

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 <u>stephanie.jones@qynergy.com</u>. Thank you.

Sincerely. HE Stephanie Jones

Quality Manager

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 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

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

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REGISTRY OF SEALED SOURCES ANIName and Complete Mailing Address of the Applicant: Qynergy Corporation13800 Osuna Rd NE Ste 21Albuquerque, NM 87109-44015505-890-68871505-792-8508 (FAX)1The Applicant is (check one):1Qustom User1Manufacturer1Distributor1XManufacturer and DistributorIf the Applicant is a Custom User, Provide the Distributor: N/A1Model Number:KRT-2000Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.);	D DEVICES SAFETY EVALUATION 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 If the Applicant is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: N/A Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: See page 2 for Details
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Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	Principal Use Code (see Appendix C): K (Gas)
Teletherapy Source, Calibration Source, etc.):	For Use by:
	A Specific Licensees Only
Betavoltaic Power Cell: A device that	Beth Specific and General Licensees
captures electrons emitted by a decaying	Both Specific and Ocheral Licensees
radioisotope for the purpose of producing	Persons Exempt from Licensing
usable electric power	
Leak-Test Frequency:	Principal Section of the 10 CFR that Applies to
X Periodic Leak-Testing is Not Required	the User (e.g., General Licensees under 10 CFR
(Exempt from leak test due to "Kr gas	Specific Licensees under 10 CFR 33.11
form)	and General Licensees under 10 CFR 31.9
6 Months	Radionuclides and Maximum Activities
Attached is justification for a leak test	(including loading tolerance):
frequency of greater than 6 months	$^{\circ}$ Kr 166.5 GBq + 20% (4.5 Ci + 20%)
CERTIFICATION:	
IN THIS APPLICATION ARE BINDING UPON THE	E APPLICANT.
THE APPLICANT AND ANY OFFICIAL EXECUTIN	NG THIS CERTIFICATION ON BEHALF OF THE
APPLICANT, NAMED IN ITEM 2, CERTIFY THAT	THIS APPLICATION IS PREPARED IN
CONFORMITY WITH TITLE 10, CODE OF FEDERA	AL REGULATIONS, PARTS 30 AND 32 AND
THEIR KNOWLEDGE AND BELIEF.	IS INVE AND CORRECT TO THE BEST OF
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE	E 25, 1948 62 STAT. 749 MAKES IT A
CRIMINAL OFFENSE TO MAKE A WILLFULLY F	ALSE STATEMENT OR REPRESENTATION TO
ANY DEPARTMENT OR AGENCY OF THE UNITE	ED STATES AS TO ANY MATTER WITHIN ITS
Certifying Officer - Typed Name and Title	
Christopher Eiting, PhD, PE, Director of Engin	ineering
Signature: () Include State	Date: 8/1/27

KRT-2000 Manufacturer's List

Machining

Team Specialty Products

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

Joining

- California Brazing 37955 Central Ct Newark, CA 94560 Phone 510-790-2300 Fax 510-791-9300
- 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
- Technical Manufacturing Industries Inc. 9901-B Southern S.E. Albuquerque, NM 87123 phone (505)-293-6136 fax (505) 275-3657
- Jona Manufacturing
 264 DP Rd.
 Los Alamos, NM 87544
 Phone (505) 662-4611

Isotope Loading

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



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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:

- o External pressure: 0 to 290 PSIA
- o Working temperature: -60 and 200 Celsius
- o Impact: 200 grams from 1 meter with hammer
- o Vibration: 25-80 Hz for 90 minutes and up to 80-2000 Hz @ 20 g-force
- o 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
- o Impact-from a tool being dropped on the device during hook up
- o 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 ⁸⁵Kr. The steel structure provides both the seal as well as limited shielding for the ⁸⁵Kr. 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 ⁸⁵Kr. The package is rated to handle pressures that far exceed the ⁸⁵Kr loading pressure of 150 psi. Note: ⁸⁵Kr 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% ⁸⁵Kr 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 (lass 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 ⁸⁵Kr.

See Attachment 2, Instructions to Users

Attachment 1

Mechanical Drawing Package



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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 ⁸⁵Kr 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



Trefoil View of KRT-2000

FOIA-2009-0173

The following attachments (**pages 15-117**) were subject to FOIA Exemption 4 and have been fully redacted:

- 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

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• Radiation Profile Measurements