

(FOR LFMS USE)
INFORMATION FROM LTS

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: PROGRAM CODE: 02120
: STATUS CODE: 0
: FEE CATEGORY: 7C
: EXP. DATE: 19941031
: FEE COMMENTS: CODE 21

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84/12

APPLICANT/LICENSEE: ST. JOSEPH MERCY HOSPITAL
RECEIVED DATE: 891023
DOCKET NO: 3001997
CONTROL NO.: 388105
LICENSE NO.: 21-00943-03
ACTION TYPE: AMENDMENT

AMOUNT: 120.
CHECK NO.: 180357

SIGNED P. Dillhoff
DATE 10-24-89

1. FEE CATEGORY AND AMOUNT: 7C \$120

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

SIGNED _____
DATE 10/27/89

9006260147 891027
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MATLSLICENSING PDR

JAN 22 1990

St. Joseph Mercy Hospital
Department of Nuclear Medicine
ATTN: Chi Chi Jacobson, M.S.
Radiation Safety Officer
5301 E. Huron River Drive
Ann Arbor, MI 48106

Gentlemen:

Enclosed is Amendment No. 56 to your NRC License No. 21-00943-03 in accordance with your request.

After review of your license we have determined that the type, form, and quantity of material authorized does not warrant the development and submittal of a decommissioning funding plan, or certification of financial assurance as described in 10 CFR 30.35 (enclosed). However, this does not relieve you of record keeping requirements relative to information which the Commission considers important to decommissioning. Therefore, we have added License Condition 22, requiring that you maintain such records as set forth in Section 30.35(g).

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.

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
John D. Jones
Materials Licensing Section

Enclosures:

1. Amendment No. 56
2. 10 CFR Part 30

RIII

Jones/gd
01/22/90 

McPherson Hospital

Livingston County's Full Service Hospital

Peter J. Schonfeld
President &
Chief Executive Officer

December 22, 1989

United States Nuclear Regulatory Commission
Region III, Office of Materials and Licensing
799 Roosevelt Road
Glen Ellyn, Illinois 60137

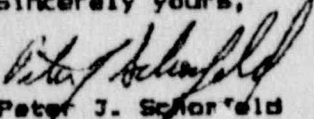
RE: AMENDMENT TO NRC LICENSE NO. 21-17830-03

Dear Sir/Madam:

McPherson Hospital would like to amend it's current NRC license in order to obtain approval for by-product material as described in 10CFR35.400. St. Joseph Hospital in Ann Arbor (NRC License No. 21-00943-03), will transport I-125 seeds to our institution for implant therapy. We accept responsibility for the use of the material at our institution upon arrival. Approximately two implants will be performed on a monthly basis.

If you have any questions or require additional information, please feel free to contact our consultant, Duane Zenn at 313-662-3177.

Sincerely yours,


Peter J. Schonfeld
President & CEO

PJS/pk



HERRICK MEMORIAL HEALTH CARE CENTER

Phil Sullivan
President
Chief Executive Officer

Harold Easton
Chairman, Board of Trustees

BOARD OF TRUSTEES
Glenn Kohler James Records
Joseph Mannino Dennis Dawson
George Eidson

December 21, 1989

United States Nuclear Regulatory Commission
Region III, Office of Materials and Licensing
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Amendment to NRC License No. 21-24368-01.

Dear Sir/Madam:

Herrick Memorial Health Care Center would like to amend it's current NRC license in order to obtain approval for by-product material as described in 10CFR35.400. St. Joseph Hospital in Ann Arbor (NRC License No. 21-00943-03), will transport I-125 seeds to our institution for implant therapy. We accept responsibility for the use of the material at our institution upon arrival. Approximately two implants will be performed on a monthly basis.

If you have any questions or require additional information, please feel free to contact our consultant, Duane Zenn at (313) 562-3197.

Best regards,

Phil Sullivan
President and Chief Executive Officer

cc: Nuclear Medicine Department File

December 20, 1989

Mr. John D. Jones
Material Licensing Section
Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mr. Jones:

In response to the control number #388105, we submit the following information for your continuous review of our application for an amendment:

1. The licensee names and the material license numbers of the three institutions which will receive the I-125 implant service and the radionuclide are:

<u>Licensee Name</u>	<u>Material License #</u>
Herrick Memorial Health Care Center	#21-24368-01
Chelsea Community Hospital	#21-20355-01
McPherson Community Health Center	#21-17830-03

These are the only three institutions we are proposing in this application to receive the service.

2. Justification for request:

The three facilities that will receive I-125 seeds from St. Joseph Mercy Hospital do not have the technical knowledge and the expertise related to I-125 seed implants. The cost of the I-125 seeds with fairly short half life of 60 days is such that it is not affordable for these institutions to have their own sources for doing a few cases a year.

The estimated number of cases per month which will require us to transport the I-125 seeds for each institution is at maximum 2 cases and with the total estimated annual transfer of sources from us at maximum of 25 transfers. The estimated total number of seeds and the amount of radioactivity for each transfer are expected to be at about 150 seeds and each at about 5 mCi nominal activity (total activity is about 750 mCi). At St. Joseph Mercy Hospital, we perform more

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than 90 radioactive implants per year. By sharing the use of the seeds and professional expertise, the cost of the implants at these receiving institutions will be feasible and accessible to local patients.

3. Procedures for Packaging and Transportation

We order the I-125 seeds from a manufacturer authorized to distribute the seeds in accordance with a specific license issued pursuant to 32.74 of 10 CFR Part 32 or under equivalent regulations of an agreement state.

Packaging: The I-125 seeds in catheters will be packaged in a lead safe box which has the shielding equivalency of not less than the original manufacturer's and in such amount that the radiation levels at package surface are less than 0.5 mR/hr and requires only Radioactive - White I label. The safe box will be locked and labeled in accordance with the Department of Transportation regulations and accompanied with the manufacturer supplied package insert that provides radiation safety instructions for handling and storing the sources.

The safe box will be locked in the trunk of the transport vehicle to guard against theft and unauthorized removal. The vehicle with the source on board at no time will be left unattended during its journey between St. Joseph Mercy Hospital and the receiving institutions.

4. Description of Typical Transfer

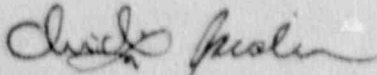
The authorized users on our NRC license #21-00943-03 for 35.400 will clinically visit the patients at the receiving institutions weekly and the authorized users who are the Radiation Oncology physicians will initiate the implant schedule and transfer the sealed source from St. Joseph Mercy Hospital to the receiving institutions. After the physician arrives at the receiving institution, the physician will transport the safe box containing the radioactive sealed seeds directly from the parking lot to the site of application. The number of seeds will be accounted for against the inventory record. After the prescribed radiation dose has been delivered, the physician will unload all the seeds back into the safe box and account for them against the inventory record. The physician will transport the safe box to the vehicle and lock it in the trunk and transport it back to St. Joseph Mercy Hospital. All the seeds will be accounted for again and entered into the master inventory record.

Page 3

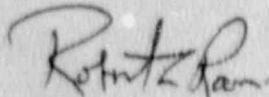
Enclosed herewith are the amendment applications for the material licenses of the three receiving institutions.

If you have any questions, please contact me at 313-572-2235.

Sincerely,



ChiChi Jacobson, M.S.
Radiation Safety Officer



Robert L. Ravin
Administrator

P.S. I have enclosed two of the three amendment applications for the receiving institutions. The third one, for the Chelsea Community Hospital, will be sent to you as soon as I receive copies from them.
Thank you.

NRCamend2

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NOV 30 1989

St. Joseph Mercy Hospital
ATTN: Ms. Chi Chi Jacobson and
Mr. Robert L. Ravin
5301 East Huron River Drive
P. O. Box 995
Ann Arbor, MI 48106

Dear Ms. Jacobson and Mr. Ravin:

We have reviewed your application for an amendment to your License No. 21-00943-03 which would allow transfer of I-125 seeds for use at Herrick Hospital, Chelsea Hospital, and McPherson Hospital. Be advised that pursuant to 10 CFR 35.11 and 35.12, each of the named institutions must apply for and be approved for a license for medical use of by-product material as described in 35.400. In addition, approval of requests of this nature require an exemption from the regulations contained in Section 35.49 of 10 CFR Part 35. These requests shall, therefore, be reviewed on a case-by-case basis. Please submit the following information in support of your application:

1. Justification for Request

Indicate the scope of the intended service. Provide an estimate of the number of transfers expected annually. Describe in detail, the reason that the facilities involved cannot receive materials solely in accordance with 10 CFR 35.49. Provide a realistic estimate of the number of seeds and the amount of radioactivity you expect to transfer on each occasion. Be advised based upon your statement, you may be required to submit information for authorization for commercial distribution and pay the appropriate fee.

2. Procedures for Packaging and Transportation

Provide detailed procedures for packaging the I-125 seeds to insure that the material may be transported with minimal possibility of accidental release of radioactive material. Make a commitment to package and transport the material in accordance with all applicable NRC and Department of Transportation Regulations. (Refer to "Guide For Preparation Of Applications For Nuclear Pharmacy Licenses" (4.3) Redistribution of Sealed Sources--Calibration and Reference Sources).

3. Description of Typical Transfer

Provide a detailed description of how a typical transfer will work i.e., how a typical transfer will be initiated, the title of the person responsible for initiating and implementing the transfer, and a general description of the events that will follow once the materials are on the site of the receiving institution.

In addition, each institution intending to use the material in filing an application for a medical license must address the following:

1. Scope of Program

Provide an estimate of the number of cases per month which will require the transport of I-125 seeds from St. Joseph Mercy Hospital.

2. Statement of Acceptance of Responsibility

Provide a statement of assurance that the facility will assume responsibility for the use of the material at their institution upon arrival.

3. File Completed Application in accordance with 10 CFR 35. Regulatory Guide 10.8 provides guidance for preparing the license application

Confirm that receipt and package opening procedures will be at least equivalent to those outlined in Appendix L of Regulatory Guide 10.8, August 1987. Model procedure Appendix Q Regulatory Guide 10.8 (Revision 2) or an equivalent procedure must be provided to insure radiation safety during implant therapy. In case the patient is not ready to receive the therapy when the material arrives at the receiving institution, procedures should be provided and secure space allocated in the event temporary storage is necessary.

Please coordinate the submittal of the above information for each institution in a manner that allows each action to be processed by this office concurrently.

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 388105.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5622.

Sincerely,

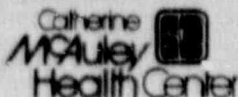
Original Signed By
John D. Jones
Materials Licensing Section

Enclosures:

1. Regulatory Guide 10.8
2. Guide for Preparation
of Applications For
Nuclear Pharmacy Licenses
3. 10 CFR Part 20

RIII

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Sponsored by the
Religious Sisters of Mercy
founded in 1831
by Catherine McAuley

St. Joseph Mercy Hospital
5301 East Huron River Drive
P.O. Box 995
Ann Arbor, Michigan 48106
(313) 572-3456

October 10, 1989

Nuclear Regulatory Commission
Region III
Division of Compliance
799 Roosevelt Road
Glen Ellyn, IL 60137

Log	OCT 15
Remitter	
Check No.	180357
Amount	\$120
Fax Category	7C
Type of Fee	AmD
Date Check Rec'd.	
Date Completed	10/27/89
By:	ut

Dear Persons:

We are requesting an amendment to our license #21-00943-03 to allow us to transfer radioactive material between St. Joseph Mercy Hospital in Ann Arbor, Michigan and the receiving institutions which are Herrick Hospital in Tecumseh, Michigan, Chelsea Hospital in Chelsea, Michigan, and McPherson Hospital in Howell, Michigan.

We submit the following itemized information to support this application.

1. Justification for this request.

The two facilities that will receive I-125 seeds from St. Joseph Mercy Hospital do not have the technical knowledge and the expertise to perform I-125 seed implants. The I-125 procedures at the two facilities will be conducted and supervised by the authorized users on our license and physics staff from St. Joseph Mercy Hospital. Nursing and other support personnel at these facilities will be trained by our staff to care for the patients with temporary I-125 implants. Another reason to transport sources from us to the two hospitals is the cost of I-125 sources. Since I-125 seeds are very expensive, most institutions with only a few cases a year cannot afford to perform them. At St. Joseph Mercy Hospital, we perform approximately 90 radioactive implants per year. The cost of these implants will be shared by the other institutions to make it financially feasible and therefore, accessible to the local patients.

2. Concurrence from the administrators.

See attached letters.

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OCT 23 1989

REGION III

CONTROL NO. 88105

OCT 28 1989

3. Identification of the type and quantity of transported radioactive material.

Radioactive Material: I-125
Form: Sealed seeds
Activity: 1Ci maximum per transfer
of Seeds: 200 seeds maximum per transfer

4. Procedures for maintaining source accountability.

In addition to the current inventory system for sources, there will be a duplicate copy to go with the authorized users to other hospital implant sites. Thus, the accountability of all the sources is verified at the site and later the information will be transferred back to the master inventory record and verified again.

5. Description of typical transfer.

The authorized user on our NRC license #21-00943-03 for 35.400 will clinically visit the patients at the receiving institution weekly and the authorized users will initiate the implant schedule and transfer the sealed source from St. Joseph Mercy Hospital to the receiving institution. After the authorized users arrive at the receiving institution, the authorized user will transport the safe box containing the radioactive sealed seeds directly from the parking lot to the site of application. The number of seeds will be accounted against the inventory record. After the prescribed radiation dose has been delivered, the authorized user will unload all the seeds back into the safe box and account them against the inventory record. The authorized user will transport the safe box to the vehicle and lock it in the trunk and transport it back to St. Joseph Mercy Hospital. All the seeds will be accounted again and entered into the master inventory record.

6. Identification of individuals who will transport the material.

The individuals transporting the radioactive material will be the authorized users for 35.400 on our license #21-00943-03.

7. Safety measures to be used in transporting the materials.

The I-125 sources in catheters shall be carried in a sealed lead shielded safe box with lock and proper labels. The safe box will be locked in the trunk of the

transport vehicle to guard against theft and unauthorized removal. The vehicle at no time will be left unattended during its journey between St. Joseph Mercy Hospital and other institution.

8. Emergency procedures in case of accidents.

In case of accidents involving transportation of radioactive sealed sources, the following procedures will be followed:

- a. If the persons transporting the sources are in such condition that he is able to communicate with the emergency crew or the state patrol, he shall, himself, or with the help of the emergency crew, immediately:

1. locate the source container
2. check the integrity of the container

If the results of the above evaluation are negative, immediately, the accident area will be roped off and guarded as a radioactive material contaminated area, and the area will be searched and surveyed until all the sealed sources are accounted.

- b. If the persons transporting the radioactive sources are unable to function as described above, there are two radiation precaution instruction sheets conspicuously posted in both the front and rear window of the transport vehicle which contain the following information:

1. This vehicle contains radioactive material which is stored in a safe box with radiation precaution sign on the box in the car trunk.
2. The personnel in the vehicle are not contaminated by radioactive material. They shall receive immediate medical attention if it is needed.
3. Immediately rope off the accident area as radiation contamination area and notify the state patrol and the following persons.
 - a. ChiChi Jacobson, Radiation Safety Officer
313-572-2235 or pager 495-2554
 - b. Surendra Rustgi, Chief of Radiation Physics
313-572-3597
 - c. Mike Rohan, Medical Physicist
313-572-4004

d. Dr. M. V. Pilepich, Director of Radiation
Oncology
313-572-3596 or pager 930-8985

9. Contamination survey of the transporting vehicle.

The radioactive source transport vehicle shall be surveyed for contamination by a calibrated GM meter after each transfer between us and other institutions. A record of survey will be maintained.

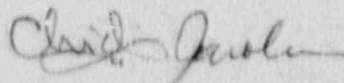
10. The receipt and package opening procedures.

Model procedures for receipt and package opening as outlined in Appendix L of Regulatory Guide 10.8, August, 1987 will be established and implemented.

Enclosed is the \$120.00 amendment fee.

If you have any questions regarding this application, please contact me at 572-2235.

Sincerely,



ChiChi Jacobson, M.S.
Radiation Safety Officer



Robert L. Ravin
Administrator

CCJ:RLR/ljm
Enclosure

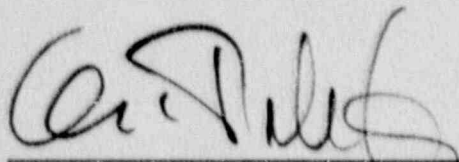
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CONTROL NO. 88105

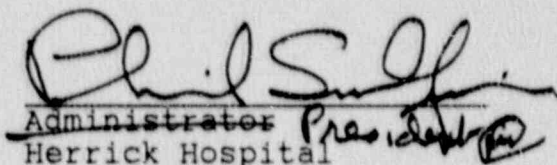
September 14, 1989

Nuclear Regulatory Commission
Region III
Division of Compliance
799 Roosevelt Road
Glen Ellyn, IL 60137

This is to confirm that Herrick Hospital, Tecumseh, Michigan
and Catherine McAuley Health Center, Ann Arbor, Michigan
wish to enter into a joint Brachytherapy Program using
I₁₂₅. CMHC will be purchasing the isotope and supply the
professional services of physicians, physicists and
dosimetrists at Herrick Hospital.



Director, Radiation Oncology
Catherine McAuley Health Center

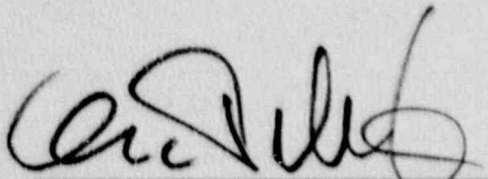


Administrator President
Herrick Hospital

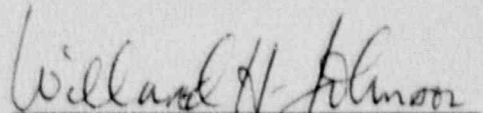
September 14, 1989

Nuclear Regulatory Commission
Region III
Division of Compliance
799 Roosevelt Road
Glen Ellyn, IL 60137

This is to confirm that Chelsea Hospital, Chelsea, Michigan
and Catherine McAuley Health Center, Ann Arbor, Michigan
wish to enter into a joint Brachytherapy Program using
 I_{125} . CMHC will be purchasing the isotope and supply the
professional services of physicians, physicists and
dosimetrists at Chelsea Hospital.



Director, Radiation Oncology
Catherine McAuley Health Center



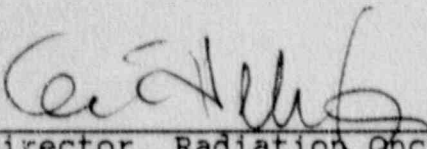
Administrator
Chelsea Hospital

CONTROL NO. 88105

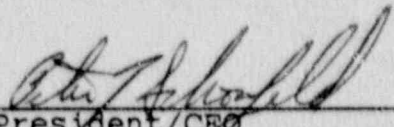
October 11, 1989

Nuclear Regulatory Commission
Region III
Division of Compliance
799 Roosevelt Road
Glen Ellyn, IL 60137

This is to confirm that McPherson Hospital, Howell, Michigan and Catherine McAuley Health Center, Ann Arbor, Michigan wish to enter into a joint Brachytherapy Program using I¹²⁵. CMHC will be purchasing the isotope and supply the professional services of physicians, physicists and dosimetrists at McPherson Hospital.



Director, Radiation Oncology
Catherine McAuley Health Center



President/CEO
McPherson Hospital

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CONTROL NO. 88105