



STATE OF TENNESSEE  
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

DIVISION OF RADIOLOGICAL HEALTH

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June 25, 2008

Mr. Richard Blanton  
Health Physicist  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Dear Mr. Blanton:

I am responding to your letter dated May 29, 2008, to Mr. Paul Sloan. We have reviewed the draft IMPEP report, which documents the preliminary findings of the review team. Attached, please find our comments and suggestions regarding certain aspects of the draft report. We appreciate the opportunity to clarify these points.

We also appreciate, very much, the professionalism and courtesy demonstrated throughout the week by you and your review team. It was a pleasure working with you, and with the NRC management representatives, as well, who participated in the latter stages of the review and the closeout meeting on April 25, 2008.

Sincerely,

A handwritten signature in cursive script that reads "Lawrence E. Nanney".

Lawrence E. Nanney  
Director  
Division of Radiological Health

cc: Mr. Paul Sloan, Deputy Commissioner, TDEC

Attachments

## ATTACHMENT

### 3.1 Technical Staffing and Training

- Page 4. P.1. L 4 Remove the phrase "... and SS&D programs, ..." During this review period, the Licensing section did not experience any staff turnover nor were there any vacant positions in the section.
- Page 4. P.1. L 6 Remove the phrase "...and weaknesses in the preparation of SS&D certificates" for the same reason as cited above.
- Page 5. P.2. L 2 Sentence should end after "sciences". We do not accept equivalent training and experience in lieu of a Bachelor's degree in the sciences.
- Page 5. P.3. L 2 Insert "and x-ray registrant fees" after the words "licensee fees".

### 4.1.2 Program Elements Required for Compatibility

- Page 12, P.2, bullet 4 "National Source Tracking System – Sterilization Requirements" is not applicable in Tennessee. The NRC has already recorded this as not applicable on our SRS data sheet.
- Page 13, Bullet 5 "Security Requirements for Portable Gauges..." needs to be removed from the list. The Division sent the portable gauge license condition to the NRC for review and it was accepted with no comments on 5/13/08. The NRC has recorded this on our SRS data sheet.
- Page 14, P 1, L 2 The remainder of the paragraph following the first use of the word "condition" should be deleted. As noted above, on 5/13/08, the NRC accepted the portable license condition without comment. The NRC has recorded this on our SRS data sheet.

### 4.2 Sealed Source and Device (SS&D) Evaluation Program

#### 4.2.1 Technical Staffing and Training

- Page 15, P 1, L3 The individual referenced has not completed a review of a new application for a sealed source in collaboration with a senior reviewer.

### Appendix C, Inspection Casework Reviews

- File No. 10      “Management review was conducted after the inspection report was dispatched to the licensee.” Documentation in the Field Office file indicates the inspection letter was dated 3/21/05, management approval was received 4/13/05 and the letter was mailed 4/14/05.
- File No. 12      “Management review was conducted after the inspection report was dispatched to the licensee.” Documentation in the Field Office file indicates the inspection letter was dated 3/17/06, management approval was received 5/12/06, and the letter mailed on 5/15/06.
- File No. 13      “Management review was conducted after the inspection report was dispatched to the licensee.” Documentation in the Field Office file indicates the inspection letter was dated 12/15/06, management approval was received 1/18/07, and the letter mailed on 1/19/07.
- File No. 15      “Management review was conducted after the inspection report was dispatched to the licensee.” Documentation in the Field Office file indicates the inspection letter was dated 12/11/06, management approval was received 12/12/06, and the letter mailed on 12/12/06.

Note: License No. listed on the report is incorrect. The number is R-47188-J14.

### Appendix D, License Casework Reviews

- File No. 6      The Division has updated this license to further restrict physician use of Y-90 Sirspheres, but has decided to continue this authorization for the physicians which we had previously approved for this use regardless of case number. This authorization was made before the advent of NRC’s three cases for approval. We have begun to use the three case criteria for Y-90 for new applicants.

### Appendix F, SS&D Casework Reviews

- File No. 1      a) We do not understand why the vibration limits listed in the Prototype Testing section of the registration are not considered to be measurable items. (See attachment related to TN-1031-D-101-B dated February 25, 2005.)

b) We do not consider a check list necessary for every amendment to a registration. A check list was not used in this case since the focus of the amendment was an issue related to an incident.

File No. 6                   The registration date is July 10, 2006.

File No. 7                   The registration date is May 9, 2006.

c) The leak test frequency justification accepted was found in the application file which was in a folder separate from the registration. Appropriate page 8 is attached.

d) The working life declaration was found as above.

File No. 8                   a) Principle use code was "instrument calibration and transmission determinations." "Cylinder Source" was device type.

c) Although no leak test frequency justification was made, we accepted the one year frequency as part of the application submitted in 1991 for this NARM registration.

File No. 11                 b) We accepted their 3 year leak test proposal submitted as Item 23 in their answer to our deficiency letter. Appropriate page attached.

File No. 12                 The only request in this amended registration was a name change for the manufacturer/distributor.

b) and c) These criteria were established in 2001 for this NARM registration.

File No. 13                 c) See item 7 c).

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: TN-1031-D-101-B

DATE: February 25, 2005

PAGE: 7 of 15

DEVICE TYPE: Gamma Gauge for Density and Fill Level Measurement

LABELING: (Continued)

belt or microwave instruments. All metal labels are made of stainless steel. Other labels may be made of mylar, PVC-Polymer, or coated polyester film. Metal labels are riveted in place, and the other labels are secured in place by adhesive.

DIAGRAMS:

See Attachments 1, 2, and 3.

CONDITIONS OF NORMAL USE:

The scintillation counter is the limiting factor with respect to temperature. The specified operating range is -4 degrees F to 122 degrees F (-20 degrees C to 50 degrees C). All the devices have been evaluated for this temperature range.

PROTOTYPE TESTING:

The LB 7400 Series of devices has been in use in the USA since 1985. The manufacturer conducted tests of the device design in August 1996. These tests were conducted with devices that are not part of this registry, but are similar in design. They are Models LB 7445 DE and LB 7446 DE. The tests consisted of endurance (15,000 shutter operations), operating temperature (-20 degrees C to 200 degrees C), vibration (50 Hz for 90 minutes), thermal (800 degrees C), and free fall (9 meters, 27 feet). Test results appear to indicate that the integrity of the devices was maintained. It is stated that no design changes were made as a result of the tests.

**Models LB 7440 CR, 7442 CR, and 7444 CR were tested for vibration at an acceleration of 1.5 g in 3 principal axes for approximately 1.5 hours in each axis. The frequency ranged from 5 to 200 Hertz at a sweep rate of 4 Hz per minute. Single amplitude ranged from 12.5 mm at 5 Hz to 0.0093 mm at 200 Hz. No evidence of damage to the device was seen. The only result of the vibration was a loosening of the transport screw that did not have its usual wire seal to secure it.**

The Amersham/AEA Technology/QSA, Inc. Model CDC.P4, CKC.P4, and CDC.93 sources have received ANSI N542-1977 classifications of C66646, C66646, and C64545 respectively.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: TN-1031-D-101-B

DATE: February 25, 2005

PAGE: 10 of 15

DEVICE TYPE: Gamma Gauge for Density and Fill Level Measurement

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

Conveyor belt applications are limited to the use of 30 mCi (1.11Gbp) of Cs-137 maximum. In addition, conveyor belts are fitted with metal barriers to prevent access to the beam.

The devices may be locked in the open position. General licensees are provided instructions to not lock the device in the open position. Specific licensees should have in place appropriate procedures which will ensure the devices will not be locked in the open position.

Devices may be installed, relocated, maintained, or repaired by the distributor, or other persons authorized in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State to perform these services. Devices may be mounted by both specific and general licensees in accordance with guidance provided by Berthold Technologies U.S.A., LLC. The device must remain in the sealed and locked closed condition at all times during the mounting process and may only be unlocked prior to commissioning in the presence of the distributor or other persons specifically licensed for device installation.

The handling, storage, use, transfer, or disposal of devices used under a specific license shall be determined by the licensing authority. Devices used under the general license shall be governed by the requirements of "SRPAR" 1200-2-10-.10 or equivalent regulations of the U.S. NRC or an Agreement State. **CR versions of the device should not be installed in vibration environments where acceleration, frequency, and single amplitude exceed the values referenced in the PROTOTYPE TESTING section of this registration. For a continuous vibration environment, the registrant could not apply the above tests or confirm that these test results would guarantee a certain life span of the device. They did state that the tests were valid for comparison to a severe vibration environment, and that the test parameters far exceed those encountered in most installations. They stated that no failure of the device due to vibration had been noted except for the single welded shutter CR version. These have now been fully replaced with the double welded CR version.**

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 in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement state to perform these services. Sources for disposal shall be shipped directly to the manufacturer in Germany, or to other persons authorized in a specific license issued by the U.S. Nuclear Regulatory Agency or an Agreement State to receive and

- Clean-up

At the end of the operation or shift, reusable items are cleaned as needed and stored in the fume hood. Protective clothing is checked for contamination and stored for reuse if appropriate. Waste items are collected in suitable containers and stored for later disposal.

As already mentioned, just prior to distribution each source is leak tested and a leak-test certificate prepared (see Appendix D). A copy of the certificate goes with the source and a copy is retained. Sources will be distributed only to recipients authorized by the appropriate regulatory authority to receive such sources. A file will be maintained of all authorized recipients and the sources they have received.

A full quality assurance program has been implemented as recommended in ANSI N542, Appendix B, and as per NARM 10F.

### 3.2 Installation, Removal, and Service of Sources

Normally more than one line source will be used at each client site. Authority is needed to allow CSI to install the line sources in the calibration device. Line sources do not require installation per se, but CTI Services personnel may be asked to demonstrate its use to the client and check out the system operation. Also, during equipment servicing, the sources will be inspected and repositioned if out of alignment.

### 3.3 Leak Testing of Sources

This subsection has two purposes: to request approval for annual leak testing of the model LS sources and to request authority to perform source leak tests.

Because of the 287-day half-life of the Ge-68 in the Model LS sources, their useful life is about 1 year. Consequently, these sources are normally replaced every year and the old source disposed as radioactive waste. Furthermore, the ceramic matrix prevents leakage from the outer containment in the traditional sense. Even with substantial damage to the model LS source containers, there is often no loss of radioactive material. If there is a loss of material, it is in the form of a dry, visible granular material that can be removed very easily. Finally, these sources are used under relatively stress-free non-industrial conditions that reduce the likelihood of damage. Therefore, CSI requests authority to specify annual leak testing of these sources. With annual leak testing, all sources will be tested prior to distribution and most will be disposed at the end of one year without further testing. If a source is used for greater than 1 year, it will be leak tested at the end of one year. Any source used after one year will be leak tested every 6 months.

Prior to shipping sources to clients, CSI is required to leak test and certify each source. During field servicing, some clients may request a leak test or the service engineer may have a concern that a leak test could confirm or relieve. Therefore, CSI requests authority to leak test all sources before shipment - see Appendix D for an example leak test certificate - and to provide client site leak tests. Leak test samples will not be mailed back or, otherwise, returned to CSI for analysis. Leak tests will be done by wiping the source with a damp filter disk or swab and counting the sample in a reproducible calibrated geometry with a beta-gamma sensitive instrument such as a "pancake" probe and suitable counter. A sensitivity of at least 0.005  $\mu\text{Ci}$  will be obtained and detected activities exceeding 0.005  $\mu\text{Ci}$  will be reported. Activities below 0.005  $\mu\text{Ci}$  will be reported as  $<0.005 \mu\text{Ci}$ . The counting instrument will be fully calibrated at least annually (within 13 months) and source checked at least once during each day used. All leak test samples with detectable activity will be disposed as radioactive waste.

### 3.4 Repair of Sources

During installation or other client site service, CSI may encounter sources with minor damage that can be easily repaired without compromising radiation safety or source quality. Such repair activities may also occur at CSI. All such activities will be done with appropriate contamination controls and exposure



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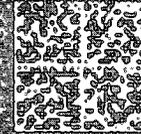
ITEM 20 Setting up the LB 7410 for measurement is done in the same fashion as our other measurement systems. A count rate from the device detectors is read into a separate evaluation unit. Comparisons between the count rates and actual lab values are used to develop the slope factor (sensitivity) for the measurement. This is what we typically call device calibration. This is usually done in a separate area away from the device itself. This calibration procedure can be performed by the customer or by the manufacturer when training the end user. There are no other calibrations necessary that would involve dismantling the device to make any adjustments to it. If it is suspected that the electronics within the device itself are not performing properly, the device would then need to be removed by a properly licensed person and returned to the manufacturer for diagnosis.

ITEM 21 Berthold Technologies U.S.A., LLC will provide device training for any of our customers who request training. If the end user is a General Licensee, Berthold Technologies is required to provide device operation training and radiation training as it applies to our devices at the customer site, before the system can be put into use. If the end user is a specific licensee, the obligations under their own operating license with their governing body would dictate whether Berthold Technologies would be required to provide specific device training. A copy of our General Licensee training manual and the specific device instructions contained in the LB 7410 operations manual have been included with this correspondence.

ITEM 22 All Berthold Technologies products associated with a device registration are shipped to our location in Oak Ridge for inspection before distribution to the end user. The procedure for the inspection has been previously submitted to the Department. No registered devices are dropped shipped by the manufacturer to the end user.

ITEM 23 The primary containment of the Am-241/Be source pellets is inside a double encapsulated stainless steel shell. Each encapsulation is welded closed to isolate the source material from the outside environment. The source capsule is housed in the stainless steel source holder (drawing 36746) inside the LB 7410. The source support disc (drawing 37569) and a spring ring keep the source capsule inside the source holder. The LB 7410 is composed of a stainless steel outer shell. Most of the components inside the outer shell are constructed of polyethylene for shielding purposes. The Am-241/Be source material is composed of the Am-241 being mixed with beryllium powders and the mixture then being pressed into pellets. The LB 7410 was not tested to a maximum temperature during prototype testing. In the event of high temperatures associated with a fire melting the polyethylene, the stainless steel outer shell would contain the source holder keeping the source capsule from reaching the outside environment. The maximum pressures that the LB 7410 was tested to would be the pressure test associated with the type A tests that were performed on the device. The maximum quantity of the source material for the LB 7410 is 300 millicuries. The radiotoxicity group for the source is listed to be A in the manufacturer's registration. None of the LB 7410 devices currently in use have experienced any problems because of an extended leak test interval. The proposed source capsule to be used for the LB 7410 is the same as the source capsule used on our Sulfur Analyzer, TN-1031-D-111-B. The method of containment of the source is similar in the LB 375 Sulfur Analyzer. The leak test interval for the LB 375 is three years and we have no knowledge of any problems associated with an extended leak test interval on that device.

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