



**Our Lady of Mercy Hospital**

U.S. Highway 30 Dyer, Indiana 46311-1799 (219) 865-2141

United States Nuclear Regulatory Commission  
Region Three  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Attention: Evelyn R. Mattson  
Materials Licensing Section

Re: Control Number 79312

September 9, 1985

Dear Evelyn,

As a reply to your August 7, 1985 letter to amend our by-product license #13-12914-01, please review the requested information in order to complete your review and approval of our requested amendment.

1. Physician user/supervisor of the bone marrow analyzer will be Melvin Hirsch, M.D., as listed on our materials license as identified above. Dr. Hirsch is an authorized user for all groups. Please note that Dr. Hirsch is also certified by the American Board of Nuclear Medicine and has had significant excess of the 8 hours training described in Guidance Directive 85-1.
2. The individual who will be performing the installation, replacement and removal of sealed sources in the bone marrow analyzer will be through the services of Professional Radiation Management, Inc.; 5213 West Lawrence Avenue; Chicago, IL 60630, specifically by certified health physicist Nicholas Lembares, M.S., who holds a Master's degree in Radiological Physics from the University of Chicago and is certified by the American Board of Radiology. License numbers: U.S.R.C.-12-20227-01, State of Illinois-IL-00527-01.

This individual will be performing the installation, replacement and removal of the source contained in the source holder according to the manufacturer's instructions and will receive training at the time of equipment installation relative to source installation, replacement and removal. A record will be maintained by individuals who receive training in this activity from the manufacturer.

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13-12914-04 PDR

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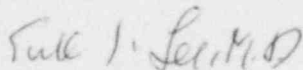
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3. The procedure for installing, exchanging and removing sealed sources from the device will be as described in the manufacturer's instructions, a copy of which is appended.
4. The method used for disposal of the sealed sources after they have decayed beyond their useful life or otherwise are no longer needed is that they will be returned to the source supplier, either Amersham, New England Nuclear, Gulf Nuclear, where they will remove the source and dispose of it, replacing it with a new source.
5. Our procedure for insuring that the bone marrow analyzer and the sealed sources are secured at all times against unauthorized use or removal of both is that during the period of time that the department is not in operation the bone marrow analyzer, as depicted on the attached photocopy of the department layout, the area is locked - both the specific room that the bone marrow analyzer is kept in and the hot lab, where a source would be stored in a lead-lined locking module prior to installation or return to the manufacturer for replacement.

The integrity of this system is maintained by the limited access by authorized staff only and special-keyed locks that are openable only by authorized staff of the Nuclear Medicine Department.

We appreciate your prompt review of this additional information. Should additional information or clarification be required, please do not hesitate to contact me as soon as possible.

Sincerely,



S. S. Lee, M.D.  
Chairperson, Radiation Safety Committee

SSL/jg  
Enclosure

Copy to: J. Daniels, Manager of Imaging Services  
N. Lembares, Health Physicist  
File

### B.5 Controlled Area

All radioactive material must be used in a controlled area. This is achieved by labelling the entry into the bone scanning room and noting that access is limited to authorized individuals. If the bone scanning room is a sub-area of a larger controlled space, then the access will be limited at the major entry. The sign must state;

CAUTION RADIATION AREA

and

CAUTION RADIOACTIVE MATERIALS.

There must also be a noticed posted in the area for workers to contact the RSO in case of an emergency, the appropriate location and telephone numbers of State Agency or regional NRC office and location of license and radiation regulation.

### B.6 Personal Monitors

All individuals who work in a controlled area must be monitor for their radiation exposure. This is the familiar film badge dosimeters that are available from several suppliers. These badges are read monthly and the operators radiation exposures are reported.

### B.7 Source Disposal/Shipping

Expended sources can be returned to the original supplier: i.e., I-125 sources to AECL in Canada and Gd-153 sources to Gulf Nuclear in Webster, Texas. These manufacturers can provide disposal information. The following is a suggested method for source disposal. These sources can be stored until the total activity is less than 70 mCi for I-125 (6 months) or 200 mCi for Gd-153 (20 months). Several sources can be shipped at one time but the total activity for I-125 must not exceed 70 mCi or 200 mCi for Gd-153. Many carriers will not ship restricted material. However, a depleted source is not considered restricted and can be sent. The shipping form should state "depleted sealed source for recycling". A statement similar to the following should be included along with the results of the most recent wipe test:

This shipment conforms to the conditions and limitations specified in 49-CFR-173.421 for excepted radioactive material in limited quantity, n.o.s. UN2910. It contains \_\_\_\_\_ sealed source(s) of I-125 (Gd-153) radionuclide(s) with an activity of \_\_\_\_\_ mCi as of \_\_\_\_\_.

Radiation Safety Officer

The following information will be of assistance when shipping non-exempt sources. The shipper's responsibilities include that where containers are supplied by the shipper, the shipper shall be responsible for determining that shipments are made in containers which have been constructed or assembled with all parts or fittings in their proper place, and marked to show the DOT or ICC specification number and authorized gross weight, e.g., DOT15A-100 (49CFR173.24(c)(1)). See Section B.2.a for package specifications.

Each shipper offering radioactive materials for transportation must provide shipping papers, to include (49CFR173.427(a)(5)):

1. The Transport Group or Groups of the radioactive material, if in normal form;
2. The name of the radionuclides and a description of their physical and chemical form, if the material is in normal form;
3. The activity of the radioactive material in Curies;
4. The type of label applied to the package, i.e., Radioactive White-I, Radioactive Yellow-II, or Radioactive Yellow-III.
5. If the quantity of radioactivity is below levels stated by NRC (10CFR71) and DOT (49CFR170-189) then the category of exempt material applies and no label is required.

Each shipper offering any dangerous article for shipment via air, highway, or rail carriers must show on the shipping papers the following certificate signed by the shipper (14CFR102.2; 49CFR173.430, 174.511, 175.654, 176.704a and 177.819):

"This is to certify that the above named articles are properly classified, described, packaged, marked and labelled, are in proper condition for transportation, according to the applicable regulations of the Department of Transportation (or Federal Aviation Administration)."

Before the actual shipment the RSO should notify the receiving party of the estimated time of arrival of the shipment. The shipment must include "shipping papers" that include all the required information about the source.

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## C. Routine Health Physics Services

### C.1 Source Changes

**WARNING:** Only individuals trained in the principles of radiation safety and protection and the device specific radiation requirements of LUNAR scanners should conduct these procedures.

#### \* C.1.a Gd-153 Source Changes

The source is encapsulated in a metal cylinder, approximately 1 inch in length and 1/8 inch diameter. This metal capsule is inside a lead-lined brass source holder (Fig. 1). For all phases of operation, the capsule need not be removed for the source holder. During a source exchange the entire source holder is returned. Operator exposure is minimized by never removing the capsule from the holder.

All the following steps should be performed without tools. Use of tools may cause damage to the equipment.

#### \* Procedure

1. Remove pad and the lucite insert from the table.
2. Use OPTION 5 (Static Counter, ref. User Manual) of the DP3 Spine software to position the arm and source at the center of the window.
3. Place a lead source holder cap onto the source collimator (Fig. 2)
4. Use the "shutter open" command of OPTION 5 to access the source holder/collimator assembly. Alternatively, the shutter may be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the source is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this open position during the exchange.
5. Turn the chuck ring (Fig. 3) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.
6. Pull the source collimator (which will have the source holder attached) out of the chuck. The source holder and collimator can now be handled as an unit.



7. Holding the source holder/collimator upright, as positioned in the scanner, unscrew the source holder from the source collimator. Put the lead cap on the source holder.

CAUTION: RADIATION PRESENT! After the collimator is removed a broad beam of radiation projects from the top of the source holder.

8. Exchange the spent source for the new source. Place the lead cap from the source holder onto the collimator. Tread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-tread. The source holder/collimator can now be handled as an unit.
9. Slide the source holder/collimator into the source chuck (Fig. 3) so that the pin on the bottom fits into the notch on the source chuck. The collimator should rest on the top of the chuck, not the chuck ring.
10. Close the shutter by using "shutter close" command of OPTION 5 or remove any tape used to hold open the shutter.
11. Verify that the shutter blade moves freely in and out of the source collimator. If necessary, adjust the location of the collimator to allow free motion.
12. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.
13. Remove the lead cap from the top of the collimator.

CAUTION: A narrow beam of radiation is now projected upward from the collimator aperture.

14. Replace the lucite insert and patient pad.
15. Monitor radiation levels around the table to insure operator safety.
16. Perform Standard Scan and QA procedure to verify proper operation.

#### C.1.b I-125 or Am-241 Source Changes

The I-125 source is encapsulated in a metal cylinder, 10 mm in length and 3 mm diameter. This metal capsule fits inside the brass source holder, SRC-0100-1 (Fig. 4). For all phases of operation, the capsule need not be removed for the source holder.

FIGURE 1  
Source Capsule and Holder for 153-Gd Capsule

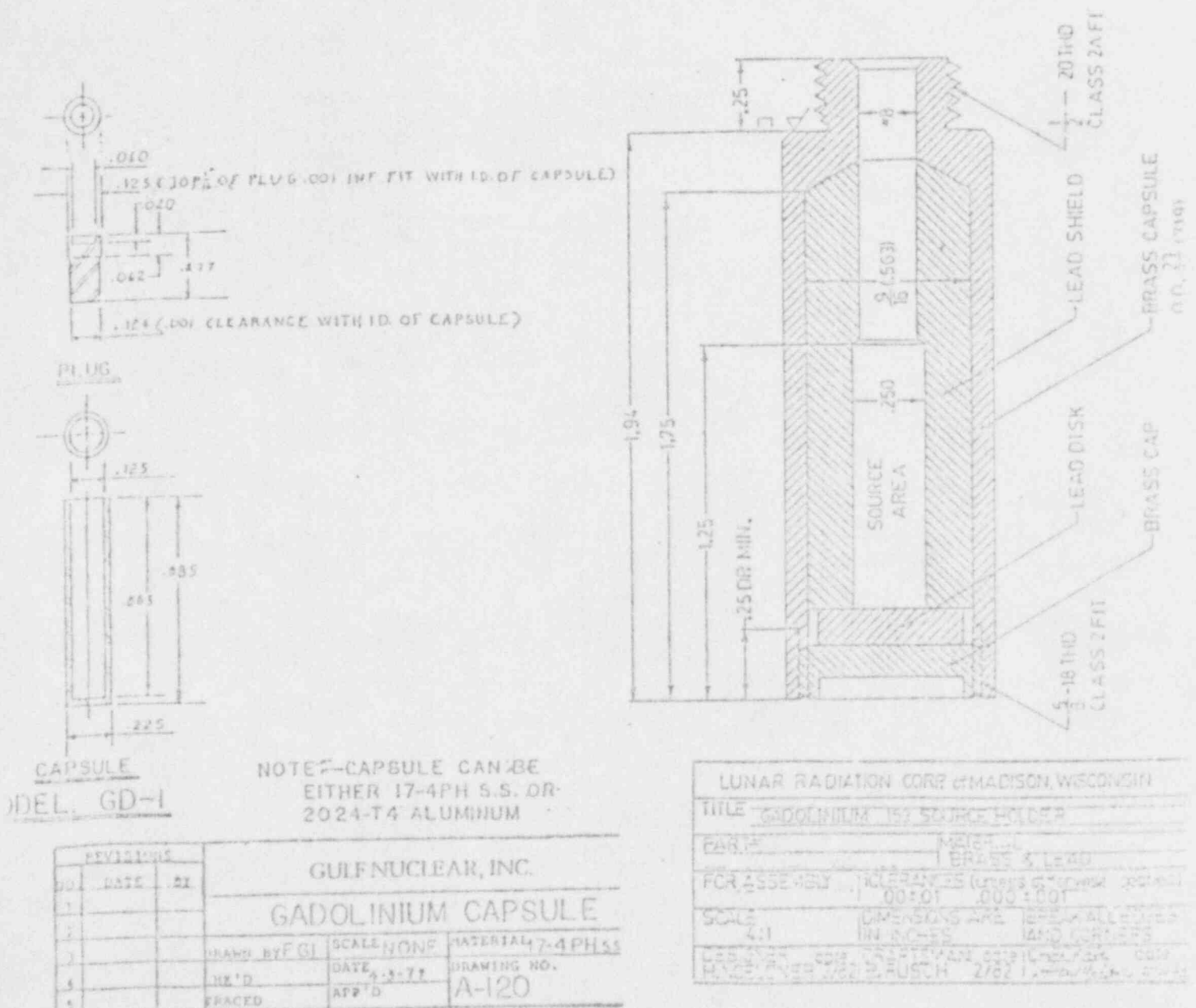
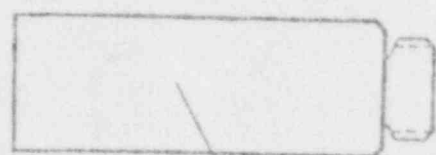
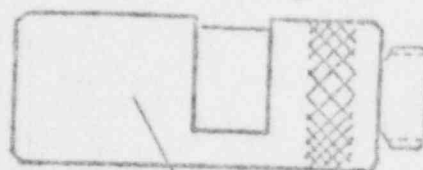




FIGURE 2  
Gd-153 Source Collimator/Holder Assembly  
for DP3 Scanner



SOURCE HOLDER



SOURCE COLLIMATOR



LEAD CAP



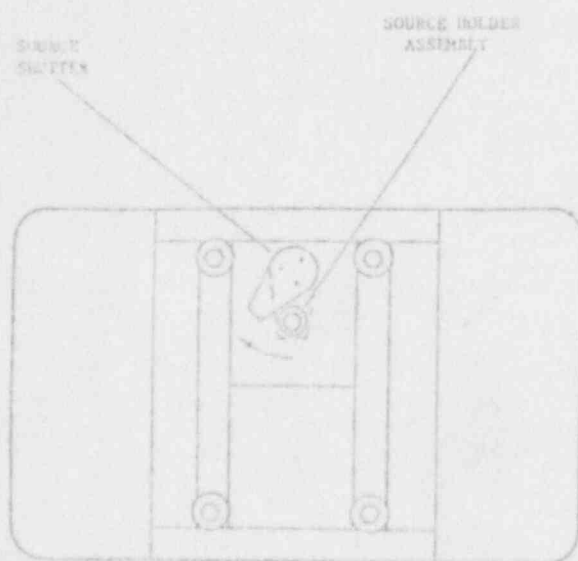


FIGURE 6  
SOURCE LOCATION & REMOVAL  
NOTE: "DASHED" lines refer to  
shutter in "occluded" position.

# Amersham

## MARKETING COMMUNICATIONS

### GADOLINIUM-153 SOURCES FOR BONE MINERAL ANALYSIS AND RESEARCH STUDIES AMERSHAM PRODUCT CODE GDC.10413

Amersham Corporation is pleased to announce its intention to supply high activity Gadolinium-153 sources to service the needs of workers in bone mineral analysis and related nuclear medicine fields. These sources will compliment Amersham Corporation's existing range of sources for bone mineral analysis. The use of these radiation source/holder assemblies when used as a component in a Lunar Radiation DP-3 or DP-4 dual photon absorptiometer allows for sensitive measurement of bone mineral content to aid in the diagnosis and monitoring of bone disease.

The illustration overleaf shows Amersham's 7mm diameter x 10mm long X1041 capsule mounted into a Lunar Radiation supplied Gadolinium-153 source holder. This assembly (Amersham product code GDC.10413) is designed for compatibility with either the Lunar Radiation DP-3 Spine/Femur scanner or DP-4 Total Body scanner.

#### Amersham Features

##### Safety

Each source contains the radionuclide in a 3mm diameter pressed pellet form which is recessed into a stainless steel insert and sealed into a TIG welded titanium capsule. Each capsule supplied with Amersham leak and wipe test certificate.

##### Regulatory Approval

The Amersham Gadolinium-153 source in X1041 capsule has been listed as suitable for licensing by the USNRC under model no. GDC.CY1.

##### High Integrity Capsules

Only the highest quality titanium is used to maintain the highest integrity capsules available. Each capsule meets the safety performance testing of ANSI/ISO 77C64444. This rating means that the Amersham capsule is the strongest available yet highest output.

##### High Output

Each source is guaranteed to meet a minimum photon output of  $1.0 \times 10^9$  photon/sec per steradian for the Eu K X-rays. The use of our titanium capsule facilitates higher 41-48 keV X-rays emission than stainless steel capsules or thick windowed aluminum capsules. This is because of the strong but thin (0.2mm) windows made possible by using titanium.

### Spectral Purity

High radionuclidic purity of >99.99% is specified for the Gadolinium-153 and maintained due to Amersham's dedicated facility in which only Gadolinium-153 sources are manufactured.

### International Shipping

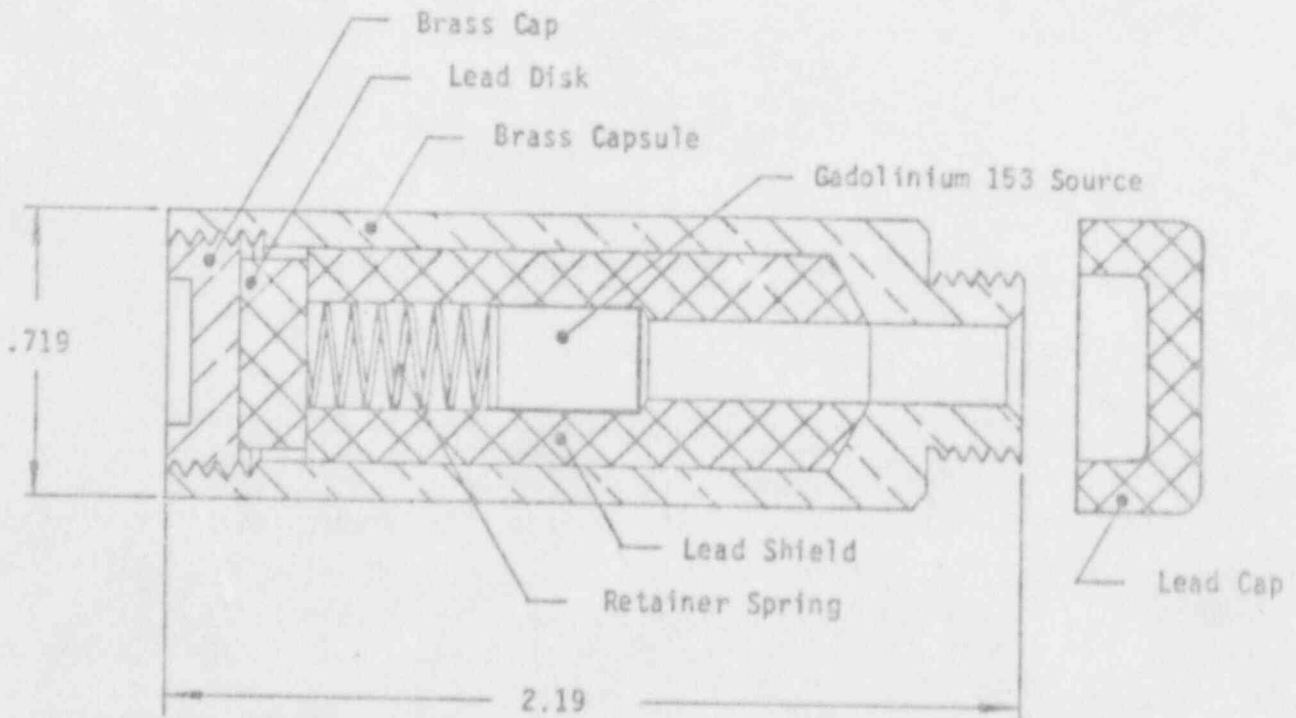
Amersham's worldwide distribution network and expertise along with the necessary containers all aid in direct shipments to most locations..

### Measurement Assurance

Amersham participates in intercomparison programs with NBS and other national laboratories to assure output measurement accuracy.

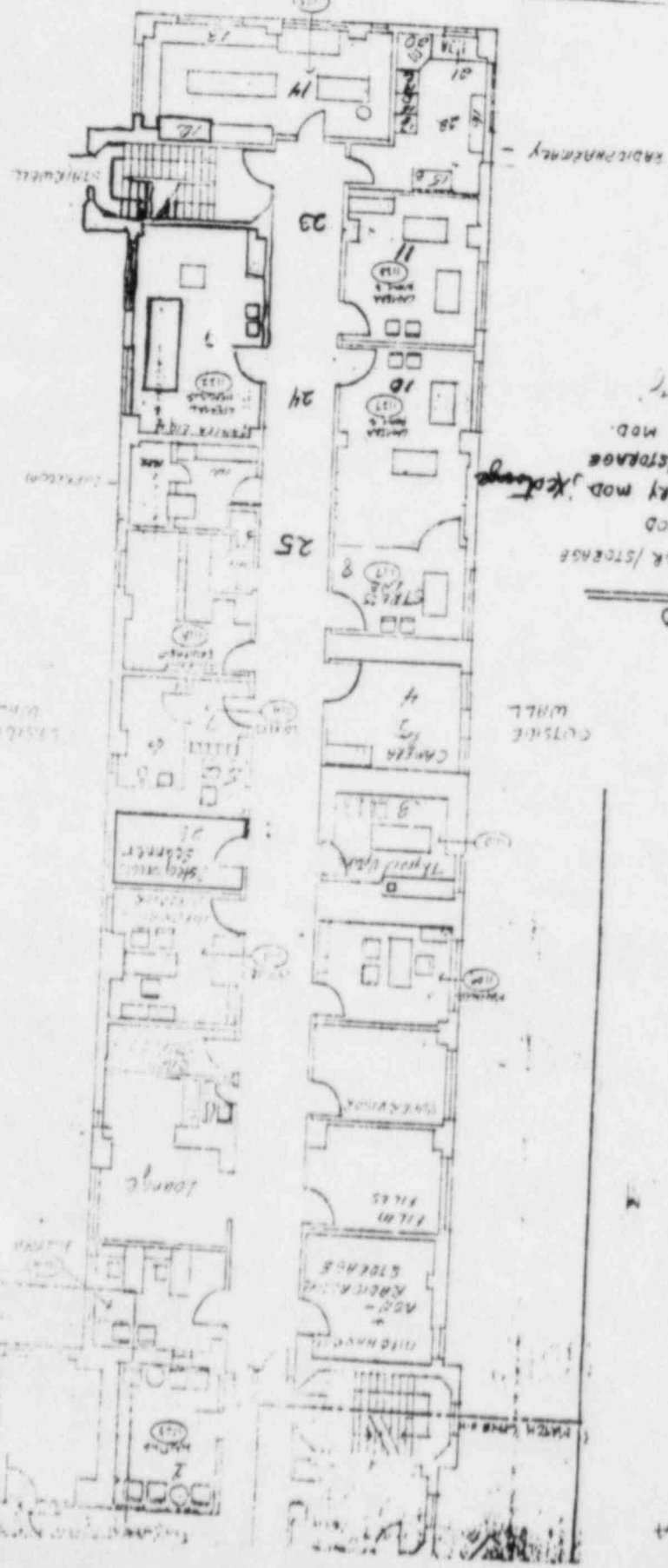
For a full updating of our source program, please contact Amersham customer service at 1-800/323-6695. For written orders or inquiries, please send to:

Amersham Corporation  
Radiation Sources Department  
2636 S. Clearbrook Drive  
Arlington Heights, IL 60005



Left of building, entrance  
 and road to west  
 side of building

OUTSIDE WALL



LEGEND

- II. GENERATOR/STORAGE
- E. KUNNE HODD
- C. INVENTORY MOD. *Keating*
- D. DECAY/STORAGE
- E. RECEIPT MOD.

OUTSIDE WALL

OUTSIDE WALL