

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

NO: MA-1159-D-101-B

DATE: January 14, 2005

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DEVICE TYPE: X-Ray Fluorescence DeviceMODEL: XLi-Series and XLp-SeriesMANUFACTURER/DISTRIBUTOR:

NITON Corporation  
900 Middlesex Turnpike, Building # 8  
Billerica, MA 01821-3926

SEALED SOURCEMODEL DESIGNATION:ISOTOPE:MAXIMUM ACTIVITYPER SOURCE:

AEA Model CUC.D1 or CUC.P1

Cadmium-109

50 millicuries (1850 MBq)

AEA Model IEC.A1

Iron-55

40 millicuries (1480 MBq)

AEA Model AMCL or AMC.P4

Americium-241

30 millicuries (1110 MBq)

Isotope Products Laboratories

Cadmium-109

50 millicuries (1850 MBq)

Model XFB-3

Isotope Products Laboratories

Americium-241

30 millicuries (1110 MBq)

Model XFB-4

AEA Model AMRB102219

Americium-241

1-5 microcuries (37-185 kBq)

Nuclear Radiation Developments  
(NRD) Model A-001

Americium-241

5 microcuries (185 kBq)

LEAK TEST FREQUENCY: 6 monthsPRINCIPAL USE: (U) X-Ray FluorescenceCUSTOM DEVICE: YES \_\_\_\_\_ NO X \_\_\_\_\_

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DEVICE TYPE: X-Ray Fluorescence Device

DESCRIPTION:

The NITON XLi and XLP Series analyzers are portable hand held devices designed for determining the content of differing elements in environmental samples, industrial hygiene samples, industrial samples, and metal alloy samples, metal alloys in-situ and in laboratory conditions. The XLi and XLP series analyzers may contain up to three sources each and one Am-241 check source.

The XLi and XLP series analyzers are similar except in external physical shape. The XLi devices are rectangular in shape, with external dimensions of 11.5 inches (29.2 cm) in length, 3.75 inches (9.5 cm) in width, and 3 inches (7.6 cm) in height. The XLP devices are rectangular in shape with a pistol-grip handle, having external dimensions of 10.75 inches (27.3 cm) in length, 3.75 inches (9.5 cm) in width, and 10.5 inches (26.7 cm) in height.

The front end cap is composed of 0.06" (1.5 mm) thick aluminum. The body of the device is constructed from injection molded Lexan 141. The sections are assembled with 4-40 UNC tamper proof screws. A liquid crystal display screen is present on the top face of the device. An aperture is present on the front 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. Electronic connectors are present on the rear end cap of the device. An optional test stand is available from Niton.

The XLi and XLP series analyzers are further represented by Model numbers described in Tables 1 and 2 of this section. These Model numbers represent differences in the number of sources used and differences in the installed software to allow for quantifying of different elements.

The devices are designed to contain one, two, or three sealed sources of Cadmium-109 to a maximum activity of 50 millicuries (1850 MBq), Iron-55 to a maximum activity of 40 millicuries (1480 MBq), and/or Americium-241 to a maximum activity of 30 millicuries (1110 MBq) per source. The sources are mounted in a source housing which is composed of 90% tungsten. There is a one-source, a two-source, and a three-source housing design. Each device contains one of these three possible source housings.

The one-source housing accommodates one Cd-109 source. Prior to January 2005, its shutter contained a built-in Am-241 calibration source of 4.5 microcuries (167 kBq). This Am-241 calibration source is an NRD Model A-001 and the shutter/source combination is manufactured exclusively for Niton by Isotope Products Labs as Product Code 50124510N. With the shutter closed, this calibration source is shielded except in the direction of the detector. The Am-241 check source is identified on the device label if it is present. After

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January 2005, devices having a one-source housing no longer required a built-in Am-241 calibration source.

The two-source housing can accommodate one or two sources installed in the instrument. The larger shutter has a hole through the shutter. This hole lets radiation through the main body of the shutter to hit a raised piece of tungsten. This raised tungsten piece shields this small amount of radiation from exiting the instrument. The radiation causes the tungsten to fluoresce tungsten x-rays, which are used by the detector for calibration purposes. An optional tungsten spacer may also be used in the shielding component of the two-shutter assembly adjacent to shutter # 2 to further collimate radiation and reduce external radiation profiles.

The three-source housing can be used for any combination of one, two, or three sealed sources installed in an instrument. The center shutter (shutter # 2) may have a built in Am-241 calibration source, AEA Model AMRB102219. With the shutter closed, this source containing 1 to 5 microcuries (37 to 185 kBq) is shielded, except in the direction of the detector. The instrument uses the radiation from this source for calibration purposes. A tungsten spacer is used in the shielding component of the three-shutter assembly adjacent to shutter # 2 to further collimate radiation and reduce external radiation profiles.

The following tables outline the possible source loading combinations and positions:

Table # 1 – XLi Series Analyzer Sources

Model Number Designation *	Shutter # 1 Source	Shutter # 2 Source	Shutter # 3 Source	Am-241 Check Source
XLi - N <sub>1</sub> 3 N <sub>2</sub> - N <sub>3</sub>	Fe-55	Cd-109	Am-241	Yes
XLi - N <sub>1</sub> 4 N <sub>2</sub> - N <sub>3</sub>	Fe-55	Cd-109	Fe-55	Yes
XLi - N <sub>1</sub> 2 N <sub>2</sub> - N <sub>3</sub>	Am-241	Cd-109	Am-241	Yes
XLi - N <sub>1</sub> 5 N <sub>2</sub> - N <sub>3</sub>	Fe-55	None	None	Yes
XLi - N <sub>1</sub> 0 N <sub>2</sub> - N <sub>3</sub>	None	Cd-109	None	Yes
XLi - N <sub>1</sub> 4 N <sub>2</sub> - N <sub>3</sub>	Fe-55	Cd-109	None	Yes
XLi - N <sub>1</sub> 2 N <sub>2</sub> - N <sub>3</sub>	Am-241	Cd-109	None	Yes
XLi - N <sub>1</sub> 1 N <sub>2</sub> - N <sub>3</sub>	None	Am-241	None	No
XLi - N <sub>1</sub> 5 N <sub>2</sub> - N <sub>3</sub>	Fe-55	None	Fe-55	Yes
XLi - N <sub>1</sub> 6 N <sub>2</sub> - N <sub>3</sub>	Fe-55	Am-241	None	No

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DESCRIPTION (Cont'd.):

- \* Where  $N_1$  is an integer from 1 through 9 that indicates basic application(s) for the analyzer,  $N_2$  is an integer from 0 through 9 that indicates the type of samples the instrument is calibrated to analyze, and  $N_3$  is a letter suffix (A, B, C, S, or X) that designates special categories for the instrument. The characters  $N_1$ ,  $N_2$ , and  $N_3$  represent software differences and do not describe the radioactive sources used. The number after  $N_1$  is representative of the radioactive sources used and is described by the table.

Table # 2 – XLp Series Analyzer Sources

Model Number Designation *	Shutter # 1 Source	Shutter # 2 Source	Shutter # 3 Source	Am-241 Check Source
XLp - $N_1 3 N_2 - N_3$	Fe-55	Cd-109	Am-241	Yes
XLp - $N_1 4 N_2 - N_3$	Fe-55	Cd-109	Fe-55	Yes
XLp - $N_1 2 N_2 - N_3$	Am-241	Cd-109	Am-241	Yes
XLp - $N_1 5 N_2 - N_3$	Fe-55	None	None	Yes
XLp - $N_1 0 N_2 - N_3$	None	Cd-109	None	Yes
XLp - $N_1 4 N_2 - N_3$	Fe-55	Cd-109	None	Yes
XLp - $N_1 2 N_2 - N_3$	Am-241	Cd-109	None	Yes
XLp - $N_1 1 N_2 - N_3$	None	Am-241	None	No
XLp - $N_1 5 N_2 - N_3$	Fe-55	None	Fe-55	Yes
XLp - $N_1 6 N_2 - N_3$	Fe-55	Am-241	None	No

- \* Where  $N_1$  is an integer from 1 through 9 that indicates basic application(s) for the analyzer,  $N_2$  is an integer from 0 through 9 that indicates the type of samples the instrument is calibrated to analyze, and  $N_3$  is a letter suffix (A, B, C, S, or X) that designates special categories for the instrument. The characters  $N_1$ ,  $N_2$ , and  $N_3$  represent software differences and do not describe the radioactive sources used. The number after  $N_1$  is representative of the radioactive sources used and is described by the table.

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Operational Features

The sealed sources are oriented so as to result in a beam of radiation perpendicular to the plane of the front of the device. The aperture on the bottom plate of the device is rectangular and ~ 1 cm. (0.39 in.) x 2 cm. (0.79 in.) in dimension. The aperture is shielded with a tungsten (~90%) shutter having 0.29 cm. (0.114 in.) thickness for the two and three-source housing designs and 0.16 cm. (0.06 in.) thickness for the one-source housing design. A Kapton dust barrier covers the aperture.

Opening of the shutter requires that the operator power on the unit, enter a password, choose a testing option, and depress the shutter trigger. The shutter will then electronically open. With the shutter open, four LEDs on the sides of the XLi and three on the sides and rear of the XLp of the unit light and alternately flash, giving a visual indication of the shutter-open status. In the case of failure of all systems, the operator can return the device to its storage case, which has shielding for this emergency purpose. Sensors continuously monitor the positions of the shutters.

Shutter operation is disabled automatically at the start up of the instrument. A user password, required to operate the instrument, prevents shutter opening by unauthorized users. To open shutter(s) and test samples: enter password to deactivate shutter locking; place measuring head of instrument against test sample (or in test stand), and depress trigger.

Additionally, for the Model numbers and basic applications described by  $N_1 = 3, 4, 6, \text{ or } 7$  (see Tables 1 and 2) an electronic interlock (proximity switch) on the front end of the instrument must be pushed against a surface before the shutters will open and a measurement taken. This interlock may not be activated on other analyzers for basic application that may require the instrument to measure small oddly shaped pieces, in an occupational setting, with little or no chance of exposure to the public.

In 2004, two new front plates are designed for use as accessories with the device. Both front plates are installed onto the device with three screw fasteners prior to sampling and each front plate temporarily replaces the normal beam aperture front plate (or kapton window bracket). A weld mask functions as a beam aperture to shield unwanted portions of both the exiting radiation beam and the x-ray fluorescence from the sample so that only the weld, and not surrounding materials, is analyzed. A front plate for hot applications, having a thermally protective cover, functions as an instrument insulator when performing sample analysis of materials at temperatures as high as 1,000° F (538° C). With the

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front plate for hot applications installed, no other components of the device are adversely affected by taking a measurement on a hot surface.

Safety Features

To obtain an analysis result, the trigger must be released, which closes the shutter. The instrument is constructed with electronically controlled tungsten source shutter(s) with automatic shutter locking. Shutters are electronically opened by the instrument at the start of a reading, and closed at the end of a reading. The position of the shutters is independently checked by Hall Effect sensors. When any shutter is in an open or partially open position, there are four LEDs that illuminate on the sides of the instrument and indicate an open shutter. When shutters are in a closed position there is an independently operated shutter locking mechanism that prevents the shutters from opening.

The shutter mechanism consists of a motor driven, electronically operated shutter. The trigger is located on the handle and connects to the shutter via an electronic connection. The shutters are "locked" out using an internal automatic locking mechanism. This lock-out mechanism automatically engages when the instrument powers off or has any loss of power. An additional internal power source will automatically close all shutters and lock the shutters in the closed position if battery power is interrupted. The closing and locking of the shutters in no power situations is this power source's only function. The source housing and aperture shutters serve as the primary radiation shielding, with the aluminum body serving as secondary shielding.

With the proper front plate attached, the device may sample materials which are at elevated temperatures. If the detector temperature inside the device rises above the required  $-25^{\circ}\text{C}$ , the instrument stops measuring the sample, the shutter is closed automatically, and an error message appears on the screen display.

Shutter(s) close and lock automatically in the event of loss of battery power. Internal capacitors store enough charge to perform this function (with over 400% of storage capacity). The instrument automatically locks the shutters when the instrument is turned off.

If the battery voltage drops to a too low voltage condition to operate the instrument, the shutter automatically closes and locks, with no help or direction from the operator. In the unlikely event of

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shutter mechanism failure, the shutter open warning lights will stay lighted. The unit is placed in its case, which has shielding for this purpose. In any shutter condition, the shielding in the case is sufficient to reduce the dose measurement on the surface of the case to less than 0.5 mRem/hr. Each device is shipped in a custom designed lockable and shielded carrying case.

LABELING:

Devices shipped to General Licensees are labeled in accordance with Massachusetts regulations 105 CMR 120.128(D)(1)(c). In addition, a copy of Massachusetts regulation 105 CMR 120.122(D), or equivalent provisions of an Agreement State or a Licensing State, will be provided to general licensees along with emergency procedures for unlikely exposed source conditions.

Devices shipped to Specific Licensees are labeled as required by Massachusetts regulation 105 CMR120.241. The labels are durable self adhesive labels. See attachments # 5 and 6 for samples of labels.

The User's Guide, supplied with the analyzer, contains general information on the components of the device, recommended safety precautions, operating instructions, and a section on maintenance of the unit. A leak test certificate and a device radiation profile are also provided with each analyzer. For devices containing an Am-241 source greater than 54 microcuries, a special form certificate is also supplied.

DIAGRAM:

Drawings of the Models XLi and XLp series analyzers are:

- Attachment #1 - XLi Analyzer Assembly
- Attachment #2 - XLp Analyzer Assembly
- Attachment #3 - Two-Source Housing Sub-assembly
- Attachment #4 - Three-Source Housing Sub-assembly
- Attachment #5 - Device Label for General Licensees
- Attachment #6 - Device Label for Specific Licensees
- Attachment #7 - One-Source Housing Sub-assembly

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CONDITIONS OF NORMAL USE:

The XLi and XLp portable x-ray fluorescence analyzers are hand held devices designed to be used for elemental analysis on environmental samples, industrial hygiene samples, industrial samples, and metal alloy samples. The devices are field instruments intended to be used on industrial sites for in-situ sample analysis, for environmental samples, and in laboratory situations. A weld mask front plate may be installed for positive material identification (PMI) of pipe, valve, and vessel welds in refineries, petrochemical, and power generating facilities. The devices are designed as a product that is used independently and not as a component of another product.

Normally, there are no anticipated extremes of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperature, or cycling of the on/off mechanism. Occasionally, materials analysis is performed on surfaces which are at temperatures as high as 1,000° F (538° C). To perform these analyses, the front plate for hot applications mounts onto the instrument. The analyzers may be used and stored between -12° C and 55° C. Storage outside of this temperature range could result in damage to the liquid crystal display.

The estimated life of the instrument is in excess of six years. It is estimated that customers will return devices to the factory for source replacement at intervals of less than 36 months. This 36 month figure is based upon experience from current users of Niton's other analytical instruments. It is a result of three main factors; source replacement, factory calibration, and software or features upgrades. At the time of source reloading, the manufacturer inspects the device for fitness of use and function. Any device which cannot perform in a reliable or safe manner after inspection and service will prompt removal of the device from active use.

As a precaution, the instrument will only operate for a six year period before an inspection by NITON is required. As a final precaution, the instrument has a software feature to ensure that the instrument is returned to NITON. The software in the instrument will not allow the instrument to be operated after six years. The unit will display a message to return the instrument to NITON if six years has been reached from the last service and inspection of the instrument.

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PROTOTYPE TESTING:

The Models XLi and XLp series analyzers have been tested in accordance with ANSI N538-1979 and achieved a classification of ANSI 23-685-985-R1. Additional temperature testing was performed between -12° C and 55° C.

The shutters for the one-source, two-source, and three-source housing designs were tested for over 500,000 measurement cycles to test for shutter mechanism wear and reliability. The manufacturer reported that no appreciable wear was measured and there was no failure of any kind to the shutter mechanisms. These cycling tests were conducted over a temperature range of -12° C to +55° C.

A redesigned shutter, having minor modifications to accommodate the new check source, was tested at room temperature for 300,000 cycles. A redesigned shutter, having a durable and lubricious coating (poly-lube) to shutter components, was tested at room temperature for more than 300,000 cycles. The manufacturer reported no appreciable wear or failures of the redesigned shutter and no adverse effects on device safety or operation.

**In November 2004, the one-source housing device's new shutter design was cycle tested to 500,000 cycles without a failure.**

A series of drop tests onto soft ground and concrete were conducted. After each drop, all shutters were opened and closed in the usual measurement configuration and all shutters still functioned properly. The source housing was inspected to check that the sources were still held in place. For five drops from 5 feet (1.5 meters) onto soft ground, there was no damage to the housing or shutter mechanism. All shutters opened and closed normally. For five drops from 5 feet (1.5 meters) onto concrete, there was no damage to the housing or shutter mechanism. All shutters opened and closed normally. These tests indicate that even repeated severe mechanical shock will not cause a source to be removed from its source holder. The drop tests as described above were also performed with the weld mask installed on the device.

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The sealed sources authorized for use in these devices meet the minimum ANSI performance classification requirements and have the following classifications:

<u>Source Model Number</u>	<u>ANSI Classification</u>
IPL Model XFB-3	77C43333
IPL Model XFB-4	77C64344
AEA Model CUC.D1	97C64344
AEA Model IEC.A1	77C33232
AEA Model CUC.P1	97C53222
AEA Model AMC.P4	77C64444
AEA Model AMCL	68C44344

EXTERNAL RADIATION LEVELS:

The manufacturer submitted measured radiation levels for the Model XLi and XLp series analyzers for all source configurations. The minimum dose rates are with all shutters closed. The maximum dose rates are in front of the instrument with shutters open and containing three sources. Other configurations were within the minimum to maximum radiation levels stated below. For the XLi and XLp devices, containing any combination of sources and having all shutters closed, the radiation levels measured at 5, 30, and 100 centimeters are less than or equal to 0.1 mR / hr (1  $\mu$ Sv / hr).

Maximum radiation levels for the XLi and XLp devices, two-source housing containing 20 mCi Fe-55 and 30 mCi Am-241 sources, were measured directly in front of the devices. The dose rates are:

<u>Distance</u>	<u>Americium-241 Shutter Open</u>	<u>Iron-55 Shutter Open</u>
5 centimeters	122 mR / hr (1.22 mSv / hr)	0.45 mR / hr (4.5 $\mu$ Sv / hr)
30 centimeters	7.9 mR / hr (0.079 mSv / hr)	< 0.05 mR / hr (< 0.5 $\mu$ Sv / hr)
100 centimeters	0.94 mR / hr (9.4 $\mu$ Sv / hr)	< 0.05 mR / hr (< 0.5 $\mu$ Sv / hr)

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Maximum radiation levels for the XLi and XLP devices, three-source housing containing 40 mCi Fe-55 and 20 mCi Am-241 and 50 mCi Cadmium-109 sources, were measured directly in front of the devices. The dose rates are:

<u>Distance</u>	<u>Cadmium-109 Shutter Open</u>	<u>Americium-241 Shutter Open</u>	<u>Iron-55 Shutter Open</u>
5 centimeters	315 mR / hr (3.15 mSv / hr)	31.4 mR / hr (0.31 mSv / hr)	0.45 mR / hr (4.5 $\mu$ Sv / hr)
30 centimeters	18.2 mR / hr (0.18 mSv / hr)	1.85 mR / hr (18.5 $\mu$ Sv / hr)	< 0.05 mR / hr (< 0.5 $\mu$ Sv / hr)
100 centimeters	1.9 mR / hr (19 $\mu$ Sv / hr)	0.18 mR / hr (1.8 $\mu$ Sv / hr)	< 0.05 mR / hr (< 0.5 $\mu$ Sv / hr)

The measurements were made with a Bicon Model MICRO REM LE survey instrument having a detection limit of 0.05 mR / hr (0.5  $\mu$ Sv / hr).

The manufacturer states that measured dose rates for the one-source housing containing a Cd-109 source were found to be comparable to the dose rates shown in the table above for the three-source housing, Cd-109 shutter open. Dose rate measurements with the weld mask indicate a slight increase in scattered radiation and longer sample times are required when using the weld mask. The manufacturer does not expect any change in operator dose due to the use of the weld mask because the weld mask will be used for a small fraction of the total measurements an operator will perform.

**In November 2004, the re-designed one-source housing device was profiled and the manufacturer reported that the results showed no change from the profile data above.**

The manufacturer states that a five year history with similar Niton XRF analyzer devices resulted in no single report to Niton of personnel dosimetry higher than normal background levels. The radiation profiles are as specified by the instruments' ANSI N538-1979 classification of ANSI 23-685-985-R1. The manufacturer further states that to achieve these levels, the customer needs to follow only the most basic of precautions, don't point the instrument at yourself. It is obvious with the XLi and XLP series devices from where the radiation is emitted, thus this most basic requirement is easily understood. The manufacturer states that these devices can be safely operated by persons not trained in radiological safety.

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QUALITY ASSURANCE AND CONTROL:

XLi and XLp series analyzers are manufactured and distributed in accordance with the Quality Assurance program of Niton Corporation. The program is on file with the Agency.

The following tests are performed on all devices:

1. Incoming inspection of all machined and prefabricated items per the appropriate components' specifications
2. Final assembly of the analyzers shall be evaluated and tested prior to shipment for operation of the shutter mechanism for a minimum of fifty cycles.
3. A radiation profile of the analyzers shall be obtained to confirm compliance with the original standards for the configuration
4. The devices are leak tested prior to shipment

All components and/or final assemblies which do not meet performance standards are rejected.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The XLi and XLp series analyzer devices shall be distributed to persons generally licensed pursuant to 105 CMR 120.122(D) or specifically licensed pursuant to 105 CMR 120.124 or equivalent provisions of the NRC, an Agreement State, or a Licensing State.
- Devices should not be subjected to conditions which exceed ANSI N542-1977 performance classification 77C33222 and ANSI N538-1979 classification ANSI 23-685-985-R1, with the exception of temperature use (-12° C to 55° C).
- It is recommended that all users take the manufacturer's safety and instructions course, or equivalent.
- The devices shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination. The wipe tests are to be collected in accordance with the procedures provided by the manufacturer for the user. The evaluation of these leak tests shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such services.
- Handling, storage, use, transfer and disposal are to be determined by the licensing authority.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd.):

- Source replacement and/or disposal, device service, and device maintenance may only be performed by Niton Corporation or persons specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such services.
- The battery, the Kapton dust barrier, the weld mask, and the front plate for hot applications may be changed by the user in accordance with the manufacturer's Operations Manual. Such service does not result in user access to the radioactive sources or degradation of any shielding.
- All labels required by this registry sheet must be clearly visible to the user at all times.
- The device will be shipped in a custom carrying case. All transportation of the device by the licensee should be in this carrying case.
- This registration sheet and the information contained in the references shall not be changed without the written consent of the Massachusetts Department of Public Health, Radiation Control Program.

SAFETY ANALYSIS SUMMARY:

The XLi and XLp series analyzers are portable devices and will not ordinarily be exposed to high mechanical shock or stress or high temperature. Normal shocks such as an occasional drop or unintentional minor hit have been predicted and incorporated into the design. The sources are contained in a 90% tungsten source holder which provides adequate shielding to the user. The shutters are designed to remain in the closed position when the instrument malfunctions.

With the shutter closed, radiation levels surrounding the devices are indistinguishable from background. The device can be safely operated by persons not having specific training in radiological protection. Personnel monitoring is considered optional based on the radiation profile data submitted.

The distributor has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiation protection.
- Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the source housing,

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and it is unlikely that any person will receive in any period of one year a radiation dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20 or equivalent Agreement State regulations.

- Under accident conditions, such as fire and explosion, associated with handling, storage, and use of the analyzers, it is unlikely that any person would receive an external radiation dose or committed effective dose in excess of the limits specified in the following chart:

<u>PART OF BODY</u>	<u>DOSE</u>
Whole body; head and trunk; active blood forming organs; gonads; or lens of eye.	15 rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm <sup>2</sup> (0.15 in. <sup>2</sup> ).	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

Based on our review of the information and test data cited below, we continue to conclude that Models XLi and XLP series analyzers are acceptable for licensing purposes. Furthermore, we continue to conclude that the devices would be expected to maintain their integrity for normal conditions of use and accidental conditions which might occur during use.

REFERENCES:

The following documents for the Models XLi and XLP series analyzers are hereby incorporated by reference and made part of this registry document:

- Letter dated January 25, 2002, with enclosures thereto.
- Letter dated April 25, 2002 with enclosures thereto.
- Letter dated May 5, 2002 with enclosures thereto.
- Letter dated May 8, 2002, with enclosures thereto.
- Letter dated May 10, 2002, with enclosures thereto.
- Letter dated May 13, 2002, with enclosures thereto.
- Letters (two) dated May 17, 2002, with enclosures thereto.
- Letters (two) dated May 21, 2002, with enclosures thereto.
- Letter dated September 5, 2002, with enclosures thereto.

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

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DEVICE TYPE: X-Ray Fluorescence Device

REFERENCES (Cont'd):

- Letter dated September 11, 2002, with enclosures thereto.
- Letter dated October 3, 2002, with enclosures thereto.
- Facsimile dated October 4, 2002, with enclosures thereto.
- Letter dated November 6, 2002, with enclosures thereto.
- Letter dated July 3, 2003, with enclosures thereto.
- Letter dated December 12, 2003, with enclosures thereto.
- Letter dated April 21, 2004, with enclosures thereto.
- Letter dated May 7, 2004, with enclosures thereto.
- Letter dated June 21, 2004, with enclosures thereto.
- Letter dated November 15, 2004, with enclosures thereto.

ISSUING AGENCY:

Massachusetts Department of Public Health  
Radiation Control Program

Date 1/14/05

Reviewer John Sumares  
John Sumares

Date 01/14/05

Concurrence Joshua Daehler  
Joshua Daehler

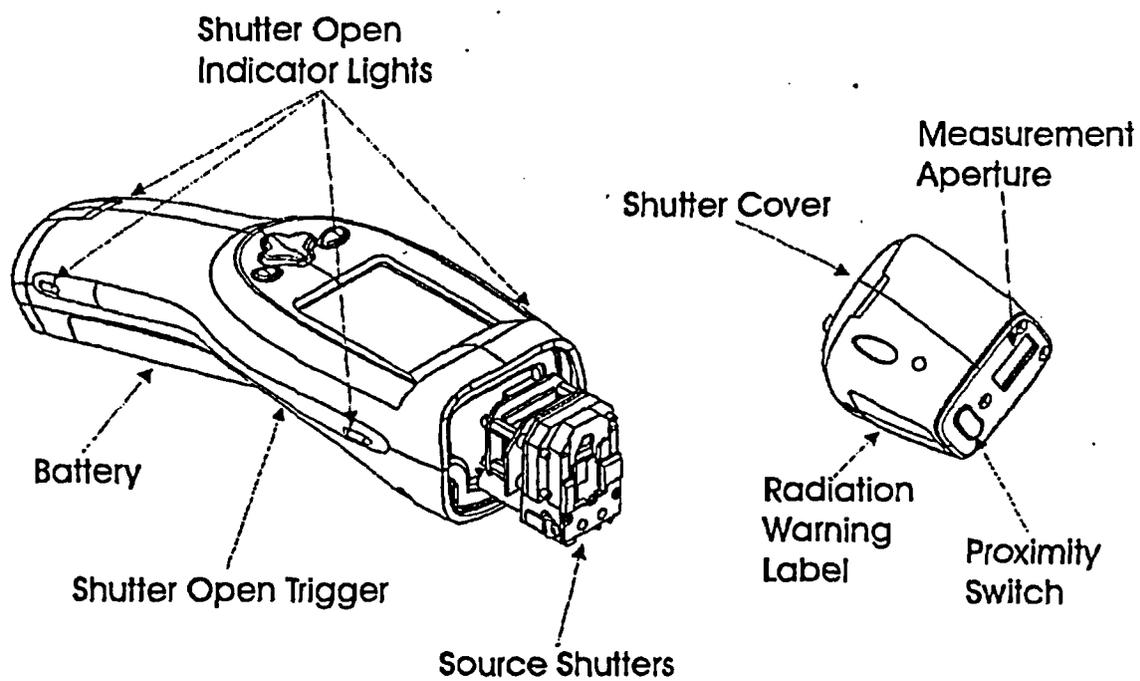
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MA-1159-D-101-B

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Attachment 1 of 7

XLi Analyzer Assembly



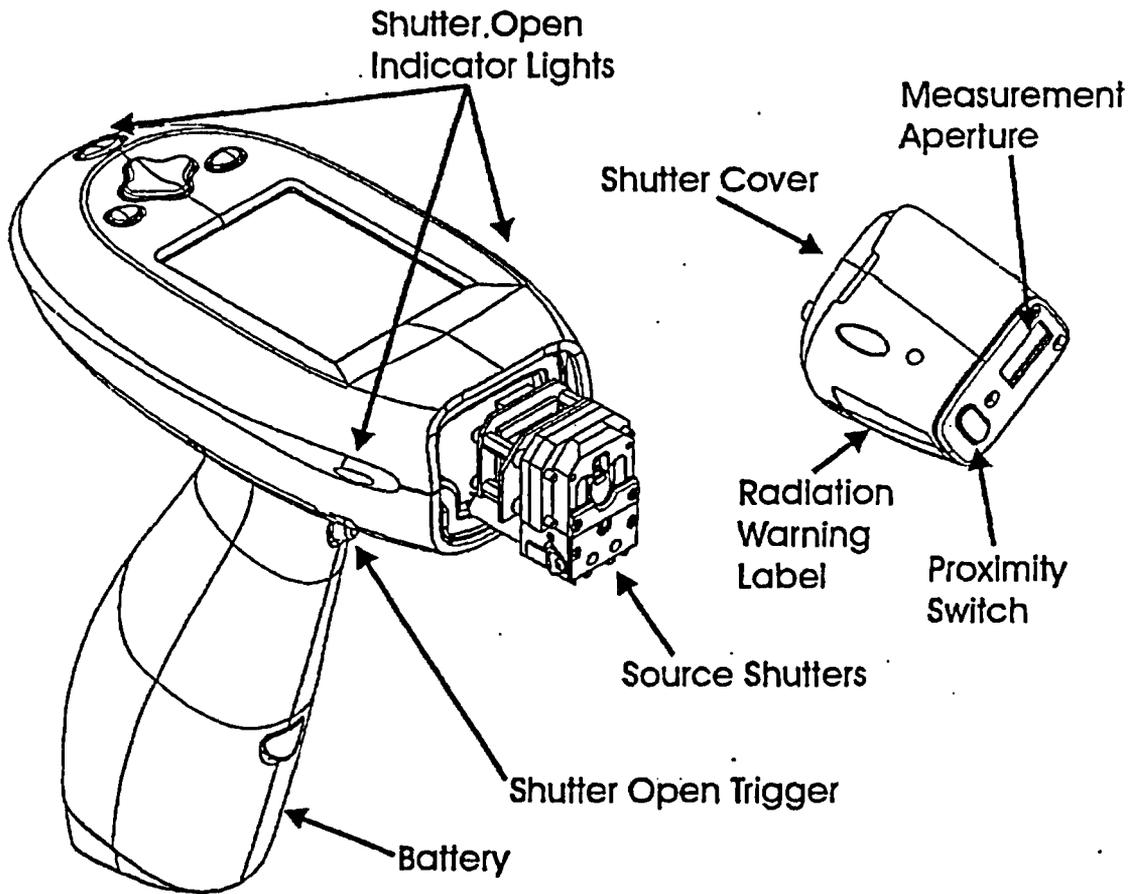
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

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Attachment 2 of 7

XLp Analyzer Assembly



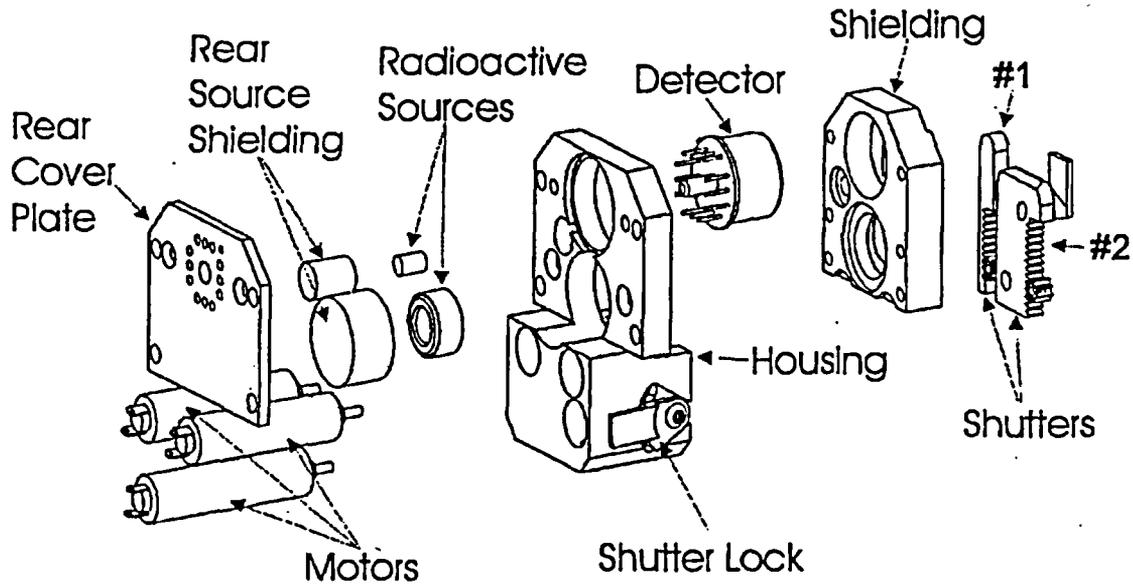
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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Attachment 3 of 7

Two-Source Housing Sub-Assembly



Two Shutter Assembly

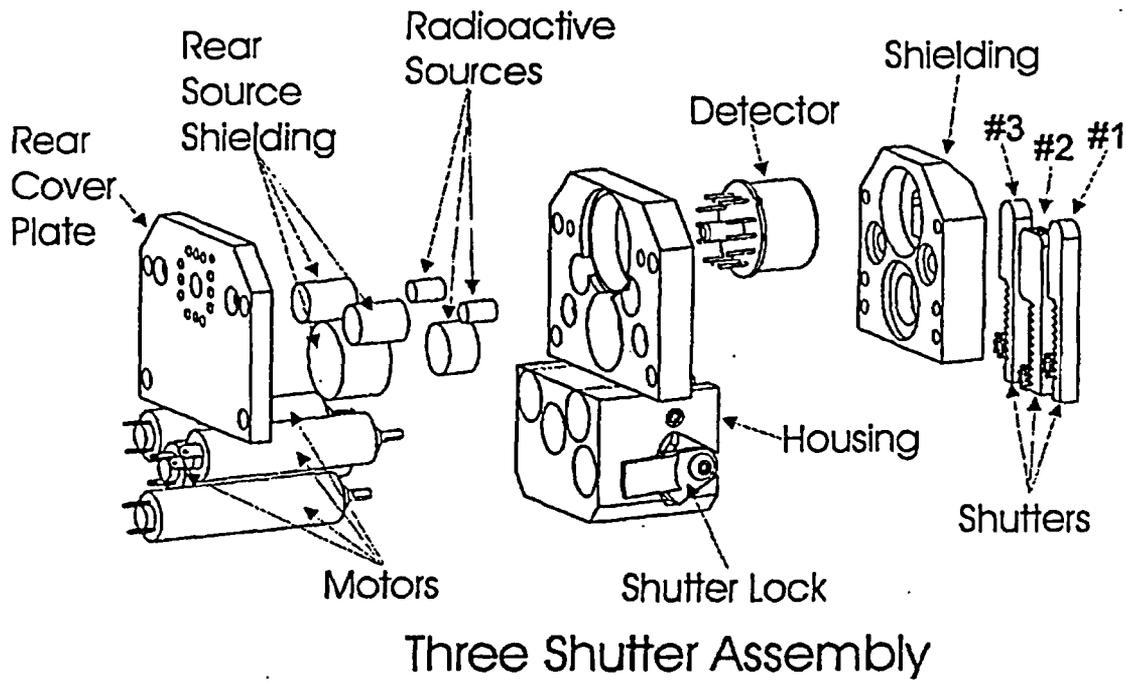
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

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Attachment 4 of 7

Three-Source Housing Sub-Assembly



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

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Attachment 5 of 7

Device Label for General Licensees

  
**CAUTION**  
radioactive material

**ISOTOPE:**

000000

000000

000000

<b>ASSAY DATE:</b>	<b>ACTIVE:</b>
000000	000000
000000	000000
000000	000000
<b>SERIAL #:</b>	<b>MODEL #:</b>
000000	000000

**DO NOT DISASSEMBLE UNIT**  
NITON Corp, Billerica, MA 01821  
800-875-1578

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 a state with which the NRC has entered into an agreement for the exercise of regulatory authority, or a Licensing State as designated by the CRCPD. See Operators Manual for all instructions to ensure safe operation. Must be leak-tested each 6 months. Device may not be sold or transferred without notifying manufacturer. This label shall be maintained on the device in a legible condition.  
Removal is prohibited.

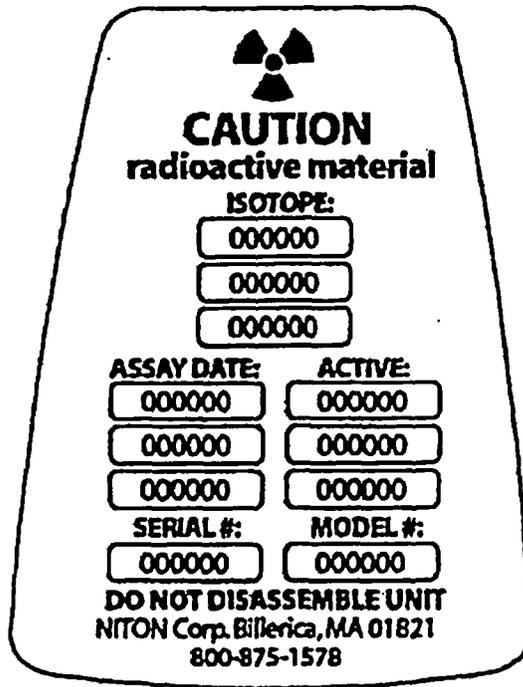
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MA-1159-D-101-B

DATE: January 14, 2005

Attachment 6 of 7

Device Label for Specific Licensees



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

NO: MA-1159-D-101-B

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Attachment 7 of 7

One-Source Housing Sub-Assembly

