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

**NO. :** NC-646-D-131-S **DATE:** June 20, 2006 **PAGE:** 1 of 7

**DEVICE TYPE:** Thin Layer Density Gauge

**MODEL No.:** 4640 & 4640-B

**MANUFACTURER/DISTRIBUTOR:** Troxler Electronic Laboratories
3008 Cornwallis Road, P.O. Box 12057
Research Triangle Park, NC 27709
(919) 549-8661

| SEALED SOURCE MODEL DESIGNATION: | ISOTOPE: | MAXIMUM ACTIVITY: |
|---|---|---|
| Troxler Drawing No. A-102112 which covers:<br>AEA Technology/QSA, Inc. Model No. CDCW556<br>Capsule Type XN.30<br>Special Form Certificate No. USA/0673/S | Cs-137 | 9 millicuries (333 MBq) |
| AEA Technology/QSA, Inc. Model No. CDCW556<br>Capsule Type X1218<br>Special Form Certificate No. USA/0614S | Cs-137 | 9 millicuries (333 MBq) |
| Isotope Product Laboratories Model # HEG-137<br>Capsule type: 3024<br>Special Form Certificate # USA/0356/S | Cs-137 | 9 millicuries (333 MBq) |

**LEAK TEST FREQUENCY:** **Twelve (12) months**

**PRINCIPAL USE:** (G) Portable Moisture/Density Gauges

**CUSTOM DEVICE:** _____ YES **X** NO

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**DEVICE TYPE:** Thin Layer Density Gauge

**DESCRIPTION:**

The Model 4640 and 4640-B Thin Layer Density Gauges are portable gauges designed to measure the density of thin layers of paving asphalt at construction sites. The device design is based on the principles of Compton scattering and photoelectric absorption of the photons to measure the density of the test materials. The measurement is made using a "backscatter mode" with the source rod tip being essentially flush with the surface of the test material. The gamma emitting radioactive material is located in a sealed source inside of the source rod tip. The emitted gamma photons that traverse the test materials are detected using Geiger-Mueller tubes located at the back of the gauge base plate. The photons are counted over a specified time period and the counts converted into a density measurement based on an internally stored calibration.

The engineering of the device was based on a sealed source containing of 8 millicuries (+/- 10%) of Cs-137 in special form. The Model 4640 gauge utilizes the AEA Technology/QSA, Inc. source, while the 4640-B may utilizes either the AEA Technology/QSA, Inc. or Isotope Products Laboratories (IPL) source. The encapsulated materials meet internationally-accepted specifications for special form certification and ANSI test criteria for classification as ANSI-77C64444/77C66535, respectively (AEA Technology/QSA, Inc., IPL).

Immediate source shielding is provided by a 1.75 inch diameter cylindrical tungsten shield located inside the gauge body. These gauges do not employ a shutter mechanism per se, but rather use the 1.75 inch tungsten block as a moveable shield. The overall outside dimensions of the gauge bodies are as follows:

| | | | | | |
|---|---|---|---|---|---|
| 4640 | 18.72" (length) | X | 9.12" (width) | X | 6.10" (height) |
| 4640-B | 18.64" (length) | X | 9.05" (width) | X | 6.10" (height) |

The overall height of the gauges, taking into account the source rod and handle, is 11.08" for both models.

**DETAILS OF CONSTRUCTION:**

The Model 4640 & 4640-B employ a moveable source rod that remains totally inside of the gauge during use and storage. The moveable source rod contains the sealed source and some immediate shielding. These gauge models employ two different types of source rod configurations:

<u>For 4640 & 4640-B with Serial Nos. up to 1670:</u>
The sealed source is housed in a 1.645" long 0.625" diameter 420 stainless steel source coup with female threads. The source , two tungsten plugs and a steel spring were inserted into the source cup and the cup was threaded onto the source rod and fusion welded.

**DEVICE TYPE:** Thin Layer Density Gauge

**DETAILS OF CONSTRUCTION (Continued):**

For 4640 & 4640-B with Serial Nos. greater than 1670:
The bottom of the source rod is machined out to receive the steel spring and tungsten plug. Then, the 420 stainless steel source cup is machined out to receive the sealed source and a stainless steel spacer. A 304 stainless steel filler ring is placed over the end of the source cup and the cup is screwed into the source rod and fusion welded.

Either configuration of source rod renders the source inaccessible to the user. In both configurations, the source rod is secured to the gauge handle with a tamper resistant pin.

The gauge bodies are constructed mostly of aluminum and have cast lead and cadmium inserts added for the purpose of additional shielding and enhancement of the radiation detection performance. Immediate shielding of the source is provided by a 3.0" high cylindrical tungsten block having a 1.75" diameter hole placed into the aluminum gauge base. Below the tungsten shielding block is a tungsten sliding block that permits the rod to be moved from the safe storage position to the measurement position at the gauge base. The source rod is secured to the gauge body via a securing rod. A tamper resistant cap is them placed over the securing rod protruding from the handle. To complete the construction, an aluminum plate having a hole the same size as the source rod is secured to the bottom of the gauge and acts as a collimating port for the emitted radiation when the rod is in the measurement position.

The gauge body is covered with a cast aluminum top shell for the 4640 and a molded plastic top shell for the 4640-B, which is secured with screws. The overall design and construction of these gauges render the source housing immovable and access to the radioactive material highly restricted. The entire device would have to be disassembled to gain access to the sealed source.

**LABELING:**

The Model 4640 & 4640-B gauges are labeled in accordance with 15A NCAC 11 .1626. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of distributor, and the words "CAUTION-RADIOACTIVE MATERIAL."

**DIAGRAM:**

See Attachment 1 for the Model 4640 source location
See Attachment 2 for the Model 4640-B source location

**DEVICE TYPE:** Thin Layer Density Gauge

**CONDITIONS OF NORMAL USE:**

The 4640 & 4640-B gauges are designed to be used by trained personnel to measure the density of thin layers of paving materials at the construction site. The user will normally be near the device only for the time period necessary to set up the gauge and perform the measurement. The frequency of this operation will be dependent upon the number of measurements needed at each site. The course capsule has a recommended working life in excess of thirty (30) years. However, the gauges should be returned to Troxler every five (5) years for a thorough manufacturer's inspection of the gauge to include an extensive inspection of the extendable source rod and its welds.

The device is designed for the following environments:

| | |
|---|---|
| Operating temperature | -10°C to 70°C ambient |
| Pressure | Atmospheric |
| Vibration | Ranges from zero to mild (tested @ a displacement of 0.1" @ 12.5 Hz) |
| Corrosion | Ranges from zero to corrosive |
| Fire | +660°C (to melt the aluminum components used for construction and secondary shielding) |

**PROTOTYPE TESTING:**

The 4640 & 4640-B gauges underwent prototype testing for mechanical, structural, and radiological integrity using measurement methodologies and testing procedures found in ANSI Standard N43.8-1979. This prototype testing included stray radiation measurements of gamma dose rates at 5 cm, 30 cm, and 100 cm for the gauges in both the "on" and "off" configurations; testing of the gauges' safety features at room temperature and at an elevated use temperature of 105°C, and at a decreased use temperature of -40°C; a leak test of the radioactive source after the safety feature/temperature testing; and an engineering evaluation of the likelihood of source retention in the source housing following a severe accident involving fire. The results of the testing showed: (1) no safety feature failure or stray radiation increase over the range of temperatures tested; (2) no loss of radioactive material from the sealed source; and (3) no loss of the shielding integrity of the device at temperatures below 660°C. The results of the prototype testing support the assignment of an ANSI standard rating of ANSI-54-664-664-R2.

**EXTERNAL RADIATION LEVELS:**

See Attachment 3 for Model 4640 radiation profile.
See Attachment 4 for Model 4640-B radiation profile.

**DEVICE TYPE:** Thin Layer Density Gauge

**QUALITY ASSURANCE AND CONTROL:**

Troxler Electronic Laboratories maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by the North Carolina Radiation Protection Section. A copy of the program is on file with the Radiation Protection Section.

**LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:**

**Distribution**: This device will be distributed as a specifically licensed device in accordance with the requirements of section .0300 of 15A NCAC 11 and/or applicable regulations of the NRC or an Agreement State. This shall not preclude the exportation of this device to a foreign entity following the applicable regulations.

**Leak Testing**: The device shall be leak tested by the user following the instructions in the "Manual of Operation and Instruction" at intervals not to exceed **twelve (12) months** using techniques capable of detecting the presence of 0.005 microcurie of removable contamination. If the level of contamination exceeds this limit, the device shall be returned to Troxler or other specifically-licensed entities for repair/disposal. Please note, Troxler maintains a customer leak test service.

**Servicing**: The 4640 & 4640-B devices require periodic maintenance of two specific gauge components by the gauge user. The scraper ring/sliding block require periodic cleaning and lubrication, and the source rod bearings require lubrication. The maintenance should be performed according to the manufacturer's instruction located in the operation and instruction manual. In addition, the gauge should be returned every five years for a thorough manufacturer's inspection of the gauge, to include an extensive inspection of the extendable source rod and its pertinent welds. Servicing of the source rod, including but not limited to source replacement, general servicing, repair, and/or disposal, shall be done by the manufacturer.

**Dosimetry**: All authorized users of these gauges should wear personnel dosimetry (film badges or TLD) in accordance with NRC or Agreement State regulations.

**Operating and Safety Instructions**: The device shall be operated in accordance with the written operating and safety instructions given in the device manual. The licensee should not attempt to remove the source rod from the gauge unless specifically authorized by his specific license.

**Training**: Use of these gauges is limited to individuals who have completed an approved training class in the basic principles of radiation safety and the proper use of these gauges. Please note, Troxler provides a training program for gauge users.

**DEVICE TYPE:** Thin Layer Density Gauge

**LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (continued):**

**Use**: Any time the gauge is not being used to make a measurement or is not under the physical surveillance of the operator, the source rod should be locked in the safe position. The operator should periodically inspect the source rod release mechanism and the gauge for loose and worn components. If any damaged components are found, the gauge should be returned immediately to the manufacturer for servicing.

**Reviewer Note**: This registration sheet and the information contained within the references shall not be changed without the written consent of the North Carolina Radiation Protection Section, Radioactive Materials Branch.

**DOCUMENTATION:**

The documentation enclosed with the device upon shipment to the user shall include the following:

1. Manual of operation and instruction,
2. Special form certificate,
3. Type "A" package testing results,
4. A copy of the final leak test results made prior to packaging,
5. Bill of lading,
6. An emergency response information sheet,
7 Troxler gauge certificate,
8. Troxler transportation guide.

**SAFETY ANALYSIS SUMMARY:**

The design of the 4640 & 4640-B gauges make the devices safe to operate by personnel trained in radiological safety. The inherent safety features of the device include: (1) a sealed source in special form, doubly encapsulated, and secured into the device; (2) the use of tungsten shielding to attenuate the radiation to lower exposure levels; (3) a positive retraction feature to assure that the extended source rod retracts into the shielded position before the gauge is picked up off the surface being tested and (4) a design that uses a moveable source rod that is not permitted to extend outside the gauge body. The radiation profile for the device both in and out of the transport case show relatively low radiation levels that are acceptable per federal regulations for exposure. Therefore, based on the information cited above and technical information provided in the application attachments, and with the condition that the licensee (*i.e.*, user) maintain the gauge(s) in accordance with the manufacturer's recommendations and the requirements of this registry sheet, we conclude that the Troxler Models 4640 and 4640-B gauges meet and exceed the requirements to be manufactured and distributed as specifically licensed devices pursuant to applicable regulations listed in 15A NCAC 11.

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**DEVICE TYPE:** Thin Layer Density Gauge

**REFERENCES:**

The following supporting documents are hereby incorporated by reference into this SS&D registry document:

1. All information and engineering drawings submitted by Troxler Electronic Laboratories Inc. in the application with attachments received September 05, 1995 and letter with attachments dated August 22, 1996 signed by Stephen A. Browne, Corporate R.S.O.; operating and instruction manual for the 4640 & 4640-B series gauges;
2. Letter with attachments dated August 8, 2000 containing a revised operating and instruction manual.
3. Letter dated March 23, 2003 (received March 24, 2004), signed by Stephen A. Browne, Corporate R.S.O.
4. **Letter with attachments dated February 14, 2006, signed by Stephen A. Browne, Corporate R.S.O.**

**ISSUING AGENCY:**

This Sealed Source & Device registry certificate is hereby amended June 20, .2006.

**Principal Reviewer**

J. Marion Eaddy III, Health Physicist Date: June 20, 2006

**Concurrence Reviewer:**

Gerald A. Speight, Health Physicist Date: June 20, 2006

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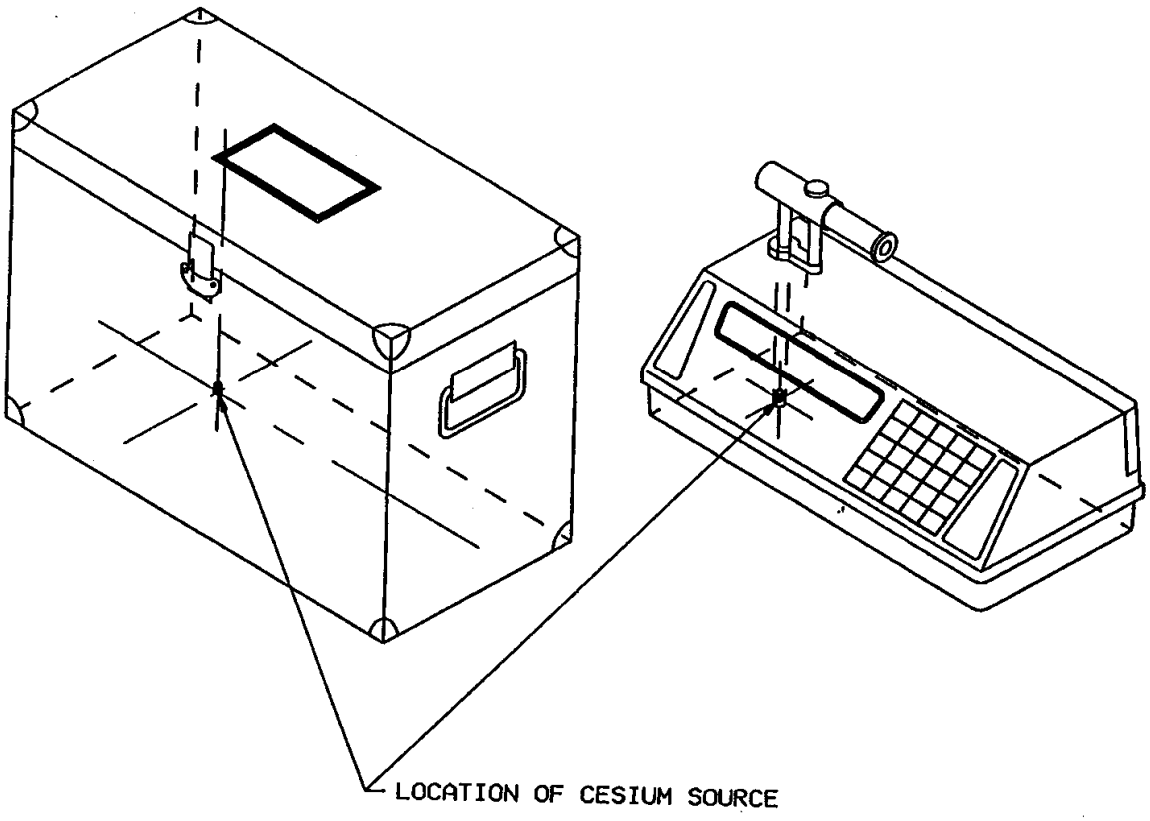
**NO. :** NC-646-D-131-S **DATE:** June 20, 2006 **ATTACHMENT:** 1 of 4

**DEVICE TYPE:** Thin Layer Density Gauge

**Attachment 1: Three Dimensional View of the 4640 Source Location**



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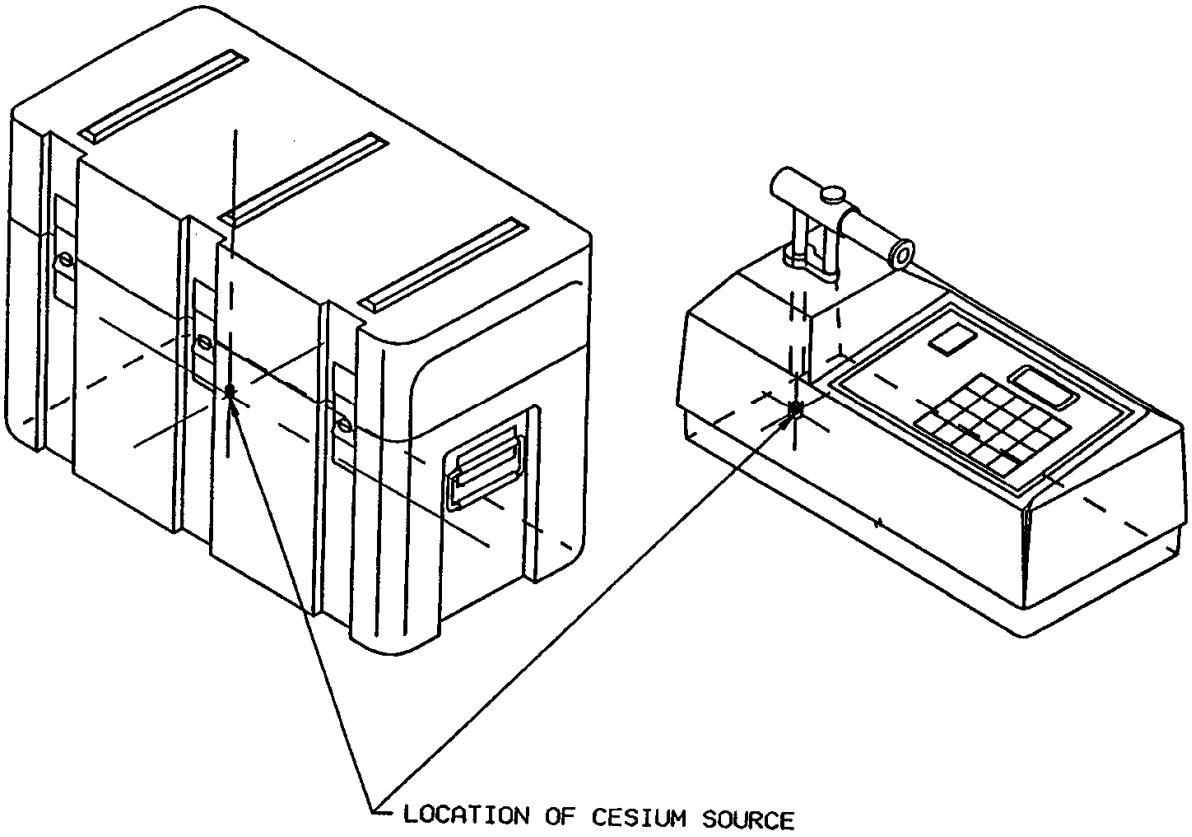
**DEVICE TYPE:** Thin Layer Density Gauge

## Attachment 2: 4640-B Gauge Source Location



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**NO. :** NC-646-D-131-S **DATE:** June 20, 2006 **ATTACHMENT:** 3 of 4

**DEVICE TYPE:** Thin Layer Density Gauge

**Attachment 3: Radiation Profiles for 4640 Gauge and Gauge in Plastic Transport Case**

Radiation Profile for 4640 Gauge

| Location | Surface | 10 cm | 30 cm | 1 meter |
|---|---|---|---|---|
| | γ | γ | γ | γ |
| Top | 2.5 | 1.1 | 0.35 | 0.1 |
| Bottom | 3.0 | 1.2 | 0.4 | 0.1 |
| Left | 3.0 | 1.5 | 0.4 | 0.1 |
| Right | 5.0 | 3.6 | 1.4 | 0.25 |
| Front | 20.0 | 7.0 | 0.8 | 0.1 |
| Back | 7.0 | 1.0 | 0.3 | 0.1 |

Radiation Profile for 4640 Gauge in Plastic Transport Case

| Location | Surface | 10 cm | 30 cm | 1 meter |
|---|---|---|---|---|
| | γ | γ | γ | γ |
| Top | 2.5 | 0.9 | 0.3 | 0.1 |
| Bottom | 1.0 | 0.5 | 0.25 | 0.1 |
| Left | 3.0 | 1.6 | 0.7 | 0.2 |
| Right | 3.5 | 1.5 | 0.4 | 0.1 |
| Front | 1.5 | 0.6 | 0.3 | 0.1 |
| Back | 7.0 | 0.7 | 0.4 | 0.1 |

Notes:
1. Gamma (γ) measurements were obtained with a Victoreen Model 2035 survey meter.
2. All measurements are in mrem/hr

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**NO. :** NC-646-D-131-S **DATE:** June 20, 2006 **ATTACHMENT:** 4 of 4

**DEVICE TYPE:** Thin Layer Density Gauge

**Attachment 4: Radiation Profiles for 4640-B Gauge and Gauge in Plastic Transport Case**

Radiation Profile for 4640-B Gauge

| Location | Surface | 10 cm | 30 cm | 1 meter |
|---|---|---|---|---|
| | γ | γ | γ | γ |
| Top | 10 | 4.0 | 0.7 | 0.1 |
| Bottom | 15 | 5 | 0.6 | 0.1 |
| Left | 8 | 4 | 0.7 | 0.2 |
| Right | 1 | 1 | 0.25 | 0.1 |
| Front | 15 | 1.5 | 1 | 0.2 |
| Back | 14 | 6 | 1 | 0.25 |

Radiation Profile for 4640-B Gauge in Plastic Transport Case

| Location | Surface | 10 cm | 30 cm | 1 meter |
|---|---|---|---|---|
| | γ | γ | γ | γ |
| Top | 1 | 0.8 | 0.25 | < 0.1 |
| Bottom | 2 | 2 | 0.4 | 0.1 |
| Left | 2 | 1.5 | 0.5 | 0.1 |
| Right | 0.4 | 0.3 | 0.2 | < 0.1 |
| Front | 3.5 | 3 | 1 | 0.2 |
| Back | 2 | 2 | 0.5 | 0.1 |

Notes:
1. Gamma (γ) measurements were obtained with a Ludlum $^{14}C$ survey meter, calibrated October, 1996.
2. All measurements are in mrem/hr