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

MAY 02 2001

Brian Hebl, M.D.
Radiation Safety Officer
Shawano Medical Center
309 N. Bartlette Street
Shawano, WI 54166

Dear Dr. Hebl:

Enclosed is Amendment No. 5 to your NRC Material License No. 48-32078-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

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, we have authorized you to use iodine-131 capsules for the treatment of hyperthyroidism only at Shawano Medical Center location at 309 N. Bartlette Street, Shawano, Wisconsin. We have not authorized you to use iodine-131 capsules for the treatment of hyperthyroidism at temporary jobsites.

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 the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application 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 Statement of Policy and Procedure 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,

William P. Reichhold

William P. Reichhold
Materials Licensing Branch

License No. 48-32078-01
Docket No. 030-34709

Enclosure: Amendment No. 5

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 5

MATERIALS LICENSE

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.

PO2220 30872

Licensee	
1. Shawano Medical Center 2. 309 N. Bartlette Street Shawano, WI 54166	In accordance with the letter received February 21, 2001, and facsimiles dated April 12, 2001 and April 20, 2001 3. License number 48-32078-01 is amended in its entirety to read as follows: 4. Expiration date June 30, 2003 5. Docket No. 030-34709 Reference No.

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. Iodine-131	**C. As identified in 10 CFR 35.300 (capsules only)**	**C. 1 Curie**

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 (limited to diagnosis and treatment of hyperthyroidism).

CONDITIONS

10. A. Licensed material in Items 6.A., 6.B., and 6.C. shall be received, stored, and used only at the licensee's facilities located at 309 N. Bartlette Street, Shawano, Wisconsin.

B. Licensed material in Items 6.A. and 6.B. (excluding generators and xenon-133) may be used only at temporary job sites of medical care facilities anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-32078-01

Docket or Reference Number
030-34709

Amendment No. 5

11. The Radiation Safety Officer for this license is Brian Hebl, 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. Robert Brucker, M.D.	10 CFR 35.100 and 35.200.
B. Kevin Dull, M.D.	10 CFR 35.100 and 35.200.
C. Stephanus J. Macrander, M.D.	10 CFR 35.100 and 35.200.
D. James E. Murphy, M.D.	10 CFR 35.100 and 35.200.
E. Kent W. Powley, M.D.	10 CFR 35.100 and 35.200.
F. John E. Sowin, M.D.	10 CFR 35.100, 35.200, **and Iodine-131 (capsules only) for treatment of hyperthyroidism.**
G. John R. Iglar, M.D.	10 CFR 35.100 and 35.200.
H. Gregory J. Knudson, M.D.	10 CFR 35.100, 35.200, **and Iodine-131(capsules only) for treatment of hyperthyroidism.**
I. Michael W. Milde, M.D.	10 CFR 35.100 and 35.200.
J. Fred D. Panzer, M.D.	10 CFR 35.100 and 35.200.
K. Brian Hebl, M.D.	10 CFR 35.100, 35.200 **and Iodine-131(capsules only) for treatment of hyperthyroidism.**
L. William O. Fletcher, M.D.	10 CFR 35.100 and 35.200 limited to cardiovascular clinical procedures
M. Michael Gitter, M.D.	10 CFR 35.100 and 35.200.
N. Stephen M. Bejvan, M.D.	10 CFR 35.100 and 35.200.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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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 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 March 27, 1998 (with attachments); and

B. Letters dated June 22, 1998, June 1, 1999, October 25, 1999 (with attachments), and May 22, 2000; and

C. Letter received February 21, 2001 (except Quality Management Program); and

D. Facsimile dated April 12, 2001 (except Quality Management Program).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 02 2001

By William P. Reichhold

William P. Reichhold
Materials Licensing Branch
Region III

facsimile
TRANSMITTAL

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION 3
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
FAX (630) 515-1259

Name:	**Sheri Kruger, Chief Nuclear Medicine Technologist**
Organization:	**Shawano Medical Center**
Fax:	**(715) 526-7249**
From:	**Bill Reichhold**
Date:	**April 3, 2001**
Pages:	**1**

The following additional information is needed to complete the review of your request.

1. Please specify a total possession limit for the Iodine-131 you plan to use for radiopharmaceutical therapy. You may request up to 1 Curies without additional justification.

2. According to 10 CFR 35.29, radiopharmacuetical therapy is not an activity authorized for mobile nuclear medicine services. Please clarify if your request for radiopharmaceutical therapy is for use only at Shawano Medical Center, located at 309 N. Bartlette Street, Shawano, Wisconsin.

3. Please submit your safety procedures for Iodine-131 therapy over 33 millicuries. OR If you will not administer over 33 millicuries of Iodine-131, please state so.

4. Please specify if you will be following the procedures in Regulatory Guide 8.39 for release of patients administered radioactive materials. If not, please confirm that you will comply with the requirements in 10 CFR 35.75. Please contact me at 630-829-9839 if you need a copy of Reg Guide 8.39.

5. The Quality Management Program (QMP) submitted with your request specifies that Iodine-125 and Strontium-89 will be used. Please clarify if you will be using only Iodine-131 or will you be using other radionuclides for radiopharmaceutical therapy. If you will be only using Iodine-131, please revise your QMP to indicate that only Iodine-131 will be used. Please submit a QMP if you plan to use other radiopharmaceuticals (such as Sr-89) for therapy.

6. Item 6.1 of your QMP states that you will investigate and report to that RSO any misadministration or recordable event, however, you do not specify any corrective actions. Please revise your QMP and include a description of your specific corrective actions.

Please send a facsimile of your response to the above within 7 days and refer to control 308712. Please call me at 630-829-9839 if you have any questions.

From the desk of:
Bill Reichhold
Bill Reichhold

facsimile
TRANSMITTAL

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION 3
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
FAX (630) 515-1259

Name:	Sheri Krueger, Chief Nuclear Medicine Technologist
Organization:	Shawano Medical Center
Fax:	(715) 526-7249
From:	Bill Reichhold
Date:	April 20, 2001
Pages:	1

The following additional information is needed to complete the review of your request.

1. Your response to Item 6 in facsimile dated April 3, 2001, did not specifically address corrective actions after a misadministration or recordable event. Please confirm that the Radiation Safety Officer (RSO) will take corrective actions when appropriate, after a misadministration or recordable event. Also confirm that the RSO will follow-up on the corrective actions to ensure that they were effective.

Please send a facsimile of your response to the above within 3 days and refer to control 308712. Please call me at 630-829-9839 if you have any questions.

From the desk of:
Bill Reichhold
Bill Reichhold

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
February 28, 2001

Brian Hebl
Radiation Safety Officer
Shawano Medical Center
309 N. Bartlette Street
Shawano, WI 54166

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE (LETTER DATED 2/13/2001)

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 _____ Termination

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 1-2 below, as applicable).

1. New and Amendment actions are normally completed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance. If you are applying for a new NRC License, you are required to provide your taxpayer identification number to our Fees Department. Please fill out the enclosed NRC Form 531 as requested.

2. Termination actions are normally completed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our License Fee & Accounts Receivable Branch (301/415-6097) for approval of the fee category and amount, if required.

We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number. Please direct any questions concerning your request to the Materials Licensing Branch at (630) 829-9887.

Materials Licensing Branch

Mail Control No. 308712
License No. 48-32078-01