

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 20-27845-01
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

ABIOMED
33 Cherry Hill Drive
Danvers, MA 01923

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

ABIOMED
33 Cherry Hill Drive
Danvers, MA 01923

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

NANCY NICHOLS

TELEPHONE NUMBER

666-777-5410

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3M AMOUNT ENCLOSED \$ 120.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

Francis M. Galasso

TYPED/PRINTED NAME

FRANCIS M. GALASSO

TITLE

VICE PRESIDENT

DATE

2-4-88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

<\$250K	\$1M-3.5M
\$250K-500K <u>XX</u>	\$3.5M-7M
\$500K-750K	\$7M-10M
\$750K-1M	>\$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

65

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

XX YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

AMD

FEE LOG

Mar. 3rd

FEE CATEGORY

3M

COMMENTS

B904060233 B80330
REG1 LIC30
20-27845-01 PNU

APPROVED BY

J. Kennedy

AMOUNT RECEIVED

8120

CHECK NUMBER

24249

DATE

3/2/88

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

5. Radioactive Materials

A.	B.	C.
Cadmium-109	Solid and sealed container manufactured by New England Nuclear. Source containers are designs already registered with NRC by the manufacturer.	450 mCi total in possession.

8. Training of Individuals

An additional researcher, Dr. Burger, will be using the sealed sources. Dr. Burger, a biophysicist, will be instructed by the RSO. A company wide meeting discussing the higher activity source and safety implications will also be held prior to the source's arrival.

9. Facilities and Equipment

In anticipation of our expanding research need, we are rebuilding our radiation laboratory so that all four sides will consist of solid 4 inch thick cinder blocks. The one story building in which the radiation laboratory is located has 17 foot high interior walls including our solid cinder block walls. The laboratory layout, indicating controlled access and locked storage container, are shown in the accompanying figure.

To ensure safety, ABIOMED will purchase a second Bicron Survey 200 Geiger-Muller counter (0-200 mR/hr) with a sensitivity to alphas >3 MeV, betas >45 KeV and x-and gamma-rays >6 KeV. This second radiation detector will include an audio sound feature to indicate room activity in real time. This audio Geiger-Muller counter will be in use whenever the source is in use and someone is in the room.

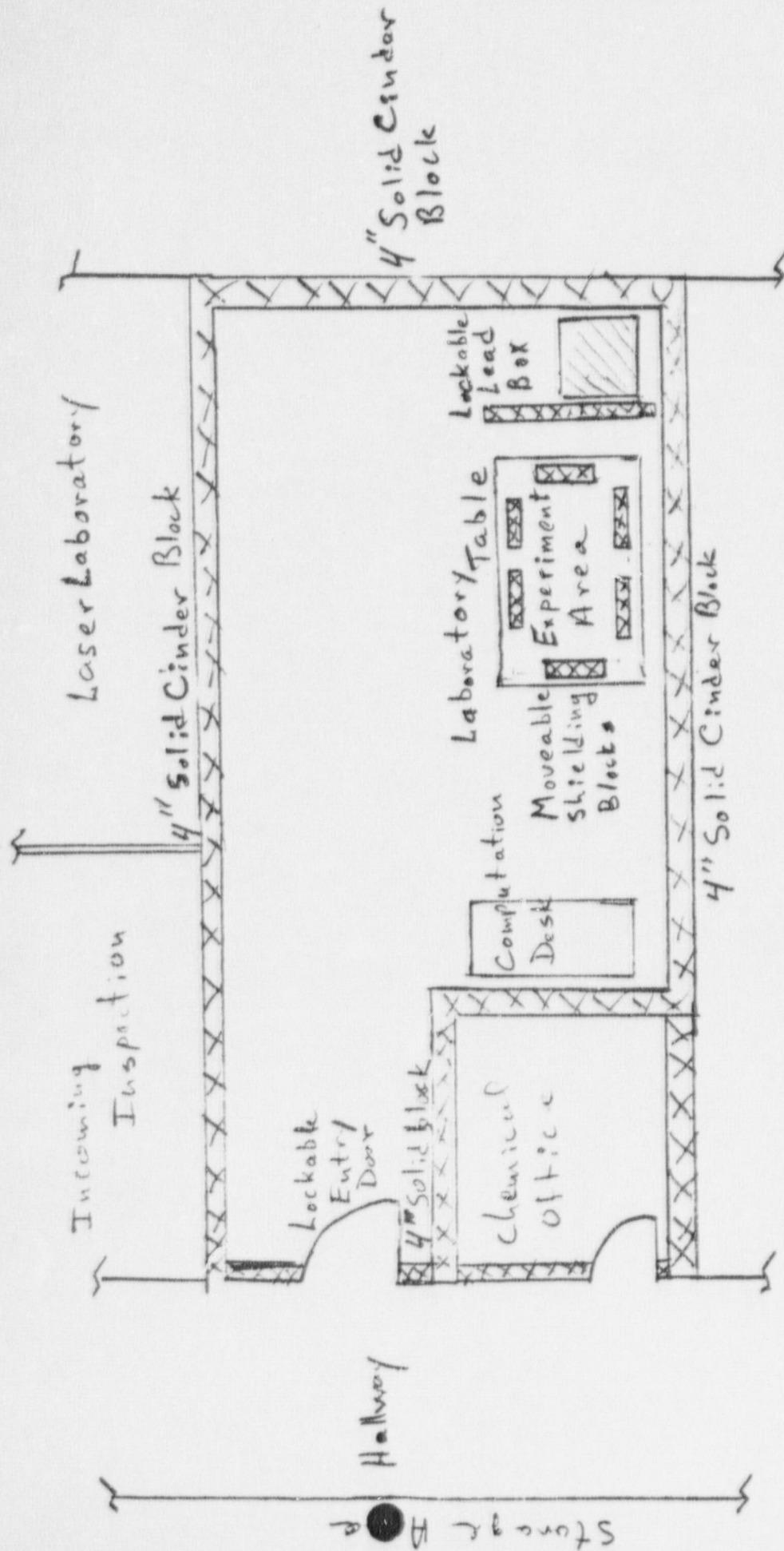
For long term storage, the source will be placed in a cylindrical lead container having an external dimension given by 4.5 cm in diameter with a 1.4 cm wall thickness, by 8 cm deep. This small lead storage receptacle is then placed into a larger lead box with external dimension given by 23.3 cm square with a 2.7 cm wall thickness, by 20 cm deep. The larger lead box has provision for locking and will be secured. Additional cinder block shielding will be placed around this storage box. (See accompanying figure).

10. Radiation Safety

Only the RSO and Dr. Burger will have authority to use this source. Transfer of the source to and from storage to the medical device will be performed with researchers fitted with a finger badge in addition to their regular whole body film badge. The audible survey meter will be active during these times to ensure prompt feedback of room activity to the researcher.

10. Radiation Safety (con't)

Whenever the source is removed or returned to storage, a survey will be made at the immediate area. Such a survey will also be conducted outside the laboratory when the source is active to ensure that no inadvertant exposure to non-radiation workers has, or does occur.



Chemical Laboratory

ABIOMED RADIATION LABORATORY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03122
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 19910930
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: ABIOMED
RECEIVED DATE: 880219
DOCKET NO: 3029275
CONTROL NO.: 108446
LICENSE NO.: 20-27845-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$120
CHECK NO.: 24249

3. COMMENTS

SIGNED
DATE

[Signature]
2/25/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-4)

1. FEE CATEGORY AND AMOUNT: 3M \$120

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT ✓
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED
DATE

S. Kimberley
3/2/88