MATERIALS LICENSE

Amendment No. 16

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.

301867

Licensee	
1. Community Memorial Hospital	In accordance with letter dated July 17, 1995 3. License Number 48-17740-01 is amended in its entirety to read as follows:
2. W180 N8085 Town Hall Road P. O. Box 408 Menomonee Falls, WI 53051	4. Expiration Date October 31, 2003
	5. Docket or Reference No. 030-13257

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
D. Iodine-125	D. As identified in 10 CFR 35.400	D. 250 millicuries
E. Palladium-103	E. As identified in 10 CFR 35.400	E. 250 millicuries

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-17740-01

Docket or Reference Number
030-13257

Amendment No. 16

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.

D. and E. Any brachytherapy procedure approved in 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at W180 N8085 Town Hall Road, Menomonee Falls, Wisconsin.

11. Radiation Safety Officer: Sherry Ness-Wenum, 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.	Sherry L. Ness-Wenum, M.D.	10 CFR 35.100, 35.200 and 35.300
B.	Richard O. Wagner, M.D.	10 CFR 35.100, 35.200 and 35.300
C.	Julie Johnson, M.D.	10 CFR 35.100, 35.200 and 35.300
D.	Prakash B. Chhabria, M.D.	10 CFR 35.100, 35.200 (excluding generators) and 35.300 (excluding iodine-131 for thyroid carcinoma).
E.	Christopher Schultz, M.D.	10 CFR 35.300, palladium-103 for uses identified in 10 CFR 35.400, and iodine-125 for uses identified in 10 CFR 35.400.
F.	Julia White, M.D.	10 CFR 35.300, palladium-103 for uses identified in 10 CFR 35.400, and iodine-125 for uses identified in 10 CFR 35.400.
G.	Colleen Lawton, M.D.	10 CFR 35.300, palladium-103 for uses identified in 10 CFR 35.400, and iodine-125 for uses identified in 10 CFR 35.400.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-17740-01

Docket or Reference Number
030-13257

Amendment No. 16

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 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 April 15, 1993; and

B. Letters dated September 14, 1993 (with attachments, excluding Item 5), December 20, 1993, February 7, 1994, April 7, 1994 (with attachment), and July 17, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 22 JANUARY 1997

By William P. Reinhold
Nuclear Materials Licensing Branch, Region III

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: 20031031
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

S7

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: COMMUNITY MEMORIAL HOSPITAL
   Received Date: 960923
   Docket No: 3013257
   Control No.: 301867
   License No.: 48-17740-01
   Action Type: Amendment

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

   * addl info 398975 - S7

3. COMMENTS

   Signed D. Hersey
   Date 9-27-96

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

FEE NOT REQUIRED

1. Fee Category and Amount: 7C

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

3. OTHER

   Signed AC
   Date 9/30/96

1996 SEP 27 AM 11:00

OCT 08 1996

RECEIVED BY LFDCB
Date Sept. 27, 1996
Log Sep 12 III
By AC
Date Completed 9/30/96

Community
Memorial Hospital
quality care close to home

CONTROL # 398975
COMMUNITY MEMORIAL HOSPITAL
W180 N8085 TOWNHALL RD
MENOMONEE FALLS, WI 53051
SEPTEMBER 18, 1996

UNITED STATES NUCLEAR REGULATORY COMMISSION
801 WARRENVILLE ROAD
LISLE, IL 60532-4351
ATTN.: BILL REICHHOLD
MAIL CONTROL NUMBER 398975

DEAR MR. REICHHOLD,

I AM SUBMITTING THIS ADDITIONAL INFORMATION REQUESTED BY YOU FOR MAIL CONTROL # 398975, IN SO DOING THIS SHOULD AVOID ANY ADDITIONAL FEES. BELOW ARE THE ANSWERS TO SOME OF THE QUESTIONS YOU HAD WHEN WE FIRST SUBMITTED THIS AMENDMENT. PLEASE FEEL FREE TO CALL ME AT 414-251-1000 EXT. 3366 WITH ANY FURTHER QUESTIONS. THANK YOU.

1. DO WE WANT 500 MCI TOTAL OF PALLADIUM AND I125 AS OUR LIMITS OR 500 MCI EACH AS OUR LIMITS? ANSWER: 500 MCI TOTAL OF PD 103 AND I 125.

2. SUBMIT INSTRUCTIONS GIVEN TO THE PATIENTS WHO RECEIVE THESE IMPLANTS, INCLUDE INSTRUCTIONS ON WHAT TO DO IF THEY PASS A SEED WITH URINATING. ANSWER: SEE ENCLOSED INFORMATION HANDOUTS.

3. SUBMIT QUALITY MANAGEMENT POLICY WITH BRACHYTHERAPY INCLUDED IN IT. ANSWER: SEE ENCLOSED QUALITY MANAGEMENT PROGRAM.

4. DR. COLLEEN LAWTON'S CERTIFICATION IS OVER 7 YEARS OLD AND MUST SHOW SOME EVIDENCE OF CONTINUING ED. OR A COPY OF A LICENSE SHOWING SHE IS ACTIVELY DOING BRACHYTHERAPY. ANSWER: PLEASE SEE DOCUMENTATION.

THANK YOU AGAIN, FOR ATTENDING TO THIS MATTER.

SINCERELY,

Noelle Geier, CNMT

NOELLE GEIER, CNMT

Continuation of 398975

FEE NOT REQUIRED

RECEIVED
SEP 2 3 1996
REGION III

Pm; 9-20-96

301867

W180 N8085 Town Hall Rd., P.O. Box 408, Menomonee Falls, WI 53052-0408 Phone: 414/251-1000
Member of Horizon Healthcare, Inc.

SEP 2 8 1996

Community
Memorial Hospital
quality care close to home

July 17, 1995

U.S. Nuclear Regulatory Commission
Radioisotopes Licensing Division
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Amendment to NRC Radioactive Material License #48-177404-01

Dear Sir or Madam:

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

1. Please add the authorized use of 35.400(f) Iodine-125 and 35.400(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer to our license. The maximum possession limit requested is 500 millicuries.

2. Please add the following physicians for authorized use of material in 35.400(f) and 35.400(g):

   a) Colleen Lawton, M.D.
   b) Christopher Schultz, M.D.
   c) Julia White, M.D.

   Please reference the attached board certifications for training and experience.

3. Also, add Colleen Lawton, M.D. for material in 35.300.

4. For these procedures we do not expect to hospitalize any patients, because the exposure rate should be below the requirements in 35.75 for release of patients containing radiopharmaceutical or permanent implants. We verify that surveys will be performed to reflect the exposure rates from the patient. These surveys will be documented.

   If a patient requires to be hospitalized because of the exposure rate from the patient, we will follow the requirements in Appendix Q "Model Procedure for Radiation Safety During Implant Therapy" of Regulatory Guide 10.8.

W180 N8085 Town Hall Rd., P.O. Box 408, Menomonee Falls, WI 53052-0408 Phone: 414/251-1000
Member of Horizon Healthcare, Inc.

5. Add rooms 005 and 022 as indicated on the attached facility diagram to our license as areas for storage of radioactive material. We wish to have these rooms available for radioactive waste in the event there would be an accident involving contaminated patients coming into our emergency room. The contaminated waste generated from such an emergency would be stored in these rooms until proper disposal of the material could be arranged.

   We verify that these rooms would be under the control of the Nuclear Medicine Department staff, if radioactive waste was present in the rooms. The rooms will be locked and posted, if radioactive waste is present with the Nuclear Medicine Staff having control of the key. Also, weekly surveys will be performed when radioactive waste is present in these rooms.

Enclosed is a check in the amount of $500.00 for the amendment processing fee. We hope that this information is sufficient to grant our request for amendment. If you have any questions concerning this amendment please direct them to Noelle Geier, Nuclear Medicine Technologist at (414)251-1000, Ext. 3366.

Thank you for your assistance.

Sincerely,

Paul Sanders

Paul Sanders
Vice President,
Professional/Ancillary Services

/pke

Enc.

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No. 25975 Expires 11/01/95

COLLEEN ANNE FOTSCH LAWTON MD
34605 SPRINGBANK RD
OCONOMOWOC WI 53066

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists
Hereby certifies that

Colleen A. F. Lawton, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On the eleventh day of June, 1987
Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Radiation Oncology

AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

M. Paul Capp, M.D.

Frank L. Lindskog, M.D.

AMERICAN BOARD

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No: 30081

Expires: 11/01/95

CHRISTOPHER SCHULTZ MD
3850 CHARTER POINT CT
BROOKFIELD WI 53045

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists
Hereby certifies that

Christopher J. Schultz, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this seventh day of June, 1990

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Radiation Oncology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

Robert G Parker
President

Secretary

AMERICAN BOARD
1933
OF
MEDICAL SPECIALTIES
EXCELLENCE
SPECIALISTS

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No 34810 Expires: 11/01/95

JULIA R WHITE MD
163 N 86TH ST
WAUWATOSA WI 53226

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

The American Board of Radiology

Kenneth L. Krabbenhoft, M.D., Executive Director
Jerome F. Wiot, M.D., Assistant Executive Director

SUITE 625
2301 W. BIG BEAVER ROAD
TROY, MICHIGAN 48084

PHONE (313) 643-0300
FAX (313) 643-0353

June 15, 1993

37500 TR 18 317
JULIA ROSE WHITE MD
3242 BELLE COURT
ROYAL OAK, MI 48073

DEAR DOCTOR WHITE:

I am pleased to inform you that you passed the June 1993 oral examination, and The American Board of Radiology grants you its certificate in RADIATION ONCOLOGY.

With personal congratulations, I am

Sincerely yours,

Kenneth L. Krabbenhoft, M.D.
Executive Director

IMPORTANT INFORMATION

1. Please return the enclosed "Request for Certificate Card" to the Board Office IMMEDIATELY. Delivery of certificates will take approximately 3-4 months.

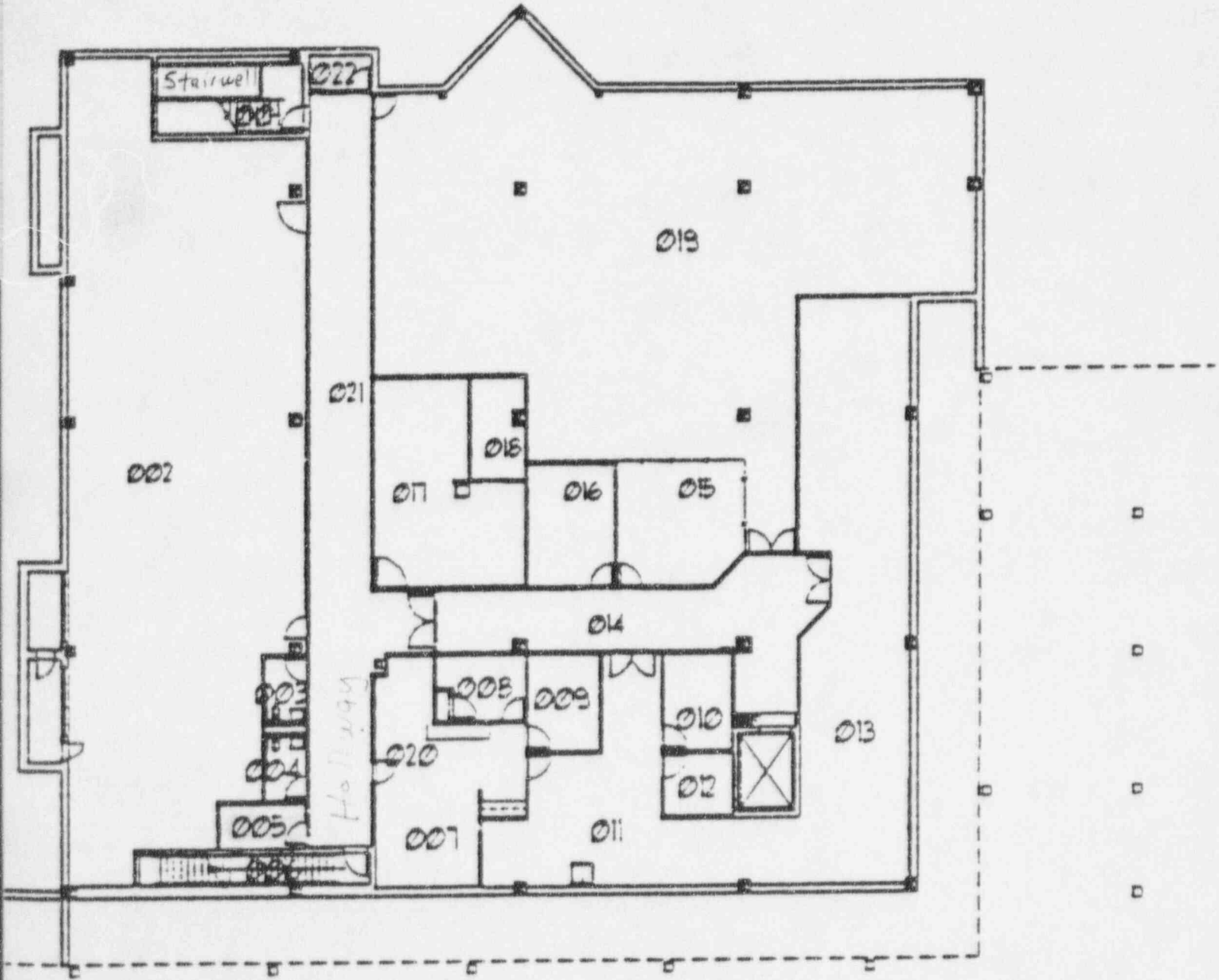
2. Your name will be included in the official ABMS Directory of Board Certified Medical Specialists unless you specify otherwise in writing to the ABMS.

3. It is your responsibility to notify your local and state medical organizations of your certification.

N

022 North, East, and West Walls are concrete

Not to Scale



004 Restroom
006 Stairwell
002 Storage Room at present

Community Memorial Hospital
FROEDTERT MEMORIAL LUTHERAN HOSPITAL
PROSTATE CENTER - RADIATION ONCOLOG'.

DISCHARGE INSTRUCTIONS FOLLOWING PROSTATE IMPLANTS

I. DIET:

Regular, unless you are on a special diet for other reasons. Additionally, some foods and liquids (acidic food or amino acid groups) can be slightly irritating to the bladder, causing increased urinary frequency, discomfort and a slower stream. Generally it is not necessary to eliminate these foods from the diet but you may wish to decrease the amount, particularly if you are having a lot of symptoms.

Acidic Foods:

Alcoholic beverages
Apples
Apple juices
Cantaloupes
Carbonated beverages
Chilies/spicy food
Citrus fruits and drinks
Coffee including decaf
Strawberries
Vinegar
Cranberries and juice
Grapes/grape juice
Guava
Peaches
Pineapple
Plums
Tea
Tomatoes
Chocolate
Vitamin B complex

II. ACTIVITY:

Avoid heavy lifting or strenuous physical activity for the first two days, once you are home. After that, you may return to your normal activity level.

III. POSSIBLE SIDE EFFECTS:

There are some side effects from the implant procedure. Overall side effects from the implant are divided into two groups immediate and late side effects:

A. IMMEDIATE POSTOPERATIVE SIDE EFFECTS:

1. Slight bleeding beneath the scrotum
2. Blood in the urine
3. Bruising and tenderness between the legs

These side effects are caused by the needles used to place the seeds. Usually twenty to twenty-five needles are used. The seeds themselves, and the catheter and other instruments used during the procedure, also can contribute to these side effects. If you should experience severe pain or severe bleeding, you should call your urologist.

A catheter is placed into the bladder during surgery and is removed several hours later. In some instances, it is left in overnight. It is normal to have some blood in the urine which will drain from the catheter. This bleeding may continue for several days, so do not be alarmed. If it becomes severe and/or is associated with large blood clots, call your urologist. Drinking plenty of water helps prevent blood clots and flushes the bladder.

After the catheter is removed it is normal to experience some burning with urination. If you cannot pass your urine within six hours after removal of the catheter, you need to contact your urologist or go to the Emergency Room for care. This is particularly true if you have a feeling of bladder fullness or bladder discomfort.

Antibiotics are given after the implant to prevent infection. You should take the antibiotic as prescribed by your physician until the medication runs out. If you develop an allergic reaction, such as a skin rash, stop the medication and contact your physician.

B. LATE SIDE EFFECTS:

1. Frequent urination
2. Burning with urination
3. Sense of urgency
4. Weaker urinary stream

After healing from the implant, most of the side effects are due to the radiation in the seeds that were placed into the prostate. The radiation causes swelling and irritation of the prostate which causes the above symptoms. Drinking plenty of fluids and avoiding caffeine-containing beverages may help to relieve these symptoms. If they are bothersome, medication from your radiation oncologist or urologist may be helpful.

IV. MEDICATIONS:

Bactrim D.S.(labeled often as Sulfa) This is an antibiotic. Please take this in the evening after your implant and then twice a day until it is gone (approximately eight days). Occasionally people may have allergic reactions to this medication. If you should develop a rash or unusual reaction please call for advice.

Aleve 200 mg This is an anti-inflammatory drug usually given for arthritis symptoms. This is an over the counter drug, so you can buy it off the shelf at the pharmacy. This medication can help reduce the inflammation from the implant. It can be taken three to four times per day and should be taken with food. Since this medication is designed to relieve symptoms, if you feel it is not helping, you may discontinue it. Many people find that they can decrease the dose after about a week. You can change the dose to suit your needs. **NOTE**: This medication can worsen ulcer symptoms. If your stomach is irritated or you have black stools after taking this medication, stop it and inform your doctor.

Tylenol extra Strength or Tylenol PM These are over the counter pain medications that you can pick up at the pharmacy. Use as directed to relieve pain and help you sleep.

V. RADIATION SAFETY:

Radiation safety is a concern of many of our patients. I-125 and Pd-103 are low energy radioactive materials and lose their activity quickly. The low energy of the seeds means that their radiation is contained within the prostate gland, for the most part. However, some amount of the radiation is given off to structures very close to the prostate, such as the rectum. The precautions listed below, that we ask you to observe, are to ensure that those around you are protected from unnecessary radiation. Objects that you touch or items that you use are NOT radioactive. Your bodily wastes (urine and stools) are NOT radioactive.

A. PRECAUTIONS:

Any pregnant or possibly pregnant woman and all children should avoid prolonged close contact with you for the first two months after the implant. They can greet you briefly and then move to a distance of six feet or more away. At a six foot distance, there is no limit to the length of time that they can be in the same room with you.

Sexual intercourse with a condom may be resumed two weeks after the implant. Your sperm may be discolored dark brown to black. This is normal and is a result of bleeding that may have occurred during the implant and is now being released into the ejaculate. After two months it will not be necessary to use a condom.

After removal of the urinary catheter, it is possible that you could lose seeds through urination or in the ejaculate following sexual intercourse. Because of the possibility of passing a seed, we ask you to strain your urine for the first week following the procedure. If you notice a seed and can retrieve it, please do so using tweezers and place the seed into the packet provided. Return the seed to the FMLH Radiation Oncology Department, at your convenience.

B. Seeds can migrate in the body. Do not be alarmed if a seed is displayed in a chest x-ray several years from now.

DATE **TIME**

		DATE	TIME
VII.	Post CT	_____	_____
	Follow-up Appointment	_____	_____

SURGEON: PROCEDURE: Prostate Seed Implant

GLOVE SIZE: POSITION OF PATIENT: Lithotomy

SKIN PREP: Betadine DRAPES: Table cover, Prep set, 1 pkg. towels

SUTURES AND NEEDLS

TIES:

PERITONEIUM:

FASCIA:

SUB-CU:

SKIN:

RETENTION:

OTHER:
- Soak template, ultrasound equipment, scope and short probe
- 60cc syringe
- Extension tubing, cut off male end and fit on probe
- Disposable stopcock on syringe end

DRESSINGS

- Betadine ointment
- 4x4 optional

INSTRUMENTS AND EQUIPMENT -

BASIC:

- Cysto instr. (23.5cc), cold biopsy forceps
- 30° + 70° Cystoscopes
- 3000 bags saline/water

SPECIAL:

- Mylar booties
- Pitchers, small and large
- Small basin
- #18 two way Foley, 5cc
- 10 cc syringe x 2
- K.Y. syringe x 2
- Toomey syringe x 2
- 60 cc syriiinge
- #22 3-wau Foley - 5cc
- Catheter drainage bag
- 1040 drape
- Gloves 7 1/2 x 4
- Penile clamp (Remo M60 plus large tube of Lubraafax - optional)
- Large red rectal tube (Toomey syringe optional for rectal irrigation)
- Cysto bladder irrigation set and light cord

2 rectal rulers

3m sticky drape for scrotum

Post-it™ brand fax transmittal memo 7671 | # of pages ▸ 1

To	From
ORICK	RAD ONC
Co.	Co.
Dept. PROSTATE CENTER	Phone #
Fax # 459-1953	Fax # 451-0344

AUTHORIZATION FOR USE OF RADIOACTIVE MATERIAL IN HUMANS FOR THERAPEUTIC PURPOSES

Colleen A. Lawton, M.D.; Assistant Professor, Radiation Oncology, was approved by the Radiation Safety Committee of the Milwaukee County Medical Complex, NRC Byproduct License number 48-04193-01, on October 29, 1987 for use byproduct materials for the following procedures:

1. Use of radiopharmaceutical for therapy.

   This permits use of any radioactive material in a radiopharmaceutical and for therapeutic use for which the Food and Drug Administration has accepted a " Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials shall comply with the package insert instructions regarding indications and method of administration.

2. Use of sources for brachytherapy.
   This permits use of radioactive material as sealed sources used in accordance with the manufacturer's radiation safety and handling instructions and in accordance with code of federal regulations as stated in 10CFR35, Subpart G-Sources for Brachytherapy and MCMC NRC license conditions.

B. David Collier, M.D.
Chair, Radiation Safety Committee

PROPOSED

Policy # 729 - 014 - 03

DELETE ~~UNIV. PRECAUTIONS CATEGORY III~~

File Section: Nuclear Medicine

Dist.: #'s 50,51

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Departmental Approval_____
Administrative Approval_____
Medical Dir. Approval_____
Medical Staff Approval_____

September, 1996 (Revised)

Policy Statement:

A Quality Management Program is maintained for the administration of radiopharmaceuticals.

Purpose:

To avoid misadministrations of radioactive materials and to ensure that radiopharmaceuticals are administered in accordance with directions of an authorized physician user.

Guidelines:

1. Written procedures for all diagnostic studies using I-125 or I-131 will be maintained, including:

   - A description of each procedure;
   - The radiopharmaceutical to be administered;
   - The dosage range to be administered;
   - The route of administration;
   - The approval and signature of an authorized physician user named on the NRC license.
   - Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

CHANGE → 2. *For* Therapeutic Radiopharmaceuticals and I-125 or I-131 sodium iodide administrations of greater than 30 uCi activity, ~~and~~ Metastron Sr-89 *or Pd 103 - Brachytherapy* follow:

   A. Written Directives

CHANGE → For all therapeutic administrations of I-131 or P-32, and for diagnostic administrations of greater than 30 uCi of I-125 or I-131 sodium iodide, ~~and~~ Sr-89 *and Pd 103* an authorized user will date and sign a "written directive" prior to the administration.

PROPOSED

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

A. Written Directives (continued)

The written directive will include:

- The patient name;
- The date;
- The radiopharmaceutical;
- The dosage;
- The route of administration (for P-32).

NEW → *For Brachytherapy, it will also include:*

- *Treatment site;*
- *Source strengths;*
- *Total number of sources;*
- *Total dose.*

NOTE: Revisions to the written directive may be made in compliance with the footnote to 10 CFR 35.32 (a)(1).

- 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 provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. Patient Identification:

Prior to administration of a radiopharmaceutical, the identity of the patient is to be verified by more than one method. These are to include asking the patient (or guardian) his name and confirming the identity by comparison to at least one of the following items of information in the patient's record:

- Birth date;
- Address;
- Social security #;
- Signature;
- Identification bracelet;
- Hospital I.D. card;
- Medical insurance card;
- Drivers license.

PROPOSED

Guidelines: (continued)

C. Verification of Proper Radiopharmaceutical:

Prior to administration of a radiopharmaceutical, specific details of the administration must be verified to confirm they are in agreement with the written directive. These details are to include:

- Correct radiopharmaceutical;
- Correct dosage (dose calibrator reading must be within +/- 10% of directive);
- Route of administration.

CHANGE → 3. If the criteria listed below meet that for a recordable event or misadministration, Policy #729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals, *as described in 10CFR35* will be followed.

A. Recordable event for I-125 or I-131:

Procedure	Recordable Event
All Diagnostic Radiopharmaceuticals (including <30 uCi NaI, I-125 or I-131).	----------
Sodium Iodide Radiopharmaceuticals (where >30 uCi NaI I-125 or I-131).	- Administration of radiopharmaceutical other than the one intended - Admin dosage differs by >10% prescribed dosage and >15 uCi - W/o written directive - W/o daily dosage record - Administration to the wrong patient

CHANGE → B. Recordable events for Sr-89, *Brachytherapy* or other qualifying Radiopharmaceuticals:

- The absence of a written directive.
- The absence of a record of the administered dose.

PROPOSED

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

B. Recordable events for Sr-89, Brachytherapy or other qualifying Radiopharmaceuticals: (continued)

- The ratio of the difference between the administered dose and the prescribed dose divided by the prescribed dose is greater that 10%, but less than 20%.
- Administration to the wrong patient.
- Administration of radiopharmaceutical other than the one intended.
- Administration of a radiopharmaceutical by a route or site of administration other than that intended by the prescribing physician.

C. Misadministration for I-125 or I-131:

	Misadministration
All Diagnostic Radiopharmaceuticals (including <30 uCi Nal, I-125 or I-131);	- Wrong patient, radiopharm, route or dosage and - Dose >5 rem Effective Dose Equivalent or 50 rem to organ
Sodium Iodide Radiopharmaceuticals (where >30 uCi Nal I-125 or I-131)	- Wrong patient - Wrong radiopharm - Admin dosage differs by >20% prescr dosage and >30 uCi.

Misadministration for Therapeutic Radiopharmaceuticals other than I-125 or I-131 (Sr-89, etc.):

- The dose is delivered to the wrong patient;
- The wrong radiopharmaceutical is delivered;
- The route of administration is wrong;
- The ratio of the difference between the administered dose minus the prescribed dose divided by the prescribed dose is greater that 20%.

PROPOSED

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

D. Ask Questions:

If any portion of the written directive and/or the necessary methods to carry out the written directive are unclear, the worker(s) must clarify these questions before continuing with the procedure.

E. Documentation of Dosage:

Refer to 10 CFR 35.32(d)(2)

After administration of the dosage, a record of the dosage given must be signed and dated by one or more of the following persons:

- An authorized user listed on the license;
- Another nuclear medicine physician, a physicist or technologist under the supervision of an authorized user.

NEW → *For Brachytherapy, this will also include:*

- *A schematic type drawing will be prepared and reviewed prior to the implantation of the radioactive material which shows the individual sources or source trains with an indication of their respective activities.*
- *After insertion of the source material, an entry into the patient's record shall be made by the radiation oncologist, the radiation oncology resident, or other appropriate individual of the treatment site, the pattern of radioactive materials used for this patient, and the source strengths. Prior to the end of the implant, another entry will be made in the patient's record which states the total dose or the treatment time to be delivered to the patient.*

PROPOSED

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

E. Documentation of Dosage: (continued)

NEW → For Brachytherapy, this will also include: (continued)

- *Dosimetric calculations will be performed and will be based upon either an appropriate set of radiographs and/or knowledge of the geometric position of the sources. The review shall include the type of implant, the statement of the source strength for each of the sources used, and the appropriateness of the calculated doses at selected points, which can be judged either by the use of a library of precalculated doses, a manual calculation at a specific point, or through experience with this type of implant. All software used for computer generated dose calculations will be tested by review of the calculated distribution for a single source of each individual source type used. This test shall be performed for each new version of software prior to its clinical use.*

The written documentation of the dosage and the written directive will be kept on file for at least three years.

4. Periodic Review of Quality Management Program:

Refer to 10 CFR 35.32(b)

On at least an annual frequency, a detailed review of the quality management program will be conducted.

The review is to include:

- A review of a representative sample of randomly selected patient dosage administrations for compliance with the above program;
- A summary of all recordable events (Refer to 10 CFR 35.2 definitions);
- A summary of all misadministrations (Refer to 10 CFR 35.2 definitions and 10 CFR 35.33 reporting requirements).

PROPOSED

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Policy # 729 - 014 - 03

Subject: Quality Management
Program for the Administration
of Radiopharmaceuticals

4. Periodic Review of Quality Management Program:
(continued)

The review is to include: (continued)

- The number of cases reviewed when a misadministration or recordable event is uncovered will expand at the next periodic review of the QMP.
- If upon periodic review or upon the suggestion of the Radiation Safety Committee a deficiency is noted in the Quality Management Program, modifications will be made immediately and the revised QMP will be submitted within 30 days to the NRC as required by 10 CFR 35.32(b)(2) and (e).
- Records of the periodic review will be maintained three years as required in 10 CFR 35.32(b)(3).

5. Annual personnel training will include:

- Inservice through meeting or written documentation with signature of personnel upon completing.
- Viewing the Radiation Safety video.

References:

1. NRC Regulations 10 CFR 35.32.

2. NRC Regulatory Guide 8.33.

3. Annual Personnel Training for Quality Management Program Procedure.

4. Hospital Policy Manual

#729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals.

March, 1994
May, 1995 (Revised)
September, 1996 (Revised)

QUALITY ASSURANCE FORM FOR THERAPEUTIC ADMINISTRATION OF SODIUM IODINE, I-125 OR I-131 DOSES ABOVE 30 MICROCURIES
OR
STRONTIUM 89 CHLORIDE (METASTRON) OR POLADIUM 103

This survey is to insure that all requirements of the Nuclear Medicine Quality Management Program are followed and to evaluate the QMP on an annual basis.

PATIENT NAME:_____ DATE:_____

NAME OF THERAPY OR RADIOIODINE PROCEDURE:_____

A. Written Directive Present: Yes No

B. Patient Identification by Name: Yes No

C. Comparison Identification:

1. Birthdate 2. Address 3. Social Security Number
4. Signature 5. Bracelet 6. Hospital ID Card
7. Insurance Card 8. Driver's License

D. Informed Consent Signed: Yes No

E. Is Calculated Administered Dose within 20% of Written Directive:
Yes No

If there is a > 20% difference, this may constitute a misadministration. Notify hospital administration, the authorized user, and the RSO.

F. Is Calculated Administered Dose within 10% of Written Directive:
Yes No

If there is a > 10% difference, this may constitute a recordable event. Notify the authorized user and the RSO.

G. Dose Prescribed in mCi _____I-125 _____I-131 _____Sr-89
on Written Directive _____Pd 103

H. Total Dose Administered _____I-125 _____I-131 _____Sr-89
in mCi _____Pd 103

I. Route of Administration/Treatment site_____

J. Was there a deviation from Written Directive Yes No

If Yes, attach a detailed explanation.

Authorized User:_____MD Date_____
on Written Directive

Dose Administered by:_____MD Date_____
Sign and Print Last Name

Form Completed By_____ Date_____
Sign and Print Last Name

JAN 2 3 1997

Paul Sanders
Vice President, Professional/
Ancillary Services
Community Memorial Hospital
W180 N8085 Town Hall Road
P.O. Box 408
Menomonee Falls, WI 53051

Dear Mr. Sanders:

Enclosed is Amendment No. 16 to your NRC Material License No. 48-17740-01 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 we have extended the expiration date of the license for five years in accordance with the regulations (10 CFR 30.36).

Also note, we have removed the license condition requiring decommissioning records because this requirement is in the regulations.

A review of your written Quality Management Program (QMP) was performed to determine whether your described policies and procedures appear to meet the objectives of the rule. Based on that review, we have no questions regarding how you will meet the objectives listed in 10 CFR 35.32.

Please be advised that the QMP will not be a condition of your license. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, you should submit your modified QMP to this office within 30 days after the modification is made, as required by 10 CFR 35.32(e).

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:

301867

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
W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 48-17740-01
Docket No.: 030-13257

Enclosure: Amendment No. 16

DOCUMENT NAME: M:\03013257.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	C							
NAME	WREICHHOLD:jaw								
DATE	01/2/97								

OFFICIAL RECORD COPY

Community
Memorial Hospital
quality care close to home

mail control #:
301867

Dec 4, 1996

Dear Mr Bill Reichhold,

In answer to your questions I have enclosed documentation of licenses for the Physicians and a new Quality Management Program dedicated to permanent implants, also I have encluded a copy of our revised Quality Management Program for diagnostic and therapeutic radio pharmaceuticals. We will have two policys - the original and one for Brachytherapy. Hopefully this will better define the information you need it to contain.

Your question about exact doses - please use 250mCi each of Pd 103 and I 125.

If you have any further questions please feel free to call me. Thank you.

Sincerely,

Nelle Geier, CNMT

RECEIVED
DEC 09 1996
REGION III

Pm: 12-4-96

W180 N8085 Town Hall Rd., P.O. Box 408, Menomonee Falls, WI 53052-0408 Phone: 414/251-1000
Member of Horizon Healthcare, Inc.

DEC 0 9

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL 11/13/96 # of pages ▶ 2

To NOELLE GEIER	From BILL REICHHELD
Dept./Agency Community Mem. Hosp.	Phone # 630-829-9839
Fax # 414-252-7197	Fax # 630-515-1259

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION 3
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

PHONE CONVERSATION RECORD

Noelle Geier. CNMT
Nuclear Medicine Department
Community Memorial Hospital
Menomonee, Wisconsin

Dear Ms. Geier,

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

1. Please indicate if you wish 250 millicuries of iodine-125 and 250 millicuries of palladium-103 for a total of 500 millicuries. OR Do you wish some other combination of these radionuclides for at total of 500 millicuries.

250 ea.

2. The following is additional information about your Quality Management Program (QMP) for sealed source brachytherapy.

   A. Please clarify if your Quality Management Program includes iodine-125 sealed sources for brachytherapy.

   B. Your submittal does not adequately describe procedures to ensure that final plans of treatment and related calculations for brachytherapy, (other than high-dose-rate remote afterloading brachytherapy), are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Examples of acceptable procedures include:

      a. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations

      b. a plan of treatment prepared in accordance with the respective written directive.

      c. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations) by an authorized user or a qualified person under supervision of an authorized user who whenever possible did not make the original calculations.

d. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources.

e. verifying source strength prior to administration.

3. Your submittal for brachytherapy administration (other than high-dose-rate administration) does not adequately describe procedures to ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Examples of acceptable procedures include:

a. verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, treatment site, number of sources, source strength and exposure time, or total dose, should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

b. prompt recording of the number of sources, the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record, and the method for verification that the sources have been loaded in the correct position.

c. source positions should be verified and frequently checked to minimize the possibility of unintentional and undetected source movement or dislodgement.

4. a. The State of Wisconsin licenses for Drs. Schultz, White, and Lawton, expired in November 1995. Please submit evidence that these Drs. are currently licensed to practice medicine in the State of Wisconsin.

b. Please submit evidence of continuing education and experience for Dr. Lawton, because Dr. Lawton's ABR certification is over 7 years old. The information submitted in your request received on September 23, 1996 shows that Dr. Lawton was approved to use radioactive materials at Milwaukee County Medical Complex on October 29, 1987, which is also over 7 years old.

Please send a "hard copy" of your response within 15 days and refer to **mail control 301867.** Please call me at 630-829-9839 if you have any questions.

Sincerely,

Bill Reichhold

Bill Reichhold

QMP

CONTROL #301867
COMMUNITY MEMORIAL HOSPITAL
W180 N8085 TOWNHALL RD
MENOMONEE FALLS, WI 53051
JANUARY 3, 1997

UNITED STATES NUCLEAR REGULATORY COMMISSION
801 WARRENVILLE ROAD
LISLE, IL 60532-4351
ATTN.: BILL REICHHOLD

DEAR MR. REICHHOLD,

I AM SUBMITTING THIS ADDITIONAL INFORMATION REQUESTED BY YOU FOR MAIL CONTROL # 301867, IN SO DOING THIS SHOULD AVOID ANY ADDITIONAL FEES. BELOW ARE THE CHANGES YOU REQUESTED TO OUR QUALITY MANAGEMENT POLICIES. PLEASE FEEL FREE TO CALL ME AT 414-251-1000 EXT. 3366 WITH ANY FURTHER QUESTIONS. THANK YOU.

THANK YOU AGAIN, FOR ATTENDING TO THIS MATTER.

SINCERELY,

Noelle Geier, CNMT

NOELLE GEIER, CNMT

RECEIVED
JAN 08 1997
REGION III

pm: 1-3-97

JAN 08 1997

Policy # - -

File Section: Nuclear Medicine

Dist.: #'s

Subject: Quality Management Program for Permanent I-125 and Pd-103 Prostate Implants in Radiation Oncology at Community Memorial Hospital

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Departmental Approval_____
Administrative Approval_____
Medical Dir. Approval_____
Medical Staff Approval_____

December, 1996

ROUGH DRAFT

Policy Statement:

A Quality Management Program is maintained for sealed source I-125 and Pd-103 brachytherapy procedures.

Purpose:

To avoid misadministrations and insure that brachytherapy procedures are carried out in accordance with the directions of an authorized user.

Guidelines:

1. Written Directives

   a. Prior to an implant, the authorized user will date and sign a "written directive" for each patient for all procedures in which sealed source I-125 or Pd-103 are to be used.

   b. Prior to the implant, the written directive will include:

      patient name
      date
      radioisotope
      source strength
      total number of sources

   c. After implantation, the written directive will contain the:

      treatment site
      total source strength
      total dose

Guidelines: (continued)

1. Written Directives (cont'd)

   d. 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 provided that the information provided by the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Patient Identification

   Prior to the procedure, the patient will be identified in a redundant fashion by the radiation oncologist. The procedure will include asking the patient's name and confirming it. In addition, one of the following will be compared to the patient's record:

   name on the patient's identification bracelet
   address
   social security number
   signature
   hospital ID card
   medical insurance card
   photograph of patient's face
   date of birth

3. It is the responsibility of all individuals participating in a brachytherapy procedure to insure that they understand their contribution to the procedure prior to initiating work. If confusion or doubt about the actions to be taken exists each individual must consult the written directive and/or the authorized user before proceeding.

4. Prior to the procedure specific details of the procedure will be verified against the written directive and plan of treatment for correctness in particular, the radioisotope, the number of sources, source strengths, treatment site and total dose.

Subject: Quality Management Program
for Permanent I-125 and Pd-103
Prostate Implants in Radiation
Oncology at Community Memorial Hospital

Guidelines: (continued)

5. Prior to the procedure, a plan of treatment will be made, using ultrasound studies. A schematic drawing of planned source placement will be made and reviewed.

6. The positions of the sources will be verified after the procedure by radiographic techniques.

7. After the procedure, the authorized user will note in the patient's record the following:

   actual number and strength of sources implanted
   site
   pattern of implantation
   total dose

8. An independent check on the dose calculation will be performed. This check consists of verifying the source manufacturer's statement of calibration by placing 10% of the sources into a source calibrator and verifying the manufacturer's measurements.

9. The computer program used to generate the plan of treatment and the dose calculations will be tested by review of the calculated distribution for single sources of I-125 and Pd-103. These tests will be performed with each software update.

10. The definition of terms, recordable event, misadministration and written directive will be taken from 10CFR35. In the event of a recordable event or misadministration, the actions specified in 10CFR35 will be followed.

11. An annual review of all brachytherapy procedures will be conducted to confirm that the statement of dose as found in the written directive is consistent with what was actually delivered to the patient. The dose will be considered to be in accordance with the written directive as long as some volume of the prostate receives that dose. Deviations of greater than +/- 10%

Guidelines: (continued)

11. will be considered recordable events while deviations of greater than 20% will be considered misadministrations. If an unintended deviation occurs, corrective actions will be instituted which consist of all relevant personnel reviewing the case to identify the source of the error and what change in policy or practice could prevent the error being repeated.

December, 1996

k:\policies\700\I125103.doc

Policy # 729 - 014 03

File Section: Nuclear Medicine

Dist.: #'s 50,51

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Departmental Approval_____
Administrative Approval_____
Medical Dir. Approval_____
Medical Staff Approval_____

December, 1996 (Revised)

Policy Statement:

A Quality Management Program is maintained for the administration of radiopharmaceuticals.

Purpose:

To avoid misadministrations of radioactive materials and to ensure that radiopharmaceuticals are administered in accordance with directions of an authorized physician user.

Guidelines:

1. Written procedures for all diagnostic studies using I-125 or I-131 will be maintained, including:

   - A description of each procedure;
   - The radiopharmaceutical to be administered;
   - The dosage range to be administered;
   - The route of administration;
   - The approval and signature of an authorized physician user named on the NRC license.
   - Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

2. For Therapeutic Radiopharmaceuticals and I-125 or I-131 sodium iodide administrations of greater than 30 uCi activity, Metastron Sr-89, the Quality Assurance form will be filled out prior to administration and to follow:

   A. Written Directives

   For all therapeutic administrations of I-131, P-32, and Sr89 and for diagnostic administrations of greater than 30 uCi of I-125 or I-131 sodium iodide an authorized user will date and sign a "written directive" prior to the administration.

Subject: Quality Management
Program for the Administration
of Radiopharmaceuticals

Guidelines: (continued)

A. Written Directives (continued)

The written directive will include:

- The patient name;
- The date;
- The radiopharmaceutical;
- The dosage;
- The route of administration (for P-32).

NOTE: Revisions to the written directive may be made in compliance with the footnote to 10 CFR 35.32 (a)(1).

- 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 provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. Patient Identification:

Prior to administration of a radiopharmaceutical, the identity of the patient is to be verified by more than one method. These are to include asking the patient (or guardian) his name and confirming the identity by comparison to at least one of the following items of information in the patient's record:

- Birth date;
- Address;
- Social security #;
- Signature;
- Identification bracelet;
- Hospital I.D. card;
- Medical insurance card;
- Drivers license.

Guidelines: (continued)

C. Verification of Proper Radiopharmaceutical:

Prior to administration of a radiopharmaceutical, specific details of the administration must be verified to confirm they are in agreement with the written directive. These details are to include:

- Correct radiopharmaceutical;
- Correct dosage (dose calibrator reading must be within +/- 10% of directive);
- Route of administration.

3. If the criteria listed below meet that for a recordable event or misadministration, Policy #729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals, as described in 10CFR35 will be followed.

A. Recordable events:

Procedure	Recordable Event
1) All Diagnostic Radiopharmaceuticals (including <30 uCi NaI, I-125 or I-131).	----------
2) Sodium Iodide Radiopharmaceuticals (where >30 uCi NaI I-125 or I-131).	- Admin dosage differs by >10% prescribed dosage and >15 uCi - W/o written directive - W/o daily dosage record
3) Therapeutic Radiopharmaceuticals (including Sr89)	- Administrated dosage differs by >10% prescribed dosage - W/o written directive - W/o daily dosage record

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

B. Misadministrations:

Procedure	Misadministration
1) All Diagnostic Radiopharmaceuticals (including <30 uCi NaI, I-125 or I-131);	- Wrong patient, radiopharm, route or dosage and - Dose >5 rem Effective Dose Equivalent or 50 rem to organ
2) Sodium Iodide Radiopharmaceuticals (where >30 uCi NaI I-125 or I-131)	- Wrong patient - Wrong radiopharm - Admin dosage differs by >20% prescr dosage and >30 uCi.
3) Therapeutic Radiopharmaceuticals (including SR89)	- Wrong patient - Wrong radiopharmaceutical - Wrong route of administration - Administered dosage differs by >20% prescribed dosage

C. Ask Questions:

If any portion of the written directive and/or the necessary methods to carry out the written directive are unclear, the worker(s) must clarify these questions before continuing with the procedure.

D. Documentation of Dosage:

Refer to 10 CFR 35.32(d)(2)

After administration of the dosage, a record of the dosage given must be signed and dated by one or more of the following persons:

Guidelines: (continued)

D. Documentation of Dosage: (continued)

- An authorized user listed on the license;
- Another nuclear medicine physician, a physicist or technologist under the supervision of an authorized user.

The written documentation of the dosage and the written directive will be kept on file for at least three years.

4. Periodic Review of Quality Management Program:

Refer to 10 CFR 35.32(b)

On at least an annual frequency, a detailed review of the quality management program will be conducted.

The review is to include:

- A review of a representative sample of randomly selected patient dosage administrations for compliance with the above program;
- A summary of all recordable events (Refer to 10 CFR 35.2 definitions);
- A summary of all misadministrations (Refer to 10 CFR 35.2 definitions and 10 CFR 35.33 reporting requirements).
- The number of cases reviewed when a misadministration or recordable event is uncovered will expand at the next periodic review of the QMP.
- If upon periodic review or upon the suggestion of the Radiation Safety Committee a deficiency is noted in the Quality Management Program, modifications will be made immediately and the revised QMP will be submitted within 30 days to the NRC as required by 10 CFR 35.32(b)(2) and (e).
- Records of the periodic review will be maintained three years as required in 10 CFR 35.32(b)(3).

Policy # 729 - 014 - 03

Subject: Quality Management
Program for the Administration
of Radiopharmaceuticals

Guidelines: (continued)

5. Annual personnel training will include:

   - Inservice through meeting or written documentation with signature of personnel upon completing.
   - Viewing the Radiation Safety video.

References:

1. NRC Regulations 10 CFR 35.32.

2. NRC Regulatory Guide 8.33.

3. Annual Personnel Training for Quality Management Program Procedure.

4. Hospital Policy Manual

   #729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals.

March, 1994
May, 1995 (Revised)
September, 1996 (Revised)
December, 1996 (Revised)

QUALITY ASSURANCE FORM FOR THERAPEUTIC ADMINISTRATION OF SODIUM IODINE, I-125 OR I-131 DOSES ABOVE 30 MICROCURIES
OR
STRONTIUM 89 CHLORIDE (METASTRON) OR POLADIUM 103

This survey is to insure that all requirements of the Nuclear Medicine Quality Management Program are followed and to evaluate the QMP on an annual basis. This form must be filled out prior to administration.

PATIENT NAME:_____ DATE:_____

NAME OF THERAPY OR RADIOIODINE PROCEDURE:_____

A. Written Directive Present: Yes No

B. Patient Identification by Name: Yes No

C. Comparison Identification:

1. Birthdate 2. Address 3. Social Security Number
4. Signature 5. Bracelet 6. Hospital ID Card
7. Insurance Card 8. Driver's License

D. Informed Consent Signed: Yes No

E. Is Calculated Administered Dose within 20% of Written Directive:
Yes No

If there is a > 20% difference, this may constitute a misadministration. Notify hospital administration, the authorized user, and the RSO.

F. Is Calculated Administered Dose within 10% of Written Directive:
Yes No

If there is a > 10% difference, this may constitute a recordable event. Notify the authorized user and the RSO.

G. Dose Prescribed in mCi _____I-125 _____I-131 _____Sr-89
on Written Directive

H. Total Dose Administered ____I-125 _____I-131 _____Sr-89
in mCi

I. Route of Administration/Treatment site_____

J. Was there a deviation from Written Directive Yes No

If Yes, attach a detailed explanation.

Authorized User:_____MD Date_____
on Written Directive

Dose Administered by:_____MD Date_____
Sign and Print Last Name

Form Completed By_____ Date_____
Sign and Print Last Name

Policy # - -

File Section: Nuclear Medicine

Dist.: #'s

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Departmental Approval_____
Administrative Approval_____
Medical Dir. Approval_____
Medical Staff Approval_____

Subject: Quality Management Program for Permanent I-125 and Pd-103 Prostate Implants in Radiation Oncology at Community Memorial Hospital

December, 1996

ROUGH DRAFT

Policy Statement:

A Quality Management Program is maintained for sealed source I-125 and Pd-103 brachytherapy procedures.

Purpose:

To avoid misadministrations and insure that brachytherapy procedures are carried out in accordance with the directions of an authorized user.

Guidelines:

1. Written Directives

   a. An authorized user will date and sign a "written directive" for all procedures in which sealed source I-125 or Pd-103 is to be used.

   b. The written directive will include:

      patient name
      date
      radioisotope
      treatment site
      source strength
      total number of sources
      total dose

   c. 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 provided that the information provided by the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

Guidelines: (continued)

2. Patient Identification

Prior to the procedure, the patient will be identified in a redundant fashion by the radiation oncologist. The procedure will include asking the patient's name and confirming it. In addition, one of the following will be compared to the patient's record:

name on the patient's identification bracelet
address
social security number
signature
hospital ID card
medical insurance card
photograph of patient's face
date of birth

3. It is the responsibility of all individuals participating in a brachytherapy procedure to insure that they understand their contribution to the procedure prior to initiating work. If confusion or doubt about the actions to be taken exists each individual must consult the written directive and/or the authorized user before proceeding.

4. Prior to the procedure specific details of the procedure will be verified against the written directive and plan of treatment for correctness in particular, the radioisotope, the number of sources, source strengths, treatment site and total dose.

5. Prior to the procedure, a plan of treatment will be made, using ultrasound studies. A schematic drawing of planned source placement will be made and reviewed.

6. The positions of the sources will be verified after the procedure by radiographic techniques.

Guidelines: (continued)

7. After the procedure, the authorized user will note in the patient's record the following:

   actual number and strength of sources implanted
   site
   pattern of implantation
   total dose

8. An independent check on the dose calculation will be performed. This check consists of verifying the source manufacturer's statement of calibration by placing 10% of the sources into a source calibrator and verifying the manufacturer's measurements.

9. The computer program used to generate the plan of treatment and the dose calculations will be tested by review of the calculated distribution for single sources of I-125 and Pd-103. These tests will be performed with each software update.

10. The definition of terms, recordable event, misadministration and written directive will be taken from 10CFR35. In the event of a recordable event or misadministration, the actions specified in 10CFR35 will be followed.

11. An annual review of all brachytherapy procedures will be conducted to confirm that the statement of dose as found in the written directive is consistent to within +/- 10% of what was actually delivered to the patient. The dose will be considered to be in accordance with the written directive as long as some volume of the prostate receives that dose.

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee WI 53226-3596
Telephone: 414 259 3000

Staffed by physicians of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

November 19, 1996

Chairman, Radiation Safety Committee
Community Memorial Hospital
W180N8085 Town Hall Road
P.O. Box 408
Memonomee, Falls, WI 53052

Dear Sir:

This is to inform you that Colleen Lawton, M.D., Christopher Schultz, M.D. and Julia White, M.D. are currently authorized for human use of byproduct materials on NRC Byproduct License number 48-04193-01, for the following procedures:

1. Use of radiopharmaceutical for therapy.

   This permits use of any radioactive material in a radiopharmaceutical and for therapeutic use for which the Food and Drug Administration has accepted a " Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials shall comply with the package insert instructions regarding indications and method of administration.

2. Use of sources for brachytherapy.
   This permits use of radioactive material as sealed sources used in accordance with the manufacturer's radiation safety and handling instructions and in accordance with code of federal regulations as stated in 10CFR35, Subpart G-Sources for Brachytherapy and FMLH NRC license conditions.

3. Use of a sealed source in a teletherapy unit.
   This permits use of cobalt-60 as a sealed source used in teletherapy unit in accordance with code of federal regulations as stated in 10CFR35, Subpart I-Teletherapy and FMLH NRC license conditions.

B. David Collier, M.D.
Chair, Radiation Safety Committee

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No. 5[illegible]21 Expires 11/31/97

CHRISTOPHER SCHULTZ MD
3850 CHARTER POINT CT
BROOKFIELD WI 53045

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No. 25975 Expires 11/01/97

COLLEEN ANNE FOTSCH LAWTON MD
34505 SPRINGBANK RD
OCONOMOWOC WI 53066

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

State of Wisconsin

DEPARTMENT OF REGULATION AND LICENSING
COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

Activity

MEDICINE AND SURGERY

No. 34810

Expires 11/01/97

JULIA R WHITE MD
163 N 86TH ST
WAUWATOSA WI 53226

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and is hereby authorized to engage in the practice indicated.

Policy # 729 - 01 - 03

File Section: Nuclear Medicine

Dist.: #'s 50,51

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

COMMUNITY HEALTH CARE SERVICES
COMMUNITY MEMORIAL HOSPITAL
Menomonee Falls, Wisconsin
POLICY MANUAL

Departmental Approval_____
Administrative Approval_____
Medical Dir. Approval_____
Medical Staff Approval_____

December, 1996 (Revised)

Policy Statement:

A Quality Management Program is maintained for the administration of radiopharmaceuticals.

Purpose:

To avoid misadministrations of radioactive materials and to ensure that radiopharmaceuticals are administered in accordance with directions of an authorized physician user.

Guidelines:

1. Written procedures for all <u>diagnostic</u> studies using I-125 or I-131 will be maintained, including:

   - A description of each procedure;
   - The radiopharmaceutical to be administered;
   - The dosage range to be administered;
   - The route of administration;
   - The approval and signature of an authorized physician user named on the NRC license.
   - Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

2. For <u>Therapeutic</u> Radiopharmaceuticals and I-125 or I-131 sodium iodide administrations of greater than 30 uCi activity, Metastron Sr-89, the Quality Assurance form will be filled out prior to administration and to follow:

   A. <u>Written Directives</u>

   For all therapeutic administrations of I-131, P-32, and Sr89 and for diagnostic administrations of greater than 30 uCi of I-125 or I-131 sodium iodide an authorized user will date and sign a "written directive" prior to the administration.

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

A. Written Directives (continued)

The written directive will include:

- The patient name;
- The date;
- The radiopharmaceutical;
- The dosage;
- The route of administration (for P-32).

NOTE: Revisions to the written directive may be made in compliance with the footnote to 10 CFR 35.32 (a)(1).

- 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 provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. Patient Identification:

Prior to administration of a radiopharmaceutical, the identity of the patient is to be verified by more than one method. These are to include asking the patient (or guardian) his name and confirming the identity by comparison to at least one of the following items of information in the patient's record:

- Birth date;
- Address;
- Social security #;
- Signature;
- Identification bracelet;
- Hospital I.D. card;
- Medical insurance card;
- Drivers license.

Guidelines: (continued)

C. Verification of Proper Radiopharmaceutical:

Prior to administration of a radiopharmaceutical, specific details of the administration must be verified to confirm they are in agreement with the written directive. These details are to include:

- Correct radiopharmaceutical;
- Correct dosage (dose calibrator reading must be within +/- 10% of directive);
- Route of administration.

3. If the criteria listed below meet that for a recordable event or misadministration, Policy #729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals, as described in 10CFR35 will be followed.

A. Recordable event for I-125 or I-131:

Procedure	Recordable Event
All Diagnostic Radiopharmaceuticals (including <30 uCi NaI, I-125 or I-131).	----------
Sodium Iodide Radiopharmaceuticals (where >30 uCi NaI I-125 or I-131).	- Administration of radiopharmaceutical other than the one intended - Admin dosage differs by >10% prescribed dosage and >15 uCi - W/o written directive - W/o daily dosage record - Administration to the wrong patient

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

B. Recordable events for Sr-89, or other qualifying Radiopharmaceuticals:

- The absence of a written directive.
- The absence of a record of the administered dose.
- The ratio of the difference between the administered dose and the prescribed dose divided by the prescribed dose is greater that 10%, but less than 20%.
- Administration to the wrong patient.
- Administration of radiopharmaceutical other than the one intended.
- Administration of a radiopharmaceutical by a route or site of administration other than that intended by the prescribing physician.

C. Misadministration for I-125 or I-131:

	Misadministration
All Diagnostic Radiopharmaceuticals (including <30 uCi NaI, I-125 or I-131);	- Wrong patient, radiopharm, route or dosage and - Dose >5 rem Effective Dose Equivalent or [illegible] rem to organ
Sodium Iodide Radiopharmaceuticals (where >30 uCi NaI I-125 or I-131)	- Wrong patient - Wrong radiopharm - Admin dosage differs by >20% prescr dosage and >30 uCi.

Misadministration for Therapeutic Radiopharmaceuticals other than I-125 or I-131 (Sr-89, etc.):

- The dose is delivered to the wrong patient;
- The wrong radiopharmaceutical is delivered;
- The route of administration is wrong;
- The ratio of the difference between the administered dose minus the prescribed dose divided by the prescribed dose is greater that 20%.

Guidelines: (continued)

D. Ask Questions:

If any portion of the written directive and/or the necessary methods to carry out the written directive are unclear, the worker(s) must clarify these questions before continuing with the procedure.

E. Documentation of Dosage:

Refer to 10 CFR 35.32(d)(2)

After administration of the dosage, a record of the dosage given must be signed and dated by one or more of the following persons:

- An authorized user listed on the license;
- Another nuclear medicine physician, a physicist or technologist under the supervision of an authorized user.

The written documentation of the dosage and the written directive will be kept on file for at least three years.

4. Periodic Review of Quality Management Program:

Refer to 10 CFR 35.32(b)

On at least an annual frequency, a detailed review of the quality management program will be conducted.

The review is to include:

- A review of a representative sample of randomly selected patient dosage administrations for compliance with the above program;
- A summary of all recordable events (Refer to 10 CFR 35.2 definitions);
- A summary of all misadministrations (Refer to 10 CFR 35.2 definitions and 10 CFR 35.33 reporting requirements).

Policy # 729 - 014 - 03

Subject: Quality Management Program for the Administration of Radiopharmaceuticals

Guidelines: (continued)

4. Periodic Review of Quality Management Program: (continued)

   The review is to include: (continued)

   - The number of cases reviewed when a misadministration or recordable event is uncovered will expand at the next periodic review of the QMP.
   - If upon periodic review or upon the suggestion of the Radiation Safety Committee a deficiency is noted in the Quality Management Program, modifications will be made immediately and the revised QMP will be submitted within 30 days to the NRC as required by 10 CFR 35.32(b)(2) and (e).
   - Records of the periodic review will be maintained three years as required in 10 CFR 35.32(b)(3).

5. Annual personnel training will include:

   - Inservice through meeting or written documentation with signature of personnel upon completing.
   - Viewing the Radiation Safety video.

References:

1. NRC Regulations 10 CFR 35.32.

2. NRC Regulatory Guide 8.33.

3. Annual Personnel Training for Quality Management Program Procedure.

4. Hospital Policy Manual

   #729-011-03, Notification/Reporting Misadministrations of Radiopharmaceuticals.

March, 1994
May, 1995 (Revised)
September, 1996 (Revised)
December, 1996 (Revised)

QUALITY ASSURANCE FORM FOR THERAPEUTIC ADMINISTRATION OF SODIUM IODINE, I-125 OR I-131 DOSES ABOVE 30 MICROCURIES
OR
STRONTIUM 89 CHLORIDE (METASTRON) OR POLADIUM 103

This survey is to insure that all requirements of the Nuclear Medicine Quality Management Program are followed and to evaluate the QMP on an annual basis. This form must be filled out prior to administration.

PATIENT NAME:_____ DATE:_____

NAME OF THERAPY OR RADIOIODINE PROCEDURE:_____

A. Written Directive Present: Yes No

B. Patient Identification by Name: Yes No

C. Comparison Identification:

1. Birthdate 2. Address 3. Social Security Number
4. Signature 5. Bracelet 6. Hospital ID Card
7. Insurance Card 8. Driver's License

D. Informed Consent Signed: Yes No

E. Is Calculated Administered Dose within 20% of Written Directive:
Yes No

If there is a > 20% difference, this may constitute a misadministration. Notify hospital administration, the authorized user, and the RSO.

F. Is Calculated Administered Dose within 10% of Written Directive:
Yes No

If there is a > 10% difference, this may constitute a recordable event. Notify the authorized user and the RSO.

G. Dose Prescribed in mCi _____I-125 _____I-131 _____Sr-89
on Written Directive

H. Total Dose Administered _____I-125 _____I-131 _____Sr-89
in mCi

I. Route of Administration/Treatment site_____

J. Was there a deviation from Written Directive Yes No

If Yes, attach a detailed explanation.

Authorized User:_____MD Date_____
on Written Directive

Dose Administered by:_____MD Date_____
Sign and Print Last Name

Form Completed By_____ Date_____
Sign and Print Last Name