APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OME 3150-0120 Expires 5-30-50

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH	IF YOU ARE LOCATED IN					
J.S. NUCLEAR REGULATORY COMMISSION DIVISION OF FUEL CYCLE JAND MATERIAL SAFETY, NMSS WASHINGTON, DC 20556	ILLINDIS, INDIANA, IDWA, MICHIGAN, MINNESOTA, MISSOUZII, ONIO, OR WISCONSIN, SEND APPLICATIONS TO					
WASHINGTON, DC 20556 LL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE DCATED IN	U.S. NUCLEAR REGULATORY COMMISSION, REGION III MATERIALS LICENSING SECTION 789 ROOSEVELT ROAD GEN ELLYN IL 60137					
ONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, NASBACHUSETTS, NEW HAMPSHIRS, NEW JERSEY, NEW YORK, PENNSYLVANIA, HODE ISLAND, OR VERMORT, BEND APPLICATIONS TO:	ARKANSAS, COLORADO, IDANO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, DKLAHOMA, BOUTH DAKOTA, TEXAS, UTAH, DR WYOMING, SEND APPLICATIONS TO:					
U.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR MATERIALS BAFETY SECTION 2 631 PARK AVENUE KING OF PRUSSIA, PA 19406	U.S. NUCLEAR REGULATORY COMMISSION, REGION IV MATERIAL RADIATION PROTECTION SECTION 611 RYAN PLAZA DRIVE, SUITE 1000 ARLINGTON, TX 76011					
LLABAMA, FLORIDA, GEORGIA, KENTUCKY, MISBISSIPPI, NORTH CAROLINA, UERTO RICO, BOUTH CAROLINA, TENNERSEE, VIRGINIA, VIRGIN ISLANDS, OR VEST VIRGINIA, SERD APPLICATIONS TO	ALASKA, ARIZONA CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON,					
U.S. NUCLEAR REGULATORY COMMISSION. REGION II NUCLEAR MATERIALS SAFETY SECTION 101 MARIETTA STREET, SUITE 2000 ATLANTA, GA 30323	AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, PRIGION V NUCLEAR MATERIALS SAFETY SECTION 1480 MARIA LANE, SUITE 210 WALNUT CREEK, CA (4696)					
ERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.	REGULATORY COMMISSION DNLY IF THEY WISH TO POSSESS AND USE LICE					
THIS IS AN APPLICATION FOR (Check appropriate /tem) A ICEN LICENSE 3. AMENDMENT TO LICENSE NUMBER	2 NAME AND MAILING ADDRESS OF APPLICANT (Include Zu Code) Biomedical Technologies, Inc. 378 Page Street					
c. RENEWAL OF LICENSE NUMERA 20-21472-01 ADDRESSIES: WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED. 378 Page Street, Stoughton, MA 02 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION	TELEPHONE NUMBER					
addressies: where licensed material will be used on possessed 3 78 Page Street, Stoughton, MA 02 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Ronald For and	2072 TELEPHONE NUMBER 617-344-9942					
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Item 5. Licensed Material

	£lement and Mass number	*** (2) \$1 10 10 10 10 10 10 10				Maximum Amount Possessed at any one time				
Α.	Calcium - 45	Α.	Any	Α.	10	millicaries				
В.	Carbon - 14	В.	Any	В.	2000	mil!icuries				
C.	Chromium - 51	C.	Any	c.	100	millicuries				
D.	Hydrogen - 3	D.	Any	D.	5000	millicuries				
E.	Iodine - 125	E.	Any	E.	75	millicuries				
F.	Phosphorus - 32	F.	Any	F.		millicuries				
G.	Sulfur - 35	G.	Any	G.		millicuries				

Item 6. Use of By-product materials

A. Hydrogen - 3 and Carbon - 14

Purified compounds containing H-3 or C-14 will be purchased and repackaged as part of research kits and systems developed by the company. No synthesis with these isotopes are planned at this time. Some purification involving less than 5mCi may be undertaken, but will not be part of an ongoing program. Only R. Forand will be involved in use of materials at the mCi level.

Technicians will use tracer level materials (less 2uCi at a time) for R & D purposes and will package materials containing less 100uCi at any one time.

These products are primarily ionized biochemicals. BTI will only handle very small quantities (<100uCi) of tritiated water.

Ali compounds are stored in Area C. Please see Floor Plan under Item 9.

B. Iodine - 125

All procedures with sodium iodide-125 are carried out in a properly functioning glove-box (containing an activated carbon filter in-line with hood exhaust, and held under negative air pressure by same hood exhaust fan; (see attached sketch in Item 9.). Compounds labelled are ionized biochemicals, proteins, peptides, nucleotide derivatives, etc. Various state-of-the-art methologies are employed. Most purifications are also done inside the glove box. . re this is not feasible, purifications are done in the adjacent fume hood, after it has been verified that no oxidizing species remain in the reaction mixture a colorimetric test with unlabelled potassium iodide. Monitoring of the breathing zone and exhausted air is done each day of the experiment or set of experiments. Only R. Forand handles/uses sodium iodide-125 and organically bound materials greater than 100uCi.

Three to eight experiments are currently done in one month. Average daily use is 1-3mCi; occasionally 5mCi may be used in one day.

All sodium iodide-125 is stored in original manufacturers' packaging and is ide the box. All organically bound iodine-125 materials are stored in the refrigerator/ freezer of Area C.

Typically, technicians handle materials at 10-20uCi/gram (less than 100uCi total). These operations are confined to Area C. Technicians also use small quantities (less than 5uCi) in Area B (Biochemistry lab).

C. Calcium - 45, Chromium -51, Phosphorus - 32, Sulfur - 35

These materials are primarily for distribution. Tracer quantities may occasionally be used for R & D and quality control.

Item 8. Training for Individuals Working in Restricted Areas

Ronald Forand, Lab Manager Maurice Lamarque, President Kathy Ouimet, Technician (supervised by R. Forand) MAURICE P. LAMARQUE
3 Regan Road
Walpole, Massachusetts 02081
(617) 492-6200

AREAS OF KNOWLEDGE AND EXPERIENCE

Sales Management Marketing Personal Selling Trade Shows

Product Management

PERSONAL

Birthdate: 2/6/48 Married 5'10" 1601bs Excellent Health

EDUCATION

Boston State College, Boston, Massachusetts B.S. Degree Major: Chemistry Minors: Physics, Math

Babson College, Wellesley, Massachuretts (Graduate School of Business Administration) M.B.A. Candidate

Special Training Courses: Effective Listening, Xerox Sales Training Courses, Real Estate Brokerage Courses and other Sales Training Courses. Numerous Technical Seminars including Molecular Biology, Biochemistry and Radiobiology.

EXPERIENCE (1979 to 1980)

Sales Manager, Collaborative Research, Inc., Waltham, Mass.

Responsible for all Sales Management activities including: Sales/Marketing Plan, Customer Service, Telephone Sales, Major Account Coverage, Sales Training and Trade Shows. Also lirected all Product Management functions.

(1974-1979)

Senior Technical Representative, Research Products Div. New England Muclear Corporation, Boston, Mass.

(1972-1974)

Technical Representative, Research Products Div. New England Nuclear Corporation, Boston, Mass.

(1969-1972)

Technical Service Assistant, Marketing Department New England Nuclear Corporation, Boston, Mass.

RADIOISCTOPE BACKGROUND

1) Education

New England Nuclear Corporation - Attended numerous seminars on the safe and effective handling of radioactive material. Programs included opening of different types of packaging, shielding, liquid scintillation counting and radioimmunoassay techniques. Attended and gave seminars to Technical Representatives and other company personnel on the effective use of radioactive compounds in Life Science Research. The topics included: Molecular Biology and Protein Biochemistry. At New England Nuclear I was continually involved with diseminating information on safe handling techniques for radioisotopes as these techniques evolved. For example: plastic shielding as an effective barrier for Phosphorous-32; charcoal trapping Icdine-125 gas released from radio-iodination; effective storage techniques for all radioactively labeled compounds made at NENC.

2) Seminars on Methods of Measuring Isotopes

Set up seminars on effective methods for quantitating various emitters: beta, gamma, beta/gamma, and alpha emitters. These programs were given by NEN personnel at Harvard University, Mass General Hospital, Boston University Medical Center, Wesleyan University and the Marine Biology Institute.

3) Harvard University Isotope Handling Course

I have attended various lectures given by Harvard Health Physics personnel on isotopes, their detection, the biological hazards involved with handling radioisotopes and dosimetry, etc.

4) Many of the Chemistry and Physics courses in my undergraduate program included topics on isotope use and measurement.

Experience:

New England Nuclear Corporation:

Carbon-14 1-5uCi
Tritium 5-10uCi
Iodine 1-5uCi
Phosphorous-32 1-10uCi

During various workshops concerning the use of radioactivity for a variety of applications, I handled small quantities of labeled compounds. Training consisted of Theory & Principles of Beta and Gamma Counting and various Radioimmunoassay Techniques.

Item 16: Training and Experience

Name: Ronald R. Forand

Date and Place of Birth: February 25, 1947, Barton, VT

Citizenship: United States

Marital Status: Married, one child

Residence:

Education:

1968 Undergraduate Research Participation Program Recipient. Isolation and Purification of Plant Glycosides

- 1970 B.S. Biochemistry, University of New Hampshire, Durham, NH
- 1973 M.S. Biochemistry, University of New Hampshire. Thesis: The Active Site Structure of Hemerythrin by Chemical Modification

Acquired the techniques of protein chemistry; procedures for the purification and characterization of proteins and peptides including ion exchange, gel-filtration chromatography, peptide mapping; determination of amino acid composition and primary structure of peptides, methods of secondary and tertiary structure investigation.

Experience:

1980-1982 Biochemist, Kor Inc., 56 Rogers St. Cambridge, MA

Develop biosynthetic capabilities for the manufacture of stable isotopically labelled biochemicals. Preparation of specifically labelled compounds with enriched deuterium, nitrogen-15, carbon-13.

Participated in the establishment of Kor Biochemicals division of research products. Prepared iodine-125 labelled compounds.

Radiation Safety Officer

Safety Committee member

1979-1980 Staff Chemist, diagnostics development, RIA Products Inc., 411 Waverly Oaks Road, Waltham, MA

Developed the "Combo-Stat-No Boil" assay kit for the vitamins B-12 and folic acid. Patent pending, assigned to RIA Products Inc.

1976-1979 Biochemiat, product development, Collaborative Research, Inc., 1365 Main Street, Waltham, MA

Technical aspects of the growth factors product line including epidermal (EGF), fibroblast (FGF), and nerve (NOF) growth factors, the cell culture derived somatomedin MSA; human fibronectin and endothelial cell growth supplement (ECGS); also development of human somatomedins, insulin-like growth factors, colony stimulating factor, human prolactin, bovine growth hormone, cell-specific serum-free growth medium, human plasminogen activator from cell culture.

Prepared iodine-125 labelled protein derivatives.

Designed tissue culture bloassays and radioreceptor assays.

1973-1976 Research Chemist, Instrumentation Laboratory, Inc., Lexington, MA

Assessed competitive protein binding methods for application to clinical diagnostics.

Developed an enzyme-linked immunoassay system for digoxin and testosterone, including chemical conjugation of the drugs to enzymes, purification of the reaction products by immunological and co-factor affinity chromatography.

1969-1973 Amino acid analyzer technician, Department of Biochemistry, University of New Hampshire, Durham, NH

Operation and maintenance of a Beckman 1200 Amino Acid 'malyzer for department personnel while acquiring bachelor's and Master's degrees.

Radioisotope Background

I. Education

3 credit hours, one semester course

University of New Hampshire, 1971

Characteristics of radiation and its interaction with matter. Methods of measurement of isotopes; Theory of instrumentation used i.e. scintillation counters, GM tubes etc. Biological hazards of radioisotopes. Practical aspects of the set-up and daily operation of a radioisotope laboratory; Waste, Dosimetry, etc. Experimental Design.

II. Experience

Place	Year	Isotopes	Max Used/day
Univ. N.H. Durham	1971-1973	H-3,6-14	5mC1
Instrumentation Lab	1973-1976	C-14	0.5mC1
Collaborative Research	1976-1979	I-125 P-32 Zn-65 H-3	6mCi 0.2mCi 0.2mCi 0.1mCi
KOR Biochemicals	1980-1982	I-125	12mCi
	1981-1982	Radiation	Safety Officer

KATHLEEN M. OUIMET

OBJECTIVE

A position in a laboratory utilizing research, analytic, and quantitative skills.

EDUCATION

North Baston, MA STONEHILL COLLEGE Graduated May of 1985 with a Bachelor of Science degree in Biology. Financed 60% of education through loans and 23% 10%/ employment. Member of Biology Society.

EXPERIENCE

Morton Hospital

Taunton. MA

January-May 1985

Volunteer Laboratory Intern -Assisted technologists in the tests being performed in each department.

-Analyzed test results.

-Assisted with paper work and controls for each test.

-Operated manchines and computers.

-Observed pathologist checking specimen's from the Operating room.

The Assonet Inn Restaurant

Assonet. MA

December 1982present

Cook in a small family restaurant.

-Train and supervise staff.

-Prepare food.

-Open in the morning and close at night.

St. Annes Hospital

Fall River, MA

August 1980-September 1984

Secretary in the Radiology Department.

-Assisted Radiologist during testing when needed. -Set up x-ray films for the Radiologist to read. -Assisted x-ray technologists when needed.

-Processed patients to be tested. -Answered phones.

-Organized files.

ADDITIONAL EMPLOYMENT Nurses aide, stock person, cashier, ice cream attendent.

INTERESTS

New developments in technology, skiing, hiking, and reading.

Radioisotope Training Primarily on-the-job 1. Periodically reviews NRC publications, i.e., CFR Part 20 and Part 19 and Regulatory Guide 8.20 and others 2. Reviews literature, text books, etc. concerning nature of radioactivity. means of measurement, health and safety issues 3. Receives in-house instructions on proper use of instrumentation, and health and safety procedures 4. To attend seminars given by consultants or other individuals.

Item 9. Facilities and Equipment

- A. Floor Plan, Explanation of Floor Plan, Glove Box ventilation sketch, and Ventilation Specifications are Attached.
- B. Sealed Sources: None
- C. Instruments

	Туре	Manufacturer	Mode1	Number Available	Radiation Detected	Sensitivity,
1.	Portable Meter	Ludlum	3	1	beta gamma	0-2MR/hr 20-300,000 cpm
2.	Gamma Counter	Packard	5136	1	gamma	0-2,000,000 cpm
3.	Liquid Scintillation	Packard	4430	1	beta	0-2,000,000 cpm

Calibration:

Ludlum: Bolton-Galinik, P.O. Box 306, Boston, MA 02139 Annually.

Packard #5136: Commercial Standard (West-Chem, 7079 Mission Gorge Rd., San Diego, CA 92120) Weekly.

Packard #4430: Commercial Standard (Amersham, 2636 S. Clearbrook Dr., Arlington Heights, IL 60005 Semi-annually.

D. Personnel Monitors: Landauer, 2 Science Rd., Glenwood, IL 60425. Film badges, ring badge. Monthly.

iomedical Technologies Inc.

378 Page Street Stoughton, MA 02072 (617) 344-9942

EXPLANATION OF FLOOR PLAN

- Area A. Offices and front entry.
- Area B. Biochemistry laboratory.
- Area C. Radio Lab.

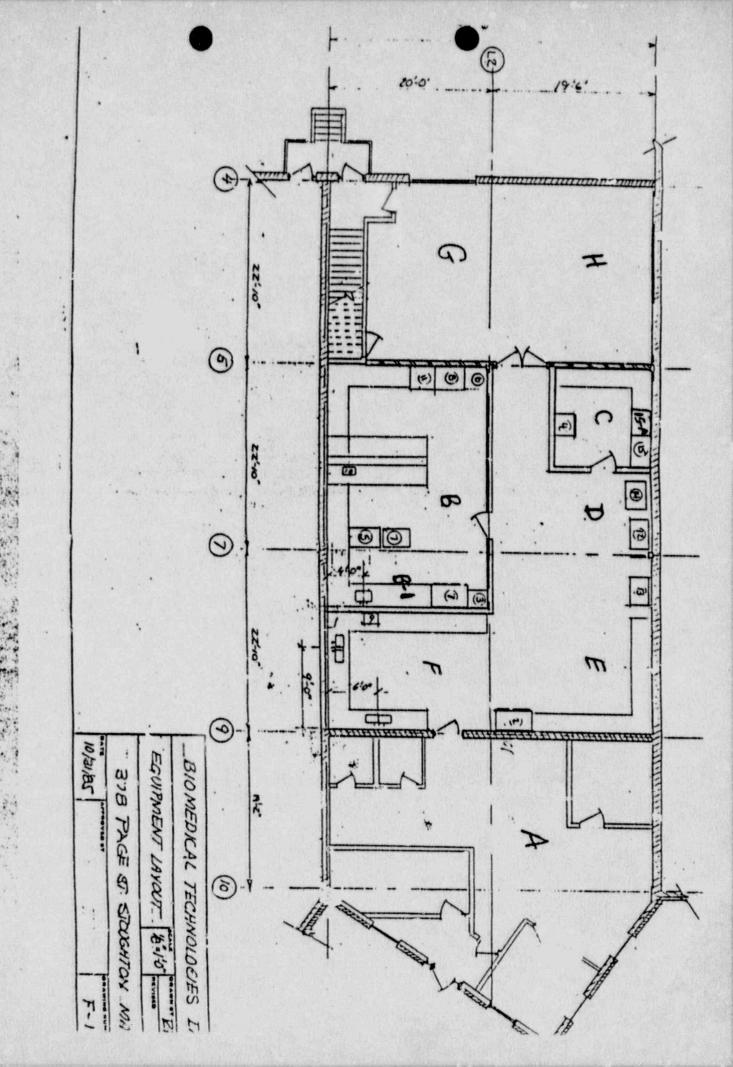
Primary lab for working with and storage of By-Product Material. This is an area restricted to authorized personnel only.

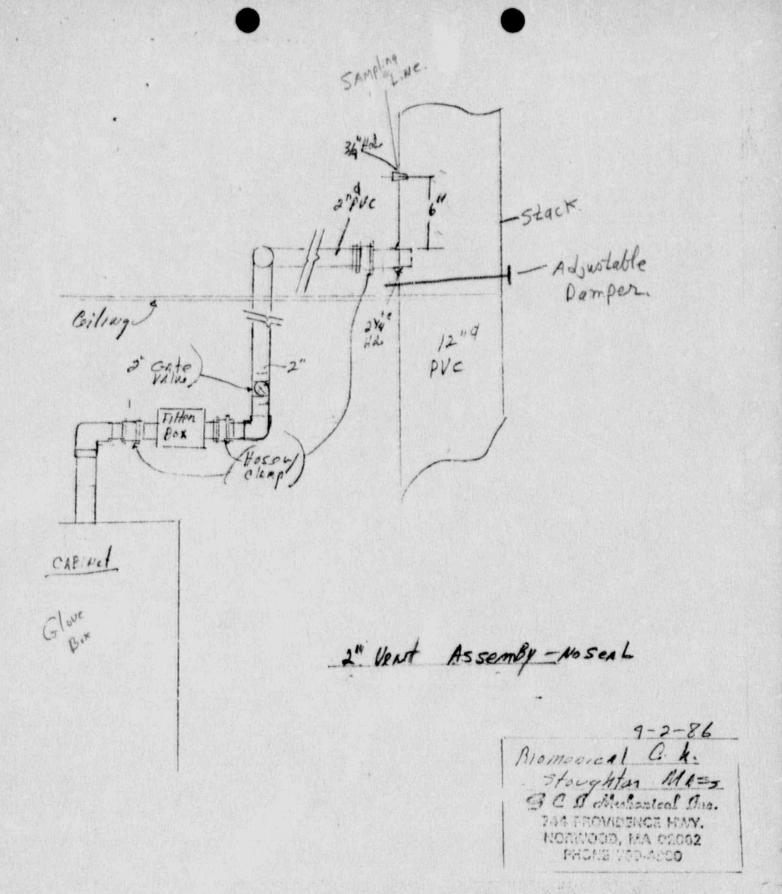
Contains a five foot fume hood, (#15) exhausted to the roof by a 12 inch PVC stack and a roof-mounted ventilator. The hood achieves in excess of 100ft/min at face with the sash 15 inches from the bench top.

Adjacent to the hood is a plexiglass glove box (#15A) with dimensions of 48 inches wide, 29 inches deep, 32 inches high which is connected to a charcoal filter and vented into the exhaust stack. Negative pressure will be achieved and controlled by a valve installed between the filter and inlet of the stack. All radioiodinations and other procedures involving potentially significant release of material to the atmosphere will be done in the glove box under proper operating conditions.

Air sampling of the stack effluent will be done to insure a release of less than 8x10-11uCi/cc and no detectable release in the breathing zone.

- Area D. Trace level area.
- Area E. Packaging and other activities with no opened containers of By-Product Materials.
- Area F. Glass washing, storage. No By-Product Materials allowed.
- Area G. Shipping/Receiving storage of finished products, including trace level quantities of By-Product Materials in packaged kits. No opened containers of materials are allowed. Received packages will be checked and opened in area D or C.
- Area H. General Storage Area.

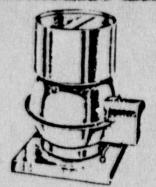






GENTRI-VANE

TYPE UCV UPBLAST



VERTICAL

All discharge air is blown up into the atmosphere away from the roof erea. Automatic dampers open when fan is energized and close when unit is turned off. The Centri-Vane Up-Blast roof ventilator is designed for use on high pressure duct systems whereventing is required through the roof. It eliminates unsightly goosenecks and provides a vertical charge ejecting the exhausted air into the atmosphe s. The UCV is compact in design and versus in usage and performance. It extends the range of the Centri-Vane Blower into many areas in both construction and in modification of existing buildings.

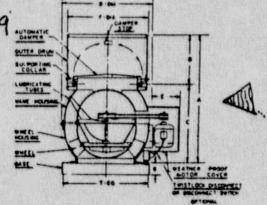
FEATURES .

Lightweight, All Aluminum Construction The UCV is all aluminum throughout. It requires no surfmaintenance and reduces installation costs. Completely Weatherproof The UCV belt drive is completely weatherproof with removable motor cover for inspection. Lubrication The UCV is equipped we extended lubricating tubes for external lubrication of the fan bearings. Non-Overloading Centrifur Wheel The specially designed impeller with its aluminum true airfoll blades has a non-overloadinhorsepower characteristic. Easily Installed The UCV mounts over a standard roof curb. A COOK VC or VCA prefabricated curb car, also be used. Disconnect A weatherproof disconnect switch or two disconnect is optional. No Backdraft Dempers Required Built-in aluminum butterfly damper prevent backdraft when unit is not in operation.

Spark Proof Orid resistant coating

DIMENSION DATA FOR UCV - CVR

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Will very with motor size

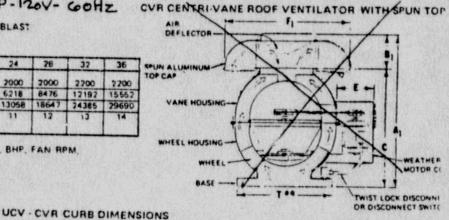
Drives through & H.P. are all variable pitch

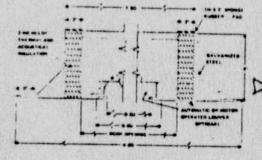
1150 cfm 0.4=1500 fpm 12"S.P. 1/317-1204- 60HZ

GUIDE FOR SELECTING THE UCV UP BLAST

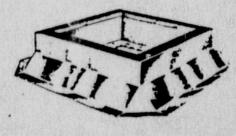
UNIT SIZE	12	14	16	18	20	7 24	78	22	75
MINIMUM	STREET, STREET		1	1	10		10	37	36
OUTLET VELOCITY	1000	1100	1200	1400	1600	2000	2000	2200	2200
MINIMUM CFM	769	1166	1662	2457	3469	6218	8476	12192	16667
MAXIMUM CFM	2922	4452	5817	7371	-	-			1000
SELECTION TABLE	-	-	3011	1/3/1	9106	13058	18647	24385	29690
SEE PAGE		1			10	1 11	12	13	14

WHEN ORDERING SPECIFY "TYPE UCV", SIZE, BHP, FAN RPM, CFM AND VELOCITY





	Curb		Gare	he ;	Gage of Mari
S-re S-re	140	. 40	v 50		
12	VCA 18	16 1/2	30 10	21	
1	VEG 27	22 1/2	33 1/7	*	
20	ACV 10	2010	33/6	47	20 GA
>4	VCG 10	101	111/1	30	H 64
*	VCG H	210	Nie.	:	
11	VC440	46 1/7	51 10	1:	
~	VCG-44			77	



E. Security

There are two entries to the premises, both of which have 2 doors which are locked during off bours. During working hours, office personnel are at the front (Ares A) where all business with visitors is conducted. A steel door isolates this area from the laboratory. Unescorted visitors are never allowed into the laboratory.

At the rear (Areas G & H) is the shipping/receiving area. Transport and carrier individuals are not allowed into the lab, which is also isolated by steel doors. All radioactive materials are stored in laboratory C, restricted only to authorized employees. Some low level solid wastes are also stored in the upstairs loft, always locked, which is inaccessible to unauthorized persons.

Item 10. Radiation Protection Program

- a. Survey Program: The survey frequency and permissable contamination levels are attached. Radionuclide workers are responsible for daily surveys to regularly establish the contamination levels in the laboratories, and a weekly survey, including wipe testing, is performed under the direction of the RSO. Radionuclide workers are also instructed to survey binds and clothing each time they leave the laboratory. A set of "General Radiation Protection Requirements and Precautions", which is posted in each laboratory, is attached.
- b. Records Management: The Radiation Safety Officer with assistance as necessary from his consultant, has been charged with the full responsibility for safe use of adioactive materials within the company. He will main ain all records required by law, including survey records, personnel monitoring records, purchase inventory records and waste disposal records. All radioactive material purchases will require his approval, and he will be responsible for receipt and checking of all materials. He will also be responsible for packaging waste for disposal and for maintenance of all disposal records.

Instructions to other radionuclide workers will include initial lectures for new workers and annual refreshers for all personnel. Items to be covered in such presentations will be the contents of 10CFR19 and 20, license conditions, general handling requirements and precautions, and radiation exposure perspective. The posted general instructions and emergency instructions will also be covered and their continual posting will serve as a constant reminder. All workers who handle radionuclides or frequent areas in which radionuclides are handled will be included in this instructional program. Instruction will be given by the RSO and/or his consultant.

Personnel Monitoring

Film badges are supplied to each person who works in an area of gamma or hard beta-emitting radionuclides, and ring badges are issued to individuals who will be involved in prolonged procedures involving millicurie quantities of such materials. These will be changed monthly with provisions for immediate telephone notification by the processor to the RSO if whole body readings in excess of 400 mrem and finger readings in excess of 1 rem are observed. The RSO and consultant will investigate all such incidents. Bioassays will be performed on persons conducting procedures involving millicurie quantities of I-125 labeled compounds. Continuous records will be kept of all such bioassays. Thyroid counts will be performed by direct measurement over the thyroid using a portable scintillation counter in irect contact with the nec... Thyroid burdens in excess of 1 nanocurie can be detected in this way. The frequency of such measurements will be monthly on all persons frequenting the laboratory in which such quantities of iodine are handled, with specific measurements made on the worker directly involved within 48 hours of each such handling. Similarly, urinalysis will be performed on persons handling quantities of tritium in excess of 10mCi per handling. The urinalysis will be performed within 48 hours of each such handling except for persons who routinely handle such quantities to warrant routine monitoring urinalysis.

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PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

- Each package containing radioactive material shall be opened in a radioisotope laboratory. Packages containing powdered, crystalline, or volatile radioactive material shall be opened in an approved hood.
- 2. Wearing protective gloves, open the outer package. Remove the packing slip and inspect it to verify that the shipment is in agreement with the nuclide(s) and quantities ordered. If special instructions for opening the isotope container are enclosed, follow the instructions.
- 3. Measure the dose rate emitted from the inner container wit appropriate survey meter. Check inner wrapping materia for contamination.
- 4. Remove inner container, and as necessary, place 3 mind shielding to minimise body exposure.
- 5. Open the inner container. Inspect and monitor contains for possible leakage from primary container (i.e. loss of riquid, discoloration of absorbing material, detection of contamination, etc.)
- 6. Notify the Radiation Protection Officer if:

a) Contamination of leakage is detected.

b) Dose rates in excess of expected values are measured.
c) There is discrepancy between the material received and

that which was ordered.

d) There are questions about special instructions for opening the isotope container.

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SURVEY FREQUENCIES

- 1. All areas in which millicurie quantities of unsealed activities are handled shall be surveyed daily with a survey meter and decontaminated if necessary. This survey is performed by laboratory personnel and a log is kept which identifies the person making the survey and the contamination levels observed.
- 2. inheratory areas where only small quantities of radioactive material fless than 1 millicurie) are used shall be surveyed at least weekly.
- 3. The weekly surveys are conducted under the supervision of the RSO
 - a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
 - b. A series of smear tests to measure contamination levels. The method for performing smear tests should be sufficiently sensitive to detect the limits below to one significant digit.

LIMITS FOR REMOVABLE SURFACE CONTAMINATION

Type of Surface	Type of Radioactive	Material(dpm/100cm2		
1. Unrestricted areas	I125 H-3,	C-14, Cr-51, P-32		
2. Restricted areas	100	100		
3. Personal clothing worn outside restricted areas	50	100		
4. Protective clothing worn only in restricted areas	50	100		

J. All radipisotope containers which will be left unattended shall be labeled with the radiation symbol, radionuclide, form, assay and date. Storage will be designated storage areas in established radioisotope laboratories, which have been properly identified and labeled by the RSO. Liquid radioactive waste shall be flushed into the sanitary sewerage system via sinks designated for this purpose by the RSO in concentrations that do not exceed those specified in 100F.20. 106. Solid radioactive waste shall be disposed of in closed, clearly identified radioactive waste container located in each lab. Enter information on waste disposed on appropriate record card on container or over sink for each disposal. 1. Objects and equipment that may have been contaminated with radioactive materials shall be surveyed for exterior surface contamination prior to their removal from the laboratory. If surface contamination is detected, the contaminated objects shall not be removed from the laboratory without the authorization of the Radiation Safety Officer. The Radiation Safety Officer shall be notified immediately m. if any of the following circumstances is know or suspected to have occurred: Exposure to external radiation in excess of the maximum permissible exposure values stated above. Exposure to inhalation, ingestion or injection of radioactive material. Accidental release of radioactive material into laboratory atmosphere, drains or ventilation systems or onto exposed Burfaces.

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GENERAL RADIATION PROTECTION REQUIREMENTS AND PRECAUTIONS

Following are the general requirements and precautions applicable to work with radioactive material:

- a. There shall be no smoking, drinking, eating, use of cosmetics, or storage of food in any area where unsealed and unpackaged sources of radioactive materials are used.
- b. There shall be no mouth-pipetting of radioactive solutions. Contact the RSO for information on the availability of remote pipetting equipment.
- c. Prior to the performance of a procedure involving radioactive material, radiation levels must be measured. Handling tongs, or a suitable remote handling device must be used for handling a source or container which emits a dose rate, at contact, in excess of 100 mR/hr.
- d. When performing procedures that might produce airborne contamination (i.e., evaporations, transfers of unsealed powdered or volatile radioactive material), approved exhaust ventilation shall be used.
- e. When hand or clothing contamination is possible, protective gloves and a lab coat shall be worn during operations involving handling of loose radicactive material. Contact the RSO for information on the availability of such items.
- f. After handling unsealed radioactive material, hands shall be washed before leaving the laboratory, and exposed hair, skin and clothing shall be surveyed for contamination. The Radiation Safety Officer shall be notified immediately if, after decontamination, residual contamination of skin, hair or personal clothing is detected.
 - g. The prescribed survey frequency and permissible contamination limits for various laboratory areas is attached. All radiation workers are responsible for assuring that the required surveys are performed as necessary. Contact the RSO if your responsibilities in this regard are not clear.
- h. Personnel monitoring devices issued by the RSO are to be worn whenever millicurie quantities of radioiodine is in use. These badges are changed at monthly intervals.
- 1. When transporting radioactive materials between rooms, seal inner container and package in unbreakable outer container.

EMERCENCY PROCEDURES FOR INCIDENTS INVOLVING RADIOACTIVE MATERIAL MINOS SPILLS: 1. NOTIFY persons in the area that a spill has occurred. 2. PREVENT THE SPREAD by covering the spill with absorbent paper. 3. CLEAN UP RADIOACTIVE MATERIAL: Using disposable gloves and remote handling tongs. Carefully fold the absorbent paper. Insert into a plastic bag, seal and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves. SURVEY THE ENTIRE AREA INVLOVED: With a G.M. Survey Meter. Check the area around the spill, your hands and clothing for contamination. Window on G.M. Survey Meter must be thin enough to measure radiation emitted by the radionuclide spilled. 5. REPORT incident to the Radiation Safety Officer. MAJOR SPILLS: 1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room. 2. PREVENT THE SPREAD by covering the spill with absorbent pads. Do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread. Assemble all potential involved personnel in an adjacent room. SHIELD THE SOURCE if practical. This spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure. CLOSE AND LOCK THE ROOM to prevent inadvertent entry by authorized personnel. 5. NOTIFY the Radiation Safety Officer immediately. 6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. Contact dose rate on skin should be reduced as far below 1 mrem/hr as possible. RADIATION SAFETY OFFICER: RONALD FORAND OFFICE PHONE: 344-9942 HOME PHONE: RADIATION SAFETY CONSULTANT: BOLTON & GALANEK, INC. OFFICE PHONE: 253-2180 HOME PHONE

Item 11. Waste Management A. Trace Level Wastes. Isotopes of half-lives ≤ 60 days a. Solids These will be held for decay-in-storage for a minimum of 10 half-lives, and disposed as regular trash. A Ludlum portable meter (model 3, sensitivity approximately 2000dpm) and a Packard Model 5136 gamma spectrometer (sensitivity approximately 100 dpm) will be used to verify background activity has been attained. Records are maintained. b. Liquids The company disposes of low level liquid wastes by release to the sanitary sewerage system in accordance with 10CFR 20.303. Currently, it includes water soluble liquids of I-125 and H-3 compounds. The company is in an industrial condominium complex with a single discharge into the main line. Average daily water use of the complex is 2000 cubic feet. From the Table 1, Column 2 of Appendix B of Part 20, our maximum is 2000uCi Iodine-125/day. Our release rate currently is less than 20uCi/day. 2. All Other Isotopes Where feasible wastes will be released to sanitary sewerage in amounts not to exceed 1% of quartities ir 10CFR 20.303. Currently we release less 10uCi/day of hydroger-3 compounds. We are using liquid scintillation media (containing less than .05uCi H-3 per gram) deemed safe for sewerage systems by state authorities. Those materials which are not suitable for the above method will be transferred to a contractor according to 10CFR 20.311. B. Moderate Level (mCi) Wastes 1. Solids Millicurie quantities (approximately 10mCi) of Iodine-125 are stored as solids (primarily absorbed to resins and/or activated charcoal) in a 55 gal. stee! drum. The drum is kept in the isotop: lab (Area C); the

cover held by the metal ring clamp. Technicians and others are not allowed access to this drum. 2. Liquids Liquids are held for several half-lives (in the freezer of Area C) to allow for decomposition of material to I. The inorganic iodide is absorbed to resins, which is treated as solids. Remaining liquids are assayed and released to sanitary sewerage if quantities do not receed the above limits. Additional Information Regarding this License I. Regarding the ALARA Con ept Company philosophy maintains that achieving exposures as low as reasonable is not only good health policy but also good business policy. Recurrent needs for remedial actions place significant burdens on management time and ultimately decreases productivity. Employees receiving significant exposures because of sloppy methodology will be transferred to duties not involving radicisotopes. Inadvertant exposures will be remedied expeditiously by removing offending source. Environment air samples will be taken from time to time to guard against burdens due to increased storage materia.s. All remedial actions will be taken to affect a "final" solution. We have no water effluents (other than sewer). We have a hood equipped with a charcoal trap rated at>95% efficient for Iodine. See enclosure. The hood effluent will be monitored by a sampling device (filter disc with air pump pulling 10L/min) mounted in the duck, post charcoal trap. Should levels exceed 1% of limits in 10 CFR, Part 20, actions will be taken to 1) locate the offending material and eliminate its contribution by physical/chemical containment such as absorption, sealing in a leak-proof container, etc. II. Our policy regarding I-J25 will encompass the following: Newly hired employees who will be working with I-125 will receive a thyroid scan at the beginning of employment and

3 months later in order to establish baseline activity and verify that the employee adhere to appropriate laboratory practices. Anyone working with o.lmCi or more of inorganic radioiodine will receive a thyroid scan within 48 hours of finishing the work. Also all laboratory employees will receive a monthly check. These measurements will be made with a portable meter having a sensitivity of lnCi. Any readings in excess of 5nCi will be verified by Mr. Bolton. Any individual with thyroid burden of 10nCi will be removed from the laboratory until source/cause of contamination is located and eliminated. III. Tritium Assays Bioassays for tritium are not required at this time per guidelines in "Applications of Bioassay for Tritium". It is anticipated that we will be working with less than 10mCi of tritium labelled compounds at one time. This value is 10% of amount in Table 1 of the above guidelines. We will not hand'e significant quantities (ImCi) of HTO. Should increased quantities of tritium be used, bioassays will be performed on at least a quarterly basis. Currently, BTI has less than 5mCi of tritium compounds. IV. Use of Phosphorus-32 Compounds Whenever millicurie quantities of a P-32 compound are in use, general policies will be the following:

- 1) Work to be done in trays, in a hood, if possible, to further contain spills.
- 2) Use of a portable Plexiglass (3/4") shield between source and worker.
- Appropriate laboratory clothing including nonpermeable gloves.
- 4) Goggles or face shield to be worn.

- 5) Use of remote handling apparatus and tools for concentrated sources.
- 6) After use and general clean-up, do rvey of area and person for "hot-spots
- Use finger badge for extensive handling procedures.
- V. Procedures for Receipt/Shipment of Liceused Material

All packages containing licensed materials will be handled in accordance to 10 CFR Part 20. Briefly, all packages received or departing the premises will be held in a single area of the shipping department designated for isotope shipments/receipts. Records of shipments/receipts will be maintained in a bound notebook. Entries will be made of smear tests of all packages of non-exempt licensed materials, nuclide and quantity of activity, destination of shipment or shipper of materials received, results of external dosage if appropriate and date.

Licensed materials will not be shipped to a customer or individual unless a current license of the user is in our file and we have determined that materials to be shipped are in accordance with his license. In some circumstances, shipments (small quantities) will be made if an authorized person of the receiver promises to forward a copy of their license promptly.

Biomedical Technologies, Inc. ATTN: Mr. Ronald Forand Radiation Safety Officer JAN 1 2 1988 378 Page Street Stoughton, MA 02072 Gentlemen: This refers to your application dated December 7, 1987, for renewal of Materials License 20-21472-01. We received your check for \$120. Your application, however, is subject to a renewal fee of \$460 as specified in §170.31 (3B) of 10 CFR 170, copy enclosed. Payment of the additional \$340 should be made to the U.S. Nuclear Regulatory Commission and mailed to my attention at our Washington, D.C. address. Your application will be processed by the Region I Licensing staff located at 631 Park Avenue, King of Prussia, Pennsylvania 19405. The additional fee, however, is required prior to issuance of the renewal. When submitting the fee, please refer to CONTROL NUMBER 108130. Sinceraly, Signed by Glenda sackson Glenda Jackson License Fee Management Branch Division of Accounting and Finance Office of Administration and Resources Management Enclosure: 10 CFR 170 cc: Ragion I DISTRIBUTION: Pending Fee File ARM/DAF R/F LFMB R/F (2) DW/RI/BTI OFFICE: ARM/LFMB ARM/LFMB SURNAME: Skimberley:rej GJackson 1/11/88 DATE: 1/12/188

(FOR LFMS USE) INFORMATION FROM LMS LICENSE FEE MANAGEMENT BRANCH, ARM PROGRAM CODE: 03214 AND STATUS CODE: 2 REGIONAL LICENSING SECTIONS FEE CATEGORY: 38 EXP. DATE: 19880131 : FEE COMMENTS: _. LICENSE FEE TRANSMITTAL REGION APPLICATION ATTACHED APPLICANT/LICENSEE: BIOMEDICAL TECHNOLOGIES, INC. RECEIVED DATE: 871210 DOCKET NO: 3020824 CONTROL NO .: 108130 LICENSE NO.: 20-21472-01 RENEWAL ACTION TYPE: FEE ATTACHED 127 AMOUNT: CHECK NO. : 3. COMMENTS B. LICENSE FEE MANAFEMENT BRANCH (CHECK WHEN MILESTONE OF IS ENTERED 151) 1. FEE CATEGORY AND AMOUNT: 2. CORPECT FER PAID. APPLICATION MAY BE PROCESSED FOR: AMENDMENT RENEWAL 1.I CENSI DTHER SIGNED

DATE