

APR 12 1994

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-94-054)

Your attention is invited to the attached correspondence which contains:

- INCIDENT AND EVENT INFORMATION.....
- PROGRAM MANAGEMENT INFORMATION.....
- TRAINING COURSE INFORMATION.....
- TECHNICAL INFORMATION.....XX
- OTHER INFORMATION.....

Supplementary information: The enclosed SS&D evaluations should be added to your catalog.

If you have further questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT: Lloyd Bolling  
 TELEPHONE: (301) 504-2327  
 FAX (301) 504-3502

*151*  
 Paul H. Lohaus  
 Office of State Programs

Enclosures:  
As stated

Distribution:  
 RBangart  
 PLohaus  
 DIR RF  
 ALL AS File  
 SS&D File  
 \*RSAOs  
 \*RSLOs

DCD (SPO1) PDR (YES  NO )

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DTE	C4/12/94	04/12/94						

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1. GA-161-D-103-S ISSUED 2/23/94.
2. RI-164-D-101-S ISSUED 2/9/94.
3. GA-269-D-101-S AMENDED PAGES 1, 7 & 11 DTD. 1/6/94.
4. WA-296-D-104-G AMENDED PAGE 1 DTD. 2/2/94.
5. TX-642-D-101-B AMENDED IN ENTIRETY 3/30/94.
6. TX-642-D-102-S AMENDED IN ENTIRETY 3/30/94.
7. TX-642-D-103-B AMENDED IN ENTIRETY 3/30/94.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: GA-161-D-103-S

DATE: February 23, 1994

Page: 1 OF 5

DEVICE TYPE: TLD Calibrator

MODEL: UD-717A

MANUFACTURER/DISTRIBUTOR:

Atlan-Tech, Incorporated  
1345 Hembree Road  
Roswell, Georgia 30076

Panasonic Technologies, Inc./MIERL  
9401 West Grand Avenue  
Franklin Park, Illinois 60131-3430

SEALED SOURCE MODEL DESIGNATION: Amersham Models SIF.31, SIF.32

ISOTOPE:

Strontium-90

MAXIMUM ACTIVITY:

1 millicurie (37 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (T) TLD Calibrator

CUSTOM DEVICE:  Yes  No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: GA-161-D-103-S

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DEVICE TYPE: TLD Calibrator

DESCRIPTION:

The UD-717A extremity dosimeter reader is a self-contained system designed to read thermal luminescent dosimeters (TLDs). The system consists of a heat lamp, a light sensor, a positioning system, electronics, control panel and an optional strontium-90 source with a maximum activity of 1 mCi for a verification check on the TLD output. The strontium-90 source is contained within a totally enclosed plastic and tungsten shielded source holder which has a shutter that is controlled by an electric solenoid. When the solenoid is energized the shutter opens and a narrow beam of radiation is directed onto a single TLD contained within a TLD magazine which fits on a channel. The top, bottom, and rear of the channel are made of aluminum plate with a lead shield behind the rear of the channel to stop any remaining radiation that might pass through. A tab is mounted on the shutter and is sensed by a photo eye to give an indication of both the closed and open position of the shutter. The shutter is designed to close by gravity should there be an electrical failure.

The UD-717A is contained within a sealed metal enclosure 36" wide by 16" tall by 22" deep. External connections and openings to the enclosure are kept to a minimum to simplify operation and enhance safety. A touch keypad and LCD display are mounted on the top and serve as the I/O for operator personnel. A magazine loading door provides access to the TLD trays. Individual TLDs are loaded into a magazine that holds 10 TLDs. The magazine is mounted in the tray which can hold up to 10 magazines. The rear of the enclosure has connections for power, computer interface, and test leads. In addition, a power switch and fuse are located on the rear panel.

There is a movement mechanism designed to move the TLD magazine so that each TLD is sequenced through several steps. One of these steps involve the movement of the TLD into position where it receives a fixed exposure from the strontium-90 source. All movements are computer controlled using stepper motors and precision ball screws.

The source holder assembly is shipped separately from the reader in a DOT-7A shipping container and is installed by the user as per detailed installation instructions outlined in the operation manual. A solenoid clamp is placed on the solenoid shaft to keep the shutter locked in the closed, shielded position prior to being packed in foam and then placed in the DOT-7A shipping container. A tag is placed on the solenoid clamp which

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DEVICE TYPE: TLD Calibrator

DESCRIPTION (cont.):

indicates that the clamp must be removed prior to use. Tamper-proof tape is placed on the top of the shipping container.

LABELING:

A label is attached to the rear of the source holder and indicates the isotope, the activity, the date, the radiation symbol, and the words, "**CAUTION-RADIOACTIVE MATERIAL**". In addition, a label is attached to the front of the source holder over the beam port and indicates "**CAUTION-HIGH RADIATION**" and the words, "**INSERT SOLENOID CLAMP PRIOR TO REMOVAL**".

DIAGRAMS:

See figures 1 and 2.

CONDITIONS OF NORMAL USE:

The UD-717A is designed for use in a normal working environment with regards to temperature, humidity, corrosive atmosphere, and vibration. The normal working environment includes 10 to 35 degrees Centigrade and 10% to 80% humidity.

PROTOTYPE TESTING:

The manufacturer states the following:

1. All sources to be used in the UD-717A will be NRC approved models.
2. During prototype testing, the shutter and solenoid were cycled repeatedly and then inspected for wear, damage, and other signs of potential failure. The shutter and solenoid showed little or no wear after the testing and it is projected that the lifetime of the shutter and solenoid should be at least 1 million cycles.
3. In the event the device is dropped from one meter onto a flat, unyielding surface, only superficial damage would result to the device. Shielding integrity would be maintained and no damage would result to the radioactive source.

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICES

NO: GA-161-D-103-S

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DEVICE TYPE: TLD Calibrator

PROTOTYPE TESTING (cont.):

4. In case of fire, damage to the source may result if temperatures exceeded the ANSI rating of the source. If this were to occur, the contamination would remain within the source holder.

EXTERNAL RADIATION LEVELS:

With a 1 millicurie strontium-90 source loaded in the device and the source shutter in the "OPEN" position, there was no detectable radiation on the exterior surface of the device. The radiation level on the exterior surface of the source holder with the shutter open was less than 0.5 mR/hr.

QUALITY CONTROL:

Quality control on the mechanical components of the device include cycling the shutter through a series of routine operations. At the conclusion of the test, all components are inspected for wear and continued ease of movement. A survey of the exposure rates on the external surface of the source holder is performed to ensure that shielding specifications are met. Atlan-Tech must satisfy themselves that the device performs satisfactorily before distribution can occur.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

The Model UD-717A device shall be distributed only to specific licensees of the NRC or an Agreement State.

Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

The UD-717A is intended for use in a controlled area by users with some training and experience relative to radiation safety. This is due to the users mounting the source holder and performing leak tests.

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SAFETY EVALUATION OF DEVICES

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DEVICE TYPE: TLD Calibrator

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (cont.):

The device shall be leak tested at 6 month intervals using techniques capable of detecting the presence of 0.005 microcuries of removable contamination.

This registration sheet and the information contained within the references shall not be changed or modified without the written consent of the issuing Agency or the NRC.

The "Operation Manual" shall be followed when operating the Model UD-717A Extremity Dosimeter Reader.

SAFETY ANALYSIS SUMMARY:

Based on the review of the information and test data contained in the references listed below, we conclude that the Model UD-717A Extremity Dosimeter Reader is acceptable for licensing purposes. Furthermore, we conclude that the device would be expected to maintain its containment integrity for normal and accidental conditions which might occur during the use specified in this certificate.

REFERENCES:

The following supporting documents for the UD-717A Extremity Dosimeter Reader are hereby incorporated by reference and are made a part of this registry document.

Atlan-Tech, Incorporated letters dated November 8, 1993, and January 25, 1994, with enclosures thereto.

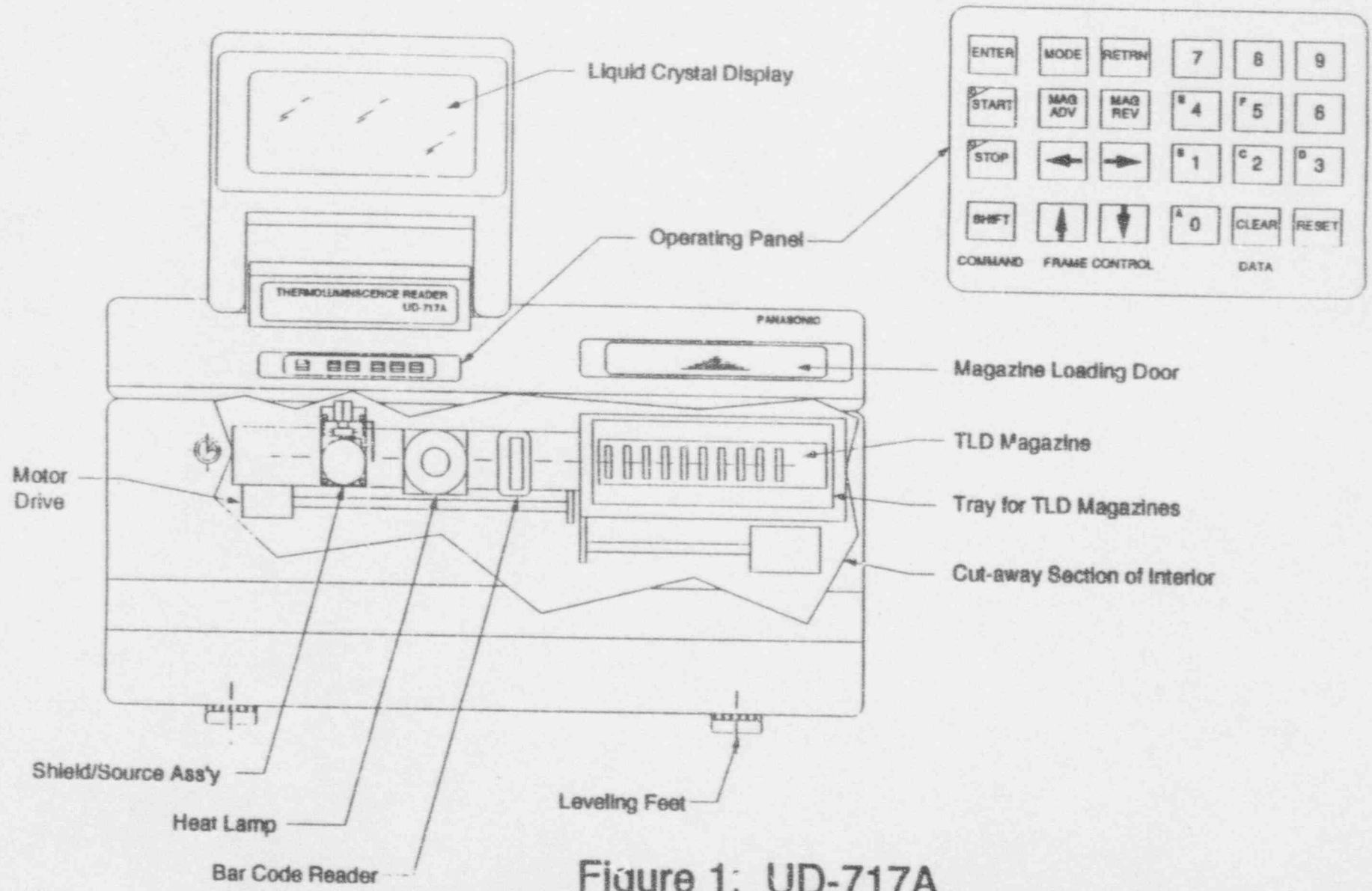
ISSUING AGENCY: Georgia Radioactive Materials Program

Date: 2-28-94

Reviewed by: Jerry W. Morris

Date: 3-4-94

Concurrence: Thomas E. Deil

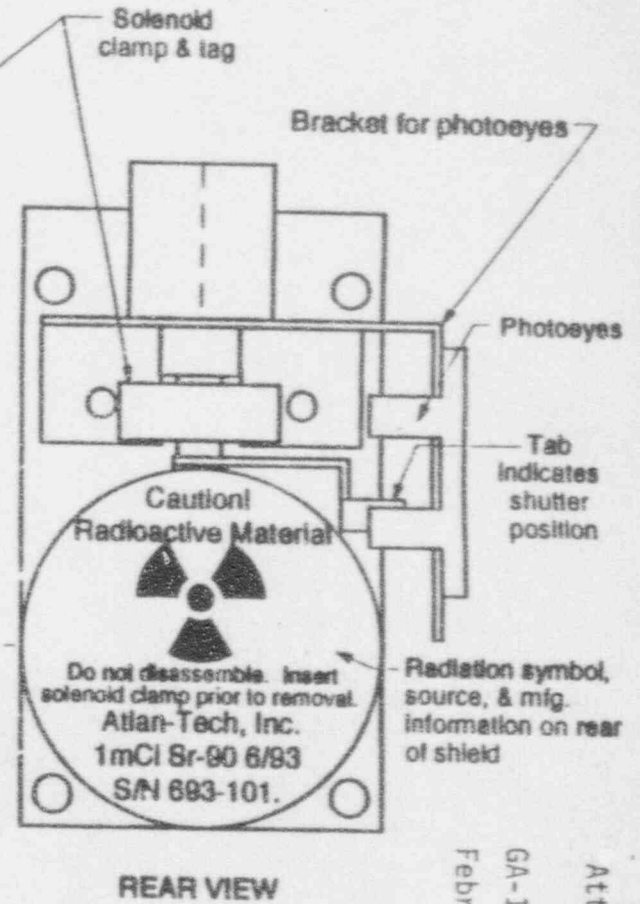
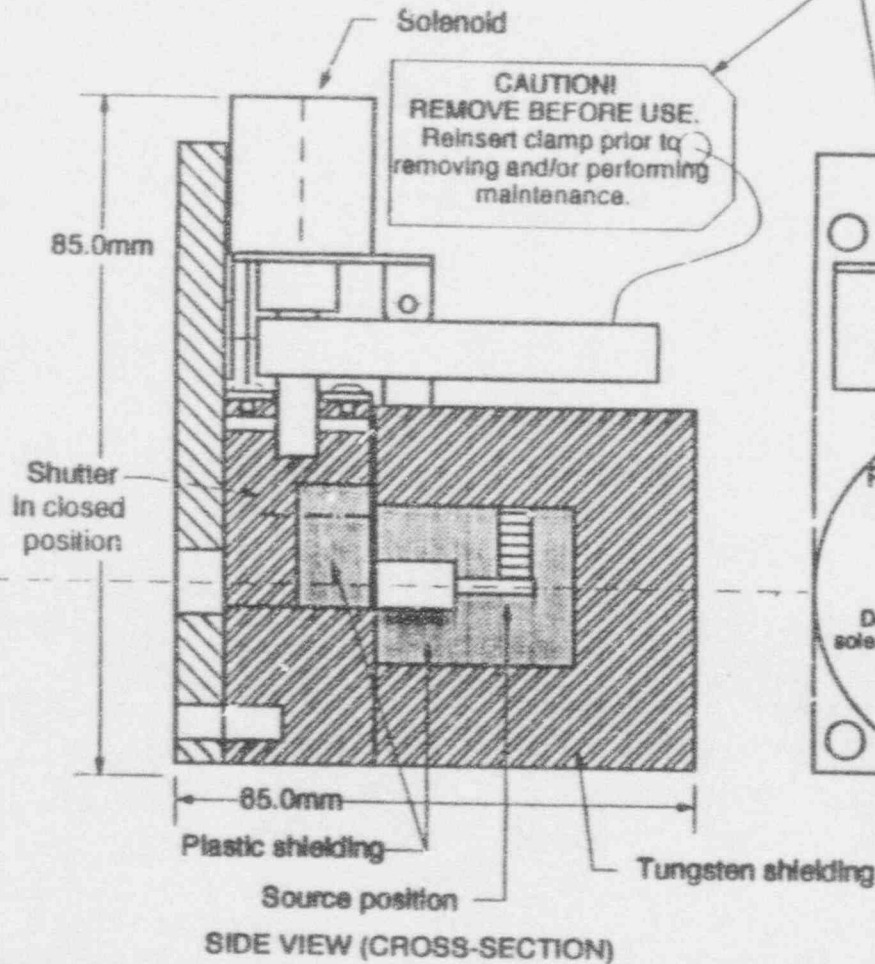
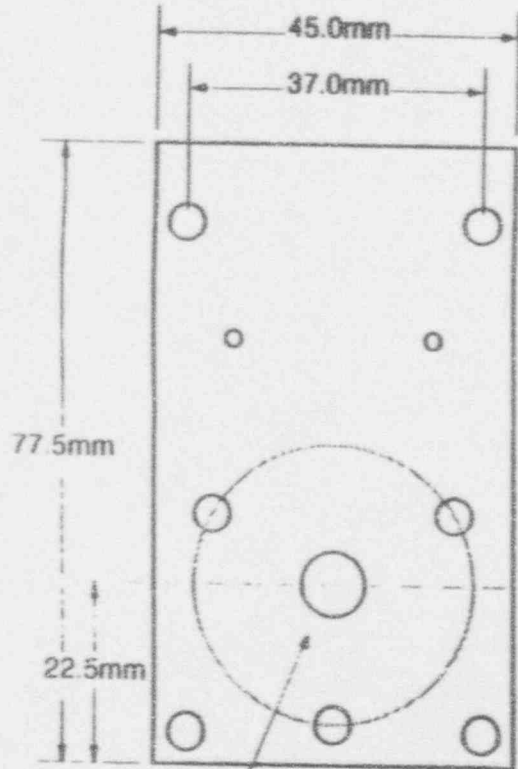
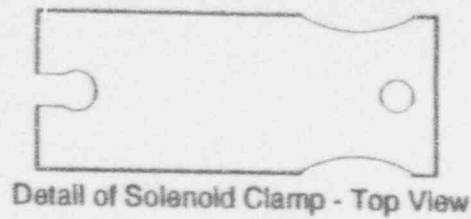


**Figure 1: UD-717A  
EXTREMITY DOSIMETER READER**

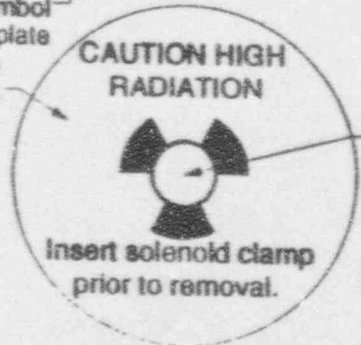


**Notes:**

Maximum source size is 1 mCi of Sr-90.  
Maximum radiation levels w/shutter closed is < 0.5 mR/hr.  
Irradiator is shipped with solenoid clamp installed. Solenoid clamp to be removed only after installation of irradiator in UD717 reader. Clamp to be reinstalled whenever maintenance is to be performed.



Radiation symbol covers front plate and prevents disassembly.



**Figure 2: UD-717A SOURCE HOLDER**

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SAFETY EVALUATION OF DEVICE

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DEVICE TYPE: Lead in Paint Spectrum Analyzer

MODEL: NITON XL Model 309

MANUFACTURER/DISTRIBUTOR:

NITON Corporation  
610 Ten Rod Road  
North Kingstown, Rhode Island 02852

SEALED SOURCE MODEL DESIGNATION:

Isotope Products Model XFB Series Capsule 3205

New England Nuclear Model NER-465 Capsule LE66

ISOTOPE:

Cadmium-109

MAXIMUM ACTIVITY:

10 millicuries

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (U) X-Ray Fluorescence

CUSTOM DEVICE: \_\_\_\_\_ YES \_\_\_X\_\_\_ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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NO.: RI-164-D-101-S

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DEVICE TYPE: Lead In Paint Spectrum Analyzer

DESCRIPTION:

The NITON XL Model 309 lead in paint spectrum analyzer is a portable, hand held device designed for determining the lead content of materials in-situ as well as laboratory situations. The device is rectangular in shape, with external dimensions of 8.20 inches in length, 3.00 inches in width, and 1.91 inches in height, (see attachment 1). The front end cap, sides, top and bottom sections are composed of 1/16 inch thick sheet aluminum. The rear end cap is constructed of steel. The sections are assembled with 4-40 tamper proof screws. A liquid crystal display screen is present on the top face of the device. An aperture is present on the bottom section of the device through which the beam of radiation is projected. Internal components include a source housing, shutter mechanism, solid state radiation detector, microprocessor, multichannel spectrum analyzer, and battery chamber.

The device is designed to contain one sealed source of Cadmium-109 to a maximum activity of 10 millicuries. The source is mounted in a source housing which is composed of tin of a minimum 90% purity. The source is secured in the source housing by a brass plug which is secured by a tamper proof screw, (see attachments 3 and 4). The sealed source is oriented so as to result in a beam of radiation angular to the plane of the device. A depiction of the beam angle and shutter window location is permanently printed on the front face plate and the top plate of the unit. The aperture on the bottom plate of the device is oval and 1cm x 2cm in rough dimension. A mylar shutter dust barrier covers the aperture. The aperture is shielded with 40 mil tungsten shutter.

The shutter mechanism consists of a spring operated plunger, which extends through the height of the device, a shutter release button and shutter safety located on the right side of the device, and the tungsten shutter located behind the aperture. The source housing and aperture shutter serve as the primary radiation shielding of the unit with the aluminum body serving as secondary shielding. Opening of the shutter requires that the operator slide the safety, depress the shutter release button, and cause complete depression of the plunger by contact with the solid material being analyzed. Removal of the device from the sample surface causes the plunger to retract by spring action, closing the shutter automatically. As the plunger extends through the body of the device, visual indication of shutter status is present by the plunger position. Failure to release the shutter safety will not allow the shutter release button to be depressed. In addition, the plunger will not depress with the shutter release button in the off position.

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DEVICE TYPE: Lead In Paint Spectrum Analyzer

DESCRIPTION (CONT'D):

In the case of failure of the spring mechanism to return the shutter to the fully closed position, the operator can manually close the shutter by depressing the plunger rod from the top of the device.

The only internal access to the device by the user is to the battery chamber located at the bottom rear of the unit. The chamber is completely encased, thereby not allowing access to any other internal components. The battery chamber is opened by the loosening of two captured thumb screws located on the rear end cap of the device.

Each device is shipped in a custom designed carrying case which has a separately provided padlock.

LABELLING:

The device is labelled in accordance with Section A.3.3 of the RI Rules and Regulations for the Control of Radiation, (R23-1.3-RAD). The label is a durable self adhesive metallic label listing the isotope, activity, assay date, device serial number, the manufacturer's name and address, and the wording "CAUTION radioactive material", and "DO NOT DISASSEMBLE UNIT". The label also contains the radiation symbol in black, printed on a yellow background. The label is affixed to the front plate of each device. See attachment 2.

DIAGRAMS:

The NITON XL Model 309 gauge is shown schematically in attachment 1. Attachment 3 depicts the source housing and source. Attachment 4 depicts the source housing location in the gauge.

CONDITIONS OF NORMAL USE:

The NITON XL Model 309 lead in paint spectrum analyzer is a hand held device designed to be used to measure the lead content in paint on structural surfaces and in samples. The device is a field instrument intended to be used in buildings, but may also be used in laboratory situations.

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DEVICE TYPE: Lead In Paint Spectrum Analyzer

CONDITIONS OF NORMAL USE (CONT'D):

The device is rated by the manufacturer for use between 40°F and 100°F in non-condensing atmospheres. It is rated for storage between 0°F and 140°F. Storage outside of this temperature could result in damage to the liquid crystal display.

PROTOTYPE TESTING:

The following prototype test procedures were conducted with the NITON XL Model 309 lead in paint spectrum analyzer.

High Temperature Test: The device was raised to 122°F (50°C). The shutter mechanism was tested for fifty cycles. No failures were noted. The device was raised to 144°F (62°C). The shutter mechanism was tested for fifty cycles. No failures were noted. The device was lowered to room temperature. The shutter mechanism was tested. No failures were noted.

Low Temperature Test: The device was lowered to 3°F (-16°C). The shutter mechanism was tested for fifty cycles. No failures were noted. The device was raised to room temperature. The shutter mechanism was tested. No failures were noted.

Shutter Cycle Test: The shutter mechanism of the device was independently tested as follows. The safety button was depressed, the device was placed against a solid surface in order to depress the plunger mechanism, thereby opening the shutter, then the device was removed from the surface allowing retraction of the plunger and closing of the shutter. Immediately following each test, the device was again placed against the solid surface without depression of the safety button to determine if the plunger would depress. In over 1,000 cycles the plunger mechanism did not fail and the plunger mechanism did not retract or the shutter open during the second attempt to depress the plunger.

In addition, to confirm opening and closing of the shutter during plunger cycle, with no source of radiation in the device, the plunger was manually depressed and the shutter was visually confirmed to open and close with release of pressure for 500 cycles.

Design prototypes of the device have been operated by the manufacturer for approximately one year with no malfunctions of the shutter or safety mechanisms experienced.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

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DEVICE TYPE: Lead In Paint Spectrum Analyzer

PROTOTYPE TESTING (CONT'D):

The sealed sources authorized for use in the device have been assigned the following ANSI N542 classifications. Isotope Products Model XFB Series Capsule 3205: ANSI 68C32232. New England Nuclear Model NER-465 Capsule LE66: ANSI 77C43343.

As a result of the prototype testing and the external radiation levels, the manufacturer claims an American National Standard N538 gauge classification for the NITON XL Model 309 lead in paint spectrum analyser as follows: ANSI 23-985-885-R1

EXTERNAL RADIATION LEVELS:

The manufacturer reports the following external radiation levels from the device, loaded with a 10mCi source of Cadmium-109. The measurements were obtained with a calibrated Keithley model 36150 ion chamber, following the methodology described in NBS Handbook 129, American National Standard N538.

SHUTTER OPEN

Distance	Maximum Radiation Level (mR/hr)
5 cm	1.0 mr/hr
30 cm	0.13 mr/hr
100 cm	<0.03 mr/hr

SHUTTER CLOSED

Distance	Maximum Radiation Level (mR/hr)
5 cm	<0.03 mr/hr
30 cm	<0.03 mr/hr
100 cm	<0.03 mr/hr

Note: The readings were obtained using a wood substrate as the backscatter medium. The shutter open radiation levels may vary with differing construction mediums. As an example, radiation profile data submitted using a sheetrock substrate reported significantly lower measurements. Measurements reported at <0.03 mR/hr reflect the lower sensitivity of the Keithley ion chamber.

The maximum radiation level measured in the primary beam, shutter open, with a 10mCi source of Cadmium-109 was reported as 23.5mR/hr at 8 inches (20cm).

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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DEVICE TYPE: Lead In Paint Spectrum Analyzer

QUALITY ASSURANCE AND CONTROLS:

NITON Corporation commits to quality control inspection of all prefabricated components of NITON XL Model 309 device. Each machined component of the device has been assigned a tolerance specification. All components which do not meet performance standards will be rejected.

Each assembled device will be evaluated and tested prior to shipment. This will include operation of the shutter mechanism for a minimum of fifty cycles, subjecting the device to temperature variation from 40°F to 105°F, and obtaining a radiation profile to confirm compliance with the original standards for the configuration. A copy of the radiation profile for the device is filed at the manufacturer and provided to the customer. The devices are leak tested prior to shipment.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

o The NITON XL Model 309 lead in paint spectrum analyzer shall be distributed to persons specifically licensed by the State of Rhode Island, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

o Authorized users should have basic radiation safety training in the use of portable gauging devices. This may be obtained by satisfactory completion of a training course offered by the manufacturer.

o The device shall be leak tested at intervals not to exceed six (6) months, using techniques capable of detecting 0.005 microcuries of removable contamination. The wipe tests are to be collected in accordance with the procedures contained in the user's manual for analysis by an appropriately licensed facility. The manufacturer will make available wipe test kits for analysis by a licensed facility.

o The device will be shipped by the manufacturer in a custom carrying case. All transportation of the device by the licensee should be in this carrying case. Each device will be shipped with a user's manual. The manual contains sections on operation of the device, radiation safety practices and procedures, hazards and standards for lead paint, and principles and theory of the device's operation. Each customer will receive the results of the leak testing of the device prior to shipment and results of the radiation survey profile of the device shipped.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

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DEVICE TYPE: Lead In Paint Spectrum Analyzer

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (CONT'D):

- o The device is field instrument designed to be operated in noncondensing atmospheres between 40°F and 100°F, and stored between 0°F and 140°F.
- o Maintenance and repair of the device shall be performed only by the manufacturer or an appropriately licensed facility. There are no user serviceable components.
- o The device should be returned to the manufacturer, or other authorized individuals for source exchange or disposal.
- o Personnel monitoring is considered optional based on the radiation profile data submitted. However, the manufacturer recommends whole body dosimetry to its customers.

SAFETY ANALYSIS SUMMARY:

When used by trained personnel in accordance with the manufacturer's instructions, it is unlikely that any person will be exposed to doses in excess of those specified in Part A of the RI Rules and Regulations for the Control of Radiation. The isotope in use, Cadmium 109, emits relatively weak photon energies, (88, 25, and 22keV), thereby limiting exposure potential to users and the general public. With the shutter closed, radiation levels surrounding the device are indistinguishable from background using a standard ion chamber survey meter. The design of the shutter mechanism prevents an open shutter and active beam unless the device is physically pressed against a solid object. In the unlikely event of shutter mechanism failure, the shutter can be manually closed without hazard to the operator. Shutter position is always visually indicated by the position of the shutter plunger. The device is assembled with tamper proof screws, discouraging attempted servicing by the customer. The environmental and temperature limitations documented by the manufacturer relate to proper operation of the liquid crystal display, not radiation safety issues.

Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released.



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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DEVICE TYPE: Lead In Paint Spectrum Analyzer

SAFETY ANALYSIS SUMMARY (CONT'D):

Therefore, based on the review of the information, test data, and radiation profiles submitted in the references stated below, we conclude that the NITON XL Model 309 lead in paint spectrum analyzer is acceptable for licensing purposes in accordance with the terms of this Certificate of Registration.

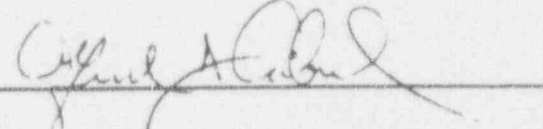
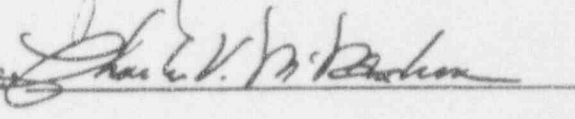
The device is authorized for distribution to specific licensees under authority of NITON Corporation's Rhode Island Radioactive Materials License 3A-105-01.

REFERENCES:

This Certificate of Registration is based on information and test data contained in the following application and supporting documents which are hereby incorporated by reference and made a part of this registry document:

NITON Corporation's application dated 10 June 1993.

NITON Corporation's letters with attachments dated 22 July 1993, 5 August 1993, 6 August 1993, 7 November 1993, 19 November 1993, 2 December 1993, 21 December 1993, 28 December 1993, 31 December 1993 and 21 January 1994.

DATE: 9 February 1994 REVIEWED BY:   
DATE: 9 February 1994 CONCURRENCE: 

ISSUING AGENCY:

State of Rhode Island and Providence Plantations  
Department of Health  
Office of Occupational and Radiological Health

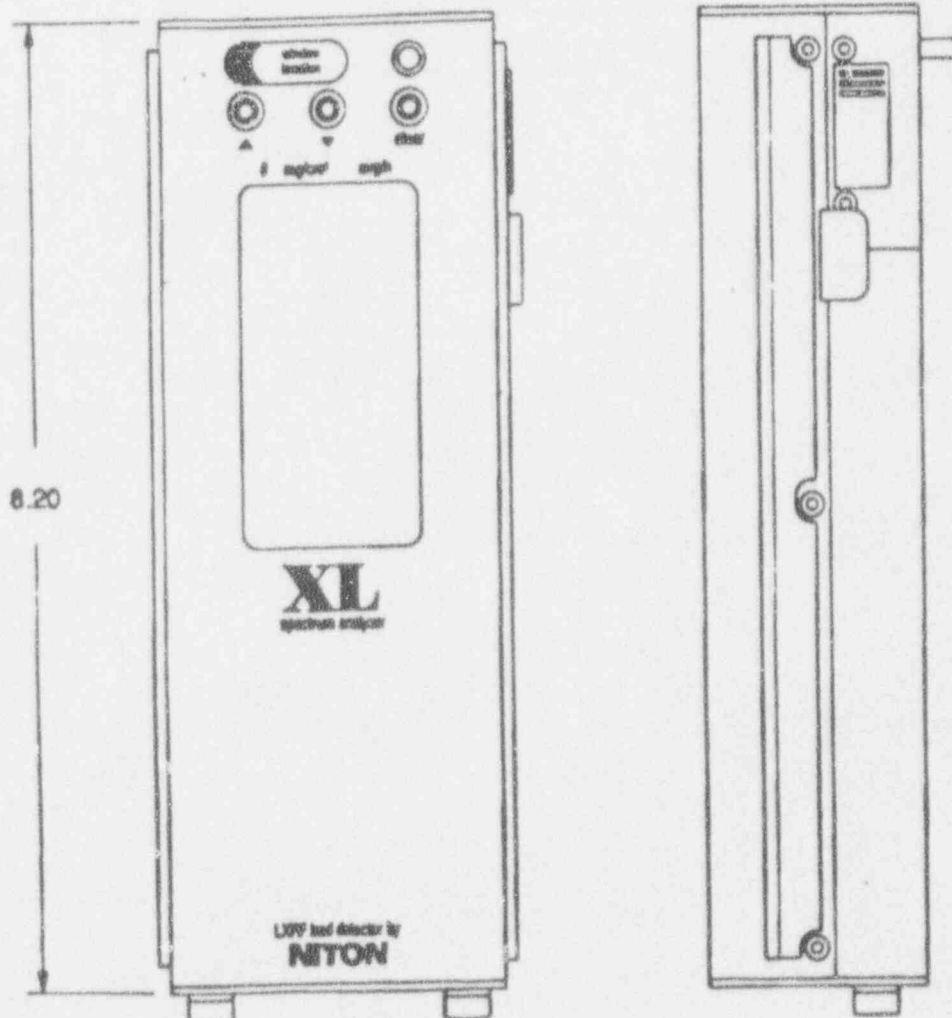
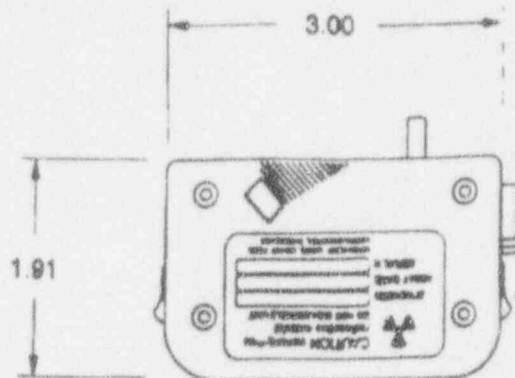
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

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ATTACHMENT 1

DEVICE TYPE: Lead In Paint Spectrum Analyzer



NITON XL Model 309  
LEAD IN PAINT SPECTRUM ANALYZER

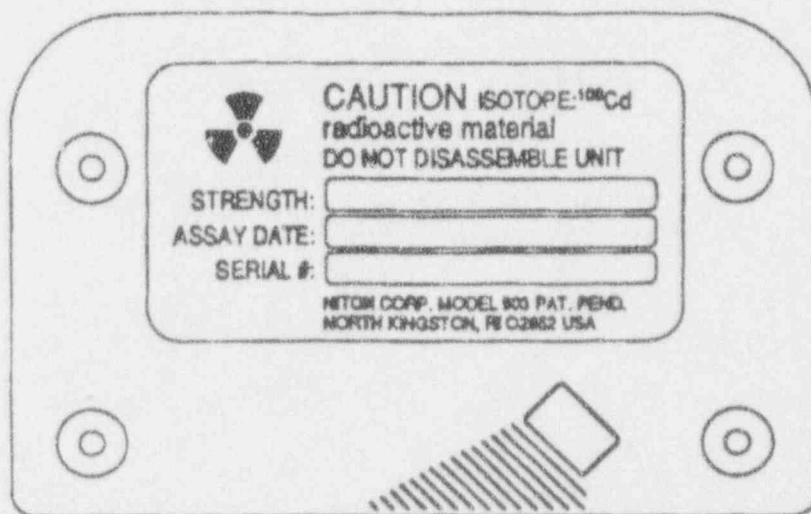
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

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DATE: 9 February 1994

ATTACHMENT 2

DEVICE TYPE: Lead In Paint Spectrum Analyzer



LABELLING

NITON XL Model 309  
LEAD IN PAINT SPECTRUM ANALYZER

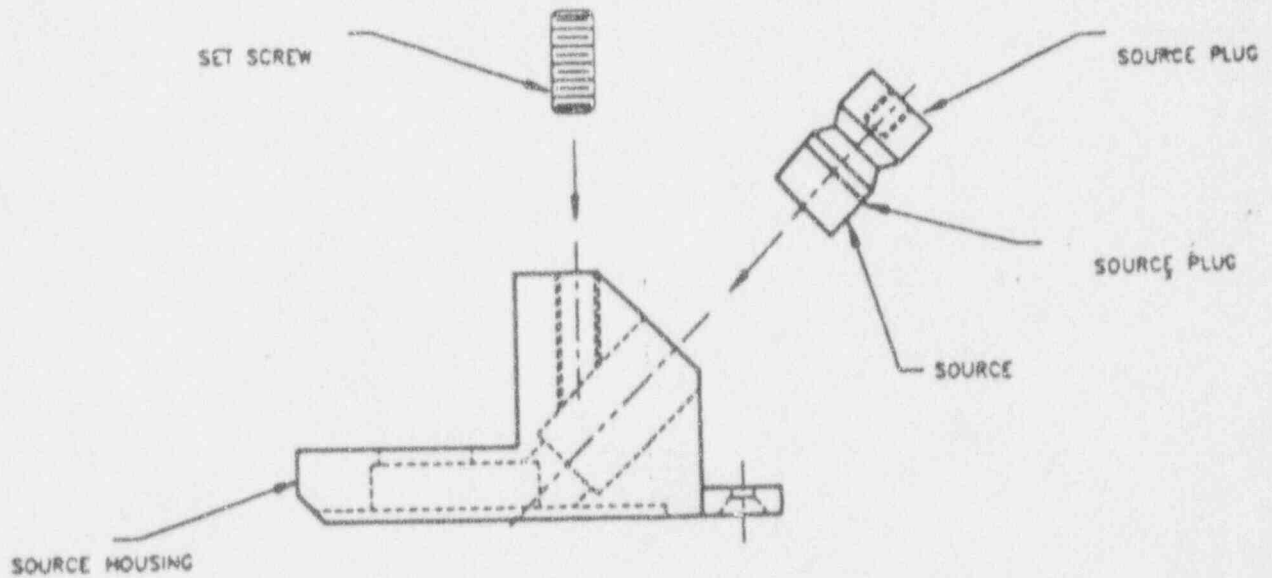
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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ATTACHMENT 3

DEVICE TYPE: Lead In Paint Spectrum Analyzer



SOURCE HOUSING ASSEMBLY

NITON XL Model 309  
LEAD IN PAINT SPECTRUM ANALYZER

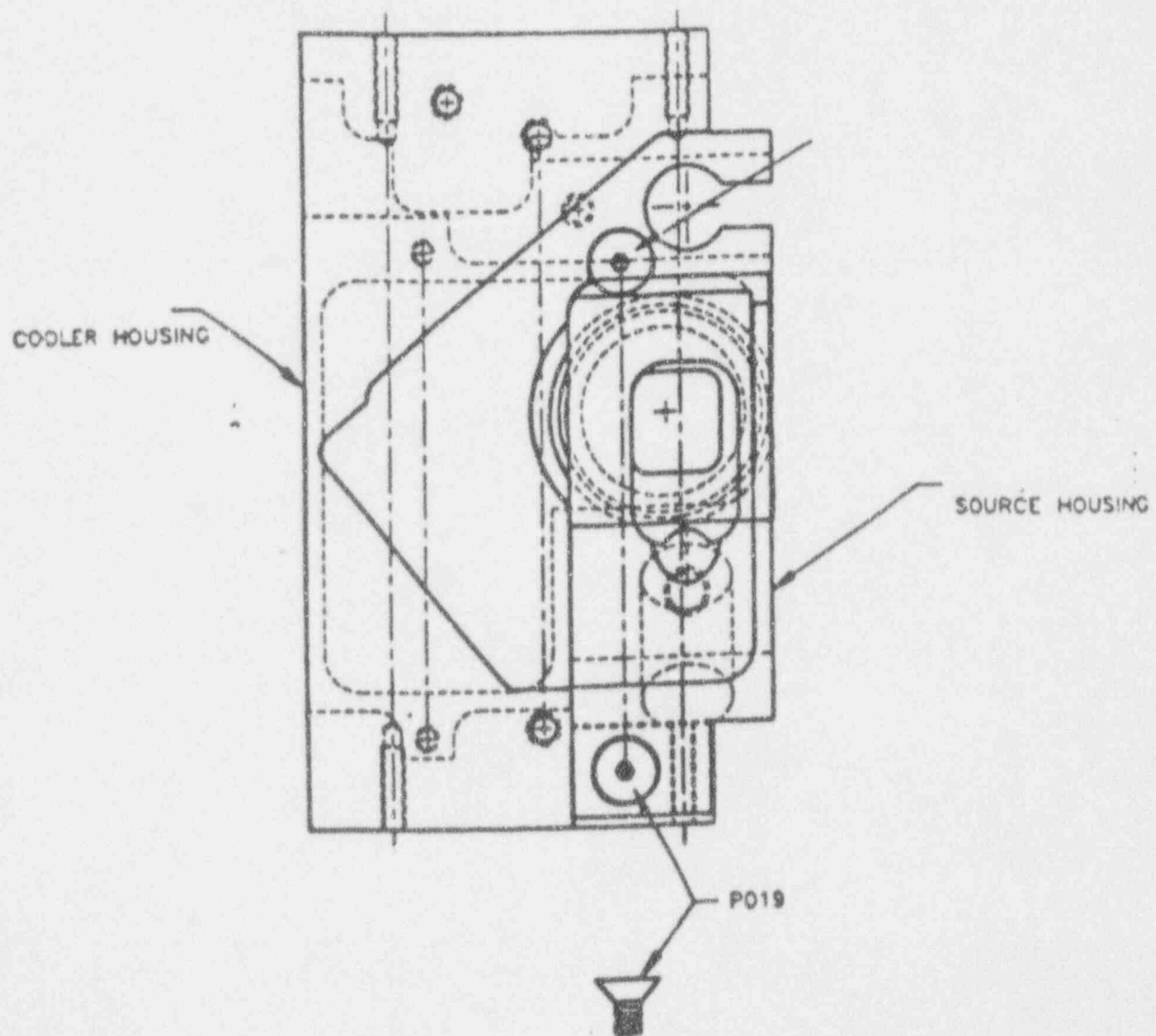
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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ATTACHMENT 4

DEVICE TYPE: Lead In Paint Spectrum Analyzer



SOURCE HOUSING ASSEMBLY  
MOUNTED IN DEVICE

NITON XL Model 309  
LEAD IN PAINT SPECTRUM ANALYZER

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SAFETY EVALUATION OF DEVICE

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DEVICE TYPE: Medical Teletherapy

MODEL: Leksell Gamma System Model 23016

MANUFACTURER/DISTRIBUTOR: ELEKTA RADIOSURGERY, INC. (Distributor)  
8 Executive Park West, Suite 809  
Atlanta, Georgia 30329

ELEKTA INSTRUMENT SA (Manufacturer)  
P.O. Box 330  
1211 Geneva 12  
SWITZERLAND

SEALED SOURCE MODEL DESIGNATION: General Electric Company  
AB ELEKTA Model No. 43047

ISOTOPE:

Cobalt-60

MAXIMUM ACTIVITY:

6600 Curies. 201 sources with a mean average  
not to exceed 32.8 Curies and no single source  
to exceed 36 Curies.

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: Medical Teletherapy

CUSTOM DEVICE:  Yes  No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: GA. 269 D- 101 - S

DATE: Amended April 7, 1994

PAGE: 7 OF 12

DEVICE TYPE: Medical Teletherapy

DEVICE TYPE: Medical Teletherapy

3. The Words: Manufactured by ELEKTA INSTRUMENT SA  
Distributed by ELEKTA RADIOSURGERY, INC.  
Radioactive isotope: Cobalt-60  
Total activity: \_\_\_\_\_ Curies  
Date of activity measurement: \_\_\_\_\_

CONDITIONS OF NORMAL USE:

The Leksell Gamma System will be installed in a clean but not necessarily sterile area with adequate lighting and ventilation, typically in a hospital. Shielding equivalent to 170-270 mm thickness of poured concrete is required to protect against scattered radiation from the unit. The 16.8 metric ton mass of cast iron and cast steel will have a fixed site after installation and should withstand any accident by ramming, collapse of building structure, or fire without loss or exposure of the Cobalt-60. The useful life of the unit is approximately 10-15 years, depending on when the source decay and convenience of the treatment exposure time require that the unit should be moved to a hot cell or equivalent environment for reloading.

PROTOTYPE TESTING:

The Leksell Gamma System has been under development and refinement in Europe since 1968. Two units have been installed in Europe and an additional installation is located in Argentina. These units have served as prototypes for the design requirements and operational performance of the Leksell Gamma System.

Measurements on an operating unit in Sweden extrapolated for the additional shielding used in current units and for the current source loading of 6600 curies, demonstrate that the unit meets the requirements of NCRP-33 for radiation leakage in the beam "off" position.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: GA. 269 D- 101 - S

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PAGE: 11 OF 12

DEVICE TYPE: Medical Teletherapy

by the manufacturer in accordance with his sealed-source registration and ANSI Standard N-542 for medical teletherapy sources.

This unit will be used within a shielded room in a hospital-type environment and will not be subject to deleterious effects of abrasion, corrosion, vibration, impact, puncture, or compressive loads. The 16.8 metric ton mass of the radiation unit should provide adequate inertial protection against any conceivable explosive or mechanical force impact which might occur in a hospital environment and should provide an adequate heat sink for any fire.

Based on the above considerations and our review of the information contained in the references below, we conclude that the Leksell Gamma System Model 23016 is acceptable for licensing purposes.

REFERENCES:

The following supporting documents for the Leksell Gamma System Model 23016 are hereby incorporated by reference and are made a part of this registry document:

Elekta Instruments, Inc. application dated November 7, 1984 and enclosures thereto.

Letter from Hansell & Post (attorney for Elekta Instruments, Inc.) dated February 1, 1985, and enclosures thereto.

Two letter from Hansell & Post dated September 17, 1985 and enclosures thereto.

Letter from Hansell & Post dated November 8, 1985, and enclosures thereto.

Letter from Hansell & Post dated December 17, 1985, and enclosures thereto.

Letters from Hansell & Post dated January 5, 1986, and January 24, 1986, and enclosures thereto.

Letters from Hansell & Post dated March 7, 1986 and enclosures thereto.

Letter from Hansell & Post dated April 21, 1986 and enclosures thereto.

Letter from Elekta Instruments, Inc. dated December 15, 1992 and enclosures thereto.

Letter from Elekta Radiosurgery, Inc. dated March 25, 1994.



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Page)

NO: WA-296-D-104-G      DATE: February 2, 1994      PAGE: 1 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

MODEL: B-0087-BS/BD

MANUFACTURER/DISTRIBUTOR: Panther Systems Northwest, Inc.  
Post Office Box 5279  
Vancouver, Washington 98668-5279  
(formerly - Industrial Process Control, Vancouver, Washington)  
(formerly - Francis Systems, Inc., Vancouver, Washington)

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation

Models: KAC.D1 (Krypton 85)  
SIF.D1 (Strontium 90)  
PHC.C1 (Promethium 147)

<u>ISOTOPE:</u>	<u>MAXIMUM ACTIVITY:</u>
Krypton 85	500 millicuries (18.5 gigabecquerels) (nominal)
Strontium 90	50 millicuries (1.85 gigabecquerels) (nominal)
Promethium 147	500 millicuries (18.5 gigabecquerels) (nominal)

LEAK TEST FREQUENCY: Six months (except Krypton 85 which doesn't require a leak test)

PRINCIPAL USE: (E) Beta Gauge

CUSTOM DEVICE: No

REGISTRY OF RADIOACTIVE SELED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G

DATE: November 4, 1993

PAGE 2 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

DESCRIPTION:

The model B-0087-BS/BD beta gauge is used for measuring paper thickness. The gauge is mounted on a large scanning frame in the paper mill. The frames used, include, but are not limited to, Francis Systems Models FUC-0086-3, FUC-0186, FUC-0286, and FUC-0386. Other frames may be developed by **Industrial Process Control** and this gauge may be used in such frames. The frame provides a degree of security and the gauge is required to be mounted in the frame.

The gauge consists of two housings made of 0.25" welded 6061-T6 aluminum plate. The lower source housing contains the beta source, shutter assembly, and associated electronics. Its external dimensions are 7.5" x 13.5" x 5.56".

The upper detector housing contains an ionization chamber type detector and associated electronics. Its external dimensions are 7.5" x 13.5" x 7.44".

The gap between the housing is 0.25" to 1.5". Paper passes continually between the housings and the gauge moves up and down the length of the frame to obtain a representative measure of the thickness of the sheet.

The source is secured in the source holder, Model No. SK-010, by a brass retaining plate and four cap screws with lock washers. The source holder is made of brass and is 3.5" in diameter and 2.0625" high. It is mounted to an assembly containing the shutter and a beam collimator. The shutter blade is made of 0.1875" machined 6061-T6 aluminum plate. The source holder is attached to the housing with four stainless steel bolts and lock washers. The source housing is closed with latches requiring a special tool.

Primary shielding is provided by the source holder, collimator and shutter. The upper detector housing also acts as a beam stop. The housings provide shielding for scatter radiation.

The shutter is opened by a rotary solenoid and closed by a spring in the solenoid. The shutter returns to the closed position, if the power fails. Microswitches sense the shutter's position and the position is indicated by lights on the control panel. A red light indicates the ON position and a green light indicates the OFF position, in accordance with ANSI N538-1979.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G

DATE: October 5, 1990

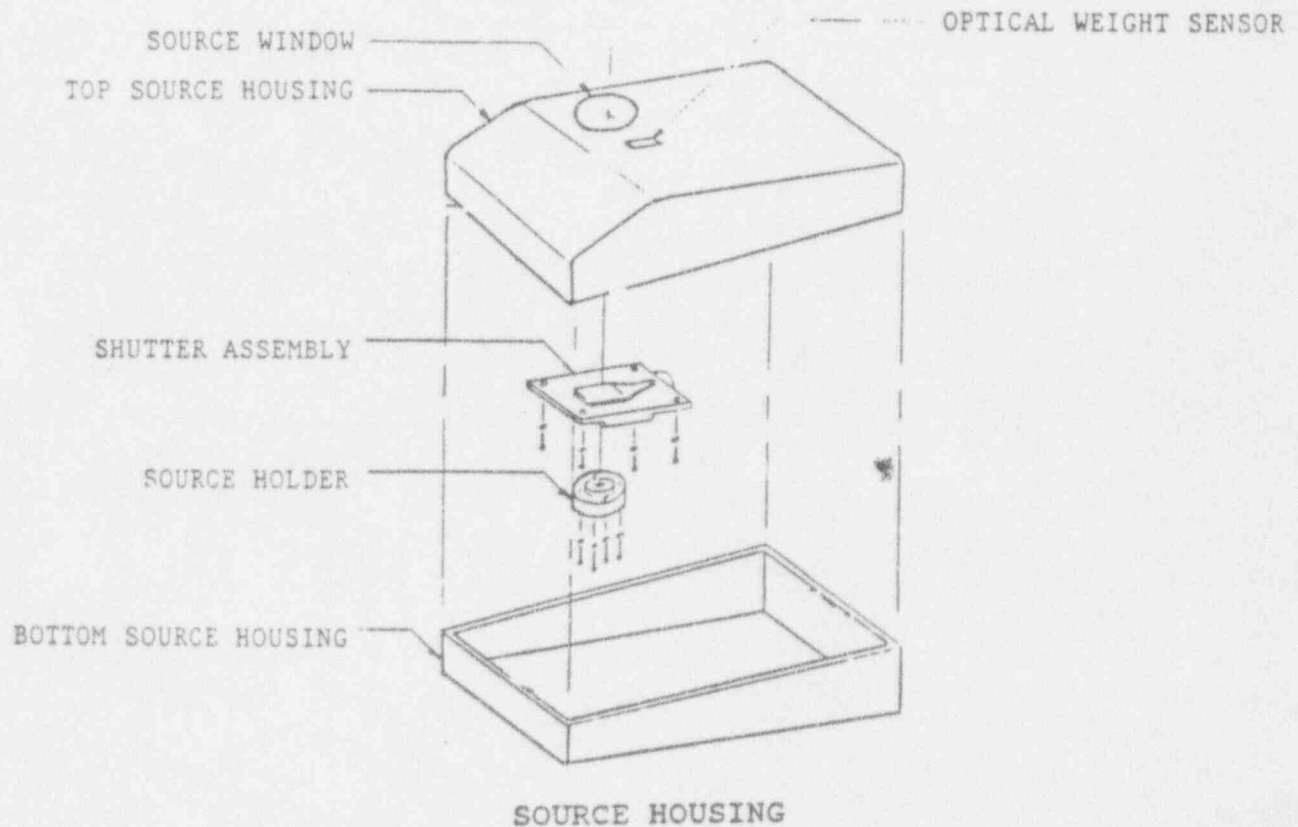
PAGE 3 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

LABELING:

The labels are aluminum and are mounted to the housing with rivets. See Appendix 1 for locations and wording.

DIAGRAM:



See Appendix 2 for diagram of gauge in one type of frame.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G      DATE: October 5, 1990      PAGE 4 OF 7

DEVICE TYPE:    BETA THICKNESS GAUGE

CONDITIONS OF NORMAL USE:

The gauges are used in paper mills to measure paper thickness. They are located out of the weather in a temperature range of 0 to 65°C. High humidity and mildly corrosive atmospheres may be present. Vibration is minimal.

PROTOTYPE TESTING:

The device was tested in accordance with ANSI N538-1979 and received the following ANSI device classifications:

ANSI NUMBER CLASSIFICATIONS	ISOTOPE	AIR GAP OPENING
43-464-465-R2	Kr-85	1.5"
43-455-575-R2	Sr-90	1.5"
43-985-985-R2	Pm-147	0.5"

All device tests were performed by Francis Systems, Inc., and are on file with the Washington State Division of Radiation Protection.

The sources were tested by Amersham Corporation and have the following ANSI classifications:

ANSI #C33232 for Kr-85.  
ANSI #C64343 for Sr-90  
ANSI #C33222 for Pm-147

EXTERNAL RADIATION LEVELS:

Maximum stray radiation dose (shutter open, window open on survey instrument, as defined in ANSI N538-1979) for the gauge is as follows:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G

DATE: November 4, 1993

PAGE 5 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

EXTERNAL RADIATION LEVELS (continued):

<u>Isotope</u>	<u>Distance</u>	<u>Exposure (mR/hr)</u>
Kr-85	5 cm	50.0
	30 cm	10.0
	100 cm	1.3
Sr-90	5 cm	45.0
	10 cm	5.0
	100 cm	0.1
Pm-147	5 cm	1.9
	10 cm	0.2
	100 cm	<0.1

QUALITY ASSURANCE AND CONTROL:

The B-0087-BS/BD gauge is manufactured in conformance with the quality assurance requirements as specified in ANSI N538-1979. Industrial Process Control will require written certification from subcontractors and suppliers for all dimensions and materials on all parts of the gauge housings and related components.

Assembly:

The individual parts are assembled by the manufacturer's Production Section. If any of the parts are found to be faulty, they may be rejected or reworked at the discretion of the company. All of the moving parts are inspected for ease of movement and for any obstructions. Particular attention is paid to critical dimensions, source holder assembly, and operation of the ON/OFF mechanism.

Installation and Testing:

The device is checked for surface radiation levels and removable contamination prior to shipment to the customer. The installation of the gauge is performed by trained Industrial Process Control personnel.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G

DATE: November 4, 1993

PAGE 6 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- The B-0087-BS/BD may be distributed to generally licensed persons in accordance with NRC or Agreement State regulations. For general licensees, the gauge with source must be mounted in a frame to assure security of and inaccessibility to the source.
- The shutter mechanism in the device shall be tested at six (6) month intervals.
- The device shall be installed and initially tested for proper operation of the source exposure mechanism, safety warning components, ON/OFF indicators, labels, external radiation levels (source exposed, source shielded), and leak tested by or under the supervision of Industrial Process Control or other persons specifically licensed by the NRC or an Agreement State. This applies to moving and reinstallation of the device as well.
- The device shall be removed from service and disposed only by Industrial Process Control or other persons specifically licensed by the NRC or an Agreement State.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data submitted by Francis Systems and Industrial Process Control, we conclude the Francis Systems and Industrial Process Control have provided sufficient information to show that the device can be safely operated by persons not having training in radiological safety. Under ordinary conditions of handling, use and storage, the radioactive material in the device will not be released or inadvertently removed. It has been shown under accident condition testing that this device will maintain source containment for at least five minutes (at 1000 degrees F).

It is unlikely that any person will receive in any period of one calendar quarter, a dose in excess of 10 percent of the limits specified in 10 CFR 20.101(a). Under accident conditions (fire or explosion) associated with use, handling and storage of the device, it is unlikely that any person would receive an external radiation dose in excess of: 15 rem to the whole body; 200 rem to the skin, hands, forearms, feet and ankles; 50 rem to other organs.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF A RADIOACTIVE DEVICE  
(Amended Pages 1, 2, 5, 6, & 7)

NO: WA-296-D-104-G

DATE: November 4, 1993

PAGE 7 OF 7

DEVICE TYPE: BETA THICKNESS GAUGE

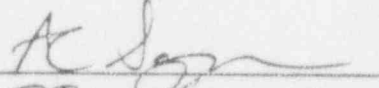
SAFETY ANALYSIS SUMMARY (continued):

Based on the above conclusions, we deem this device acceptable for distribution to individuals who are generally licensed either by NRC or equivalent Agreement State regulations.

REFERENCES:

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made a part of this registry document:

- A. Letter and attachments dated September 12, 1990.
- B. Letter and attachments dated September 24, 1990.
- C. Letter and attachments dated October 3, 1990.
- D. Letter and attachments dated July 27, 1993.

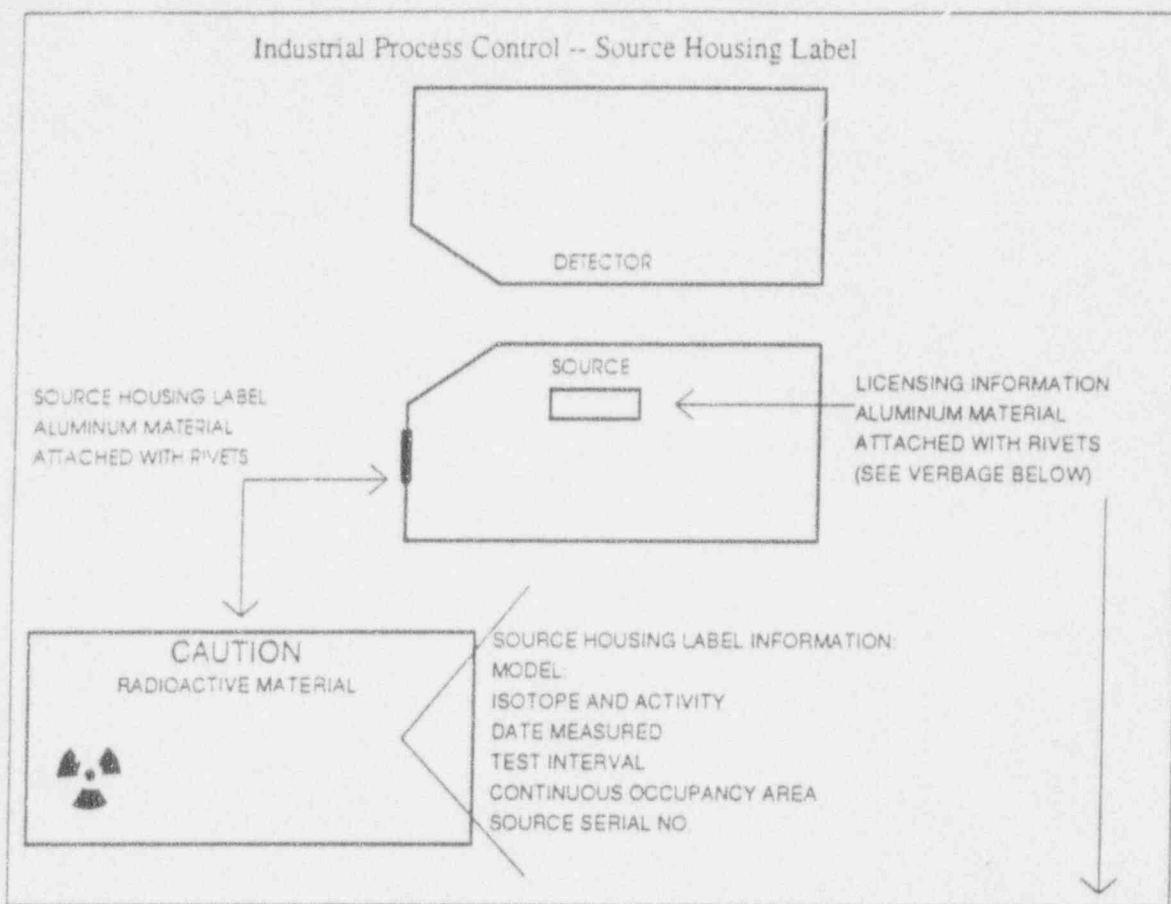
DATE: 22 NOVEMBER 1993 REVIEWED BY: 

DATE: 11/22/93 REVIEWED BY: 

ISSUING AGENCY:

STATE OF WASHINGTON, DEPARTMENT OF HEALTH, DIVISION OF RADIATION PROTECTION, P.O.  
BOX 47827, OLYMPIA, WASHINGTON 98504-7827

APPENDIX 1



The receipt, possession, use and transfer of this device are subject to a general license or equivalent and the regulations of the U.S. NRC or of Agreement States.

Operation of this device shall be immediately suspended until any necessary repairs have been made if there is any indication of possible failure of or damage to the shielding or containment of radioactive material, or the on-off mechanism or indicator.

The sealed radioactive source contained in this device shall be tested at installation and every six months thereafter for leakage of radioactive material, except that devices containing only Krypton 85 need not be tested.

This device shall not be transferred, abandoned or disposed of except by transfer to a person holding a specific radioactive material license to receive this device.

This device shall be tested for proper operation of the on-off mechanism and indicator at intervals not to exceed six months.

Maintenance, tests or other service involving the radioactive material, its shielding and containment shall be performed by persons holding specific radioactive license to provide these services.

Installation, relocation, and initial radiation surveys of devices containing radioactive materials, and maintenance, repair, leak testing. Installation and replacement or disposal of sealed sources containing radioactive material used in this device shall be performed only by persons holding a specific license to perform this service.

**REMOVAL OF LABEL IS PROHIBITED.**

INDUSTRIAL PROCESS CONTROL

Vancouver, WA 98661


U.S.A.

(206)750-9783



Industrial Process Control  
Source Holder Model SK-010 Label

**CAUTION**  
RADIOACTIVE MATERIAL



MOD \_\_\_\_\_  
\_\_\_\_\_ mc \_\_\_\_\_

SER \_\_\_\_\_

DATE MEAS. \_\_\_\_\_

ANSI NO. \_\_\_\_\_

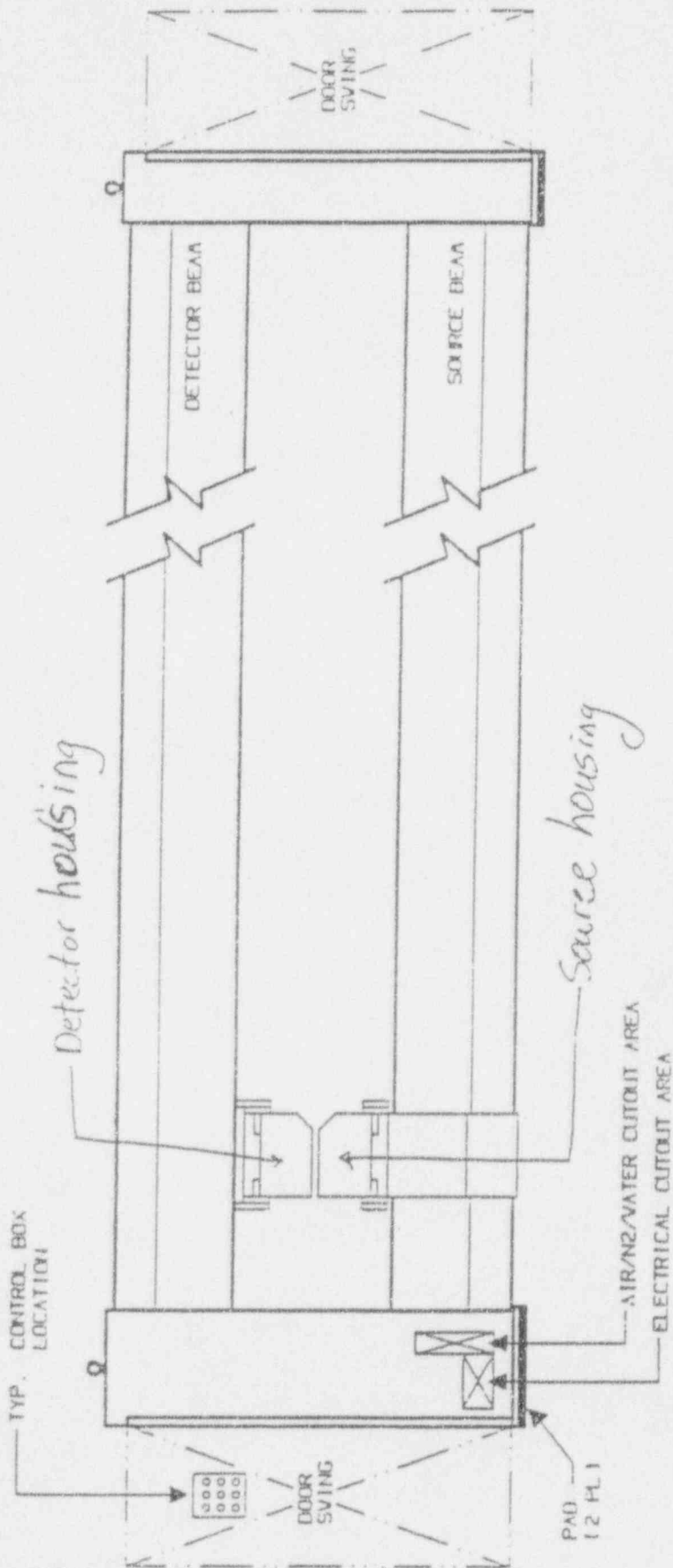
REMOVAL OF THIS LABEL  
IS PROHIBITED

INDUSTRIAL PROCESS CONTROL  
VANCOUVER, WA  
U.S.A

WA-296-D-104-G

February 2, 1994

IR ZONE | DESCRIPTION | DATE | APPROVED



MATERIAL		TITLE	
DRAWN		DUAL BEAM SCANNER	
CHECK		SIZE	FIG. NO.
DESIGN		A	
NFG.		F/CA	(ENG. 110)
DATE			

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: TX0642D101B

AMENDED IN ENTIRETY

DATE: March 30, 1994

PAGE 1 OF 4

DEVICE TYPE: Detector Cell

MODEL: 111019

MANUFACTURER/DISTRIBUTOR: TREMETRICS Inc.  
Division of Thermo Instrument Controls Inc.  
2215 Grand Avenue Parkway  
Austin, Texas 78728

SEALED SOURCE MODEL DESIGNATION: U.S. Radium Model LAB-784\*  
New England Nuclear Model NER-004  
Amersham/Searle Model NBC  
NRD Inc. Model N1001

ISOTOPE: Ni-63

MAXIMUM ACTIVITY: 20 millicuries

LEAK TEST FREQUENCY: 36 Months

PRINCIPAL USE: Ion Generator, Chromatography

CUSTOM DEVICE:  YES  NO

CUSTOM USER:

\*This source is no longer supplied. However, some devices containing this source may still be in use.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: TX642D101B

AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 2 OF 4

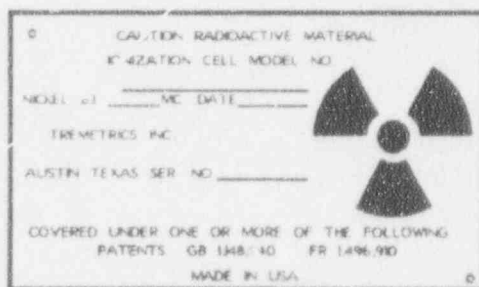
DEVICE TYPE: Detector Cell

DESCRIPTION: The radioactive foil is mounted inside a stainless steel cylinder coated with teflon or boron nitride. This cylinder is mounted within a metal enclosure to form a small cell. The metal enclosure is heated with a 50 to 100 WAH heater, wired in series with a thermostat. This thermostat opens at 400 degrees Celsius to prevent operation of the cell above this temperature.

The Model 111019 cell was known in the past by designated part numbers. These numbers are:

110320 - 0001	113550 - 3204
113027 - 3200	114400 - 3200
113550 - 3200	114400 - 3201
113550 - 3201	114400 - 3204

LABELING: The model 111019 detector cell is designated to operate in the old Micro-Tek Instruments Models MT150 and MT220 gas chromatographs. This cell is also used in the Tracor Models 222, 550, and 560 gas chromatographs. This cell may also be sold as a separate detector cell to authorized recipients. On the side of each detector cell a label is attached with drive rivets. This label contains the company name, radiation trefoil, detector cell model number, isotope, amount of activity, date of assay, serial number of the cell and the words "CAUTION RADIOACTIVE MATERIAL". For those devices distributed to general licensees, another tag will be added to the exterior surface of the gas chromatograph which specifies all details and conditions of general license distribution and the requirements that the user must follow as set out in the Texas Regulations for Control of Radiation 41.28 (d) (1) (ii). These tags have a pressure sensitive adhesive and are of tamperproof construction.



CONDITIONS OF NORMAL USE: This detector cell is designed to produce an ionized atmosphere for quantitative measurement of elements in gas streams. This detector cell is designed to operate in the laboratory as well as the production environment.

PROTOTYPE TESTING: The cell was tested extensively for heater failure. It was found that the heater fails if the temperature sensor fails. Radioactive contamination outside the cell will be unlikely.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: TX642D101B

AMENDED IN ENTIRETY

DATE: March 30, 1994

PAGE 3 OF 4

DEVICE TYPE: Detector Cell

EXTERNAL RADIATION LEVELS: No external radiation levels will exist.

QUALITY ASSURANCE AND CONTROL: Each source foil is manufactured and shipped under the manufacturer's quality assurance program. When each cell is assembled, it undergoes testing to determine if removable contamination greater than 0.005 microcuries shows on external surfaces of the cell. The cell undergoes heat tests to 425° degrees Celsius in acid, caustic and organic solvent atmospheres. Tracor then performs the following tests prior to shipment:

1. A careful visual inspection of the cell.
2. Measurement of the ionization current of the cell to meet minimum performance criteria.
3. Determination of a standard sample using the cell.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The Model 111019 electron capture detector cell shall be distributed to persons specifically and generally licensed. The detector cell may be distributed as a separate unit or in TREMETRICS Model MT150, MT220, 222, 550, or 560, gas chromatographs.
2. The Model 111019 electron capture detector may be installed or removed by the user.
3. The device shall be leak tested at 36 month intervals.
4. Temperature sensors in the cell will limit the maximum temperature to 400° Celsius.
5. The label on the cell will be etched or stamped with the radiation caution symbol and wording without a color requirement.
6. If the Model 111019 electron capture detector is distributed to a generally licensed person, another tag will be added to the exterior surface of the gas chromatograph which specifies all details and conditions of general license distribution and the requirements that the user must follow as set out in the Texas Regulations for Control of Radiation 41.28 (d) (1) (iii).

SAFETY ANALYSIS SUMMARY: Based upon review of information and test data presented, this device can be operated safely by persons having no training in radiation safety. Further, under normal conditions of use the source cannot be inadvertently removed. It is unlikely that any person will receive an external radiation dose.

REFERENCES: This safety review is based on information contained in Tracor letters with drawings and procedures dated, March 26, 1968, April 17, 1968, January 15, 1969, September 7, 1977, January 6, 1978, January 18, 1978 December 14, 1982, August 2, 1983, May 18, 1984, July 27, 1984, August 23, 1990, May 19, 1992, October 26, 1992 (received December 17, 1992) and February 24, 1994.

DATE: March 30, 1994

REVIEWED BY: Floyd R. Hamiter  
Floyd R. Hamiter

DATE: March 30, 1994

REVIEWED BY: Ralph S. Heyer  
Ralph S. Heyer

ISSUING AGENCY: Texas Department of Health  
Bureau of Radiation Control

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

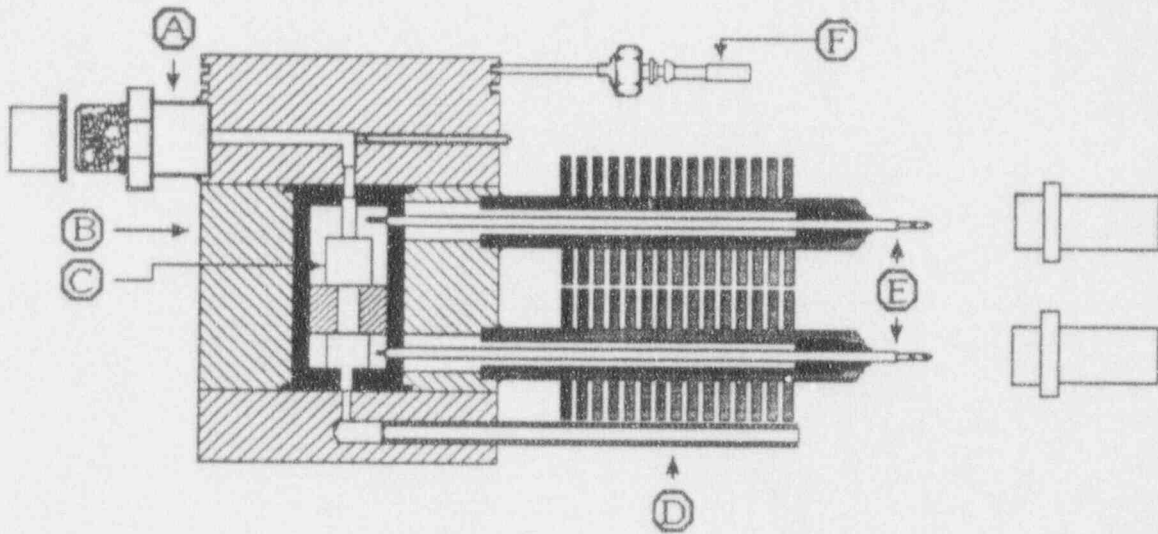
NQ: TX642D101B

AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 4 OF 4

DEVICE TYPE: Detector Cell

DIAGRAM:



Cut-away View of  
the Model 111019 Electron Capture Detector Cell

- |                                      |                                |
|--------------------------------------|--------------------------------|
| A. Connection from Gas Chromatograph | D. Exhaust Port                |
| B. Detector Cell Body                | E. Electrodes                  |
| C. Ni-63 foil                        | F. Thermostat/heater connector |

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NQ: TX642D102S

AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 1 OF 4

DEVICE TYPE: Detector Cell

MODEL: 111020

MANUFACTURER/DISTRIBUTOR:

TREMETRICS Inc.  
Division of Thermo Instrument Controls Inc.  
2215 Grand Avenue Parkway  
Austin, Texas 78728

SEALED SOURCE MODEL DESIGNATION: U. S. Radium Model LAB-508-3

ISOTOPE: Hydrogen-3

MAXIMUM ACTIVITY: 150 millicuries

LEAK TEST FREQUENCY: N/A

PRINCIPAL USE: Ion Generator, Chromatography

CUSTOM DEVICE: \_\_\_\_\_ YES  NO

CUSTOM USER: N/A

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: TX642D102S

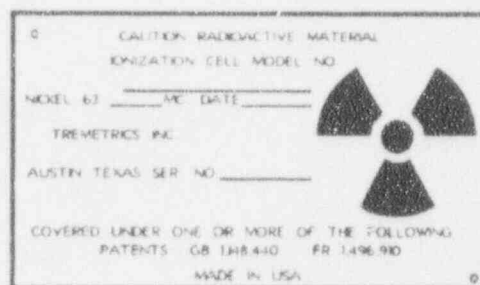
AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 2 OF 4

DEVICE TYPE: Detector Cell

DESCRIPTION: The radioactive foil is mounted inside a stainless steel cylinder coated with teflon or boron nitride. The cylinder is mounted in a metal enclosure which forms a small cell. The metal enclosure is heated using a 55 to 100 watt heater controlled by a temperature sensor. The sensor is adjusted at the factory to prevent the foil from attaining a temperature in excess of 150° Centigrade.

LABELING: The Model 111020 detector cell is designed to operate in the old Micro-Tek Instruments Models MT150 and MT220 gas chromatographs. This cell is also used in the Tracor Models 222 and 550 gas chromatographs. On the side of each detector cell a label is attached with drive rivets (see diagram below). On the side of each detector cell a label is attached with drive rivets. This label contains the company name, radiation trefoil, detector cell model number, isotope, amount of activity, date of assay, serial number of the cell and the words "CAUTION RADIOACTIVE MATERIAL".



CONDITIONS OF NORMAL USE: This detector cell is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. This detector cell is designed to operate in the laboratory as well as the production environment.

PROTOTYPE TESTING: The cell was tested extensively for heater failure. It was found that the heater fails if the temperature sensor fails. Radioactive contamination outside the cell will be unlikely.

EXTERNAL RADIATION LEVELS: No external radiation levels will exist.

QUALITY ASSURANCE AND CONTROL: Each source foil is manufactured and shipped under the manufacturer's quality assurance program. When each cell is assembled, it undergoes testing to determine if removable contamination greater than 0.005 microcuries shows on external surfaces of the cell. The cell undergoes heat tests to 150 degrees Centigrade in acid, caustic and organic solvent atmospheres. Tracor then performs the following tests prior to shipment:

1. A careful visual inspection of the cell.
2. Measurement of the ionization current of the cell to meet minimum performance criteria.
3. Determination of a standard sample using the cell



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NO: TX642D102S

AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 3 OF 4

DEVICE TYPE: Detector Cell

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The Model 111020 electron capture detector cell shall be distributed to persons specifically licensed. The detector cell may be distributed as a separate unit or in TREMETRICS Model MT150, MT220, 222, or 550 gas chromatographs.
2. The Model 111020 may be installed or removed by user.
3. Because of high temperatures, this unit must be exhausted to the outside directly or to a hood system.
4. Limits on the maximum operating temperature do not allow the cell temperature to exceed 150° Centigrade.
5. The label on the cell will be etched or stamped with the radiation caution symbol and wording without a color requirement.

SAFETY ANALYSIS SUMMARY: Based upon review of information and test data presented, this device can be operated safely by persons having no training in radiation safety. Further, under normal conditions of use the source cannot be inadvertently removed. The temperature sensing device in the cell will always fail in open position, thus preventing cell temperatures from exceeding 150° Centigrade. If the unit is installed and operated properly, there is not internal or external radiation hazard.

REFERENCES: This safety review is based on information contained in Tracor letters with drawings and procedures dated, March 26, 1968, April 17, 1968, January 15, 1969, September 7, 1977, January 6, 1978, January 18, 1978, August 23, 1990, October 26, 1992 (received December 17, 1992) and February 24, 1994.

DATE: March 30, 1994

REVIEWED BY: Thoyl R. Hunter

DATE: March 30, 1994

REVIEWED BY: Walter D. Hays

ISSUING AGENCY: Texas Department of Health  
Bureau of Radiation Control

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

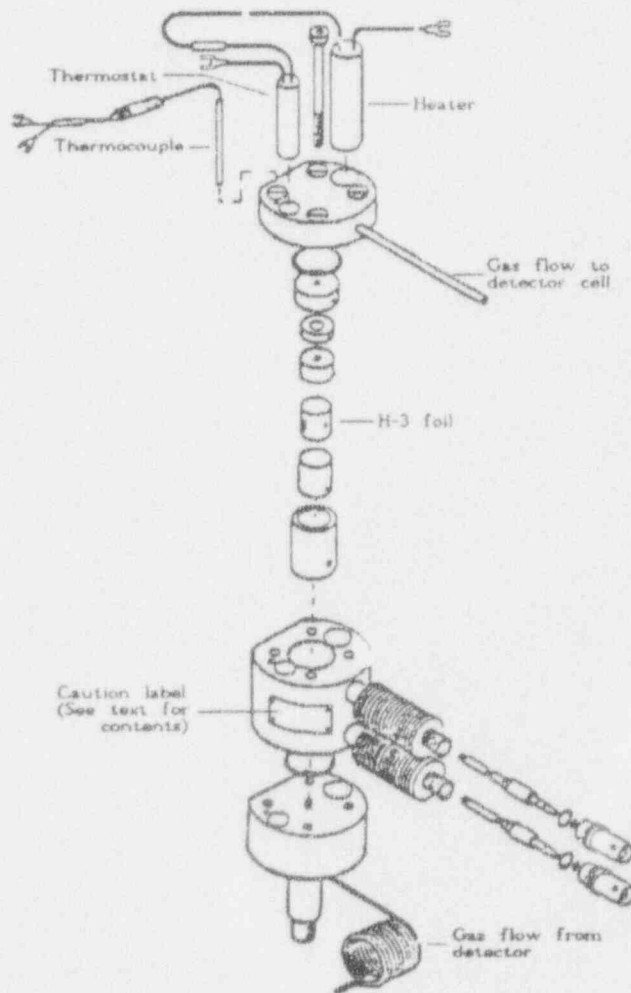
NO: TX642D102S

AMENDED IN ENTIRETY  
DATE: March 30, 1994

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DEVICE TYPE: Detector Cell

DIAGRAM:



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NQ: TX642D103B

AMENDED IN ENTIRETY  
DATE: March 30, 1994

PAGE 1 OF 4

DEVICE TYPE: Detector Cell

MODEL: 115500

MANUFACTURER/DISTRIBUTOR:

TREMETRICS Inc.  
Division of Thermo Instrument Controls Inc.  
2215 Grand Avenue Parkway  
Austin, Texas 78728

SEALED SOURCE MODEL DESIGNATION:

U. S. Radium Model LAB-784\*  
New England Nuclear Model NER-004  
Amersham/Searle Model NBC  
NRD Inc. Model N1001

ISOTOPE: Ni-63

MAXIMUM ACTIVITY: 20 millicuries

LEAK TEST FREQUENCY: 36 months

PRINCIPAL USE: Ion Generator, Chromatography

CUSTOM DEVICE: \_\_\_\_\_ YES X NO

CUSTOM USER: N/A

\*This source is no longer supplied. However, some devices containing this source may still be used.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

AMENDED IN ENTIRETY

NO: TX642D103B

DATE: March 30, 1994

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DEVICE TYPE: Detector Cell

DESCRIPTION: The radioactive foil is mounted inside a stainless steel cylinder coated with teflon or boron nitride. This cylinder is mounted within a metal enclosure to form a small cell. The metal enclosure is heated with a 50 to 100 WAH heater, wired in series with a thermostat. This thermostat opens at 400° Centigrade to prevent operation of the cell above this temperature. The model 115500 cell was known in the past by designated part numbers. These part numbers are:

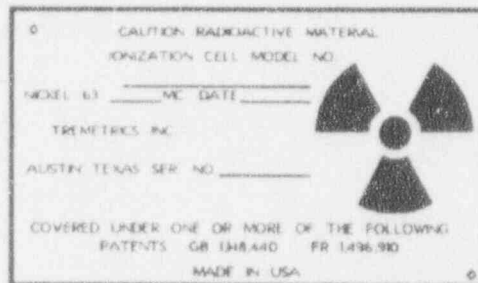
114800 - 3203

114800 - 3204

117540 - 3204

This electron capture detection cell is of essentially identical construction as the Model 111019 (TX0642D101G) except that one side of the cell cylinder is flattened so that two detector cells may be mounted in the same space more easily.

LABELING: The model 115500 detector cell was originally designed to operate in Tracor Models 540, 560, 565, and 570 gas chromatographs. It may also be sold as a separate detector cell to authorized recipients (See Limitations and/or other Considerations). On the side of each detector cell a label is attached with drive rivets. This label contains the company name, radiation trefoil, detector cell model number, isotope, amount of activity, date of assay, serial number of the cell and the words "CAUTION RADIOACTIVE MATERIAL". For those devices distributed to general licensees, another tag will be added to the exterior surface of the gas chromatograph which specifies all details and conditions of general license distribution and the requirements that the user must follow as set out in the Texas Regulations for Control of Radiation 41.28 (d) (1) (iii). These tags have a pressure sensitive adhesive and are of tamperproof construction.



CONDITIONS OF NORMAL USE: This detector cell is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. This detector cell is designed to operate in the laboratory as well as the production environment.

PROTOTYPE TESTING: The cell was tested extensively for heater failure. It was found that the heater fails if the temperature sensor fails. Radioactive contamination outside the cell will be unlikely.

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DEVICE TYPE: Detector Cell

QUALITY ASSURANCE AND CONTROL: Each source foil is manufactured and shipped under the manufacturer's quality assurance program. When each cell is assembled, it undergoes testing to determine if removable contamination is greater than 0.005 microcuries shows on external surfaces of the cell. The cell undergoes heat tests to 425 degrees Centigrade in acid, caustic and organic solvent atmospheres. Tracor then performs the following tests prior to shipment:

1. A careful visual inspection of the cell.
2. Measurement of the ionization current of the cell to meet minimum performance criteria.
3. Determination of a standard sample using the cell.

EXTERNAL RADIATION LEVELS: No external radiation levels will exist.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: Each source foil is manufactured and shipped under the manufacturer's quality assurance program. When each cell is assembled, it undergoes testing to determine if removable contamination greater than 0.005 microcuries shows on external surfaces of the cell. The cell undergoes heat tests to 425° Centigrade in acid, caustic and organic solvent atmospheres. TREMETRICS then performs the following tests prior to shipment:

1. The Model 115500 electron capture detector cell may be distributed to both generally and specifically licensed persons. The detector cell may be distributed as a separate unit or in TREMETRICS gas chromatographs to specific licensees. The detector cell is distributed to general licensees as a separate unit or in TREMETRICS gas chromatographs.
2. The Model 115500 may be installed or removed by the user.
3. The device shall be leak tested at thirty-six month intervals.
4. Temperature sensors in the cell still limit the maximum temperature to 400° Centigrade.
5. The label on the cell will be etched or stamped with the radiation caution symbol and wording without a color requirement.
6. If the Model 115500 electron capture detector is distributed to a generally licensed person, another tag will be added to the exterior surface of the gas chromatograph which specifies all details and conditions of general license distribution and the requirements that the user must follow as set out in the Texas Regulations for Control of Radiation 41.28 (d) (1) (iii).

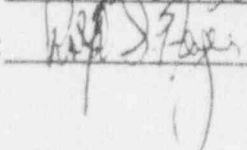
SAFETY ANALYSIS SUMMARY: Based upon review of information and test data presented, this device can be operated safely by persons having no training in radiation safety. Further, under normal conditions of use the source cannot be inadvertently removed. It is unlikely that any person will receive an external radiation dose.

REFERENCES: This safety review is based on information contained in Tracor letters with drawings and procedures dated, January 6, 1978, October 13, 1982, December 14, 1982, January 12, 1984, May 18, 1984, July 27, 1984, March 16, 1990, August 23, 1990, May 19, 1992, October 26, 1992 (received December 17, 1992) and February 24, 1994.

DATE: March 30, 1994

REVIEWED BY: 

DATE: March 30, 1994

REVIEWED BY: 

ISSUING AGENCY: Texas Department of Health  
Bureau of Radiation Control

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE

NQ: TX642D103B

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DEVICE TYPE: Detector Cell

DIAGRAM:

