VOID SHEET

TO: License Fee Management Branch

FROM: CASSANDRA FRAZIER

SUBJECT: VOIDED APPLICATION

Control Number: 93647

Applicant: Children's Hospital

Date Voided: 12/22/92

Reason for Void: Combine with Co. No. 94211
This is additional Information
to be combine with Amendment
request 94211

C Frazier 1-21-92
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

310319

Comments: 9406140133 920121
PDR ADOCK 03002713
C PDR

Log completed ☑ ML

Processed by: SAC 9/29/93 3D

Rec'd

April 9 III 198968 6/29 $500 - $250 refunded earlier DH
3E

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B
EXP. DATE: 19960531
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION III

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CHILDREN'S HOSPITAL
RECEIVED DATE: 920702
DOCKET NO: 3002713
CONTROL NO.: 393647
LICENSE NO.: 34-03111-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $500.00
CHECK NO.: 1218265

3. COMMENTS

SIGNED P Leventhal
DATE 7-6-92

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

1. FEE CATEGORY AND AMOUNT: 1B (BE) $250

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

3. OTHER $250 Refunded

SIGNED Rita Jacque
DATE 7/8/92

RECEIVED
JUL 17 1992
REGION III

NRC FORM 313
(9-88)
10 CFR 30, 32-33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 6-30-90

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

- [X] A. NEW LICENSE or
- [X] B. AMENDMENT TO LICENSE NUMBER 34-03111-02
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Children's Hospital
700 Children's Drive
Columbus, Ohio 43205

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

Children's Hospital
700 Children's Drive
Columbus, Ohio 43205

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jerome G. Dare

TELEPHONE NUMBER: (614) 461-2829

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3E
AMOUNT ENCLOSED $500

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

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

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

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Margaret A Margello	Margaret A. Margello	Assistant Executive Director	6/26/92

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
Amd	Jul 9 III	7B (3E)	$250 Refunded add 3E when issued if applicable

AMOUNT RECEIVED	CHECK NUMBER
$500	198968

RECEIVED
JUL 02 1992
REGION III

APPROVED BY: Rita Jolques 7/8/92 — DATE

NRC FORM 313 (9-88)

JUL 2 1992

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7.5 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE RECORDS AND REPORTS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

CONTROL NO. 19647

The Children's Hospital and
Children's Hospital Research Foundation
Item 5 & 6
06/92

Item 5: Radioactive Material

The radionuclide requested is Cesium-137 as a sealed source in a single source. The manufacturer is Westinghouse, Hanford, WA. The Model is C-1000. The maximum amount of Cs-137 possessed in the irradiator at any one time will not exceed 900 Curies.

Item 6: Purpose

The licensed material will be used in a Nordion International, Inc. Gammacell 1000 Elite research irradiator for the irradiation of transfusion specimens.

CONTROL NO. 93647

Items 7, 8 & 9

BLOOD IRRADIATOR
SAFETY PROGRAM

PRINCIPLE

The Gammacell 1000 is used to irradiate blood products to passivate lymphocytes for prevention of graft verses host disease. The gamma source is caesium-137. For the protection of hospital personnel, the radiation safety protocol must be strictly adhered to.

EQUIPMENT LOCATION

The irradiator will be located in room 2152 (Transfusion Service) of the Department of Laboratory Medicine. The key to operate the equipment will not be accessible to non-Blood Bank personnel.

PROTOCOL

Dr. Linda A. Chambers, Medical Director of the Transfusion Service, in conjunction with Dr. Jerry Dare, Radiation Protection Officer, will be responsible for the radiation safety program within the section. They will demonstrate a clear understanding of:

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. The license and regulations of NRC.

TRAINING

All Blood Bank employees must receive adequate training before working with the irradiator. Training information will be reviewed on an annual basis and any time new procedures or policies involving the equipment are instituted. Training will include information on:

1. The principles and fundamentals of radiation safety and good safety practices related to the use of radioactive materials.

2. The use of radiation safety detection instruments.
3. The design and operation of the irradiator.

Personnel will successfully complete a written exam to document their understanding of information presented by the trainer. They will also demonstrate competency by completing several irradiation procedures under the supervision of the trainer. All documentation of training of each employee will be maintained within the Blood Bank indefinitely.

RADIATION SAFETY PROGRAM

10.1 Personnel Monitoring Equipment

The Gammacell 1000 Elite research irradiator is self-shielded and can be safely operated in an exiting laboratory environment. The external radiation levels are less than 0.08 millirem per hour at 1 Meter from the source and less than 0.25 millirem per hour at the surface of the unit. Personnel monitoring will be provided for any individual who will operate the unit and receive, or is likely to receive, a dose equivalent of 25% of the Maximum Permissible Dose Equivalent as specified in 10CFR20.101(a). Film badges will be made available for the above intent at a change frequency of 1 month.

10.2 Radiation Detection Instruments

A calibrated, operable survey meter that can measure up to several hundred milliRoentgens per hour will be available.

10.3 Leak-Testing

The Children's Hospital and Children's Hospital Research Foundation will establish and implement the model procedure for leak-testing sealed sources in Appendix H in USNRC Regulatory Guide 10.8, Rev. 2, 08/87. The leak-test sequence will be performed by or under the supervision of the radiological safety officer.

10.4 Operating and Emergency Procedure

The Children's Hospital and Children's Hospital Research Foundation will establish and implement operating and emergency procedures for the use of the Gammacell 1000 Elite unit.

10.5 Plans for Installation and Certain Repairs

The Children's Hospital and Children's Hospital Research Foundation will install and repair the unit as directed by the supplier.

Item 11: WASTE MANAGEMENT

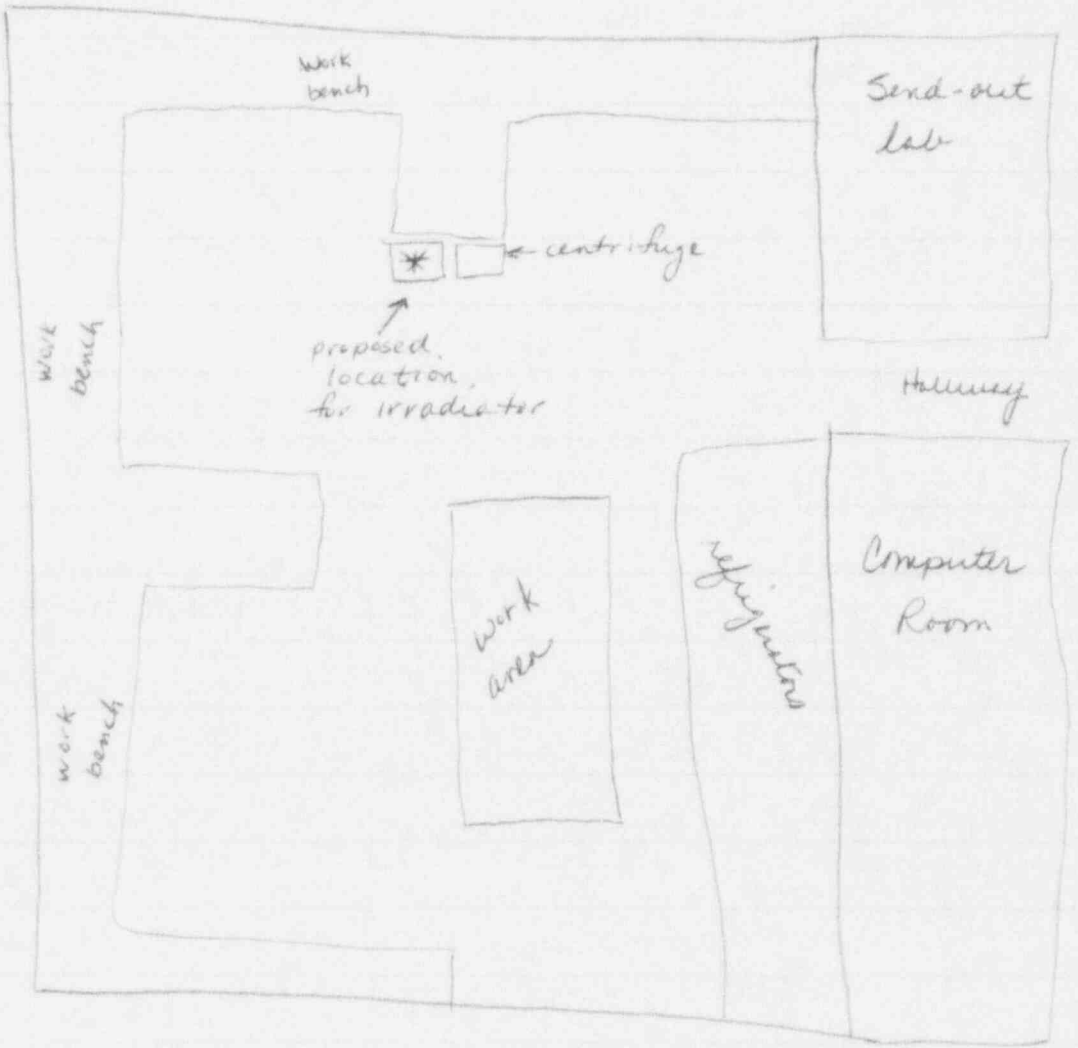
11.1 Authorized Disposal

The Children's Hospital and Children's Hospital Research Foundation will option for disposal to transfer the radioactive source to an authorized recipient as specified in 10CFR20.301(a).

11.2 Transportation

The Children's Hospital and Children's Hospital Research Foundation will adhere to the requirements of 10CFR71 in transportation of the irradiator for the purposes of disposal or other reasons.

Hallway



Rm 2152

NRC Form 240A
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

VOUCHER COVER SHEET

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
1		C	H	I	L	D	R	E	N	'	S		H	O	S	P	I	T	A	L						
2		A	T	T	N		J	E	R	O	M	E		G		D	A	R	E							
3		7	0	0		C	H	I	L	D	R	E	N	'	S		D	R	I	V	E					
4		C	O	L	U	M	B	U	S		O	H		4	3	2	0	5								
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7		O	V	R	P	Y	M	P	T		F	E	E		A	P	P	L		D	T	D				
8		6	/	2	6	/	9	2		C	K		1	9	8	9	6	8								

ACCOUNT NO: AA905 AMD CD NO: _____

FEE CATEGORY: 3E. CONTROL NO: 393647

DATE RECEIVED: 7/7/92

CHECK AMOUNT: $500.00

AMOUNT RETAINED: $250.00

AMOUNT REFUNDED: $250.00

COMMENTS: _____

31X6875

GOVERNMENT CODE: Y N

DOCUMENT NUMBER	
TRANSACTION CODE	AMOUNT
B&R NUMBER	
FIN	
FEE RETAINED CODE 303	FEE PAID CODE 410
DISCOUNT (CODE 000) TAKEN	DISCOUNT (CODE 415) LOST
AMOUNT PAID $250.00	
	FINAL Y N

SIGNED: M. Messier

DATE: 7/8/92

Children's Hospital

700 Children's Drive
Columbus, Ohio 43205

614/461-2027
614/461-2633 (FAX)

Children's HOSPITAL

4
030-03111
5-31-30
7B
Insp fee
1
Combined
w/ 9421
9/2-11

December 15, 1992

U.S. Nuclear Regulatory Commission
Materials Licensing Branch
799 Roosevelt Road
Glen Ellyn, IL 60137

ATTENTION: Ms. Patricia Pelkie

Subject: Amendment to NRC License #34-03111-02

Dear Ms. Pelkie;

We would like to request that Phosphorus - 33 in any chemical or physical form be authorized on our license for research and development with a possession limit of 50 millicuries.

Our check for $360 is attached. Thank you very much.

Sincerely,

Marg Margello

Margaret A. Margello
Assistant Executive Director

cc: Radiation Safety Committee
Orman Berg
Philip R. Johnson, MD
Mario Marcon, PhD
Sue O'Dorisio, MD, PhD

Margaret A. Margello
Assistant Executive Director

Combined w/ Co Po 9421

Children's Hospital

700 Children's Drive
Columbus, Ohio 43205-2696

614/461-2000
614/461-2688 (FAX)

Children's HOSPITAL

October 6, 1992

U.S.Nuclear Regulatory Commission
Materials Licensing Branch
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention: Mr. John D. Jones

Subject: Followup for License No. 34-03111-02

Re: Control Number 93647

Dear Mr. Jones:

The following additional information is submitted in the application for the use of a sealed source of Cesium-137 in a blood irradiator.

1. Item 8. Training

The following individuals will be included as training instructor for the personnel using the blood irradiator:

a. Jerome G. Dare, Radiation Safety Officer
b. Orman B. Berg, Assistant Radiation Safety Officer
c. Jean Gunter, Laboratory Manager, Transfusion Service

The abovenamed will be trained by a factory representative during the installation of the said irradiator.

2. Item 9. Facilities and Equipment

a. The irradiator will be in a locked room to meet the requirements of 10CFR20.207. In addition the irradiator will be secured with key/lock system and access limited to designated trained personnel.

b. The room where the irradiator will be located will have an automatically operated fir detection and control system that is adequate to ensure the integrity of the irradiator and source in a fire.

3. Item 10.4 Operating and Emergency Procedures

Designated personnel will be trained to use the irradiator; each will be provided with a written copy of the operating and emergency procedures.

Centennial 1892 1992

3. A copy of the operating and emergency procedures will be conspicuously posted at the control station of the irradiator. Topics in the "Irradiator Standard Operating Procedures" will include
   a. "Principles and Fundamentals of Radiation Safety";
   b. "Results of Installation Radiation Survey";
   c. "Good Safety Practices Related to the use of Radioactive Materials";
   d. "Steps followed for the Protection of the Operators";
   e. "The Determination and Recording of Radiation Doses to Persons Operating the Irradiator";
   f. "Basic Design of the Irradiator";
   g. "Step-by-Step Procedures for the Operation of the Irradiator";
   h. "Methods to Ensure That Only Authorized Persons Will Use the Irradiator";
   i. "Inspections, Test Procedure and Maintenance to Ensure That All Safety Interlocks, Devices and Components Associated with the Irradiator Function Properly";
   j. "Prohibit All Modifications to Irradiator";
   k. "Emergency Procedures";
   l. "Telephone Numbers of Importance - RSO, Irradiator Manufacturer's Representative and NRC".

4. <u>Installation</u>

All installation and service of the irradiator will be done by the instrument's manufacturer or someone licensed to provide such installation and/or service. Designated member(s) of the Biomedical Engineering Staff will be in during the installation. They will provide the small routine maintenance as allowed by the manufacturer.

Sincerely,

Jerome G. Darr
Radiation Safety Officer

AUG 0 4 1992

Children's Hospital
ATTN: Jerome G. Dare
700 Children's Hospital
Columbus, OH 43205

License No. 34-03111-02
Control No. 93647

Dear Mr. Dare:

We have reviewed your application dated June 26, 1992 and find that we will need additional information as follows:

1. Item 8. Training

   Provide the name of the training instructor and submit the person's qualifications. The qualifications should show either that the person has received specific instruction using the irradiator (or a similar irradiator) or will be trained by a factory representative when the irradiator is installed.

2. Item 9. Facilities and Equipment

   a. If your irradiator will not be locked in a room, explain how the requirements of §20.207 of 10 CFR Part 20 will be met. Section 20.207 states that licensed materials in an unrestricted area must be under the constant surveillance and immediate control of the licensee.

   b. Confirm the room where the irradiator will be located will have an automatically operated fire detection and control system that is adequate to ensure the integrity of the irradiator and source in a fire. Alternatively, you should describe the conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls that ensure a very low level of radiation risk attributable to fires.

3. Item 10.4 Operating and Emergency Procedures

   Provide assurance that personnel trained to use the irradiator will be provided with written operating and emergency procedures and that a copy of these procedures will be maintained at the control station conspicuously posted in the area. List the topics covered in the procedures and provide assurance that the following topics will be included:

   a. Step-by-step procedures for operation of the irradiator.

   b. Determination and recording of radiation doses to persons operating the irradiator.

AUG 0 4 1992

c. The methods to ensure that only authorized persons will use the irradiator.

d. Inspections, test procedures, and maintenance to ensure that all safety interlocks, devices, and components associated with the irradiator are functioning properly. Prohibited modifications (for example, changing the safety control system or removing the source) should be stated.

e. Emergency situations, e.g., when a survey reveals abnormal radiation levels around the irradiator, personnel should leave the irradiator room, lock the door, and contact the individual responsible for the irradiator program. Telephone numbers for the irradiator manufacturer's representative and the NRC should be included. In addition, your procedures should require that a survey be made with a radiation survey meter outside the irradiator room to determine whether further restriction of the area is necessary.

4. Installation

State that all installation and servicing of the irradiator will be done by the instruments manufacture or by someone specifically licensed to provide installation and servicing. Indicate any servicing you intend to perform e.g., replacing light bulbs, routine maintenance suggested by the manufacturer.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 93647.

If you have any questions or require clarification of any of the above stated information, contact us at (708)790-5625.

Sincerely,

Original Signed By
John D. Jones
Materials Licensing Section

RIII
JDJones
08/04/92

NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 35

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, 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.

Add: 3E

Licensee	
1. Children's Hospital	In accordance with application dated June 26, 1992
2. 700 Children's Drive Columbus, OH 43205	3. License number 34-03111-02 is amended in its entirety to read as follows:
	4. Expiration date May 31, 1996
	5. Docket or Reference No. 030-02713

Oct 18 11
78
34-03111-02

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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Hydrogen-3	E. Any	E. 499 millicuries
F. Carbon-14	F. Any	F. 49 millicuries
G. Phosphorus-32	G. Any	G. 1 curie
H. Sulfur	H. Any	H. 1 curie
I. Scandium-46	I. Any	I. 10 millicuries
J. Ruthenium-103	J. Any	J. 10 millicuries
K. Tin-113	K. Any	K. 10 millicuries

4

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03111-02

Docket or Reference number
030-02713

Amendment No. 35

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
L. Iodine-125	L. Any	L. 50 millicuries
M. Cesium-137	M. Sealed source (which have been evaluated by and registered with the NRC or an Agreement State)	M. 100 millicuries
N. Chromium-51	N. Any	N. 500 millicuries
O. Technecium-99m	O. Any	O. 1 curie
P. Niobium-95	P. Any	P. 20 millicuries
Q. Rubidium-86	Q. Any	Q. 50 millicuries
R. Phosphorus-33	R. Any	R. 50 millicuries
S. Cesium-137	S. Sealed source (Nordion International, Inc. C-1000)	S. 900 curies

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

E. through L. To be used for small case laboratory research including animal studies.

M. To be used for instrument calibration.

N. through R. To be used for laboratory research including animal studies.

COPY

9. Authorized Use (Continued)

S. To be used in a Nordion International, Inc. Gammacell 1000 Elite irradior for irradiation of transfusion specimens (excluding the irradiation of explosives and flammable materials).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 700 Children's Drive, Columbus, Ohio.

11. Licensed material shall be used by, or under the supervision of, individuals designated by Children's Hospital Radiation Safety Committee, Thomas V. Lloyd, M.D., Chairperson.

12. The Radiation Protection Officer for the activities authorized by this license is Jerome G. Dare.

13. A. (1) The source(s) specified in Item(s) 7.R. and 7.S. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03111-02

Docket or Reference number
030-02713

Amendment No. 35

13. (Continued)

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

E. The licensee is authorized to collect leak test samples for analysis by or tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-125 and/or iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

16. The Radiation Safety Officer shall conduct a semiannual program audit and confirmatory radiation survey of each location where radioactive material will be utilized.

17. The Licensee shall ensure that the quorum of the radiation safety committee include as a minimum, the radiation safety officer, the management representative and persons representing the activities that will use radioactive material.

18. The licensee shall establish a bioassay program for individuals handling millicurie amounts of tritium in accordance with frequencies and procedures contained in Regulatory Guide 8.32, "Criteria For Establishing A Tritium Bioassay Program."

19. The licensee shall follow procedures contained in Appendix M.3, "Measuring and Recording Molybdenum Concentration," of Regulatory Guide 10.8, Revision 2, August 1987.

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03111-02

Docket or Reference number
030-02713

Amendment No. 35

20. (Continued)

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

21. The licensee shall maintain records of information important to safe and effective decommissioning as listed in Condition 10. per the provisions of 10 CFR 30.35g until this license is terminated by the Commission.

22. 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 a person specifically licensed by the Commission or an Agreement State to perform such services.

23. 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 26, 1992.

B. Letters dated July 27, 1990 (excluding references to interim storage and isotopes with half-lives greater than 65 days); March 21, 1991 (excluding references to interim storage and isotopes with half-lives greater than 65 days), October 6, 1992, and December 15, 1992.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 26, 1993

By Caroline A. Tuzzi
Materials Licensing Section, Region III

COPY

Amendment No. 35

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, 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.

394211

Licensee	
1. Children's Hospital	In accordance with application dated June 26, 1992
2. 700 Children's Drive Columbus, OH 43205	3. License number 34-03111-02 is amended in its entirety to read as follows:
	4. Expiration date May 31, 1996
	5. Docket or Reference No. 030-02713

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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Hydrogen-3	E. Any	E. 499 millicuries
F. Carbon-14	F. Any	F. 49 millicuries
G. Phosphorus-32	G. Any	G. 1 curie
H. Sulfur	H. Any	H. 1 curie
I. Scandium-46	I. Any	I. 10 millicuries
J. Ruthenium-103	J. Any	J. 10 millicuries
K. Tin-113	K. Any	K. 10 millicuries

COPY

ML 30 DF

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 34-03111-02
Docket or Reference number 030-02713
Amendment No. 35

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
L. Iodine-125	L. Any	L. 50 millicuries
M. Cesium-137	M. Sealed source (which have been evaluated by and registered with the NRC or an Agreement State)	M. 100 millicuries
N. Chromium-51	N. Any	N. 500 millicuries
O. Technecium-99m	O. Any	O. 1 curie
P. Niobium-95	P. Any	P. 20 millicuries
Q. Rubidium-86	Q. Any	Q. 50 millicuries
R. Phosphorus-33	R. Any	R. 50 millicuries
S. Cesium-137	S. Sealed source (Nordion International, Inc. C-1000)	S. 900 curies

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

E. through L. To be used for small case laboratory research including animal studies.

M. To be used for instrument calibration.

N. through R. To be used for laboratory research including animal studies.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03111-02

Docket or Reference number
030-02713

Amendment No. 35

9. Authorized Use (Continued)

S. To be used in a Nordion International, Inc. Gammacell 1000 Elite irradior for irradiation of transfusion specimens (excluding the irradiation of explosives and flammable materials).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 700 Children's Drive, Columbus, Ohio.

11. Licensed material shall be used by, or under the supervision of, individuals designated by Children's Hospital Radiation Safety Committee, Thomas V. Lloyd, M.D., Chairperson.

12. The Radiation Protection Officer for the activities authorized by this license is Jerome G. Dare.

13. A. (1) The source(s) specified in Item(s) 7.M. and 7.S. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

13. (Continued)

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

E. The licensee is authorized to collect leak test samples for analysis by or tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-125 and/or iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

16. The Radiation Safety Officer shall conduct a semiannual program audit and confirmatory radiation survey of each location where radioactive material will be utilized.

17. The Licensee shall ensure that the quorum of the radiation safety committee include as a minimum, the radiation safety officer, the management representative and persons representing the activities that will use radioactive material.

18. The licensee shall establish a bioassay program for individuals handling millicurie amounts of tritium in accordance with frequencies and procedures contained in Regulatory Guide 8.32, "Criteria For Establishing A Tritium Bioassay Program."

19. The licensee shall follow procedures contained in Appendix M.3, "Measuring and Recording Molybdenum Concentration," of Regulatory Guide 10.8, Revision 2, August 1987.

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 34-03111-02
Docket or Reference number 030-02713
Amendment No. 35

20. (Continued)

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

21. The licensee shall maintain records of information important to safe and effective decommissioning as listed in Condition 10. per the provisions of 10 CFR 30.35g until this license is terminated by the Commission.

22. 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 a person specifically licensed by the Commission or an Agreement State to perform such services.

23. 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 26, 1992.

B. Letters dated July 27, 1990 (excluding references to interim storage and isotopes with half-lives greater than 65 days); March 21, 1991 (excluding references to interim storage and isotopes with half-lives greater than 65 days), October 6, 1992, and December 15, 1992.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 26, 1993

By Cynthia D. Pederson
Materials Licensing Section, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B
EXP. DATE: 19960531
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION ~~III~~

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CHILDREN'S HOSPITAL
RECEIVED DATE: 921029
DOCKET NO: 3002713
CONTROL NO.: 394211
LICENSE NO.: 34-03111-02
ACTION TYPE: AMENDMENT

See Pg. 17 Overdue Invoice List MR 0123-92

2. FEE ATTACHED
AMOUNT: ~~$~~
CHECK NO.: ~~~~

3. COMMENTS

SIGNED P Declatt
DATE 10-30-92

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

1. FEE CATEGORY AND AMOUNT: 7B $390

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

3. OTHER

SIGNED Peter Jacques
DATE 12/1/92

390

RECEIVED
DEC 03 1992
REGION III

92 DEC -2 AM 9:22

Children's Hospital

700 Children's Drive
Columbus, Ohio 43205-2696

614/461-2000
614/461-2633 (FAX)

Children's HOSPITAL

October 12, 1992

U.S.Nuclear Regulatory Commission
Materials Licensing Branch
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention: Mr. John D. Jones

Subject: Followup for License No. 34-03111-02

Re: Control Number 93647

Dear Mr. Jones:

Nordion International, Inc., our proposed vendor, had issued a new source design for consideration as the source containment for this blood irradiator. Children's Hospital and Children's Hospital Research Foundation is requesting that source design capsule #C1001 as manufactured by Nordion International, Inc. be included as an alternative source encapulation for the use of a sealed source of Cesium-137 in a blood irradiator.

Log Oct 18 III
Remitter
Check No. 221273 $390
Amount $15
Fee Category
Type of Fee Amd
Date Check Rec'd. 11/30
Date Completed 12/1
By: Ky

Sincerely,

Jerome G. Dare
Radiation Safety Officer

RECEIVED
OCT 29 1992
REGION III
CONTROL NO. 94211

Centennial 1892 1992

JAN 2 7 1993

Children's Hospital
ATTN: H. Hugh Harroff Jr., DVM
Administrative Director
700 Children's Drive
Columbus, OH 43205

Dear Mr. Harroff:

Enclosed is Amendment No. 35 to your NRC License No. 34-03111-02 in accordance with your request.

Please note that we have not authorized Nordion International, Inc. Model C1001 sealed source as requested. Our records indicate that this sealed source has not been reviewed and approved by our sealed source and device registration section. If you wish to have this sealed source included on your license, the manufacturer must have the sealed source evaluated by NRC or an Agreement State.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive 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. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

39421

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (708) 790-5625.

Sincerely,

Original Signed By
Cassendra F. Frazier
Materials Licensing Section

Enclosure: Amendment No. 35

RIII
Frazier/bt
01/26/93

Children's Hospital
Research Foundation

700 Children's Drive
Columbus, Ohio 43205-2696

614/460-8000
614/460-7088 (FAX)

Children's HOSPITAL

January 14, 1992

U.S. Nuclear Regulatory Commission
Materials Licensing Branch
799 Roosevelt Road
Glen Ellyn, Illinois 60137

ATTENTION: Ms. Patricia Pelkie

Subject: Change of Contact Person (NRC License #34-03111-02)

Dear Ms. Pelkie:

Children's Hospital, Inc. (CHI) of Columbus, Ohio wishes to inform the Nuclear Regulatory Commission of a change in appropriate contact person for all matters involving NRC license #34-03111-82. Mrs. Margaret A. Margello will be leaving CHI in February of 1993. In accordance, effective immediately I will be the appropriate contact person for the NRC. I can be reached at the following address:

H. Hugh Harroff, Jr., DVM
Administrative Director
Children's Hospital Research Foundation
700 Children's Drive
Columbus, Ohio 43205

Telephone - 614-460-8040 FAX - 614-460-7088

I look forward to continuing the constructive relationship that our institution has enjoyed with the NRC over the past several years, and to my interaction with you.

Sincerely,

H. Hugh Harroff, Jr. DVM

H. Hugh Harroff, Jr., DVM
Administrative Director

cc: Radiation Safety Committee
Orman Berg
Margaret Margello
Jerry Dare, PhD

CONVERSATION RECORD

TIME Afternoon | DATE Dec. 16, 1992

○ VISIT ○ CONFERENCE X TELEPHONE

○ INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Marnella--FEES HQ

ORGANIZATION (OFFICE, DEPT.ETC.): Headquarters

TELEPHONE NO.:

SUBJECT

Children's Hospital 34-03111-02 CoNo. 93647

SUMMARY

Called to inquire about above licensee on Inspection Overdue List. Marnella indicated that because this was a medical issue that I could go ahead and work on it. If admin. has any trouble putting milestones into system than they should contact her. Flag on case can be circumvented long enough to process this licensing amendment. She indicated that I could go ahead and work on amendment.

ACTION REQUIRED

Work on license amendment

NAME OF PERSON DOCUMENTING CONVERSATION: Cassandra Frazier

SIGNATURE: December 16, 1992

DATE:

ACTION TAKEN

SIGNATURE

TITLE

DATE

NOV 4 1992

Children's Hospital
ATTN: Jerome G. Dare
Radiation Safety Officer
700 Children's Drive
Columbus, OH 43205-2696

Gentlemen:

This refers to your letter dated October 12, 1992, for an amendment to Materials License 34-03111-02.

Your request is subject to an amendment fee of $390 as specified in fee Category 7B of §170.31, 10 CFR 170, which went into effect August 24, 1992. A copy of the July 23, 1992, Federal Register notice regarding the revisions to the Commission's license and annual fee regulations (10 CFR 170 and 10 CFR 171) is enclosed.

Payment of the $390 fee should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

U.S. Nuclear Regulatory Commission
ATTN: Cheryl Phillips
License Fee and Debt Collection Branch, OC/DAF
Mail Stop MNBB 4503
Washington, D.C. 20555

Your application will be processed by the Region III Licensing staff located at 799 Roosevelt Road, Glen Ellyn, Illinois 60137. The fee, however, is required prior to issuance of the amendment. When submitting the fee, please refer to CONTROL NUMBER 394211.

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 and will void this action.

Sincerely,

/S/

Cheryl Phillips
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
July 23, 1992, Federal Register notice

cc: Region III

DISTRIBUTION
Pending Fee File
OC/DAF R/F
LFDCB R/F (2)

OFFICE:	OC/LFDCB	OC/LFDCB	OC/LFDCB
NAME:	REJacques	CPhillips	MMessier
DATE:	11/4/92	11/ /92	11/4/92

ASJ1 B:\CH.AMD