	Form 313 1 U.S. / (12-81)	NUCLEAR REGULATORY C	OMMISSION	1. APPLICATION FOR: (Check and/or complete as appropriate)			
	APPLICATION FOR BY			a. NEW LICENSE			
See	ttached instructions for details.			b. AMENDMENT TO:			
	leted applications are filed in dupli of Nuclear Material Safety, and Sa			,			
Washi	ngton, DC 20555 or applications in H Street, NW, Washington, D. C. o	ay he filed in person at the	Commission's office at				
	PLICANT'S NAME (Institution, firm,		3. NAME AND TITLE OF PERSONNEL STATES APPL				
1	R. Squibb & Sons, 1		John P. Gresh				
	EPHONE NUMBER: AREA CODE - L) 545-1300, Ext. 2		TELEPHONE NUMBER: A (201) 545-1300	AREA CODE - NUMBER EXTENSION			
4. AP	PLICANT'S MAILING ADDRESS (Indicates to which NRC correspondence, uld be sent.)	clude Zip Cadel	5. STREET ADDRESS WHEI (Include Zip Code) Rt #1, North Bruns	RE LICENSED MATERIAL VILL DE USED			
	Box 191		Lawrenceville-Prin Princeton, NJ 08	aceton Road Addendum			
New	Brunswick, N.J. 08		Demonstration Site	9 - U.S #2			
	DIVIDUAL(S) WHO WILL USE	OR DIRECTLY SUPERV					
	e Items 16 and 17 for required traini FULL NAME		Applicant	ZITHE /			
a. Sc	ee Addendum #1		Check No. 50660/ Amount Face \$ 460-3A				
b.			Type of Fc. R	eneway			
c.			Received Sy.	Stown			
	DIATION PROTECTION OFFICER		Attach resing it person ser free year open a furthered in Items 16 and 17 and describe his responsibilities under Item 15.				
Jol	nn P. Gresh	:	See Addendum #				
		8. LICENSED	MATERIAL NAME OF MANUFACTUR	ER MAXIMUM NUMBER OF			
L I N E	ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	AND MODEL NUMBER (II Sealed Source)	MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL			
NO.	. A	8	c REC	EIVED BY LEAS			
(1)	See Addendum #2		Date	1/2/22			
123	Dec Addendam #2		Log	de 3 /2			
(2)	8504260266 85	0415	By.	9/1/02			
(3)	RE01 L1C30 29-00139-02	PDR	Orig. To.	1110			
(4)			Action Go	mol C/2/C			
		DESCRIBE USE OF L	ICENSED MATERIAL	74.00			
111	Processing and distribution to authorized recipients under part 33						
(2)	Title 10, Research and Development as defined in section 30.4 Title 10 Code of Federal Regulations part 30.						
	TO Code of rederal	regulacions p		ElT			
(3) %,			information in this record was accordance with the Freed	to deleted in 140mg			
(4)	ORM 313 [112-81)	The state of the s		O O O S			

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RESPIRATORY PROTECTIVE EQUIPMENT, ETC. See Addenda #5 and #6.								
14. WASTE DISPOSAL								
Nuclear Diagnostic Lab., Inc., P.O. Box 791, Peekskill, NY 10566								
b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.								

NRC.FORM 313 ((12-81)

910

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

- 15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures lit needed; day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
- 16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - Radioactivity measurement standardization and monitoring techniques and instruments.
 - Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or onthe-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the opticant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our 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.

a. LICENSE FEE REQUIRED (See Section 170,31, 10 CFR 170)	b. CERTIFYING OFFICIAL ISignatures		
	Patrick N. Rava		
(1) LICENSE FEE CATEGORY:	d. TITLE Director, Quality Control Services		
(2) LICENSE FEE ENCLOSED: \$ 460.00	e. DATE 5/17/5'3		

RADIATION SAFETY COMMITTEE MEMBERSHIP

- Mr. P. A. Rava, Committee Chairman, Director, Quality Conrol Services
- 2) Mr. F. Golub, Director, Personnel and Industrial Relations
- 3) Mr. G. Thompson, Head, Radiopharmaceutical Manufacturing
 - 4) Mr. H. R. Harrison, V.P. and Regulatory Counsel
 - 5) Dr. E. Banta, Director, Medical Services
 - 6) Dr. S. Barker, General Manager, Diagnostics
 - 7) Dr. P. Roets, Manager, Personnel and Industrial Hygiene and Safety
 - 8) Dr. D. Benson, Manager, Radiopharmaceutical Quality Control
- 9) Mr. J. P. Gresh, Manager, Health Physics Department

"<mark>OFFICIAL RECORD CO</mark>PY"

NEW BRUNSWICK

•					
Byproduct material (element and mass number)	Chemical and/or physical form	Maximum amount of licensee may poss		-	
Any byproduct material with Atomic Numbers between 3 and 83.	Any	50 Curies total, Strontium 90 and exceptions:			
inclusive, except		Iodine 131		Curies	
Strontium 90		Iodine 125		Curies	
		Phosphorus 32	10	Curies	
		Chromium 51	2	Curies	
		Cobalt 60	50	Millicurie	s
		Selenium 75	5	Curies	
		Molybdenum 99- Technecium 99m		Curies	
	_		_		

Hydrogen 3

Any

5 Curies

LAWRENCEVILLE

Byproduct material (element and mass number)	Chemical and/or Physical Form		radioactivity which sess at any one time
Hydrogen 3	λny	5000 Mill	icuries ×
Carbon 14	λny	2000 Mill	icuries - Pr
Phosphorus 32	Any	50 Mill	icuries - La Maria
Iodine 125	Any	200 Mill	icuries
Sulfur 35	Any	1000 Mill	icuries.
Sodium 22	Any	5 Mill	icuries
Calcium 45	Any	5 Mill	icuries.
Chromium 51	Any	100 Mill	icuries
Chlorine 36	Any	300 Mill	icuries
Strontium 85	Any	10 Mil1	icuries
Niobium 95	Any	10 Mil1	icuries
Cerium 141	Any	10 Mill	icuries.
Scandium 46	Any	10 Mil1	icuries
Nickel 63*	Any	100 Mil1	
Iodine 129	Any	2 Mill	icuries

* This includes Nickel 63 sealed sources used in Hewlett-Packard elelctron capture detectors previously described in those pending amendment approval for our biproduct license which expired 6/30/83.

DEMONSTRATION SITES ANYWHERE IN U.S. UNDER NRC JURISDICTION Radioimmunoassay Kits

Patrick A. Rava

(b)(6)	

EDUCATION: B.S., Pharmacy, St. John's University -

- (b)(6)

M.S., Radiological Health, Rutgers University

(b)(6)

EXPERIENCE:

November, 1981 to Present

Director, Quality Control Services E. R. Squibb & Sons, Inc.

•

April, 1977 to November, 1981

Department Head, Environmental Control E. R. Squibb & Sons, Inc.

April, 1975 to

at it begands a bottle, and

Manager, Radiopharmaceutical Quality Control E. R. Squibb & Sons, Inc.

April, 1977 1962 to

April, 1975

Manager, Health Physics Department

E. R. Squibb & Sons, Inc.

December, 1961 to May, 1962

Assistant Department Head

Radiopharmaceutical Quality Control

and Health Physics

E. R. Squibb & Sons, Inc.

1960 to

Health Physics Supervisor

December, 1961

Radiopharmaceutical Production

E. R. Squibb & Sons, Inc.

1957 to 1960

Supervisor

Radiopharmaceutical Production

E. R. Squibb & Sons, Inc.

1956 to 1957

Technician

Radiopharmaceutical Production

E. R. Squibb & Sons, Inc.

JOHN P. GRESH

Personal Data						
Address: (b)(6)						
Marital Status:						
Date of Birth:	(b)(6)					(1)
Height: (b)(6)	Weight:	(b)(6)	Phy	sical	Defects:	(b)(6)

Education

College: Rutgers The State University

Curriculum: Biological Science and Marketing

Degree: Bachelor of Science

In addition, I have completed the following graduate level courses:

Imperial College, London, England

Summer School in Health Physics,

(b)(6)

Contamination Control, Philadelphia, Pa.

Radiological Health - Dept. HFW,

(b)(6)

I am a member of the Nuclear Medicine Society, the Health Physics Society and the N-14 Committee (ANSI) representing the Radiopharmaceutical Industry of the Atomic Industrial Forum. I am currently an active member on the PMA Subcommittee on Low Level Radioactive Waste Materials.

Employment

1. April 1975 to present

Manager, Health Physics Department

E. R. Squibb & Sons, Inc.

Direct the company's Health Physics Department which provides radiation safety services for radiopharmaceutical production, quality control, marketing, distribution and research and development. Included in administrative duties are budget planning and control, supervisory training, organizing and

J. P. Gresh Page 2

directing radiological health studies, investigations and procedures, providing a liason between company and regulatory authorities (State and Federal) and the direction and supervision of essential records and files.

2. September, 1969 to April, 1975

Health Physics Supervisor E. R. Squibb & Sons, Inc.

Supervised Health Physics functions in the production and testing of radiopharmaceuticals. Duties included internal as well as environmental monitoring of radioactive liquids and gaseous and controlling radiation and contamination levels in operational areas. In addition, coordinated research projects, testing organic compounds tagged with ³H and ¹⁴C and setting up laboratories to handle these compounds safely.

3. August 1968 - September, 1969

Radiopharmaceutical Production Supervisor E. R. Squibb & Sons, Inc.

Supervised and organized operations involved in the manufacturing, packaging and shipping of radioactive materials.

4. December, 1966 to August, 1968

Research Technician E. R. Squibb & Sons, Inc.

Assisted in the development and biological testing of new compounds tagged with 131 Iodine and 99m Tc Technetium.

5. 1962 to 1967

Quality Control Technician E. R. Squibb & Sons, Inc.

Tested radionuclides for final approval. Gained experience in using a Victoreen electroscope, gamma ray spectrometer and spectrophotometer.

6. 1958 - 1962

Manufacturing Technician E. R. Squibb & Sons, Inc.

Manufactured and filled radiopharmaceuticals.

RADIATION DETECTION INSTRUMENTS

A. FORTY-FIVE (45) PORTABLE IONIZATION-TYPE SURVEY INSTRUMENTS

- Fourteen (14) Eberline Model PIC6A ionization chamber survey meters; gamma; 1 mr/hr to 1000 R/hr
- 2. One (10) Eberline RO-2 ion chamber; beta-gamma, x-ray; >1
 mr/hr to 5000 mr/hr
- 3. Three (3) Teletector Model #6112 and #6112D; beta-gamma; 0.1 mr/hr to 1000 R/hr
- 4. Seven (7) Victoreen Model #497 survey meters; beta-gamma; 1 mr/hr to 1000 mr/hr
- 5. Two (2) Victoreen Model #471; beta-gamma, x-ray, alpha; 0.1 mr/hr to 300 R/hr
- 6. Three (3) Victoreen Model 470A; beta-gamma, x-ray; <1 mr/hr to 1000 R/hr</p>
- 7. Two (2) Ludlum Model L-1 and L-4 survey meters; beta-gamma, x-ray; <1 mr/hr to 1 R/hr
- 8. One (1) Nuclear Chicago Model #2650 survey meter; gamma; 1 mr/hr to 1 R/hr
- One (1) Keithley Model 36100 survey meter; beta-gamma, x-ray; 0.1 mr/hr to 20 R/hr
- 10. Two (2) Nuclear Associates Minimonitor; beta-gamma, x-ray; 0 to 5K cpm

B. SEVENTY (70) GM-TYPE SURVEY AND MEASURING INSTRUMENTS

- Fourteen (14) Eberline Model E-120 with end window GM probes; gamma, x-ray; 0 to 50K cpm
- 2. Thirty (30) Eberline Model RM-14 with end window GM probes; beta-gamma, x-ray; 0 to 500K cpm
- Five (5) Baird Atomic Model 441A rate meter with window GM probes; beta-gamma, x-ray; 0 to 500K cpm
- 4. Four (4) Eberline Models HFM-2, HFM-2A and PMC-4B hand and foot counters; beta-gamma; 0 to 500 cpm
- 5. Two (2) Eberline Model FM-12 beta gamma floor monitor; beta-gamma; 0 to 50K cpm

6. One (1) Eberline Model MS-2 scaler rate meter with end window GM tube; beta-gamma, x-ray; 0 to 500K cpm

The world the first referen

- 7. One (1) Eberline Model MS-2 with alpha scintillation detector; alpha; 0 to 500K cpm
- 8. One (1) Packard Model 34-29 scaler timer with end window GM tube; beta-gamma; 0 to 900K cpm
- 9. Seven (7) Eberline Model PRM-6 pulse rate meter with plutonium gamma probes; beta-gamma, x-ray; 0 to 500K cpm
- 10. Five (5) Eberline Model RM-19 rate meter with LEG-1 probe; beta-gamma; 0 to 500K cpm
- C. EIGHTY-EIGHT (88) SCINTILLATION-TYPE DETECTORS AND COUNTERS
 - Twenty-four (24) area monitors Nuclear Measurements Corporation with gamma alarm system with rate meters and twenty-four point recorders; gamma; 0.1 mr/hr to 100 mr/hr
 - 2. Three (3) Keithley Model 35056 Transport Index Monitoring systems; beta-gamma; 0 to 999 mr/hr
 - 3. One (1) Canberra Model 8180 multichannel analyzer with GeLi detection system; gamma; EO2 to EO6 cpm
 - 4. One (1) Nuclear Data Model 4420 multichannel analyzer with computer and 2 GeLi detectors; gamma; E02 to E06 cpm
 - 5. Three (3) Baird Atomic Model 530 spectrometers with sodium iodide well-type crystal; gamma; E02 to 9.9E06 cpm
 - 6. Three (3) Nuclear Model 300 spectrometers with sodium iodide well-type crystal; gamma; E02 to 9.9E06 cpm
 - 7. One (1) Medotope Model 210 spectrometer with sodium welltype crystal; gamma; E02 to 9.9E06 cpm
 - 8. One (1) Nuclear Chicago single channel analyzer with well-type sodium iodine crystal; gamma; E02 to E06 cpm
 - 9. One (1) Searle Analytic Model 1197 spectrometer with sodium iodine well-type crystal; gamma; E02 to E06 cpm
 - 10. One (10) Packard multichannel analyzer Model 9042 with well-type sodium iodide crystal; gamma; E02 to E06 cpm
 - 11. Three (3) Intertechnique Model #SL4000 liquid scintillation counters; beta; E01 to E06 cpm
 - 12. Two (2) Beckman Model #LS7500 Liquid scintillation counters; beta; E01 to E06 cpm

- 13. One (1) Ludlum Model 2200 spectrometer with well-type sodium iodide crystal; gamma: E02 to E06 cpm
- 14. Three (3) Baird Atomic ADC Models 345 and 300 amplifier analyzer thyroid uptake counting system with 1 x 1/2" sodium iodide crystal; gamma; EO2 to EO6 cpm
- 15. One (1) Tennelec Model TC-940 spectrometer with sodium iodide well-type crystal; gamma; E02 to E06 cpm
- 16. Two (2) Beckman Model LS-100C liquid scintillation counter; beta; EOI to EO6 cpm
- 17. Two (2) Packard Model #2425 liquid scintillation counter; beta; E01 to E06 cpm
- 18. One (1) Packard Model #930 spectrazoom multichannel analyzer; gamma; E02 to E06 cpm
- 19. One (1) Beckman Model LS-300 liquid scintillation counter beta; E01 to E06 cpm
- 20. One (1) Packard Model 2405 liquid scintillation counter; beta; E01 to E06 cpm
- 21. One (1) Packard Model 3310 liquid scintillation counter; beta: E01 to E06 cpm
- 22. One (1) Packard Model 5385 liquid scintillation counter; beta; E01 to E06 cpm
- 23. One (1) Beckman Model LS-355 liquid scintillation counter; beta; E01 to E06 cpm
- 24. One (1) Beckman Model LS-150 liquid scintillation counter; beta; E01 to E06 cpm
- 25. One (1) Beckman Model LS-250 liquid scintillation counter; beta; E01 to E06 cpm
- 26. One (1) Beckman Model LS-254 liquid scintillation counter; beta; E01 to E06 cpm
- 27. One (1) Nuclear Chicago Model #4320 autogamma counter; gamma; E02 to E06 cpm
- 28. One (1) Searle Model #4320 autogamma counter; gamma; E02 to E06 cpm
- 29. One (1) Nuclear Enterprise Model 16 auto spectrometer with well-type sodium iodide crystal; gamma; E02 to E06

Reflective Control of the Authority

- 30. One (1) Nuclear Enterprise Model 1186 auto spectrometer with well-type sodium iodide crystal; gamma; E02 to E06 cpm
- 31. One (1) Atomic Development Model 955-151 scaler timer with sodium iodide crystal; gamma; EO2 to EO6 cpm
- 32. Three (3) Packard Model #LS7500 liquid scintillation counters; beta; E01 to E06 cpm
- 33. One (1) Atomic Development I-131 capsule sorting machine with sodium iodide flat faced crystals; gamma; EO2 x 9.9E05
- 34. One (1) Atomic Development Co-57 capsule sorting machine; gamma; EO2 to 9.9EO5
- 35. One (1) Tennelec Model 246 spectrometer with sodium iodide crystal; E02 to E06 cpm
- 36. Two (2) Packard radiochromatographic scanners; gamma; E01 to E06 cpm
- 37. One (1) Packard Model 3375 liquid scintillation Counter; beta; E01 to E06 cpm
- 38. One (1) LKB Rackbeta Model 1215 liquid scintillation counter; beta; E01 to E06 cpm
- 39. One (1) LKB Rackbeta Model 1211 liquid scintillation counter; beta; E01 to E06 cpm
- 40. One (1) Beckman Model 8000 well-type gamma counter; gamma; E02 to E06 cpm

D. TWELVE (12) IONIZATION-TYPE MEASURING INSTRUMENTS

- Two (2) Victoreen Model 888 source calibrators; gamma;
 .05 mCi to 2E3
- One (1) Capentec Model CRC6 source calibrator; gamma; 0.5 mCi to 2E3
- One (1) Capentec Model CRClON source calibrator; gamma;
 0.5 mCi to 2E3
- 4. Five (5) Capentec Model CRClOR source calibrators; gamma; 0.5 mCi to 2E3
- 5. One (1) Capentec Model CRC17 source calibrator; gamma; 0.5 mCi to 2E3
- 6. Two (2) Medotopes Model 238-2 source calibrator; gamma; 0.5 mCi to 2E3 .

- E. SEVENTY-EIGHT (78) PORTABLE AND STATIONARY AIR SAMPLERS
 - 1. Twenty-six (26) MSA Model G part #456058 breathing zone air samplers with multichange units part #456690
 - 2. Two (2) high volume air samplers Unico Model #550
 - 3. Two (2) Neptune dyno pumps Model 4K for room air sampling
 - 4. Forty-eight (48) stationary room air samplers with Gelman #190036 flow meters in each room

Radiopharmaceuticals are manufactured by E. R. Squibb and Sons, Inc. in New Brunswick, New Jersey. This manufacturing facility includes provisions for the storage of raw materials, intermediate products and finished products. Sterile areas are provided for all aseptic operations and sanitary areas are provided for all nonaseptic phases of operation.

This facility (see Figures #1, #2, and #3) was specifically designed and constructed for the handling of radiopharmaceuticals. Processing of radioactive materials is carried out in gloveboxes equipped with leaded glass windows. In all cases, shielding is adequate to prevent exposure of operating personnel to excessive radiation levels. Rooms and gloveboxes are provided with forced ventilation to protect operators from volatile radioactive materials.

Each glovebox is equipped with a damper which will prevent the spread of a fire through the ventilation system. Any smoke or water vapor released by the fire and not stopped by the local fire damper will be contained in the glovebox. In addition, smoke detectors have been encased in the ducts of each filter bank system. When activated, valves located on each side of the filter bank will close automatically, and releases of airborne activity would be contained within the ducts of the ventilation system.

The hot cells are constructed of steel and concrete equivalent to four inches of lead for I-131 Iodine and eight inches of lead for the Mo-99 Molybdenum operations.

The steel and concrete used in the walls, flooring and ceiling of the hot cell's range from 14 inches to more than three feet in thickness.

The facility layout is such that movement of supplies, equipment and materials into processing areas does not interfere with adjacent work areas. The layout provides for easy access for purposes of maintenance and efficiency of operation. No unnecessary movement of materials is permitted through areas in which exposure to radiation could occur. Personnel movement in the facility does not require passage through radiation areas to gain access to nonradioactive materials areas.

Holding tanks and storage facilities for the radioactive materials to decay are remotely located, and are not in the normal path of travel of personnel or equipment.

Clean areas, radiation areas and high radiation areas are situated and segregated so that no unnecessary exposure is received by personnel. This layout also provides for contamination control. A personnel monitoring area and a protective clothing change room is located adjacent to the

radioactive materials area. Shower and locker room facilities are also provided. The layout of the facility is such that the products progress in sequence of operations from the manufacturing, filling and packaging areas to the final holding area for shipment. The loading dock is adjacent to the holding area. By use of conveyor belts and by judiciously locating the various stations in the complete manufacturing process, contact with and handling of any radioactive material is minimal.

· 成果

Selected portions of the production and storage areas are monitored by use of a "built in" area monitoring system. An indicating and alarm panel is located in the Health Physics Office, thus assuring access to information regarding any unusual dose rates in the monitored areas and rapid response with corrective actions. The instrument ranges from 0.1 mr/hr to 100 mr/hr. Local alarms are provided with visual and audible alarms to alert persons entering these areas of any abnormal condition. The instrumentation provided has the capability of detecting the highest anticipated radiation levels with positive readout at the lowest possible levels. To assure optimum coverage of all areas, the detector locations have been chosen with great care.

The manufacturing areas are served by a nonrecirculating air conditioned supply system utilizing all outside air introduced through a prefilter and a high efficiency particulate filter. A general system exhausts the various spaces through filtration equal to that of the supply system. Fume hoods, wherein particulate matter is the expected contaminant, are exhausted through an F-85 and a HEPA filter followed by a 1" high efficiency carbon filter to arrest any possible gaseous contaminant. The Mo-99 - Tc-99m cave is exhausted through an F-85 and a HEPA filter and three 1" charcoal filters. Certain manufacturing gloveboxes are also exhausted through an F-85, a HEPA and 3 one inch high efficiency carbon filters. Other manufacturing gloveboxes where less volatile radionuclides are processed are exhausted through an F-85 and a HEPA filter followed by 2 one inch high efficiency carbon filters.

Each of the twelve fume hood system filter bank service from one to five fume hoods or other ancillary equipment. Each fume hood system has a manual air bypass to be used during filter changes.

Each glovebox filter banks services up to five glovebox units or similar equipment. Each glovebox system has access to an auxiliary system offering identical filtration. There are no bypasses to allow passage of unfiltered exit air. There are eleven glovebox systems and six auxiliary systems available for use during filter changes or maintenance.

Filtration for three hot cells is accomplished by employing two identical exhaust systems. One is in continuous operation, while the other exhaust system serves as an auxiliary system when the primary is shut down for decay prior to filter changes or maintenance. Each system is filtered by three Flanders roughing, three Flanders HEPA and nine one-inch equivalent MSA activated charcoal filters. There are no bypasses to allow passage of unfiltered cave system air.

Each filter bank is equipped with before and after continuous sample tubes used to check charcoal filter efficiencies. They are changed on a weekly basis. The sample tubes are counted and an evaluation is made as to which bank should be changed, if applicable. There is no definite filter change criterion. Each system is examined individually to provide the most effective reduction in effluent.

The combination of particulate and gaseous filters described serves to reduce the effluent of other radionuclides such as Se-75, Mo-99, etc. to the lowest practicable level.

All exhaust systems are discharged to the effluent exhaust stack. The system used for sampling exit air from the stack is comprised of six one-inch lines within the exit duct. Each of these hold six pitot tubes facing upstream. The one-inch lines connect to two two-inch lines that pass through the main exhaust duct, then combine into a six-inch line. The system is drawn by a fan that exhausts to another exit duct prior to entry back to the main duct exhaust. The effluent air sample drawn from the six-inch line post fan, runs continuously at 10 liters per minute and is changed daily. The radioactivity collected in the sampler is constantly measured by the stack alarm detector which will sound an alarm in the Health Physics operations area should the maximum allowable activity for I-131 Iodine specified in Appendix B, Table II, Column I of 10CFR20 is exceeded.

Fire protection is provided at each branch connection to gloveboxes and fume hoods, etc. by means of a spring-loaded fusible link fire damper. Carbon filters are protected by means of ionization-type detectors in the duct work. Generally, detectors will isolate a filter fire from the air stream by closing metal-seated shutoff valves and transfer the effluent to the standby filters, or stop the fan, depending on the type system involved.

The plant is also equipped with an auxiliary generator which will automatically engage in the event of an electrical power failure. The generator is capable of maintaining the air systems and emergency lighting for the plant.

The following described the radiation protection program at E. R. Squibb & Sons, Inc.

Squibb's radiation safety program extends into all areas which use, store or receive radioactive materials. These areas are located at designated buildings (see plot plans) in Lawrenceville and New Brunswick. The Radiation Safety Committee is responsible for assuring that all operations involving radioactive materials are carried out in total conformance with our overall radiation safety program under the control of the Radiation Safety Officer.

The committee has the authority and responsibility for the approval or disapproval of all proposals for radionuclide use prior to purchase of the materials. The committee reviews and assesses the adequacy of the facilities and the equipment which will be used by individuals handling radioactive materials. Furthermore, the committee has (1) established operating, handling and general emergency procedures as well as a Radiological Contingency Plan and, (2) insured through the Health Physics Department that the individuals have been adequately trained and well experienced in the proper handling of radionuclides and are knowledgeable of the radiation safety operating procedures.

To this extent, Squibb has developed Health Physics training films unique to the total operation.

The Radiation Safety Committee consists of a chairman and members as follows (see Addendum 1 for Organizational Structure):

Director, Quality Control Services (Chairman)
Director, Medical Services
Director, Personnel and Industrial Relations
Regulatory Counsel
Radiation Safety Officer
Manager, Radiopharmaceuticals
Manager, Radiopharmaceutical Quality Control
General Manager, Diagnostics
Manager, Personnel and Industrial Hygiene and Safety

With the concurrence of the committee, alternates may attend committee meetings.

The committee shall meet on a regularly scheduled basis at least once every three months and more frequently, if necessary or desirable. Special meetings may be called by any member of the committee. Any five of the nine members or their designees will constitute a quorum for purposes of conducting committee business. Any five of the nine members or their designees will constitute a quorum for purposes of conducting committee business.

Minutes of the committee meetings will be kept by a secretary chosen from the membership by the chairman, and copies will be provided to all members of the committee as well as to management.

Responsibilities of the Radiation Safety Committee are as follows:

- 1. The main responsibility of the committee is radiation safety at all E. R. Squibb & Sons, Inc. sites designated in the byproduct license.
- Any rules, regulations and decisions of the committee will be binding for any users of radioisotopes as specified in the byproduct license.
- 3. The implementation of these rules, regulations and decisions will be carried out by the radiation safety officer, who is responsible to the committee as a whole, that his duties are carried out as described in the Radiation Safety Manual.
- 4. Proposals for use and distribution of licensed materials within the licensed sites must be approved by the Radiation Safety Committee.
- 5. The committee will order removal of any person who has been exposed to a higher radiation dose than regulations permit, or which is deemed excessive to good operations.
- 6. The committee chairman will submit reports required by the Nuclear Regulatory Commission in accordance with Title 10 CFR Part 20.
- 7. Each member of the committee shall be thoroughly familiar with all federal and state regulations pertaining to radiation safety and radioisotope operations.
- 8. The committee shall continuously review the enforcement of radiation safety rules as set by federal and state regulations.

Primary responsibility and authority for radiation safety shall lie with the Radiation Safety Committee which shall delegate this responsibility and authority to the Radiation Safety Officer (Health Physicist) for implementation.

The main responsibility of the Radiation Safety Officer is:

I. AREA, PROCESS AND PERSONNEL MONITORING

To properly assess the duties of the Radiation Safety Officer, a distinction should be made between area and process monitoring.

A. PROCESS MONITORING

When a new procedure is instituted or an established procedure modified, the Radiation Safety Officer must be called in to insure radiation safety of the process. Once operational, monitoring procedures will be established by the Radiation Safety Officer. The responsibility for implementation of these procedures ("self-policing") will rest with the operating group. However, the Radiation Safety Officer has the duty to spot check at any time to see that operational monitoring is being carried out properly.

B. AREA MONITORING (RESTRICTED AND UNRESTRICTED AREAS)

It is the responsibility of the Radiation Safety Officer to establish survey and monitoring schedules, execute or supervise the monitoring operations, evaluate the results of these operations, maintain adequate records and spot check at any time to insure that operational area monitoring is adequate.

C. PERSONNEL MONITORING

The Radiation Safety Officer monitors, evaluates and keeps records of personnel as follows:

II. RECORDS

The Radiation Safety Officer must maintain legal records as required by federal and state agencies and reports of radiological activities. Representative reports are: daily logs, periodic summary reports, unusual incident reports special work permits, minor injury reports, requests for medical service, records of radioactive material or shipments, and a record of all locations where radioisotopes are used at all Squibb facilities.

In addition, the Radiation Safety Officer must:

- A. Be thoroughly familiar with all state, federal and management regulations pertaining to processing and handling of radioisotopes and radiation producing devices.
- B. Advise supervisors and personnel in all aspects of the radiation protection program.
- C. Evaluate hazardous operating conditions and suggest to supervision safe procedures to be followed.
- D. Control the movement of all radioactive materials within the facility.

- E. Establish emergency procedures for all dangerous operations.
- F. Supervise decontamination.
- G. Supervise waste disposal procedures.
- H. Educate workers in the principles and hazards of ionizing radiation and the various steps taken for their protection.
- I. Perform studies and research, whenever possible, in particular areas of the radiation protection field.

In order to accomplish the above program, the Radiation Safety Officer should have a secretary, experienced health physics supervisors and technicians, as assistants. The assistants shall perform the majority of the routine duties which include the following:

- A. Thyroid counting
- B. Area contamination surveys
- C. Area radiation surveys
- D. Air contamination surveys
- E. Personnel monitoring issue and receipt
- F. Special work permit handling
- G. Investigational surveys

The majority of the Radiation Safety Officer's time should be concerned with the following:

- A. Training
- B. Hazard evaluation and elimination
- C. Consultation and review of all new experiments or procedures involving radiation and radioisotopes
- D. Supervision of waste disposal procedures
- E. Advise supervisors in all aspects of the radiation protection program
- F. Performed studies and research
- G. Maintain all records pertinent to our license
- H. Inform the Radiation Safety Committee of all aspects of the program

- I. Insure that adequate and calibrated monitoring devices are available
- J. Spot contamination surveys
- K. Recordkeeping isotope inventory, etc.

Reed Instruments, a subcontractor for Bionucleonics, calibrates and maintains certain surveying equipment for Squibb. See Addendum #4 for a list of radiation detection instruments employed in our operation.

There are scintillation-type detectors and counters which are not calibrated by Reed Instruments. These are standardized with certified reference sources prior to use by operating technicians.

All of our calibrated survey equipment is calibrated every three months and/or after each repair.

The following criteria are used in assessing the areas and operations which mandate the usage of personnel monitoring devices. Personnel monitoring devices are issued to all of the following:

- 1. Individuals handling or testing radioactive materials in excess of exempt quantities.
- 2. Persons operating radiation producing machines.

- 3. Individuals who have access or enter a "High Radiation Area."

 This is an area where there exists a level of radiation such that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.
- 4. Individuals entering a "restricted area" under the circumstances whereby it is possible to receive 25% of the applicable quarterly value as specified in 10CFR20:101.
- 5. Individuals entering or working in a restricted area. This is an area where there exists a level of radiation such that a major portion of the body could receive a dose of 2 mr/hr or a 100 mrem to the whole body in any seven consecutive days.
- 6. Individuals entering or assigned duties in a "radiation area." This is an area in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirem or in any 5 consecutive days or dosage in excess of 100 millirems.
- 7. Any individual that Health Physics feels should be issued a personal monitoring device.

Once it is determined that a monitoring device is required, the Health Physics Department shall be responsible for its issuance and submittal to a film badge processor for exposure evaluations.

Our primary type of monitoring device is the whole body film badge. These are issued either weekly or monthly. Weekly badges are issued to individuals involved with the manufacturing and testing of radioactive products. Monthly badges are issued to individuals involved in low-level research and development operations. Any deviation in the frequency at which personnel monitoring devices are exchanged is determined by the Health Physics Department.

All people involved in the manufacturing and testing of radioactive products are issued and required to wear ring TLD's. Once again, any deviation from this practice is determined by the Health Physics Department. The basis for the issuance of any special rings to any other monitoring device is determined after a health physics evaluation is conducted on the manufacturing and chemical processes. The type of radionuclide, amount of radioactivity and unique isotope characteristics also are primary factors determining the need of special monitoring equipment.

Individuals are made aware that personal monitoring is required by the radiation signs posted to designate restricted, radiation and high radiation areas. They are also reminded through regularly scheduled radiation safety talks as well as through standard health physics procedures and policies. For example:

- The procurement and inventory of isotopes is controlled by the Health Physics Department. Before any work begins or film badges issued, testing and manufacturing procedures are evaluated and individuals are advised of safe-handling techniques.
- 2. Maintenance can be performed in a controlled area only by issuance of a Special Work Permit by Health Physics personnel. The particular job is reviewed and cleared by the Health Physics Department before film badges are issued to maintenance personnel.
- 3. Individuals responsible for using radioactive material shall notify their subordinates of the necessity of monitoring devices. These people are referred to the Health Physics Department before film badges are issued.
- 4. Training seminars are also utilized to inform personnel of the necessity of personal monitoring devices.

The following procedures have been established for evaluating radiation exposures:

- 1. All radiation exposure reports are reviewed upon receipt.
- 2. A notification level of 1.2 Rem has been established with our supplier (R. S. Landauer, Jr. and Co.). If, by chance, one of our personnel exceeds the limit, that individual would be informed immediately and the following action taken.
 - a. The individual would be immediately removed from the controlled area.
 - b. Past work records for the exposure period would be evaluated and reviewed. From this information, a probable cause would be determined and preventative measures taken to avoid a recurrence of this type.

The Health Physics bioassay program consists of thyroid uptake evaluations and urine analysis by all individuals manufacturing, testing or using radioactive materials in excess of exempt quantities.

Thyroid uptakes are normally required when individuals work with more than exempt quantities of I-125 or I-131, depending on the chemical or physical form, type of equipment, type of process and handling procedures.

Thyroid measurements for I-125 and I-131 are required biweekly. Squibb investigational limits for I-131 iodine have been established as 0.07 uCi. The investigational limit for I-125 iodine is 0.05 uCi. The maximum permissible dose to the thyroid, however, is outlined in 10CFR20:103.

If any individual should receive a dose to the thyroid in excess of these limits, he or she is prohibited from working with any I-125 or I-131. An investigation is performed to determine the probable cause of the thyroid dose and action is taken to prevent a recurrence.

Urinalyses are normally required when individuals work with millicurie quantities of I-125 and I-131, depending on the chemical form, type of equipment, type of process and handling procedures.

Manufacturing personnel are required to submit urine samples for monthly analysis. Nondetectable amounts of activity are recorded as <E-05 uCi/cc.

Any detection of significant amounts of activity in urine samples shall be questioned to determine the cause of ingestion. If body burdens are approached or exceeded, the individual shall be removed from the controlled area and a full report submitted in accordance with 10 CFR Part 20:403.

In addition, training seminars are given to groups at unspecified demonstration sites using low activities of Iodine-125. It is desirable that Squibb have the authorization to allow its representatives to possess at any one time up to the maximum of 100 microcuries of I-125 iodine in the form of IN-VITRO Radioimmunoassay Kits for demonstrations and use at temporary locations throughout the country.

The following products and typical of the kits which will be used at these training sessions:

T4 Squibb I-125

T4 CLASP I-125

T3 U-SQUIBB I-125

Digoxin-Squibb I-125

Digoxin-CLASP I-125

T3-SQUIBB I-125

Cortisol-SQUIBB I-125

Estriol-SQUIBB I-125

Angiotensin I-125

All of these are IN-VITRO I-125 iodine products.

The Squibb representatives, responsible for these training seminars, have had extensive training in radiation safety and the handling of radioactive materials.

All radioactive waste generated at such demonstrations will be appropriately packed with materials furnished by our trained shipping personnel. Any liquid radioactive waste will be contained in enough absorbent material to absorb twice the quantity of liquid. This material is returned to E. R. Squibb & Sons, Inc. in New Brunswick, N.J.

The demonstrations are conducted on tables covered with absorbent paper. Upon completion, surveys are made with a low range gamma-beta survey meter.

Licensed materials, when not in use, will be secured against unauthorized removal by storage in a locked room.

No pipetting by mouth is permitted and personnel handling radioactive materials will wear gloves.

The following Standard Operating Procedures for these Customer Training Courses are:

- 1. All procedures with radioactive materials must be performed over absorbent paper and in trays.
- All personnel handling radioactive materials must wear a projective clothing (i.e., lab coat) including rubber gloves.
- 3. There shall be no pipetting by mouth allowed at any time.
- 4. The area containing the radionuclide will be locked when no one is in attendence.
- 5. All radionuclides not in use must be stored in a safe manner in a locked or otherwise inaccessible area.
- 6. There shall be no eating, drinking, smoking or storing of food in the area which contains the radionuclide.
- 7. No liquid radioactive waste will be placed into any sanitary sewer system.
- 8. All radioactive waste will be properly packaged and shipped to the New Brunswick, N.J. Radiopharmaceutical Manufacturing facility for proper disposal.
- 9. The Squibb representative working in the area which contained the radionuclide must survey the area for radioactive contamination using an end window Geiger-Muller tube with a 2 mg/cm2 windkow.

The Squibb representative must assure that the area is completely free (no d/m above background) of contamination before he releases the area back to the general public.

MEDOTOPES, BUILDING #124
MANUFACTURING ROOMS

O - OVEN

MODIFIED GLOVE BOX WITH PASS THRU

- GLOVE BOX WITHOUT PASS THRU

- INCUBATOR

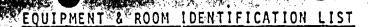


FIGURE #1

MANUFACTURING ROOMS BUILDING #124

ROOM #146

- 42 Lucite Glove Box - R & D
- 43 Glove Box - R & D
- 44 Lucite Glove Box - Not in use
- Lucite Glove Box Not in use, Lucite Glove Box Not in use 45
- 46
- 47 Oven - Rubratope Capsule Drying
- 48 Fume Hood - Rubratope Co-57 Capsule Manf. & Filling

ROOM #147

- 35 Fume Hood - Rubratope Co-60 Capsule Manf. & Filling
- Depyrogenation Oven Not in use Modified Glove Box & Not in use 36
- 27 & 27A
 - 37 Glove Box - Robengatope Manufacturing
 - Autoclave "T"
 - Autoclave "U"
 - 38 Fume Hood - R & D

ROOM #148

- Modified Glove Box Albumotope I-131 Inj. Manufacturing 32 & 32A
- Modified Glove Box Albumotope I-131 Inj. Manufacturing 33 & 33A
 - Glove Box Diagnostic Capsule Dejunking & Counting 39
 - 40 Glove Box - Diagnostic Capsule Manufacturing & Filling
- 28 & 28A Modified Glove Box - Not in use
 - Fume Hood

ROOM #149 Quality Control Chemist's Lab

ROOM #150

- 60 Oven - Sethotope
- 61 Incubator - Sethotope
- Glove Box Sethotope Manufacturing 62
- 31 & 31A
- Modified Glove Box at vendor Modified Glove Box Not in use 30 & 30A
 - Glove Box Cesium 137 Ref. Std. Manufacturing & Filling Glove Box Cobatope Co-60 Ref. Std. Manf. and Filling . 62
 - 63
- 29 & 29A Modified Glove Box - Not in use
 - Fume Hood Sethotope Glassware

FIGURE #1

MANUFACTURING ROOMS BUILDING #124

ROOM. #151

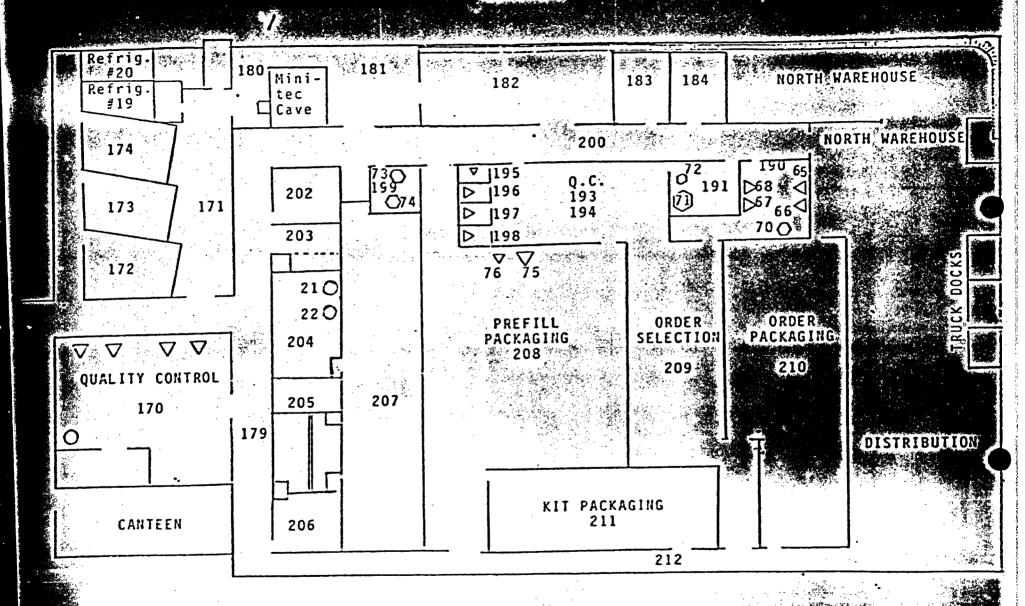
- Glove Box Cobatope Co-57 Ref. Std. Manf. &. Filling
- 34 Glove Box - Not in use
- 53 Glove Box - Not in use
- 54 Glove Box - R & D
- Glove Box Sethotope Liquid Waste Evaporation 55
- Glove Box Hipputope Manufacturing

ROOM #152

- 57
- Fume Hood Raw Material Dispensing Exhaust Hood Raw Material Dispensing 58
- 59 Weighing Exhaust Hood - Raw Material Dispensing

ROOM #153

- 49 -Fume Hood - In Service
- 25 & 25A Modified Glove Box Not in use
 - 50 '- Glove Box Not in use
 - :51 Shaker Hood Not in use
- 26 & 26A Modified Glove Box Not in use



7 - FUME HOOD

O :- OVEN

C = GLOVE BOX

ROOM. #170 - Quality Control Lab

HATE - MARAGENIA CORRIDOR #171 - Behind Caves

ROOM #172 - Cave (Hot Cell)

A. Iodotope Therapeutic Oral Manufacturing and Filling

B. Bulk I-131 Storage and Dispensing

ROOM #173 - Cave (Hot Cell) Research

ROOM #174 - Cave (Hot Cell) lodotope Therapeutic Capsule Manufacturing and Filling

REFRIGERATORS #19 & #20

Storage for prefills prior to packaging

B. Storage of Water for Injection and some raw materials:

C. //Storage of Co-57 and Co-60 with B12

CORRIDORS - 179, 200 and 212

ROOMS = 204, 205, 206 and 207 (See Figure #3)

ROOM #202 - Supervisors Office

ROOM #203 - Storage of empty lead containers and spare Minitec Generators

ROOM #180 - Behind Minited Cave

ROOM #181 - Front of Minitec Cave - Manufacturing, Filling and -Sourcing of Minitec

ROOM #182 - A. Minitec Packaging Assembly of Minitec Columns into wings

ROOM #183 - Mens Room

ROOM #184 - Prime Container Allocation Room

ROOM #190 - 65, 66, 67, 68 - Fume Hoods - Storage of Iodotope Therapeutic Capsules. 70 - Glove Box - Storage of empty pigs for Therapeutic Capsules.

FIGURE #2

ROOM #191 - 71 - Glove Box - Indotope Diagnostic Capsules
Manufacturing and Filling
72 - Glove Box - Vacuum Cleaner for Indotope
Diagnostic Capsules

ROOMS 193 thru 198 - Quality Control

ROOM #199 - 73 - Lucite Glove Box - Research 74 - Lucite Glove Box - Research

ROOM #208 - Prefill Packaging Room
75 - Fume Hood - Diagnostic Capsule Packaging
76 - Fume Hood - Diagnostic Capsule Packaging

ROOM #211 - Kit Packaging Room

ROOM #209 - Order Selection Room

ROOM #210 - Order Packaging Room

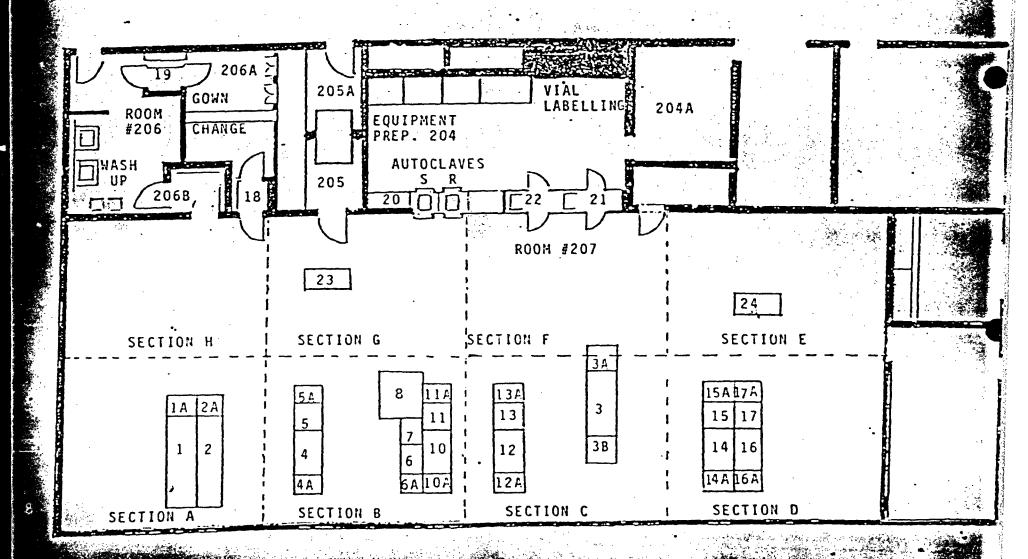


FIGURE #3

ROOM #206 - Wash Up Room

ROOM #205A - Gown Change Room

ROOM #206B - Exit from Room #207

ROOM #205 - Equipment Pass-Thru

ROOM #205A - Equipment Pass-Thru

ROOM #204A - Entrance to Vial Labelling and Equipment Prep Room

ROOM #204 - Vial Labelling and Equipment Preparation Room

20 - Laminar Flow Hood

21 - Depyrogenation Oven

22 - Depyrogenation Oven

ROOM #207 - Filling Room

1 & 1A - Nct in use.

2 & 2A - Albumotope I-131 Syringe Assembly Hood and Pass-Thru

3A - Albumotope I-131 Syringe Dilution Hood and Pass-Thru

3 - Albumotope I-131 Syringe Filling

3B -- Pass-Thru

4 & 4A - Chromitope Sodium Filling Hood and Pass-Thru

5 & 5A - Chromitope Sodium Manufacturing and Dilution Hood and

Pass-Thru

6,6A,7 & 8 - Not in use

10 & 10A - Robengatope Filling Hood and Pass-Thru

11 & 11A - Robengatope Dilution Hood and Pass-Thru

12 & 12A - Sethotope Filling Hood and Pass-Thru

13 ° 13A - Sethotope Dilution Hood and Pass-Thru

.4A - Albumotope (I-131) Inj. Filling Hood and Pass-Thru

12 - 15A - Albumotope (I-131) Inj. Dilution Hood and Pass-Thru

16 & 16A - Hipputope Filling Hood and Pass-Thru

17 & 17A - Hipputope Dilution Hood and Pass-Thru

23 - Laminar Flow Transfer Cart

24 - Laminar Flow Transfer Cart

HICH THE LAND CO.