NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 08

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, 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.

Licensee	In accordance with letter dated June 21, 1985
1. St. Patrick Hospital	3. License number 25-16773-02 is amended in its entirety to read as follows:
2. 500 W. Broadway P. O. Box 4587 Missoula, Montana 59801	4. Expiration date August 31, 1989
	5. Docket or Reference No. 030-14734

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 listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 2 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group VI of Schedule A, Section	C. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	C. 2 curies total for all sources authorized in Subitem 6.C.
D. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	D. Any	D. 3 millicuries of each byproduct material authorized in Subitem 6.D.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 25-16773-02

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E.	Iodine-131	E. Any iodine that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State Regulations.	E. 300 millicuries
F.	Phosphorus-32	F. Any phosphorus-32 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State Regulations.	F. 50 millicuries
G.	Xenon-133	G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	G. 1 curie

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. In vitro studies.

E. For treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma.

F. For treatment of polycythemia vera, leukemia, and bone metastases.

G. Blood flow or pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at St. Patrick Hospital, 500 West Broadway, Missoula, Montana.

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

William J. Birck, M.D.

Groups I and II
In vitro studies
Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction
Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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12. (continued)

Hugh C. Huntley, M.D.	Groups I, II, and III In vitro studies Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases Xenon-133
David W. Burgan, M.D.	Groups I, II, and III In vitro studies Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma Xenon-133
Thomas Andrew Layne, M.D.	Groups I, II, and III In vitro studies Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction Xenon-133
David J. Rickles, M.D.	Group VI
Albert R. Ward, M.D.	Groups I, II, and III In vitro studies Iodine-131 for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma
Wesley E. Root, M.D.	Groups I, II, and III In vitro studies Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma Xenon-133

13. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

14. Patients containing iodine-131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
25-16773-02

Docket or Reference number
030-14734

Amendment No. 08

15. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

    A. Has the prior written permission of the hospital's administrator and its Radiation Safety Committee, and

    B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    C. Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

    The licensee shall maintain for inspection by the Commission, copies of the written permission specified in Subitem A above and of the license(s) specified in Subitems B and C above. These records shall be maintained for 5 years from the time the licensee grants its permission under Subitem A above.

16. 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. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

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

17. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 12, 1984, and letters dated July 10, 1984, and June 21, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 26 1985

By Original Signed By
Jack E. Whitten
Nuclear Materials Safety Section
Region IV
Arlington, Texas 76011

Official Record Copy

m140

AUG 9 1985

4

St. Patrick Hospital
ATTN: Dr. Albert R. Ward
500 W. Broadway
P.O. Box 4587
Missoula, Montana 59806

Gentlemen:

Application Dated April 17, 1985, for an Amendment to Materials Licenses 25-16773-02 and 25-18361-01 and our Request for the License Fee Dated May 15, 1985.

This refers to the subject application and our letter (copy enclosed) in which we notified you that amendment fees totalling $240 were required.

Please be advised that, unless we hear from you within 30 days from the date of this letter, we will consider your application as being abandoned.

The submission of any future applications with the prescribed fee would not be affected by this action.

Sincerely,

Original Signed By
Glenda Jackson

Glenda Jackson
License Fee Management Branch
Office of Administration

Enclosure:
Letter dated 5/15/85

cc: Region IV

DISTRIBUTION:
Pending Fee File
Weekly Reading File
Materials Reading File

Dup 85 10 46425

OFFICE	LFMB:ADM	LFMB:ADM					
SURNAME	REJacques:rej	GJackson					
DATE	8/7/85	8/8/85					

NRC FORM 318 (10-80) NRCM 0240

OFFICIAL RECORD COPY

St. Patrick Hospital

August 8, 1985

Glenda Jackson
License Fee Management Branch
Office of Administration
United States Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Ms. Jackson:

Enclosed is a $240.00 payment to the United States Nuclear Regulatory Commission as requested by you in your letter of May 15, 1985 for amendment fees. This refers to CONTROL NO. 460603. This refers to amending MATERIALS LICENSE 25-16773-02 (St. Patrick Hospital) and MATERIALS LICENSE 25-18361-0 (Missoula Community Medical Center).

I have forwarded preliminary letters with the signature of each respective hospital administrator to Mr. Witten at the Arlington, Texas office.

Thank you for you help in this matter.

Sincerely,

Albert R. Ward, M.D.
Radiation Safety Officer
St. Patrick Hospital
Department of Radiology
P.O. Box 4587
Missoula, Montana 59806

AEW/aw

cc

'85 AUG 12 P2:43
U.S.N.R.C.
LIC. FEE MGMT. BRANCH

April 4 - IV

Applicant
Check No. 43091 (A 120 each)
Amount/Fee Category $240 - 7C
Type of Fee amd
Date Check Rec'd. 8/12/85
Received By Jacques

Dupe
8510240429

MAY 15 1985

St. Patrick Hospital
ATTN: Dr. Albert R. Ward
500 W. Broadway
P.O. Box 4587
Missoula, Montana 59806

MAY 15 1985

Gentlemen:

This refers to your letter dated April 17, 1985, for an amendment to Materials License 25-16773-02 (St. Patrick Hospital) and 25-18361-01 (Missoula Community Medical Center) to change the authorized users.

Amendment fees totalling $240 are required as specified in §170.31 (7C) of 10 CFR 170, copy enclosed. Payment should be made to the U.S. Nuclear Regulatory Commission and mailed to my attention at our Washington, D.C. address. In addition, we are returning your letter for the Hospital Administrators' signatures to indicate their concurrence with your request.

Your application will be processed by the Region IV Licensing staff located at 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011. The fees and Hospital Administrators' signatures, however, are required prior to issuance of the amendments. When submitting the fees, please refer to CONTROL NUMBER 460603.

Sincerely,

Original Signed By
Glenda Jackson

Glenda Jackson
License Fee Management Branch
Office of Administration

Enclosures:
1. 10 CFR 170
2. Letter dated 4/17/85

cc: Region IV

DISTRIBUTION:
Pending Fee File
Weekly Reading File
Materials Reading File

8510240423

OFFICE	LFMB:ADM	LFMB:ADM					
SURNAME	FBrown:rej	GJackson					
DATE	5/14/85	5/14/85					

NRC FORM 318 (10-80) NRCM 0240

OFFICIAL RECORD COPY

LLW
Paul Lj.

St. Patrick Hospital

June 21, 1985

Mr. Larry White, Administrator
St. Patrick Hospital
500 W. Broadway
P.O. Box 4587

Dear Mr. White,

I am in the process of amending the Nuclear Medicine material license for St. Patrick Hospital, license # 25-16773-02 to add William J. Birck, M.D. to the list of aurthorized users and to delete John M. Fritts, M.D. from the list of authorized users.

To complete this process, I need your signature to indicate your concurrence with this request.

Cosigning this letter I think will be satisfactory.

We are similarly amending Missoula Community Medical Center's material license at the same time. Amendment fees total $240.00 which I anticipate to be shared equally between the two hospitals.

Thank you very much for your help with this.

Sincerely,

Albert R. Ward, M.D.,
Radiation Safety Officer
St. Patrick Hospital

Lawrence L. White, Jr.
Administrator

ARW/mk

apr. 4 IV

Applicant.....
Check No. 43091 (18402)
Amount/Fee Category $120.-7C
(Type of Fee) amendment
Date Check Rec'd 8/12/85
Received By J. Robinson

see Aug 5 IV for Missoula
460745

460745
460603

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
William J. Birck, MD	Montana

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Diagnostic Radiology		June, 1984

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Cancer Foundation Santa Barbara Cottage Hospital, California 8/81 to 7/84	35	120
b. RADIATION PROTECTION	" "	5	35
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	" "	5	30
d. RADIATION BIOLOGY	" "	5	35
e. RADIOPHARMACEUTICAL CHEMISTRY	" " >200	8	40

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	25 mCi	Santa Barbara Cottage	8/81-7/84	Diagnosis
Tl 201	3 "	"	"	"
Xe133	10 "	"	"	"
In 111	.5 "	"	"	"
I 123	.2 "	"	"	"
Ga 67	5 "	"	"	"
I 131	150 "	"	"	Therapy
Cr 51	.1 "	"	"	Diagnosis
I125	.01	"	"	"

460603 460745

NRG FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

William Joseph BIRCK, M.D.

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	98	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	8	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	31	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	133	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
~~In-111~~	CISTERNOGRAPHY	15	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	94	
OTHER			
Tc-99m	BRAIN IMAGING	13	
	CARDIAC IMAGING	21	
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	224	
	LUNG IMAGING	125	
	BONE IMAGING	505	
OTHER			

460603

~~460745~~

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	3	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	28	
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	105	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	✓	
Other Ga^{67} Tl^{201} Tc^{99} HIDA Schilling Tc^{99} DTPA Tc^{99} Necks Lymphoscintigraphy	Body Cardiac Biliary intrinsic factor renal flow/scan	76 221 40 24 31 5 6	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

Red cell mass 8
cerebral blood flow 6

March, April, May, June 1982; May, 1984
approx. 672 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
James T. McClintock

b. NAME OF INSTITUTION
Cancer Foundation of Santa Barbara

c. MAILING ADDRESS
300 W Pueblo

d. CITY
Santa Barbara, CA 93105

5. MATERIALS LICENSE NUMBER(S)
0104-42

6. PRECEPTOR'S SIGNATURE
James T McClintock

7. PRECEPTOR'S NAME *(Please type or print)*
see 4.a

8. DATE
21 June '84

NRC FORM 313M SUPPLEMENT B
(9-81)