NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 39

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.

301749

Licensee	
1. Crittenton Hospital, Radiology	In accordance with the letter dated August 15, 1990
2. 1101 W. University Drive Rochester, MI 48307-1831	3. License Number 21-13562-01 is amended in its entirety to read as follows:
	4. Expiration Date January 31, 2001
	5. Docket or Reference No. 030-02157

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 (not to exceed 1 curie of I-131)
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. Four sources, not to exceed 300 millicuries each

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

0/1

2 ML 30 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-13562-01
Docket or Reference Number: 030-02157
Amendment No. 39

C. Medical use described in 10 CFR 35.300

D. In vitro studies.

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

CONDITIONS

10. Location of Use: 1101 W. University Drive, Rochester, Michigan.

11. Radiation Safety Officer: Alan A. Reidinger, 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. Alan A. Reidinger, M.D.	10 CFR 35.100, 35.200, 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
B. Ken Yen Shei, M.D.	10 CFR 35.100, 35.200, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
C. Doo Dyun Bahn, M.D.	10 CFR 35.100, 35.200, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
D. Alexander S. Ullman, M.D.	10 CFR 35.100 and 31.11.
E. Kanak Jarde, M.D.	10 CFR 35.100, 35.200, Soluble phosphorus-32 for treatment of polycythemia vera, leukemia, and bone metastases, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
F. Manijeh Hakimi, M.D.	10 CFR 31.11.
G. Richard K. J. Brown, 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: 21-13562-01
Docket or Reference Number: 030-02157
Amendment No. 39

13. 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.

14. 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 November 2, 1990; and

    B. Letters dated August 15, 1996 and October 2, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/23/96

By Michael F. Weber
Nuclear Materials Licensing Branch, Region III

COPY

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 2B
Exp. Date: 20010131
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: CRITTENTON HOSPITAL
   Received Date: 960820
   Docket No: 3002157
   Control No.: 301749
   License No.: 21-13562-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: 0

3. COMMENTS

Signed D. Hersey
Date 8-23-96

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

1. Fee Category and Amount: 7C 2B $440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 10/15/96

Log Aug 12 III
Remitter
Check No. 147431
Amount $440
Fee Category 7C 2B
Type of Fee AMD
Date Check Rec'd 10/15/96
Date Completed
By: SC

96 AUG 26 AM 11:20

CRITTENTON

Michael Chopp, Ph.D.
Crittenton Hospital,
Dept. of Radiology
1101 W. University Dr.
Rochester MI.48063
August, 15 1996

Materials Licensing Center
US Nuclear regulatory Commission, Region III
801 Warrensville Road
Lisle, IL 60532-4351

Re: License No. 21-13562

Dear Sir:

We request to amend our radioactive materials license to accomodate a total of 800 millicuries of Gd-153 in order to aquire the Vantage Nonuniform Attenuation Correction system for quality control of our camera. This system contains two line sources, with an activity of 200-250 mCi per line source. We will conform to all NRC radiation protection requirements and recommendations. This line source will be leak tested every six months.

Thank you for your consideration.

Sincerely,

Michael Chopp, Ph.D.
Medical Physicist

PM 8/16/96

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

CRITTENTON HOSPITAL
ATTN: MICHAEL CHOPP, PH.D.
MEDICAL PHYSICIST
1101 W. UNIVERSITY DRIVE
ROCHESTER, MICHIGAN 48307-1831

TYPE OF ACTION

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

REQUESTED DATE: 8-15-96

LICENSE NUMBER: 21-13562-01

CONTROL NUMBER: 301749

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	$ 0.00
AMOUNT DUE	$ 440.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. 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	8/28/96	

Distribution: OC/DAF/RF
Pending Fee File: OC/DAF/SF(LF-3 2 7)
LFARB R/F (2) Region 3

DATE: Aug. 28, 1996

NRC FORM 577 (1-95)

OCT 24 1996

Alan A. Reidinger, M.D.
Radiation Safety Officer
Crittenton Hospital
1101 W. University Drive
Rochester, MI 48307-1831

Dear Dr. Reidinger:

This refers to the letters dated August 15, 1996 and October 2, 1996 from your medical physicist, Michael Chopp, Ph.D., and to our phone conversation on October 21, 1996.

Enclosed is Amendment No. 39 to your NRC License No. 21-20242-01 in accordance with your request.

As we discussed on October 21, 1996, your license was also updated in accordance with current NRC policy. Specifically: (1) the previous License Condition No. 13 was dropped since molybdenum-99/technetium-99m generators are no longer used at your facility, (2) the previous License Condition No. 14 was dropped since it has been superseded by NRC regulations, (3) License Condition No. 13, which contains a general possession limit, was added, and (4) License Condition No. 14 was updated.

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

301749

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.: 21-13562-01
Docket No.: 030-02157

Enclosure: Amendment No. 39

DOCUMENT NAME: M:\03002157.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	C							
NAME	MWEBER:jaw								
DATE	10/23/96								

OFFICIAL RECORD COPY

SEP 2 3 1996

Michael Chopp, Ph.D.
Medical Physicist
Crittenton Hospital
Dept. of Radiology
1101 W. University Drive
Rochester, MI 48307

Dear Dr. Chopp:

We have reviewed your letter dated August 15, 1996 requesting an amendment to License No. 21-13562-01 and find that we need additional information as follows.

ROOM CHANGES

State whether the addition of the ADAC unit will require any changes to the rooms for which sketches are included in your license. If room changes are necessary, you must submit updated sketches of the modified areas.

AUTHORIZED USERS

State which physicians currently listed on the license will use this device. Please note, the physicians must be qualified to use materials included in 10 CFR 35.200.

ACTIVITY

The maximum activity approved by NRC per source is 300 millicuries. Your letter indicates that the maximum activity is 250 millicuries. Please clarify.

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 301749.

If your have any questions or require clarification on any of the information stated above, you may contact us at (630) 829-9887.

Sincerely,
Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No. 21-13562-01
Docket No. 030-02157

DOCUMENT NAME: M:\03002157.CL6

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

OFFICE	DNMS/RIII	C									
NAME	MWEBER:jaw										
DATE	09/20/96										

OFFICIAL RECORD COPY

CRITTENTON

Michael Chopp, Ph.D.
Medical Physicist
Crittenton Hospital
Dept. of Radiology
1101 W. University Drive
Rochester, MI
October 2,1996
License # 21-13562-01
Docket # 030-02157

Michael F. Weber
Nuclear Materials Licensing Branch
United States
Nuclear Regulatory Commisssion
Region III
801 Warrenville Road
Lisle, Illinois 60632-4351

Dear Mr. Weber:

Thank you for your letter dated September 23,1996. The following is the information you requested concerning our application.

ROOM CHANGES: The addition of the ADAC unit will not necessitate any changes to the room.

AUTHORIZED USERS: Alan A. Reidinger, M.D.; Ker Yen Shei, M.D.; Doo Dyun Bahn, M.D.; Kanak Jarde, M.D.; Richard K.J. Brown, M.D. All the mentioned physicians are qualified and approved to use materials included in 10 CFR 35.200.

ACTIVITY: We are requesting a maximum activity per source of 30 millicuries.

Thank you for your efforts. I hope that the information provided clarifies any questions you may have had concerning our application.

Sincerely,

RECEIVED
OCT 2 1 1996
REGION III

Michael Chopp, Ph.D.
Medical Physicist

10-9-96

CRITTENTON HOSPITAL
1101 W. University Drive • Rochester, MI 48307-1831 • (313) 652-5000

OCT 2 1 1996