

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

OFFICIAL RECORD COPY

Licensee		
1. St. Joseph's Hospital and Medical Center	3. License Number	29-10191-03
2. 703 Main Street Paterson, New Jersey 07503	4. Expiration Date	August 31, 2001
	5. Docket or Reference No.	030-34198
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Cesium 137	A. Sealed source	A. Not to exceed 1450 curies per source and 3480 curies total
9. Authorized use		
A. In Gammacell 1000 self-shielded irradiator for the irradiation of material except explosives, flammables, or corrosives.		

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at 703 Main Street, Paterson, New Jersey.
- B. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.
- In accordance with the requirements set forth in 10 CFR 30.36(b), 40.42(h), and 70.38(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.
11. A. Licensed material shall be used by, or under the supervision of, Sreenivasa Murthy, M.S.
- B. The Radiation Safety Officer for this license is Sreenivasa Murthy, M.S.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

29-10191-03

Docket or Reference Number

030-34198

13. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

29-10191-03

Docket or Reference Number

030-34198

14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
15. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
16. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated June 10, 1996
 - B. Letter dated July 25, 1996

Date AUG - 4 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Sheri Ann Arredondo

By

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

AUG - 4 1996

License No. 29-10191-03
Docket No. 030-34198
Control No. 123416

Mr. Sreenivasa Murthy, M.S.
Radiation Safety Officer
St. Joseph's Hospital and Medical Center
703 Main Street
Paterson, New Jersey 07503

Dear Mr. Murthy:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Until your license is terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name change; or

Mr. Sreenivasa Murthy, M.S. -2-
St. Joseph's Hospital and Medical Center

- b. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).
- 4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.
- 5. Request and obtain a license amendment before you:
 - a. permit anyone to work as an authorized user under the license;
 - b. change Radiation Safety Officer;
 - c. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - d. add or change the areas of use, or address or addresses of use identified in the license application or on the license; or
 - e. change ownership of your organization.
- 6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

OFFICIAL RECORD COPY

Mr. Sreenivasa Murthy, M.S. -3-
St. Joseph's Hospital and Medical Center

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

Sheri A. Arredondo
Division of Nuclear Materials Safety

License No. 29-10191-03
Docket No. 030-34198
Control No. 123416

Enclosures:

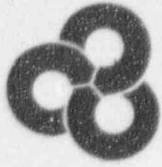
1. License No. 29-10191-03
2. 10 CFR Parts 2, 19, 20, 30, and 170
3. NRC Forms 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\2910191.03

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Arredondo						
DATE	07/31/96		07/ /96	07/ /96	07/ /96	07/ /96	

OFFICIAL RECORD COPY



St. Joseph's Hospital and Medical Center

703 Main Street • Paterson • New Jersey • 07503 • (201) 754-2000

Continuing Commitment to Care

July 25, 1996

MS 16
K-6

U.S. Nuclear Regulatory Commission
Attn.: Ms. Sheri Arredondo
Region one
475 Allendale Road
King of Prussia, Pennsylvania 19406

Dear Ms. Arredondo:

Reference: Docket # 030 - 34198
Mail Control # 123416

We are in receipt of your letter dated July 17, 1996 regarding our application for Blood Irradiator. Following response chronologically corresponds to the additional information you have requested in your aforementioned letter.

1. We conform that the Blood Irradiator will only be used for irradiating blood and blood plasma. No other flammable or corrosive materials will be irradiated using this unit.
2. We confirm that the training provided for individuals using the Irradiator will include the Principles and fundamentals of radiation safety and good safety practices related to the use of the Irradiator, and the use of radiation detection instruments.
3. We confirm that all repairs and alterations involving removal of shielding or access to the source will be performed by the supplier or other persons who are specifically licensed by NRC or an Agreement state for such work.
- 4.

As requested in your letter, I am sending a duplicate copy of this letter to your attention. Thank you for your cooperation regarding this matter. In case you have any questions regarding the contents of this communique, you may reach me at (201) 745 - 2681.

Sincerely,

Sree Murthy, M.S.
Chief Medical Physicist / R.S.O.

123416

JUL 17 1996

Docket No. 030-34198
Control No. 123416

Mr. Sree Murthy
Radiation Safety Officer
St. Joseph's Hospital & Medical Center
703 Main Street
Paterson, New Jersey 07503

Dear Mr. Murthy:

This is in reference to your application dated June 10, 1996. In order to continue our review, we need the following additional information:

1. Confirm that you will not irradiate flammable or corrosive materials. For this purpose, flammable will mean any material with a flash point at a temperature below the temperature you expect irradiated products to reach during irradiation. However, in no case should any material with a flash point below 145 degrees Fahrenheit be irradiated. For this purpose, corrosive will mean any material with a pH less than 4.0 or greater than 10.0. You may propose different definitions if justification is provided.
2. In section 8.1 of your application, you describe the training that will be given to operators of the irradiator. This training should include the principles and fundamentals of radiation safety and good safety practices related to the use of the irradiator, and the use of radiation detection instruments. Please confirm that training for individuals using the irradiator will include these topics.
3. In section 8.1 of your application, you describe the training for individuals performing maintenance. Any repairs or alterations involving removal of shielding or access to the source must be performed by the supplier or other persons who are specifically licensed by the NRC or an Agreement State for such work. Please confirm that any repairs or alterations involving removal of shielding or access to the source will be performed by the supplier or other persons who are specifically licensed by the NRC or an Agreement State for such work.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123416. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5342.

OFFICIAL RECORD COPY

ML 10

S. Murthy -2-
St. Joseph's Hospital and Medical Center

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:
SHERI A. ARREDONDO

Sheri A. Arredondo
Division of Nuclear Materials Safety

Docket No. 030-34198
Control No. 123416

DOCUMENT NAME: P:\STJOES

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Arredondo						
DATE	07/17/96		07/ /96	07/ /96	07/ /96	07/ /96	

OFFICIAL RECORD COPY



St. Joseph's Hospital and Medical Center

703 Main Street • Paterson • New Jersey • 07503 • (201) 754-2100

Office of the President

June 10, 1996

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406

L 10191
030-34198
03510

Dear Nuclear Regulatory Commission :

Reference: License # New
Mail Control #

Please find enclosed the application for the Gammacell high dose blood irradiator manufactured by Nordion International Inc.

A check for the amount of \$ 1200.00 has been enclosed to cover the license fee as indicated in item # 12 of NRC form 313.

Thank you for your cooperation regarding this matter. In case you have any questions regarding the contents of this application, please contact our Chief Physicist / R.S.O., Mr. Sree Murthy at (201) 745 - 2681.

Sincerely,

Sister Jane Frances Brady
President.

123416

Affiliated hospital of The University of Medicine and Dentistry of New Jersey and Seton Hall University

OFFICIAL RECORD COPY

ML 10

JUL -8 1996

(5-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (INBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-6064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5386

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)



A. NEW LICENSE



B. AMENDMENT TO LICENSE NUMBER _____



C. RENEWAL OF LICENSE NUMBER _____

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

St. Joseph's Hospital & Medical Center
703 Main Street
Paterson, New Jersey 07503

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

St. Joseph's Hospital & Medical Center
703 Main Street
Paterson, New Jersey 07503

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Sree Murthy, M.S.

TELEPHONE NUMBER

(201) 754 - 2681

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

3 EAMOUNT ENCLOSED \$ **1200.00**

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 (62 STAT. 749) MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Sr. Jane Frances Brady, President

SIGNATURE

x

DATE

June 10, 1996

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
-------------	---------	--------------	-----------------	--------------	----------

\$

APPROVED BY

DATE

ATTACHMENT TO ITEM # 5

	Item	Description
1	Radio-nuclide	Cesium - 137
2	Number of Curies per source	1 (one)
3	Source manufacturer	AECL /Nordion
4	Source Model number	C-3001
5	Number of sources in the irradiator	<u>1 (one)</u> Sealed source* of 1450 Ci/source and a total of 1450 Ci (53.7 TBq) (Nominal) $\pm 20\%$ providing a central dose rate of 850 Rad/Min $\pm 20\%$
6	Maximum amount that will be possessed at any one time	3480 Ci (128.9 TBq)**

* Manufacturer's Product Information literature is enclosed.

** This is to accommodate the total activity during source change if any.

ATTACHMENT TO ITEM #6

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

The Gammacell 1000 Elite Model 1 blood irradiator will be used for the irradiation of blood and blood products. The sealed sources are contained in the self-shielded Gamacell 1000/3000 and the external radiation levels are illustrated in the attached chart.

ATTACHMENT TO ITEM #7

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM : THEIR TRAINING AND EXPERIENCE.

Mr. Sreenivasa Murthy is the Radiation Safety Officer for this license. Mr. Murthy will be familiar with:

1. The basic design, operation, and preventive maintenance of the irradiator.
2. The principles and practices of radiation protection.
3. The biological effects of radiation
4. The written procedures for routine and emergency irradiator operations.
5. Our application for the license, our license, and regulations of NRC.

Mr. Murthy is currently approved as the R.S.O. on the NRC License # 29-10191-02. Mr. Murthy's Resume has been enclosed for your reference. Mr. Murthy will attend a one week RSO course is offered by Nordion at the:

Canadian Irradiation Center
535 Cartier Boulevard
P.O.Box 320
Laval, Quebec
H7N 4Z9
CANADA
(514) 687 - 5165

ATTACHMENT TO ITEM # 8

8.1 Training Program

All the personnel who will be operating the blood irradiator will be under the direct supervision of the Radiation Safety Officer. The irradiator operators and the maintenance operators will be trained for the following :

Operator Training Program:

After the installation of the blood irradiator, Nordion will train all individuals who will be designated as users. The method of training will include the following :

- Review of Operator's Manual
- Demonstration of all the operating features of the unit
- Explanation of how to calculate and change the timer setting to receive the desired absorbed dose.
- "Hands On" performance of how to initiate and complete a proper irradiation cycle for each operator.

Maintenance Training Program:

The unit will be maintained by Nordian and, at a later stage, St. Joseph's Hospital may elect to train a biomedical technician or designee on site. The Nordian representative or the in-house designee will have training that will include the following :

- Review of relevant sections of the Operator's manual.
- Review of routine maintenance requirements 9Eg. Inspection of electrical connections, lubrication of drive chains, fuse replacement, wipe test, safety interlocks, switch adjustments)
- review and demonstration of parts replacement (fuses, switches, relays, etc.)
- "Hands On" performance of trouble shooting techniques and parts replacement

Other Training Program:

Not applicable

8.2 Evaluation of Individuals competency and Training program

At the completion of the training all attendees will be evaluated for the competency of the basic principles of Radiation, Operation of the unit, and emergency procedures to follow, by administering a written 25 multiple-choice test. A minimum of 20 correct answers (80%) will constitute the trainees's understanding of the subject. The written examination will be conducted under the supervision of the Radiation Safety Officer.

8.3 On - the-Job Training :

Individuals who will be hired to operate the Blood irradiator will be provided with "on the job" training. The training will include but not limited to:

- Inservice from the Radiation Safety Officer as outlined in item 8.1 and a competency evaluation as outlined in item 8.2.
- Under the supervision of the Radiation Safety Officer or his designee., observe a minimum of 10 (ten) blood irradiator procedures by a trained individual.

8.4 Training Instructor

Mr. Sreenivasa Murthy, the Radiation Safety Officer, is responsible for the training and evaluation of the individuals competency.

8.5 Record Maintenance

All the pertinent training documents and the individuals competency evaluations will be maintained at the Radiation Safety Office. All these records will be maintained for a minimum of three years.

ATTACHMENT TO ITEM # 9.1

9.1.a Blood Irradiator room layout diagram

See attached diagram

9.1.b Blood Irradiator location and control of access to the radioactive material.

Blood irradiator will be located in the Xavier building Room # XG 14. The room will always be kept locked. Only the trained personnel and the Radiation Safety Officer will have access to this room. All other ancillary staff must be accompanied by a trained operator or the Radiation safety Officer.

9.1.c Fire protection considerations.

The area where the Blood Irradiator is situated is monitored by a fire detection system and the room is provided with a water sprinkler system.

Security office will have access to this room for those situations and will inform the Radiation Safety Officer or his designee for immediate assistance.

The Nordion Blood irradiator is a self contained unit and has been tested for fire safety. The unit can withstand a temperature of 800° Celsius for 10 minutes and 400° Celsius for 1 hour.

ATTACHMENT TO ITEM # 9.2

A Ludlum Model 14C with pancake chamber will be used to measure the ambient radiation rate level on a quarterly basis.

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.

A Cesium - 137 Calibration source SR # S-436, Model # 773, SN 127 of activity on the date of calibration Aug. 10, 1983, 163 mCi and dose rate 53.14 mR/hr is available for the calibration of survey meters. The current decayed activity and the dose rate for the source is 121.17 mCi and 39.5030 mR/hr. See the enclosed Source decay data for more details.

The Gammacell 1000 Elite is a self-shielded device. We do not anticipate any ambient dose to any operator's or to the staff that may be in the vicinity of the unit while not being used. The ambient exposure will be measured by placing a Thermoluminescent Dosimeter in close proximity to the unit and monthly data will be provided on the external radiation levels.

Thermoluminescent Dosimeters services are currently provided by Landauer company.

ATTACHMENT TO ITEMS # 10.1

The Radiation Safety Committee Charter and Radiation Safety Officer's delegation of authority has already been set up according to the NRC License # 29-10191-02 under which St. Joseph's Hospital is operating. The same committee will oversee this license.

ATTACHMENT TO ITEMS # 10.2

The Gammacell 1000 Elite is a self-shielded device. We do not anticipate any ambient dose to any operator's or to the staff that may be in the vicinity of the unit while not being used. The ambient exposure will be measured by placing a Thermoluminescent Dosimeter in close proximity to the unit and monthly data will be provided on the external radiation levels.

Thermoluminescent Dosimeters services are currently provided by Landauer company.

ALARA program does not apply in this situation.

ATTACHMENT TO ITEMS # 10.3

We will implement the procedure for leak-testing the Gammacell 1000 Elite Model 1 blood irradiator that was provided by Nordion International Inc. Wipe test procedure attached

ATTACHMENT TO ITEMS # 10.4

No Radiopharmaceutical will be utilized under this license.

ATTACHMENT TO ITEMS # 10.5

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide, Revision 2.

ATTACHMENT TO ITEMS # 10.6

OPERATING PROCEDURES

Section 7 of the Operator's manual outlines the operating procedures for the unit. All operator's will be trained accordingly and the manual will always be at the console.

EMERGENCY PROCEDURES

The sources are always in a shielded position and are never in danger of exposing the operator to any direct radiation. The only situation for radiation hazard is during an active fire hazard. As noted above in section 9.1c, the unit can withstand a temperature of 800° Celsius for 10 minutes and 400° Celsius for 1 hour. Security office will have access to this room for such situations and will inform the Radiation Safety Officer or his designee for immediate assistance.

ATTACHMENT TO ITEMS # 11.1 & 11.2

We will establish and implement the general guidance and model procedure for waste disposal that was published in Appendix R to Regulatory Guide 10.8, Revision 2.

Note:

1. The Gammacell 1000 Elite, Model A Cs - 137 blood irradiator will be returned to Nordion for disposal.

ATTACHMENT TO ITEMS # 12

Please find enclosed the licensing fee for this application in the amount of \$1200.00 dollars.

High Dose Blood Irradiator

(Summary)

The Nordion Gammacell Blood Irradiator will be located in the Blood Bank department on the Ground Floor of Xavier Building.

- a) The installation will be performed by the Nordion International , Inc.
- b) Preventive maintenance will be performed annually by Nordion International, Inc.
- c) Emergency Procedure and the contact telephone numbers will be posted at the site of the unit.
- d) All personnel involved in the use of the unit will be trained by the Nordion technicians.
- e) A floor plan for the Blood bank department with the irradiator will be developed for the Radiation protection survey, after the installation.
- f) A Radiation protection survey of the unit will be performed immediately after the installation.
- g) A wipe test of the irradiator sample chamber will be performed on a quarterly basis.
- h) The Radiation Protection Survey for the ambient dose level will be performed on a quarterly basis.

Note: The Cesium Sources in the Blood Irradiator does not move. The Blood sample is positioned in the sample cell. The sample chamber moves into the source irradiator chamber. Sources cannot be reached for quarterly wipe test. Wipe test will be limited to the wipe testing of the sample chamber.

WIPE TEST PROCEDURE

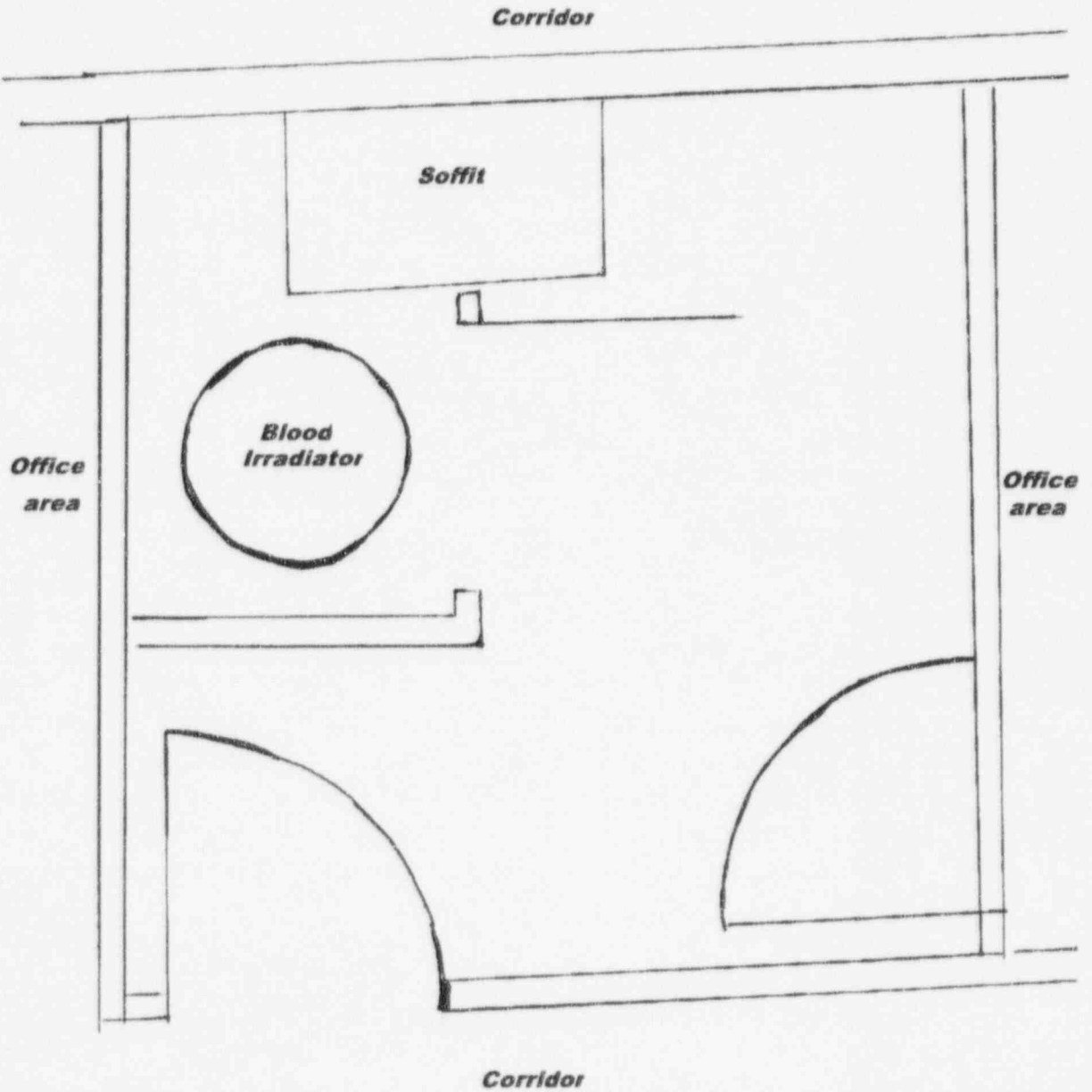
The following wipe test procedure is taken from Section no. 9 of the operators manual provided by Nordion International Inc.

1. Unplug the Gammacell blood irradiator from the wall unit.
2. Remove the front panel and storage box.
3. Thoroughly wipe the entire surface of the sample chamber cavity using high wet-strength material.
4. Move the sample chamber to the **IRRADIATE** position.
5. Thoroughly wipe the outside of the rotor.
6. Repeat, with a new wipe, the top of the radiation shield
7. Repeat, with a new wipe, the bottom of the radiation shield.
8. Count all three wipes in an area where there is background radiation only.

DIAGRAM OF BLOOD IRRADIATOR INSTALLATION

Direction: 1 → East

Scale 1 cm → 1'



Cs-137 Calibration Source Decay Data

Isotope : Cesium 137
Manufacturer : Nuclear Associates
Model Number : 773 SN 129
Serial Number : S - 436
Source Calibration date : 10-Aug-83
Activity on calibration day : 163 mCi
Output on Calibration day : 53.14 mR/hr @ 1 m.

Measurement date 10-Jun-96
Elapsed time 4688 days
Half life : 10957.5 days
Decay Factor: 0.7434
Decayed Activity : 121.17 mCi
Decayed Output at 1 m : 39.5030 mR/hr.

Calibrated by: Sree Murthy, M.S., Chief Physicist / R.S.O.
 St. Joseph's Hospital and Medical Center
 703 Main St., Paterson, NJ 07503

NRC license #: 29 - 10191 - 02

Distance in cm	Dose Rate in mR/hr with attenuation factor					10-Jun-96
	1	0.25	0.1	0.025	0.01	
10	3950.30	987.58	395.03	98.76	39.50	
20	987.58	246.89	98.76	24.69	9.88	
30	438.92	109.73	43.89	10.97	4.39	
40	246.89	61.72	24.69	6.17	2.47	
50	158.01	39.50	15.80	3.95	1.58	
60	109.73	27.43	10.97	2.74	1.10	
70	80.62	20.15	8.06	2.02	0.81	
80	61.72	15.43	6.17	1.54	0.62	
90	48.77	12.19	4.88	1.22	0.49	
100	39.50	9.88	3.95	0.99	0.40	
110	32.65	8.16	3.26	0.82	0.33	
120	27.43	6.86	2.74	0.69	0.27	
130	23.37	5.84	2.34	0.58	0.23	
140	20.15	5.04	2.02	0.50	0.20	
150	17.56	4.39	1.76	0.44	0.18	
160	15.43	3.86	1.54	0.39	0.15	
170	13.67	3.42	1.37	0.34	0.14	
180	12.19	3.05	1.22	0.30	0.12	
190	10.94	2.74	1.09	0.27	0.11	
200	9.88	2.47	0.99	0.25	0.10	



St. Joseph's Hospital and Medical Center

703 Main Street • Paterson • New Jersey • 07503 • (201) 754-2000

Continuing Commitment to Care

RADIATION SAFETY EMERGENCY PROCEDURES

In the event of a radiation hazard or a need for clarification regarding the radiation safety and ation hazard by a radiation producing equipment or by the use of a radioactive material, following personnel must be contacted in the ORDER OF LISTEING.

Title	Person	Hosp. extension	@ Home	Beeper	Hosp. Beeper
Physicist on call				(201) 977-1315	
<u>Radiation safety Officer:</u>	Sree Murthy	2681	(718) 317-0062	(800) 374-4434 Pin# 43847	
Asst. Radiation Safety Officer	Khalil Ibrahim	2674	(908) 721-1531	(800) 327-0816	
Radiology supervisor on call				(201) 977-7172	
Radiology Administrative Director	Edward Montague	2696			*71-099
Vice President -Clinical Services	Melvyn Pataschnick	2040			

In the event of a mis-administration or overdose of radiation, following agencies must be contacted within 24 hrs.

- US Nuclear Regulatory Commission, Regiuon 1**
 475, Allendale Road
 King of Prussia, PA 19406-1415
 Phone: (800) 432-1156
- Bureau for Radiation Protection**
 25 Arctic Pkwy
 Trenton, NJ 08625
 Phone: (609) 292 - 7172
- Director, Office of Inspection & Enforcement**
 US Nuclear Regulatory Commission
 Washington, D.C. 20555
 Written Report only

Posting Location: Nuclear Medicine, Nuclear Cardiology, Radiation Therapy, X-ray, CT scanner, Therapy Simulator, Telephone Switch room, Security Office, Regan 4-South, Non-invasive cardiology, O.R. bulletin board, Blood irradiator room, Emergency room

Revised on June 10, 1996

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

```
: PROGRAM CODE: 03510  
: STATUS CODE: 3  
: FEE CATEGORY: -----  
: EXP. DATE: 0  
: FEE COMMENTS: -----  
: DECOM FIN ASSUR REQD: ..  
: .....  
: .....
```

A. REGION

I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. JOSEPH'S HOSP. & MEDICAL CTR.
RECEIVED DATE: 960708
DOCKET NO: 3034198
CONTROL NO.: 123416
LICENSE NO.:
ACTION TYPE: NEW LICENSE

2. FEE ATTACHED
AMOUNT: 1200.00
CHECK NO.: 108240

- ### 3. COMMENTS

SIGNED
DATE

M. A. Perlman
2/11/96

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

1. FEE CATEGORY AND AMOUNT: 3E 8/200

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

3. OTHER -----

SIGNED
DATE

B. Brown
2/17/96

Log *July 2*
Remitter
Check No. *108240*
Amount *\$1,200*
Pay to the order of *3C*
City *ARP*
State *7/10/66*
Date Completed
By *B. Bro*

1226 JUL 15 PM 3 21