NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 47

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.

302294

Licensee	
1. St. Mary's Medical Center 2. 407 East Third Street Duluth, MN 55805	In accordance with letter dated January 24, 1997 3. License Number 22-02396-03 is amended in its entirety to read as follows: 4. Expiration Date June 30, 2005 5. Docket or Reference No. 030-02210

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. 1 Curie
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Gadolinium-153	E. Sealed sources (North American Scientific, Inc. Model 3601)	E. 8 sources, not to exceed 250 millicuries each

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

ML30 0/1

COPY 4

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-02396-03

Docket or Reference Number
030-02210

Amendment No. 47

C. Medical use described in 10 CFR 35.300.

D. In vitro studies.

E. Four sources to be used in Adac Laboratories Transmission Line Source Housing VANTAGE devices for medical radiography in humans. Four sources in shipping containers for replacement of the sources.

CONDITIONS

10. Location of Use: Licensed material shall be used only at 407 East Third Street, Duluth, Minnesota.

11. Radiation Safety Officer: Russell Reichter, M.D.

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

Authorized Users	Material and Use
A. Roger T. Collins, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
B. Mark B. Kilen, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
C. Charles C. Drexler, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
D. Stephen L. Towle, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11.
E. Christian M. Peterson, M.D.	10 CFR 35.100, 35.200, (excluding xenon-133) and 35.300.
F. Raymond C. Flaa, M.D.	10 CFR 31.11.
G. Russel E. Reichter, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 22-02396-03

Docket or Reference Number 030-02210

Amendment No. 47

Authorized Users	Material and Use
H. William Schwartau, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
I. Douglas J. Lane, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding Iodine-131 for thyroid carcinoma therapy), 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
J. Robert E. McGeachie, M.D.	10 CFR 31.11.
K. William D. Witrak, M.D.	10 CFR 35.100, 35.200, 35.300 and gadolinium-153 in VANTAGE devices for medical radiography.
L. Patrick Schoenfelder, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
M. Bruce J. Derauf, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
N. David G. A. Alexander, M.D.	10 CFR 35.100, 35.200, iodine-131 for treatment of hyperthyroidism and thyroid carcinoma and gadolinium-153 in VANTAGE devices for medical radiography.
O. Michael E. Ryan, M.D.	10 CFR 35.100, 35.200, iodine-131 for treatment of hyperthyroidism and thyroid carcinoma and gadolinium-153 in VANTAGE devices for medical radiography.
P. Michael R. Rich, M.D.	10 CFR 35.100, 35.200, limited to cardiovascular clinical procedures and gadolinium-153 in VANTAGE devices for medical radiography.
Q. Michael J. Lucca, M.D.	10 CFR 35.100, 35.200, limited to cardiovascular clinical procedures and gadolinium-153 in VANTAGE devices for medical radiography.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-02396-03

Docket or Reference Number
030-02210

Amendment No. 47

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 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 January 20, 1995;

B. Letter received May 22, 1995; and

C. Letters dated January 24, 1997 and March 11, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 2 1 1997

By Collleen C. Casey
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: 20050630
Fee Comments: CODE 21 NON-REPORTING
Decom Fin Assur Reqd: N

S6

RECEIVED IV AMD 19

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. MARY'S MEDICAL CENTER
   Received Date: 970206
   Docket No: 3002210
   Control No.: 302294
   License No.: 22-02396-03
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: ~~477845~~

3. COMMENTS

Signed D. Hersey
Date 2-11-97

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 DC
Date 2/14/97

FEB 21 1997

Log Feb 6 III
Remitter
Check No. 477842
Amount $440
Fee Category 7C
Type of Fee Amd
Date Check Rec'd 2/14
Date Completed 2/21/97
By: DC

ST MARY'S
MEDICAL CENTER

MEMBER OF BENEDICTINE HEALTH SYSTEM

407 East Third Street
Duluth, Minnesota 55805
(218) 726-4000
FAX (local) 720-2391
FAX 1-800-272-2391
(TDD/TTY) 726-4333

January 24, 1997

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Request For Amendment to St. Mary's Medical Center's NRC License

St. Mary's Medical Center requests an amendment be made to our NRC License #22-02396-03. We have enclosed a check in the amount of $440.00 to cover the amendment fee. The following license changes are requested:

1. Please see attachments showing the layout in Rooms 207 and 205. Two ADAC dual detector, variable angle camera's have replaced the previous Siemens 7500 gamma cameras in these rooms.

2. Request licensing for 1 Curie Limit of Gadolinium-153 line sources. Two shielded line sources will be supplied by North American Scientific. The Vantage Gd-153 line source specifications are as follows:

Quantity: 2 line sources, potential of 4 maximum (set of two sources for decay when replacing spent sources). North American Scientific will return spent sources when possible.

Activity: 200-250 mCi line source x 2 for a total of up to 500 mCi/system.

Active Length: 508 ± 3 mm

Overall Length: 521.7 ± 3 mm

Active Diameter: 1.5 ± 0.1 mm

Overall Diameter: 3.05 ± 0.1 mm

Uniformity: ±5% over entire surface area

pm; 2-3-97

Contaminants: Eu-152, Eu-153, Eu-154 <0.005% of total content

North American is the acting supplier of Gd-153 for ADAC Laboratories (Model 3601 - Registration #CA10S121.

Wipe tests of the sealed sources will be performed upon receipt, every 6 months, and upon shipment following manufactures recommendations. All records will be maintained for NRC review.

All previous submissions will continue to be in effect.

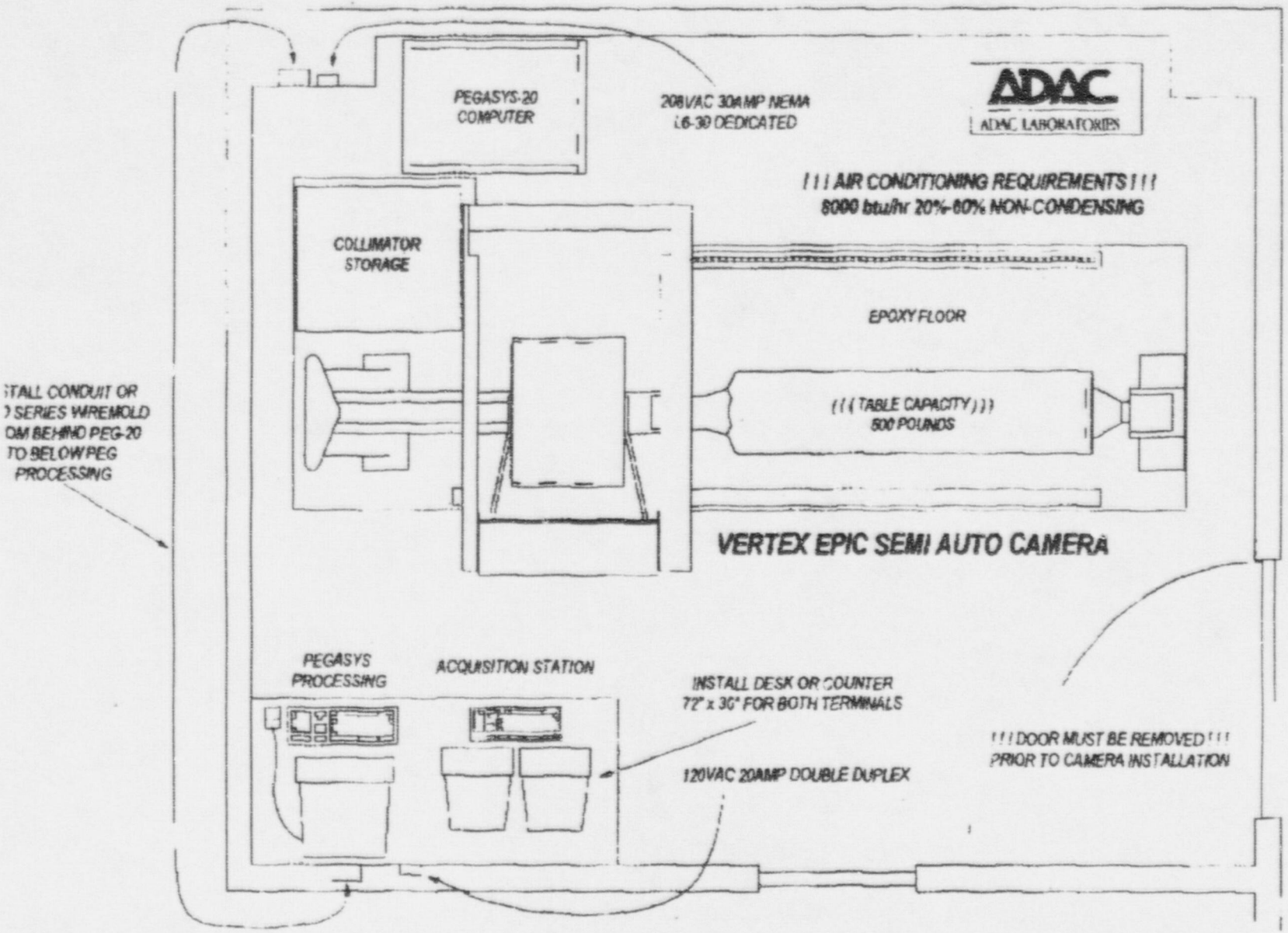
Sincerely,

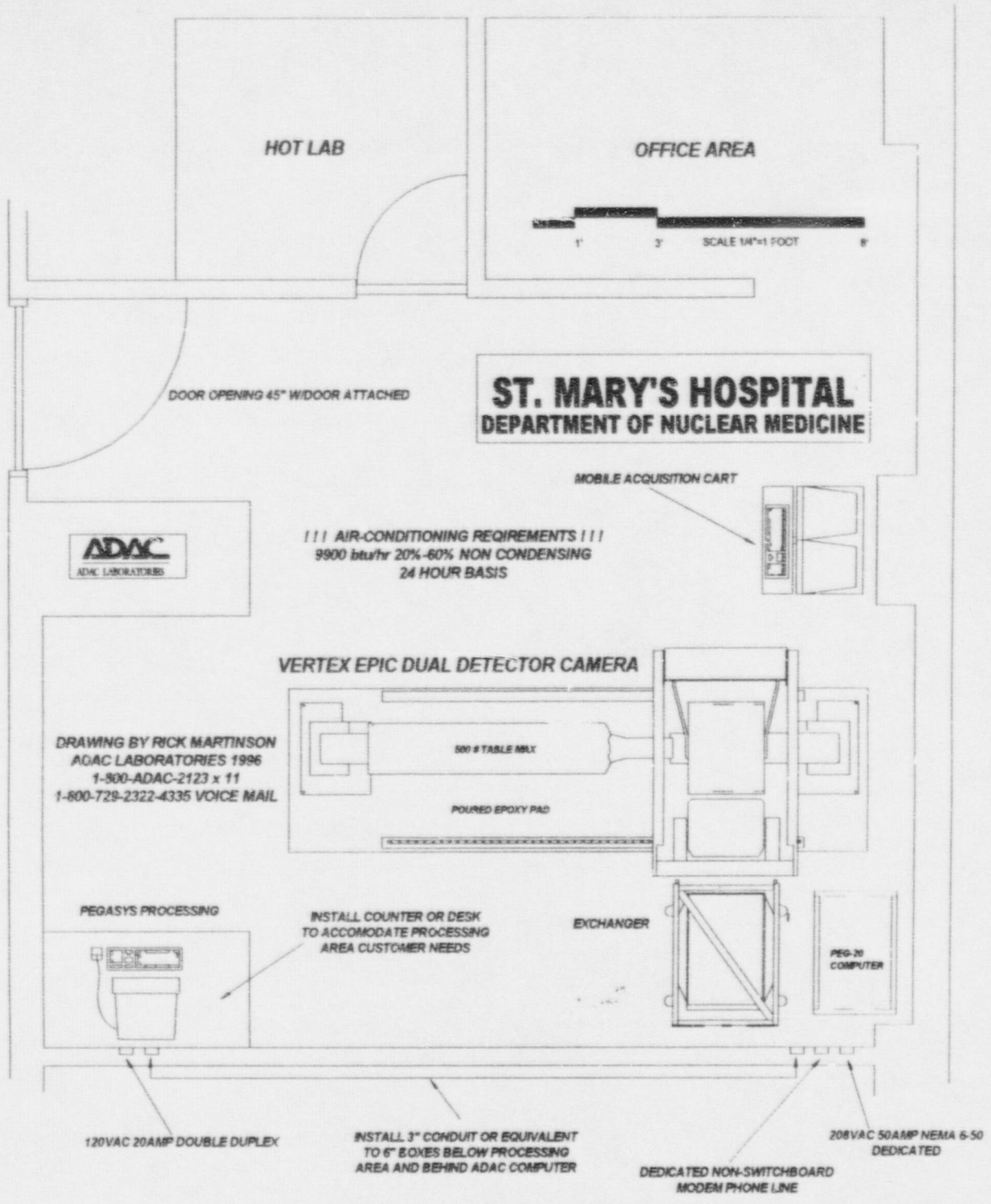
Mark J. Huber
Vice President for Professional Services

kc

c: Pat Engelhaupt

Enclosure




HOT LAB
OFFICE AREA
1'
3'
SCALE 1/4"=1 FOOT
8'
DOOR OPENING 45" W/DOOR ATTACHED
ST. MARY'S HOSPITAL
DEPARTMENT OF NUCLEAR MEDICINE
MOBILE ACQUISITION CART
ADAC
ADAC LABORATORIES
!!! AIR-CONDITIONING REQIREMENTS !!!
9900 btu/hr 20%-60% NON CONDENSING
24 HOUR BASIS
VERTEX EPIC DUAL DETECTOR CAMERA
DRAWING BY RICK MARTINSON
ADAC LABORATORIES 1996
1-800-ADAC-2123 x 11
1-800-729-2322-4335 VOICE MAIL
500 # TABLE MAX
POURED EPOXY PAD
PEGASYS PROCESSING
INSTALL COUNTER OR DESK
TO ACCOMODATE PROCESSING
AREA CUSTOMER NEEDS
EXCHANGER
PEG-20
COMPUTER
120VAC 20AMP DOUBLE DUPLEX
INSTALL 3" CONDUIT OR EQUIVALENT
TO 6" BOXES BELOW PROCESSING
AREA AND BEHIND ADAC COMPUTER
DEDICATED NON-SWITCHBOARD
MODEM PHONE LINE
208VAC 50AMP NEMA 6-50
DEDICATED

Loc may

MAR 2 1 1997

Mark J. Huber
Vice President for
Professional Services
St. Mary's Medical Center
407 East Third Street
Duluth, MN 55805

Dear Mr. Huber:

Enclosed is Amendment No. 47 to your NRC Material License No. 22-02396-03 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.

A. Please note that, at this time, we changed the expiration date in item no. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.

B. 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).

302294

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
Colleen C. Casey
Nuclear Materials Licensing Branch

License No.: 22-02396-03
Docket No.: 030-02210

Enclosures: 1. Amendment No. 47
2. 10 CFR Part 30

DOCUMENT NAME: M:\03002210.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 CCfC	C							
NAME	CCASEY:jaw								
DATE	03/19/97								

OFFICIAL RECORD COPY

ST MARY'S
MEDICAL CENTER

MEMBER OF BENEDICTINE HEALTH SYSTEM

407 East Third Street
Duluth, Minnesota 55805
(218) 726-4000
FAX (local) 720-2391
FAX 1-800-272-2391
(TDD/TTY) 726-4333

March 11, 1997

Ms. Colleen Casey
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Colleen,

As per our telephone conversation today, I am providing the additional information that you requested for completing our license amendment. This information is in reference to control #302294 for our license #22-02396-03.

Our request is for the licensing of 2 Curie Limit of Gadolinium-153 line sources is to be authorized by the following user's of the license:
Roger T. Collins, M.D.
Mark B. Kilen, M.D.
Charles C. Drexler, M.D.
Russell E. Reichter, M.D. (RSO)
William Schwartau, M.D.
Douglas J. Lane, M.D.
William D. Witrak, M.D
Patrick Schoenfelder, M.D.
Bruce J. Derauf, M.D.
David G.A. Alexander, M.D.
Michael E. Ryan, M.D.
Michael R. Rich, M.D.
Michael J. Lucca, M.D.

With the potential for both of our new camera systems to have the Vantage Gd-163 line source added to each camera/detector, I am asking that we further amend the quantity of line sources from 2 to 4, with a potential maximum of 8 line sources. This further changes our maximum potential Curie Limit from the original request of 1 to 2.

Pm: 3-11-97

Should you need additional information please contact me at the address below. Thank you for your assistance in determining the proper licensing requirements for our site. Your suggestions and advice has been very helpful.

Sincerely,

Patrick J. Engelhaupt
Director Imaging Services
St. Mary's Medical Center
407 East Third St.
Duluth MN, 55805
(218) 726-4040

c: Mark Huber
R.E. Reichter, M.D. (RSO)