Qynergy Corporation
3800 Osuna Road NE Suite 2
Albuquerque, NM 87109-4401
Office: (505) 890-6887
Fax: (505) 792-8508

1 August 2007

John Yankovich
United States Nuclear Regulatory Commission
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 20852-2738

RE: Request for SS&DR for KRT-2000 Betavoltaic Power Cell

Dear Mr. Yankovich:

Qynergy Corporation requests a Sealed Source and Device Registration number for the KRT-2000 Betavoltaic Power Cell (also known as the QynCell ™). Qynergy gives permission for the following documents to be reproduced and made available to the public.

- SS&DR Application
- Mechanical Drawing Package
- Instructions to Users
- KRT-2000 Label

Qynergy has included the following documents for information only and requests that they not be duplicated, distributed, or made available to the public. Due to the nature of the technical and manufacturing processes referenced within these documents, these items are regarded as "Qynergy Proprietary and Confidential".

- Prototype Test Report
- Addendum to Prototype Test Report
- KRT-2000 Design Report and Appendices 9.1, 9.2, 9.3, and 9.4
- Qynergy Quality Manual
- Radiation Profile Measurements

Your timely attention to this matter is greatly appreciated. If you have any questions, I can be reached at either (505) 314-1422 or stephanie.jones@qynergy.com. Thank you.

Sincerely,

Stephanie Jones
Quality Manager

b/1

Attachments: SS&DR Application
Mechanical Drawing Package
Instructions to Users
KRT-2000 Label
Prototype Test Report
Addendum to Prototype Test Report
KRT-2000 Design Report
KRT-2000 Design Report Appendix 9.1
KRT-2000 Design Report Appendix 9.2
KRT-2000 Design Report Appendix 9.3
KRT-2000 Design Report Appendix 9.4
Qynergy Quality Manual
Radiation Profile Measurements

Cc: Todd Bisio, President, Qynergy
Christopher Eiting, Director of Engineering, Qynergy
Viswanath Krishnamoorthy, Director of Technology and Quality Assurance, Qynergy

REGISTRY OF SEALED SOURCES AND DEVICES SAFETY EVALUATION	
Name and Complete Mailing Address of the Applicant: Qynergy Corporation 3800 Osuna Rd NE Ste 2 Albuquerque, NM 87109-4401 505-890-6887 505-792-8508 (FAX)	**Name, Title, and Telephone Number of the Individual to Be Contacted if Additional Information or Clarification is Needed by the NRC:** Stephanie Jones Quality Manager 505-314-1422
The Applicant is (check one): ( ) Custom User ( ) Manufacturer ( ) Distributor (X) Manufacturer and Distributor	**If the Applicant is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:** N/A
If the Applicant is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: N/A	**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:** See page 2 for Details
Model Number: KRT-2000	**Principal Use Code (see Appendix C):** R (Gas)
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Betavoltaic Power Cell: A device that captures electrons emitted by a decaying radioisotope for the purpose of producing usable electric power	**For Use by:** (X) Specific Licensees Only ( ) General Licensees Only ( ) Both Specific and General Licensees ( ) Persons Exempt from Licensing
Leak-Test Frequency: (X) Periodic Leak-Testing is Not Required (Exempt from leak test due to ^{85}Kr gas form) ( ) 6 Months ( ) Attached is justification for a leak test frequency of greater than 6 months	**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):** Specific Licensees under 10 CFR 33.11 and General Licensees under 10 CFR 31.9 **Radionuclides and Maximum Activities (including loading tolerance):** ^{85}Kr 166.5 GBq + 20% (4.5 Ci + 20%)

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

Certifying Officer – Typed Name and Title
Christopher Eiting, PhD, PE, Director of Engineering

Signature: Christopher Eiting **Date:** 8/1/07

KRT-2000 Manufacturer's List

Machining

1. Team Specialty Products
   1400 Eubank Blvd SE
   Albuquerque, NM 87123
   Phone 505-291-0182 fax 505-271-8354

Joining

1. California Brazing
   37955 Central Ct
   Newark, CA 94560
   Phone 510-790-2300 Fax 510-791-9300

2. EB Industries
   90 Carolyn Blvd.
   Farmingdale, NY 11735
   Phone 888-468-1991 Fax 631-752-7866

Testing

1. Eckert & Ziegler Isotope Products
   24937 Avenue Tibbitts
   Valencia, CA 91355
   Phone (661) 309-1010

2. Technical Manufacturing Industries Inc.
   9901-B Southern S.E.
   Albuquerque, NM 87123
   phone (505)-293-6136 fax (505) 275-3657

3. Jona Manufacturing
   264 DP Rd.
   Los Alamos, NM 87544
   Phone (505) 662-4611

Isotope Loading

1. Eckert & Ziegler Isotope Products
   24937 Avenue Tibbitts
   Valencia, CA 91355
   Phone (661) 309-1010

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Web: www.qynergy.com

1 CONDITIONS OF USE

Intended Use

The device is a prototype power cell that generates small amounts of power (microwatts) over a long time (years). The device will be used as a demonstration model for customers that have applications where small powers are needed for long periods of time. Customers will then provide specifications for new models that will be registered independently from the demonstration model.

Types of Users

The power cells will be connected to the systems that they are intended to power. The installation will be performed by radiation certified technicians (overseen by radiation safety officers) in licensed facilities. The systems they will power are primarily detection and security systems manufactured by government contractors and used by the Department of Homeland Security and the Department of Defense.

Locations of Use

This model will be tested within licensed facilities only, and will not be fielded. All radiation safety requirements will be followed including the establishment of shielded storage areas, radiation areas when in use, and ALARA practices for trained radiological workers as well as non-radiological workers in the facilities.

Occasions When Persons Will Be Near the Device and the Frequency of These Occasions

Radiation certified workers will be the only users of this model and will be near the device during set up of a demonstration. Demonstration set ups will consist of attaching wires from the system requiring power to the wires exiting the sealed device. After the initial set up, there is no requirement that a worker be near the source. Radiation barriers can be established and appropriate security measures can be taken to allow long term demonstrations.

Normal Use Conditions

This device is designed and manufactured for use as a power cell on demonstration systems housed in controlled factory settings. This device should not be subjected to conditions during use, handling, storage, and transport that exceed ISO/99/CX3344 as defined below:

- External pressure: 0 to 290 PSIA
- Working temperature: -60 and 200 Celsius
- Impact: 200 grams from 1 meter with hammer
- Vibration: 25-80 Hz for 90 minutes and up to 80-2000 Hz @ 20 g-force
- Puncture: 50 grams from 1 meter with nail
- Corrosive environment: Not to be used in a highly corrosive environment such as acids, sea water or salts.

This device has been evaluated based on these conditions and tested based on the following possible modes of failure under normal use conditions:

- Drop-from no more than a table height
- Impact-from a tool being dropped on the device during hook up
- Impact-from another package dropped onto the packaged device during transport
- Heat-from an overheated electronic part in the system the device is connected to
- Vibration-from small fans on the systems the device is connected to
- Vibration-from transport vehicles

The registered device will not come into contact with any corrosives during normal use. Also, the materials of construction are not detrimentally affected by the expected exposure to radiation either from internal or external sources during normal operation.

Expected Working Life of the Source/Device (Years, Operations)

The expected useful life of the KRT-2000 is 20 years. No regular maintenance is required. Actual working life is dependent on activity and power requirements for the end user. At the end of the working life of the device, the KRT-2000 will be returned to the manufacturer specified subcontractor for disposal. No devices will be returned to Qynergy.

2 CONSTRUCTION OF THE PRODUCT

The KRT-2000 is a single wall, welded pressure vessel constructed of 316 stainless steel. It has a hermetic ceramic to metal feedthrough for electrical connection to the converters inside the device, and a brazed and crimped copper fill tube for the introduction of ^{85}Kr. The steel structure provides both the seal as well as limited shielding for the ^{85}Kr. Additional shielding may be required once installed as part of a larger system for demonstration. The package is leak tested prior to the introduction of ^{85}Kr. The package is rated to handle pressures that far exceed the ^{85}Kr loading pressure of 150 psi. Note: ^{85}Kr is a beta and gamma emitter. All beta radiation is shielded by the steel case.

Within the pressure vessel, epoxied to the inside walls, are two PC boards upon which are soldered the semiconductor converters that generate the electrical power. 5% ^{85}Kr gas and 95% Ar fill the remainder of the space. The crimped fill tube and electrical feedthrough are protected by a cap that is fastened into place. Two electrical leads exit the cap and provide the electrical power output.

See Attachment 1 Mechanical Drawing Package.

Handling and Installation

The device has a radiation signature and should be handled according to ALARA recommended practices. During transport, the KRT-2000 should be carried inside its shielded shipping container. Once it is ready for installation, the KRT-2000 should be handled with tongs to position it into its mounting brackets or clips. See Attachment 2 Instructions to Users for further details. Once in position, the wires can be attached to the system the KRT-2000 will be powering and additional shielding (lead or tungsten recommended) can be put into place.

Materials

See Attachment 1 Mechanical Drawing Package.

Dissimilar Materials

Mismatch in Coefficient of Thermal Expansion (CTE) between dissimilar materials will not be a concern in this design as the operational temperature range is small enough that the dimensional changes will not appreciably affect the integrity of the hermetic seal. The locations of the dissimilar materials are in the electric feedthrough and the fill tube. The feedthrough is rated for a temperature range of -268C to 450C. The CTE mismatch between the 316 SST and the Copper fill tube is very small.

The KRT-2000 is only designed for operation in an air environment, hence galvanic corrosion effects will be negligible.

3 LABELING

All devices are labeled with the trefoil symbol on the large face of the device. The opposite large face of the device is labeled with the following:

QYNCELL
Caution: Radioactive Material
Kr-85
Serial Number
Part Number
Activity and Date of Assay
www.qynergy.com

All labels are permanently etched into the outside surface of the device package. See Attachment 3 KRT-2000 Label for details.

4 PROTOTYPE TESTING

The device has been tested according to standard procedures in ISO2919:1999 (ANSI/HPS N43.6-1997 Sealed Radioactive Sources – Classification equivalent). In

order to meet the demands of normal use conditions and possible failure modes under those normal use conditions, the device has been tested to the following classes:

Temperature:	Class X
(Modified Class 3 with expanded temperature range of -60 to 200°C)	
External Pressure:	Class 3
Impact:	Class 3
Vibration:	Class 4
Puncture:	Class 4

All prototypes were pressurized with He and leak tested according to ISO9978:1992 (ANSI/HPS N43.6-1997 Section A.2.2.5 equivalent). All devices passed classification ISO/99/CX3344.

5 RADIATION PROFILES

Radiation profiles for the KRT-2000 devices were both modeled and directly measured at contact, 5 cm, 30 cm, and 100 cm from all faces of the device. Direct measurements were completed for a 5.49 Ci loading (slightly higher than the 5.4 Ci maximum including tolerance). Maximum dose rates are present along the axis passing through the large faces of the KRT-2000. The theoretical model was validated using these direct measurements.

Distance (cm)	Total Dose Rate (mrem/hr)
0 (Contact)	3200
5	1220
30	109
100	11

Maximum Measured Dose Rates for 5.49 Ci KRT-2000

6 QUALITY ASSURANCE AND QUALITY CONTROL

The Qynergy Quality Manual details the quality control of these devices from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B). The program covers design and document control, purchasing, training, calibration records, device numbering, production, assay quality control, and confirming orders. The program also ensures that

1. The materials of construction and the final assembly meet the design specifications
2. The final product is leak tested.
3. A final radiation profile is performed.
4. A test is performed that verifies the KRT-2000 is operational and all safety components are operating properly.

5. A visual and mechanical inspection of critical safety components and components susceptible to failure under extreme conditions is performed.

In addition the program allows for the tracking of as-built specifications for each individual device including all version controlled documentation used in the manufacturing process.

All documents and activities related to the manufacturing of KRT-2000 cells are governed by the Qynergy Quality Manual.

7 INSTALLATION, SERVICING, AND INSTRUCTIONS TO USERS

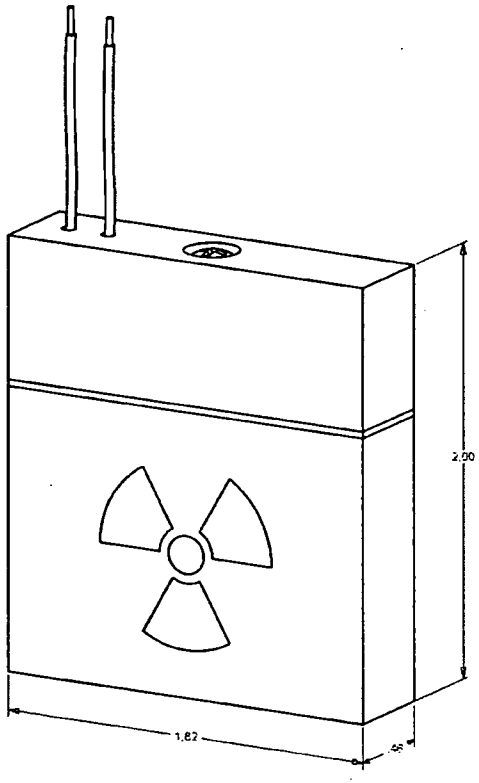
Installation, relocation, and radiation surveys may be performed by specific licensees. Maintenance, repair, source exchange, calibration, and training will be provided by the distributor. No leak testing is required following the initial leak test performed by the manufacturer due to the gas form of the ^{85}Kr.

See Attachment 2, Instructions to Users

Attachment 1

Mechanical Drawing Package

REVISIONS			
REV	DESCRIPTION	DATE	APPROVED
A	UPDATED PART LIST, ADDED UNLOADED VIEW, UPDATED TITLE BLOCK	02/23/07	C. ETING



ISO VIEW SHOWING LOADED QYNCELL

ITEM	QTY	PART NO.	DESCRIPTION	MATERIAL
18	A/R	HD Microsystems #PI-2566	POLYIMIDE COATING	POLYIMIDE
17	A/R	MasterBond #EP21TDCHT	NON CONDUCTIVE EPOXY	EPOXY
16	A/R	Jaguar Ind. #JKY22-0	22 GA. WIRE -BLACK	COPPER/KYNAR
16	A/R	Jaguar Ind. #JKY22-2	22 GA. WIRE -RED	COPPER/KYNAR
14	1	Swagelok#SS-4-VCR-6-200	1/8" TUBE TO 1/4" VCR ADAPTER	304 SST
13	A/R	MasterBond Supreme #1 10/s	ELECTRICALLY CONDUCTIVE EPOXY	EPOXY
12	A/R	McMasterCarr#91458A88	LOCTITE 271 HIGH STRENGTH THREAD LOCKER	EPOXY
11	1	McMasterCarr#90826A619	PAN-HD #4-4- 5/8"LG	SST
10	1	McMasterCarr#91400A050	PAN-HD #2-56 1/8"LG	SST
9	1	McMasterCarr#7113K802	RING TERMINAL	SST
8	A/R	Jaguar Ind. #JKY30-0	30 GA. WIRE	COPPER/KYNAR
7	A/R	Indium #121 and flux #3	SOLDER	TIN/SILVER
6	2	KRT-2200-1 REV A	PC BOARD ASSEMBLY	FR-4/GOLD
5	1	KRT-2100-1 REV A	LID ASSEMBLY	SST/COPPER/CERAMIC
4	1	KRT-2004-1 REV A	BOTTOM CAP	SST
3	1	KRT-2003-1	GASKET	KALREZ
2	1	KRT-2002-1 REV A	CAP	SST
1	1	KRT-2001-1 REV A	CASE	SST

PARTS LIST

NOTES: UNLESS OTHER WISE SPECIFIED

1. ALL DIMENSIONS IN INCHES
2. DIMENSIONS AND TOLERANCING PER ASME Y14.5M-1994
3. ASSEMBLE PER KRT-2000 ASSEMBLY PROCEDURE
4. LASER ETCH OR EQUIVALENT, TREFOIL ON SIDE SHOWN, FOLLOWING TEXT OTHER SIDE, CENTERED:

QYNCELL
CAUTION - RADIOACTIVE MATERIAL
KRYPTON-85
ACTIVITY
DATE OF LOADING
SERIAL NUMBER
PART NO. KRT-2000 REV
WWW.QYNERGY.COM

5 APPLY THREAD LOCKER PER LOCTITE SPECS

APPROXIMATE MASS: 100 GRAMS

THIRD ANGLE PROJECTION

	SIGNATURE	DATE
Designed	Edward Romero	12/4/2006
Checked	Edward Romero	12/4/2006
Approved	Chris Eting	12/4/2006

Qynergy®
www.qynergy.com

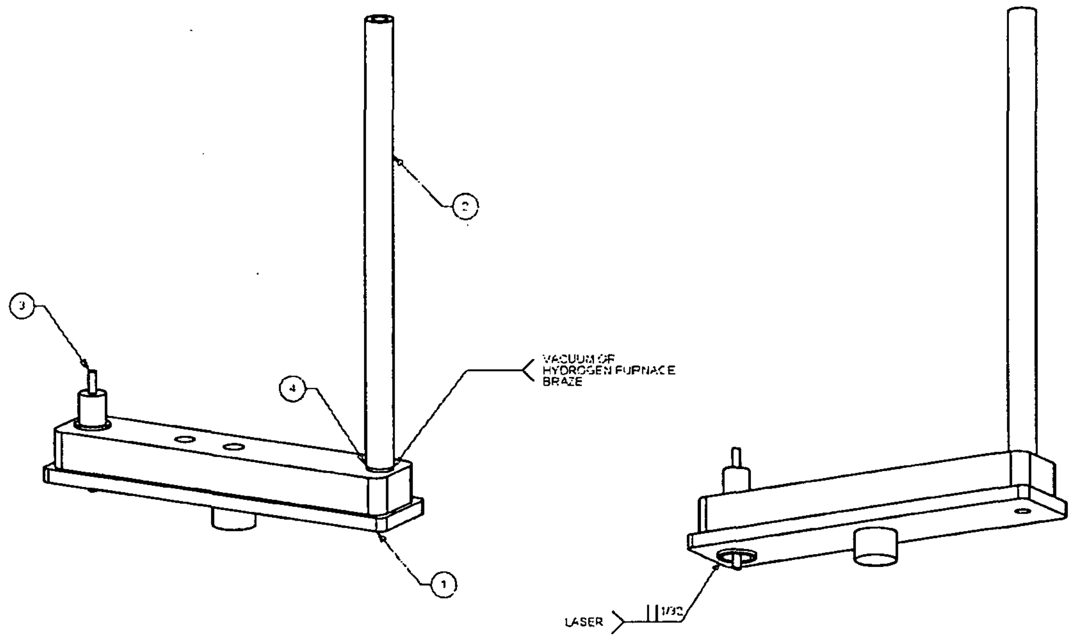
QYNCELL
KR-85 QYNCELL
MODEL KRT-2000 QYNCELL

PART NO.	REV	SHEET
KRT-2000	A	D. ~~1 of 2~~ 12/1

KRT-2000

-9-

REV	DESCRIPTION	DATE	APPROVED
A	CHANGED PART # ON ITEM #3 TO -06(MOLIBDENUM CONDUCTOR), UPDATED REV'S	03/01/07	C. EITING



PROCEDURE:

STEP 1: BRAZE JOINT IS MADE
STEP 2: ITEM #3 IS WELDED

NOTES: UNLESS OTHER WISE SPECIFIED

1. ALL DIMENSIONS IN INCHES
2. DIMENSIONS AND TOLERANCING PER ASME Y14.5M-1994
3. SURFACE TEXTURE PER ANI/ASME B 46.1-1985
4. REMOVE ALL BURRS AND BREAK SHARP EDGES TO A MAXIMUM OF .015
5. ALL INSIDE CORNERS TO BE .015 RADIUS MAX
6. COUNTERSINK 82 DEGREES ALL TAPPED HOLES TO MAJOR DIAMETER
7. COUNTERSINK 82 DEGREES APPROXIMATELY .03/.06 DEEP ALL DRILLED HOLES
8. PARTS TO BE THOROUGHLY CLEANED TO REMOVE ALL OIL, GREASE, DIRT AND CHIPS

PARTS LIST

ITEM	QTY	PART NO.	DESCRIPTION	MATERIAL
4	A/R	N/A	BRAZING COMPOUND	82%Au, 18%Ni
3	1	Ceramaseal 9297-06-W	SINGLE CONDUCTOR FEEDTHROUGH	MISC.
2	1	KRT-2102-1 REV A	FILL TUBE	COPPER
1	1	KRT-2101-1 REV A	LID	316 SST

THIRD ANGLE PROJECTION

	SIGNATURE	DATE
	Edward Romero	12/4/2006
	Edward Romero	12/4/2006
	Chris Eting	12/4/2006

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QYNCELL
KR-85 QYNCELL
LID ASSEMBLY

PART NO. KRT-2100-1

KRT-2100 A D ~~1 of 1~~

Attachment 2

QYNCELL INSTALLATION-INSTRUCTIONS TO USERS

Only authorized and properly trained personnel may open a package containing a QynCell. Please verify that the package is in good condition and that the QynCell is properly shielded in its shipping container.

Please note that the QynCell must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" indicated on the registration certificate. No modifications may be made to the QynCell for use in the desired location. Compromising the integrity of the QynCell case could result in a release of radioactive material.

Installation

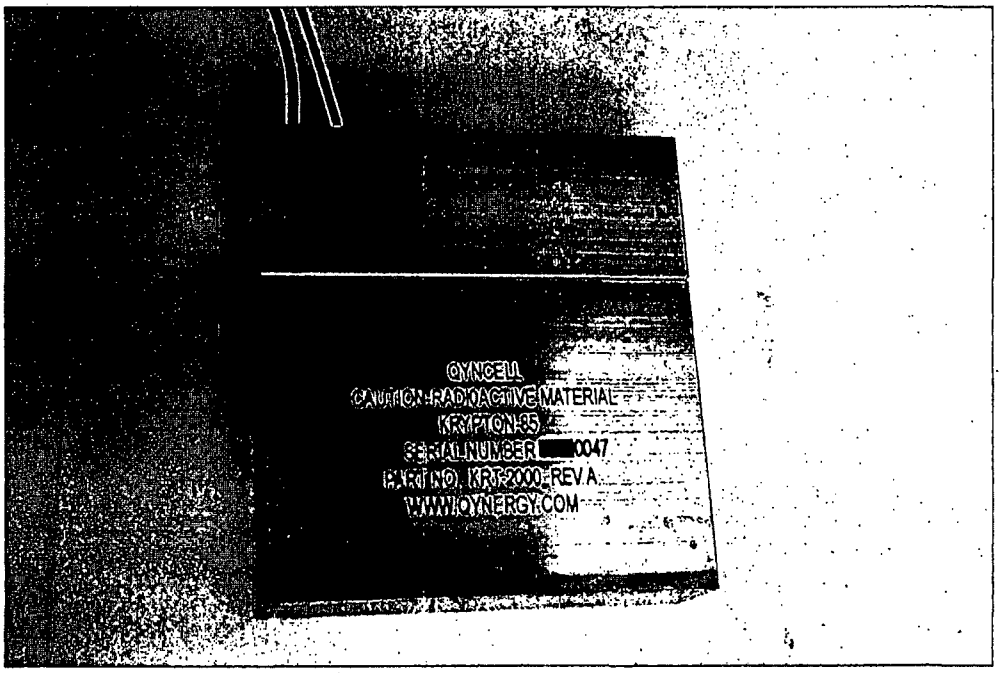
1. Establish a perimeter around the QynCell package before opening. The QynCell contains ^{85}Kr and has a gamma radiation signature. Please see the accompanying documents for dose rates.
2. Open the package according to your shipping and receiving procedures for radioactive sources.
3. Verify dose rates and perimeter location once unpacked.
4. Use lead or other heavy metal shielding to reduce exposure during installation.
5. Do not remove the screw in the cap of the QynCell.
6. There are two wires leading from the top of the QynCell. Connect the black wire to ground and the red wire to the positive input of the system you are trying to run. Connection can be via soldering iron or screw terminals. Power is immediately available just like a battery.
7. If mounting is necessary, you must use exterior metal clips to hold in place. Clip into place so that the information label is visible. Do not puncture the QynCell in any way. Do not use tape as this will cover the labeling and can degrade from radiation. Do not weld or use any adhesives to keep the QynCell in place.
8. Finish placing shielding and perimeter barriers as needed for the location in which the QynCell has been installed.

Troubleshooting/Servicing

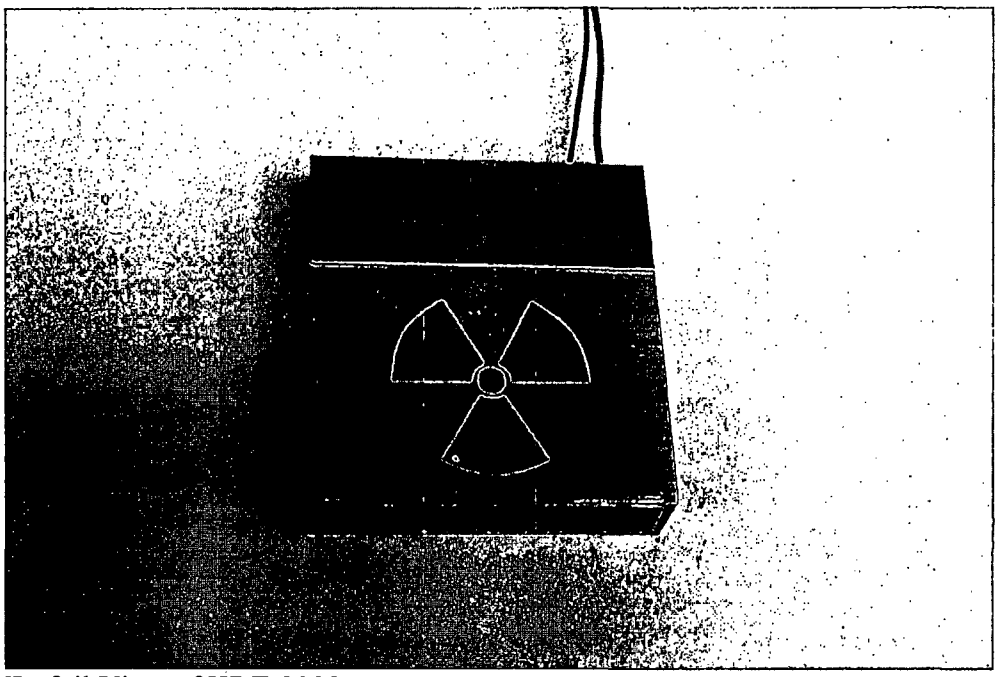
1. If the QynCell does not provide power, ensure wires are properly connected.
2. If the QynCell continues to fail to provide power, notify the manufacturer immediately. Do not attempt to repair.
3. When the QynCell stops providing adequate power, please return it to the manufacturer specified subcontractor and notify the manufacturer. Follow your shipping and receiving instructions for radioactive materials. Do not attempt to repair.

Attachment 3

KRT-2000 Label



Information Label View of KRT-2000


Trefoil View of KRT-2000

Prototype Test Report

PROPRIETARY
AND
CONFIDENTIAL

Isotope Products Laboratories
An Eckert & Ziegler Company

QYNERGY PROPRIETARY
DO NOT DISTRIBUTE

TEST PROTOCOL APPROVAL

Source Model No. 2000 QYNCELL Drawing No. QSI-KRT-2000, Rev. A (attached) 3 Sep 07

Target Sealed Source Classification: ☐ DOT: Capsule < 200 g; one dimension > 5 mm.

Tests to be performed:

☑ Temperature Class 3 ☑ Pressure Class 3 ☑ Impact Class 3
☑ Vibration Class 4 ☑ Puncture Class 4 ☐ Bending Test N/A

☑ Inactive Capsule
☐ Active Capsule Nuclide: ____ Activity: ____

LEAK TEST WILL BE BY HELIUM LEAK TEST CONDUCTED AT PTL.

INITIAL TEST PROTOCOL APPROVAL

Originator (name): LLOYD L. FLOWERS

Test Engineer - Date: 15 MAY 07

Signing indicates agreement with the testing procedures described herein

Ana R. Ramirez Date: 15 MAY 07
Director of Quality Operations/
Regulatory Affairs Manager

[signature] Date: 15 May 07
Radiation Safety Officer/Sr. Health Physicist
Alternate Radiation Safety Officer

FINAL REPORT AND SUMMARY APPROVAL

Originator (*name*): LLOYD L. FLOWERS

Test Engineer - Date: 2 JUL 07

Signing indicates agreement with all of the documentation contained within this report.

Frida Fan Date: 3 Jul 07
Director of Quality Operations /
Regulatory Affairs Manager

Ana R. Ramirez Date: 3 Jul 07
Radiation Safety Officer/ Sr. Health Physicist/
Alternate Radiation Safety Officer

Isotope Products Laboratories
An Eckert & Ziegler Company

Test Report No. TR0173
Effective Date 03 JUL 07
Control Date: 03 JUL 07
Initials RM
Page 2 of 27

Temperature Test Class 3

Capsule ID number: 0025 VERIFIED by initial: RM
Capsule ID number: 0026 VERIFIED by initial: RM

Low Temperature, ~~-40°~~ -60° C (20 minutes)

Fix thermocouple to capsule or capsule chamber to provide as accurate temperature readings of the capsule as possible. Using "dry ice", test is preformed in an atmosphere of CO_2. Source shall be cooled to the test temperature in less than 45 minutes., and held at ~~-40° C~~ -60°C (or lower) for a period of 20 minutes, then allowed to gradually re-warm to ambient temperature

Verify temperature during test using a type K thermocouple.
Set timer to 45 minutes. Start timer.
Set Timer1 for 45 minutes. Start timer. Start cooling source. Record temperature after 45 minutes -78.0°C.
Set Timer2 for 20 minutes. Start timer when the capsule or capsule chamber temperature reaches ~~-40° C.~~ -60°C. -60°C
Allow the capsule/s to soak at ~~-40° C~~ for 20 minutes.
Record the temperature reading from the thermocouple, every 5 minutes during the test.

-60°C

Start ~~-40° C~~ 20 minute soak	Temp (° C)	Initial
Temperature @ 5 minutes	-81.7	RM
Temperature @ 10 minutes	-85.3	RM
Temperature @ 15 minutes	-83.9	RM
Temperature @ 20 minutes	-81.5	RM

Allow source/sources to gradually re-warm to ambient temperature.

Test Conducted By: Mark J. Williams Date: 16 MAY 07

+200°C PER CUSTOMER'S REQUEST.

High Temperature Test, ~~+180° C~~ (1 hour)

Verify temperature during test using a type K thermocouple. Fix thermocouple to capsule or capsule chamber to provide as accurate temperature readings of the capsule as possible. Place the capsule or capsule chamber in the furnace. Set the furnace temperature to ~~+180° C~~ +200°C with a ramp time not to exceed 10 min.
Set Timer1 for 10 minutes. Start timer. Start furnace. Record temperature after 10 minutes 207°C.
Set Timer2 for 60 minutes. Start timer when the capsule or capsule chamber temperature reaches ~~+180° C.~~ +200°C. +200°C
Allow the capsule/s to soak at ~~+180° C~~ for 1 hour.
Record the temperature reading from the thermocouple, every 5 minutes.

* TEMPERATURE CHANGES PER CUSTOMER REQUEST. RM. 15 MAY 07

Isotope Products Laboratories
An Eckert & Ziegler Company

Test Report No. TR0173
Effective Date: 03 JUL 07
Control Date: 03 JUL 07
Initials: RM
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SYNERGY PROPRIETARY
DO NOT DISTRIBUTE

200°C JA. 15 MAY 07 Page of

Start ~~180° C~~ 1hr. soak	Temp (° C)	Initial
Temperature @ 5 minutes	212.5	JA
Temperature @ 10 minutes	215.2	JA
Temperature @ 15 minutes	205.8	JA
Temperature @ 20 minutes	214.6	JA
Temperature @ 25 minutes	221.7	JA
Temperature @ 30 minutes	226.8	JA
Temperature @ 35 minutes	231.9	JA
Temperature @ 40 minutes	236.0	JA
Temperature @ 45 minutes	231.5	JA
Temperature @ 50 minutes	227.2	JA
Temperature @ 55 minutes	222.3	JA
Temperature @ 60 minutes	216.6	JA

Test Conducted By: Lloyd A. Howe Date: 16 MAY 07

Temperature testing is complete perform evaluation tests.

Equipment

Equipment	Manufacturer	Model No.	IPL ID or Serial Number	Calibration Date	Calibration Due Date
Furnace	Ney-Vulcan	3-550	DKW 011611	Reference	N/A
Thermometer	Extech	422130	020508860	27 SEP 06	27 SEP 07
Timer	Control Co.	5000	221230127	13 OCT 06	13 OCT 07
500 ml quench tank	Polar Ware Co.	1062	N/A	Reference	N/A

Isotope Products Laboratories
An Eckert & Ziegler Company

Test Report No. TR0173
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~~SYNERGY PROPRIETARY~~
~~DO NOT DISTRIBUTE~~

Post Test Evaluation For TEMPERATURE **Test**

Visual examination notes:
SOME DISCOLORATION WAS OBSERVED NEAR THE GASKET REGION.
WIRES PROTRUDING FROM THE QUANCELLS MELTED AT THE POINT WHERE THEY MEET THE METAL. THIS OCCURRED WITH THE TWO CAPSULES, 0025 & 0026.
NO OTHER CHANGE OR DAMAGE OBSERVED.

☑ Inactive test source – ~~no additional leak test required~~ 11. 15 MAY 07 HELIUM LEAK TEST BY PTL.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.1.3 Immersion test with a liquid scintillator.

The source is immersed for a minimum of 3 hours at room temperature in a liquid scintillation solution, which does not attack the source's outer surface material. The source is stored away from light to avoid photoluminescence. The sealed source is then removed and the activity of the liquid scintillation is measured.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.3.1. Wet wipe test.

Wipe all surfaces of the source with swab moistened with a liquid, which will not attack the source's outer surface material. The swab is then assayed.

Test	Capsule ID	Counts per minute detected	Net Activity (nCi)	Activity limit (nCi)	Test result	Initial & Date
				5		
				5		
N/A	Background		N/A	N/A	N/A	

Instrument Information:

Instrument Manufacturer:	
Instrument Model:	
Efficiency for selected nuclide:	
Calibration Date:	
Next Calibration Date	

External Pressure Test Class 3 & 4

Capsule ID number: 0030 VERIFIED by initial: JF
Capsule ID number: 0031 VERIFIED by initial: JF

Low pressure
Temperature: ambient
Test range: atmosphere to 25 kPa abs. = **7.4 "Hg"**
Conduct the low-pressure test in air.
Place the source in the chamber and expose it to the test pressure for two periods of 5 minutes each. Use lab timer to time periods. Return the pressure to atmosphere between the periods.

Test Conducted By: Lloyd J. Flores Date: 16 May 07

High pressure
Temperature: ambient
☑ **Class 3** Test range: atmosphere to 2MPa = **276 psig**
☐ **Class 4** Test range: atmosphere to 7MPa = **1001 psig**

Conduct the high-pressure test by a hydraulic method using water as the medium of contact. Place the source in the chamber and expose it to the test pressure for two periods of 5 minutes each. Use lab timer to time periods. Return the pressure to atmosphere between the periods.

Test Conducted By: Lloyd J. Flores Date: 16 May 07

External Pressure testing is complete, perform visual and leak evaluation tests.

Equipment

NOTE: Record information on table as applicable.

Equipment	Manufacturer	Model No.	IPL ID or Serial Number	Calibration Date	Calibration Due Date
350 ml pressure vessel	Parr Instruments Co.	4760 series	N/A	N/A	N/A
0-2000 psi pressure gauge	Ashcroft	Dresser 35 1009SW0 2L 2000#/BR	PG-02-1	26 Sep 06	26 Sep 07
Vacuum pump				N/A	N/A
Pressure regulator 0-30"Hg	PRESSUREMENT	T3400/3V	9270-96	26 Sep 06	26 Sep 07
Jar	Nalgene	N/A	N/A	N/A	N/A
Timer	CONTROL Co.	5000	22123012 7	13 Oct 06	13 Oct 07

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Post Test Evaluation For EXTERNAL PRESSURE **Test**

Visual examination notes:
0030: No Change Or Damage Observed.

0031: No Change Or Damage Observed.

☑ Inactive test source – ~~no additional leak test required.~~ 11.15 May 07 Helium Leak Test By PTL.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.1.3 Immersion test with a liquid scintillator.

The source is immersed for a minimum of 3 hours at room temperature in a liquid scintillation solution, which does not attack the source's outer surface material. The source is stored away from light to avoid photoluminescence. The sealed source is then removed and the activity of the liquid scintillation is measured.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.3.1. Wet wipe test.

Wipe all surfaces of the source with swab moistened with a liquid, which will not attack the source's outer surface material. The swab is then assayed.

Test	Capsule ID	Counts per minute detected	Net Activity (nCi)	Activity limit (nCi)	Test result	Initial & Date
				5		
				5		
N/A	Background		N/A	N/A	N/A	

Instrument Information:

Instrument Manufacturer:	
Instrument Model:	
Efficiency for selected nuclide:	
Calibration Date:	
Next Calibration Date	

Impact Test Class 3

Capsule ID number: 0025 VERIFIED by initial: RM
Capsule ID number: 0026 VERIFIED by initial: RM

A 200-gram hammer is dropped onto the capsule from 1 meter. A plumb guide tube is used to guide the hammer to the target capsule. The target capsule is placed on a steel billet. The hammer is guided with the intent to strike the capsule impacting the most vulnerable area.

1. Adjust the drop height, gap the distance between the anvil and bottom of the drop tube to no less than the height of the test capsule.
2. With the release pin inserted and using a magnetic grab tool, load the 200g hammer.
3. Position the capsule. Record the capsule orientation.
4. Install acrylic test shield for containment.
5. Pull release pin to drop the hammer.
6. Using forceps gently lift weight and remove source for evaluation.

Test Conducted By: Lloyd J. Flores Date: 17 May 07

Impact test is complete; perform evaluation tests.

Equipment

NOTE: Record information on table as applicable.

Equipment	Manufacturer	Model No.	IPL ID or Serial Number	Calibration Date	Calibration Due Date
Impact Test Fixture Class 2 & 3	IPL	Custom	None	N/A	N/A
200g Hammer	IPL	Custom	IPL A6548-2-6	7 SEP 06	7 SEP 07

Impact Test Fixtures and hammers are designed to meet the requirements of ISO 2919, 7.4 Impact Test, 7.4.1 Apparatus, 7.4.1.1 Steel hammer, and 7.4.1.2 Steel anvil.

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Post Test Evaluation For IMPACT **Test**

Visual examination notes:
0025: MARKS WERE SEEN WHERE THE IMPACT WEIGHT STRUCK THE CAPSULE: NO OTHER CHANGE OR DAMAGE OBSERVED.

0026: NO CHANGE OR DAMAGE OBSERVED.

☑ Inactive test source – ~~no additional leak test required~~ 4. 15 MAY 07. HELIUM LEAK TEST BY PTL.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.1.3 Immersion test with a liquid scintillator.

The source is immersed for a minimum of 3 hours at room temperature in a liquid scintillation solution, which does not attack the source's outer surface material. The source is stored away from light to avoid photoluminescence. The sealed source is then removed and the activity of the liquid scintillation is measured.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.3.1. Wet wipe test.

Wipe all surfaces of the source with swab moistened with a liquid, which will not attack the source's outer surface material. The swab is then assayed.

Test	Capsule ID	Counts per minute detected	Net Activity (nCi)	Activity limit (nCi)	Test result	Initial & Date
				5		
				5		
N/A	Background		N/A	N/A	N/A	

Instrument Information:

Instrument Manufacturer:	
Instrument Model:	
Efficiency for selected nuclide:	
Calibration Date:	
Next Calibration Date	

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Vibration Test Class 4

Capsule ID number: 0028 Verified by initial: [illegible] (Capsule 1)
Capsule ID number: 0029 Verified by initial: [illegible] (Capsule 2)

Fix the source securely to the platform. Each test consists of 3 complete test cycles of 30 minutes duration or longer sweeping the vibration frequency from 25 Hz to 80 Hz while maintaining 1.5 mm amplitude peak to peak and sweeping the vibration frequency from 80 Hz to 2000 Hz while maintaining 20 g acceleration. Conduct the test by sweeping through all frequencies in the range at a uniform rate, from minimum to maximum and return to minimum. Test is conducted in each axis of the source per ISO2919:1999, section 7.5.2. A maximum of three axes is tested. Conduct additional tests at each resonance frequency found for 30 minutes. Use a timer to verify timed test intervals.

Capsule 1 Axis 1 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes (0.110 OCT/MIN)

Sweep 1: Date: 16 MAY 07 Start Time: 13:45:11 End Time: 14:16:05 Duration: 30 MIN 54 SEC
Sweep 2: Date: 16 MAY 07 Start Time: 14:16:10 End Time: 14:46:18 Duration: 30 MIN 8 SEC
Sweep 3: Date: 16 MAY 07 Start Time: 14:46:23 End Time: 15:16:33 Duration: 30 MIN 10 SEC

Capsule 1 Axis 1 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times, 30 minutes (0.29 OCT/MIN)

Sweep 1: Date: 18 JUN 07 Start Time: 08:20:45 End Time: 08:51:02 Duration: 30 MIN 17 SEC
Sweep 2: Date: 18 JUN 07 Start Time: 08:51:11 End Time: 09:21:35 Duration: 30 MIN 24 SEC
Sweep 3: Date: 18 JUN 07 Start Time: 09:21:42 End Time: 09:51:59 Duration: 30 MIN 17 SEC

Capsule 1 Axis 2 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes

Sweep 1: Date: 17 MAY 07 Start Time: 08:16:05 End Time: 08:46:31 Duration: 30 MIN 26 SEC
Sweep 2: Date: 17 MAY 07 Start Time: 08:46:41 End Time: 09:15:03 Duration: 30 MIN 22 SEC
Sweep 3: Date: 17 MAY 07 Start Time: 09:15:11 End Time: 09:45:29 Duration: 30 MIN 18 SEC

Capsule 1 Axis 2 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times, 30 minutes

Sweep 1: Date: 18 JUN 07 Start Time: 10:07:56 End Time: 10:38:18 Duration: 30 MIN 22 SEC
Sweep 2: Date: 18 JUN 07 Start Time: 10:38:31 End Time: 11:08:53 Duration: 30 MIN 22 SEC
Sweep 3: Date: 18 JUN 07 Start Time: 11:09:11 End Time: 11:39:40 Duration: 30 MIN 29 SEC

Capsule 1 Axis 3 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes

Sweep 1: Date: 14 JUN 07 Start Time: 12:04:48 End Time: 12:05:11 Duration: 30 MIN 23 SEC
Sweep 2: Date: 14 JUN 07 Start Time: 12:05:20 End Time: 12:35:46 Duration: 30 MIN 26 SEC
Sweep 3: Date: 14 JUN 07 Start Time: 12:36:05 End Time: 13:06:27 Duration: 30 MIN 22 SEC

Capsule 1 Axis 3 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times, 30 minutes

Sweep 1: Date: 20 JUN 07 Start Time: 11:52:11 End Time: 12:22:34 Duration: 30 MIN 23 SEC
Sweep 2: Date: 20 JUN 07 Start Time: 12:22:51 End Time: 12:53:15 Duration: 30 MIN 24 SEC
Sweep 3: Date: 20 JUN 07 Start Time: 12:53:25 End Time: 13:28:47 Duration: 30 MIN 22 SEC

Capsule 2 Axis 1 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes

Sweep 1: Date: 17 May 07 Start Time: 09:46:10 End Time: 10:16:24 Duration: 30 MIN 14 SEC
Sweep 2: Date: 17 May 07 Start Time: 10:16:31 End Time: 10:46:49 Duration: 30 MIN 18 SEC
Sweep 3: Date: 17 May 07 Start Time: 10:46:53 End Time: 11:17:11 Duration: 30 MIN 18 SEC

Capsule 2 Axis 1 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times, 30 minutes

Sweep 1: Date: 18 Jun 07 Start Time: 12:12:24 End Time: 12:42:45 Duration: 30 MIN 21 SEC
Sweep 2: Date: 18 Jun 07 Start Time: 12:42:55 End Time: 13:13:11 Duration: 30 MIN 16 SEC
Sweep 3: Date: 18 Jun 07 Start Time: 13:43:40 End Time: 13:43:59 Duration: 30 MIN 19 SEC

Capsule 2 Axis 2 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes

Sweep 1: Date: 22 May 07 Start Time: 13:28:56 End Time: 13:59:14 Duration: 30 MIN 18 SEC
Sweep 2: Date: 22 May 07 Start Time: 14:02:11 End Time: 14:32:29 Duration: 30 MIN 18 SEC
Sweep 3: Date: 22 May 07 Start Time: 14:33:12 End Time: 15:03:29 Duration: 30 MIN 17 SEC

Capsule 2 Axis 2 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times, 30 minutes

Sweep 1: Date: 18 Jun 07 Start Time: 14:44:23 End Time: 15:16:45 Duration: 30 MIN 22 SEC
Sweep 2: Date: 18 Jun 07 Start Time: 15:16:53 End Time: 15:37:16 Duration: 30 MIN 23 SEC
Sweep 3: Date: 18 Jun 07 Start Time: 15:37:25 End Time: 16:07:54 Duration: 30 MIN 29 SEC

Capsule 2 Axis 3 25 Hz to 80 Hz to 25 Hz at 1.5 mm amplitude, 3 times, 30 minutes

Sweep 1: Date: 14 Jun 07 Start Time: 13:44:25 End Time: 14:14:38 Duration: 30 MIN 18 SEC
Sweep 2: Date: 14 Jun 07 Start Time: 14:14:45 End Time: 14:45:05 Duration: 30 MIN 20 SEC
Sweep 3: Date: 14 Jun 07 Start Time: 14:45:11 End Time: 15:15:23 Duration: 30 MIN 12 SEC

Capsule 2 Axis 3 80 Hz to 2000 Hz to 80 Hz at 20g acceleration, 3 times 30 minutes

Sweep 1: Date: 20 Jun 07 Start Time: 14:02:11 End Time: 14:32:34 Duration: 30 MIN 23 SEC
Sweep 2: Date: 20 Jun 07 Start Time: 14:32:40 End Time: 15:03:05 Duration: 30 MIN 25 SEC
Sweep 3: Date: 20 Jun 07 Start Time: 15:03:11 End Time: 15:33:35 Duration: 30 MIN 24 SEC

Test notes and deviations
Recorded By Lloyd L. Flowers Date 2 Jul 07 Reviewed and Approved Judd Jan Date 3 Jul 07
Noted resonance frequencies No Resonance Frequencies Detected for Capsules 0028 and 0029.

Test Conducted By: Lloyd L. Flowers Date: 2 Jul 07

Vibration testing is complete; perform visual and leak evaluation tests.

Equipment

NOTE: Record information on table as applicable.

Equipment	Manufacturer	Model No.	IPL ID or Serial Number	Calibration Date	Calibration Due Date
Amplifier	MB Dynamics	SS250	007518	N/A	N/A
Shear Accelerometer	Kistler	8636B50 M05	20607	15 Sep 05	15 Sep 07
Shear Accelerometer	PCB	J353 B01	10422 or 10421 (As underlined)	15 Sep 05	15 Sep 07
Timer	Control Company	5000	221230127	13 Oct 06	13 Oct 07

* For reference use only.

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Post Test Evaluation For VIBRATION **Test**

Visual examination notes:
No Change Or Damage Observed For Both Capsules That Were Tested For The Vibration Parameters, 0028 & 0029.

☑ Inactive test source – ~~no additional leak test required~~ 15 May 07 Helium Leak Test By PTL.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.1.3 Immersion test with a liquid scintillator.

The source is immersed for a minimum of 3 hours at room temperature in a liquid scintillation solution, which does not attack the source's outer surface material. The source is stored away from light to avoid photoluminescence. The sealed source is then removed and the activity of the liquid scintillation is measured.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.3.1. Wet wipe test.

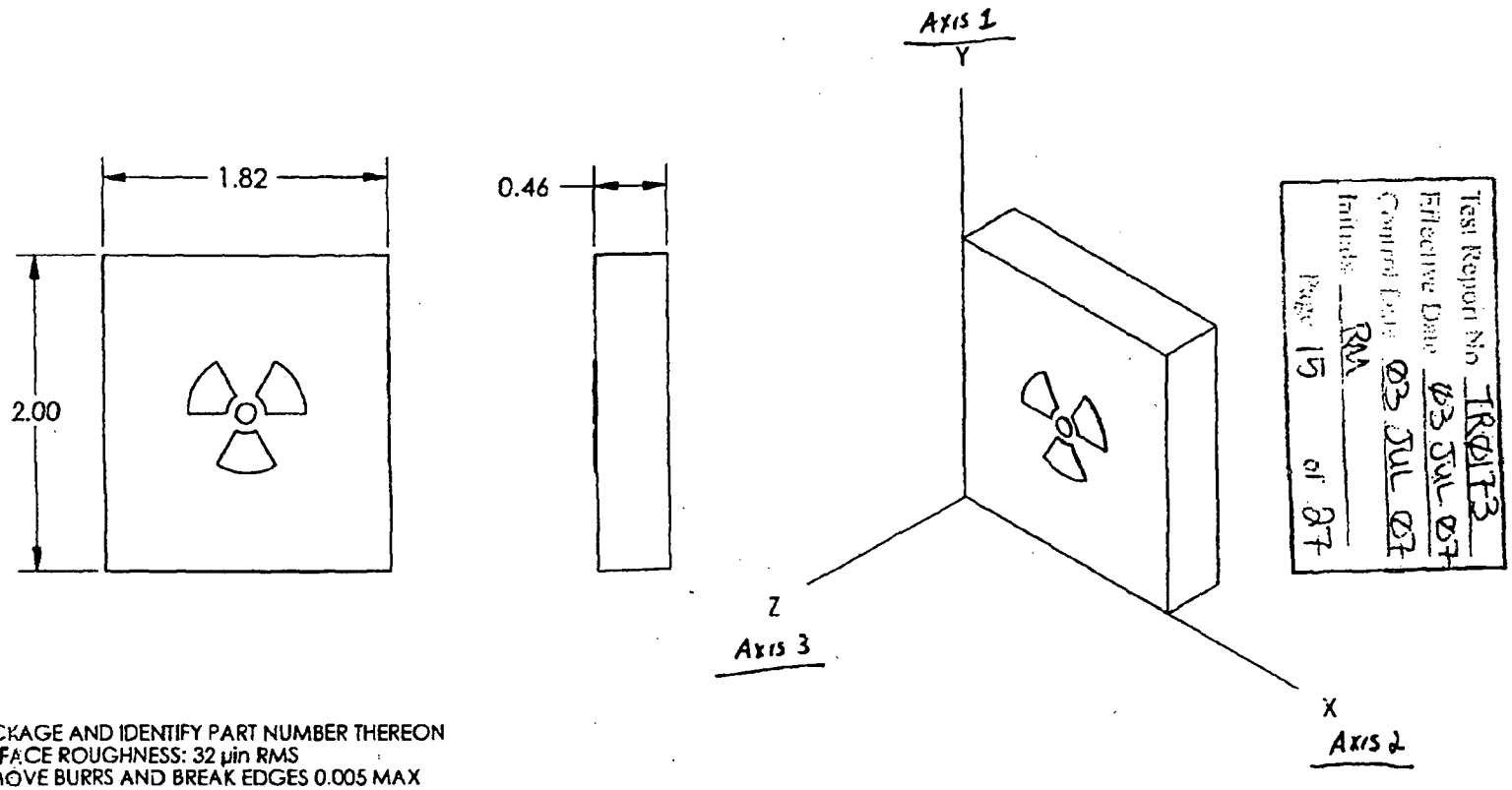
Wipe all surfaces of the source with swab moistened with a liquid, which will not attack the source's outer surface material. The swab is then assayed.

Test	Capsule ID	Counts per minute detected	Net Activity (nCi)	Activity limit (nCi)	Test result	Initial & Date
				5		
				5		
N/A	Background		N/A	N/A	N/A	

Instrument Information:

Instrument Manufacturer:	
Instrument Model:	
Efficiency for selected nuclide:	
Calibration Date:	
Next Calibration Date	

Axes Used In Vibration Testing



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4. PACKAGE AND IDENTIFY PART NUMBER THEREON
3. SURFACE ROUGHNESS: 32 µin RMS
2. REMOVE BURRS AND BREAK EDGES 0.005 MAX
1. MATERIAL:
NOTES: UNLESS OTHERWISE SPECIFIED

P/N

Eckert & Ziegler
Isotope Products
Valencia, California 91355

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES; METRIC UNITS (mm) ARE IN MILLIMETERS.

TOLERANCES (UNLESS OTHERWISE SPECIFIED)
X.XXX ± .003 INCH ANGULAR TOLERANCE OF 0°±30'
X.XX ± .005 INCH FRACTIONAL DIMENSIONS ±1/32"
X.X ± .03 INCH REFERENCE DIMENSIONS () N/A
X. ± .1 INCH SURFACE ROUGHNESS µINCH MAX
ALL DIMENSIONS ARE FINISHED DIMENSIONS

THIRD ANGLE PROJECTION

DRAWN	THK
ME/CHECKER	LF
ENGINEER	THK
SCALE	NONE
SIZE	A
TITLE	QYNERGY CAPSULE
SERIES TITLE	DRAFT
CAGE CODE	32993
DRAWING NO.	Qynergy
REV	0
SHEET	1 OF 1

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Change Date: 03 JUL 07
Initials: RM
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Puncture Test Class 4

Capsule ID number: 0025 VERIFIED by initial: [signature]
Capsule ID number: 0026 VERIFIED by initial: [signature]

A 50-gram hammer/pin is dropped onto the capsule from 1 meter. A plumb guide tube is used to guide the hammer to the target capsule. The target capsule is placed on a steel billet. The hammer is guided with the intent to strike the capsule impacting the most vulnerable area.

1. Adjust the drop height, gap the distance between the anvil and bottom of the drop tube to no less than the height of the test capsule.
2. With the release pin inserted and using a magnetic grab tool, load the 50g hammer/pin.
3. Position the capsule. Record the capsule orientation.
4. Install acrylic test shield for containment.
5. Pull release pin to drop the hammer.
6. Using forceps gently lift weight and remove source for evaluation.

Test Conducted By: [signature] Date: 17 May 07

Puncture test is complete perform evaluation tests.

Equipment	Manufacturer	Model No.	IPL ID or Serial Number	Calibration Date	Calibration Due Date
Puncture Test Fixture Class 4, 5 & 6	IPL	Custom	None	N/A	N/A
50g Hammer/pin	IPL	Custom	IPL A6550-3	7 SEP 06	7 SEP 07

Puncture Test Fixtures and hammer/pins are designed to meet the requirements of ISO 2919, 7.6 Puncture Test, 7.6.1 Apparatus, 7.6.1.1 Steel hammer, and 7.6.1.2 Hardened steel anvil.

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Post Test Evaluation For PUNCTURE **Test**

Visual examination notes:
0025: A SMALL DENT WAS EVIDENT FOLLOWING THE PUNCTURE TEST. THE DENT WAS AT THE POINT OF PUNCTURE. NO OTHER CHANGE OR DAMAGE OBSERVED.

0026: SAME OBSERVATIONS AS ABOVE.

UPON SHAKING BOTH CAPSULES, THERE WAS SOUND OF SOMETHING LOOSE WITHIN THE CAPSULE.

☑ Inactive test source – ~~no additional leak test required~~ 11 MAY 07 HELIUM LEAK TEST BY PTL.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.1.3 Immersion test with a liquid scintillator.

The source is immersed for a minimum of 3 hours at room temperature in a liquid scintillation solution, which does not attack the source's outer surface material. The source is stored away from light to avoid photoluminescence. The sealed source is then removed and the activity of the liquid scintillation is measured.

☐ Leak test evaluation shall be by ISO 9978:1992(E) 5.3.1. Wet wipe test.

Wipe all surfaces of the source with swab moistened with a liquid, which will not attack the source's outer surface material. The swab is then assayed.

Test	Capsule ID	Counts per minute detected	Net Activity (nCi)	Activity limit (nCi)	Test result	Initial & Date
				5		
				5		
N/A	Background		N/A	N/A	N/A	

Instrument Information:

Instrument Manufacturer:	
Instrument Model:	
Efficiency for selected nuclide:	
Calibration Date:	
Next Calibration Date	

Test notes and deviations

Recorded By LLOYD L. FLOWERS Date 2 JUL 07
Reviewed and Approved Omar Ramirez Date 3 Jul 07

TEST SOURCES OF ACTUAL SIZE, FILLED WITH HELIUM GAS, WERE SUBJECTED TO VARIOUS TESTS.

THE TESTING PARAMETERS FOLLOWED WERE TEMPERATURE CLASS 3, PRESSURE CLASS 3, IMPACT CLASS 3, VIBRATION CLASS 4, AND PUNCTURE CLASS 4, IN ACCORDANCE WITH ISO 2919(1999).

THE TEMPERATURE TEST RANGE WAS FROM -60°C (LOW TEMPERATURE) AND 200°C (HIGH TEMPERATURE). THERE WAS SOME DISCOLORATION NEAR THE GASKET REGION OF THE CELLS. WIRES PROTRUDING FROM THE CELLS MELTED AT THE POINT WHERE THEY MEET THE METAL.

THE IMPACT TEST LEFT THE MARK OF THE TEST WEIGHT ON THE CELLS. THE MARKS ON ONE CELL WAS READILY EVIDENT.

THE PUNCTURE TEST LEFT A SMALL DENT AT THE POINT OF IMPACT ON ONE CELL. SOME LOOSE MATERIAL WAS HEARD ON BOTH CAPSULES UPON SHAKING.

NO OTHER CHANGE OR DAMAGE WAS OBSERVED.

UPON COMPLETION OF THE TESTS CONDUCTED 16 MAY 07 THROUGH 20 JUN 07, THE CAPSULES WERE SUBMITTED TO PACIFIC TESTING LABORATORIES, INC. FOR HELIUM LEAK TESTING PER ISO 9978, 6.1. SEE ATTACHED PTL REPORTS.

AS A RESULT OF THE TEST SOURCES PASSING ALL THE PHYSICAL TESTS TO WHICH THEY WERE SUBJECTED, IT IS RECOMMENDED THAT THE 4002-KRT-2000 CAPSULES BE CLASSIFIED AS ISO/99/C33344.

REVISIONS			
REV	DESCRIPTION	DATE	APPROVED
A	UPDATED PART LIST, ASSEMBLY DRAWING AND VIEW. UPDATED TITLE BLOCK	[illegible]	[illegible]

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Date 02 JUL 03
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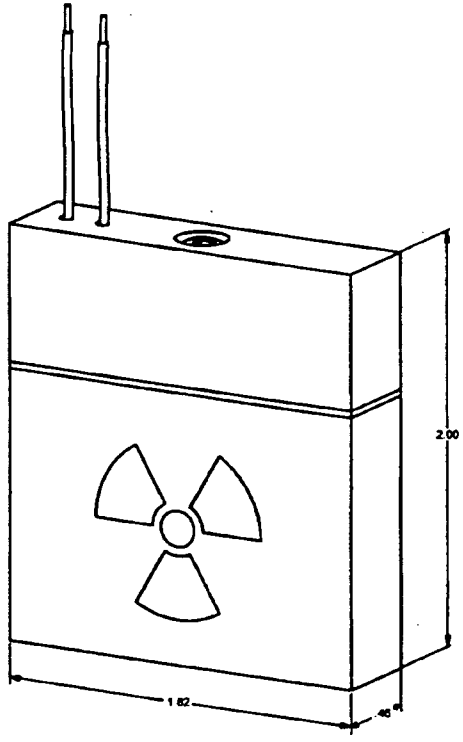

ISO VIEW SHOWING LOADED GYNCELL

NOTES UNLESS OTHER WISE SPECIFIED

1. ALL DIMENSIONS IN INCHES
2. DIMENSIONS AND TOLERANCING PER ASME Y 14.5M-1994
3. ASSEMBLE PER KRT-2000 ASSEMBLY PROCEDURE
4. LASER ETCH OR EQUIVALENT, TREFOIL ON SIDE S-HOWN FOLLOWING TEXT OTHER SIDE CENTERED

GYNCELL
CAUTION - RADIOACTIVE MATERIAL
KRYPTON-85
ACTIVITY
DATE OF LOADING
SERIAL NUMBER
PART NO. KRT-2000 REV
WWW.GYNERGY.COM

5 APPLY THREAD LOCKER PER LOCTITE SPECS

APPROXIMATE MASS: 100 GRAMS

ITEM	QTY	PART NO.	DESCRIPTION	MATERIAL
14	A/R	[illegible]	POLYURETHANE	POLYURETHANE
13	A/R	[illegible]	NON CONDUCTIVE EPOXY	EPOXY
12	A/R	[illegible]	22 GA. WIRE-BLACK	COPPER/TIN/AR
11	A/R	[illegible]	22 GA. WIRE-RED	COPPER/TIN/AR
10	1	[illegible]	CAP TUBE TO MP VCR ADAPTER	304 SST
9	A/R	[illegible]	ELECTRICALLY CONDUCTIVE EPOXY	EPOXY
8	A/R	[illegible]	LOCTITE 271 HIGH STRENGTH THREAD LOCKER	EPOXY
7	1	[illegible]	MACHINED LID, UMLO	SST
6	1	[illegible]	MACHINED 44 UMLO	SST
5	1	[illegible]	HEAD TERMINAL	SST
4	A/R	[illegible]	22 GA. WIRE	COPPER/TIN/AR
3	1	[illegible]	SOLDER	TIN/LEAD
2	1	KRT-2000-1 REV A	PC BOARD ASSEMBLY	PC BOARD
1	1	KRT-2100-1 REV A	LID ASSEMBLY	ELECTROFORM/ALLOYS
4	1	KRT-2004-1 REV A	BOTTOM CAP	SST
3	1	KRT-2003-1	GASKET	METAL
2	1	KRT-2002-1 REV A	CAP	SST
1	1	KRT-2001-1 REV A	CASE	SST

PARTS LIST

KRT-2000	GYNCELL KR-85 GYNCELL MODEL KRT-2000 GYNCELL
KRT-2000	A D 1 of 2

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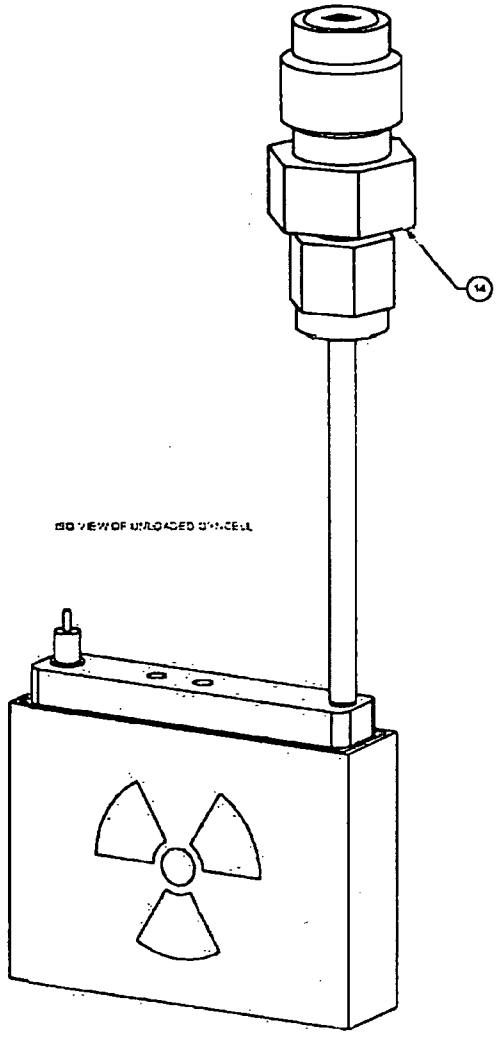
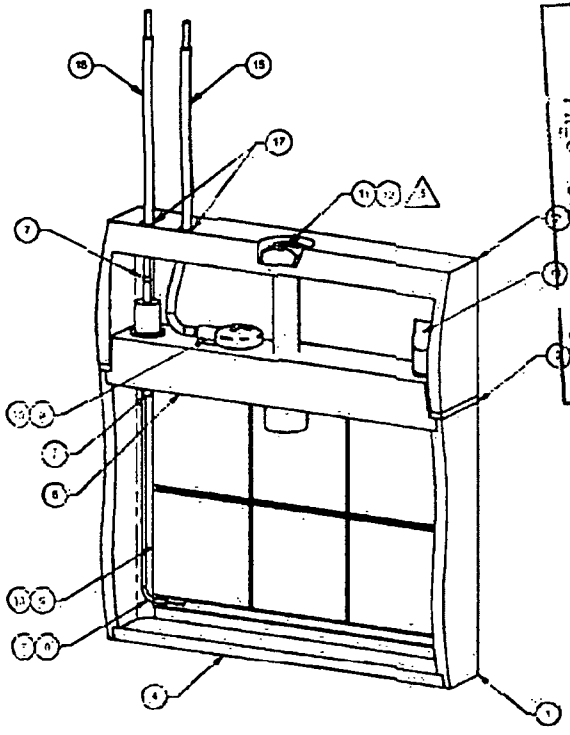


ISO VIEW OF UNLOADED QYNCELL



CUTAWAY ISO VIEW OF LOADED QYNCELL

REVISIONS			
REV	DESCRIPTION	DATE	APPROVED
A	[illegible]	[illegible]	[illegible]

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	Qynergy
KRT-2000	QYNCELL KR-48 QYNCELL MODEL KRT-2000 QYNCELL
	KRT-2000 A D 2 of 2

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PACIFIC TESTING LABORATORIES, INC.
24950 Avenue Tibbitts, Valencia, CA 91355-3426, USA
TEL: (661) 257-1437
FAX: (661) 257-2411

Test Report No. TR070628
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TEST REPORT

In Account With ISOTOPE PRODUCTS LABORATORIES 24937 Avenue Tibbitts Valencia, CA 91355 Attn: Lloyd Flowers	Date June 28, 2007	Page 1 of 7 Pages
	W.O. Number 34908	Specification None specified
	P.O.No. 30453	Received 06-21-2007

IDENTIFICATION : Six (6) 'Capsules' were submitted by the customer for Helium Leak Testing in accordance Isotope Products purchase order number 30453. The 'Capsules' were identified as follows:

IDENTIFICATION

Qyncell Dummy Sealed Helium Source, P/N KRT-2000, Rev. A
S/N's 0025, 0026, 0028, 0029, 0030, and 0031

SPECIFICATION : None specified.

REFERENCE : Purchase Order Number 30453.

TESTING : Helium Leak Test(Bell Jar).

SUMMARY : No leakage, in excess of 1.0 X 10^{-8} ATM cc/sec of helium, was detected on six (6) 'Capsules' identified within this report. The test results, reported herein, are submitted for customer evaluation.

Respectfully submitted,
PACIFIC TESTING LABORATORIES, INC.

Michael Shin
Laboratory Director

Donald W. Belanger
Staff Engineer

HELIUM LEAKAGE RATE TESTING

INTRODUCTION : Six (6) 'Capsules' were submitted by the customer for helium leak testing in accordance with Isotope Products purchase order number 30453.

REQUIREMENT : Isotope Products Laboratories purchase order number 30453:

'Helium leak rate shall not exceed 1.0 x 10^{-8} ATM cc/sec'

CONDITIONING : None, tested in an 'as received' condition.

TEST METHOD : The vacuum chamber background was measured and recorded prior to each of the six capsules being helium leak tested. The vacuum chamber was evacuated to the required test pressure of one atmosphere without the specimen. The helium leak rate was recorded every 5 seconds for a period of one minute. This data will be considered the background helium indication of the empty vacuum chamber.

The Capsules were individually placed into a vacuum chamber that was attached to a Helium Leak Detector and the chamber was evacuated to the required test pressure of one atmosphere. The helium leak rate test data was recorded every five seconds for a period of approximately one minute.

The specimen was subjected to the helium leak test as stated in this report using a Varian Leak Detector Model Number 960, I.D. Number EC0698. The leak detector was calibrated using a Veeco Calibrated Helium Leak, Model Number SC-4, Serial Number 19256, ID# EC0856, (calibrated 08/15/2006, calibration due 08/15/2007). The sensitivity of the instrument was such to detect a leak greater than or equal to 2.0 X 10^{-11} ATM cc/sec of helium, with an external pressure of one atmosphere.

The background helium indication of the empty vacuum chamber was subtracted from the recorded helium leak rate test data for each capsule tested as stated within this report. The test result at the end of the one minute test time was recorded as the 'net leak rate' for each capsule.

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RESULTS :

All of the capsules received were visually examined prior to testing.

Capsule S/N 0025 and 0026, when individually placed into the vacuum chamber, expirenced a delay in the evacuation time required to reach proper test pressure of approximately 10 to 15 seconds. It was observed in the visual inspection that the material encapsulating the wire feed through on the capsules was different in color from the remaining four capsules received for testing. See photographs at the end of this report. This material could be expirencing outgassing when the vacuum pressure was applied. This outgassing increases the test pressure during the test which translates to a higher helium indication which may not necessarily be due to helium gas present. A helium leak was determined after the 60 second test time. The 'net leak rate' for each capsule is indicated on the following pages of this report.

Capsule S/N 0028, 0029, 0030 and 0031, when invidually placed into the vacuum chamber, did achieve the required test pressure for testing. The 'net leak rate' for each capsule is indicated on the following pages of this report.

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RESULTS : **continued:**

HELIUM LEAK RATE DATA

SPECIMEN	Observed Helium Leak Rate
	Atm cc/sec
Qyncell Dummy Sealed Source Helium, S/N 0025	8.0×10^{-9}
Qyncell Dummy Sealed Source Helium, S/N 0026	7.8×10^{-9}
Qyncell Dummy Sealed Source Helium, S/N 0028	$< 1.0 \times 10^{-9}$
Qyncell Dummy Sealed Source Helium, S/N 0029	$< 1.0 \times 10^{-9}$
Qyncell Dummy Sealed Source Helium, S/N 0030	$< 1.0 \times 10^{-9}$
Qyncell Dummy Sealed Source Helium, S/N 0031	$< 1.0 \times 10^{-9}$

SUMMARY : **The test results, reported herein, are submitted for customer evaluation. See photographs of capsules on following pages. Helium leak rates reported are observed leak rates and does not necessarily conclude that no leaks are existing.**

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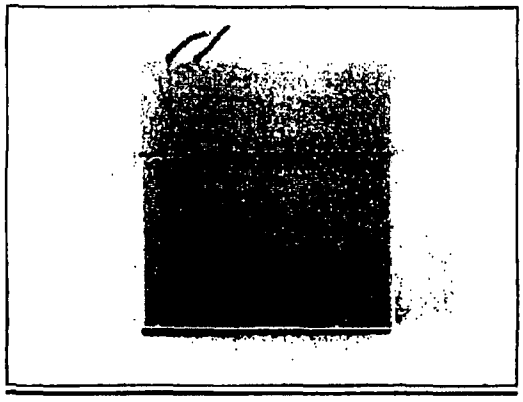
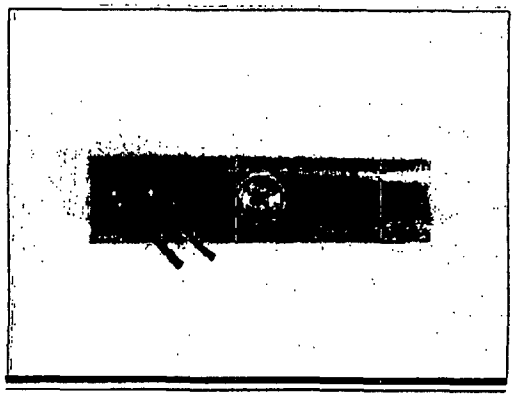
PHOTOGRAPHS

Capsule S/N 0025





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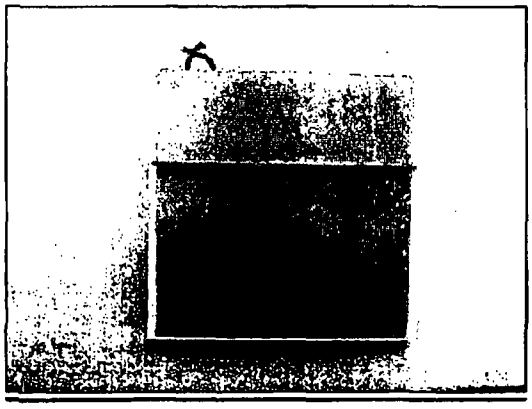

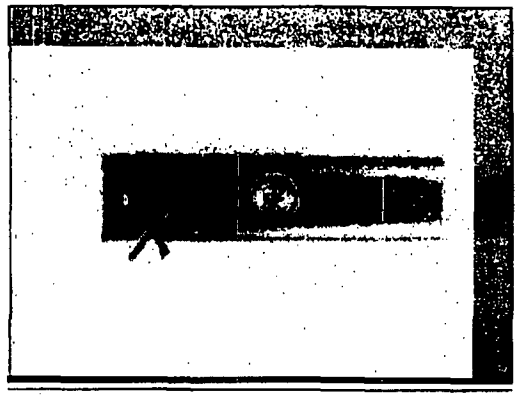

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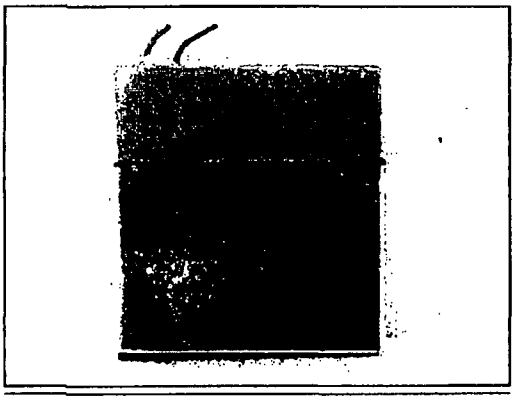
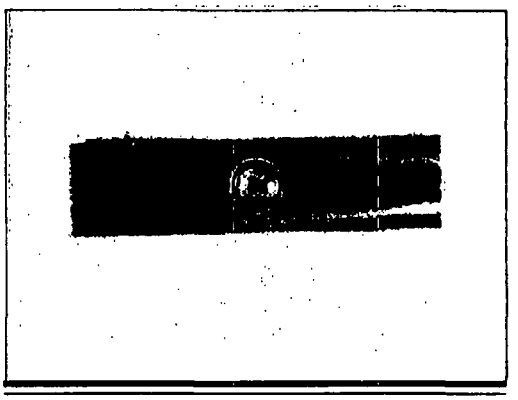
PHOTOGRAPHS

Capsule S/N 0028





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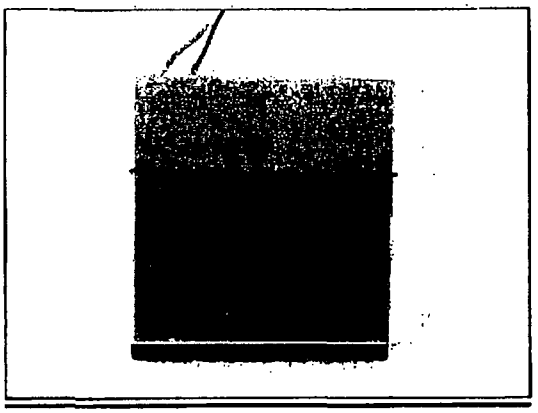

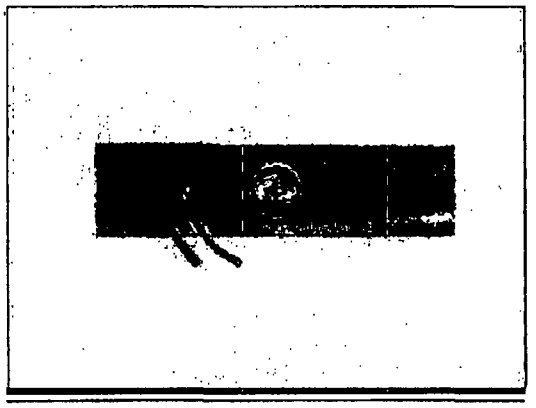

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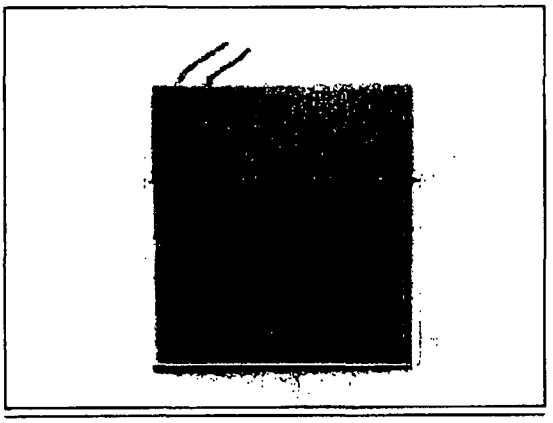
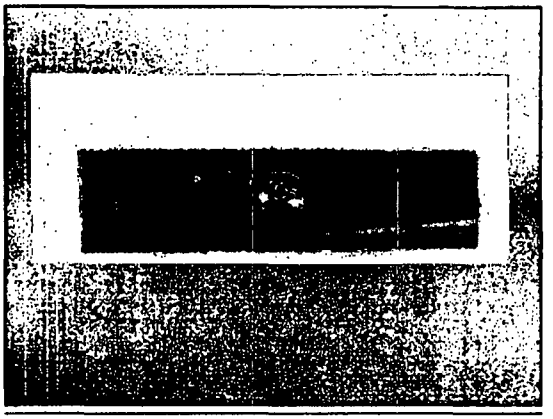
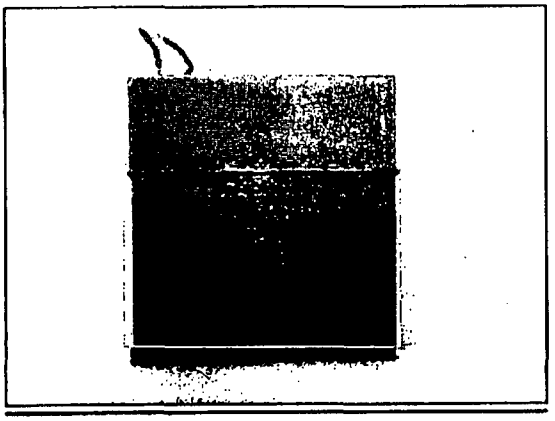
PHOTOGRAPHS

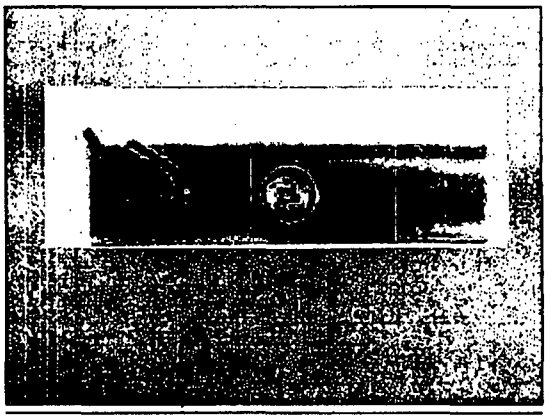
Capsule S/N 0030





Capsule S/N 0031





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Eckert & Ziegler Isotope Products

Addendum to Test Report TR0173

Capsule Test Date: 3 Jul 07
Capsule Tested: KRT-2000
Revision Date: 24 Jul 07

The changes to TR0173 are documented in the following summary:

1. The classification is changed from ISO/99/C33344 to ISO/99/CX3344. The change from 3 to X indicates that the temperature test was a special test. As noted in the test report (TR0173), the temperature range was from -60° C to 200°C instead of the temperature classification 3 with the temperature range of -40°C to 180°C. Pages 1 and 2 should read Temperature Class X.

2. The model number of the capsules is changed from 4002-KRT-2000 to KRT-2000. This change will affect page 18 of the test report.

3. The welding callout on the drawing needs to be indicated on the drawing. Page 2 of the drawing (KRT-2000 Rev. A) does not have the welding callout. The attached page 2 of the drawing will replace this page of the test report, page 20.

The above amendments are clerical and do not affect the test report. The addendum will be attached to test report TR0173.

Lloyd J. Flowers — Test Engineer — 25 Jul 07 — Date

Frida Jan — Director of Quality Operations/ Regulatory Affairs Manager — 26 Jul 07 — Date

Ana R. Ramirez — ~~Radiation Safety Officer~~/Sr. Health Physicist/ Alternate Radiation Safety Officer — 26 Jul 07 — Date

Test Report No. TR0173
Effective Date: 26 Jul 07
Control Date: 26 Jul 07
Initials: MS
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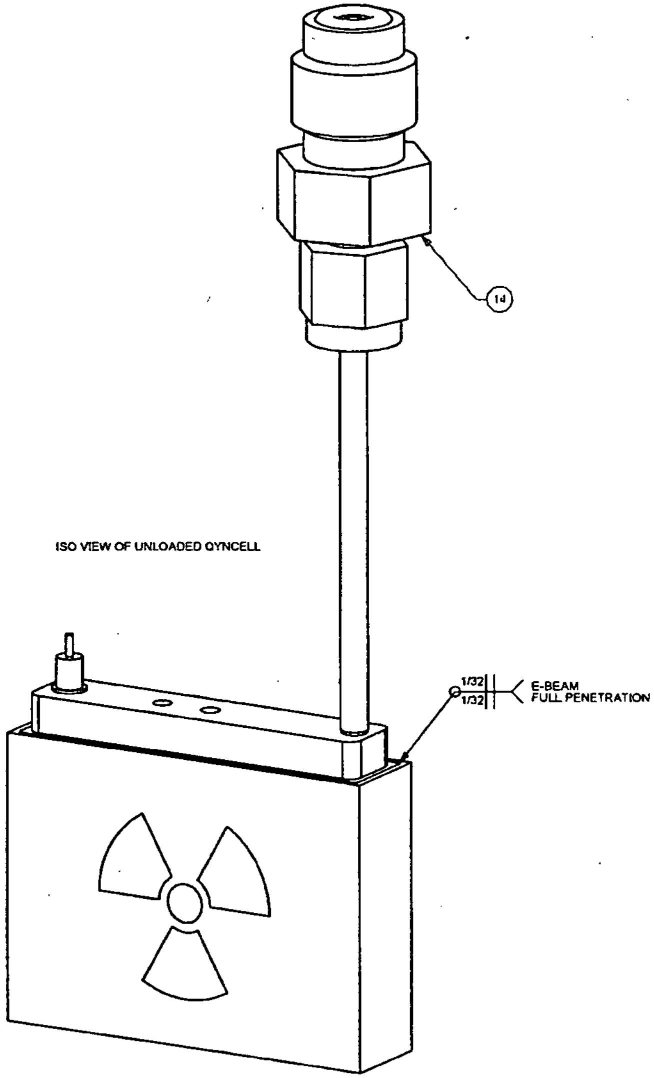
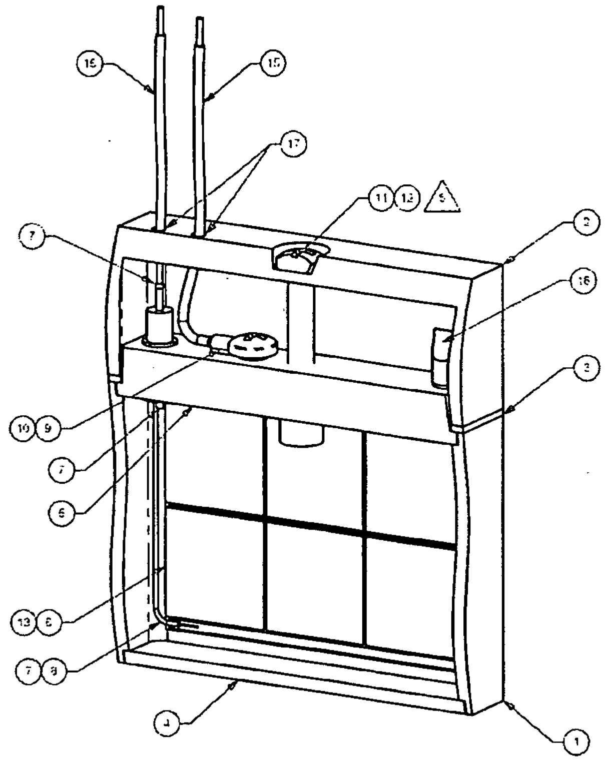
REV	DESCRIPTION	DATE	APPROVED
A	UPDATED PART LIST, ADDED UNLOADED VIEW, UPDATED TITLE BLOCK	02/23/07	C. EITING



ISO VIEW OF UNLOADED QYNCELL



CUTAWAY ISO VIEW OF LOADED QYNCELL

Qynergy®
www.qynergy.com

QYNCELL
KR-85 QYNCELL
MODEL KRT-2000 QYNCELL

	SIGNATURE
Drawn	Edward Romero
Checked	Edward Romero
Approved	Chris Eiting

KRT-2000

KRT-2000 A D 2 of 2

FOIA-2009-0020A

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ARE BEING WITHHELD IN THEIR ENTIRETY

FOIA EXEMPTION 4

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Quality Manual

Approval Log

	Name & Title	Phone & E-Mail	Signature & Date
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Revision Log

Revision	Date	Author(s)	Summary of Revisions/Comments
A	8/1/07	Stephanie Jones and Chris Eiting	Initial release

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1 ORGANIZATION

Qynergy Corporation is organized in the following manor:

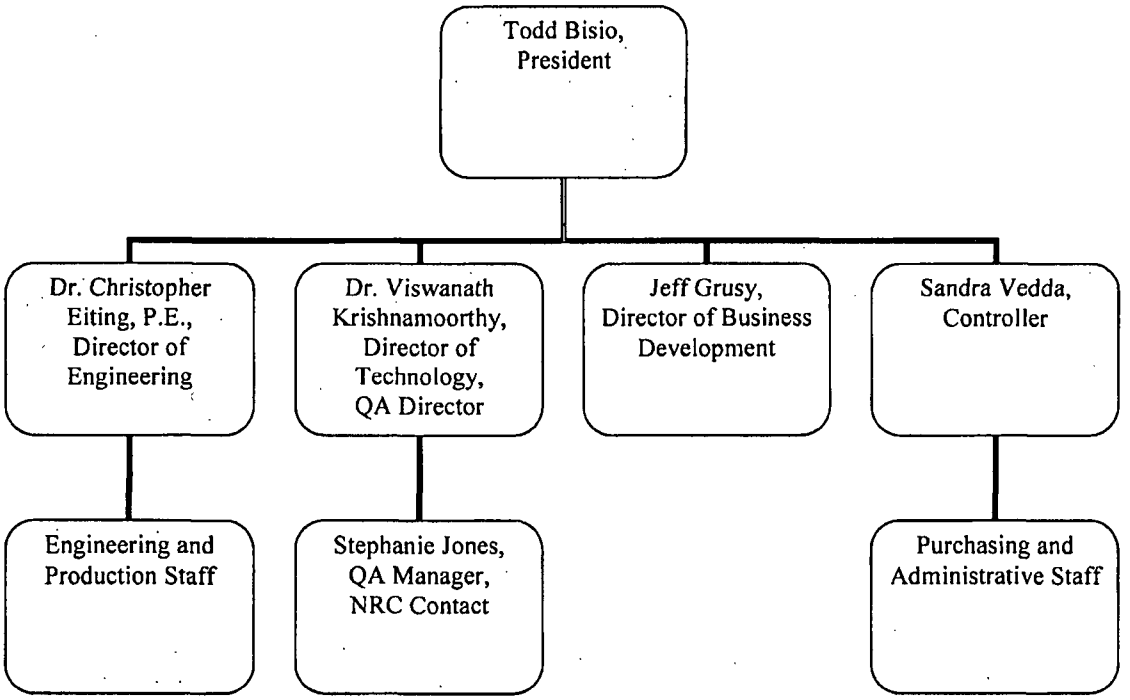

Figure 1: Organizational chart.

The primary responsibilities of the principles are:

- President – steward of corporate mission and strategy; primary interface with Board of Directors; final budget authority
- Director of Engineering – directs engineering and production staff; final design and production authority
- Director of Technology, QA Director – directs internal research & development efforts; final Quality Program authority; authorized to halt production for quality issue
- Director of Business Development – directs business development and marketing efforts
- Controller – directs accounting and purchasing-related activities
- QA Manager – ensures QA Program is enforced; ensures safety regulations are followed; serves as NRC contact; authorized to halt production for quality issue

2 PERSONNEL

All employees of Qynergy must be qualified to perform their jobs and trained appropriately. Personnel files for every employee are maintained by the Controller and include: resumes (complete with education and work experience), training certificates, employee evaluations, and medical records (as appropriate).

2.1 Training

On-the-job, task-specific training is accomplished as necessary. When an employee has been trained for a specific task, the QA Manager ensures that a Training Certificate is completed and filed in the employee's personnel file. Formal training, such as off-site software training, coursework, etc. is also documented in the same way.

2.2 Qualified Users

Any employee who has been trained on a piece of equipment or to perform a specific task is known as a "Qualified User". The QA Manager maintains a master Qualified User List which is located in the directory "S:\Quality Assurance\Personnel Training Records".

2.3 Evaluations

Employees are evaluated by their supervisors on an annual basis. Evaluations are based on observations of employee work habits and skills, as well as progress toward specific individually defined goals. All evaluations are documented and filed in the personnel files. Supervisors are responsible for ensuring proper documentation of employee evaluations.

2.4 Medical Records

Qynergy does not currently keep any employee medical records on file. If, in the future, specific medical records are identified that may affect job performance, supervisors will be responsible for adding these documents to the personnel files.

3 EQUIPMENT

All test and measurement equipment used for production or testing of Qynergy products is controlled, calibrated, and maintained. Each piece of equipment has a log file for recording maintenance and calibration activities.

3.1 Equipment Log

A log file (stored in "S:\Quality Assurance\Equipment Logs") exists for every piece of equipment used for production or testing of Qynergy products. The file is updated after every maintenance and calibration event. The file includes: manufacturer, model and serial number, calibration procedures, calibration frequency, qualified calibration personnel, date calibrated, due date for calibration, procedures for and records of routine and unscheduled maintenance, nature of the maintenance performed, date maintenance was performed, date equipment is due for maintenance, and the frequency of the maintenance.

3.2 Calibration

All equipment used for production or testing of Qynergy products that can be calibrated is on a yearly calibration schedule. All calibration standards are traceable to NIST or an equally valid national authority. The Calibration Reminder file in "S:\Quality Assurance\Equipment Logs" lists all equipment requiring calibration, along with due date, calibration date, and calibrator (company or individual). The file automatically

highlights equipment that is due for calibration within the next 30 days. Once calibration has occurred, the calibration certificate (if external calibration) is scanned and saved to the "S:\Quality Assurance\Calibration Certificates" directory and the equipment log is updated. All calibrated equipment is marked with a calibration sticker that contains the due date, calibration date, and calibrator (company or individual).

3.3 Special Equipment

Pieces of equipment used for production or testing of Qynergy products that require special handling or storage procedures are marked as such. A label with the special procedures is affixed to the equipment or case.

4 DESIGN AND DOCUMENT CONTROL

All aspects of the design and production of Qynergy products are documented. The QA Manager is responsible for ensuring that all documents contain all pertinent information and conform to all pertinent regulations and specifications.

4.1 Document Control

All documents that are related to a Qynergy product are revision controlled. The latest version of every document is approved by the QA Manager and all affected department heads. An approval signature block and a modification summary are included at the beginning of every product-related document. Once a document version has been approved, the QA Manager converts it to PDF and releases it for use. Only the released versions (approved and converted to PDF) of documents are available for use; this ensures document revisions are not used until ready. Released versions of all product-related documents are kept in the "S:\Quality Assurance" in their appropriate folders. The Master Document List (also in "S:\Quality Assurance") contains all of the released documents titles, version numbers, dates of release, primary author, and whether the document is currently under revision. Any substantive change to a controlled document causes a revision; minor grammatical or spelling changes do not. The NRC Contact is responsible for notifying the NRC of any revisions pertinent to an NRC licensed device.

4.2 Top Level Assembly Drawing

Every product has a unique part number which also serves as the name of the Top Level Assembly Drawing for the product. The Top Level Assembly Drawing includes drawings of the assembled product as well as references to all other documents associated with the product. The final Top Level Assembly Drawing for every product is located in the "S:\Quality Assurance\Design Records\Top Level Assembly Drawings" folder.

4.3 Design Report

Every product has associated with it a Design Report which includes all information related to the design of the product. Product specifications, modeling and analysis results, rationale for critical design decisions, and test results are all included in this document. The final version of this document is located in "S:\Quality Assurance\Design Records".

5 MATERIAL AND SERVICE PROCUREMENT

All materials and procedures used to produce Qynergy products meet specifications and pertinent regulations. Procurement of materials or services is controlled to ensure conformance with specifications.

5.1 Supplier Selection

All suppliers of parts or services related to Qynergy products are chosen based on past history of providing identical or similar materials or services and the supplier's technical capability. The supplier's technical capability is determined by direct evaluation of the facility or by analysis of the quality of previously supplied materials or services. If the quality of the product cannot be determined through inspection or testing, the selection of a supplier is based on the results of an audit of the supplier's operations. The Qualified Suppliers List (in "S:\Quality Assurance\Supplier Records"), which is a controlled document maintained by the QA Manager, contains all of the suppliers qualified for providing materials or services related to Qynergy products. The document also contains the audit history of each supplier; supplier audits must occur at least every three (3) years.

5.2 Procurement

Before procuring a material or service, Qynergy provides to the supplier a scope of work and technical requirements, identification of the documents that should accompany the material or service, identification of the documents that the supplier should keep on file, requirements for reporting and approving dispositions of nonconformance, and the signature of an authorized Purchasing Agent who reports to the Controller. In lieu of forwarding all the relevant information to the supplier each time an order is placed, Qynergy may initiate a written contract with a supplier which contains all the relevant information. Before ordering a material or service from a supplier under contract, the Purchasing Agent ensures the supplier has the most recent contract documentation. To procure a material or service, the requestor completes a Purchase Order Form (approved form in "S:\Quality Assurance\Forms") and receives approval from the appropriate signature authorities. The Purchasing Agent contacts the supplier and places the order.

5.3 Receipt Inspection

All procured items are subject to some level of receipt inspection. The extent of the inspection depends on the item and supplier and is subject to the discretion of the QA Manager. All receipt inspections must, at a minimum, verify: quantity, part ID & size, conformance to specifications, and paperwork. New, non-audited suppliers will require 100% inspection, but items from audited suppliers with good past performance can be subject to sample inspections only. The inspection sampling rate increases if the quality of a material or service decreases. All components of an NRC licensed device that are not manufactured by an NRC licensee are subject to 100% inspection. Any nonconforming material or service is documented in the Supplier Nonconformance Log (in "S:\Quality Assurance\Supplier Records") and tagged by the QA Manager.

6 INVENTORY

After procured items are received and inspected, they are taken to the controlled inventory area. Only items that have been through the receipt inspection process (which may be sample inspection, depending on the item) are taken to the inventory area. All items are labeled (either individually or as a group of like items) and segregated, and items requiring special handling are either labeled with the special handling instructions themselves or labeled "Special Handling Required". Instructions for items marked "Special Handling Required" are located in "S:\Quality Assurance\Production Records\Special Handling Instructions". Items which have a shelf life are marked with their expiration date and receipt date, and are used on a first-in/first-out basis. Any material identified as nonconforming during the inspection process is documented in the Supplier Nonconformance file (see Section 5.3), tagged, and placed in a separate nonconforming inventory area. Qynergy products which have been through final inspection and test are also kept in the controlled inventory area. Periodically, a physical inventory is performed by the QA Manager.

7 PRODUCTION PROCEDURES AND PROCESSES

Qynergy has written procedures for all production processes. The procedures include the machinery and equipment to be used, required worker qualifications, equipment settings, and hold points for inspection and testing. Every product also has a corresponding traveler that is used for recording progress through the manufacturing process. All process documents associated with a Qynergy product are referenced in the Top Level Assembly Drawing (see Section 4.2) and the Traveler for a given product. All production processes are controlled documents, as described in Section 4, so the current released versions are PDF files located in "S:\Quality Assurance\Procedures".

8 INSPECTION AND TESTING

Qynergy performs inspection and testing to ensure that all materials, devices, and production procedures conform to the appropriate specifications and regulations. All inspection points and their results are documented on the Traveler for each individual product. Travelers are hard copies. Once a Traveler is complete, it is considered a controlled document. It is scanned into a PDF format and stored in "S:\Quality Assurance\Production Records".

8.1 Product Inspection

All in-process and final inspection and testing procedures (and appropriate hold points) for a given Qynergy product are described in the production process document. Acceptance criteria, receipt inspection criteria, inspection and test points, inspection sample size determination, final inspection procedures, and nonconformance provisions are all included in the production process document. The traveler is used to record inspection results, including the date and inspector. All inspections are performed by someone other than the person who accomplished the work being inspected. 100% of devices manufactured under an NRC license are subject to a final operational check and removal contamination test (gas loaded devices are exempt from contamination test). Items that pass all inspection points are labeled and taken to the controlled inventory area

(see Section 6). Items that do not pass an inspection point are held for the QA Manager to disposition. Possible dispositions are: send on, rework, or pull for nonconformance. The QA Manager's disposition is also recorded on the traveler. If pulled for nonconformance, the product is tagged, recorded in the "Product Nonconformance Log" located in "S:\Quality Assurance\Production Records\Non-Conformance Records", and sent to the nonconforming inventory area.

8.2 Process Inspection

Production processes are subject to periodic inspection. The file "Process Inspection Log", located in "S:\Quality Assurance\Internal Audit Records\Process Inspection Records", includes an inspection checklist for each production process and a record of all inspections (including date and inspector). Members of the production staff may perform inspections at any time, but the QA Manager inspects each process at least once per year. If a production process is found to be insufficient, the inspection results and their impact on previously manufactured products are evaluated by the QA Manager and other departments as appropriate. Corrective actions are taken as necessary, which may include customer notification or product recall.

9 NONCONFORMING MATERIALS

Qynergy ensures that materials and devices that do not conform to specifications are not used in production or distributed. Nonconforming materials may be found through receipt inspection (see Section 5.3), in-process and final inspection and testing (see Section 8.1), and devices returned by customers (see Section 11). All nonconforming materials are segregated, placed into the nonconforming inventory area (see Section 6), and documented as appropriate (Supplier Nonconformance Log, Product Nonconformance Log, or Deviation Log). Periodically, the QA Manager dispositions the items in the nonconforming inventory area. Items may be introduced back into production, reworked, sent back to the manufacturer, held for further analysis, or discarded at the discretion of the QA Manager.

10 PACKAGING AND TRANSPORTATION

Packaging and shipping of all Qynergy products are completed according to the Packaging and Shipping Procedure located in "S:\Quality Assurance\Procedures". This procedure includes instructions for inspecting packages, evaluating shipping methods, and assigning transportation companies. This procedure also includes the Pre-Shipping Checklist which ensures items are packaged properly, all product related documentation is included or sent to the customer and all appropriate notifications for shipping have been completed. Completed checklists are stored in "S:\Quality Assurance\Shipping and Packaging Records".

11 DEVIATIONS AND CUSTOMER COMPLAINTS

Qynergy applies rigorous inspection methods throughout the manufacturing process in order to ensure that customers receive quality products. For the rare case that a customer may have a problem with a product after it has passed its inspection points, Qynergy has a Deviation Documentation Procedure located in "S:\Quality Assurance\Procedures".

Customer complaints are logged into the Deviation Log as they are received. Each customer complaint record includes: name of complainant, nature and date of complaint, corrective action taken, cause of failure and model and serial number of device. Analysis is then performed to determine the cause of the deviation. The results are recorded in the Deviation Trend Analysis file. The Quality Manager then reviews the finding and initiates notification to customers and the NRC when appropriate. All notifications are recorded in the Deviation Notification Log. The Quality Manager also checks the Deviation Trend Analysis file at least annually for any trends that may indicate manufacturing issues. All customer complaint and deviation records are stored in "S:\Quality Assurance\Deviation (Customer) Records".

12 AUDITS

In order to ensure policies and procedures are functional and being used as intended, Qynergy periodically performs an internal audit on our Quality Program according to the Internal Audit Procedure located in "S:\Quality Assurance\Procedures". The Internal Audit Procedure includes audit acceptance criteria, records and procedure checklists, and deficiencies and corrective actions checklists. Internal audits are performed by either the Quality Assurance Manager or the Quality Assurance Director. Both are independent observers of the processes and procedures being audited. Qynergy's Internal Audit Procedure also requires verification checklists for supplier audits. This ensures that supplier audits have been completed with the frequency required, and that they have been performed according to the Supplier Audit Procedure located in "S:\Quality Assurance\Procedures".

13 RECORDS AND DOCUMENTATION

All records, procedures, checklists, logs, and other documentation related to Qynergy's Quality Assurance Program are kept electronically in "S:\Quality Assurance". Documents requiring signatures are also kept as a hard copy in the Quality Assurance Program Files with the Quality Assurance Manager. Any written procedures, forms, or drawings are created and revised according to the Document Creation and Revision Procedure located in "S:\Quality Assurance\Procedures".

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ARE BEING WITHHELD IN THEIR ENTIRETY

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