

TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH



RADIOACTIVE MATERIAL LICENSE

Amendment 41

Pursuant to Tennessee Department of Environment and Conservation Regulations, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Tennessee Department of Environment and Conservation and orders of the Division of Radiological Health, now or hereafter in effect and to any conditions specified below.

LICENSEE 1. Name Berthold Technologies U.S.A., LLC 2. Address 99 Midway Lane Oak Ridge, TN 37830		3. License number R-01082-E12 amended in its entirety
		4. Expiration date May 31, 2012
		5. File no. R-01082
6. Radioactive Material (Element and Mass Number) <p style="text-align: center;">See</p>	8. Chemical and/or physical form <p style="text-align: center;">Supplementary</p>	9. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time. <p style="text-align: center;">Sheets</p>

10. Authorized Use

See Supplementary Sheets

CONDITIONS

11. Unless otherwise specified, the authorized place of use is the licensee's address stated in item 2, above.

See Supplementary Sheets

For the Commissioner
Tennessee Department of Environment and Conservation

Date of Issuance May 7, 2002

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By: *Charles Arnott*
DIVISION OF RADIOLOGICAL HEALTH
Charles Arnott
Health Physicist

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(9-92)

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|---|--|---|
| <p>6. Radioactive Material (Element and Mass Number)</p> <p>A. Cobalt 60
Cesium 137
Americium 241
Curium 244
Americium 241:Be</p> | <p>8. Chemical and/or Physical Form</p> <p>A. Sealed source (Any model source which has been approved by the State of Tennessee for distribution by the licensee in a Registration contained in the Registry of Sealed Sources and Devices maintained by the U.S. Nuclear Regulatory Commission)</p> | <p>9. Maximum Radioactivity and/or Quantity of Material Which Licensee May Possess at Any One Time</p> <p>A. No single source to exceed the maximum activity authorized in the Registry of Sealed Sources and Devices as applicable. Total not to exceed 15 curies of Cobalt 60, or 60 curies of Cesium 137, or a combination not to exceed a ratio of one (1). Total not to exceed 10 curies of Americium 241, 3.5 curies of Curium 244, and 3.5 curies of Americium 241:Be.</p> |
|---|--|---|

10. Authorized Use

- A. For receipt, possession, storage, training/demonstration, and distribution within Berthold Technologies Devices approved by the State of Tennessee in the Registry of Sealed Sources and Devices. Also, for receipt, possession, storage, and distribution within transport shieldings. This license does not authorize source installation at the licensee's address in Item 2 of the license.

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Conditions (continued)

12. The licensee shall comply with applicable provisions of 1200-2-4, 1200-2-5, and 12002-10 of "State Regulations for Protection Against Radiation."
13. A. Radioactive material authorized by this license shall be used by individuals who have been trained in accordance with statements, representations, and procedures contained in letter dated April 30, 2002. Records of individual training shall be maintained for inspection by the Department, and shall be in possession of the licensee during work at temporary job sites along with a copy of letter dated April 30, 2002.
- B. The Radiation Safety Officer for this license is Mark Morgan. The Alternate Radiation Safety Officer for this license is Martin (Gus) Norton.
14. A. The licensee is authorized to install, relocate, maintain, repair, test, and service devices authorized by this license or EG&G Berthold devices that are listed in the Registry of Sealed Sources and Devices maintained by the U. S. Nuclear Regulatory Commission. The licensee is authorized to perform shutter and/or sealed source leak tests for any device listed in the above Registry.
- B. Except as provided in C. of this condition and Condition 22, installation, replacement, removal from service and disposal of sealed sources containing radioactive material used in devices shall be performed only by the device manufacturer, or other persons authorized by this Department, the U. S. Nuclear Regulatory Commission, or another Agreement State to perform these services. Sources for disposal shall be shipped directly to the manufacturer in Germany under proper authorization, or to other persons authorized by this Department, the U. S. Nuclear Regulatory Commission, or another Agreement State to perform these services. The licensee is authorized to install, replace, remove from service, and dispose of Berthold Technologies P 2608-100 sources in dip tubes which are not part of a registered device in accordance with Procedure Number 0014 submitted with letter dated March 1, 1999.

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- C. Notwithstanding the authorizations in this condition, the licensee is authorized to provide services for EG&G Berthold devices that contain sources not approved in the Registry of Sealed Sources and Devices for use in that device, and devices that have modifications not approved in the Registry. However, this authorization does not include any activity that modifies the source, source holder, source assembly, or removes the source assembly for any purpose other than for replacement with a properly registered and approved source assembly or disposal of the non-approved source or assembly.
15. A. The licensee shall distribute only sealed sources and/or devices for which a sealed source and device registration certificate has been issued by the U. S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210(e) or an Agreement State.
- B. Distribution is authorized to persons specifically or generally licensed pursuant to 1200-2-10-12 or 1200-2-10-10(2) of "State Regulations for Protection Against Radiation", as appropriate, or equivalent provisions of the regulations of the U. S. Nuclear Regulatory Commission or another Agreement State.
16. In distributing devices to generally licensed persons, the licensee shall:
- A. Report to the Department at its offices located at 3rd Floor, L & C Annex, 401 Church Street, Nashville, Tennessee 37243-1532, all transfers of such devices to persons for use under the general license in 1200-2-10-10(2).
- B. Report to the U. S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.
- C. Report to the responsible Agreement State agency all transfers of devices manufactured and distributed pursuant to 1200-2-10-13(5) for use under a general license in that state's regulations equivalent to 1200-2-10-10(2).

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- D. Reports required by A, B, and C of this condition shall identify each general licensee by name; mailing address for the location of use; the name, title, and phone number of a responsible individual defined as "the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements"; the serial number and model number of the device; date of transfer; name and license number of the reporting company; the specific reporting period; the type of device transferred; and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons generally licensed under 1200-2-10-.10(2) during the reporting period the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.
- E. Keep records showing the name, address, and a responsible individual for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 1200-2-10-.10(2) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State. The record shall show the date of each transfer, the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this condition. The records required by this part shall be maintained for a period of five years from the date of the recorded event.
17. Radioactive material authorized by this license shall be stored at the licensee's facility in the "Restricted Access Storage Room", 99 Midway Lane, Oak Ridge, TN 37830 in accordance with statements, representations, and procedures contained in application dated April 3, 2002, with attachments, including information dated May 2, 2001, and letter dated May 16, 2001.
18. Radioactive material authorized by this license may be used at the licensee's facility in Condition 17 of this license and at temporary job sites of the licensee, in areas not under exclusive Federal jurisdiction, throughout the State of Tennessee.

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Before radioactive materials can be used at a temporary job site at any federal facility, the jurisdictional status of the job site must be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction. A response should be obtained in writing or a record should be made of the name and title of the person at the Federal agency who provided the determination and the date that it was provided. Authorization for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained either by: (1) filing an NRC Form-241 in accordance with 10 CFR 150.20(b), "Recognition of Agreement State Licenses", or (2) by applying for a specific NRC license.

Before radioactive materials can be used at a temporary job site in another State, authorization shall be obtained from the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

19. Any design and production changes of licensed devices to be distributed in the USA shall be approved by this Department before implementation.
20. The licensee shall use radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the references in the licensee's Registrations issued by the State of Tennessee for its sealed sources and devices. These references shall be considered requirements of the license.
21. A. Sealed sources authorized by this license shall be tested for leakage and/or contamination at intervals not to exceed three (3) years except for Berthold Technologies Model 7501 which is not required to be tested. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to transfer, the sealed source shall not be put into use until tested.
B. The tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.

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- C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Division of Radiological Health, Tennessee Department of Environment and Conservation, 3rd Floor L&C Annex, 401 Church Street, Nashville, Tennessee, 37243-1532, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons authorized by this Department, the U. S. Nuclear Regulatory Commission or another Agreement State to perform such services.
22. The licensee shall not open sealed sources or remove them from their source holders except that sources may be removed during Part II Audits, and as authorized in Condition 14 of this license.
23. The licensee is authorized to perform leak tests of customer sealed sources and possess any radioactive material contained on the test media as a result of the tests in accordance with the documents referenced in Condition 34 of this license. Records of leak tests in microcuries shall be provided to the customer.
24. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under this license. Records of inventories shall be maintained for inspection by the Department.
25. After installation, the licensee shall survey each device distributed under this license for radiation levels and conduct a test for proper operation of the on-off mechanism and indicator, if any. Records of these surveys and tests shall be provided to the recipient of the device.
26. The licensee shall test each device distributed under this license for leakage of radioactive material. A record of this test shall be provided to the recipient of the device.

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27. No generally licensed device shall be installed by the licensee in such a manner or in such a location that any person could receive more than 0.5 rem in a calendar year under ordinary circumstances of use.
28. A. The licensee shall furnish a copy of the general license contained in 1200-2-10-.10(2) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 1200-2-10-.10(2).
- B. The licensee shall furnish a copy of the general license contained in the U. S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 1200-2-10-.10(2), or alternatively, furnish a copy of the general license contained in 1200-2-10-. 10(2), to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or the Agreement State. If a copy of the general license in 1200-2-10-.10(2) is furnished to such person, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 1200-2-10-.10(2).
29. The licensee shall provide training for general licensees at the time of device installation in accordance with Berthold Technologies Procedure Number 03 contained in application dated April 3, 2002, with attachments.
30. Each device distributed to general licensees shall bear a durable, legible, clearly visible label or labels approved by the Department which contain in a clearly identified and separate statement:
1. Instructions and precautions for safe installation, operation, and servicing of the device (documents such as operating and service manual may be identified in the label and used to provide this information);
 2. The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and identification of the radioactive material by isotope, quantity; and

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3. The information called for in the following statement in the same or similar form:

The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)

Note: If specified elsewhere in labeling affixed to the device, the model, serial number, and manufacturer or distributor may be omitted from this label.

31. No maintenance, repair, or testing of any licensed device in which the shutter is required to be open shall be performed at the licensee's authorized place of use unless the device is on the floor within the storage room with the primary radiation beam directed to the floor. The licensee shall perform surveys for these events in accordance with SRPAR 1200-2-5-.61. Records of these surveys shall be maintained for inspection by the Department.
32. The licensee is authorized to possess, distribute, install, and service LB 7444 devices that have been modified to add the lead collimator insert into the shutter aperture in accordance with the documents referenced in TN-1031-D-101-B of the Registry. The lead collimator shall be inserted by the device manufacturer except that the licensee may insert the collimator for previously distributed devices and the one device in storage at the licensee's address. The licensee shall insert the collimator into installed devices when called upon to de-mount and service the unit unless this time frame is not acceptable to the regulatory agency maintaining jurisdiction for the location of the installed device. Devices in storage shall have the collimator inserted as soon as possible. The licensee shall contact the regulatory agency maintaining jurisdiction for its concurrence in the time frame for insertion, and shall provide written verification to them and the Department of its completion.

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The licensee shall provide written notification of this authorization to its customers with LB 7444 devices installed before the date of this amendment.

33. No provision of this license relieves the licensee from compliance with other Federal, State and local laws, ordinances, and regulations applicable to the licensee's activities.
34. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 8, and 9 of this license in accordance with statements, representations, and procedures contained in application dated April 3, 2002, with attachments, including information dated May 2, 2001, application dated April 8, 2002, and letters dated May 16, 2001, March 30, 2002, April 8, 2002, and April 30, 2002.