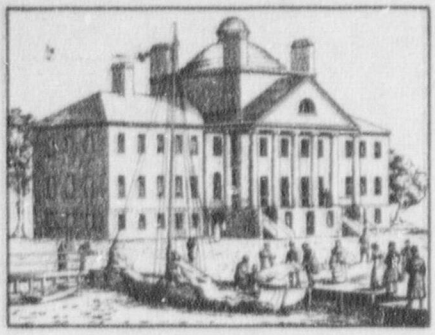

MASSACHUSETTS GENERAL HOSPITAL

J. ROBERT BUCHANAN, M.D.
General Director

Boston, 02114
Telephone (617) 726-2425

Cable Address "Massgenral"
RADIATION SAFETY DEPT.

January 26, 1987

Mr. Jack Davis
Nuclear Materials Safety Section B
Division Of Radiation Safety and Safeguards
NRC
631 Park Avenue
King Of Prussia, Penn. 19406

RE: Mail Control No. 106523

Dear Mr. Davis:

The following information pertains to your letter of January 8, 1987:

GAMMACEL 1000B CELL IRRADIATOR
AMENDMENT TO LICENSEE NO. 20-03814-81

RESPONSE TO NRC REQUEST FOR ADDITIONAL INFORMATION.
Docket # 30-08448
Central #106523

1.) Responsible individuals: Jane B. Brandhorst, R.N., Research Fellow; William Gallagher, M.D.; Graeme Fisher, Research Technologist. These individuals are in the lab or in the building full-time. At least one of these people will be on duty and immediately available whenever the irradiator is in operation.

2.) Training of responsible individuals:
Jane Brandhorst, R.N., Research Fellow, is the full-time on-site supervisor of the Gammacell 1000 cell irradiator and its most frequent user. Ms. Brandhorst received training in the safe handling of radionuclides in a two day seminar conducted by the Radiation Safety Section of the NCI/Frederick Cancer Research Center, Fort Detrick, Maryland in 1975. Since that time she has been a certified user of the following irradiators:

1975-1982 Philips MG301 (Frederick Cancer Research Center).
1982-1983 JL Shepherd Mark I (Johns Hopkins Medical School).
1983-1986 JL Shepherd Model 143 (SUNY Medical School, Stony Brook, NY).

Further details of training and experience are attached (Appendix A).

William Gallagher, M.D., the proposed permit-holder, is in the lab part-time, in the building full-time. Dr. Gallagher has extensive prior experience with radioisotope labelling and was certified in radiation safety at MGH after successful completion of the institution's course in radiation protection

in 1985 (certificate #388). He has had experience in the operation of the institution's Picker Vanguard Model K16 x-irradiator.

Further details of training and experience are attached (Appendix A).

Graeme Fisher, a newly hired research technologist, is on-site full-time. Mr. Fisher will be certified in radiation safety after successful completion of the MGH course. He will receive on-the-job training in the operation of the cell irradiator.

3.a.1,2: Outline of training program: The principles and fundamentals of radiation safety, and the use of radiation detection instruments are taught by the MGH Radiation Safety Officer, named below. Their outline of the radiation safety course is attached. (Appendix B).

3.a.3,4: Instruction in the design and operation of the irradiator, and emergency procedures: The instruction manual for users provided by the manufacturer contains detailed information which will be used to teach operating and design principles. The design of this unit renders it quite safe to use. The radiation source is 137-Cesium which is permanently sealed in a lead shield. A sample placed in the 3" by 8" chamber rotates to the source, and in so doing, seals the port. At no time is the operator or the environment exposed to unshielded radiation. Two hands (on separate switches) are required to activate chamber rotation; this eliminates the possibility of trauma to hand or fingers as the chamber rotates to close the port.

All electronic and mechanical elements that might require servicing are outside the sealed source and can be safely approached. If one of these elements should fail to function properly, the supervisor will contact MGH Radiation Safety and the manufacturer to assure that any adjustments are properly made by trained personnel.

3.b. Radiation Safety Examination: The MGH Radiation Safety Office will provide a copy of the examination used for certification in their course. (Appendix C).

3.c. On the job training of users: All laboratory personnel who use radionuclides in any form, including sealed sources such as the cell irradiator, are required to take the MGH radiation protection course and be certified by examination. To this general framework of information will be added operating and safety principles specific to the cell irradiator. The on-site supervisor will use the irradiator manual to illustrate design and operation, accompanied by demonstration of actual operation. The trainee will operate the unit only under the direct supervision of the on-site supervisor until such time as competence is thoroughly established.

3.d. Name and training of the teaching program instructor, the MGH Radiation Safety Officer is contained in Appendix D.

3.e. All records documenting the training of users will be maintained for a period of three (3) years.

Sincerely,

Frank P. Castronovo, Jr.

Frank P. Castronovo, Ph.D.
Radiation Safety Officer

cc: Ms. Maryanne Spicer
Ms. Jane Brandhorst, R.N.

FPC:db

APPENDIX A

Further Details Of Training and Experience For:

Jane Brandhorst, R.N., and William Gallagher, M.D.

Radiation Safety Committee

of the Massachusetts General Hospital

TRAINING/EXPERIENCE FORM

FOR LABORATORY PERSONNEL

HANDLING RADIONUCLIDES

A. Type of Training	Where Trained	Duration	On the Job	Formal Course
1. Principles and practices of radiation protection	NCI/Frederick Cancer Research Center Fort Detrick Frederick, MD	2 days	8 yrs	2 days
2. Measurement and monitoring of radioactivity	"	"	"	"
3. Calculations basic to use and measurement of radioactivity	"	"	"	"
4. Biological effects of radiation	"	"	"	"

B. Experience with Radionuclides

Isotope	Max. amount	Where experience was gained	Duration	Type of Use
^{137}Cesium	1200 Ci	Frederick Cancer Research Ctr Johns Hopkins Medical Ctr SUNY at Stony Brook HSC	8 yrs 1 yr 3 yrs	Operation of various cell irradiators
^{3}H thymidine	0.1mCi	Frederick Cancer Research Ctr	8 yrs	in vitro assays
^{125}Iodine	2.0mCi	Frederick Cancer Research Ctr	8 yrs	in vivo assays (mice)

C. Name Jane S. Brandhorst

D. Permit Holder William J. Gallagher, MD

E. Date November 12, 1986

Return to: Radiation Safety Committee, Gray 2

Radiation Safety Committee
of the Massachusetts General Hospital

TRAINING/EXPERIENCE FORM FOR LABORATORY PERSONNEL HANDLING RADIONUCLIDES

A. Type of Training	Where Trained	Duration	On The Job	Formal Course
1. Principles and practices of radiation protection	Mass. General Radiation Protection Course Certificate #388	20 hrs		x
2. Measurement and monitoring of radioactivity	"	"		"
3. Calculations basic to use and measurement of radioactivity	"	"		"
4. Biological effects of radiation	"	"		"

B. Experience with Radionuclides

Isotope	Max. Amount	Where experience was gained	Duration	Type of Use
^{125}I	5mCi	Univ. of Chicago Med. Ctr.	3 mos (1976)	iodination of antibodies
~~^{125}I~~	10mCi	UCLA Med. Ctr.	2 yrs	in vivo &
^{35}S	5mCi	Sepulveda VA Med. Ctr.	(1981-83)	in vitro labelling of
^{3}H	1mCi			antibodies
x-irradiation	250kV	Mass. General Hospital	1.5 yrs (1985-present)	cell inactivation

C. Name William Gallagher, MD

D. Permit Holder William Gallagher, MD

E. Date 1/15/87

Return to: Radiation Safety Committee, Research 5

3/86

APPENDIX B

Outline For MGH Radiation Safety Course (Part I)

LECTURE OUTLINE
(10 hours)

LECTURE NO.	TOPIC
1	Introduction The MGH Radiation Safety Office Natural Radiation Radioactivity (Principles and Production)
2	Interaction with Matter Instrumentation Dosimetry Biological Effects
3	External and Internal Radiation Protection
4	Principles and Practices of Radiation Safety Radiation Protection Regulations Past NRC Inspections Maximum Permissible Dose ALARA

APPENDIX C

Exam For MGH Radiation Safety Course (Part I)

IC RADIATION PROTECTION FOR LABORATORY PERSONNEL

Assignment for Lecture #4

1. List the following relative to the radioactive material used in your laboratory or clinic: (max of 5)

a.

#	radionuclide	T½p	radiation emissions	chemical form
1				
2				
3				
4				
5				

b. What parameters determine the internal toxicity of a radioactive compound?

c. Rate the biotoxicity of the above compounds; 1 = least toxic: 5 = most toxic.

2. Perform a simple radiation survey of your work area during a typical experiment. Include the following data;

a. sketch of laboratory
b. shielding
c. survey meter results (list model)
d. wipe test results (how counted)

APPENDIX D

Name and Training Of Radiation Safety Instructor

Frank P. Castronovo, Jr., Ph.D.

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
Frank P. Castronovo, Ph. D.	Massachusetts

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Pharmacy Registration	Pharmacy	1965
American Board of Radiology	Medical Nuclear Physics	1978
American Board of Science in Nuclear Medicine	All branches with special competence in Radiopharm. and Radiochemical Science	1979

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	(1) Rutgers - 1962 (2) Rutgers - 1963-64 (3) Johns Hopkins - 1965-70	40 60 60	
b. RADIATION PROTECTION	(1) Rutgers - 1963-64 (2) Johns Hopkins - 1965-70 (3) Brookhaven Nat'l Lab. - Summer 1964	60 30 700 on the	job training
c. MATHEMATICS PERTAINING TO THE USF AND MEASUREMENT OF RADIOACTIVITY	(1) Rutgers - 1963-64 (2) Johns Hopkins - 1965-70	30 30	24
d. RADIATION BIOLOGY	(1) Rutgers - 1963-64 (2) Johns Hopkins - 1965-70	30 60	
e. RADIOPHARMACEUTICAL CHEMISTRY	(1) Rutgers - 1962 (2) Johns Hopkins - 1965-70	30 60	24

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{99}Mo	1 Ci	Squibb	1964-1965	Research
^{137}Cs	500 μCi	Johns Hopkins	1965-70	Research
^{99m}Tc	1 Ci	Johns Hopkins, MGH	1965-80	Research (Clinic)
^{125}I	5 mCi	MGH	1975-80	Research
^{114m}In	5 mCi	Johns Hopkins	1967-70	Research