

## MATERIALS LICENSE

Amendment No. 23

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.

301816

Licensee	In accordance with the letter dated August 27, 1996 3. License Number 24-01090-03 is amended in its entirety to read as follows:
1. St. John's Regional Medical Center	
2. 2727 McClelland Boulevard Joplin, MO 64801	4. Expiration Date June 30, 2003
	5. Docket or Reference No. 030-12728

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 radiopharma- ceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharma- ceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharma- ceutical identified in 10 CFR 35.300	C. As needed (not to exceed one curie of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed

## 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.

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

24-01090-03

Docket or Reference Number

030-12728

Amendment No. 23

## 9. Authorized Use (Continued)

D. Medical use described in 10 CFR 35.400.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2727 McClelland Boulevard, Joplin, Missouri.
11. Radiation Safety Officer: Jennifer Hann Fisher
12. Licensed material listed in Item 5 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

- |                                   |                           |
|-----------------------------------|---------------------------|
| A. Jose Maria Pacheco-Gil, M.D.   | 10 CFR 35.300 and 35.400. |
| B. Jeffrey Francis Schaffer, M.D. | 10 CFR 35.100 and 35.200. |
| C. Tom Fielder, M.D.              | 10 CFR 35.100 and 35.200. |
| D. Duane Eugene Myers, M.D.       | 10 CFR 35.300 and 35.400. |
| E. Douglas W. Ditzel, M.D.        | 10 CFR 35.300 and 35.400. |
| F. John Stucka, Jr., D.O.         | 10 CFR 35.100 and 35.200. |
13. Notwithstanding the requirements of 10 CFR 35.400(d) the licensee may use iridium-192 as seeds encased in nylon ribbon for intraluminal, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

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15. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. 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 March 23, 1993;
  - B. Letters dated August 15, 1994, August 27, 1996 (training request only); and
  - C. Letter received February 21, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

9/17/96

By

*Michael F. Weber*

Nuclear Materials Licensing Branch, Region III

## BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 02120  
Status Code: 0  
Fee Category: 7C  
Exp. Date: 20030630  
Fee Comments: CODE 23  
Decom Fin Assur Req'd: N

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## LICENSE FEE TRANSMITTAL

## A. REGION

## 1. APPLICATION ATTACHED

Applicant/Licensee: ST. JOHN'S REGIONAL MEDICAL CTR.  
Received Date: 960910  
Docket No: 3012728  
Control No.: 301816  
License No.: 24-01090-03  
Action Type: Amendment

## 2. FEE ATTACHED

Amount: 440  
Check No.: 310687

## 3. COMMENTS

Signed  
Date

D. Hensley  
9-11-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

## 1. Fee Category and Amount:

7C \$440

## 2. Correct Fee Paid. Application may be processed for:

Amendment ☒  
Renewal ☐  
License ☐

## 3. OTHER

Signed  
Date

SC 9/17/96

1996 SEP 16 AM 11:31  
1996 SEP 16

SEP 23 1996

Log	<u>Sep 6 III</u>
Remitter	
Check No.	<u>310687</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>AmD</u>
Date Check Rec'd	<u>9/16/96</u>
Date Completed	<u>9/17/96</u>
By:	<u>SC</u>





2727 McClelland Blvd. • Joplin, MO 64804-1695 • (417) 781-2727

27 August 1996

Region III  
United States Nuclear Regulatory Commission  
801 Warrenville Road  
Lisle, IL 60532-4351

Dear Sirs:

**RE: Amendment of NRC Materials License No. 24-01090-03**

We request an exemption from individual monitoring for the nurses delivering care to those patients receiving therapeutic amounts of radiopharmaceuticals or undergoing brachytherapy implants.

Additionally, we request our license be amended to reflect our intent, following the directions outlined in 10 CFR Part 19, Section 19.12, to instruct those employees **unlikely to receive in excess of 100 mrem annually** on a periodic basis only. We plan to inservice these individuals during initial orientation and routinely thereafter.

We have enclosed a check in the amount of \$440, as directed by 10 CFR 170, to cover the amendment costs.

Our discussion and reasons in support of our amendment requests follow.

**With respect to the exemption from film badging request:**

An analysis of the radiation exposure accumulations as indicated by the film badge dosimetry of a cross-section of the specified nursing population reveals that no nurse exceeded 230 mrem total in a 44 month period. Over the time evaluated, the radiation oncologists treated approximately 55-60 (15-16 cases per year) patients with either brachytherapy or therapeutic radiopharmaceuticals.



St. John's  
Regional Medical Center

Pm 9/6/96

RECEIVED

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REGION III

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Further, calculations using data gathered from separate film badge monitors placed in defined constant locations in the patient's room, together with the elapsed times indicated on the nursing logsheet, yield a conservative estimate of the exposure rate at the nurse's position near the patient of seven (7) mrem/hr. Typically, a difficult or long implant demands frequent nursing intervention with the patient. Our nursing logsheet demonstrates that these visits were on the order of less than five minutes duration, but did on occasion span 20 minutes. The average total time accrued per case per nurse was approximately 70 minutes (this number is conservative since we rounded all entries to the nearest higher increment divisible by five--so, two or three minutes became five, seven minutes became ten, and so on). ***Under these conditions, each nurse would have to assist 61 brachytherapy cases per year in order to possibly accumulate one-tenth of the MPD for an occupationally exposed individual (500 mrem).*** As noted earlier, St. John's has maintained a fairly constant 15 to 16 brachytherapy cases per year.

The exemption is important for several reasons:

An exemption would eliminate the majority of the paperwork headaches created by adding, tracking and deleting individuals as turnover in the nursing work force occurs.

An exemption would mean that our main monitoring method would be the in-room area radiation monitors and the nursing logsheet. As the previous paragraphs demonstrate, our exposure estimates projected from the in-room radiation monitors and the nursing logsheet are far more conservative than the totals accrued by monitors worn by individuals. ***We will continue using this alternate monitoring method, and will evaluate the results (with regard to reinitiating film badging for the nurses) yearly.***

Exempting the nurses from the individual monitoring requirement would allow more nurses to participate in the shared care of the brachytherapy patient, thus further reducing any one individual nurse's risk.

An exemption would remove the emphasis from the individual monitoring process, and place it on continuing application of good radiation safety practices, education and attention to the nursing guidelines detailed for each brachytherapy or radiopharmaceutical procedure.

Exempting the nurses from the individual monitoring requirement would mean that all nurses throughout the hospital (excepting the cardiac catheterization labs and special procedures nurses in Radiology) would follow the same radiation safety guidelines, which would streamline and facilitate rotating individuals into the areas of greatest need, with minimal re-instruction.

**With respect to the request relaxing yearly training requirements for employees at low (less than 100 mrem annually) risk from incidental occupational radiation exposure:**

The great majority of employees at St. John's Regional Medical Center have very little, if any interaction with radioactive materials in any form.

These employees serve in many different areas of the hospital, including Materials Management, Central Sterile, Communications, Food and Nutrition Services, Patient Accounts, Operations Analysis, Community Relations, to name a few.

St. John's follows a Radiation Safety Program that uses guidelines arranged in groups or Levels, that address radiation safety practices, issues and responsibilities on a scale of decreasing complexity and involvement. The program is arranged in five levels. The five levels complement and refer to a policy stating general radiation safety guidelines.

Level I guidelines are quite extensive and address radiation therapists, dosimetrists, physicists, physics assistants, nurses and radiation oncologists. Level II guidelines are only slightly less involved than Level I, in that no mention of teletherapy equipment is made. Level II staff include nuclear medicine technologists, radiological technologists, nurses involved special procedures, and so on. Level III guidelines address practical radiation safety methods for the majority of the employees in patient care services.

In preparing these guidelines, we considered those assigned activities during normal and abnormal situations that might involve exposure to radiation and/or radioactive material and which might reasonably be expected over during the duration of the licensed facility. Currently, all departments instruct their staff to review these guidelines annually. Additionally, all staff view, at least yearly, a Safety video, specifically tailored to St. John's Regional Medical Center, which addresses the general radiation safety guidelines as well other pertinent safety issues.

We will maintain annual inservicing of our Level I and Level II staff. The (Level III) nurses assigned to the care of patients receiving therapeutic amounts of radioactive materials or undergoing brachytherapy procedures, will maintain, at least annually, assisted as well as self-directed radiation safety training. All other employees identified in Level III, Level IV and Level V will receive radiation safety training at orientation and periodically thereafter.

***The hospital will continue to require all staff to view the Safety video, with its general radiation safety guidelines, annually.***

Thank you for your attention to these requests. If you need any additional information, please contact our Radiation Safety Officer, Jennifer Hann Fisher, at (417) 625-2488.

Sincerely,



Coleen Cameron, MSN  
Assistant Vice President, Patient Care Services

SEP 23 1996

Coleen Cameron, Assistant Vice President  
Patient Care Services  
St. John's Regional Medical Center  
2727 McClelland Boulevard  
Joplin, MO 64801

Dear Mr. Cameron:

This refers to your letter dated August 27, 1996, and to our telephone conversations with Ms. Jennifer Hann Fisher of your staff on September 16 and 17, 1996.

Enclosed is Amendment No. 23 to your NRC License No. 24-01090-03. This amendment only authorizes the modifications to your training program as described in your August 27, 1996 letter. The request for the exemption from individual monitoring of nurses has not been approved at this time. If you wish to pursue this request, you must ask, in writing, for an exemption from 10 CFR 20.1502, and provide adequate justification. The justification must address the requirement to monitor individuals who enter high radiation areas (see 10 CFR 20.1502(a)(3)). Please refer to Control Number 301816 in your letter.

Note that your license was also updated in accordance with current NRC policy. Specifically, License Condition No. 8.C. now includes a possession limit of one curie for iodine-131.

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 III office at (630) 829-9887 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. Unless your license has been 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.

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2. 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
  - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;
  - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - f. Change ownership of your organization.
5. 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 certifying official rather than a consultant.

You will be periodically inspected by 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 Policy and Procedures for NRC Enforcement Actions. 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.

Sincerely,

Original Signed By  
Michael F. Weber  
Nuclear Materials Licensing Branch

License No. 24-01090-03  
Docket No. 030-12728

Enclosure: Amendment No. 23

DOCUMENT NAME: M:\03012728.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" =  
Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>							
NAME	MFWeber:brt								
DATE	09/19/96								

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

September 11, 1996

Jennifer Hann Fisher, M.S.  
Radiation Safety Officer  
St. John's Regional Medical Center  
Radiology Department  
2727 McClelland Boulevard  
Joplin, MO 64801

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter Dated 08/27/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License                      ☒ Amendment                      ☐ Renewal  
☐ Termination                      ☐ Auth User (Amendment not required)  
☐ Other \_\_\_\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301816  
License No. 24-01090-03