

MATERIALS LICENSE

Amendment No. 18

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.

301937

Licensee

1. Langlade Memorial Hospital
2. 112 East Fifth Avenue
Antigo, WI 54409

In accordance with letter dated
October 2, 1996
3. License Number 48-17481-01 is amended
in its entirety to read as follows:

4. Expiration Date November 30, 2003

5. Docket or
Reference No. 030-128236. 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. Iodine-131

C. Any
radiopharmaceutical
identified in 10 CFR
35.300C. Not to exceed
1 curie

D. Strontium-89

D. Any
radiopharmaceutical
identified in 10 CFR
35.300

D. As needed

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.
- C. and D. Medical use described in 10 CFR 35.300.

050019

9702050298 970114
PDR ADOCK 03012823
C PDR

COPY

d/ ml
230
50

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

48-17481-01

Docket or Reference Number

030-12823

Amendment No. 18

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 112 East Fifth Avenue, Antigo, Wisconsin.
11. Radiation Safety Officer: F. Joseph McCauslin, D.O.
Alternate Radiation Safety Officer: David J. Hadford, M.D.
12. Authorized Users:
 - A. F. Joseph McCauslin, D.O., for material in 10 CFR 35.100, 35.200 and I-131 in amounts not to exceed 30 millicuries per treatment and Sr-89.
 - B. David J. Hadford, M.D., for material in 10 CFR 35.100, 35.200 and I-131 in amounts not to exceed 30 millicuries per treatment and Sr-89.
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 June 15, 1993; and
 - B. Letters dated April 14, 1994 (with attachments), April 12, 1995, June 19, 1995, July 6, 1995, and April 30, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 14, 1997

By

Richard W. Water
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
Exp. Date: 20031130
Fee Comments: CODE 21
Decon Fin Assur Req'd: N

SS

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: LANGLADE MEMORIAL HOSPITAL
Received Date: 961009
Docket No: 3012823
Control No.: 301937
License No.: 48-17481-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 74783

3. COMMENTS

Signed
Date

S. Hersey
10-16-96

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
Date

SC 10/22/96

OCT 28 1996

Log	OCT 8 III
Remitter	
Check No.	74783
Amount	\$440
Fee Category	7C
Type of Fee	Amnd
Date Check Rec'd	10/21/96
Date Completed	10/22/96
By:	SC

1996 OCT 21 AM 11:39



LANGLADE COUNTY MEMORIAL HOSPITAL

Religious Hospitaliers of St. Joseph

October 2, 1996

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

RE: Amendment to NRC Radioactive Materials License #48-17481-01

Dear Sir or Madam:

Please amend the above referenced radioactive materials license to reflect the following:

1. Delete the following physicians from our authorized user list:

D. M. Nowinski, M.D.	G. H. Brister, M.D.
Henry Kamemoto, M.D.	Vina Luthra, M.D.
Donald M. Nowinski, M.D.	John R. Sorenson, M.D.
Christopher Kelly, M.D.	C.R. Edmonson, M.D.
James Collison, M.D.	

2. Please add the use of I-131 and Sr-89 as described in 10 CFR 35.300 to our authorized use list. We verify that we will not perform procedures using I-131 in amounts over 30 millicuries. The possession limit will be "as needed".
3. Please add F. Joseph McCauslin, D.O. and David J. Hadford, M.D. for authorized use of I-131 (in amounts less than 30 mCi) and Sr-89. Attached is the documentation of their training and experience.

RECEIVED

OCT 09 1996

REGION III

Pm: 10-7-96

112 East Fifth Avenue, Antigo, WI 54409
715-623-2331

OCT 09 1996
301937

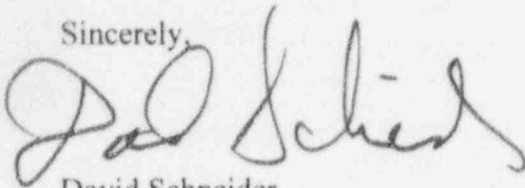
4. Attached is a copy of our Quality Management Program which will be implemented for these procedures.

Enclosed is a check in the amount of \$440.00 to cover the amendment processing fee.

If you have any questions, please call Scott Henricks in the Nuclear Medicine Department at 715-623-9274.

Thank you for your assistance.

Sincerely,

A handwritten signature in dark ink, appearing to read "David Schneider". The signature is fluid and cursive, with the first name "David" written in a larger, more prominent script than the last name "Schneider".

David Schneider
Administrator

**EXHIBIT 3
SUPPLEMENT B**

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p><i>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.</i></p>			
<p>1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS</p> <p>FULL NAME David J. Badford, M.D.</p> <p>CITY Antigon</p> <p>STATE WI</p> <p>ZIP CODE 54409</p>		<p>KEY TO COLUMN C</p> <p>PERSONAL PARTICIPATION SHOULD CONSIST OF:</p> <p>1. Supervised examination of patients to determine the indication for radiopharmaceutical diagnosis and/or treatment and recommendation for subsequent steps.</p> <p>2. Collaboration in dose calibration and exact administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.</p> <p>3. Supervised period of training to ensure physician is capable of performing procedures and to ensure patients through diagnosis and/or therapy of treatment.</p>	
<p>2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN</p>			
ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be written in duplicate on separate sheet.) D
	Thyroid scan	38	
	Thyroid uptake	62	
	Lung perfusion scan	213	
	Lung ventilation study	180	
	Aerosol ventilation scan	6	
	Renal flow scan	37	
	Brain scan	51	
	Liver/spleen scan	4	
	Bone scan	115	
	Gastrointestinal study	25	
	LeVeen shunt study	1	
	Cystogram	0	
	Barium swallow	0	
	Cardiac perfusion scan	363	
	Cardiac stress ventriculogram	1	
	Cardiac rest ventriculogram	79	
Gallium scan	5		

EXHIBIT 3 (Continued)

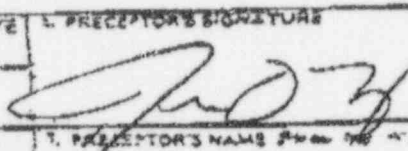
PROPOSED PHYSICIAN USER			
David J. Hadford, M.D.			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
ISOTOPE	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS (Additional information or comments may be included (not in duplicate on separate sheet.)
A	B	C	D
P-32 (Bone)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	2	
P-32 (Cervical)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	17	
Am-241	INTRACAVITARY TREATMENT		
Co-60	INTERSTITIAL TREATMENT		
Co-137	INTRACAVITARY TREATMENT		
Li-6	INTERSTITIAL TREATMENT		
Co-60	TELETHERAPY TREATMENT		
S-80	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Na-22/ Tl-201	GENERATOR		
Sm-153/ In-113m	GENERATOR		
Ta-182m	REAGENT KITS		
Count	Sr89Cl Treatment of Bone Metastasis	3	
3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING			
LOCATION		DATES	CLOCK HOURS OF EXPERIENCE
Creighton University Radiology Program		7/1/91 - 6/30/95	640
4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR'S SIGNATURE	
a. NAME OF SUPERVISOR			
John D. Terry, M.D.			
b. NAME OF INSTITUTION			
Creighton University/St. Joseph Hos.			
c. MAILING ADDRESS		6. PRECEPTOR'S NAME (Print name in print)	
601 North 30th Street		John D. Terry, M.D.	
d. CITY		Vice Chair, Department of Radiology	
e. STATE		f. DATE	
Omaha, Nebraska 68131		2/14/96	
g. MATERIALS LICENSE NUMBER(S)			
01-05-01			

EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER David J. Radford, M.D.		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED Nebraska/North Dakota		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
American Board of Radiology		Board Eligible Passed Writens		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	Creighton University Radiology Program 7/1/91 - 6/30/95	100	640	
b. RADIATION PROTECTION	Creighton University Radiology Program 7/1/91 - 6/30/95	30	640	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Creighton University Radiology Program 7/1/91 - 6/30/95	20	640	
d. RADIATION BIOLOGY	Creighton University Radiology Program 7/1/91 - 6/30/95	20	640	
e. RADIOPHARMACEUTICAL CHEMISTRY	Creighton University Radiology Program 7/1/91 - 6/30/95	30	640	
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	HOW USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Tc-99m	100	St. Joseph Hospital	640	Nuc Med
I-131	150	St. Joseph Hospital	640	Nuc Med
SR-89	10	St. Joseph Hospital	640	Nuc Med

SFN 6733
CRM
RAD 686

NORTH DAKOTA DEPARTMENT OF HEALTH

Page 1 of 10 pages
Amendment No. 48

RADIOACTIVE MATERIAL LICENSE

Pursuant to Section 23-20.1-01 through Section 23-20.1-11 of Chapter 23-20.1 of the North Dakota Century Code, and Article 33-10 of the North Dakota Administrative Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of the North Dakota Department of Health and to any conditions specified below:

License		3. License Number 33-09805-01 is amended in its entirety.
1. Name	UniMed Medical Center	4. Expiration Date
2. Address	Third Street SE and Burdick Expressway Minot, ND 58701	December 31, 1997
		5. Reference Number
		072

6. Radioactive Materials (element and mass number)	7. Chemical and/or physical form	8. Maximum quantity which licensee may possess at any one time
A. Any radioactive - material identified in Subsection 1 ("Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies") of Section 33-10-07-06 of the ND Radiological Health Rules.	A. Any radiophar- macautical identified in Subsection 1 of Section 33-10-07- 06.	A. As needed.

SPN 6731
Form
RAD 686A

NORTH DAKOTA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Page 2 of 10

License No. 33-09905-01
Assignment No. 37

Supplemental sheet

- | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| B. Any radioactive material identified in Subsection 1 ("Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies") of Section 33-10-07-07. | B. Any radiopharmaceutical identified in Subsection 1 of Section 33-10-07-07, except radioactive gases or aerosols. | B. As needed. |
| C. Any radioactive material identified in Subsection 1 ("Use of Radiopharmaceuticals for Therapy") of Section 33-10-07-08. | C. Any radiopharmaceutical identified in Subsection 1 of Section 33-10-07-08. | C. As needed. |
| D. Any radioactive material authorized for use as calibration and reference sources by Subsection 5 of Section 33-10-07-05. | D. Any | D. As authorized by Subsection 5 of Section 33-10-07-05. |
| E. Any radioactive material authorized for in vitro clinical or laboratory tests by section 33-10-03-04 (subsection 2, subdivision f) | E. Any | E. 111 megabecquerels (3 millicuries) |
| F. Xenon 133 | F. Gas | F. 2700 megabecquerels (100 millicuries) |
| G. Cesium 137 | G. Sealed sources | G. 20 sources, no single source to exceed 2.6 gigabecquerels (70 millicuries) |

SPR 6713
Form
RAD 686A

NORTH DAKOTA DEPARTMENT OF HEALTH

RADIOACTIVE MATERIAL LICENSE

Supplemental sheet

Page 5 of 10

License No. 31-09805-01
Amendment No. 37

- B. Radioactive material listed in Items 6.A. and 6.B. (except generators), 6.D., and 6.F. may be used at the Franciscan Initiatives Incorporated Physicians Office Building at 400 SE Burdick Expressway in Minot, North Dakota.
1. The licensee shall comply with the following chapters of the North Dakota Radiological Health Rules:

Chapter 33-10-01, General Provisions
Chapter 33-10-03, Licensing of Radioactive Material
Chapter 33-10-04, Standards for Protection Against Radiation
Chapter 33-10-07, Use of Radionuclides in the Healing Arts
Chapter 33-10-10, Notices, Instructions, and Reports to Workers - Inspections
Chapter 33-10-11, Fees for Issuance of License and Registration Certificates and Inspections
Chapter 33-10-13, Transportation of Radioactive Material

- A. Radioactive material identified in Items 6, 7, and 8 may be used by, or under the supervision of, individual physicians as follows:

Physician

Authorized For

M.D. Knudsen, M.D.
D.J. Trzpuo, M.D.
Richard Johnson, M.D.
Richard Crisera, M.D.
Mark W. Whitman, M.D.
Kenneth Keller, M.D.
Kiernan-J. Minehan, M.D.
F. Joseph McCauslin, D.O.
David J. Mills, M.D.

A-G, & K
A-G, & K
A-G, & K
A-E
A-D, F & G
A-D, F & G
C,D, & G-N
A-F
A, B, Iodine 131 for
hyperthyroidism in C and
D-F

- B. The Radiation Safety Officer is Adrian Markus, MS, DABR.
- Except as otherwise specifically provided by this license, radioactive material to be administered to humans shall be procured in prepackaged

JAN 15 1997

David Schneider, Administrator
Langlade Memorial Hospital
112 East Fifth Avenue
Antigo, WI 54409

Dear Mr. Schneider:

Enclosed is Amendment No. 18 to your NRC Material License No. 48-17481-01 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 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).
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.

301937

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,

D. Schneider

-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
Gidget Watson
Nuclear Materials Licensing Branch

License No. 48-17481-01
Docket No. 030-12823

Enclosure: Amendment No. 18

DOCUMENT NAME: M:\03012823.CL7

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								
NAME	GMWatson:brt								
DATE	01/14/97 GW								

OFFICIAL RECORD COPY

DATE: _____

SUBJECT: **QUALITY MANAGEMENT PROGRAM**
 (Nuclear Medicine Department)

POLICY

The purpose of the Quality Management Program is to ensure the safe use of any therapeutic dosage of a radiopharmaceutical, or any dosage of quantities greater than 30 microcuries of either Sodium Iodine I-125 or I-131. This procedure shall be followed for every above referenced procedure to ensure that the objectives of 10 CFR 35.32 are met.

TRAINING

Prior to the technologist performing any procedures using greater than 30 uCi of radioactive Iodine-131, Iodine-125, or radiopharmaceutical therapy, this technologist will be trained to execute the following procedures.

PROCEDURE

1. Each patient receiving any therapeutic dosages of a radiopharmaceutical or any dosage of quantities greater than 30 uCi of either Sodium Iodide I-125 or I-131 will have an authorized user, or a physician under his supervision, sign and date a written directive. This written directive must specify the dose, radiopharmaceutical, the patient name, the date to be administered, and route of administration. Also, it must be present prior to administering the dose. If a medical emergency should arise, the requirement may be deviated from in accordance with 10 CFR 35.32 (a)(1) footnotes.
2. The patient shall be identified by more than one method as the individual named in the written directive before administering the radiopharmaceutical dosage. First, identify by asking the patient's name and confirm the name. Secondly, identify the patient by comparison with corresponding information in the patient's record: Birthdate, address, Social Security number, signature, the name on the patient's ID bracelet, hospital ID card, or the name on the patient's medical insurance card.

3. The individual administering the radiopharmaceutical will confirm that the radiopharmaceutical, dosage, and route of administration are in agreement with the written directive, that is, the dosage will be measured in the dose calibrator and the results compared with the prescribed dose found in the written directive prior to dose administration.
4. If the Nuclear Medicine technologist does not understand how to carry out the written directive or cannot clearly read the written directive, he or she must contact the authorized user who wrote the written directive before continuing the procedure.
5. A written record of the amount and name of the radiopharmaceutical administered, along with the date and signature or initials of the person administering the dose, will be kept for each patient. These records will be kept for at least three (3) years.
6. Periodic reviews will be conducted on a semi-annual basis. Due to the fact that we treat less than twenty (20) patients in a six (6) month period, the review will include all patients treated from the previous six (6) months up to the date of review (or a representative sample according to 10 CFR 32.110, if the number of procedures increases). A comparison will be made in these reviews between the actual dose administered and the prescribed dose in the written directive. This review will include the following: Radiopharmaceutical administered, route of administration, recordable events, misadministrations or a statement to the effect that there were no deviations from the written directive. If deviations are identified in these periodic reviews the cause will be determined and the action will be taken to prevent recurrence. Actions may include new or revised policies, additional training, or increased supervisory review of work. The audits will be documented on the attached Quality Management Program Audit Form.
7. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable. This oral revision will be documented immediately in the patient's record and a revised written directive will be signed and dated by an authorized user, or a physician under the supervision of an authorized user, within 48 hours of the revision.
8. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable. This oral directive will be documented immediately in the patient's record, and a written directive will be prepared, signed, and dated by an authorized user or a physician under the supervision of an authorized user within 24 hours of the oral directive.

9. Any revision to written directives will be dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.
10. A review of each administration will be performed prior to the administration to the patient to ensure that all requirements are met. This review will be documented on the attached patient audit form. A second review will be made by an authorized user or other supervised individual (technologist, etc.) to confirm that all requirements of the QMP are met. The second reviewer will sign the patient audit form.
11. The licensee will evaluate and respond within thirty (30) days of the discovery of a recordable event by assembling the relevant facts, including the cause of the recordable event, and identifying what, if any, corrective action is required to prevent it from recurring. These findings will then be retained on an auditable form for a period of three (3) years from the time the recordable event occurred. The attached audit form will be used.

At each quarterly Radiation Safety Committee meeting, these findings will be reviewed to ensure that the Quality Management Program is effective. Beginning on the third quarter of 1994, and each year thereafter the QMP's policies and procedures will be re-evaluated to determine whether the program needs revision in order to be more effective. If any revisions are needed to the QMP they will be implemented and submitted to the NRC within thirty (30) days of the date in which they were reviewed. This will be part of the annual review. Records of this review will be maintained for at least three (3) years.

**QUALITY ASSURANCE FORM FOR RADIOPHARMACEUTICAL THERAPEUTIC ADMINISTRATIONS
AND SODIUM IODIDE I-125 OR I-131 DOSES ABOVE 30 MICROCURIES**

THIS SURVEY IS TO ENSURE THAT ALL REQUIREMENTS OF THE NUCLEAR MEDICINE QUALITY MANAGEMENT PROGRAM ARE FOLLOWED AND TO EVALUATE THE QUALITY MANAGEMENT PROGRAM.

PATIENT NAME: _____

NAME OF THERAPY PROCEDURE ORDERED: _____

_____ DATE: _____

A. WRITTEN DIRECTIVE PRESENT: CIRCLE ONE YES NO

B. PATIENT IDENTIFICATION BY NAME: CIRCLE ONE YES NO

C. COMPARISON IDENTIFICATION: CIRCLE ONE

BIRTH DATE

ADDRESS

BRACELET

SIGNATURE

INSURANCE CARD

DRIVER'S LICENSE

HOSPITAL ID CARD

SOCIAL SECURITY NUMBER

D. CALCULATED ADMINISTERED RADIATION DOSAGE IS WITHIN 20% OF WRITTEN DIRECTIVE: CIRCLE ONE YES NO

IF NO, EXPLAIN _____

E. CALCULATED ADMINISTERED RADIATION DOSAGE IS WITHIN 10% OF WRITTEN DIRECTIVE: CIRCLE ONE YES NO

IF NO, EXPLAIN _____

F. DOSE ADMINISTERED _____ I-125 _____ I-131

_____ OTHER _____

G. ROUTE OF ADMINISTRATION _____

H. ADMINISTERED BY: _____

I. WAS THERE ANY DEVIATION FROM THE WRITTEN DIRECTIVE? CIRCLE ONE YES NO

IF YES, EXPLAIN _____

FORM COMPLETED BY _____ DATE _____
SIGN AND PRINT LAST NAME

SECOND REVIEW BY _____ DATE _____

NRC Quality Management Program Audit

DEPARTMENT _____

DATE OF REVIEW _____

1. WRITTEN DIRECTIVE COMPLIANCE RATE:

TOTAL CASES: _____

WRITTEN DIRECTIVE PRIOR TO R_x: _____

COMPLIANCE RATE: _____ %

BREAK DOWN OF TOTAL CASES BY ISOTOPES:

I-131	_____	I-125	_____
Sr-89	_____	Cs-137	_____
P-32	_____	Sr-90	_____
Co-60	_____	Ir-192	_____
Au-198	_____	Pd-103	_____
OTHER	_____	OTHER	_____

2. CONTENT IS ACCEPTABLE _____ %

3. INSTRUCTION TO SUPERVISED INDIVIDUALS _____ % COMPLIANCE

4. TWO METHODS OF PATIENT ID PERFORMED:

TOTAL CASES: _____ COMPLIANCE RATE: _____ %

5. R_x IN ACCORDANCE WITH WRITTEN DIRECTIVE _____ % COMPLIANCE

6. UNINTENDED DEVIATIONS:

NUMBER _____ APPROPRIATE ACTION BY STAFF _____

COMMENTS: _____

7. RECORDABLE EVENTS:

NUMBER _____ APPROPRIATE ACTION BY STAFF _____

COMMENTS: _____

8. MISADMINISTRATIONS:

NUMBER _____ APPROPRIATE ACTION BY STAFF _____

COMMENTS: _____

9. PROCEDURE CHANGES NEEDED: (CIRCLE ONE) YES NO

IF YES, ATTACH A COPY OF CHANGES MADE.

DATE CHANGES SENT TO NRC _____

AUDIT PERFORMED BY: _____

REVIEWED BY: _____

RADIATION SAFETY OFFICER

HOSPITAL ADMINISTRATION



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

October 22, 1996

F. Joseph McCauslin, D.O.
Radiation Safety Officer
Langlade Memorial Hospital
112 East Fifth Avenue
Antigo, WI 54409

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/02/96)

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 ☒ Amendment ☐ Renewal
☐ Termination ☐ Add 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. 301937
License No. 48-17481-01