NRC FORM 313
(1-84)
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.

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)*

- [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 Biogenics Corporation
1800 East Pershing Road
Decatur, IL 62526

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

1800 East Pershing Road
Decatur, IL 62526

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Donald G. MacKellar

TELEPHONE NUMBER: 217-875-3930

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.

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. FACILITI

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3-M
AMOUNT ENCLOSED $ 700.00

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	TYPED/PRINTED NAME	TITLE	DATE
Donald G. MacKellar	Donald G. MacKellar	Director, Regulatory Affairs	6/6/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

[ ]	<$250K	[X]	$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)*

c. NUMBER OF BEDS
NA

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
03E	June 7	3M		

AMOUNT RECEIVED	CHECK NUMBER	CONTROL NO.	DATE
$700	17567		6/14/85

PRIVACY ACT STATEMENT ON THE REVERSE

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

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Section 5 - Radioactive material to be used.

All of the isotopic materials shown below except number 3 will be used as "labeled" organic compounds of varying identity. These compounds are usually drugs or insecticides and are stable, solid materials. Alternately solutions of these products will be used.

	Element Mass	Maximum Amount*
1.	Hydrogen 3 (tritium)	10 curie
2.	Carbon 14	100 curie
3.	Nickel 63 foil; Perkin Elmer Instrument 3920, Detector #009-0282, Serial 1399	15 mc

Section 6 - Purposes for which Licensed Material will be used.

These licensed materials, with the exception of Number 3, are prepared as "labeled" chemical compounds for scientific research. The test compounds are administered to small animal subjects by standard dosing techniques such as oral gavage, skin painting or injection. The animals are held for a designated time, usually two to seven days. The animals are then examined to determine the disposition of the labeled material.

The majority of all tracer work conducted is done with radiocarbon. During a period of one year only one or two projects will be performed with the other isotopes requested; 95% of all testing will be done with C-14.

The ^{63}Ni sealed source (#3) is used in a gas chromatograph detector unit for chemical analysis.

Section 7 - Persons Responsible for Radiation Safety Programs.

1. Corporate Radiation Safety Officer: Dr. K. S. Loveday

   Dr. Loveday is a Corporate manager of American Biogenics Corporation. He is located at the Woburn, Massachusetts, facility of the corporation where he is the approved Radiation Safety Officer under a separte NRC License. A form 313A is attached listing Dr. Loveday's training and experience.

   Dr. Loveday will not be resident at the site covered by this license. He will review plans and SOPs for handling licensed material both in general and for specific projects.

* Includes material in use and stored as waste pending disposal.

He will visit the Decatur location at least twice a year and as necessary to respond to any problems. He is routinely available for telephone discussion of ongoing work. He will supervise the activities of the location Radiation Safety Officer.

2. Location Radioaction Safety Officer: Cathryn S. Heneghan, B.S.

Ms. Heneghan's training and experience in radiation work are described in the attached 313 supplement form. She is also trained and active in the non-radiation areas of industrial hygiene and safety, and she is the Associate Safety Officer at American Biogenics Corporation's Decatur location.

Ms. Heneghan will provide day-to-day radiation safety supervision to the technical personnel using licensed material. She will participate in preparing working protocols and in handling radiactive waste.

She wil be responsible to contact Dr. Loveday for discussion of problem areas.

Section 8 - Training for Users of Licensed Material.

Two of the proposed users of licensed material have extensive experience in working with isotope labeled compounds.

The training and experience of Drs. Mayhew and Woolson are shown on the attached supplemental form 313.

Other technical personnel who have a need to work in the isotope area will be given special training by the experienced users and the Radiation Safety Officer. This training will include a review of the applicable Standad Operating Procedures, safety policies, personal monitoring procedures, protective clothing and information about the specific material to be used. These technicians will work under the supervision of an experienced user until their competence is satisfactory to the Radiation Safety Officer.

Training is further discussed in Section 10, par. c.

Access to the isotope area will be restricted to trained personnel.

Section 9 - Facilities and Equipment.

The rooms designated for handling and storing licensed radioisotope material consist of a laboratory, animal holding area, and a storage room. The location of these rooms is shown on the attached building plan. Details of the arrangement of each room are shown on the sketch attached. Major pieces of equipment are identified and discussed later in this section.

1. Laboratory: The radiotracer laboratory is designed for functional utility and safety with particular emphasis on prevention of contamination and personal protection. Working surfaces are designed for easy cleaning and are usually protected by absorbent covers which can be disposed as radioactive waste.

Conditioned air is supplied through a central ceiling mounted diffuser. Exhaust air is withdrawn through the hoods which contain filters. Air flow is regulated to keep room pressure less than corridor pressure.

2. Animal holding area (Item 6 on drawing). This unit consists of two each - two cubic meters stainless steel and glass chambers of the type frequently used as inhalation exposure chambers. These chambers are supplied with conditioned air which is exhausted through a separate stack extending above the roof line. No significant radiation is expected in this air flow. The chambers are equipped so that urine and feces from the animals will be contained for possible analysis or safe disposal.

3. Storage Room for Isotope Material and Radioactive Waste. This room is located in the basement of Building 1 and is of 12 inch poured concrete construction with a steel door. Access is limited to radiation trained personnel and no other material is stored in the room.

4. Fume Hoods. A fume hood is available in the laboratory (identified by number 1 in the lab sketch. The fume hood has a bench area of approximately 15 square feet and is equipped with two (2) sliding front windows and panels. Generally, the hood fan is turned on during working hours and will run continuously whenever radioactive material is handled.

Average air velocities through the open hood face in the existing system range from 80 fpm to 110 fpm. Air flow patterns and air velocities will be determined periodically (3-month intervals). Additional checks will be conducted prior to actual operations on the hood bench, (e.g. sample evaporation, vacuum drying, etc.), and whenever changes of flow conditions are indicated.

For measurement of air flows, an Alnor Velometer set for low flow velocities will be used. Checks of air flow patterns will be conducted with a smoke pipe in order to detect cross-drafts under certain conditions.

Effluent filters are installed in the fume hood as indicated in the drawing in order to collect airborne radioactive materials before release to the outside. The filter system consists of two (2) filters:

1. Charcoal filter bed - Type PCB, 4 x 8, charcoal granules. Mfr.: R. R. Waites, Decatur, IL

2. HEPA filter - 99.997% - 3 microns

The filters will be checked twice per year with a magnehelic gauge; replacement will be annually.

4b. Canopy Hood (Item 2). A suspended canopy hood, 5' x 5', covers the area occupied by this "oxidizer" unit. This hood serves to remove any hazardous vapors which may possibly leak from the oxidizer. The exhaust air is filtered similar to the fume hood.

5. Sample Oxidizer. Radioactive samples are burned in the oxidizer at an efficiency of 98% or better, which means that under normal conditions all C-14 or H-3 present in a sample will be converted to either $^{14}CO_2$ or $^{3}H_2O$ and collected in a trapping system without escaping from the unit. Trace amounts could, however, be released in the event of a deficiency in the trapping system. In that case, isotopic components would be vented along with the fumes away from the operator.

Individual samples burned in this instrument contain generally 3 to 5 x 10^{-3} microcuries of either C-14 or H-3; if, for instance, a loss of 50% of radiocarbon occurs during 50 consecutive burns, the release of radioactivity would be well below the maximum permissible concentration in air considering dilution by dispersion in the effluent air, which is approximately 300 CFM for this hood as demonstrated by the following theoretical evaluation: loss of 50% from 50 samples during 1 hour operation: equal to approximately 2.5 x 10^{-1}uc; Total air volume per one hour based on 300 CFM turn-over: equal to 18,000 cubic feet or 504,800 liter; Estimate release: 2.5 x 10^{-1} uc per 504,800 liter of air per hour = 5 x 10^{-7}uc/liter; MPC: for $^{14}CO_2$ in air: 5 x 10^{-5}uc/ml and for ^{3}H in air: 5 x 10^{-6}uc/ml.

6. Waste Receptacles. Several waste containers (approximately 5 gallon) are conveniently located in each work area for use of solid radioactive waste resulting from biological experiements and analytical operations.

Large 55 gallon drums are stationed in the radioactive waste storage room. Waste collected during the working time in the smaller lab containers will be transferred daily into these large drums.

Liquid waste material containing radioactivity will be collected in the lab work area in stainless steel safety cans equipped with caps and trigger-grip handles. Each room is supplied with at least one of these cans. One or two large 30 gallon double-wall drums are available to receive the liquids from the smaller cans. The large collection drums are located in a separate radioactive waste room.

7. Storage in Work Area.

1. Raioactively tagged chemicals, test articles and sealed sources will be stored in laboratory cabinets (refer to item in sketch of tracer lab). These cabinets are secured with locks except when materials are removed for use or returned. In comliance with 20.203(e) each cabinet door will carry in a conspicuous manner signs bearing the conventional radiation caution symbol and the words: CAUTION - RADIOACTIVE MATERIALS.

2. Radioactively tagged materials (chemicals, specimen and solutions) requiring storage under cooled or freezing conditions will be held in specially designated laboratory refrigerator and/or freezer units. The doors of these refrigerator and freezers are maintained locked and radiation signs are mounted in a conspicuous manner on the outside as described above.

8. Containment Device. A safety hood will be used with the balance, whenever radioactively labeled materials such as dry chemicals, powder-like dust samples, charcoal, ground plant tissue and soil are weighed. The purpose of this device is to reduce the risk of uptake of possible airborne materials during the weighing process by the operator.

The safety chamber is custom fabricated from optically clear plexiglass and measures 34 x 21 x 21 inches. The box (open at the bottom) will be placed over the instrument and is seated on the weighing table. Two glove ports in front (approximately 6 inches in diameter) allow access to the instrument and work area. The unit is completely portable and easy to decontaminate after use. A 3/4 inch vinyl tube is sealed to the rear of the chamber to provide for connection of a vacuum tubing. The chamber is operated under slightly reduced pressure using a vacuum pump to prevent escape of airborne material into the breathing zone of the operator. A drying tube filled with an adsorbant (e.g. charcoal or silica gel) and a flow meter are connected in line downstream between the safety chamber and pump. This filtering system is flexible; liquid scrubbers (wash bottles) could be used in place of the dry adsorbants or may be added as an additional trapping device in special situations.

9. Other Laboratory Equipment.

Shielding:	Lead bricks for use in storage cabinets and on workbench. Small lead storage containers.
Protective Clothing:	One lead apron, lead gloves; disposable lab coats, gloves and respiratory masks. Safety glasses, face shield.
Respirators:	Type MSA supplied for each lab worker.
General Lab Ware includes:	Safety pipet fillers; disposable pipets, test tubes, beakers and bench covers, automatic pipettors
Remote Handling Equipment:	Grip tongs and 2 foot jaw tongs.

10. Radiation Instruments and Calibration.

Line #	Type of Instrument	Manufacturer's Name	Model Number	Number Available	Radiation Detected (alpha, beta, gamma, neutron)	Sensitivity Range (milliroentgens/hour or counts/minute
	A	B	C	D	E	F
1	G-M Survey Meter	Texas Nuclear Corp.	2650	1	alpha, soft beta, gamma	0.1 - 100 mr/hr
2	Log Series Survey Meter	Texas Nuclear Corp.	9800	1	soft beta, gamma	(1.5-2 mg/cm^2 thickness 0.02-200 mr/hr)
3	Liqu. Scint. Counter	Tractor Analytical Inc.	Mark III (6880)	1	beta, gamma (low level)	5-800.000 cpm
4	Tritium Air	Texas Nuclear Corp.	9160	1	H-3 (beta)	20 uc/m^3
5	Well Scintill. Detector	Nuclear Chicago Corp.	DS-202(v)	1	Low energy gamma	10 to 1 x 10^6 cpm

TYPE OF USE OF INSTRUMENTS LISTED IN ITEM 10

(1) Portable Geiger-Mueller Survey Meter is used for general laboratory survey work: checking suspected contamination on work areas, contamination prevention, monitoring of isotope shipments and packing material, measuring of radiation levels on waste drums and storage areas.

(2) The Log Series Survey Meter is permanently in operation to monitor the laboratory and/or work area environment. The instrument is portable and can be placed near areas with suspected presence of airborne radiation.

(3) The liquid scintillation counting system is used primarily for assaying low-energy beta emitters in a variety of samples from experimental applications, bioassay samples, surface "wipe" samples, effluent trap samples.

(4) The Tritium Monitor measures primarily atmospheric contamination oif tritium. An audible in-built alarm system is generated by means of an adjustable setting. A hose attachment is provided to check table tops, workbenches, hands, clothes, etc.

(5) The Well Scintillation Counter has the capability to assay liquid samples or small solid objects or powders containing radioisotopes emitting gamma radiation.

10b. Calibration of Instruments.

1. Contract calibration is done twice a year by:

Stan A. Huber Consultants, Inc.
235 Essex Lane
New Lenox, IL 60451 (2 times/year)

2. Routine calibration by applicant is done as follows:

1. Calibration of G-M Survey Meter (Model 2650)

a. Calibration and Performance Checking by Applicant

A low activity radium-226 source (Model 184100- Amersham/ Searle) with 2 different mr/h-values (2.5 and 32) serves as a standard. This standard button is supplied by the manufacturer along with the instrument. It has been measured at the factory using the same monitoring unit and probe, after the instrument was intially calibrated by a cesium-137 standard. The values are listed on the inside of the calibration button storage compartment.

Routine Performance Checking:

1. Adjust the battery control, if necessary, to bring the meter needle to the center of the green bar region.

2. The beta shield is removed from the probe and the source is placed squarely on the end window. Side 1 (2.5 mr/hr) will be used to check the lower end of the instrument's range; side 2 (32 mr/hr) is applied to check the higher instrument range.

3. If the average reading does not fall with 5% of the value stamped on the side of the source facing the detector window, an adjustment shall be made using the calibration control until the meter reading agrees.

The instrument will be calibrated against the Ra-source (2 levels, high/low) at monthly intervals. The instrument will be also calibrated following repair and/or replacement of batteries. The date of testing and the instrument performance will be recorded in the equipment log.

This calibration will be performed by the acting radiation officer (Item 7).

2. Calibration of Log Series Survey Meter (Model 9800)

a. Performance Checks by Applicant

The same standard source (radium-226) as described in paragraph 1 shall be used to check the performance of the instrument.

This type of calibration against the standard source shall be conducted at 3 month intervals. The values obtained at each check are recorded in the instrument log with reference to date and to the geometrical position of source in relation to the probe. The response of the instrument to the standard source will be checked at 2 reproducible positions (e.g., high and low)

3. Calibration of Liquid Scintillation Counter (Mark III)

a. Instrument Calibration by Applicant

Instrument calibration will be conducted by means of the automatic calibration check (program L) as described in the instruction manual. This program checks for any change in the gain of the detector or for other significant changes in the instrument's performance.

An internal, unquenched liquid scintillation standard is positioned in the counting chamber and is used to determine the pulse height spectrum developed by the radiation absorbed from the external standard. When the calibration is within ±2% of the value obtained at the last service, the calibration may be considered normal. If not, adjustment of calibration potentiometer shall be performed as described in the instrument's instruction manual.

The instrument performance test will be conducted at monthly intervals, and, if necessary, more often (e.g., following servicing or temporary shut-down and prior to use in bioassays, work area and effluent monitoring, equipment wipe tests and trapped air samples).

Efficiency calibration curves will be constructed routinely at 3-month intervals using 4 to 6 standards in the quench range of interest. ^{14}C and ^{3}H Quenched Standard Sets obtained from Amersham Corporation with a calibration accuracy of ±3% will be

used. These standards have been assayed for activity comparison with standards obtained from the U. S. National Bureau of Standards (as stated by manufacturer). For occasional work with other radionuclides similar efficiency calibrations will be conducted using appropriate standards.

Counting efficiency calibrations are conducted by the Section Head of the Tracer Lab. In addition to routine tests, calibrations are also conducted prior to contamination control of work areas and equipment and prior to conducting bioassays on lab personnel.

4. Calibration of Tritium Air/Monitor (Model 9160)

a. Calibration performed by Applicant

A radioactive source (radio-lead) supplied with the instrument will be used for sensitivity checks. The source shall be fitted snugly into the intake port on the back of the chassis. The meter is then zeroed and the range switch set to the "x 10" position.

If calibration is correct, the panel meter will read the value marked on the back of the source case. If the panel meter does not provide the value as marked on the back of the source case, the instrument shall be recalibrated. Sensitivity adjustments shall be conducted in accordance with the procedure described in the instruction manual by the Section Head (Item 6a).

This type of calibration will be conducted prior to use.

Identification of Standard Source Plate: Model 50AF-07 (Texas Nuclear Corporation).

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Section 1Ø - Radiation Protection Program.

1. General Radiation Protection Procedures and Rules

Personnel working in the radioisotope lab will operate under good housekeeping principles at all times. Radioactive solutions, contaminated glassware or animal tissues are not permitted to accumulate. The lab will be thoroughly cleaned at the end of each day and all working surfaces surveyed and decontaminated in order to obtain reliable results. All permanent or working solutions are stored in the locked radioisotope cabinet or in the locked refrigerator, and all solutions not rquiring storage will be properly discarded and the containers cleaned.

Test set-ups and operations are done on smooth, easily cleaned surfaces covered with disposable absorbent material. Particular attention will be exercised to avoid spills. Radioactive solutions are always covered and shall bear the radiation caution label and proper description of content.

Disposable gloves and safety glasses are worn whenever radioactive materials are handled. Protective clothing, lab coats and respiratory devices are worn for all appropriate operations. Face shields are provided for exceptional conditions.

Pipetting of solutions is never done by mouth; safety pipet fillers and Eppendorf automatic pipettors are available. Smoking, eating or drinking are not permitted in the radioisotope lab. Personnel will wash hands and forearms frequently, and always before leaving the work area for any reason.

Periodic, and if necessary, additional urinalyses are conducted on each person. Methods and frequencies are described in Attachment No. 6 in reference to Item 12.

2. Laboratory Surveys and Procedures to Control Release to Unrestricted Areas

a. Surface Contamiantion Control

Routine surveys of the designated laboratory areas are conducted once every month by the Location RSO. A portable GM counter (Texas Nuclear Corp.) is used to monitor radiation levels on bench tops and equipment surfaces. A base value of 5Ø cpm above background count rate shall be considered acceptable. The decontamination procedures will be applied, if necessary, including follow-up checks.

Bench top and equipment surfaces will be checked for contamination with smear (wipe) tests. A circular piece of filter paper of approximately 5 cm diameter will be moistened with ethylene glycol or glycerol and will be rubbed over about one square-foot area of suspected surface. The smear sample will be placed immediately into a scintillation vial containing water and liquid scintillator for direct assay in the counter. In order to establish a baseline value, a suvey of the area designated for test set-up will be conducted prior to the use of radioactive material. Repetitive surveys will be performed when the amount of radioactivity changes, and when deposits from airborne material are suspected.

Clothing and hands will be surveyed several times during the work to determine external contamination to the personnel. If contamination is found, corrective action will be taken to remove it. Gloves will be changed often.

b. Control of Volatile and Airborne Contaminants

Volatile radioactive materials are rarely handled in our laboratory, however, it is recognized that due to chemical reactions some gaseous wastes in the form of vapors may be generated. Also particulate matter in the form of dusts can be carried by air currents through the ventilating system. Filters are provided in the exit air of each fume hood (see Item 13) and reduce the danger of excessive discharge through the stack at any given occasion.

Air samples will be taken routinely at the hood stacks at weekly intervals during periods when work is in progress. A silica gel absorbent system will be used to monitor stack effluents. The air samples will be obtained downstream at the upper part of the hood shaft.

In situations where occasional higher levels of air concentrations are suspected, measurements will be conducted more frequently during the special operation and after. The results are recorded and will be compared with the permissible concentrations. The activities measured under normal lab conditions will form the radiation background. Radiocarbon and tritium activities collected with the silica gel samples will be assayed by dissolution of the gel and subsequent liquid scintillation counting.

Air is leaving the existing fume hood at a rate of 865 cft per minute. We estimate that ^{14}C-tagged material handled in the hood may rarely exceed 10 uc on a given

day of which only fractional quantities would be converted to vapors during any given hour per day. At a volatilization rate of 1% per hour, a concentration of 7×10^{-8} microcuries per liter of air is calculated from this, which is well below the permissible concentrations (Table II, Appendix B, Part 20 of 10 CFR) of any of the isotopes requested for possession.

In the event that gaseous materials are released in excess of permissible quantities, corrective measures will be taken immediately. The existing source in the hood area will be sealed or vapors will be freeze-trapped in appropriate setups. Any leakage will be detected by the routine breathing zone samples.

Air samples will be collected with a suction pump and filter assembly in the immediate working area of ongoing experiments, e.g., near animal exposure chambers, in and around incubators holding test media (soil and/or water), in the waste storage area and in the breathing zone of the operator while processing treated samples (excreta, tissue, soil, etc.)

Special attention will be paid during weighing of powdered radioactive material. The air intake of the air sampler will be placed close to the nose of the operator to monitor contamination in the breathing zone.

During operation of the sample oxidizer, periodic air samples will be collected in front of the instrument to assure that the environment is free of contamination. Even so, there will be little expectation of radioactive material being present since the overhead exhaust will direct the air flow away from the instrument and operator.

A continuous air monitor (Texas Nuclear 9800 Log-series) is permanently in operation to monitor levels of airborne radiation.

c. Control of Release of Radioactivity into Effluent Water

Liquid waste generated from biological experiments, chemical operations (e.g., extraction) and hydrolysis and leaching studies, also fluids collected from decontamination processes, such as rinses of cages, fecal and urine collectors, glassware and other equipment, are placed into appropriate liquid waste disposal containers (double wall) and held under controlled storage prior to removal by the commercial waste disposal service. Very small quantities of radioactivity, however, may enter the effluent system from daily glassware washings and equipment decontamination.

The average effluent volume from the plant (American Biogenics Corporation) is approximately 265 cubic meters per month or 8.7 cubic meters per day. We estimate that the routine daily disposal of radioactivity will not exceed Ø.5 microcuries in average, giving a concentration of 5.7×10^{-8} uc/ml, which is below the limits set forth in Table II, Appendix B, Part 2Ø of 1Ø CFR. In order to control the daily quantities to be allowed for discharge, an estimate of each equipment rinse will be made before final cleaning or washing in the sink. The evaluation of residual activity includes radiometric assays of representative liquid sample aliquots by liquid scintillation counting techniques.

3. Sealed Source Leak Tests.

Each detector cell will be tested for leakage and/or contamination at 6-month intervals. The procedure is in accordance with the instructions provided along with the wipe-test kits supplied by Nuclear Radiation Development Corp. If the leak test for any gas chromatograph detector reveals an activity of Ø.ØØ5 uc or more, the detector will be immediately removed from the instrument and will be returned to the respective manufacturer for repair or disposal.

The results of the leak tests for each detector will be maintained in a file with the radiation safety officer.

4. Records Management Program.

Materials inventory: all incoming radioactive labeled material is registered in the materials log. Data regarding transfer, usage and disposal of certain quantities of the material will be recorded in the balance sheet. These records are maintained in the tracer lab.

Storage of treated samples or test articles will be recorded in regard to location, type of material, quantity, type and concentration of radioactivity contained, date and project identification. The storage log is located in the tracer lab.

Records of surveys (routine and additional) will be kept in the survey log book. The records include physical lab surveys, bench top areas, equipment effluent and personnel monitoring. The results and evaluations are available for review by employees, company management and NRC inspectors.

Records of instrument calibrations are also included in the records file.

5. Instructions to Personnel.

a. Personnel in the Tracer Lab

The staff at the present time consists of: Cathy S. Heneghan

C. S. Heneghan will be closely supervising the activities in the radiotracer lab in the capacity as radiation protection officer.

Other personnel may work in this laboratory after special training and approval by the radiation safety officer. Training experience is presently shown for Dr. E. Woolson and Dr. Dale Mayhew. This is detailed in Section 8.

b. The Responsibilities and Duties of the Location Radiation Safety Officer

The radiation safety officer is responsible for the radiological safety in the laboratory. It is his or her duty to see that the rules set forth for the proper and safe conduct of radiotracer experiments are observed and enforced. The location RSO is responsible to the corporate RSO, Dr. K. Loveday.

The radiation safety officer shall conduct frequent reviews and inspections of the ongoing work, the equipment and monitoring devices and the use of protective clothing to assure compliance with the rules. The entries in the lab log book for routine and other surveys, instrument performance checks, bioassays, etc., will be checked monthly or more often if necessary; the data will be checked for correctness and compared to MPC values.

The Radiation Protection Officer is responsible for receipt and inventory of isotope material. Other duties include the revision or introduction of rules and/or procedures as different situations occur, e.g., due to change of isotope and/or change of activity.

Special procedures shall be prepared involving change and frequency of personnel [illegible] environment monitoring, bioassays, analytical metho[illegible], etc. The details of such modifications or additional tests shall be worked out prior to initiation of the specific type of work. The technician will be trained thoroughly in the various techniques and procedures for protection.

It is the responsibility of the radiation protection officer to see that each worker is made familiar with all pertinent instructions and trained in the conduct of

each procedure (e.g., monitoring, assays, evaluation). Each worker shall become familiar with the availability and use of safety-related equipment. A training program has been developed for this purpose and will be expanded as the day-to-day work may require.

c. The Training Program will Include as a Minimum The Following:

1) theoretical instructions as to the principles of radiation protection. Each worker in the radiotracer lab has read and will use as a continuing reference the NCRP Reports Nos. 30 and 39: "Safe Handling of Radioactive Materials", and "Basic Radiation Protection Criteria".

2) studying and acquiring knowledge about the physical properties of isotopes (radiation, decay rates, etc.) particularly of those requested for the license and which will be handled the day-to-day work.

3) on-site demonstrations and excercises in each of the established survey procedures, air monitoring and air sampling methods, the evaluation of measurements and comparison to MPC and other criteria. Each worker will read and use as a reference NCRP Report Nos. 57 and 59: "Instrument and Monitoring Methods for Radiation Protection", and "Permissible Dose from External Sources of Ionizing Radiation".

4) instructions in the use of containment devices, shielding and safeguards for protection against radiation.

5) safe handling of treated animals and animal excreta, tissues and carcasses.

6) instructions in proper work habits, cleanliness, decontamination, disposal and emergency procedures.

An instruction and training program is presently underway. Theoretical instructions and actual exercises with procedures such as surveys and air sampling are conducted while establishing base-line values for the various operations.

6. Use of Radioactive Materials in Animals.

All radioactively treated animals will be confined to the radiotracer laboratory areas. Only personnel listed on the application have access to this area. The rooms will be locked when unattended.

The personnel in the radiotracer lab are instructed in the proper handling of animals with emphasis on contamination prevention and radiation safety. Whenever treated animals are removed from the cages for bleeding or other procedures, gloves and disposable lab coats shall be worn. A respirator mask shall also be worn to protect against uptake of volatile radioactivitty exhaled by the animal. The same protective clothing will be worn during collection of excreta and during dissection. Benches are covered with disposable absorbent, plastic backed paper.

At the end of the experiment, treated animals will be sacrificed. The various tissues and organs will be collected for analytical and radiometric assays. The carcass will be held in the proper waste storage along with other biological radioactive material prior to disposal by the commercial radioactive waste disposal service with the exception that when the radioactivity arises from trition or ^{14}C and is less than Ø5 uc/g, the carcass may be incinerated. Radioactively treated animals will never be rerouted for use in other tests.

Small animal cages will be cleaned and decontaminated exclusively in the tracer lab. This process includes measurement of residual radioactivity adhering to the sides and floors of the cages as part of the over-all recovery of the initially applied quantity of radioactivity (material balance).

Cages used with dogs are also decontaminated by workers in the lab. Rinse fluids are collected and the concentration of radioactive content will be determined from representative sample aliquots. Cleaning and retention of rinse fluids continues until concentrations are as low as 2ØØ disintegrations per minute. Collected rinse fluids are retained for disposal by the commercial disposal service.

7. Emergency Procedures.

Due to an unforeseen situation, radioactive material could be spilled causing radioactive contamination and radiation levels in excess of the quantities normally handled. The following emergency procedures relate to the nature and quantities of isotopes requested by the applicant and are not applicable to high energy radionuclide accidents.

The first action will be to minimize undue spread of the material in order to prevent exposure to personnel. Persons working in the area shall be informed immediately and will be asked to stay away or leave the immediate area or the room. The ventilation system shall be shut down and the doors of the lab closed.

The radiation protection officer shall then prepare to recover the bulk of the material for containment. Gloves and disposable lab coat and a respirator mask must be worn. AFter removal of the radioactive material, the ara will be cleaned using proper decontamination procedures (special absorbent cleaning fluids, surface monitoring, etc.). If volatile radioactive material is suspected, air monitoring of the immediate area shall be conducted as soon as possible. Personnel monitoring (hands, body, eyes) and bioassays (urinalyses) shall be conducted following the accident, with appropriate follow-up assays until clearance of body content is confirmed.

8. Procedures for Receiving an Opening Packages Containing Radioactive Test Material.

Upon receipt of a package a wipe test (wet smear) of the external shipping package and the internal containers will be made to be sure that no leakage has occurred. If radioactive contamination in excess of 0.01 microcuries (equal 22,000 dpm) is found per 100 cm^2 of package surface, appropriate procedures shall be followed in accordance with 20.205(b)(2): The licensee shall immediately notify the final delivering carrier and by telephone and telegraph, mailgram or facsimile, the NRC Inspection and Enforcement Regional Office (Region III) in Glen Ellyn, Illinois.

If the external check reveals no radiation or quantities less than 0.01 microcuries, the shipping container and packaging material shall be removed in an isolated area of the lab. The label will be inspected to insure that the information (radionuclide and amount) is correct and corresponds to the requested product technical data sheets. Package inserts shall be examined for instructions regarding special conditions of storage, stability and chemistry. A laboratory log number shall be assigned to the sample by the Projects Administration group.

Section 11 - Waste Management.

Radioactive waste material is collected and stored as shown below. When sufficient material is accumulated, it is removed by a licensed commercial contractor:

U. S. Ecology Corp.
Box 7246
Louisville, KY 40207

1. Solid and liquid wastes - containing less than .05 uc/g such as table covers, animal tissues and scintillation liquids are segrated and dispersed of by incineration in a high temperature incinerator.

2. Non-Biological solid waste of higher radioactivity is accumulated in the laboratory in plastic bags. These bags are transferred to heavy 50 gal. steel drums in the isotope storage room and held for contractor disposal.

3. Liquid waste of higher radioactivity is collected in 5 gal. cans and then transferred to double walled 50 gal. drums in the radioisotope storage area for later contractor disposal.

4. Animal tissues are stored in a specially designated freezer until near time for contractor pick up and then transferred to 50 gal. steel drums packed as directed by the disposal service. This includes enclosing in double heavy wall plastic bags and addition of absorbent material specified by the State of Washington.

5. The location in radiation safety officer is responsible for safe handling of all radioactive waste.

Rq Sect 8 A 4

FORM NRC 313M-SUPPLEMENT A (8-78) — 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
Edwin A. Woolson, Ph.D.	----

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
None	None	None

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			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{14}C	1-2 μc	U.S. Department of Agriculture	20 years	Synthesis of labeled compounds
^{3}H	" " " "	" " " " " " " "	" " " "	Metabolism Studies
^{74}As	" " " "	" " " " " " " "	" " " "	
^{63}Ni	" " " "	" " " " " " " "	" " " "	Bioaccumulation studies

Rq Sect 8 A3

FORM NRC 313M SUPPLEMENT A
(8-78)

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
Dale A. Mayhew, Ph.D.	None

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
None	None	None

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	Marietta College Portions of Course		
b. RADIATION PROTECTION	On analytical methods of analyses covered handling measurement and safety of radioisotopes	20	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Indiana University School of Medicine - Graduate Research		3 years
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{131}I	100 μc	Indiana University School of Medicine	3 years	insulin radio-immunoassay
^{125}I	" " "	" " " " " " " " "	" " " "	glucose metabolism
^{14}C	" " "	" " " " " " " "	" " " "	tissue digests
^{125}I	" " "	Pfizer Laboratories - Diabetes Study Group		carbohydrate metabolism & insulin assay
^{14}C	" " "	" " " " " " " "		

CONTROL NO. 79136

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Rq. Sect 7

FORM NRC 313M SUPPLEMENT A
(8-78)

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
Kenneth S. Loveday, Ph.D., Corporate RSO	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
None	None	None

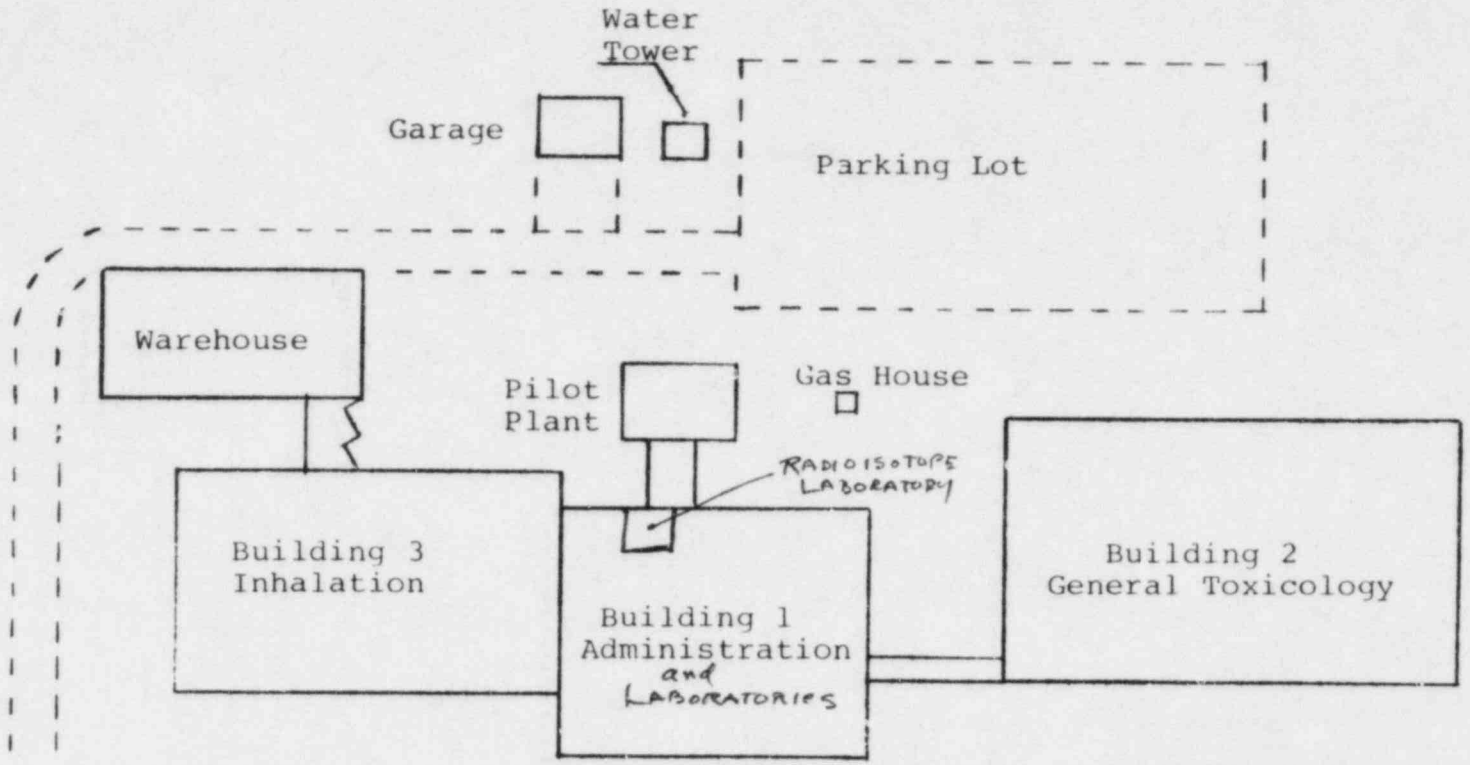
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

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	MIT Department of Microbiology - 1969-1976	4	5 years
b. RADIATION PROTECTION	Harvard Medical School Boston, MA - 3/76-4/76	4	2
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	MIT Department of Microbiology - 1969-1976	4	5 years
d. RADIATION BIOLOGY	" " " " " " " " " " " "	"	" "
e. RADIOPHARMACEUTICAL CHEMISTRY	" " " " " " " " " " " "	"	" "

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	10mCi	MIT	5 years	Cell culture, Microbiology
^{32}P	10mCi	"	" "	" "
^{14}C	1mCi	"	" "	" "
^{3}H	10mCi	Children's Hospital/ Boston	3 years	" "
^{14}C	1mCi	" " " "	" "	" "
^{3}H	10mCi	Bioassay Systems Corp., Boston, MA	4 years	" "
^{14}C	1mCi	" " " "	" "	" "
^{32}P	5mCi	" " " "	" "	" "

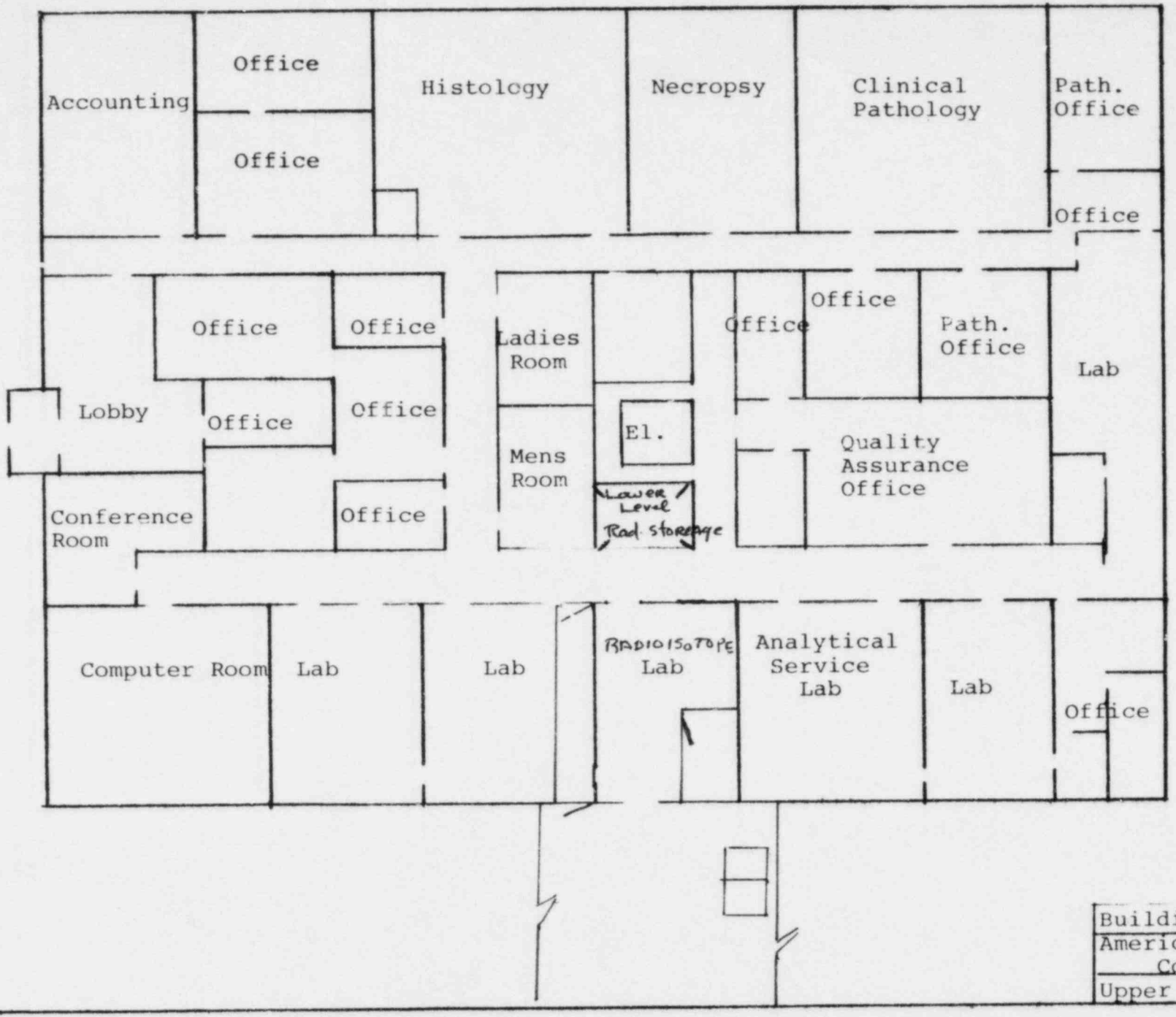
CONTROL NO. 79136



CONTROL NO. 79136

By Secty B1

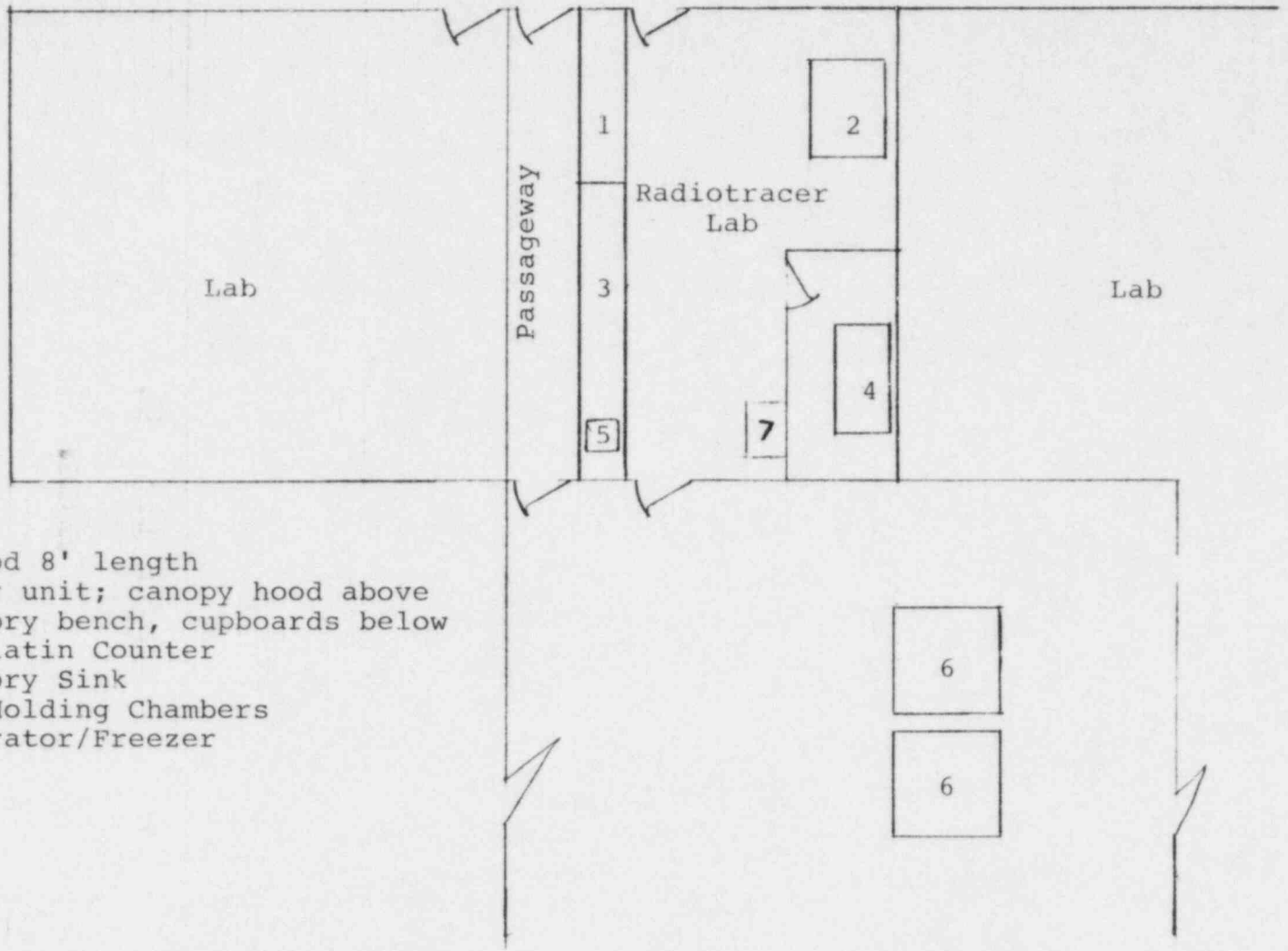
Building Layout	
American Biogenics Corporation	
	ABC-1



Building 1
American Biogenics Corporation
Upper Level | ABC-7

CONTROL NO. 79130

Rej. Sept 82



1. Fume Hood 8' length
2. Oxidizer unit; canopy hood above
3. Laboratory bench, cupboards below
4. Scintillatin Counter
5. Laboratory Sink
6. Animal Holding Chambers
7. Refrigerator/Freezer

CONTROL NO. 7 9 1 3 0

Ref. Sect 9 B2

Radiotracer Lab	
American Biogenics Corporation	
Building 1	ABC-8