

MATERIALS LICENSE

Amendment No. 40

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.

301847

Licensee

1. Bloomington Hospital
2. P.O. Box 1149
Bloomington, IN 47402

In accordance with the letter dated
September 10, 1996
3. License Number 13-10408-C2 is amended in
its entirety to read as follows:

4. Expiration Date August 31, 2000

5. Docket or
Reference No. 030-016446. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Any byproduct
material identified
in 10 CFR 35.100A. Any
radiopharmaceutical
identified in 10 CFR
35.100

A. As needed

B. Any byproduct
material identified
in 10 CFR 35.200B. Any
radiopharmaceutical
identified in 10 CFR
35.200

B. As needed

C. Any byproduct
material identified
in 10 CFR 35.300C. Any
radiopharmaceutical
identified in 10 CFR
35.300(excluding
iodine-131 for
thyroid carcinoma)C. As needed (not to
exceed one curie of
iodine-131)D. Any byproduct
material identified
in 10 CFR 35.400D. Any brachytherapy
source identified in
10 CFR 35.400

D. As needed

E. Any byproduct
material identified
in 10 CFR 31.11

E. Prepackaged Kits

E. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

220033

9610220203 960925
PDR ADOCK 03001644
C PDR

COPY

2 ML
30
SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-10408-02

Docket or Reference Number

030-01644

Amendment No. 40

- C. Medical use described in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma).
D. Medical use described in 10 CFR 35.400.
E. In vitro studies.

CONDITIONS

10. Locations of Use: 605-625 West Second Street, Bloomington, Indiana and 2620 Coda Drive, Bloomington, Indiana.
11. Radiation Safety Officer: William Van de Riet, Ph.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 UsersMaterial and Use

- | | |
|-----------------------------------|--|
| A. Douglas D. Geiger, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| B. Jonathan T. Stafford, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| C. Donald C. Buehner, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11. |
| D. Philip R. Doering, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11. |
| E. James G. Ferguson, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11. |
| F. Julie A. Hornback-Widman, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding Iodine-131 for thyroid carcinoma) and 31.11. |
| G. Bruce N. Monson, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma), and 31.11. |
| H. Phillip S. Rudman, M.D. | 10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma). |
| I. George K. Wolfer Jr., M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding Iodine-131 for thyroid carcinoma) and 31.11. |
| J. Douglas W. Widman, M.D. | 10 CFR 35.300 (excluding Iodine-131 for thyroid carcinoma), 35.400 and 31.11. |

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-10408-02

Docket or Reference Number

030-01644

Amendment No. 40

Authorized UsersMaterial and Use

- K. Bharati R. Kharkar, M.D. 10 CFR 35.400, 31.11, phosphorus-32 for treatment of polycythemia vera, leukemia, bone metastases and intracavity treatments, and strontium-89 for palliative treatment of bone metastases.
- L. Stephen L. Bellis, M.D. 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma), 35.400 and 31.11.
- M. T. L. Megremis, M.D. 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma), 35.400 and 31.11.
- N. Roger A. Reimers, M.D. 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma), 35.400 and 31.11.
13. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.
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.
15. This license is based on the licensee's statements and representations listed below:
- A. Application dated April 25, 1990; and
- B. Letters dated March 7, 1991, June 30, 1994, and September 10, 1996; and
- C. Letter received July 14, 1994.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

9/25/96

By

Michael T. Webb
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: 20000831
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A REGION

1. APPLICATION ATTACHED

Applicant/Licensee: BLOOMINGTON HOSPITAL
Received Date: 960919
Docket No: 3001644
Control No.: 301847
License No.: 13-10408-02
Action Type: Amendment

2. FEE ATTACHED

Amount: 440.00
Check No.: 3806-78

3. COMMENTS

Signed
Date

Marcia Pearson
9/25/96

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
Date

SC 9/25/96

1996 SEP 25 AM 10:50

| | |
|------------------|------------|
| Log | Sep 10 III |
| Remitter | |
| Check No. | 380698 |
| Amount | 440 |
| Fee Category | 7C 2B |
| Type of Fee | AMD |
| Date Check Rec'd | 9/25/96 |
| Date Completed | |
| By: | SC |



Bloomington Hospital . PO 1149 . Bloomington, Indiana 47402 . 812-336-6821

September 10, 1996

Mailed Certified- Return Receipt

US Nuclear Regulatory Commission
Region III
Materials Licensing Branch
801 Warrenville Road
Lisle, Illinois 60532

Re: License No. 13-10408-02

Dear Staff:

We are requesting amendment of our NRC License as follows:

1. Delete Charles R. Ellis, M.D. as an authorized user on the license as he has retired from active practice.
2. Change the authorized use for Bruce N. Monson, M.D. "for material in 10 CFR 35.100, 35.200, and 31.11" to "for material in 10 CFR 35.100, 35.200, 35.300 (excluding I-131 for Thyroid CA), and 31.11". A copy of the Preceptor Statement for Dr. Monson is included.
3. Update the facility diagram for our Nuclear Medicine area to that shown on the attached sketches.

A check for the amendment fee is attached.

Sincerely yours,

Nancy Carlstedt
President

Enclosure: Preceptor Statement
Facility Diagram
\$440 Check

a:\msword\usnrc.doc

RECEIVED

SEP 19 1996

REGION III

301847
OCT 02 1996
SEP 19 1996

pm: 9-17-96

EXHIBIT 3
SUPPLEMENT 8

[illegible]

**EXHIBIT 3
SUPPLEMENT B**

| SUPPLEMENT | | 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. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS <div style="border-bottom: 1px solid black; margin-bottom: 5px;">FULL NAME Bruce Nathaniel Monson, M.D.</div> <div style="border-bottom: 1px solid black; margin-bottom: 5px;">STREET ADDRESS 9665 Harbor Point Dr. #54</div> <div style="display: flex; justify-content: space-between;"> <div style="border-bottom: 1px solid black; width: 30%;">CITY Bloomington</div> <div style="border-bottom: 1px solid black; width: 30%;">STATE IN</div> <div style="border-bottom: 1px solid black; width: 30%;">ZIP CODE 47401</div> </div> | | KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: 1-Secondary evaluation of patients to determine the suitability for radioactive diagnosis and/or treatment and recommendation for physical course. 2-Participation in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. 3-Admission 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 <small>A</small> | CONDITIONS DIAGNOSED OR TREATED <small>B</small> | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION <small>C</small> | COMMENTS <small>(Additional information or examples may be submitted to duplicate on separate sheets.) <small>D</small></small> |
| | Thyroid scan | 52 | |
| | Thyroid uptake | 35 | |
| | Lung perfusion scan | 245 | |
| | Xenon ventilation study | 0 | |
| | Aerosol ventilation scan | 221 | |
| | Renal flow scan | 300 | |
| | Brain scan | 5 | |
| | Liver/spleen scan | 19 | |
| | Bone scan | 726 | |
| | Gastroesophageal study | 18 | |
| | LeVeen shunt study | 0 | |
| | Cytovex | 0 | |
| | Meckel's diverticulum | 0 | |
| | Cardiac perfusion scan | 107 | |
| | Cardiac stress ventriculogram | 1 | |
| Cardiac rest ventriculogram | 96 | | |
| Cellulose scan | 94 | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

PATIENT ISOTOPE SUMMARY

TOTAL PATIENTS

BRUCE MONSUN

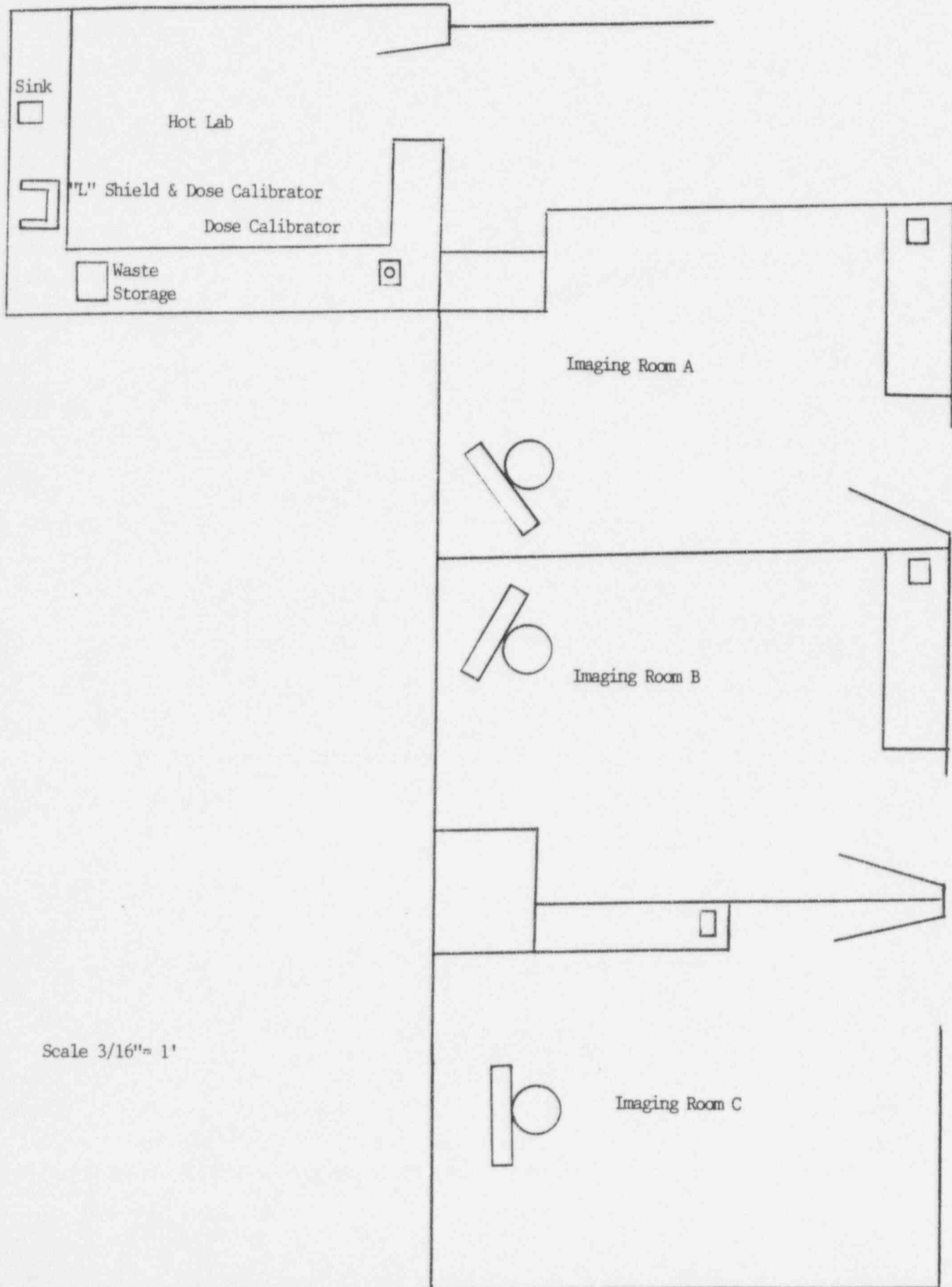
| STUDY | OCT 89 | DEC 89 | APR 90 | DEC 90 | JULY 92 | MAY 93 | TOTAL |
|---------------------------|--------|--------|--------|--------|---------|--------|-------|
| THYROID UPTAKE ONLY | 8 | 7 | 6 | 4 | 8 | 3 | 36 |
| THYROID SCAN ONLY | 14 | 11 | 9 | 6 | 9 | 3 | 52 |
| BLOOD OR PLASMA VOLUME | 1 | 1 | 2 | 1 | 1 | 1 | 7 |
| RED CELL MASS | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RED CELL SURVIVAL | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LIVER/SPLEEN SCAN | 3 | 2 | 5 | 3 | 5 | 1 | 19 |
| LIVER SPECT/ECT SCAN | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SCHILLINGS TEST | 2 | 3 | 1 | 3 | 3 | 2 | 14 |
| SCHILLINGS WITH IF | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| MECKELS/BOWEL IMAGING | 1 | 2 | 0 | 0 | 0 | 0 | 3 |
| PIPIDA | 16 | 16 | 12 | 10 | 10 | 7 | 71 |
| BONE SCAN LIMITED | 18 | 21 | 25 | 15 | 13 | 2 | 94 |
| BONE VASCULAR FLOW | 11 | 18 | 22 | 16 | 15 | 2 | 84 |
| BONE SCAN WHOLE BODY | 109 | 107 | 143 | 120 | 125 | 19 | 623 |
| 3 PHASE BONE SCAN | 9 | 0 | 0 | 0 | 0 | 0 | 9 |
| BONE SPECT/ECT SCAN | 1 | 1 | 0 | 2 | 2 | 0 | 6 |
| VASCULAR FLOW (RVEF) | 4 | 5 | 2 | 1 | 2 | 1 | 15 |
| MUGA/CARDIAC MOTION STUDY | 20 | 16 | 24 | 10 | 15 | 11 | 96 |
| THALLIUM STRESS | 7 | 17 | 12 | 23 | 16 | 10 | 85 |
| THALLIUM REST | 8 | 21 | 18 | 28 | 18 | 14 | 107 |
| THAL TREADMILL | 7 | 16 | 8 | 20 | 16 | 10 | 77 |
| MYOCARDIAL/PYP | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PERFUSION LUNG SCAN | 43 | 40 | 40 | 47 | 45 | 30 | 245 |
| VENTILATION LUNG SCAN | 36 | 35 | 41 | 43 | 41 | 25 | 221 |
| BRAIN VASCULAR FLOW | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| BRAIN IMAGING STATIC | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| BRAIN SPECT/ECT SCAN | 1 | 2 | 1 | 0 | 0 | 0 | 4 |
| CEREBRAL WASHOUT STUDY | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CISTERNOGRAM | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RENAL SCAN DTPA | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| RENAL BOLUS FLOW | 58 | 48 | 61 | 50 | 52 | 31 | 300 |
| HIPPURAN SCAN | 60 | 48 | 62 | 52 | 53 | 31 | 306 |
| RESIDUAL URINE STUDY | 8 | 6 | 10 | 0 | 0 | 0 | 24 |
| GALLIUM SCAN LIMITED | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| GALLIUM SCAN WHOLE BODY | 26 | 14 | 19 | 11 | 13 | 11 | 94 |
| I-131 WHOLE BODY SCAN | 1 | 3 | 1 | 3 | 1 | 0 | 9 |
| ADRENAL SCAN | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NUC VOIDING CYSTOGRAM | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| PARATHYROID SCAN | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| TESTICULAR SCAN | 0 | 0 | 1 | 1 | 1 | 0 | 3 |
| GASTRIC EMPTYING TIME | 7 | 7 | 0 | 1 | 3 | 0 | 18 |
| GI BLEEDING STUDY | 1 | 3 | 4 | 2 | 4 | 3 | 17 |
| BONE DENSITY SINGLE | 8 | 0 | 0 | 0 | 0 | 0 | 8 |
| BONE DENSITY DUAL | 9 | 8 | 14 | 11 | 7 | 9 | 58 |
| TOTAL NUC MFD PROCEDURES | 498 | 480 | 642 | 483 | 479 | 226 | 2708 |
| THYROID THERAPY I-131 | 2 | 3 | 2 | 2 | 0 | 2 | 11 |
| THYROID THERAPY ABLATION | 1 | 0 | 0 | 1 | 0 | 0 | 2 |
| P-32 THERAPY | 1 | 1 | 0 | 0 | 0 | 0 | 2 |
| TOTAL THERAPY PROCEDURES | 4 | 4 | 2 | 3 | 0 | 2 | 15 |

6-30-94

[Signature]

FACILITY DIAGRAM

Item 9.1



OCT 02 1996

Nancy Carlstedt
President
Bloomington Hospital
P.O. Box 1149
Bloomington, IN 47402

Dear Ms. Carlstedt:

This refers to your letter dated September 10, 1996, and to our telephone conversation with Mr. William Herbst of your staff on September 25, 1996.

Enclosed is Amendment No. 40 to your NRC License No. 13-10408-02 in accordance with your request.

As discussed with Mr. Herbst, your license was also updated in accordance with current NRC policy. Specifically: (1) License Condition No. 8.C. now includes a possession limit of one curie for iodine-131, and (2) the previous License Condition No. 15 was dropped since it has been superseded by NRC regulations.

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).

301847

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,

N. Carlstedt

-3-

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.: 13-10408-02

Docket No.: 030-01644

Enclosure: Amendment No. 40

DOCUMENT NAME: M:\03001644.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="checked" type="checkbox"/> | | | | | | | |
| NAME | MWEBER:jaw | | | | | | | | |
| DATE | 09/29/96 | | | | | | | | |

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 20, 1996

William Van De Riet, Ph.D.
Radiation Safety Officer
Bloomington Hospital
P. O. Box 1149
Bloomington, IN 47402

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated September 10, 1996)

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. 301847
License No. 13-10408-02