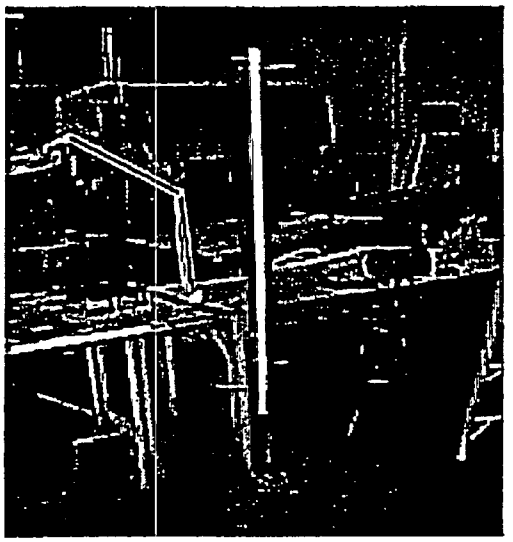

Figure 1-2. Test setup for impact.

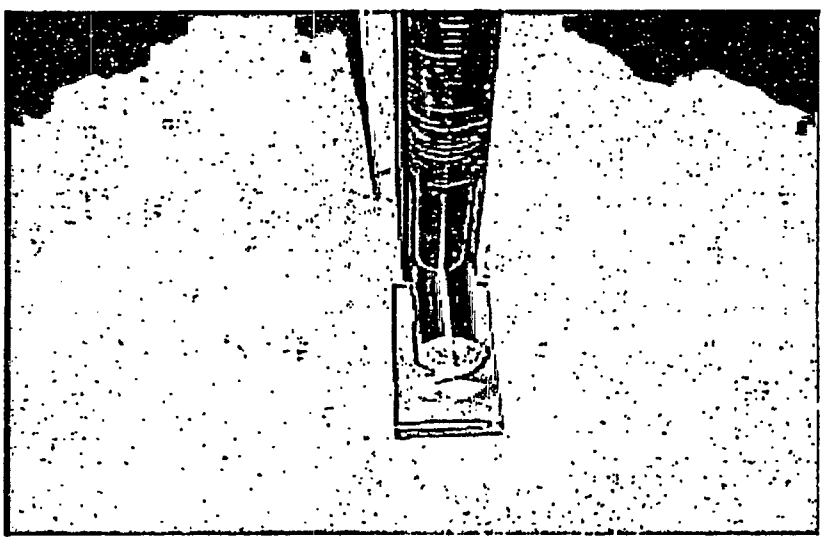

Figure 1-3. Test setup for impact.

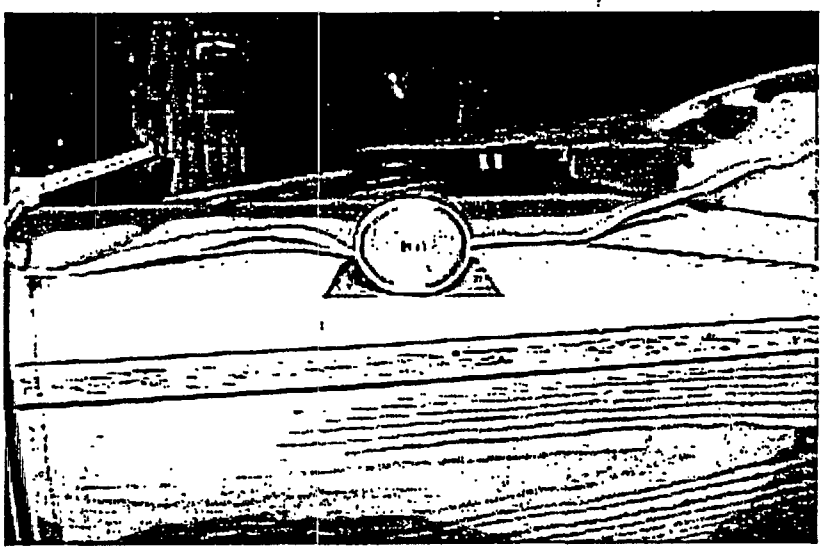

Figure 1-4. Condition of the 3-inch Teletherapy Capsule following the impact test.

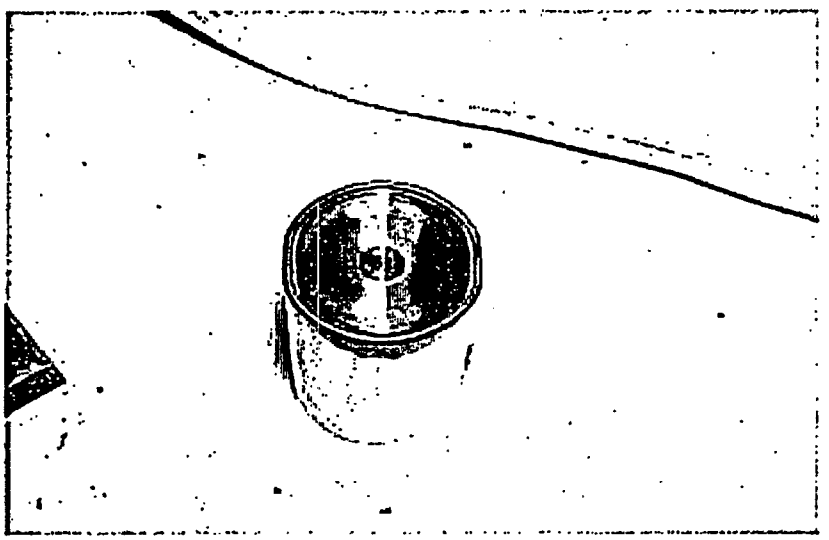

Figure 1-5. Condition of the 3-inch Teletherapy Capsule following the impact test.

SECTION 2

BENDING (LOAD) TEST SUMMARY

Test Start-Finish Dates: 22 February 2005

Responsible Test Technician: Don Hensley

2-1 TEST HARDWARE

One (1) Teletherapy Capsule, measuring 8 inches

2-2 TEST REQUIREMENTS WITH TOLERANCES

Lay the test item across two smooth solid parallel support cylinders that are twice the test item diameter (2D) and 10D apart. Slowly apply a 450-pound (2,000 N) force to the most vulnerable part of the test item using a third parallel cylinder (4D) centered between the supports. The cylinders should have a Rockwell hardness of 50 to 55. Remove the force after reaching the test limit and note any evidence of bending.

Tolerance:
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Force: ±1%

2-2.1 Test Specification:

ISO 2919:1999(E), Paragraph 7.7.1

2-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100315	Thermo/Hygrometer	Mannix	SAM990DW	10/13/2005
100352	Load Cell	Omegadyne	LCWD-5k	2/22/2006

CUSTOMER FURNISHED FIXTURES AND SUPPORT EQUIPMENT

P/N	S/N	Nomenclature (description, model, manufacturer etc.)
Not marked	Not marked	Cylinder (1 ea.)
Not marked	Not marked	Bending Test Fixture (1 ea.)

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 item was not operating during the bending test.

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

Atmospheric Conditions: Temp (°C): 22 Relative Humidity (%): 63 Pressure: Site Ambient

Run	Pounds/force	Time	Observation
1	450	1050	Bent approximately 5/8 inch

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).

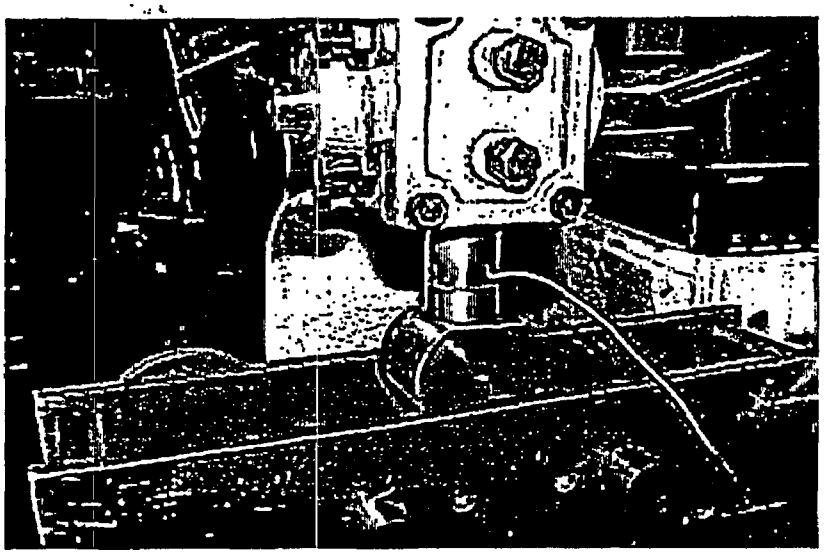

Figure 2-1. Test setup for bending (load).

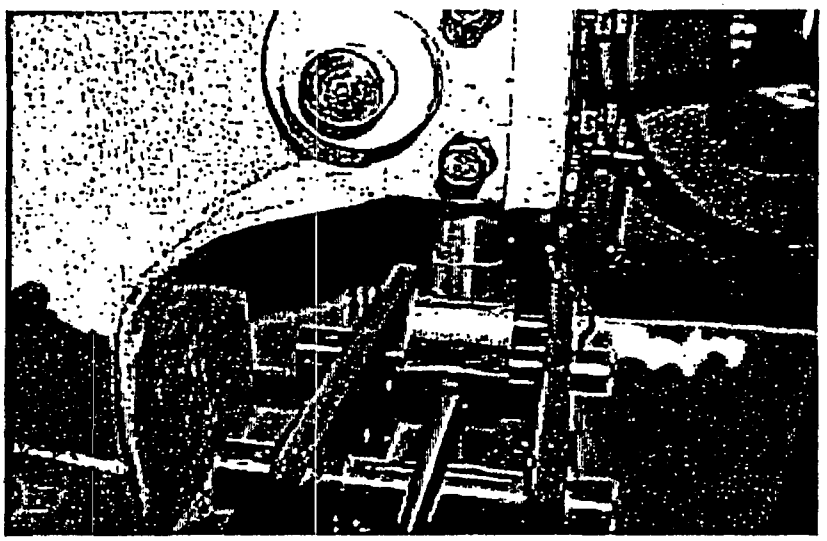

Figure 2-2. Test setup for bending (load).

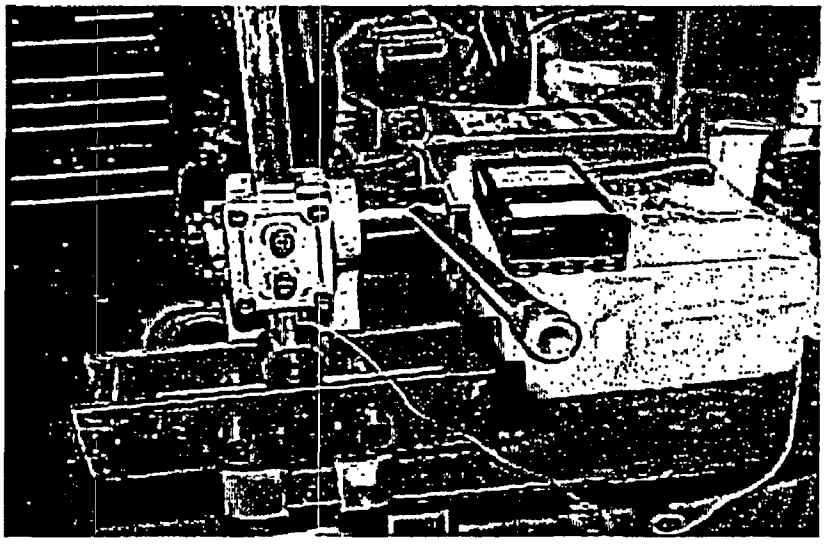

Figure 2-3. Test setup for bending (load).

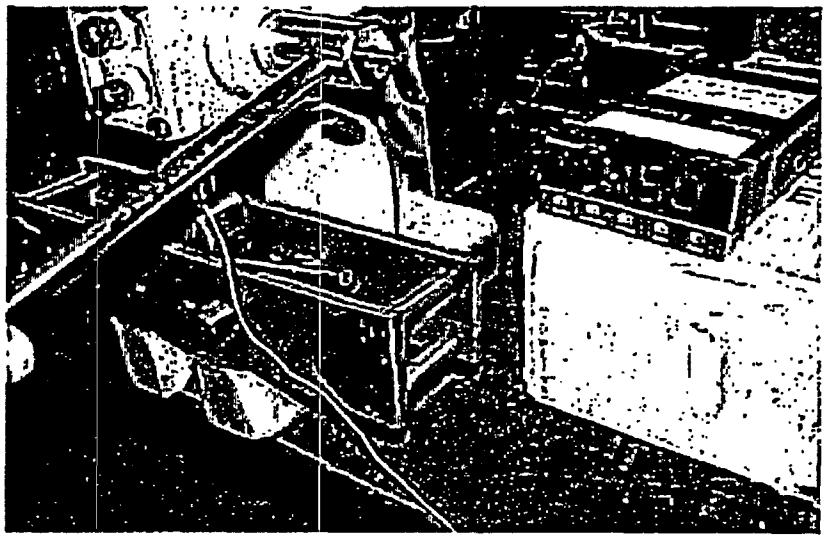

Figure 2-4. Test setup for bending (load).

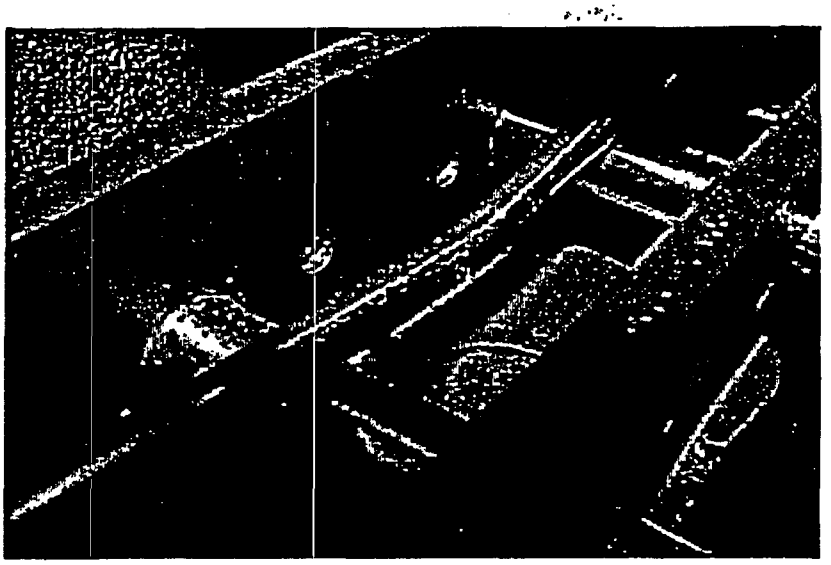

Figure 2-5. Condition of the 8-inch Teletherapy Capsule following the bending (load) test.

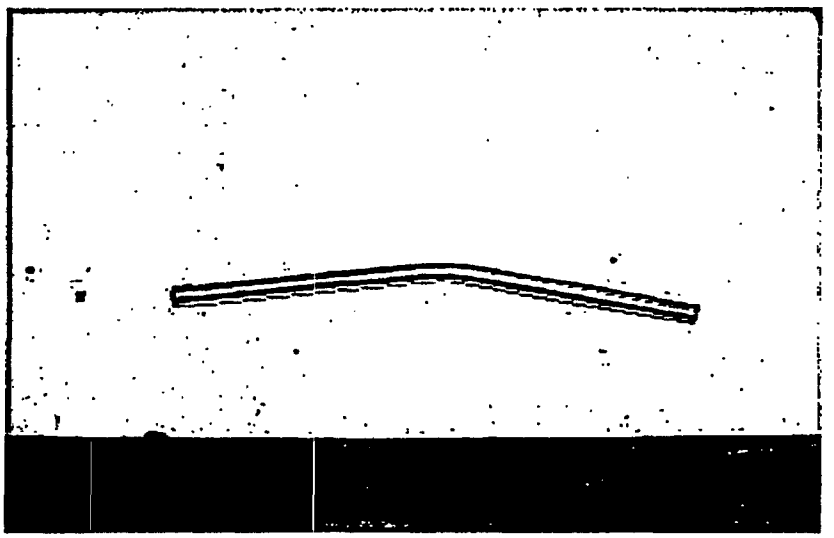

Figure 2-6. Condition of the 8-inch Teletherapy Capsule following the bending (load) test.

SECTION 3

BENDING (HAMMER) TEST SUMMARY

Test Start-Finish Dates: 23 February 2005

Responsible Test Technician: Don Hensley

3-1 TEST HARDWARE

One (1) Teletherapy Capsule, measuring 8 inches

3-2 TEST REQUIREMENTS WITH TOLERANCES

The test item shall be rigidly clamped in a horizontal position so that one-half of its length protrudes from the face of the clamp. Orient the free end of the test item in a manner that is likely to cause maximum damage when struck by the flat face of a steel hammer. Strike the test item with an impact equivalent to a free vertical fall of 1.4 kg (3.0865 lb) through 1 meter. Note any evidence of bending.

Tolerance:
Standard Ambient: 25±10°C, 20 - 80% Relative Humidity, Site Pressure
Force: ±1%

3-2.1 Test Specification:

ISO 2919:1999(E), Paragraph 7.7.2

3-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100207	Tape Measure (50 foot)	Lufkin	C-213w/Blank	Indefinite
100255	Scale	Setra	EL 4100S	9/1/2005
100315	Thermo/Hygrometer	Mannix	SAM990DW	10/13/2005

CUSTOMER FURNISHED FIXTURES AND SUPPORT EQUIPMENT

P/N	S/N	Nomenclature (description, model, manufacturer etc.)
Not marked	Not marked	Hammer Impact Tool (1 ea.)
Not marked	Not marked	Bending Test Fixture (1 ea.)

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 item was not operating during the bending test.

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

Atmospheric Conditions: Temp (°C): 23 Relative Humidity (%): 56 Pressure: Site Ambient

Run	Time	Observation
1	1135	The test item bent

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).

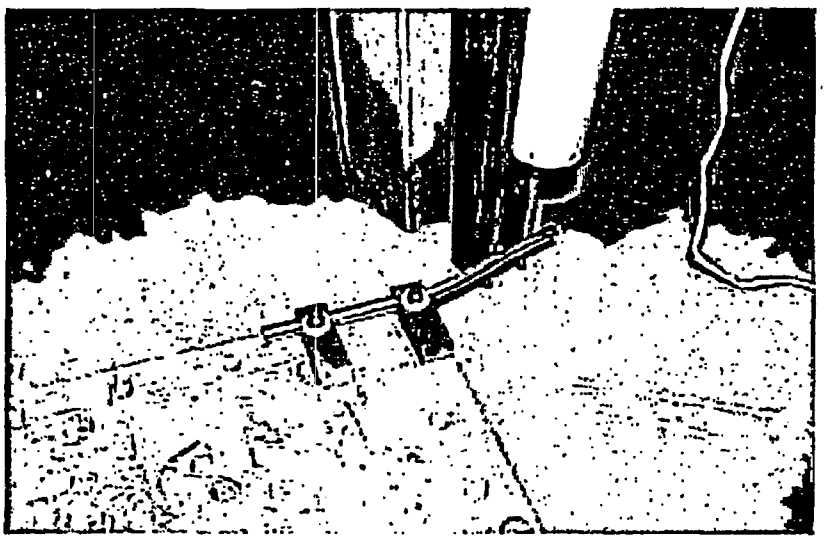

Figure 3-1. Test setup for bending (hammer).

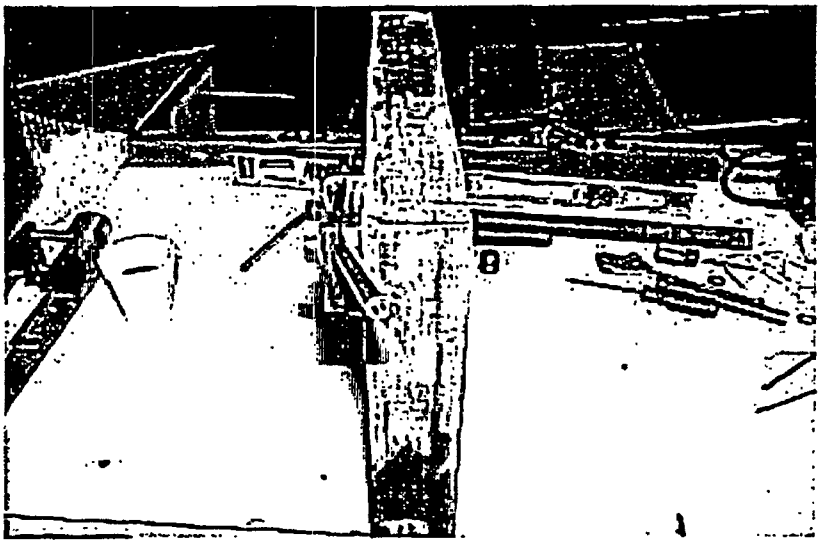

Figure 3-2. Test setup for bending (hammer).

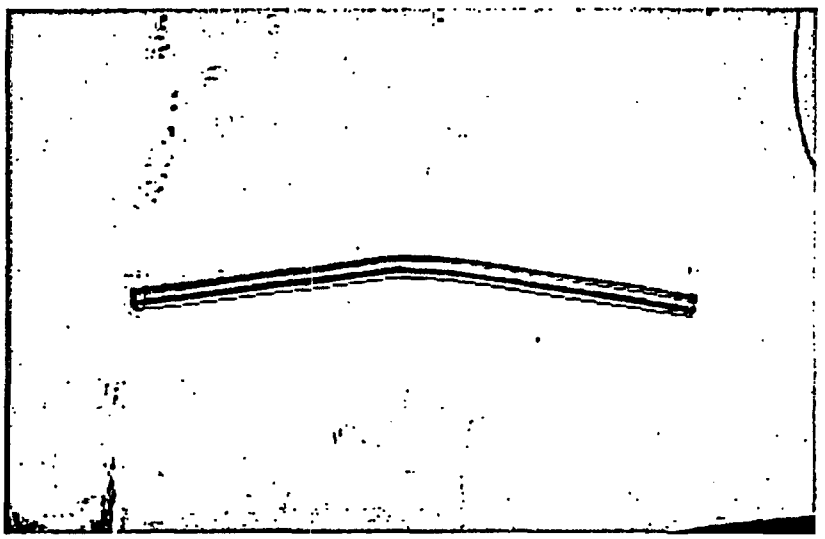

Figure 3-3. Condition of the 8-inch Teletherapy Capsule following the bending (hammer) test.

SECTION 4

HOT LIQUID BUBBLE TEST SUMMARY

Test Start-Finish Dates: 23 February 2005

Responsible Test Technician: Don Hensley

4-1 TEST HARDWARE

One (1) Teletherapy Capsule, measuring 3 inches
One (1) Teletherapy Capsule, measuring 8 inches

4-2 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 (2) minutes.

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

4-2.1 Test Specification:

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

4-3 TEST SETUP

QUALTEST FURNISHED MEASUREMENT & TEST EQUIPMENT (including any rentals)

QTI #	Item	Manufacturer	Model Number	Calibration Due
100102	Temperature Calibrator	Omega Eng.	OMNI-CAL IIA8	5/5/2005
100315	Thermo/Hygrometer	Mannix	SAM990DW	10/13/2005

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 item was not operating during the hot liquid bubble test.

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

Atmospheric Conditions: Temp (°C): 24 Relative Humidity (%): 53 Pressure: Site Ambient

Run	Time	Water Temperature	Duration	Observation
1	1322	92.9°C	2-minutes	No evidence of bubbles

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

None

4-5 ENVIRONMENTAL TEST DATA

Compliance verified through test setup and observation (reference photos). The test items were returned to the customer following the completion of the test.

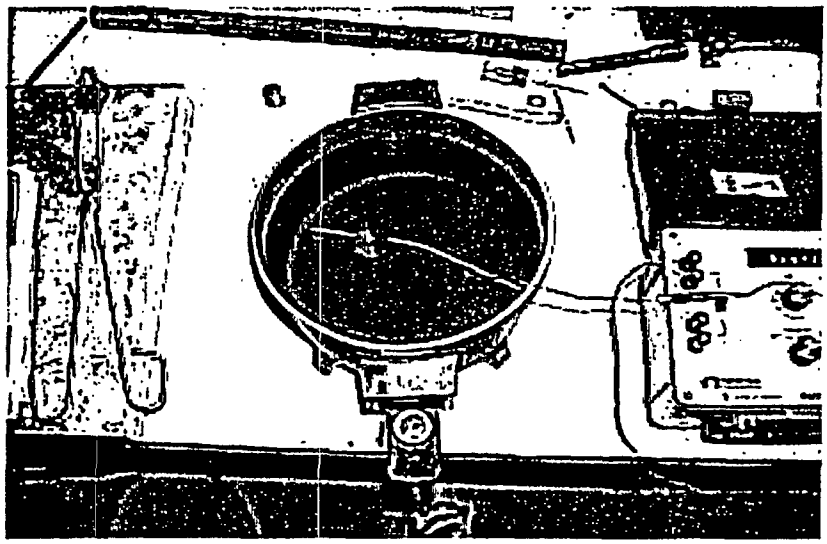

Figure 4-1. Hot liquid bubble test.

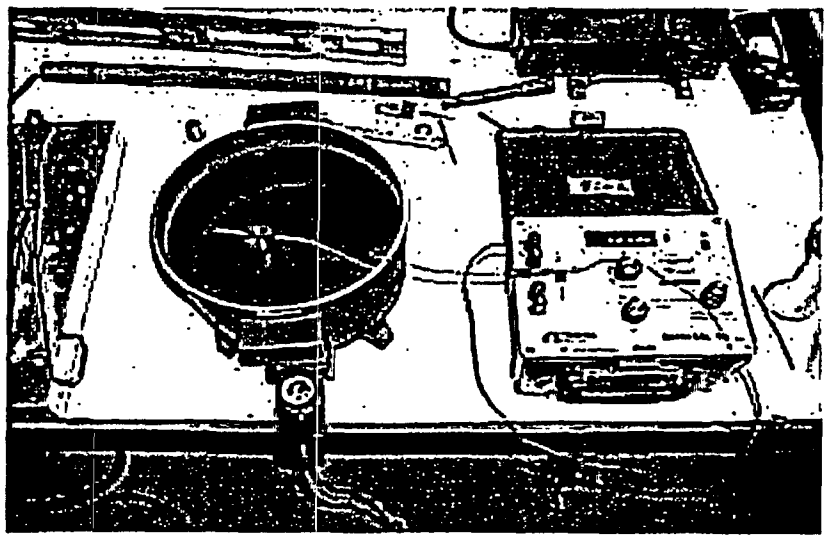

Figure 4-2. Hot liquid bubble test.

Attachment 4

Copy of I4-OP-52,

Co-60 Source Loading Procedure

I³ International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

TITLE:	Number:	Effective Date:
Co-60 SOURCE LOADING PROCEDURE	I4-OP-52	2/11/05
PRI:	Page:	Superceded Date:
Steve Laflin	1 of 5	2/01/05

PRI Signature and Date:	Document Control Signature and Date:	Quality Assurance Signature and Date:
2.10.05	Paula Rushett 2-10-05	2/10/05

COPY

Hot Cell Technicians

HCT name
(printed)_____Signature_____Initials_____

HCT name
(printed)_____Signature_____Initials_____

NOTE: ALLOW CAPINTECH TO WARM UP ½ HOUR BEFORE USING. Verify that zero and background are within tolerance.

1.0 PURPOSE

To outline the procedure for fabrication of sealed source cobalt capsules and to document source measurement, leak test, and other information required on each sealed source certificate.

2.0 POTENTIAL HAZARDS

The hazards associated with the implementation of this procedure include:

- Potential exposure to hazardous materials (i.e. radioactive material/waste, chemicals, acids, bases, etc.) including their by-products.
- Industrial hazards associated with the inspection and handling of transportation packages such as rigging, crane operations, forklift operations, pinch points, manual lifting, strains, trips, slips and falls.

3.0 APPLICABILITY AND LIMITATIONS

Procedure addresses all types and designs of cobalt sealed source capsules.

4.0 DEFINITIONS

None

5.0 RESPONSIBILITIES

I³ Quality – Verify procedure is current revision for manufacture of Co-60 sealed sources. Reviews completed procedure and approves sources for shipment.

CONTROLLED COPY

I³ Technician – Performs steps outlined in this procedure to include filling of capsules, assaying capsules, welding of capsules, leak testing capsules and decontaminating as required.

6.0 EQUIPMENT AND MATERIALS

6.1 Inner capsules and end caps

6.2 Outer capsules and end caps

6.3 Q-Tip smears

7.0 PROCEDURE

Operation Supervisor (OP) Verify that Tech performing the welding and N.D.T. (Leak Testing) of Sealed Sources is qualified and certifications are current.

OP Signature_____ Date_____

Name of Welder_____

Name of N.D.T. Inspector_____

7.1 Acquire customer loading request information and record in space below.

Customer Name/Number_____

Number of Sources_____

Activity Requested per Source_____ I³ Capsule model #_____

Date of manufacture_____

7.1.1 **Operation Supervisor (OP)** Obtain source inner and outer capsules to be used and record the outer capsule I³ Serial Number in the following manner; MMYY-# #, i.e.(0205- 01) in the space below. If multiple sources are to be manufactured, then record each Serial Number in APPENDIX A, step 7.7.1.

I³ Serial Number_____

7.2 Prep inner and outer capsules by performing the following:

7.2.1 Place capsules and end caps in ultrasonic filled with Toluene and clean for 5 minutes.

NOTE After capsules and end caps are cleaned, use cotton liners to handle cleaned capsules.

7.2.2. Press an end cap in one end of both the inner and outer capsule, maintaining a open end on each capsule, and weld per specified settings in the Co-60 Capsule Welding Log Book.

7.2.3 Test fit inner to outer capsule to ensure ease of assembly inside of the hot cell. When working with multiple sources, keep inner source inside of outer source until ready to load .

7.3 From Co-60 Storage Status board, determine the Shielded Storage pigs that will be used to fill the capsule.

7.4 Place prepared inner and outer capsules (as described in step 7.2) into hot cell. Retrieve material to be loaded as determined in step 7.3.

7.5 Place inner capsule into shielded loading pig, and set the shielded pig inside a plastic catch tray.

7.6 Re-verify weights of pellet storage containers against corresponding Source Log Book and completed procedure.

7.7 Load inner source capsule with Co-60 pellets following steps below and record in Appendix A.

7.7.1 Record inner source capsule number.(If inner capsule is not marked with a serial number, then record the serial number on the outer capsule). Do not separate inner and outer pairs of source.

7.7.2 Record specified loading weight.

7.7.3 Weigh loading pan and record weight.

7.7.4 Pour determined amount of pellets into loading pan and record weight.

7.7.5 Subtract loading pan weight from combined pan and pellet weight and record as net weight.

7.7.6 Load pellets into inner source. Check area for any loose pellets.

7.7.7 If all of the material in a Pellet Storage Container is not used, reweigh unused material and document in the corresponding Source Set Log Book and C0-60 status Board.

7.7.8 If needed, insert spacers to fill void in capsule. Place cap into end of inner capsule.

7.8 Set up welder per Co-60 Capsule Settings Log Book for inner source capsule.

7.9 Weld end cap onto inner source and decontaminate capsule to lowest levels practical.

7.10 Place welded inner source capsule into an outer source capsule. Install and weld outer source end cap onto source per specified settings in Co-60 source capsule welding log book for outer source.

Qualified Welder Signature_____Date_____

7.11 Perform a leak check on outer sealed source by placing source capsule in leak chamber filled with a mixture of 50% H_2O and 50% Alcohol and vacuum to -20 inches of water for 2 minutes. Observe for any bubbles present. Document leak test results on Source Certificate for each source welded.

N.D.T. Inspector_____Results_____Date_____

7.12 Perform a wet Q-Tip smear of outer sealed source. Count the smear. When source smear is less than 1000 dpm, place in clean container. (quart can) Document survey results in the space below and on the Sealed Source Calibration Contamination and Leak Test Certificate.

Source S.N. #_____ Smear count_____

Technician Signature_____Date_____

7.13 If sealed source is not to be removed from hot cell following smear test, then identify outside of clean container and log on Isotope Storage board all pertinent information.

7.14 Forward this procedure and any accompanying paperwork or certificates to Q.A. for approval.

8.0 REFERENCES

8.1 Weld Standard

8.2 N.D.T. Examiner Standard

9.0 ATTACHMENTS

9.1 Sealed Source Certificate Calibration Contamination and Leak Test Certificate

9.2 Appendix A

9.3 Source Decay Chart

9.4 Welder Settings

9.5 Welding Qualification Record

International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

COPY

SEALED SOURCE CALIBRATION CONTAMINATION AND LEAK TEST CERTIFICATE OF CO-60 SOURCE FOR

CUSTOMER: Amersham

I^3 MODEL NUMBER: INIS-SF-X.X-YY-Z

SERIAL NUMBER: 0205-01

REFERENCE DATE: February 28, 2005

ACTIVITY [ ] Ex. 4

Each source is manufactured by doubly encapsulating cylindrical Co-60 pellets 1.0 mm tall by 1.0 mm in diameter within inner and outer stainless steel capsules.

Physical Data

			Energy (MeV)	Yield
Isotope:	Co-60	γ_1	1.1732	100%
Half-life:	1925.2 days	γ_2	1.3325	100%
λ:	3.60E-04 d^{-1}			

Testing Results

Type	Method	Results
Removable Contamination	Wet Swab	< 1000 dpm
Leakage Test	Vacuum Bubble	No Leakage Observed

Technician: _____ Signature _____ Date

Verified: _____ Signature _____ Date

SAMPLE

Quality Assurance: _____ Signature _____ Date

The seller makes no warranty or representation expressed or implied, that the materials furnished under this agreement will not result in injury or damage when used for purposes authorized, or will accomplish the results for which they are requested or intended, or will not be destroyed, damaged, lost or otherwise altered in physical or chemical properties in the process of the Buyer's performance of and use of the material furnished.

COPY

APPENDIX A
MULTIPLE SOURCE LOADING SHEET

EACH INNER AND OUTER CAPSULE WITH THE SAME NUMBER ENGRAVED ON THEM IS CONSIDERED ONE SOURCE. BEFORE INSERTING INNER SOURCE INTO OUTER SOURCE, VERIFY THAT THE NUMBERS MATCH.(Example: # 1 INNER , # 1 OUTER , # 2 INNER, # 2 OUTER.)

SOURCE NUMBER Step 7.7.1	SPECIFIED WEIGHT (gms) Step 7.7.2	LOADING PAN WEIGHT (empty) Step 7.7.3	PAN / PELLET WEIGHT (loaded) Step 7.7.4	NET PELLET WEIGHT Step 7.7.5	TECH. INITIALS Steps 7.7.1-7.7.5	VERIF. INITIALS Steps 7.7.1-7.7.5

I³ International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

COPY

Source Decay Chart

I³ Model Number: INIS-SF-X.X-YY-Z

Serial Number: 0205-01

Date	Activity (Ci)	Activity (TBq)
February-05		
March-05		
April-05		
May-05		
June-05		
July-05		
August-05		
September-05		
October-05		
November-05		
December-05		
January-06		
February-06		
March-06		
April-06		
May-06		
June-06		
July-06		
August-06		
September-06		
October-06		
November-06		
December-06		
January-07		
February-07		
March-07		
April-07		
May-07		
June-07		
July-07		
August-07		
September-07		
October-07		
November-07		
December-07		
January-08		
February-08		
March-08		
April-08		
May-08		
June-08		
July-08		
August-08		
September-08		
October-08		
November-08		
December-08		
January-09		
February-09		
March-09		
April-09		
May-09		
June-09		
July-09		
August-09		
September-09		
October-09		
November-09		
December-09		
January-10		
February-10		
March-10		
April-10		
May-10		
June-10		
July-10		
August-10		
August-10		
September-10		
October-10		
November-10		
December-10		
January-11		
February-11		
March-11		
April-11		
May-11		
June-11		
July-11		
August-11		
September-11		
October-11		
November-11		
December-11		
January-12		
February-12		

Ex. 4

I³ International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

WELDER SETTINGS
FOR SOURCE MODEL: INIS-SF-X.X-YY-Z

	Inner Capsule	Outer Capsule
Type of Capsule:		
Wall Thickness:	in	in
Outside Diameter:	in	in
Length:	in	in
Amperage	A	A
Ratational Speed:	rpm	rpm
Weld Duration:	sec	sec
Gas Flow:	cfm	cfm
Post Flow:	cfm	cfm
Pre-purge:	cfm	cfm
Electrode Si	40 mils	40 mil

SEQUENCE		PULSE	
INITIAL A	1	PTS	150
INITIAL SLOPE	1	PEAK	50
FINAL SLOPE	2	BKG A	5
FINAL A	4		

CLEAN WELD AREA OF CAPSULE AND LID WITH TOLUENE PRIOR TO WELDING.

Weld Technician: _____ _____
Signature Date

International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

WELDING QUALIFICATION RECORD FOR CO-60 CAPSULES

TECHNICIAN NAME: _____

INDIVIDUALS MUST SHOW FAMILIARITY WITH SETTINGS AND ADJUSTMENTS OF THE MILLER MAXSTAR 200 TIG WELDER. WELD SETTINGS MAY CHANGE ACCORDING TO SIZE OF CAPSULE AND WALL THICKNESS.

WELDER SETTINGS		INSPECTOR INITIALS
AMPERAGE	_____	_____
PROCESS	_____	_____
OUTPUT	_____	_____
PULSE	_____	_____
SEQUENCE	_____	_____
ADJUST	_____	_____
TURNTABLE SPEEDS AND CONTROLS	_____	_____
ELECTRODE HEIGHT AND DISTANCE	_____	_____
SLIDE AND STINGER POSITION	_____	_____
POWER LOCATIONS AND SWITCHES	_____	_____
GAS CONNECTIONS AND GAUGES	_____	_____

THIS CERTIFIES THAT HAS _____ HAS SUCCESSFULLY COMPLETED THE ABOVE REQUIREMENTS AND IS QUALIFIED TO OPERATE THE CO-60 WELDING SYSTEM.

INSPECTOR: _____ _____
Signature Date

REQUALIFICATION DATE: _____

Attachment 5

Welder Qualificaiton Sheet, Welder Settings Sheet

I³ International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

WELDING QUALIFICATION RECORD FOR CO-60 CAPSULES

TECHNICIAN NAME: _____

INDIVIDUALS MUST SHOW FAMILIARITY WITH SETTINGS AND ADJUSTMENTS OF THE MILLER MAXSTAR 200 TIG WELDER. WELD SETTINGS MAY CHANGE ACCORDING TO SIZE OF CAPSULE AND WALL THICKNESS.

WELDER SETTINGS		INSPECTOR INITIALS
AMPERAGE	_____	_____
PROCESS	_____	_____
OUTPUT	_____	_____
PULSE	_____	_____
SEQUENCE	_____	_____
ADJUST	_____	_____
TURNTABLE SPEEDS AND CONTROLS	_____	_____
ELECTRODE HEIGHT AND DISTANCE	_____	_____
SLIDE AND STINGER POSITION	_____	_____
POWER LOCATIONS AND SWITCHES	_____	_____
GAS CONNECTIONS AND GAUGES	_____	_____

THIS CERTIFIES THAT HAS _____ HAS SUCCESSFULLY COMPLETED THE ABOVE REQUIREMENTS AND IS QUALIFIED TO OPERATE THE CO-60 WELDING SYSTEM.

INSPECTOR: _____ _____
Signature Date

REQUALIFICATION DATE: _____

International Isotopes Inc.
(Including International Isotopes Idaho Inc. subsidiary)

WELDER SETTINGS
FOR SOURCE MODEL: INIS-SF-X.X-YY-Z

	Inner Capsule	Outer Capsule
Type of Capsule:	_____	_____
Wall Thickness:	_____ in	_____ in
Outside Diameter:	_____ in	_____ in
Length:	_____ in	_____ in
Amperage	_____ A	_____ A
Ratational Speed	_____ rpm	_____ rpm
Weld Duration:	_____ sec	_____ sec
Gas Flow:	_____ cfm	_____ cfm
Post Flow:	_____ cfm	_____ cfm
Pre-purge:	_____ cfm	_____ cfm
Electrode Size:	40 mils	40 mils

SEQUENCE	
INITIAL A	1
INITIAL SLOPE	1
FINAL SLOPE	2
FINAL A	4

PULSER	
PPS	136
PEAK	50
BKG A	5

CLEAN WELD AREA OF CAPSULE AND LID WITH TOLUENE PRIOR TO WELDING.

Weld Technician: _____ _____
Signature Date

Attachment 6

2004 ERG
Guide 163

POTENTIAL HAZARDS

HEALTH

- Radiation presents minimal risk to transport workers, emergency response personnel and the public during transportation accidents. Packaging durability increases as potential hazard of radioactive content increases.
- Undamaged packages are safe. Contents of damaged packages may cause higher external radiation exposure, or both external and internal radiation exposure if contents are released.
- Type A packages (cartons, boxes, drums, articles, etc.) identified as "Type A" by marking on packages or by shipping papers contain non-life endangering amounts. Partial releases might be expected if "Type A" packages are damaged in moderately severe accidents.
- Type B packages, and the rarely occurring Type C packages, (large and small, usually metal) contain the most hazardous amounts. They can be identified by package markings or by shipping papers. Life threatening conditions may exist only if contents are released or package shielding fails. Because of design, evaluation and testing of packages, these conditions would be expected only for accidents of utmost severity.
- The rarely occurring "Special Arrangement" shipments may be of Type A, Type B or Type C packages. Package type will be marked on packages, and shipment details will be on shipping papers.
- Radioactive White-I labels indicate radiation levels outside single, isolated, undamaged packages are very low (less than 0.005 mSv/h (0.5 mrem/h)).
- Radioactive Yellow-II and Yellow-III labeled packages have higher radiation levels. The transport index (TI) on the label identifies the maximum radiation level in mrem/h one meter from a single, isolated, undamaged package.
- Some radioactive materials cannot be detected by commonly available instruments.
- Water from cargo fire control may cause pollution.

FIRE OR EXPLOSION

- Some of these materials may burn, but most do not ignite readily.
- Radioactivity does not change flammability or other properties of materials.
- Type B packages are designed and evaluated to withstand total engulfment in flames at temperatures of 800°C (1475°F) for a period of 30 minutes.

PUBLIC SAFETY

- **CALL Emergency Response Telephone Number on Shipping Paper first. If Shipping Paper not available or no answer, refer to appropriate telephone number listed on the inside back cover.**
- **Priorities for rescue, life-saving, first aid, fire control and other hazards are higher than the priority for measuring radiation levels.**
- Radiation Authority must be notified of accident conditions. Radiation Authority is usually responsible for decisions about radiological consequences and closure of emergencies.
- As an immediate precautionary measure, isolate spill or leak area for at least 25 meters (75 feet) in all directions. • Stay upwind. • Keep unauthorized personnel away.
- Detain or isolate uninjured persons or equipment suspected to be contaminated; delay decontamination and cleanup until instructions are received from Radiation Authority.

PROTECTIVE CLOTHING

- Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection against internal radiation exposure, but not external radiation exposure.

EVACUATION

Large Spill

- Consider initial downwind evacuation for at least 100 meters (330 feet).

Fire

- When a large quantity of this material is involved in a major fire, consider an initial evacuation distance of 300 meters (1000 feet) in all directions.

EMERGENCY RESPONSE

FIRE

- Presence of radioactive material will not influence the fire control processes and should not influence selection of techniques.
- Move containers from fire area if you can do it without risk.
- Do not move damaged packages; move undamaged packages out of fire zone.

Small Fires

- Dry chemical, CO_2, water spray or regular foam.

Large Fires

- Water spray, fog (flooding amounts).
- Dike fire-control water for later disposal.

SPILL OR LEAK

- Do not touch damaged packages or spilled material.
- Damp surfaces on undamaged or slightly damaged packages are seldom an indication of packaging failure. Most packaging for liquid content have inner containers and/or inner absorbent materials.
- Cover liquid spill with sand, earth or other non-combustible absorbent material.

FIRST AID

- Medical problems take priority over radiological concerns.
- Use first aid treatment according to the nature of the injury.
- Do not delay care and transport of a seriously injured person.
- Give artificial respiration if victim is not breathing.
- Administer oxygen if breathing is difficult.
- In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
- Injured persons contaminated by contact with released material are not a serious hazard to health care personnel, equipment or facilities.
- Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.