NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 57

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.

301677

Licensee	
1. Aultman Hospital Department of Radiology	In accordance with letter dated July 24, 1996
2. 2600 Sixth Street, S.W. Canton, OH 44710	3. License Number 34-01312-01 is amended in its entirety to read as follows:
	4. Expiration Date January 31, 2005
	5. Docket or Reference No. 030-02675

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 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. As needed
G. Chromium-51	G. Any	G. 3 millicuries
H. Carbon-14	H. Any	H. 3 millicuries
I. Iron-59	I. Any	I. 3 millicuries

030065

2-30 NL SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-01312-01
Docket or Reference Number: 030-02675
Amendment No. 57

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
J. Hydrogen-3	J. Any	J. 3 millicuries
K. Phosphorus-32	K. Any	K. 3 millicuries
L. Sulfur-35	L. Any	L. 3 millicuries
M. Iodine-125	M. Any	M. 10 millicuries
N. Iodine-131	N. Any	N. 10 millicuries

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 35.400.

E. 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.

F. In vitro studies.

G. through N. In vitro studies.

CONDITIONS

10. Location of Use: 2600 Sixth Street, S.W., Canton, Ohio.

11. Radiation Safety Officer: Wayne R. Hedrick, Ph.D.

12. Authorized Users:

A. Robert N. DiSimone, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 31.11, and Items 6.G. through 6.N. for in vitro studies.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 34-01312-01

Docket or Reference Number 030-02675

Amendment No. 57

B. Thomas B. Poulton, M.D., for material in 10 CFR 35.100 and 35.200.

C. S. L. Hissong, M.D., for material in 10 CFR 35.100, 35.200, and 31.11.

D. Bruce Howard Wolf, M.D., for material in 10 CFR 35.100, 35.200, 35.300, and 31.11.

E. Myron R. Puterbaugh, M.D., for material in 10 CFR 35.300 and 35.400.

F. Allen R. Rovner, M.D., for material in 10 CFR 35.100, 35.200 and 31.11.

G. Carlos V. Rozenbom, M.D., for material in 10 CFR 35.300 and 35.400.

H. Pushpa Bathija, M.D., for material in 10 CFR 35.300 (excluding thyroid carcinoma).

I. William R. Wallace, M.D., for material in 10 CFR 35.100, 35.200, 35.300, and 31.11.

J. James D. Geihshler, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.

K. Charles E. Smith, for material in 10 CFR 35.300.

L. Barry S. Rose, M.D., for material in 10 CFR 35.100, 35.200 and 31.11.

M. Wayne R. Hedrick, Ph.D., for material in Items 6.G. through 6.N. for in vitro studies.

N. James H. Rudick, M.D., for material in 10 CFR 35.300 (excluding thyroid carcinoma).

O. Steven F. Sands, M.D., for material in 10 CFR 35.100, 35.200, 35.300, (excluding iodine-131 for thyroid carcinoma), and 31.11.

P. Lawrence G. Hanelin, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 31.11.

Q. Robert H. Crabtree, M.D., for material in 10 CFR 31.11 and Items 6.G., 6.H., 6.J., 6.L., 6.M. and 6.N. for in vitro studies.

R. Philip Schneider, M.D., for material in 10 CFR 35.300 and 35.400.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 34-01312-01

Docket or Reference Number 030-02675

Amendment No. 57

S. Scott A. Whalen, Ph.D., for material in Items 6.G. through 6.N. for in vitro studies.

T. Marshall L. Chalfant, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

13. 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 July 18, 1994 excluding Quality Management Program.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 5, 1996

By _____
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: 20050131
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

55

N1

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: AULTMAN HOSPITAL
RECEIVED DATE: 960802
DOCKET NO: 3002675
CONTROL NO.: 301677
LICENSE NO.: 34-01312-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 430.00
CHECK NO.: 516899

3. COMMENTS

SIGNED M. Mannan
DATE 8/12/96

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 SC
DATE 9/17/96

1996 AUG 12 AM 10:57

SEP 23 1996

Log Aug 4 III
Remitter
Check No. 516899 / 522933
Amount $430 / $10
Fee Category 7C
Type of Fee AmD
Date Check Rec'd 8/12/96
Date Completed 9/17/96
By: SC

Aultman Hospital
2600 Sixth Street S.W.
Canton, Ohio 44710
(216) 452-9911

Richard J. Pryce
President

July 24, 1996

License Management Section
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Sir:

This constitutes an application for amendment of NRC Byproduct Material License No. 34-01312-01 issued to Aultman Hospital, Canton, Ohio.

Marshall L. Chalfant, M.D. is to be added as an authorized user for radiopharmaceuticals for therapy (35.300). Dr. Chalfant was certified in Diagnostic Radiology by the American Board of Radiology in June 1993. The preceptor form for Dr. Chalfant is enclosed.

In accordance with paragraph 35.13 Marshall L. Chalfant, M.D. is permitted to work as an authorized user for uptake, dilution and excretion studies (35.100) and for imaging and localization studies (35.200). Notification of a his authorized user status was provided previously.

Enclosed is a check for $430.00 to cover the cost of this license amendment.

Sincerely,

David Thiel, Vice President
Diagnostic and Therapeutic Services

RECEIVED
AUG 1 - 1996
REGION III

PM: 7-29-96

JUL 31 1996

301677

NRC 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

MARSHALL L. CHALFANT, M.D.

STREET ADDRESS

5615 Nethercreek Ave N.W.

CITY | STATE | ZIP CODE

Massillon | OH | 44646

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		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

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		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	6	
	TREATMENT OF HYPERTHYROIDISM	43	
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		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other	Sr 89 treatment for metastatic disease involving the bones	6	

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

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

a. NAME OF SUPERVISOR: D.B. Sodee, M.D.

b. NAME OF INSTITUTION: MetroHealth Medical Center

c. MAILING ADDRESS: 2500 MetroHealth Drive

d. CITY: Cleveland, Ohio

5. MATERIALS LICENSE NUMBER(S): 34-03749-10

6. PRECEPTOR'S SIGNATURE: D Bruce Sodee MD

7. PRECEPTOR'S NAME *(Please type or print)*: D BRUCE SODEE MD

8. DATE: 20 June 95

FORM NRC-313M-SUPPLEMENT B
(8-78)

DATE: 8-2-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: John Madera

LICENSEE: Ault man Hosp

LICENSE NUMBER: 34-01312-01

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not been started.

☑ Appears to be a(n) AMD - yes process in!

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.
Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☐ Licensee is adding authorized users.
A check is included _____. No check is included _____.
Amendment is necessary _____. Amendment is not necessary _____.
(Information for the license file)

☐ Other: _____

Thank You For Your Help!!! 02/02/95

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

AULTMAN HOSPITAL
ATTN: DAVID THIEL
2600 SIXTH STREET, S.W.
CANTON, OHIO 44710

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-24-96

LICENSE NUMBER: 34-01312-01

CONTROL NUMBER: 301677

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$	$ 440.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 440.00
PAYMENT RECEIVED	$ 430.00
AMOUNT DUE	$ 10.00

☐ Your request was received without the prescribed application fee.

☒ We received your Check No. 516899 in the amount of $ 430.00. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield	SC	
SHIRLEY CRUTCHFIELD	8/15/96	

Distribution: OC/DAF RF
Pending Fee File OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) Region 3

DATE: Aug. 23 1996

SEP 2 4 1996

David Thiel, Vice President
Diagnostic and Therapeutic
Services
Aultman Hospital
Department of Radiology
2600 Sixth Street, S.W.
Canton, ON 44710

Dear Mr. Thiel:

Enclosed is Amendment No. 57 to your NRC Material License No. 34-01312-01 in accordance with your request.

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.

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.

301677

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
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 34-01312-01
Docket No.: 030-02675

Enclosure: Amendment No. 57

DOCUMENT NAME: M:\03002675.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									
NAME	GWATSON:jaw									
DATE	08/05/96 GW									

OFFICIAL RECORD COPY