

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: MA-8154-D-802-B
(Supersedes NR-0143-D-102-B)

DATE: September 27, 2004

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DEVICE TYPE: X-Ray Fluorescence Analyzer

MODEL: Lab-X 1000 Series (Models 1001, 1002, 1004, 1005, 1006, 1009, and 1011)
Lab-X 2000 Series (Models 2001, 2002, and 2005)

DISTRIBUTOR: Oxford Instruments America, Inc.
(Formerly Oxford Instruments Inc.
Analytical Systems Div.)
130A Baker Avenue Extension
Concord, MA 01742

MANUFACTURER: Oxford Analytical Instruments, Ltd.
20 Nuffield Way
Abingdon, Oxon OX14 1TX, England

SEALED SOURCE MODEL DESIGNATION: Amersham Corp. Models IEC.L1, CUC.D1,
CLCL, or AMC.D2

<u>ISOTOPE:</u>	<u>MAXIMUM ACTIVITY</u>
Iron-55	20 millicuries (740 MBq) - IEC.L1 source
Cadmium-109	3 millicuries (111 MBq) - CUC.D1 source
Curium-244	30 millicuries (1.11 GBq) - CLCL source
Americium-241	10 millicuries (370 MBq) - AMC.D2 source

LEAK TEST FREQUENCY: 24 months

PRINCIPAL USE: (U) X-Ray Fluorescence

CUSTOM DEVICE: YES ___ NO X

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DEVICE TYPE: X-Ray Fluorescence Analyzer

DESCRIPTION: These devices are no longer distributed.

The Lab-X 1000 and 2000 Series consist of an electronic module and an analysis head which are permanently fixed into the instrument cabinet. The Lab-X 2000 Series analyzers are very similar to the Lab-X Models 100, 200, and 320. The primary difference is that the Lab-X 2000 Series does not use adhesive to secure the sources, but rather uses screw clamps, improving the device safety. For both series, samples for analysis are loaded in to the sample port in the turntable and are rotated beneath the main radiation shield until they are positioned above the radioactive source. The device may contain one or two sources. This depends on the intended use of the device. The turntable has two sample ports in the 2000 Series and three sample ports in the 1000 Series and each port has a polycarbonate and/or mylar window to prevent the sample from coming into direct contact with the source. Most of the radiation from the source is stopped by the main radiation shield which is lead-lined. Extra shielding for direct radiation is provided by lead covering the bottom of the turntable. To limit the main leakage of scattered radiation, the sample holders are made from brass [wall thickness 5 mm (0.2 in.)]. The rear panel, through which the cables from the detectors pass, is lined with lead. It is impossible to gain access to the sources or to dismantle the analysis head without first releasing the two locks which, in combination with two hidden dowels, hold the mounting plate securely to the mild steel box. Removal of the turntable is only possible by first releasing the main radiation shield, which is held in place by six screws from within the turntable enclosure.

The applicant states that it takes a trained service person with the keys to the locks approximately 30 minutes to gain access to the main radiation shield. The distributor stated that under no circumstances would keys be provided to users who possessed the device under a general license.

The sealed source models to be used in each of the analyzers are:

<u>Device Model No.</u>	<u>Source Configuration</u>
1000 Series	
Lab-X 1001	IEC.L1
Lab-X 1002	IEC.L1 and CUC.D1
Lab-X 1004	IEC.L1 and CLCL
Lab-X 1005	CUC.D1
Lab-X 1006	CLCL
Lab-X 1009	AMC.D2
Lab-X 1011	IEC.L1 and AMC.D2

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DESCRIPTION (Cont'd):

<u>Device Model No.</u>	<u>Source Configuration</u>
2000 Series	
Lab-X 2001	IEC.L1
Lab-X 2002	CUC.D1 and IEC.L1
Lab-X 2005	CUC.D1

LABELING:

The devices are labeled in accordance with Section 20.203, 10 CFR Part 20. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of manufacturer, date of assay, and the words "CAUTION-RADIOACTIVE MATERIAL".

Devices distributed to persons generally licensed are labeled in accordance with Section 32.51, 10 CFR Part 32.

The labels are made of aluminum and are permanently attached to the devices.

DIAGRAM:

See attachments 1-3.

CONDITIONS OF NORMAL USE:

The Lab-X analyzers are normally used as production control or quality control devices. They are generally used in laboratory environments such as those found in oil refinery labs, coal testing plants, foundry labs, etc. Occasionally, an analyzer may be mounted in a mobile unit for on-site testing. The source manufacturer recommends a working life of 5 to 10 years.

PROTOTYPE TESTING:

These devices are no longer distributed. The following description was active during distribution.

Amersham Corporation has tested the sealed sources to the following ANSI N542 equivalent classifications:

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PROTOTYPE TESTING (Cont'd):

<u>Source</u>	<u>Classification</u>
IEC.L1	77C44342
CUC.D1	77C64344
CLCL	77C64344
AMC.D2	77C64545

The manufacturer tested three analyzer heads to demonstrate that the head would withstand the vibration associated with the transport of the device. The devices, less the counters and preamplifier assemblies, were placed on a bench top two inches away from a spex 8000 mixer mill. The mill had been modified to transmit a vibration frequency of 1200 cycle per minute directly to the bench top. This test was run for a total of 160 minutes in two work days. Upon examination, no screws or fixtures were found to be vibrated loose as a result of this test.

In lieu of prototype testing, the following additional supporting information was provided:

Lab X demonstration equipment has been transported by car and van in Europe and in the United Kingdom since 1972. On no occasion has there been any reported failure or hazard resulting from such transportation. Examples of these applications are:

- The original analysis head used in the Lab X analyzer was designed for a portable mineral analyzer (PMA) which was often taken in trucks and jeeps to remote sites. The current design is essentially the same as the PMA head.
- One customer in Europe has purchased a Lab X (i.e., 2 lab X-200 analyzer heads in one cabinet) which has been permanently mounted in a mobile unit.
- One analyzer head for a European customer has been modified for on-line analysis attached to a conveyor belt.
- The manufacturer claims that in the extremely unlikely event that a sealed source or mounting should be detached, it will nonetheless remain with the locked radiation enclosure and will not pose a radiation hazard.

The applicant indicates that the analyzer head of the Lab X Models 100, 200, and 320 are very

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PROTOTYPE TESTING (Cont'd):

similar in design and construction to the Lab X Model 2000 Series and that the Lab X Model 100, 200, and 320 have been deemed acceptable for licensing purposes.

These devices have been manufactured and distributed under an NRC specific license by Oxford Instruments Inc. since 1982 (2000 Series) and 1987 (1000 Series).

EXTERNAL RADIATION LEVELS:

The manufacturer reports that the maximum external radiation levels from the devices do not exceed 0.25 mR/hr (2.5 μ Sv/hr) at the surface or 0.10 mR/hr (1.0 μ Sv/hr) at 10 cm from the surface.

QUALITY ASSURANCE AND CONTROL:

These devices are no longer distributed. The following description was active during distribution.

Each instrument is fully assembled, complete with appropriate sources, and tested by Oxford Analytical Instruments, Oxford, England. Surfaces are measured for no detectable surface radiation above 0.10 mR/hr (1.0 μ Sv/hr). The sealed source, complete with source mounting bar, is removed and sent by Amersham International to Amersham Corporation, Arlington Heights, Illinois. The source is inspected, leak tested and sent to Oxford Instruments North America Inc. for installation into the unit bearing the manufacturer's serial number which was tested with the source. The leak test results are shipped with the instrument to the ultimate user. Copies of the user's current NRC license or Agreement State license will be on file at Analytical Marketing, Inc. for inspection.

Sources will be installed by a factory trained engineer with over three years experience who is fully qualified and trained in procedures for handling and testing radioactive sources and devices (see NRC License No. 20-19842-01).

Oxford Instruments, Inc. maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with the Source Containment and Device Branch.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The devices shall no longer be commercially distributed.
- The devices shall be used only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.
- The devices shall not be subjected to conditions which exceed the ANSI N542 classification of 77C33232.
- REVIEWER NOTE: Upon transcription of conditions and descriptions onto this registration from the superseded Registration No. NR-0143-D-102-B, the above condition that the devices shall not be subjected to conditions which exceed the ANSI classification of 77C33232 appeared to conflict with the Prototype Testing description. Review of the sealed source registration for the Model IEC.L1 sealed source indicates that the source achieved an ANSI N542 classification of 77C33232. Review of the references indicated in this registration demonstrate a lack of supporting documentation for the claim that the Model IEC.L1 sealed source achieved a higher ANSI N542 classification of 77C44342. Therefore, the above condition should remain in effect.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The devices shall be leak tested at intervals not to exceed 24 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- Sealed sources contained in these devices shall be installed, serviced, removed from service or disposed of only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- This registration certificate and the information contained within the references shall not be changed without the written consent of the Commonwealth of Massachusetts, Radiation Control Program.

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SAFETY ANALYSIS SUMMARY: The devices are no longer distributed.

On June 24, 1993, in the last active registration issued for these devices, the U.S. Nuclear Regulatory Commission concluded that:

The Lab-X 1000 Series (Models 1001, 1002, 1004, 1005, 1006, 1009, 1011) and Lab-X 2000 Series (Models 2001, 2002, 2005) devices are not current products manufactured by Oxford Analytical Instruments, Ltd. However, the devices are handled in repairs, replacements, and disposals.

The Oxford Analytical Instruments, Ltd., Model Lab-X 1000 and Model Lab-X 2000 Series devices are designed to be used by persons working under laboratory conditions. The laboratories may be stationary or in mobile field units. The use of x-ray fluorescence analysis is not a new technique and has been successfully used by many companies and many device configurations for years. The construction of the Oxford instrument models does not allow an authorized person to gain access to the inside of the cabinet that contains the source shield and sources.

In the event of a non-controllable event such as a fire, the melted lead shielding would flow onto and around the source causing the sample turntable to fall out of alignment and preventing any possible movement of the samples. The sources are attached by screws to the source holder on the Model Lab-X 2000 Series. At temperatures in excess of 660°C, the aluminum case and turntable would melt, causing the unit to melt into the steel box that acts as the device's base. This would contain all components, prevent a spread of contamination, and maintain some shielding. Given these facts, the probability is very low that a person would receive a radiation dose or dose commitment in excess of the dose specified in Column IV of the table in Section 32.4, 10 CFR Part 32.

Given the dose rate of 0.1 mR/hr at 10 cm from the devices, it would be unlikely that a person would be exposed to greater than 0.5 R per year under foreseen conditions.

The U.S. Nuclear Regulatory Commission, based on review of the information and test data contained in references, continued to conclude that the Models Lab-X 1000 and Lab-X 2000 series x-ray fluorescence analyzers can be used by persons not trained in radiation safety and that the devices are acceptable for licensing purposes under the provisions of Section 30.33 (specific license), Section 31.15 (general license), and Section 32.51 (manufacturing license) and that the device is expected to maintain its shielding integrity under conditions that may arise from the

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SAFETY ANALYSIS SUMMARY (Cont'd):

proposed uses.

In 2004, the distributor of these devices, Oxford Instruments America, Inc., provided applications to terminate all of their specific radioactive material licenses maintained with the Agency. On August 27, 2004, the distributor indicates that they will no longer distribute these devices, that these devices have been out of production for many years, and that these devices have not been modified since June 24, 1993, the date of the last active registration for these devices.

As of October 2003, Oxford Instruments America, Inc. has stopped providing any services, including disposal, of these devices. Oxford Instruments America, Inc. indicates that their sister company, Oxford Instruments Measurement Systems of Elk Grove, Illinois, will continue to accept devices for disposal.

Oxford Instruments America, Inc. estimates that, as of August 27, 2004, 200 Lab-X 1000 and 75 Lab-X 2000 Series devices have been shipped and that approximately 80 Lab-X 1000 and 25 Lab-X 2000 Series devices are still in use.

REFERENCES:

The following supporting documents for the Models Lab-X 1000 Series (Models 1001, 1002, 1004, 1005, 1006, 1009, 1011) and the Lab-X 2000 Series (Models 2001, 2002, 2005) are hereby incorporated by reference and are made a part of this registry document.

- Oxford Instruments, Inc. letters dated November 16, 1992, August 20, 1992, December 16, 1991, April 8, 1987, April 29, 1983, January 20, 1983, and November 18, 1982, each with any enclosures thereto.
- Oxford Instruments America, Inc. letter dated August 27, 2004.

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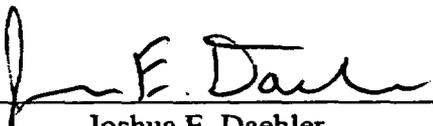
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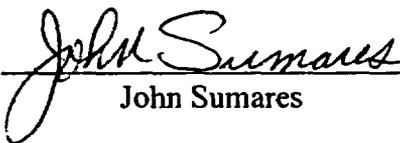
ISSUING AGENCY:

Massachusetts Department of Public Health
Radiation Control Program

Date: 09/27/04

Reviewer: 
Joshua E. Daehler

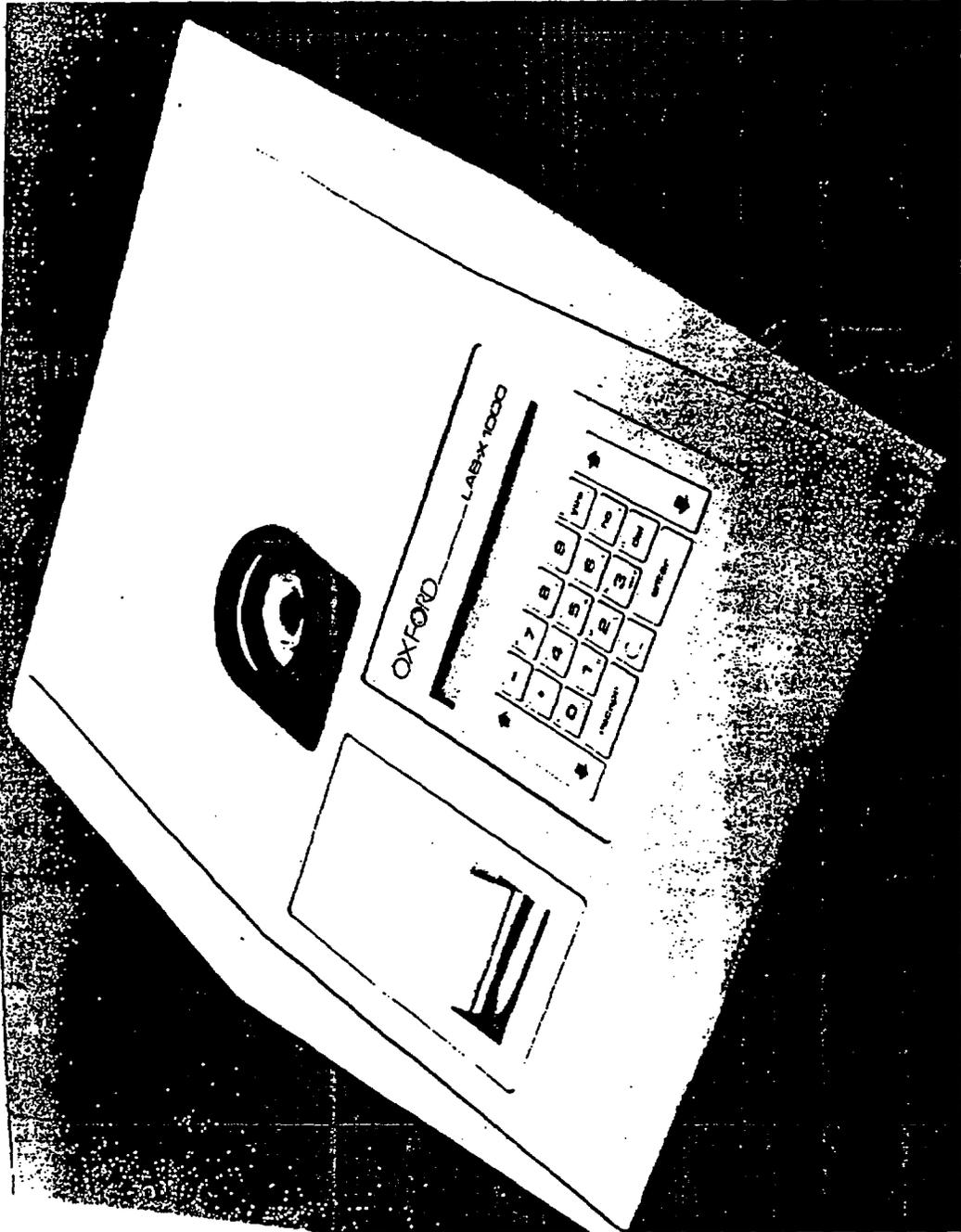
Date: 9/27/04

Concurrence: 
John Sumares

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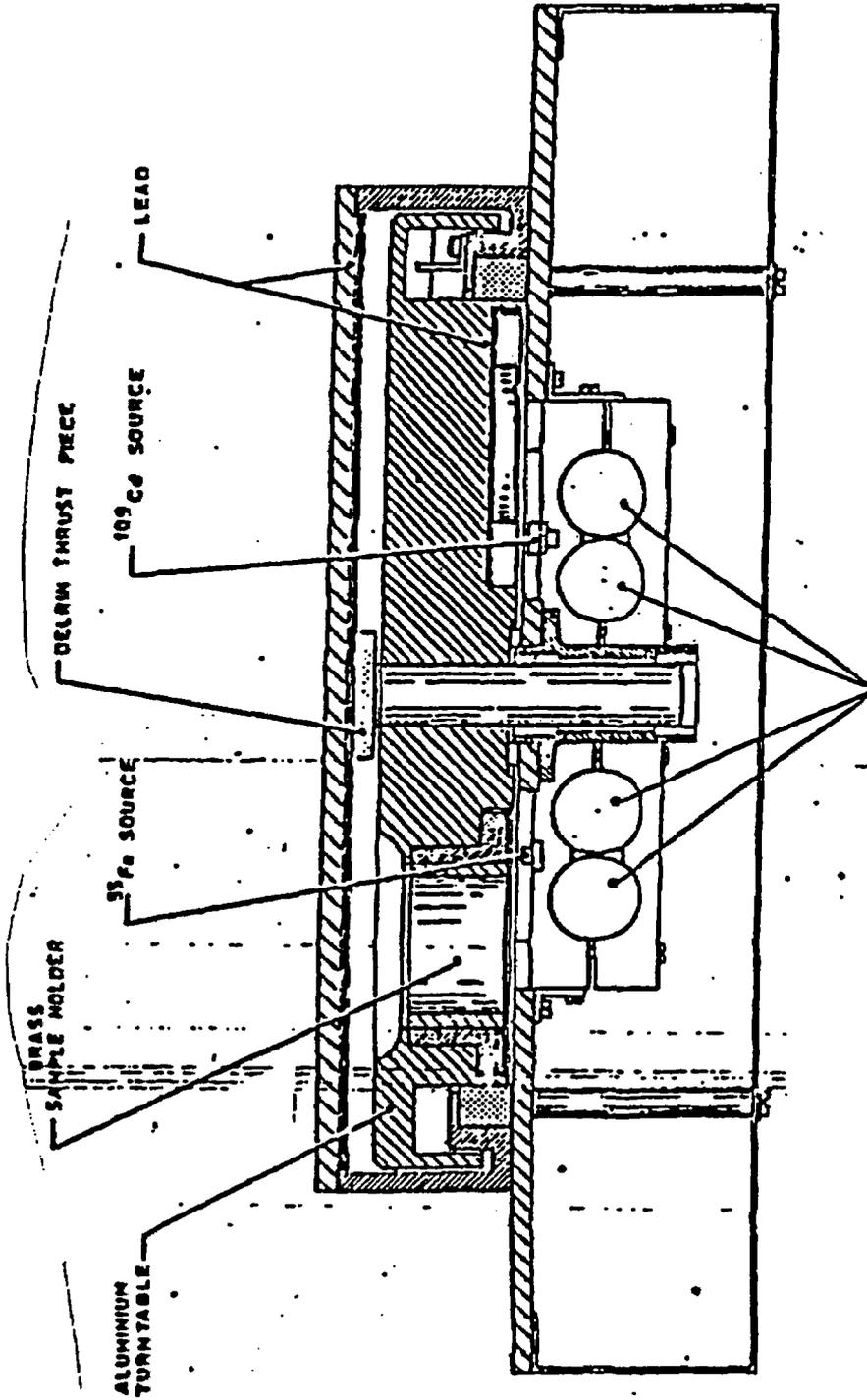
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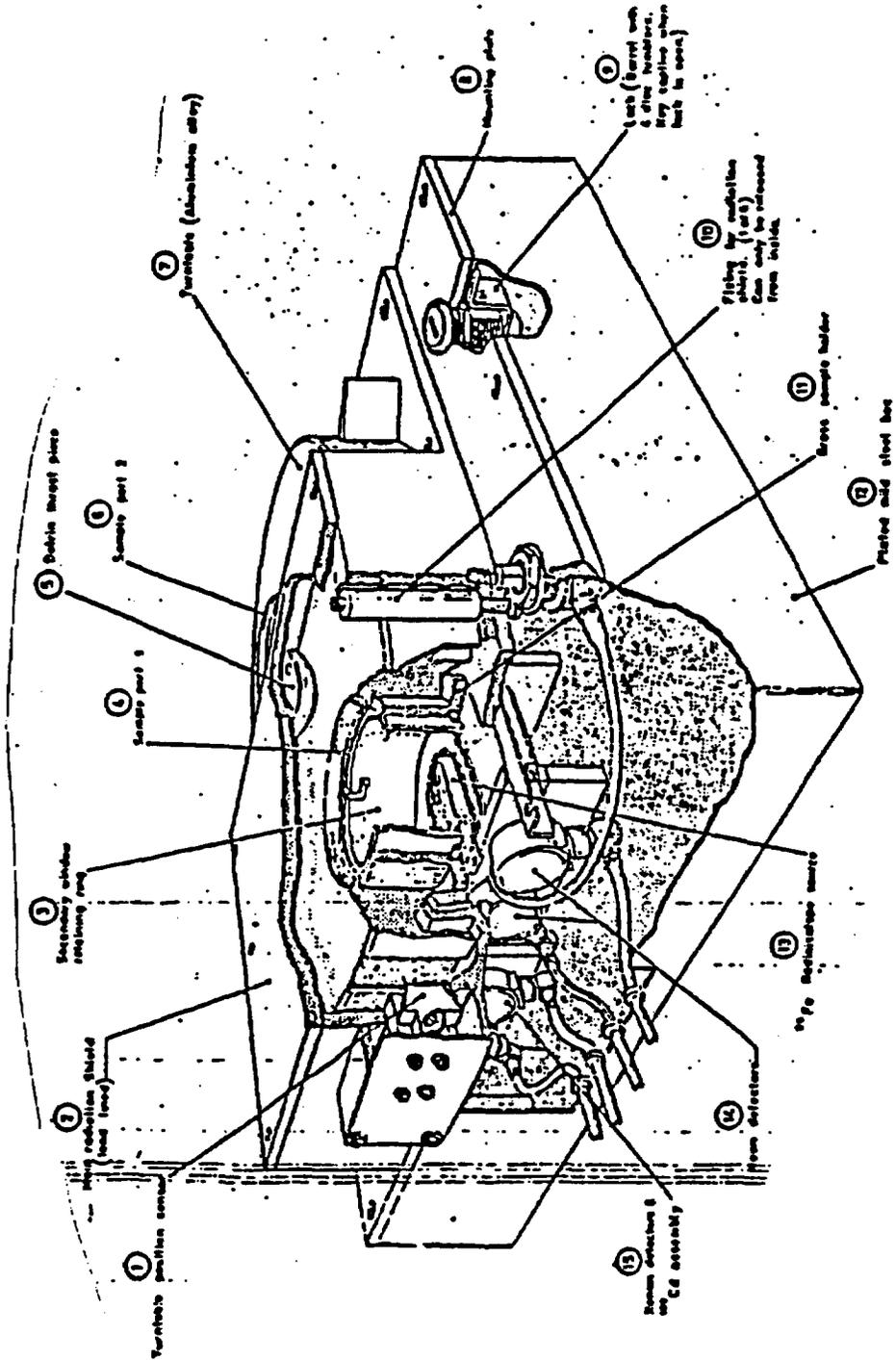


SECTION THROUGH RADIATION ENCLOSURE
LAB-X 2001 TO 2005

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LAB-8 2001 TO 2005
CUTAWAY VIEW OF RADIATION ENCLOSURE