NRC FORM 313
17-86)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS 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 HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY 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)

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

American Bio-Technologies, Inc.
359 Allston Street
Cambridge, MA 02139

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

American Bio-Technologies, Inc.
359 Allston Street
Cambridge, MA 02139

8912060101 880106
REG1 LIC30
20-28133-01 PDR

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Edmund C. Dunkel, PhD

TELEPHONE NUMBER: (617) 547-5535

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. See Attached

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

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

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

9. FACILITIES AND EQUIPMENT. See Attached

10. RADIATION SAFETY PROGRAM. See Attached

11. WASTE MANAGEMENT. See Attached

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY: 3 part L.
AMOUNT ENCLOSED: $1,200

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	TYPED/PRINTED NAME	TITLE	DATE
Edmund C Dunkel	Edmund C. Dunkel, PhD	Vice President, Immunology and Virology	11/18/87

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

[X]	< $250K	[ ]	$1M–3.5M
[ ]	$250K–500K	[ ]	$3.5M–7M
[ ]	$500K–750K	[ ]	$7M–10M
[ ]	$750K–1M	[ ]	>$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors): 7

c. NUMBER OF BEDS: N/A

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)

[X] YES [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Dkt. 8I	3L 3M	Ck No. 158 lost - never deposited by NRC. 8I, 7Y 88 for 3m app fee + Dkt. 9I 0409 for 3m amdt fee	S. Kimberley
AMOUNT RECEIVED: $1,200 $820	CHECK NUMBER: 158 See Dkt 1492			DATE: 12/9/87

* Ck No. 1492 rec'd 7/29/89 for 3m app fee ($700) and 3m amdt fee ($120) for 109929

103089

19 NOV 1987

5. RADIOACTIVE MATERIAL

Element and Mass Number	Chemical Form	Maximum Amount
Hydrogen [H3]	deoxy 5' cytidine triphosphate deoxy 5' adenosine triphosphate deoxy 5' guanosine triphosphate deoxy 5' thymidine triphosphate	
	Maximum amount of [3H] to be possessed	100 mCi
Phosphorus [32P]	deoxy 5' cytidine triphosphate deoxy 5' adenosine triphosphate deoxy 5' guanosine triphosphate deoxy 5' thymidine triphosphate [32P]-cytidine triphosphate [32P]-adenosine triphosphate [32P]-guanosine triphosphate [32P]-thymidine triphosphate	
	Maximum amount of [32P] to be possessed	10 mCi
Sulphur [35S]	deoxy 5' cytidine triphosphate deoxy 5' adenosine triphosphate deoxy 5' guanosine triphosphate deoxy 5' thymidine triphosphate	
	[35S] methionine	
	Maximum amount of [35S] to be possessed	50 mCi
Carbon [14C]	deoxy 5' cytidine triphosphate deoxy 5' adenosine triphosphate adenosine 5' triphosphate cytidine 5' triphosphate uridine 5' triphosphate [14C] methylated protein markers	
	Maximum amount of [14C] to be possessed	50 mCi

6. PURPOSE FOR WHICH LICENCED MATERIAL WILL BE USED.

Research and Development as defined in 10 CFR30.4 (q).

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

The individual responsible for implementation of the Radiation Safety Program at American Bio-Technologies, Inc. is the Radiation Safety Offier, Edmund C. Dunkel, PhD. In his capacity as Radiation Safety Officer, he is chairman of the Radiation Safety Committee and responsible for maintaining all pertinent data on radioisotope ordering, monitoring of shipments, and correct use of radioisotopes in experiments at American Bio-Technologies, Inc. Dr. Dunkel is assisted in his duties by the Radiation Safety Committee comprised of Dr. Charles Vaslet (Biosafety Officer, American Bio-Technologies), Dr. Albert Gold (Senior Scientist, Molecular Biology, American Bio-Technologies, Inc.), and Ms. Audrey Sykes (Director of Laboratories, American Bio-Technologies, Inc). Summaries of the Radiation Safety Officers and Radiation Safety Committee members Training and experience in the correct handling of radioisotopes is attached to this application on NRC Form 313M Supplement A.

The duties of the Radiation Safety Committee are to review protocols for the use of radioisotopes at American Bio-Technologies, Inc. Prior to approval of radioisotope use at the facility, the Radioisotope Committee will determine the correct procedure for receipt, storage and handling of the radioactive material at American Bio-Technologies, Inc. in order to minimize personnel exposure and keep radioactive use areas at the lowest possible levels of radiation. The Radiation Safety Committee will meet according to schedules recommended in 10 CFR part 20.

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

Training in, and the safe use of radionucleotides for Drs. Dunkel, Vaslet and Gold and for Ms. Sykes has been described in item #7 of this application. Other laboratory employees will receive copies of the American Bio-Technologies, Inc. Radioisotope Safety Manual (enclosed along with this application) and individual instruction in the safe use of radionucleotides from either Dr. Dunkel or Ms. Sykes before the use of radioactive materials begins and yearly thereafter in compliance with 10 CFR 19.. After satisfactory completion of the training program, employees will be allowed to use radionucleotides in experiments at American Bio-Technologies, Inc. under the direct supervision of either Dr Dunkel, Dr Vaslet, Dr Gold or Ms Sykes. Documentation on the type and amount of radioisotope used in each individual experiment will be maintained by the investigator for each experiment. Monitoring of all work areas will be performed for each radioisotope experiment during and at the conclusion of each experiment. Results of the monitoring tests will be maintained by the investigator. Copies will be kept on file in the Radiation Safety Office.

9. FACILITIES AND EQUIPMENT

A. Radioisotope Use Areas

Radioactive material will be used in two areas of American Bio-Technologies, Inc., 359 Allston Street, Cambridge, MA, 02139. A diagrammatic representation of these areas is included along with this application. The first area is the Molecular Biology Laboratory occupying a 500 sq. ft. area (Letter A on the map). Two radioisotope waste disposal containers are located in the lab. Gloves and laboratory coats are available as you enter the laboratory. All personnel are required to wear lab coats in radioisotope use areas. Lab coats will remain inside the laboratory.

In addition, a leucite protective shield for work with [32P] and a leucite box are located in the lab. This containment box is designed for the storage of all [32P] radioactive waste in separate dated, sealed bags until the radioactivity of these compounds has disintegrated below recommended levels (a minimum of 10 half lives [150 days]).

The second area in which radioisotopes will be used at American Bio-Technologies, Inc. is the Central Facilities Area (Letter B on the map). This area encompasses 1200 sq ft. and is equipped with 2 waste disposal containers for radioactivity and refrigerator/freezer storage areas for radioisotopes. Gloves and laboratory coats are available as you enter the laboratory. All personnel are required to wear lab coats in radioisotope use areas. Lab coats will remain inside the Central Facilities Area.

Radioisotope signs are posted on all doors entering the Molecular Biology lab and the General Facility Area and on the freezer where radioisotopes are stored. No smoking and no food (eating) signs are posted on the doors.

B. Monitoring Equipment

A Beckman Model LS 8100 scintillation counter will be used to monitor all wipe tests for [3H], [32P], [35S] and [14C]. This model scintillation counter is reliable and well adapted for use in these types of safety screening activities.

A Ludlum Model 3 Geiger counter will be used routinely to detect gamma radiation. This model Geiger counter has a sensitivity of 0-200 mRad/hour. This Geiger counter will be used routinely to detect radioisotope contamination to work surface areas in all experiments involving the use of [32P]. In addition, the Geiger counter will be used to monitor the continued safe storage of isotopes @ -20C and -80C in the Central Facilities Area. All radioisotope laboratories at American Bio-Technologies, Inc. will be monitored monthly by the Radiation Safety Officer. All radioisotope work areas will be monitored by the investigator at the completion of experiments involving the use of radioactive material. The survey meter will be calibrated by an approved vendor (F. X. Masse Associates) initially and at six months intervals as required by guidelines in 10 CFR 20.

10. RADIATION SAFETY PROGRAM

The radiation safety program at American Bio-Technologies, Inc. is described in the enclosed Radiation Safety Manual. Included are procedures for:

ordering radioactive materials,
receipt of radioactive materials,
safe use of radioactive materials, and
safe disposal of radioactive materials.

In addition, all individuals approved by the Radiation Safety committee for use of radioactive material will wear a film badge provided by R. S. Landauer. Badges will be sent to R. S. Landauer monthly for analysis.

All individuals also will have access to a Ludlum Model 3 survey meter with an appropriate Geiger muller probe. Survey meters will be calibrated by an approved calibration vendor (F. X. Masse and Associates) when the meter is acquired and at six months intervals.

All uses of radioactive material will first be approved by the Radiation Safety Committee. All areas and pieces of equipment where radioactive material are present will be labeled with the "Radioactive Materials" label. Form NRC-3 will also be posted in both radioisotope laboratories.

11 WASTE MANAGEMENT

1. Liquid waste will be disposed of in appropriate non-breakable containers located in the Molecular Biology Laboratory and the Central Facilities Area. As stated in the Radiation Safety Manual, concentrations of radionucleotides within the limits expressed in 10 CFR 20 will be disposed of down the drain.Radioactive material exceeding this level will be placed in storage containers provided by an approved waste contractor (Radiac Research). These liquid disposal containers will be held in the Central Facilities Area and will be picked up by the approved waste contractor when the containers are full.

2. Solid waste ([3H], [35S] and [14C]) will be placed in the radioactive disposal containers located in the 2 radioactive laboratory areas at American Bio-Technologies, Inc. These isotopes will be transferred to a large radioactive waste container located in the Central Facilities Area. When this container is full, it will be disposed of by the approved waste contractor (Radiac Research).

All [32P] radioactive waste will be bagged, labeled and stored in the leucite box located in the Molecular Biology Lab for a minimum of 10 half lives (150 days). After this time, the procedure described in the Radiation Safety Manual for disposing of decayed [32P] will be followed.

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Dr. Edmund C. Dunkel, Radiation Safety Officer	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Indiana U of Pa. 1975	8 hrs.	1 hr.
b. RADIATION PROTECTION	Baylor College of Medicine 1980 University of Southern Cal. 1978	3 hrs. 3 hrs.	1 hr. 1 hr.
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Indiana U. of Pa. 1975	3 hrs.	2 hrs.
d. RADIATION BIOLOGY	Indiana U. of Pa. 1975 Eye Research Institute Harvard Medical School 1983	3 hrs. 1 hr.	
e. RADIOPHARMACEUTICAL CHEMISTRY	None		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
H-3	5 mCi	Baylor, Eye Res Inst, USC	9 years	Research in situ hybridiz.
Cr-51	2 mCi	Baylor, USC	5 years	uptake expts.
P-32	10 m Ci	Baylor, Eye Res. Inst.	7 years	hybridization labeling
S-35	5 m Ci	Eye Res. Institute	5 years	hybridizations labeling

Radioisotope Use and Training [redacted]tory- Dr. Charles Vaslet, Radi[redacted]on Safety Committee Member

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Dr. Charles A. Vaslet	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	West Va. University 1972 Brandeis Univer. 1978 Genex Corp. 1983	8 hrs. 2 hrs	 2 hrs. 1 hr.
b. RADIATION PROTECTION	West Va. Univ. 1972 Brandeis Univ. 1978 Genex Corp. 1983	8 hrs. 2 hrs.	 2 hrs. 1 hr.
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	West Va. Univ. 1972 Brandeis Univ. 1978 Genex Corp. 1983	8 hr.	 2 hrs. 1 hr.
d. RADIATION BIOLOGY	None		
e. RADIOPHARMACEUTICAL CHEMISTRY	None		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
H-3	3 mCi	Genex Corp	5 years	Research
P-32	10 mCi	Brandeis University	2 years	Nick Translations
		Eye Research Institute	2 years	labeling expts.
S-35	5 mCi	West Va. University	course work	labeling DNA,RNA
		Eye Research Institute	2 years	labeling DNA,RNA

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Albert Mark Gold, Ph. D.	Not Applicable

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Neutron Activation Analysis Laboratory; Washington U. St. Louis, Spring, 1974	10 Hours	
b. RADIATION PROTECTION	Washington U. Medical Center Radiation Safety Lectures 1976 Tufts U. Grad. Student Radiation Safety Course 1977	10 Hours	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Dr. Palmer Steward's lecture in Radiation Physics 1976	2 Hours	
d. RADIATION BIOLOGY	Graduate Course in Radiation Biology at Washington U., St. Louis 1976	4 Credits	
e. RADIOPHARMACEUTICAL CHEMISTRY	125I labeling the random terpolymer PGAL at Washington U. St. Louis 1977		25 Hour

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
125 I	1 mCi	Wash. U. Med. Center	4 weeks	RIA
51 Cr	1 mCi	Jewish Hosp. of St. L.	4 Weeks	cytotoxicit
3 H	1 mCi	Tufts U., Medford	2 years	hybridiz.
35 S	1 mCi	Tufts U., Medford	3 years	polypeptide
32 P	1 mCi	Dana-Farber Cancer I.	2 years	hybridiz.
14 C	100 uCi	Dana-Farber Cancer I.	2 years	protein
32 P	1 mCi	Harvard U.; Biol. Labs	2 years	DNA
35 S	1 mCi	BioTechnica International	1 year	DNA

Radioisotope Use and Trai[redacted]g History- Audery Sykes, [redacted]diation Safety Committee Member

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Audrey G. S. Sykes	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

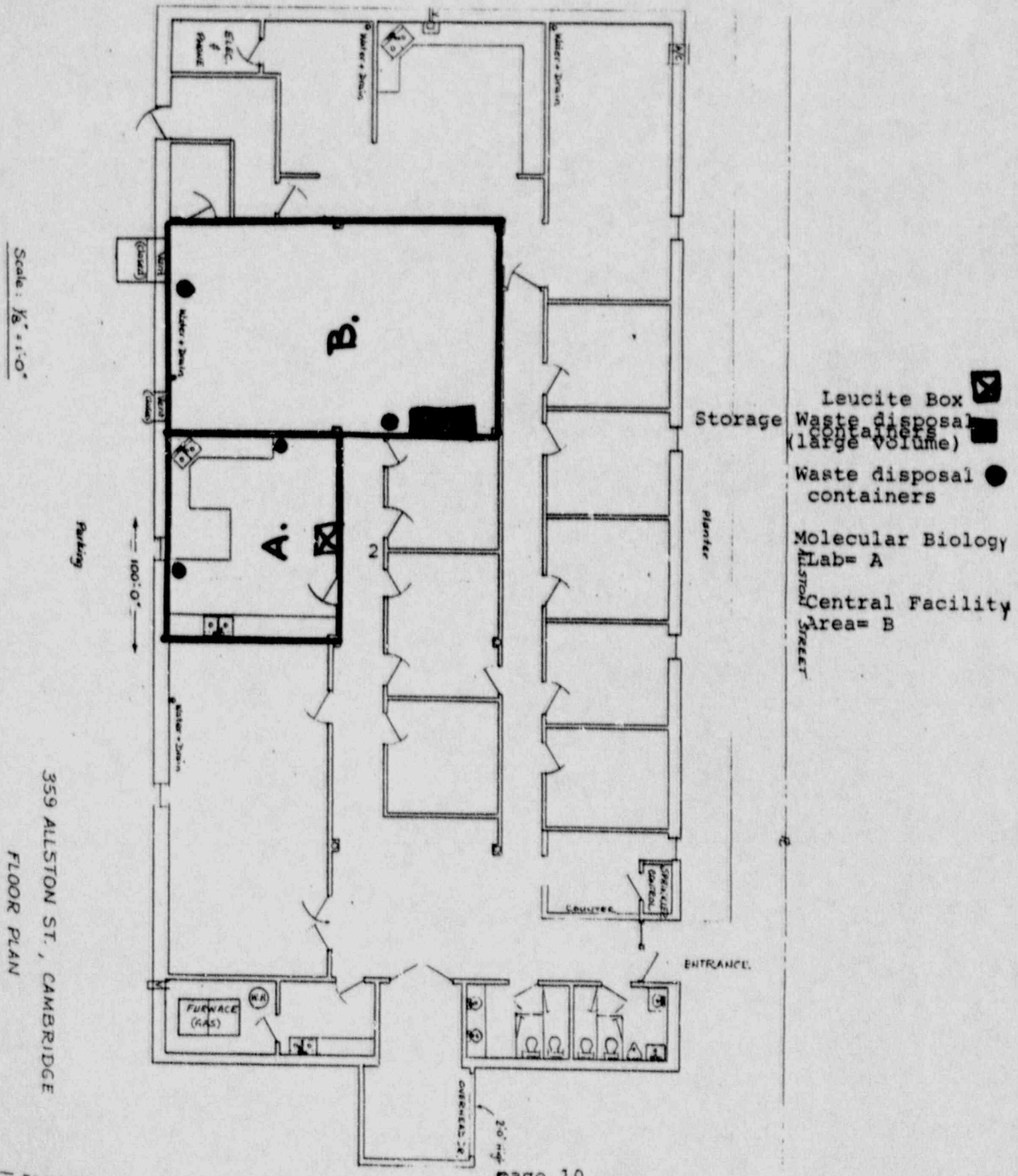
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Carnegie Mellon University 1980	3 hrs.	
b. RADIATION PROTECTION	Carnegie Mellon Univ. 1980 Genex Corp. 1981-1984 Genetics Inst. 1984-1987	3hrs.	3 hrs. 8 hrs.
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Carnegie Mellon Univ. 1980 Genex Corp. 1981-1984	3 hrs.	3 hrs.
d. RADIATION BIOLOGY	None		
e. RADIOPHARMACEUTICAL CHEMISTRY	None		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
P32	1 mCi	Genex Corp	4 years	DNA Labeling
		Genetics Inst.	3 years	RNA labeling
S35	5 mCi	Genex Corp.	4 years	Protein Labelin
		Genetics Inst.	3 years	Protein labelin
C14	1m Ci	Genex Corp	4 years	Protein labelin
H3	1 m Ci	Genetics Inst.	3 years	Protein labelin

Map of Radioisotope Use Areas at American Bio-Technologies.



RADIATION SAFETY MANUAL

American Bio-Technologies, Inc.

359 Allston Street

Cambridge, MA 02139

November 1987

Table of Contents

RADIATION SAFETY

I. General Safety Instructions and Precautions for Radioisotope Users

All individuals working with radioactive materials will adhere to the following minimum safety requirements:

[1] Maintain daily exposure to radiation as low as possible.
[2] No smoking, eating, drinking, application of facial cosmetics or storage of food or beverages will be permitted in any area where unsealed sources of radioactive materials are used, handled, transferred or stored.
[3] No mouth pipetting of radioactive solutions will be permitted.
[4] After handling unsealed radioactive material, hands shall be washed before leaving the laboratory and exposed skin, hair and/or clothing shall be surveyed for contamination.
[5] When hand or clothing contamination is possible, protective gloves and lab coat shall be worn.
[6] Insure that containers of radioactive materials are appropriately marked and labeled indicating the contents, date and responsible user(s).
[7] Objects and equipment which may have been contaminated shall not be removed from the controlled area without appropriate prior survey for the presence of contamination. If contamination is detected, the object or piece of equipment must be satisfactorily decontaminated as directed by the Radiation Safety Officer.
[8] Whenever possible, the user should perform a trial experimental run using non-radioactive (or low activity) material to establish the adequacy of equipment and procedures.

[9] All work which may result in significant airborne concentrations of radioactive materals (e.g. heating, evaporation to dryness etc.) shall be performed in a properly operating hood.

II. ORDERING AND RECEIVING OF RADIONUCLIDES

1. All Radioactive materials are ordered by or with the approval of the Radiation Safety Officer. Individuals desiring such materials must request same of the Radiation Safety Officer who will maintain an inventory record which must be checked before additional material is ordered. The Radiation Safety Officer must also check to ascertain that the individual requesting the material has been properly trained and authorized to supervise the use of this material.

2. The Radiation Safety Officer will supervise the receipt of all incoming shipments of radionuclides and will be responsible for assuring that they are contamination free before releasing them for active use within the facilities. Such monitoring will include measurement of the dose rate at the surface and at 3 ft. from the surface of the package, a wipe test on the surface (results must be less than 200 d/m/100cm^2), monitoring of packing material upon opening; and a wipe test on the inside container outside the shielding and on the inner most container. (Again, contamination must be less than 200 d/m/100cm^2). Gloves and a lab coat must be worn during this procedure and an appropriate record kept of all such receipts and measurements.

3. Upon release of the approved shipment to the authorized user, the Radiation Safety Officer will instruct the user in any special precautions to be employed (e.g. due to unusual conditions of the shipment), and of any additional monitoring and/or handling care necessary when handling the primary container.

III. AREA SURVEY PROGRAM

A. Individual users of unsealed radioactive materials are expected to perform routine area surveys of the work places and laboratories to insure that working surfaces, floor, equipment, etc are free of removable contamination and that external radiation exposures are maintained at a minimum.

B. In addition to self-evaluation, the Radiation Safety Officer will perform area surveys of radiation work areas at appropriate intervals to insure that external and internal exposure of personnel to radiation is maintained as low as reasonably possible.

IV. AREA SURVEY PROCEDURES

1. All radioactive materials handling areas will be surveyed on each day of use with an appropriate low-range survey meter and decontaminated if necessary. For daily surveys where no abnormal radiation levels are found, only the date, the identification of the person performing the survey and the fact that no abnormal levels were observed need be recorded.

2. Laboratory areas where only small quantities of radioactive material are used (less than 1 mCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1mR/hr.

b. A series of wipe tests to measure contamination levels. The method for performing wipes will be sufficiently sensitive to detect 200 dpm per 100 cm^2. For beta emitters such as P-32, wipes may be measured by placing them in close proximity to the thin window of a G-M survey meter. A reading of 0.05

mR/hr is approximately equivalent to 200 dpm on the wipe. Wipes of preparation areas or other high background areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

a. Location, date and identification of equipment used, including the serial number and pertinent counting efficiencies.
b. Name of the person conducting the survey.
c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
d. Measured exposure rates, keyed to locations on drawing (point out rates that require corrective action).
e. Detected contamination levels, keyed to locations on drawing.
f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/cm^2.

V. PRECAUTIONS FOR WORK WITH P-32

The following safety instructions shall apply to work with millicurie quantities of P-32.

1. A plexiglass L-shield shall be used to shadow-shield the operator whenever millicurie levels of P-32 are being handled.

2. Disposable gloves shall be worn whenever handling unsealed quantities of P-32.

3. A body badge shall be worn while working with millicurie quantities of P-32.

4. Hands, all exposed skin surfaces, and clothing shall be monitored before leaving the laboratory after handling millicurie quantities of P-32.

VI. RADIOACTIVE WASTE DISPOSAL PROCEDURES

1. Each laboratory will be equipped with a closed-top waste container for the routine collection of dry radioactive waste, plus liquid waste containers for collection of segregated liquid waste as necessary.

2. Records will be kept by laboratory personnel of all activity placed in these containers.

3. When these containers are full, the radiation safety officer will be notified and arrangements made to treat this activity as necessary and to transfer this material to a waste drum with appropriate record transfer.

4. The liquid waste containers are unbreakable containers. These containers should not be overfilled with liquid.

5. Radionuclide waste should be segregated according to half-life. For example, P-32 wastes, which may be stored for decay, should be collected separately from longer-lived materials.

6. Wastes from short-lived materials such as P-32 may be segregated and stored for decay. At least 10 half-lives should elapse before disposal as normal trash is allowed, and all such waste must be surveyed with a thin window survey meter without shielding in a low background area before disposal. Waste reading background may be disposed as non-radioactive and appropriate records must be maintained.

7. All normal trash leaving a radioisotope laboratory shall be monitored with an end-window survey meter before removing it from the laboratory. Materials exhibiting contamination above background levels shall be segregated as radioactive waste. Records shall be kept of the daily monitoring of the normal trash.

8. Low level liquid wastes that are soluble or dispersible in water may be disposed of into the drain systems in concentrations and quantities that comply with regulations in 10CFR part 20. In such cases, each laboratory will have a designated sink for such disposal. The sink will be posted by the Radiation Safety Officer and that posting will contain a listing of permissible discharge concentrations and a record sheet for logging all such disposals.

VII. BIOASSAY PROGRAM FOR INTERNAL RADIATION MONITORING

I. General

Appropriate internal radiation monitoring shall be conducted on any individual working with unsealed radioactive materials where a potential exists for receiving radiation doses from internal emitters in excess of 20% of the limits established in 10 CFR part 20. All records of such bioassays will be maintained by the Radiation Safety Office.

II. Hydrogen-3 Urinalysis

A. All individuals routinely working with unsealed quantities of H-3 in excess of 10 mCi will participate in the urinalysis program conducted by the Radiation Safety Officer.

B. The Radiation Safety Officer will arrange for routine monthly urinalysis of all such individuals.

C. If radioassay indicates the presence of greater than 10% of a maximum permissible body burden (less than 3 uCi/Liter), the Radiation Safety Office will initiate an immediate investigation of the work place, local exhaust system, work practices, procedures etc. to determine the cause of the increased H-3 uptake. Where appropriate, air samples and wipe tests of surfaces will be taken. Depending on the actual

level of H-3 in the urine, the individual also may be temporarily restricted from further exposure.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LMS

PROGRAM CODE: -----
STATUS CODE: 3
FEE CATEGORY: ----------
EXP. DATE: 0
FEE COMMENTS: ----------

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: AMERICAN BIO-TECHNOLOGIES, INC.
RECEIVED DATE: 871119
DOCKET NO: 30100334
CONTROL NO.: 105089
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $1200
CHECK NO.: 1558

3. COMMENTS

SIGNED [signature]
DATE 12/7/87

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

1. FEE CATEGORY AND AMOUNT: 3L 3M ~~$1200~~ $700

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ----------
RENEWAL ----------
LICENSE ----------

3. OTHER ----------

SIGNED S. Kennedy
DATE 12/9/87

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LMS

PROGRAM CODE: 22500
STATUS CODE: 3
FEE CATEGORY: 3L-3M
EXP. DATE: 0
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: AMERICAN BIO-TECHNOLOGIES, INC.
RECEIVED DATE: 871119
DOCKET NO: 3030334
CONTROL NO.: 108089
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED $1200
AMOUNT: ~~$1200~~
CHECK NO.: ~~158~~

3. COMMENTS

SIGNED [signature]
DATE 12/7/87

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 I. ENTERED 1-4-88)

1. FEE CATEGORY AND AMOUNT: 3L 3M ~~$1200~~ $700

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED [signature]
DATE 12/9/87

CONVERSATION RECORD

TIME

DATE 7/19/89

TYPE

☐ VISIT ☐ CONFERENCE ☑ TELEPHONE ☑ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Jeff Lubs	American Bio-Tech	

SUBJECT

Inv due - on letter of 4/8/89

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Jeff returned my call to Victoria McKenzie on 4/18/89 - He asked if it was regarding payment due. I said yes & he said he was handling it & $820 check should go out today. I gave him proper mailing address to send directly to me & the control no & reference.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	Glenda Jackson	7/19/89

ACTION TAKEN

SIGNATURE	TITLE	DATE

APR 0 4 1989

American Bio-Technologies
ATTN: Ms. Victoria McKenzie
359 Allston Street
Cambridge, MA 02139

Dear Ms. McKenzie:

Enclosed is a copy of our January 5, 1989 letter informing you that an application fee of $700 is required for the issuance of License 20-28133-01 and an amendment fee of $120 is required for your November 21, 1988 amendment request. As of this date, the fees have not been paid. Section 170.41 of the enclosed 10 CFR 170 provides that, "where the Commission finds that an applicant or licensee has failed to pay a prescribed fee required in this part, the Commission will not process any application and may suspend or revoke any license or approval issued to the applicant or licensee or may issue an order with respect to licensed activities as the Commission determines to be appropriate to carry out the provision of this part, ..."

You are requested to remit the $700 application fee and $120 amendment fee within 20 days from the date of this letter. When submitting the fees, please refer to CONTROL NUMBER 109929.

Sincerely,

Glenda Jackson
License Fee Management Branch
Division of Accounting and Finance
Office of the Controller

Enclosures:
1. 1/5/89 Letter
2. 10 CFR 170

DISTRIBUTION
Pending Fee File
OC/DAF R/F
LFMB R/F (2)
DW/REGI/amerbio
GJackson

OC/LFMB
GJackson:kb
04/4/89

JAN 05 1989

American Bio-Technologies
ATTN: Ms. Victoria McKenzie
359 Allston Street
Cambridge, MA 02139

Dear Ms. McKenzie:

This is to confirm our telephone conversation of December 27, 1988 concerning the license fee required for Materials License 25-28133-01. The license was issued January 6, 1988 in accordance with Dr. Edmund C. Dunkel's November 18, 1987 application. Our records show that Check No. 158 ($1,200), which accompanied the application, was never deposited by the Commission.

As specified in fee Category 3M of §170.31, 10 CFR 170, copy enclosed, an application fee of $700 is required for the November 18, 1987 application for the new license and an amendment fee of $120 is required for Dr. Charles Vaslet's November 21, 1988 amendment request. Payment of the fees totalling $820 should be made payable to the U.S. Nuclear Regulatory Commission and mailed to my attention.

Your November 21, 1988 amendment request will be forwarded to the Region I Licensing Staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406 for further processing upon receipt of the $820 fee. When submitting the fee, please refer to CONTROL NUMBER 109929.

If you have any questions concerning this matter, please let me know. My telephone number is (301) 492-8740.

Sincerely,

Signed by
Glenda Jackson

Glenda Jackson
License Fee Management Branch
Division of Accounting and Finance
Office of Adminstration and
Resources Management

Enclosure:
10 CFR 170

DISTRIBUTION
Pending Fee File
ARM/DAF R/F
LFMB R/F (2)
DW/GJ2/AMBIO

ARM/LFMB
GJackson:kb
01/5 /89

CONVERSATION RECORD

TIME 3:45 | DATE 12/27/88

TYPE

☐ VISIT ☐ CONFERENCE ☒ TELEPHONE

☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Victoria McKenzie	American Bio-	617-547-5535

SUBJECT

for requirements - License 20-28133-01

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Told Ms McKenzie that we never rec'd replacement check for Check No. 1578 for 11/8/87 app. as requested by us 5/4/88. She asked that we just start new & send ltr for replacement check & amdt fee for 11/21/88 request.

ACTION REQUIRED

Write for fee

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	B Jacobus	12/29/88

ACTION TAKEN

SIGNATURE	TITLE	DATE