NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 54

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.

301914

Licensee	
1. St. Elizabeth Hospital 2. 1506 South Oneida Street Appleton, WI 54915	In accordance with letter dated September 24, 1996 3. License Number 48-10219-01 is amended in its entirety as follows: 4. Expiration Date June 30, 1994 5. Docket or Reference No. 030-03466

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 10 curies of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed sources (Byk Mallinckrodt Model CI L BV)	E. Two sources not to exceed 10 curies each

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.

270129

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01

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030-03465

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D. Medical use described in 10 CFR 35.400 and for instrument calibrations.

F. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy and for instrument calibration. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1506 South Oneida Street, Appleton, Wisconsin and at 1611 Madison Street, Appleton, Wisconsin.

11. Radiation Safety Officer: Stanley Reed, M.S.

12. Authorized Users:

A. John I. Halloran, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

B. Gregory J. Knudson, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

C. Patrick O'Brien, M.D., for material in 10 CFR 35.100 and 35.200, limited to cardiovascular clinical procedures.

D. Henry Chessin, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

E. Stanley A. Reed, M.S., for sources in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit for survey meter calibration.

F. Robert G. Brucker, M.D., for material in 10 CFR 35.100 and 35.200.

G. T. O. Reinke, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

H. Robert R. Kinde, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.400 and iridium-192 in remote afterloading brachytherapy unit.

I. James E. Murphy, M.D., for material in 10 CFR 35.100 and 35.200.

J. Timothy H. Seline, M.D., for material in 10 CFR 35.100 and 35.200.

K. Michael W. Milde, for material in 10 CFR 35.100 and 35.200.

L. Stephanus J. Macrander, M.D., for material in 10 CFR 35.100 and 35.200.

M. Fred D. Panzer, M.D., for material in 10 CFR 35.100 and 35.200.

N. Peter Podlusky, M.D., for material in 10 CFR 35.100.

O. Kent W. Powley, M.D., for material in 10 CFR 35.100 and 35.200.

P. Sue A. Hausserman-Dugan, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

Q. Uri Vaisman, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

R. Rosita Sio Go, M.D., for material in 10 CFR 35.300, 34.400, 35.500 and iridium-192 in remote afterloading brachytherapy unit.

S. William O. Fletcher, M.D., for material in 35.100 and 35.200 limited to cardiovascular clinical procedures.

T. M. David Yoseloff, M.D., for material in 35.100, 35.200 and 35.500.

U. John R. Iglar, M.D., for material in 10 CFR 35.100 and 35.200.

V. Robert A. Belgam, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 in remote afterloading brachytherapy unit.

W. Kevin Dul, M.D., for material in 10 CFR 35.100 and 35.200.

X. Marion H. Scholz, M.D., for material in 35.400 and iridium-192 in remote afterloading brachytherapy unit.

Y. Brian Hebl, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

Z. Stephen M. Brink, M.D., for material in 10 CFR 35.500.

13. Pursuant to 10 CFR 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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Docket or Reference Number
030-03466

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14. The licensee shall maintain records of information related to decommissioning at the location listed in item 2 as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

15. A. Access to the rooms housing the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

16. Prior to initiation of a treatment program, and subsequent to each source exchange for the Nucletron, Micro-Selectron HDR afterloading brachytherapy units, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.

(2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101.

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b)

B. Records of the survey results shall be maintained for inspection by the Commission for the duration of the license.

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C30-03466

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17. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of the sealed sources contained in the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit(s).

B. Any maintenance or repair operations on the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

18. 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 December 27, 1988 (except Item 9.3.2.G.5., and Attachment 10.12.4); and

B. Letters dated August 10, 1988, December 5, 1988, December 30, 1988, March 29, 1989 (excluding Item 4.C. and Item 5.), July 1., 1989, February 25, 1992, April 2, 1992, September 14, 1992. November 5, 1992, December 11, 1992, and letter dated September 24, 1996 (excluding the request for exemption from 10 CFR 35.404).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Nov 6, 1996

By _____
Nuclear Materials Licensing Branch, Region III

R9

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 2
Fee Category: 7C 2B
Exp. Date: 19940630
Fee Comments: CODE 21
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. ELIZABETH HOSPITAL
   Received Date: 961003
   Docket No: 3003466
   Control No.: 301914
   License No.: 48-10219-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 323134

3. COMMENTS

Signed D. Hersey
Date 10/16/96

1996 OCT 18 PM 3:43

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 AC
Date 10/18/96

OCT 28 1996

Log OCT 7 III
Remitter
Check No. 323134
Amount #440
Fee Category 7C 2B
Type of Fee AMD
Date Check Rec'd 10/4/96
Date Completed 10/4/96
By: AC

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

September 24, 1996

United States Nuclear Regulatory Commission
Region III
Medical Licensing Department
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No. 48-10219-01

Dear Medical License Reviewer:

St. Elizabeth Hospital is requesting an amendment to their byproduct material license to allow the use of radionuclides at an additional address (1611 Madison Street). This building is adjacent to St. Elizabeth Hospital and will have an enclosed connecting passage linking the two buildings. One of the existing nuclear medicine imaging cameras will be relocated to this facility and existing technical staff will cover both areas. Radionuclides will be received at both locations and complete hot lab facilities will also be maintained at both areas. The waste decay-in-storage will use the existing basement locked room at St. Elizabeth Hospital. Please refer to the attached blueprint which provides the layout of the proposed cardio-pulmonary center. All existing license safety requirements and procedures will be maintained for this new use area in accordance with our current byproduct license.

In addition, St. Elizabeth Hospital requests that if patients receive temporary episcleral treatments (eye plaques) using I-125 sealed sources they can be released from hospital confinement while the sealed sources are in place (exception to §35.404). Radiation safety requirements for the public (§20.1301) will be maintained and radiation safety guidance will be provided to the patient.

Please contact S. Reed (414-738-2190) for questions regarding these requests. A timely response would be appreciated so that the project plan may continue.

Respectfully submitted,

Otto L Cox
Otto L. Cox, Chief Executive Officer

Stanley A. Reed
Stanley A. Reed, MS, Medical Physicist

Attachment

RECEIVED
OCT 0 3 1996
REGION III
OCT 0 3 1996

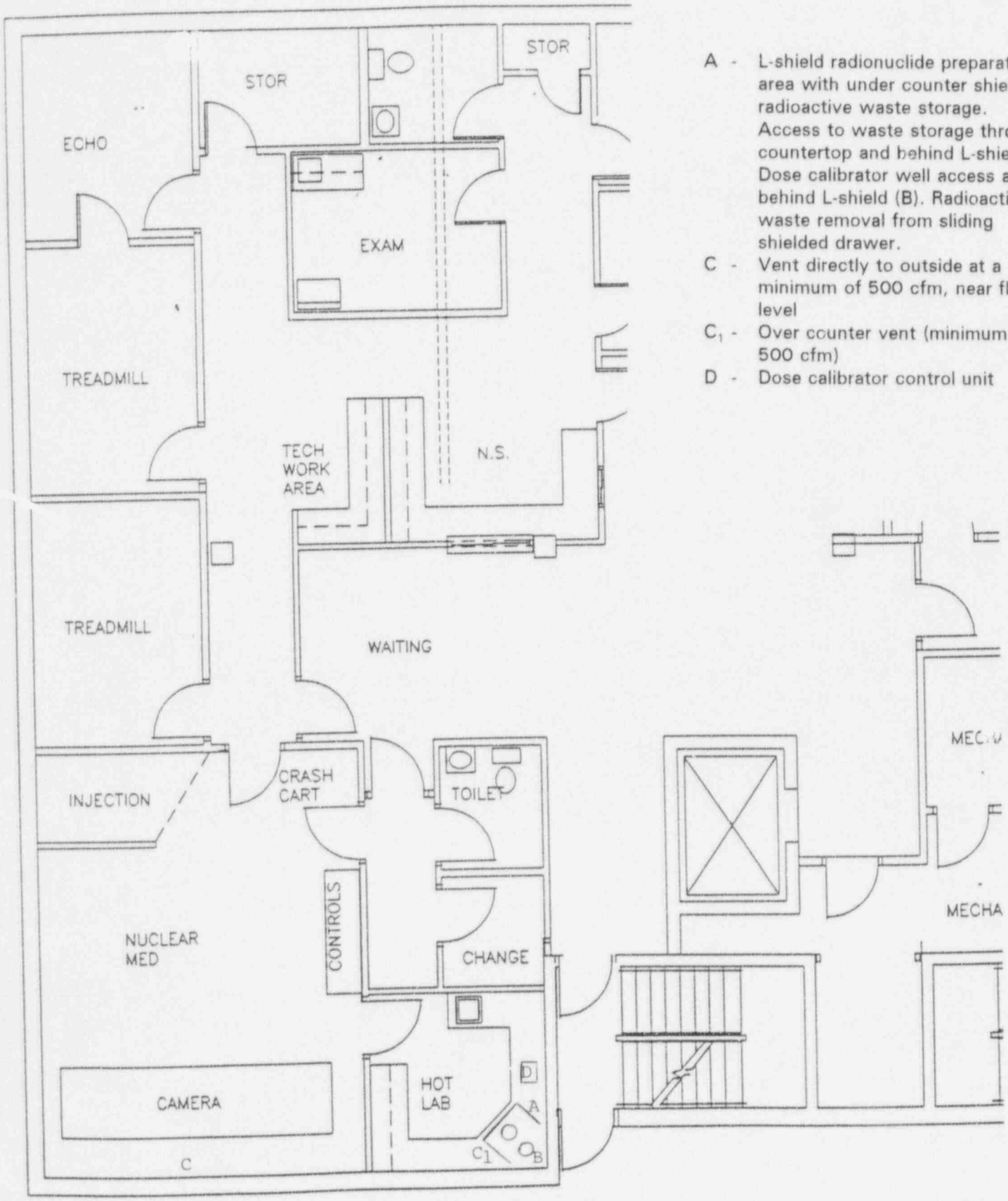
pn: 9-30-96

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949

301914

N →

Cardio-Pulmonary Center



A - L-shield radionuclide preparation area with under counter shielded radioactive waste storage. Access to waste storage through countertop and behind L-shield. Dose calibrator well access also behind L-shield (B). Radioactive waste removal from sliding shielded drawer.

C - Vent directly to outside at a minimum of 500 cfm, near floor level

C_1 - Over counter vent (minimum 500 cfm)

D - Dose calibrator control unit

BASEMENT FLOOR PLAN

SCALE: 1/8" = 1'-0"

NOV 0 7 1996

Stanley A. Reed, M.S.
Medical Physicist
St. Elizabeth Hospital
1506 South Oneida Street
Appleton, WI 54915

Dear Mr. Reed:

Enclosed is Amendment No. 54 to your NRC Material License No. 48-10219-01 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 note License Condition No. 18.B. By referencing your letter dated September 24, 1996, we have approved your new facility at 1611 Madison Street. However, we have not granted you an exception to the requirements of 10 CFR 35.404 at this time. In order to continue our review of your exemption request we need additional information. When submitting this additional information, you must indicate in your correspondence that it is additional information to Control No. 301914. We will re-activate our review of your request when you provide the following information.

1. Provide an explanation or justification as to why you cannot or choose not to abide by the requirements of 10 CFR 35.404;

2. Describe how the iodine-125 eye plaques will be controlled to prevent their loss or mis-use by the patient when outside the control of the hospital;

3. Provide a copy of the radiation safety guidance that you will provide to the patients.

4. Provide calculations and the results of your evaluations demonstrating compliance with the dose limits of 10 CFR 20.1301.

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:

301914

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.

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
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 48-10219-01
Docket No.: 030-03466

Enclosure: Amendment No. 54

DOCUMENT NAME: M:\03003466.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	N							
NAME	EMATSON:jaw								
DATE	11/6/96								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

October 7, 1996

Stanley A. Reed, M.S.
Radiation Safety Officer
St. Elizabeth Hospital
Department of Radiology
1506 South Oneida Street
Appleton, WI 54915

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 09/24/96)

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 X 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. 301914
License No. 48-10219-01