REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION

NO: FL-1334-D-101-G DATE: October 28, 2010 PAGE 1 of 12
Revision 0

DEVICE TYPE: Low Power Battery Source

MODEL: P-100a
P-100b
P-100c
P-200a
P-200b

MANUFACTURER/DISTRIBUTOR: City Labs, Inc.
301 Civic Court
Homestead, FL 33030

SEALED SOURCE MODEL DESIGNATION: BV-1

ISOTOPE:	MAXIMUM ACTIVITY:
Hydrogen 3 (Tritium)	20 curies per device 335 millicuries per foil

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (T) Other [Power generation]

CUSTOM DEVICE: _____YES __**X**__NO

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DESCRIPTION:

The NanoTritium™ battery series are controlling devices that produce voltage and current by means of an ionized atmosphere. The Model P100 and P200 series batteries are designed to provide low voltage and current for microelectronic applications such as SRAM memory backup sensors and microprocessors. The device design is based upon the principle of tritium beta emissions that ionize a semiconductor's P-N junction in a manner similar to the photovoltaic effect.

The tritium is bound in a solid form as a metal hydride thin foil and layered in between semiconductor layers as shown in Attachment 3. Tritium decay produces beta emissions that impinge directly on semiconductor P_N junction surfaces, thereby inducing electron-hole pair ionization of the semiconductors environment. The P-N junction's electric field sweeps away positively and negatively charged ionization particles to electrical leads on the hermetically sealed package as show in Attachments 1 and 2. The minimum activity per device is 225 mCi of tritium and the maximum activity per device is 20 Ci. The device is hermetically sealed to 10^{-8}atm*cc/sec. The device is packaged to conform to MIL-STD-883 and other applicable industry standards and test specifications. The assembly of the device is shown in Attachments 2 and 3.

The engineering of the device makes it impossible for an individual to receive a dose commitment in excess of the 15 rem whole body limit even in an accident scenario such as fire and explosion.

Table 1

NanoTritium™ BATTERY SPECIFICATIONS

Dimensions:	See Attachments 2a – 2c
Voltage:	0.5 – 20.0 Volts
Battery Age:	Power Output
Initial 12 years 15 years 20 years	0.62 – 10.0 µW 0.32 – 5.08 µW 0.27 – 4.29 µW 0.20 – 3.24 µW

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LABELING:

A label on the outer surface of the battery housing contains the following information:

- The trefoil symbol and/or the words “CAUTION – RADIOACTIVE MATERIAL”
- Serial number
- Manufacturer/distributor name
- Model number
- Isotope, activity, date of assay.

Picture of labeled assembly: See Attachment 1

DIAGRAM:

See attachments:

Attachment 1	Photograph of NanoTritium™ Battery
Attachments 2.a, 2.b & 2.c	Scale engineering drawings of various device package configurations
Attachment 3	Concept drawing of multiple alternating sandwich structure
Attachment 4	Concept drawing of ionizing atmosphere in device operation

CONDITIONS OF NORMAL USE:

These devices are designed to serve as low power sources to electronics, microelectronics, sensors and other devices and are expected to be subjected to environments typically experienced by fielded electronic hardware. The NanoTritium™ battery systems have been tested and found to operate as designed in temperatures ranging from - 40ºC to 80ºC and at pressures from 0 to 1 atmosphere. It is not anticipated that the devices will be subjected to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, thermal cycling and on/off mechanism cycling. The estimated working life of these devices is 15-20 years.

An operating manual will be supplied to users upon purchase of the device. Users will be instructed to return the devices back to City Labs, Inc. if damaged or when they have reached the end of their serviceable working life.

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PROTOTYPE TESTING:

Sealed prototype testing of these devices was performed independently by separate companies and was tested at standard ambient conditions, unless stated otherwise, in accordance with MIL-STD-883E, Method 1019.9 utilizing test conditions A1 and A2 (tracer gas: helium, fine leak) and fell within the acceptable leak rates (MIL-STD-883E Method 1014.10, Test Condition A1, Table II (fixed conditions for Test Condition A1). The prototype device test had leak test rates of less than 1×10^{-8} atm. Cc/sec (He) which satisfy the passing criteria for MIL-STD-883E for package cavities ≥ 0.5 and <1.0 cm^3.

The prototype package tests were also conducted at standard ambient conditions, unless otherwise stated for:

Hermiticity by NTK Technical Ceramics per NTK YS-1002 Standard, Rev. G, per. 7.2 and per NTK YS-1009 Standard, Rev. F. and by Kyocera Corporation per AS-1003 Rev. B/TMP-4001.1, as per MIL-STD-883, Method 1014, Test Condition A4;

;

Thermal shock by NTK Technical Ceramics per Method 1011.9, Cond. B, MIL-STD883E per NTK YS-1002 Standard Rev. G. and by Kyocera Corporation per AS-1003 Rev. B/TMP-4002.1 MIL-STD-883, Method 1011, Test Condition B;

Temperature/thermal cycling by NTK Technical Ceramics per Method 1010.7, Condition C, MIL-STD-883E per NTK YS-1002 Standard, Rev. G. and by Kyocera Corporation per AS-1003 Rev. B/TMP-4003.1 MIL-STD-883, Method 1010, Test Condition C;

Electrical insulation functionality/resistance by NTK Technical Ceramics per MIL-STD-883E, Method 1003, Condition D (100V DC @ 25° C, 50% R.H.) per NTK YS-1002 Standard, Rev. G and MIL-STD-883, Method 1003 Condition D (100 V DC @ @ 25° C, 50% R.H.) per NTK YS-1009 Standard, Revision F. and by Kyocera Corporation per AS-1003 Rev. B/TMP-2001 MIL-STD-883, Method1033 test condition D; and

Solderability by NTK Technical Ceramics per MIL-STD-883E, Method 2003.7 per NTK YS-1002 Standard, Rev. G and MIL-STD-883E, Method 2003 (except aging test) per NTK YS-1009 Standard Rev. F. and by Kyocera Corporation per AS-1003 Rev. B/ TMP-3005 per MIL-STD-883E, Method 2003, MIL-F14256, QQ-S571.

Steam Aging:	Not Applicable
Flux:	Type RMA
Solder Temperature:	260°C ± 5°C
Solder Dipping Time:	5 ± 0.5 seconds

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EXTERNAL RADIATION LEVELS:

Radiation levels from the package meet the requirements of 64E-5.304, F.A.C., 10CFR 20.1201 and 10CFR 32.51a.2.ii in that operators will not receive in one year a radiation dose in excess of 10% of the annual dose limits and under accident conditions (such as fire and explosion) associated with the handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table 10 CFR 32.24. In addition, radiation surveys for maximum radiation levels from the package above a typical background radiation level were 0.00 mR/hr and 0.00 mSv/hr at 0.00 cm, 5.00 cm and 30 cm.

Since the decay characteristics of tritium involve the emission of low energy beta particles, there is no measurable exposure rate emanating from the hermetically sealed, metallic electronic package. In addition, the tritium is bound up in a solid form within the metallic foil construction. Furthermore, the metallic seal (Kovar, a Fe/Ni-Co alloy of high density) utilized in the battery housing serves as an impenetrable barrier to any tritium beta emissions.

Some beta particle kinetic energy may be converted into X-rays through the Bremsstrahlung process. However these X-rays are easily and efficiently attenuated by almost any media (including the Kovar metallic seal) and therefore do not pose an external threat due to X-ray penetration to the exterior battery packaging.

QUALITY ASSURANCE AND CONTROL:

All NanoTritium™ battery systems shall be manufactured within a quality control system registered as compliant to ISO 9001:2000 guidelines and will utilize a certified ISO consultant throughout the certification processes.

LIMITATIONS OR OTHER CONSIDERATIONS OF USE:

⇒ These devices shall be distributed to persons who are generally licensed.

⇒ All NanoTritium™ battery systems shall be accompanied by a full set of instructions on proper handling, use, and procedures for return of the damaged or malfunctioning units to City Labs, Inc. The end user must follow instructions for re-packaging and return of devices in accordance with U.S. Department of Transportation guidelines and City Labs, Inc. certified procedures.

⇒ The recommended maximum soldering temperature for NanoTritium™ battery systems is 200ºC.

⇒ Repair or disassembly of the NanoTritium™ battery systems shall only be done by the manufacturer City Labs, Inc.

⇒ Handling, storage, use, transfer and disposal of these generally licensed devices are to be determined by the licensing authority.

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LIMITATIONS OR OTHER CONSIDERATIONS OF USE Continued:

⇒ This registration sheet and the information contained within the references shall not be changed without the written consent of the State of Florida, Bureau of Radiation Control.

SAFETY ANALYSIS SUMMARY:

Based on the review of the information and test data cited below, we continue to conclude that the NanoTritium™ battery systems are acceptable for generally licensing purposes. Furthermore, we continue to conclude that these devices are expected to maintain their containment integrity for normal and accidental conditions of use, which might occur during the uses specified in this registration certificate. The NanoTritium™ battery systems design provides adequate safety characteristics to ensure that individuals do not receive radiation exposures in excess of applicable regulatory limits.

- These devices can be safely operated by persons not having training in radiological protection provided the optical access cover of the laser transceiver is not opened.
- Under normal conditions of handling, storage, and use of the device, the Tritium (Hydrogen 3) contained in these devices will not be released to the environment. In addition, it is unlikely that any one person will receive in a period of a year a radiation dose in excess of 10 percent of the limits specified in 64E-5.304, F.A.C. (10 CFR 20.1201).

REFERENCES:

The following supporting documents for the NanoTritium™ battery systems are hereby incorporated by reference and are made a part of this registration document:

Correspondence dated June 8, 2009 with attachments;

Correspondence dated June 17, 2009 with attachments;

Correspondence dated March 19, 2010 with attachments;

Correspondence dated June 3, 2010 with attachments; and

Correspondence dated June 18, 2010 with attachments.

The information provided by the manufacturer for distribution of the NanoTritium™ battery systems is incorporated into State of Florida, Radioactive Materials License Number 4230-1.

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ISSUING AGENCY:

State of Florida
Department of Health
Bureau of Radiation Control
Radioactive Materials Program
Bin # C21
4052 Bald Cypress Way
Tallahassee, FL 32399-1741
(850) 245-4545

Reviewed By: Concurrence:

Paul E. Vause, Jr.
Environmental Administrator

Charles Hamilton.
Environmental Consultant

Date: October 28, 2010

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Attachment 1: **Photograph of NanoTritium™ battery** (Specific attention re: Label Components)

Figure 1 (not to scale)

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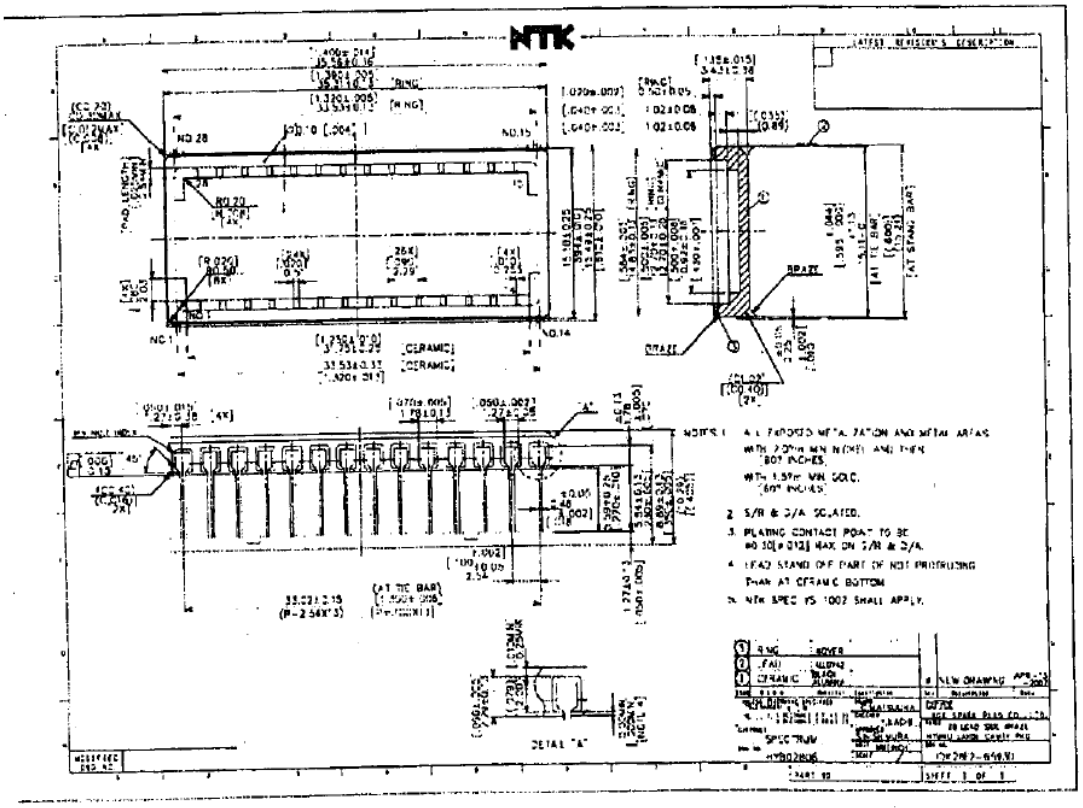
2.a)



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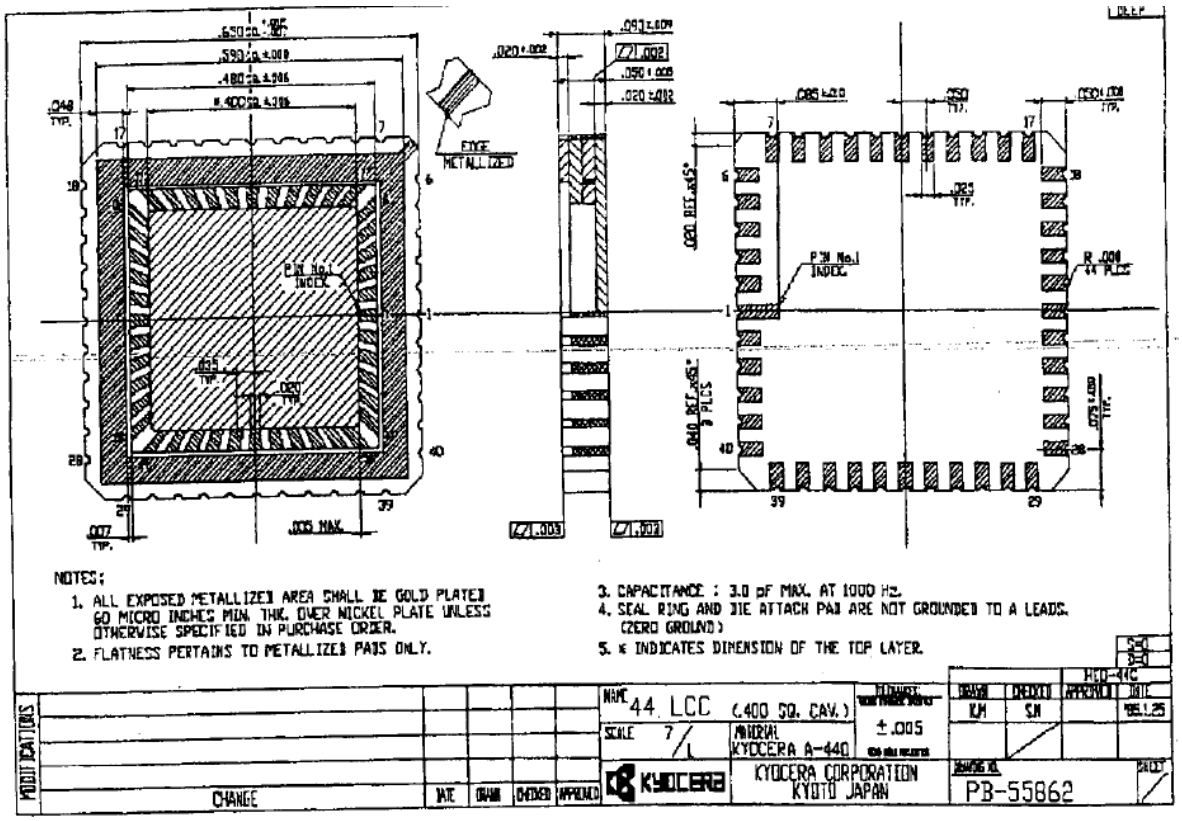
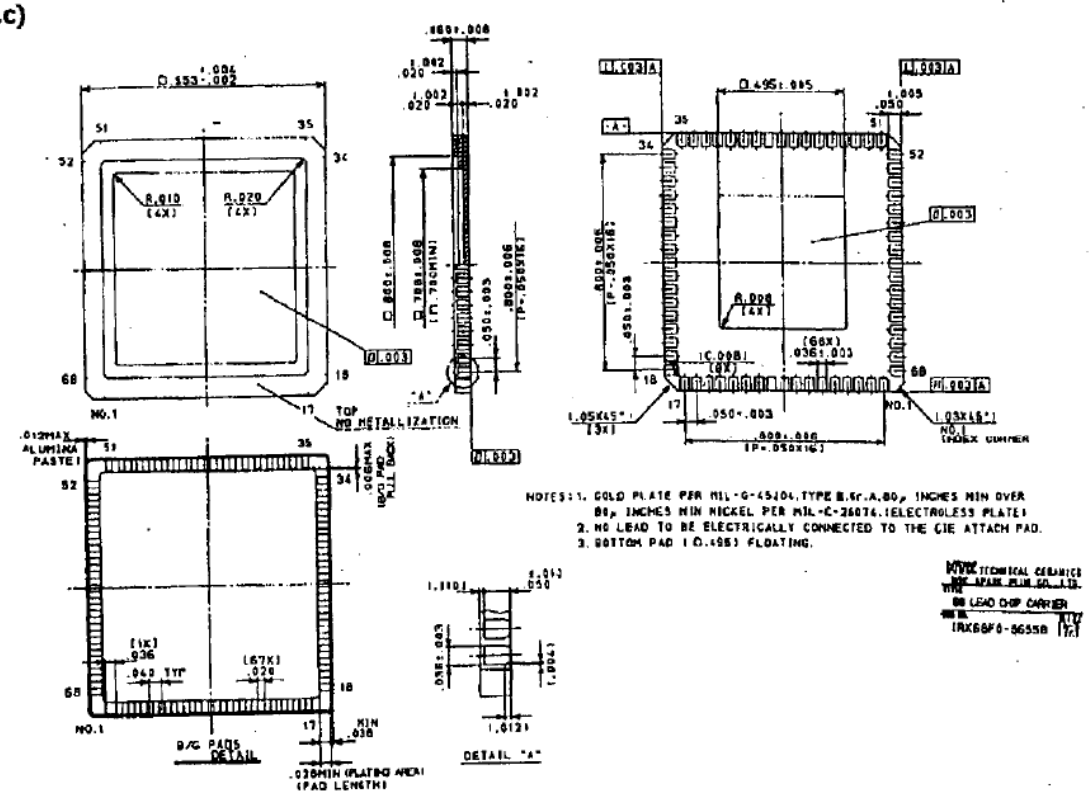


2.c)



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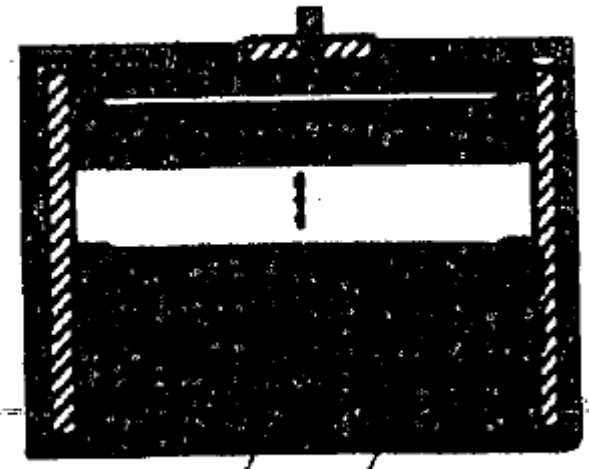
Concept drawing of multiple alternating sandwich structure
(tritium source and semiconductor P-N junction)



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Attachment 4: Concept drawing of ionizing atmosphere in device operation