



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

November 6, 2007

Stephanie Jones
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3800 Osuna Rd. N.E. Ste. 2
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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE
SEALED SOURCE AND DEVICE EVALUATION FOR THE KRT-2000
BETAVOLTAIC POWER CELL

Dear Ms. Jones:

This letter is in response to your application dated August 1, 2007, requesting Sealed Source and Device registration of the KRT-2000 Betavoltaic Power Cell (QynCell™). In reviewing your application, we find that some additional information is required to complete our review. In the enclosure of this letter, we have summarized the issues not addressed in your application.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions regarding this correspondence, please contact me at (301) 415-6231, or Tomas Herrera at (301) 415-7138.

Sincerely,

/RA/ (T. Herrera for):

Joshua Palotay
U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management
Programs - MSSA/SSSB

Enclosure: As stated

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JJankovich

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**Additional Information for an Application
Requesting Sealed Source and Device Registry of the
KRT-2000 Betavoltaic Power Cell (QynCell™)**

Qynergy Corporation application, dated August 1, 2007, contained insufficient information regarding the issues below. Guidance on addressing these issues may be found in “Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration,” NUREG-1556, Vol. 3, Rev. 1. The document is available on the NRC web-site: www.nrc.gov.

1. Summary Information

- 1.1 You indicate that the principal use of this device will be “Specific Licensees under 10 CFR 33.11 and General Licensees under 10 CFR 31.9.” Please note that the provisions in 10 CFR 32.51 (a)(2)(i-iii) specify the requirements for a device to be Generally Licensed (GL). According to our review of the “Radiation Profile Modeling and Measurements,” the device does not appear to meet the criteria.

Do you intend the Principal Use of the device to be for Specific Licensees, or General Licensees?

If you wish to register the device as a GL product, please provide design information that meets the GL criteria in 10 CFR 32.51 (a)(2)(i-iii).

2. Construction of the Product

- 2.1 On Attachment 1 of the Mechanical Drawing Package, item 3 on the drawing indicates a KALREZ gasket is used between the cap and the case. It is also referenced on page 9 of the KRT-2000 Design Report. Based on the diagram and the KRT-2000 Design Report, it is unclear as to the functional or preventative purposes of the gasket and its ability to withstand the reported radiation field over the duration of the expected useful life of the device. However, it has been noted that on page 6 of the Design Report you state that “Special care was taken to select materials that are highly resistant to beta and gamma radiation.”

Is it intended for the KALREZ gasket to contribute to the containment of the radioactive material?

Please provide information on the design function of the KALREZ gasket. If the gasket is to contribute to the containment of radioactive material, include its tested or expected performance in regard to radiation damage due to exposure to radiation fields consistent with the radioactive material being used.

- 2.2 The application describes the installation of the wire “feedthrough” in Design Report, Section 5.5 (page 9, paragraph 2). Please delineate the component, the component materials, and any changes of these materials that may take place in a radiation environment.

- 2.3 The application refers to the use of additional shielding of lead or tungsten (e.g. Handling and Installation, Page 5, Paragraph 1; Attachment 2, Page II, Item 8). Please provide additional information on the use of such shielding regarding the need for it. Also provide technical specifications such as, dimensions, configuration, and wall thickness.
- 2.4 The application refers to the electrical feedthrough as an “off the shelf item” (Design Report, Page 9, Section 5.5). Please provide a detailed drawing of this item, showing the individual components of this assembly, and specify the material for each component. Please also address the behavior of the materials in a radiation environment.
- 2.5 Please describe the “hand crimper process” that you intend to use to seal the pressurized containment (Design Report, Section 5.6, Page 9). Please provide information on the tool, the process that your company will use, reliability measures for the process, and quality assurance measures that you will use. A reference to another company’s registration certificate, such as your Appendix 9.4, is not acceptable.

3. Drawings

- 3.1 The application refers to color coding of technical information in the drawings (e.g., Design Report, Page 8, for Figure 3 or Page 13 for Figures 6, 7, 8, and 9). Please provide an electronic copy of the application (i.e., a CD or an e-mail) that shows the information in color. Please provide an assembly drawing of the Model KRT-2000 power cell that shows the components that are referenced in the drawing on Page 9.
- 3.2 Please provide non-proprietary copies of Figure 1 (Page 6) and Figure 2 (Page 7) in electronic form. We intend to use these illustrations in the registration certificate.

4. Radiation Profiles

- 4.1 Page 1 of the document states that “Measurements were taken from each of the six faces of the KRT-2000 with a calibrated Fluke survey meter.” Please provide the model number and calibration date of the detector which was used, along with the maximum and minimum range of detection of the detector.

5. Prototype Testing

Please note that the applicable guidance (NUREG-1556, Vol. 3, Sec. 10.5, Page 10-11) calls for prototype testing “a complete representation of the final product.” However, several tests in the application were conducted with partial assemblies.

- 5.1 In regard to Section 7.1 “Helium Leak Testing of the KRT-2000 After Manufacturing” (Design Report, Page 17), please clarify the condition of the fill tube (i.e., open, crimped, etc.). Describe the rationale why the test would be representative of a completed unit.

- 5.2 In regard to Section 7.5, "Fill Tube Crimp Test" (Design Report, Page 21), the application provided test results with the crimp joints tested "separately." Describe the rationale why the tests would be representative of the completed unit.
- 5.3 The Test Report #TR0173 by Pacific Testing Laboratories, Inc., dated June 28, 2007, indicated "out-gassing" (Page 3 of 4) for source units. Please address why out-gassing was found acceptable and why it would not affect the integrity of the containment for pressurized Kr-85 gas.
- 5.4 The impact and puncture test specifies that the hammer is guided with the intent to strike the capsule, impacting the most vulnerable area (Prototype Test Report, Page 8). Please provide information regarding the orientation of the capsule during the impact and puncture test and what area of the capsule made contact with the hammer.
- 5.5 Please provide justification as to why the areas impacted by the hammer during the impact and puncture tests were considered the most vulnerable.

6. Labeling

- 6.1 Provide an illustration of the device, showing the information that is discussed in the application (Section 3 "Labeling," Page 5).

7. Installation, Servicing, and Instructions to Users

- 7.1 Information and details regarding the mounting device and apertures were not included in the provided document. Please provide drawings of the mounting device and apertures, mounting procedure, and related information.

8. Proprietary Information

- 8.1 You have labeled certain portions of your application as proprietary information. In order for the NRC to treat the information requested as proprietary, the NRC requires a notarized affidavit requesting the information to be proprietary. Please refer to 10 CFR 2.390(b)(4)(i) through (v).