VOID SHEET

TO: License Fee Management Branch

FROM: RIII - _____

SUBJECT: VOIDED APPLICATION

Control Number: 304463

Applicant: Madison Community Hospital

License Number: 21-32128-01

Docket Number: 030-34847

Date Voided: 12/2/98

Reason for Void: Applicant unable to respond to deficiency request in a reasonable amount of time. No refund due.

Michael L Weber 12/2/98

Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

___ Refund Authorized and processed

✓ SC No Refund Due

___ Fee Exempt or Fee Not Required

140034

Comments: _____ Log completed ✓

_____ Processed by: SC 12/11/98

9812140193 981202
PDR ADOCK 03034847
C PDR

ML30

JAW

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code:
Status Code: 3
Fee Category:
Exp. Date: 0
Fee Comments:
Decom Fin Assur Reqd:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: MADISON COMMUNITY HOSPITAL
   Received Date: 980929
   Docket No: 3034847
   Control No.: 304463
   License No.:
   Action Type: New Licensee

52

2. FEE ATTACHED
   Amount: 1800
   Check No.: 1699

3. COMMENTS

Signed D. Hersey
Date 10-1-98

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

1. Fee Category and Amount: 7C #1800

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

3. OTHER

Signed SC
Date 10/6/98

Log Oct 4 III
Remitter
Check No. 1699
Amount #1800
Fee Category 7C
Type of Fee Fee
Date Check Rec'd 10/
Date Completed 10/6/98
By: SC

* For Madison Comm. Hosp.

AA905 APP 7C

oct 4 III

1699

COMMUNITY MEDICAL CENTER, P.C.
30071 STEPHENSON HWY.
MADISON HTS., MICHIGAN 48071
(810) 585-4760

FIDELITY BANK
BIRMINGHAM, MICHIGAN 48009
74-1265-724

9/28/98

PAY TO THE ORDER OF U S Nuclear Regulatory Commission $ **1,800.00

One Thousand Eight Hundred and 00/100********** DOLLARS

U S Nuclear Regulatory Commission
License Fee & Accounts Rec
P O Box 954514
St. Louis, MO 63195-4514

MEMO AM4580-98

E Carole Shaya

"001699" :072412655: 00**151**309"

Security features details on back.

RECEIVED
1998 OCT -5 PM 2:17

30443

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

September 28, 1998

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

Dear Agent:

Enclosed please find a completed application for a Nuclear Regulatory License on behalf of the Madison Community Hospital along with a check in the amount of $1,800. Dr. Farideh R. Bagne has been designated as the authorized agent for the Hospital. Please contact her regarding any aspects of this application. She is also the Radiation Safety Officer for this license and will be available to answer any questions regarding our application. Dr. Bagne may be reached at the address above, or you may contact her at (248) 583-7393, Pager # (810) 856-1234. You may also Fax her at (248) 588-9140.

She will be contacting your office to discuss our application.

Sincerely,

Ezra Shaya, MD
Chairman
Executive Board

:bhw

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

September 30, 1998

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

Dear Agent:

The Madison Community Hospital plans to start a program for cancer treatment using ultrasound-guided prostate implant with Iodine-125 radioactive seeds (10CFR, Part 35.400 materials). As the Radiation Safety Officer I have already implemented this program in 1996 at St. Joseph Mercy Hospital, Pontiac, Michigan (NRC License No. 21-11651-01) and in 1997 at Oakland General Hospital, Madison Heights, Michigan (NRC License #21-11494-01). The programs at both hospitals have been running successfully and have been inspected on several occasions by the NRC without any violations.

The proposed program I intend to set up at Madison Community Hospital is in every aspect identical to the above two hospitals. Since we have a number of patients waiting for this procedure, we would greatly appreciate it if the licensing procedure could be expedited. Should you have any questions regarding this application, please contact me and I will provide the necessary documents or answers immediately.

For further reference, I can be reached at the address above, or you may phone me at (248) 583-7393, Fax (248) 588-9140. Thank you for your cooperation.

With kind regards,

Farideh R. Bagne, PhD, JD
Licensed & Board Certified Medical Physicist

cc: NRC File

c:\madison\bagne\applica.ltr

Madison Community Hospital

APPLICATION FOR MATERIAL LICENSE
ATTACHMENT A

Item 5 - Radioactive Material

Byproduct Material	Amount:
Materials in 35.400 (Iodine - 125 Seeds)	As needed

Item 6 - Purpose

Brachytherapy prostate implant and other medical uses (therapeutic treatments).

Item 7 - Individuals Responsible for Radiation Safety Program and Their Training Experience.

Radiation Safety Officer: Dr. Farideh R. Bagne

Dr. Bagne is certified by the American Board of Radiology in Radiological Physics (Nuclear Medicine, Radiology and Radiation Therapy). She has been the Radiation Safety Officer for brachytherapy on a number of hospital licenses from NRC, including: St. Joseph Mercy Hospital, License # 21-1165101 (Pontiac, Michigan); Oakland General Hospital, License # 21-11494-01 (Madison Heights, Michigan), and American Oncologic Associates of Michigan, License # 21-26488-01 (Pontiac, Michigan). A copy of her board certification is already on file with NRC.

Item 8 - Training for Individuals Working in or Frequenting Restricted Areas.

We will establish and implement the model training program that is published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT8.1 that identifies the groups of workers who will receive training and the method and frequency of training.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

Item 9 - Facilities and Equipment

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to the Regulatory Guide 10.8, Revision 2 as shown below:

1 The source will be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance will be traceable by documented measurements to a standard certified within 5 percent accuracy the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The course will be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law will be used to correct for change in exposure rate due to changes in distance or source decay.

6. A cored will be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

Alternatively calibration of survey meters will be performed by Radiological Physics Service, Inc., License #21-26253-01, or by another licensed service.

Instrumentation

Survey meters:

a. Manufacturer: Victoreen
b. No. of Instruments Available: 1
c. Model No.: 493
d. Maximum Range: 0 to 50 mR/hr.
e. Minimum Range: 0 to 0.5 mR/hr.

a. Manufacturer: Victoreen
b. No. of Instruments Available: 1
c. Model No. 495
d. Maximum Range: 0 to 1000 mR/hr.
e. Minimum Range: 0 to 0.1 mR/hr.

Dose Calibrator:

a. Manufacturer: Capintec
b. Model No. CRC-4

Facility Drawing

See attached diagrams.

Item 10 - Radiation Safety Programs
We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide, Revision 2.

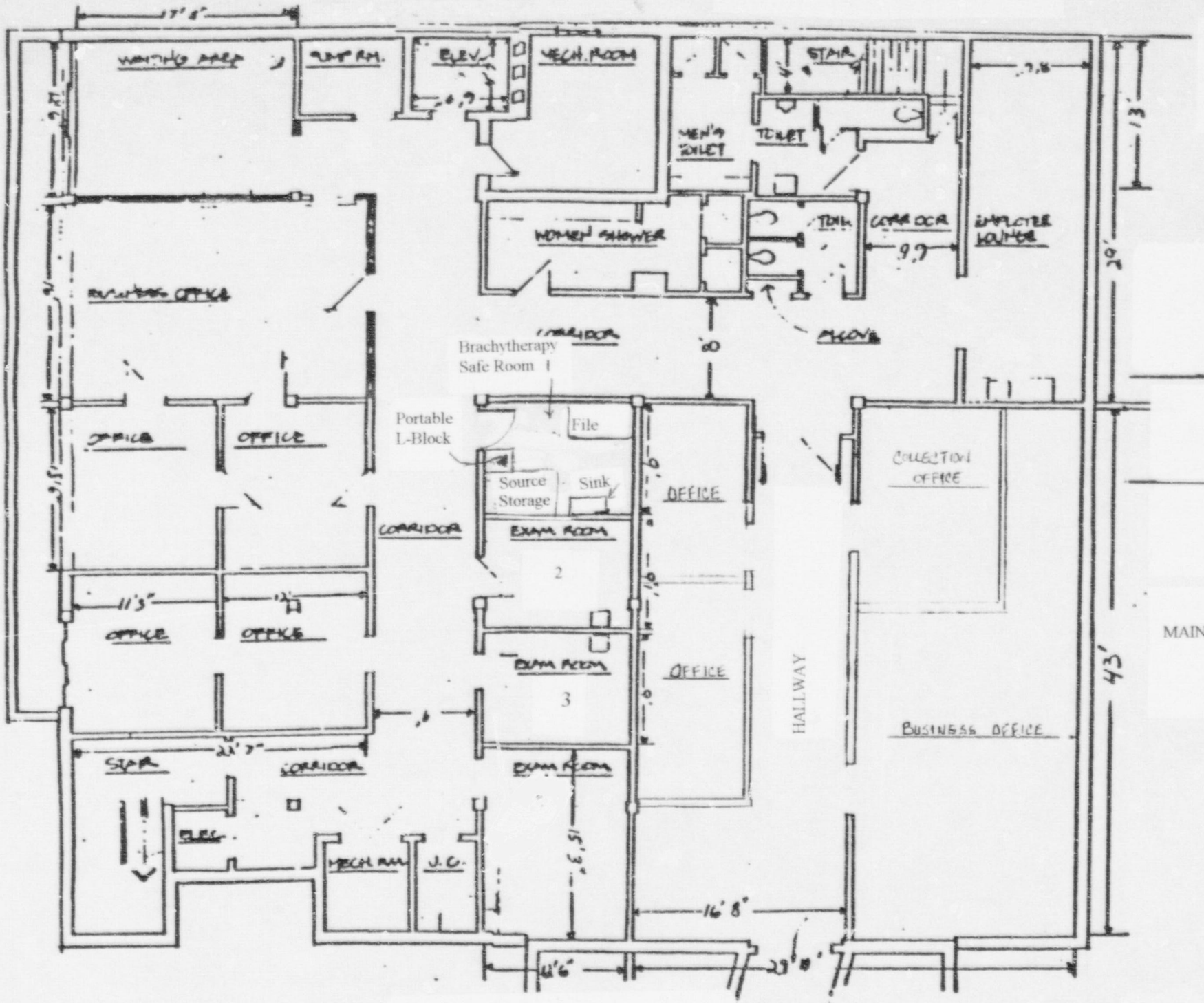
Item 10.1 Program

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization changers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

Parking Area



BUILDING EXTERIOR

MADISON COMMUNITY HOSPITAL MADISON HEIGHTS, MICHIGAN

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license.

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. identify program problems and solutions.

Responsibilities The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments.;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Office (RSO), and the Teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;

8. recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, action, recommendations, decision, and numerical results of all votes taken; and

10. Ensure that the by-product material license is amended if required prior to any changes in facilities, equipment, policies, procedures and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but no less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plan,

housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: All Employees
From: Ezra Shaya, M.D.
Chief Executive Office/Chairman of the Board
Subject: Delegation of Authority

Dr. Farideh R. Bagne has been appointed Radiation Safety Officer and is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Office is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

10.3 - Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA.

We will establish ad implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

ALARA PROGRAM

Madison Community Hospital
September 14, 1998

1. Management Commitment

   a. We, the management of this Hospital, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment,

we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include review of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

3. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

* The NRC has emphasized that the investigational levels in this program are not new dose limits, but as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

10.4 **Procedure for Leak Testing Sources.**
We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

MODEL PROCEDURE

1. We will make a list of all sources to be tested. This will include at least the isotope, the activity on a specified date, and the physical form.

2. If we will be testing sources stronger than a few millicuries, we will set out a survey meter, preferably with a speaker, so we can monitor our exposure rate.

3. We will prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper suitable. We will number each wipe so we will know for which source it is to be used. Samples will be taken as follows:

   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

   e. Continue the same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from sue to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR {art 21 and paragraph 35.59(e)(2)of 10 CFR Part 35.)

   g. Sign and date the list of sources, data, and calculations.

10.5 **Guidance for Ordering and Receiving Radioactive Material (§ 30.51 and 20.205)**

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulator Guide 10.8, Revision 2.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      1. Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      2. The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

      1. The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      2. The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security

FROM: Dr. F.R. Bagne, Radiation Safety Officer

SUBJ: Receipt of Packages Containing Radioactive Material
Madison Community Hospital

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package on top of the counter, sign the logbook, and relock the door. Call RSO and notify her of the shipment arrival.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the Hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our Hospital Radiation Officer, Dr. F.R. Bagne, at Ext. 393.

	Name	Office Phone	Home Phone/ Pager
Radiation Safety Officer	Dr. F.R. Bagne	393	810-856-1234
Radiology Manager	Sandy Piotrowski	391	
Radiology Director	Dr. Nefcy		
Nuclear Medicine Physician	Dr. R. Gunabalan	585-5115	

MODEL PROCEDURE:

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.250(b) of 10 CFR Part 20. Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III". Yellow III labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFP Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 173.403 of 49 CFR Part 172))

   d. Open the package with the following precautionary steps:

      1) Remove the packing slip

      2) Open the out package following the supplier's instructions, if provided.

      3) Open the inner package and verify that the contents agree with the packing slip.

      4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packaging material.

      5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

1) If contaminated, treat this material as radioactive waste.

2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Checked to ensure that the material received is the material that was ordered.

10.7 - Records of Byproduct Material Use

We will establish and implement the model procedure for keeping an inventory of implant sources (Section 30.51, 35.21, 35.406) that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you every perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

10.8 **Procedure for Radiation Safety During Implant Therapy**

We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in paragraph 20.105(b) of 10 CFR Part 20.

2. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Temporary Implant Sources," Exhibit 20, or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line" and in the surround hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

8. Do not release any patient who has received a temporary implant from the Hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the Hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

We will use the forms in Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy," Exhibit 20, "Nursing Instructions for Patients Treated with Temporary Implant Sources," and Exhibit 21, "Sample Cesium Implant Source Log."

11. Waste Management Procedure for Waste Disposal

GENERAL GUIDANCE

1. All radioactivity labels will be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass will be defaced or removed.

2. Employees are reminded that nonradioactive waste such as leftover reagents, boxes and packing material should not be mixed with radioactive waste.

3. Occasionally all procedures will be monitored to ensure that radioactive waste is not created unnecessarily. All new procedures will be reviewed to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, the entire impact of various available disposal routes will be considered. The occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxi-city, carcinogenicity, pathogenicity, flammability), and expense will be considered.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If we use this procedure, we will keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Small departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 210 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

    a. Check your radiation detection survey meter for proper operation;

    b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

    c. Remove any shielding from around the container;

    d. Monitor all surfaces of each individual container;

    e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from of the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RETURNING IODINE-125 SEEDS TO THE MANUFACTURER

Excess or unused iodine will be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.457(8) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

Madison Community Hospital

IODINE-125 SOURCE LOG

The following individuals are authorized to handle Iodine-125 Sources:

Dr. F.R. Bagne		

1.) **Receipt** (attach all paperwork)

Date: Time:
No of Sources:
Activity 1) Individual _____ mCi 2) Total _____ mCi

Manufacturer: Type:
Received by: Placed in:

2.) **Removal**

Date: Time:
Number of Sources Removed: Total Activity: _____mCi
Patient Name: Removed:
Location: _____ Room No._____ O.R. No._____

Removed by: _____ Purpose:_____

3.) Returned to Safe:

Date: Time:
No. of Sources: Total Activity:_____mCi

History: _____
Done by: _____

4.) Return to Manufacturer: (Attach all paperwork)

Date: Time:
No. of Sources: _____ Activity:_____mCi
Done by: _____

MADISON COMMUNITY HOSPITAL

PACKAGE RECEIPT AND MONITOR LOG

Date Rec'd	Purchase Ord. No.	Packing Slip No.	mCi	iso	Chemical	Supplier	Catalogue Number	Pkg. OK?	mR/Hr Surf	Notes	Init

c:\madison\bagne\monitor.log

Madison Community Hospital

SURVEY METER CALIBRATION REPORT

Owner:_____ Department:_____

Manufacturer:_____ Type: ○ Ion Cahmger ○ GM ○ Nal (T1) ○ _____

Meter Model:_____ Meter S/N:_____ Probe Model: _____ Probe S/N_____

Calibratrion Source: _____mCi of _____m/R/Hr. at _____ in on _____, 19____

Instrument Checks: Battery Check: _____mR/Hr. or _____

Constancy Check: ○ Integral Chgeck Source Indicates _____mR/Hr.

○ _____mCi of _____ Indicates _____mR/Hr.

Calibration Geometry: 

Window: ○ Open ○ Closed ○ Fixed

Dist. (Feet)	mR/Hr. Today	Scale: Rdng	CorFac	Scale: Rdng.	CorFac	Scale: Rdng.	CorFac	Scale: Rdng.	CorFac

Correction Factors: _____ _____ _____ _____

Name:_____ Date:_____

Calibration Sticker:

Cald____ - ____ - ____ With _____
// _1_ Window:_____

Scale CorFac
_____ _____ bat:"_____mR/Hr."

_____ _____ _____

_____ _____ chk:"_____mR/Hr."

c:\madison\bagne\Calibra.rep

Madison Community Hospital

30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

PROCEDURE FOR ORDERING I-125 SEEDS

1. Use standing purchasing order #_____ from Madison Community Hospital.

2. Determine the activity of the I-125 seeks (6711, I-125, Type 109) from the pre-plan _____ mCi of type_____.

3. Determine the total number of seeds _____.

4. Check with the radiation oncologist to ensure the written directive is completed.

5. MCH's NRC License is #_____.

6. MCH's Amersham Account # is _____.

7. Call:

   Amersham Healthcare
   Medi-Physics, Inc.
   2636 S. Clearbrook Drive
   Arlington Hts., IL 60005
   Customer Service: 1-800-228-0126
   Technical Information: 1-800-554-0157

   Give:
   - Total # of I-125 Seeds_____
   - Type of Seed: ☐ 109 ☐ 6711
   - Activity per Seed _____
   - Date of Insertion: _____
   - Date of Delivery: _____
   - Location of Delivery: Hand deliver to MCH's Radiology Department.
   - Your Name:_____
   - Give Dr. Bagne's Phone No. (248) 583-7393.
   - Refer to MCH's Account and Purchase Order Numbers.

8. Fax a copy of the prescription to MCH to Betty Wynn at 248-588-9140.

9. Amersham's Order No._____

10. File this sheet in nurse's I-125 patient book and a copy in the patient's Hospital chart.

11. Patient_____ Order Date_____

Madison Community Hospital

SHORT-LIVED IMPLANT SOURCE LOG

Only the following individuals may handle threse sources: _____

_____

RSO:_____ Date: _____

	No.	iso	act	
Received On:_____	_____	_____	_____	iso each
	_____	_____	_____	
	_____	_____	_____	

Date	Time	no	mC1	no	mC1	no	mC1	Patient Name	mR/hr	Init.

c:\madison\bagne\impsource.log

Madison Community Hospital

PATIENT NAME_____ **TOTAL SCORE**_____

DATE OF VISIT_____

AUA SYMPTOM CODE

Please fill out this short questionnaire to help us find out more about any urinary problems you might have; for Questions 1 through 5, circle the number. Circle the number in the column that best describes your situation; for Question 6, circle the number in the row which best describes your situation.

	Not At All	Less Than One Time in Five	Less Than Half the Time	About Half The Time	More Than Half The Time	Almost Always
1. Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. Over the past month or so, how often have you had to urinate, less than two hours after you finished urinating?	0	1	2	3	4	5
3. Over the past month or so, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. How often do you find it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month or so, how often have you had a weak urinary stream?	0	1	2	3	4	5

	Not At All	Once Every 8 Hours	Once Every 4 Hours	Once Every 3 Hours	Once Every 2 Hours	At Least Once Every Hour
6. Over the past month or so, how often did you most typically get up at night to urinate?	0	1	2	3	4	5

c:\madison\bagne\auasymp.frm

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL-OPERATING ROOM

CERTIFICATION OF RADIATION HAZARD STATUS

At _____AM / PM on _____ (date) the brachytherapy implant of _____ (patient) was completed. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any **CAUTION** signs have been left in place, or if you have any questions about the radiation status of this room, please call MADISON COMMUNITY HOSPITAL or the attending Radiation Oncologist.

Please return this form to MADISON COMMUNITY HOSPITAL or call (248) 588-8000.

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

RADIATION SAFETY SURVEY FORM
IODINE-125 PROSTATE SEED IMPLANT

Patient_____ Date:_____

Activity in mCi per seed _____ # of seeds _____ Total Activity _____

1. Indicate those locations to be surveyed.
2. Record values bellow.
3. Limit nurses and staff to 2.0 mR in any hour.
4. Limit visitors and other patients to 100 mRem total.
5. Make sure some diagnostic equipment isn't interfering with the survey.
6. Upon completion of this form, return to Radiation Safety Office at MADISON COMMUNITY HOSPITAL.

Survey Instrument used_____ Background reading (mR/hr) _____

	Room		Room
1.	OR Floor-	1.	Bedside-
2.	Patient Groin-	2.	1 m from patient-
3.	1 m from patient-	3.	6 ft from patient-
4.	6 ft from patient-	4.	Urine container-
5.	Table tops-	5.	Bathroom-
6.	Urine bag-	6.	Floor-
7.	Urine container-	7.	Bed-
8.	Staff bodies/feet-	8.	Table tops-
9.	Needles-	9.	Trash-
10.	Template/Stepper-	10.	
11.	Trash-		
12.	Done By:_____		Done By:_____

Madison Community Hospital

U.S. GUIDED IODINE-125 PROSTATE IMPLANT BRACHYTHERAPY
ULTRASOUND INFORMATION SHEET

Patient's Name: _____ Date:_____

Ultrasound: 1st_____ 2nd_____ 3rd_____ Other_____

Number of Contours Outlined _____ Total Volume: _____cc Sagittal Views:_____

Patient Under Hormonal Therapy: _____ Re-Ultrasound Needed: _____

Physician:_____ Tech: _____

Urologist:_____

Special Instructions:

_____

_____

_____

_____

_____

This form is to be filed in the patient's chart immediately.

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL

CERTIFICATION OF RADIATION HAZARD STATUS

On _____(date) the patient_____ was permanently implanted with _____mCi total activity of radioactive I-125 seeds. In accordance with 10 CFR 35.75, the patient may be discharged provided **the measured dose rate is at or below 1.0 mR/hr at 1.0 meter**.
Survey instrument used: _____
mR/hr at 1.0 meter: _____

At _____ AM / PM on _____(date) the room was surveyed and the patient was discharged. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any **CAUTION** signs have been left in place, or if you have any questions about the radiation status of this room, please call MADISON COMMUNITY HOSPITAL or the attending Radiation Oncologist.

Please return this form to MADISON COMMUNITY HOSPITAL or call (248) 588-8000.

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

1-125 PROSTATE SEED IMPLANT
NEEDLE GUIDESHEET

Patient Name_____ ID#_____Date_____Done By:_____

Inferior										Superior
Plane #										
Needle #:										
1.....										
2.....										
3.....										
4.....										
5.....										
6.....										
7.....										
8.....										
9.....										
10.....										
11.....										
12.....										
13.....										
14.....										
15.....										
16.....										
17.....										
18.....										
19.....										
20.....										
21.....										
22.....										
23.....										
24.....										
25.....										
26.....										

c:\madison\bagne\ndlguide.sht

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

PATIENT IDENTIFICATION

IODINE-125 PROSTATE SEED IMPLANT

Patient Name: _____ Date:_____

Prior to the administration of any Seed, identify the patient by two or more of the following methods, then compare to the patient's record.

a. Patient's Name _____

b. Birth Date _____

c. Address _____

_____

_____

d. Social Security # _____

e. ID Wrist Band/Hospital ID_____

f. Name on Patient's Medical Insurance:_____

g. Photo of Patient's Face_____

h. Patient's Signature _____

Done By_____

Signature_____

Madison Community Hospital

ULTRASOUND GUIDED PROSTATE IMPLANT FLOWSHEET

Patient:_____ Physician_____ Date:_____ Done By: _____

	Yes	No	Date
I. PRELIMINARY STATUS			
Consult Status			
Initial Simulation Films Taken Complex			
CT Scan for Pubic Arch Study Done			
Ultrasound Volume Study Done			
Ultrasound Images Labeled as to Sequence (Base to Apex)			
Target Volume Indicated on each Image			
Urethra Marked if Sparing Desired			
Target Volume ____ Desired Isotape____ Desired MPD__ GY			
II. **PRE-PLAN**			
Volume Study Signed by Oncologist & sent to Dosimetry			
Number of Seeds Required by Plan_____ Plus_____ Extra			
Activity of Individual Seeds = _____mCi			
Total Contours Planned _____			
Pre-Plan Reviewed by 2 Physics People			
Pre-Plan Approved & Signed by Radiation Oncologist			
III. **ORDERING**			
Written Directive Part I & Prescription completed			
Seeds Ordered (Written Directive Part II)			
Delivery Date _____ Implant Date_____			
IV. **DAY OF IMPLANTATION**			
Patient Identification Completed (Written Direction Part III)			
Needle Loading Verified by 2 Physics People			
All Factors Checked Prior to Treatment			
Treatment Administered without Problems			
O.R. Surveyed After Implantation			
All Seeds Accounted for After Implantation			
Written Directive Part IV and Notice of Treatment Completed			
Patient Given Post-Implant Instructions, Pb Packet & Strainer			
Patient and Room Surveyed Prior to Discharge			
All Radioactive Signs Removed & Stored after Patient Release			
V. **POST-IMPLANTATION**			
Post-Implant Simulation Films Taken-Complex			
Check Simulation Films taken-Simple			
CT Scan of Pelvis with 0.5 cm cuts done for Post-Plan			
Post-Treatment Verification Plan Done			
Post-Treatment Plan Reviewed by 2 Physics People			
Post-Treatment Plan Approved and Signed by Oncologist			
Final Billing Completed			

Answers of "NO" should be explained if not self-explanatory

Madison Community Hospital

CT-BASED PUBIC ARCH INTERFERENCE STUDY FOR I-125 PROSTATE SEED IMPLANT PATIENTS

Requested by: _____

Patient Name _____

Done By: _____

Date: _____

Utilizing the Treatment Planning CT Scan, I have evaluated the position of the pubic arch in relation to the prostate gland.

_____ The arch should not impede the progress of the Brachytherapy needles.

_____ The arch may interfere with the treatment.

_____ Other: _____

_____

_____

_____

Physician Approval

c:\madison\bagne\archint.stu

Madison Community Hospital

RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY

Patient: _____ Room:_____ Date: _____

PREPARATION

- ☐ Schedule a private room in a low traffic area.
- ☐ Mark a visitors' "safe line" on the floor.
- ☐ Brief the nursing staff on radiation safety measures.
- ☐ Supply their nursing staff with personnel radiation dosimeters.

IMPLANT

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedure.
- ☐ Insert the implant.
- ☐ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- ☐ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

- ☐ Make a radiation survey of the patient to assure that all sources have been removed.
- ☐ Count the number of sources removed from the patient to assure that all sources have been removed.
- ☐ Remove the "Radioactive Materials" sign.

Madison Community Hospital
Madison Hts., MI
SPECIAL RADIATION ISOLATION ORDERS
Iodine-125 Prostate Seed Implant

Addressograph

Total Activity: _____ mCi Assay Date:_____ Site of Application:_____

Patient Name_____

Attending Physicians:_____

Date of Insertion:_____ Time of Insertion_____

THIS PATIENT IS IN RADIATION ISOLATION UNTIL ORDERS ARE RESCINDED BY RADIATION ONCOLOGIST

1. Nurses - Not more than _____ minutes in any one hour at bedside and not more than _____ minutes in nay one hour at six (6) feet.
2. No pregnant visitors or visitors under 18 years of age.
3. Visitors should sit at least _____ feet from the patient and limit their stay to _____ minutes per hour.
4. Surgical dressings to be changed only by the physician or individual designated by him/her and trained in techniques applicable to such cases.
5. In the event of the patient's death, contact the Radiation Oncologist and Brachytherapy RSO immediately.
6. The room cannot be reused until surveyed and declared radiation free.
7. Additional instructions: _____

EXPOSURE RATES (mR/hr)

Background	Bedside	One Meter	Six Feet	Date	Initials

IN CASE OF EMERGENCY, or for further information, call 248-588-8000, Ext. 391

Name	Title	Office	Pager/Home

AT TIME OF PATIENT DISCHARGE, SEND THIS FORM TO THE RADIATION SAFETY OFFICE AT MCH.

Madison Community Hospital

TEMPLATE/WORKSHEET
NOTICE OF BRACHYTHERAPY TREATMENT
ULTRASOUND-GUIDED IODINE-125 PROSTATE SEED IMPLANT

Name:_____

M/R No.:_____ Age:_____ Date of Birth_____

Referring Physicians: _____

_____

(List all physicians involved in care of patient)

Diagnosis: Prostate Carcinoma, Stage_____, (T_____, N_____, M____
Gleason Score ____ + ____ = ____, Initial PSA ____ng/ml, (___/___)

Date of Treatment: Day:_____ Date: _____

☐ 120 Gy (12,000 cGy)

Site: Prostate Gland Prescribed Dose: ☐ 160 Gy (16,000 cGy)

Needle Placement by Urologist: _____

(Full Name of Urologist)

No. of Needles_____ No. of Seeds_____

Seed Strength:_____mCi Total Activity:_____mCi

RESPONSE TO TREATMENT	
	Patient is status post external beam radiotherapy with 4500 cGy to pelvis.
	Patient tolerated procedure without difficulty.
	Fluoroscopy was used intraoperatively to evaluate the seed distribution pattern.
	Integrity of bladder and urethra confirmed by cystoscopy performed by Dr.:
ADDITIONAL PROPOSED TREATMENT	
	None-pending final dosimetry.
	Patient to begin external beam radiotherapy to pelvis for additional dose of 4500 cGy in: ☐ 4 Weeks ☐ 4 to 6 Weeks ☐ 6 Weeks ☐ 6 to 8 Weeks ☐ 8 Weeks
FOLLOW-UP SCHEDULE	
	Return to clinic in one day for orthogonal simulation.
	Return to clinic in three days for orthogonal simulation (For Friday Implants Only).
	Return to clinic in two weeks for CT/simulation for final dosimetry.
	Return to clinic in two weeks for CT/simulation for treatment planning of the pelvis and final seed implant dosimetry.
	Patient to see Dr._____ (urciogist in ☐ 1 wk for follow-up ☐interim for follow-up as needed.

_____
Attending Radiation Oncologist

cc: Medical Records - Cancer Registry

Madison Community Hospital

30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

To Patient:

You have selected to have a radioactive seed implantation to the prostate performed at Madison Community Hospital in Madison Heights, Michigan, for your prostate cancer.

The purpose of this letter is to inform you that, if for any reason, it is necessary for you to cancel your scheduled procedure:

WE MUST RECEIVE WRITTEN NOTIFICATION OF YOUR DESIRE TO CANCEL OR POSTPONE YOUR PROCEDURE AT LEAST THIRTY (30) DAYS PRIOR TO THE SCHEDULED SURGERY. IF WE DO NOT RECEIVE SUCH NOTIFICATION, IT WILL BE NECESSARY TO CHARGE YOU THE COST OF THE RADIOACTIVE SEEDS EVEN THOUGH THEY ARE NOT USED

We regret the necessity for this policy. The seeds are individually ordered for each patient and therefore cannot be easily transferred to another patient; they also have a "limited lifespan" and cannot be held for a significant period of time without being used. When the seed are shipped to Madison Community Hospital, the Hospital is then responsible to the manufacturer for the cost of the seeds, whether or not they are used. Depending on the number and type of seeds ordered, this cost could range from a minimum of $1,200.00 to more than $4,500.00 for which you would be held responsible.

We regret any inconvenience that this policy may cause you and trust that you will understand the necessity for it.

Sincerely,

F.R. Bagne, PhD
President, Chief Executive Officer

Date:_____ Time_____ AM/PM

Patient's Signature_____

Witness: _____

Madison Community Hospital

CONSENT FORM - IODINE-125 PROSTATE SEED IMPLANT

I,_____, know that I have a condition requiring radiation therapy. I have authorized Dr. _____ to perform the radiation therapy procedure known as **Ultrasound-Guided Iodine-125 Prostate Implant Brachytherapy**. I understand that this procedure is for the purpose of **controlling prostate cancer** and, although no specific result has been guaranteed, it is expected to **kill cancer cells in the prostate gland**. I understand that **POSSIBLE** complications are as follows: **Immediately post-op: slight bleeding beneath the scrotum; blood in the urine; bruising and tenderness between the legs. Later: frequent urination; burning with urination; sense of urgency; weakened urinary stream. Possible long-term side effects: narrowing of the urethra; impotence; loss of bladder control; damage to bladder; damage to rectum; rare risk of seed migration into a lung; or, rare risk of seed migration into ejaculatory fluid.**

I understand that an identification photograph of my face will be taken. In addition, photographs may be taken of me or parts of my body to be used for medical records. Also, if in the judgement of my physicians, medical research, education, or science will be benefitted by their use, such photographs and information relating to my case may be published and republished, either separately or in connection with each other, in professional journals or medical books or used for any other purpose which they may deem proper in the interest of medical education, knowledge or research, provided, however, that is specifically understood that, in any such publication or use, I shall not be identified by name.

I acknowledge that the doctors have explained to me the nature and purpose of the procedure and what the procedure is expected to accomplish, together with the known risks. I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees hav been made to me as to the results of the operation or procedure. Possible alternate methods of treatment, if any, have been explained, as have the results likely if I remain untreated.

With a full understanding of all the foregoing, and realizing that no guarantee or assurance has been given by anyone as to the results that may be obtained from this therapy, I do hereby request and authorize Dr. _____ and whomever they may designate to assist them to administer radiation treatments with **Iodine-125** radioisotope therapy to me.

Date_____ Time_____ ___AM/PM

Signature of Patient_____

Signature of Closest Relative or Legal Guardian_____

Physician's Signature_____

Witness:_____

Madison Community Hospital

DISCHARGE INSTRUCTIONS
RADIOACTIVE SEED IMPLANT
FOR PROSTATE CANCER

1. You may notice some blood in your urine. This is normal and should subside in approximately 24 hours. If after 24 hours the bleeding persists, or you begin to pass blood clots, you should contact your urologist.

   It is common to experience frequent urination, burning with urination, a sense of urgency or a decrease in the force of the urinary stream. These symptoms will gradually decrease as the seeds lose their strength, but may be present to some degree for 6-12 months after the implant. Drink plenty of fluids and void caffeine containing beverages to help relieve the symptoms.

2. If you experience any light-headedness, dizziness or a temperature over 100°, please contact your urologist right away.

3. Avoid heavy lifting or strenuous physical activity for two days. After that, you may return to normal activity.

4. No restriction on your travel or physical contact with other adults. If a child or pregnant woman is in the same room as you for more than 5-10 minutes, they should stay 6 feet or more away. since the radiation is coming from the prostate, children should not sit on your lap during the initial 2 month period following the implant. Do not sleep in the same bed as a pregnant woman or child.

5. Although rare, an occasional seed may be lost via urination within the first week following the implant procedure. If a seed is passed, it should be retrieved and returned to the Michigan Institute for Radiation Oncology. Strain your urine for the first week following the implant. If a seed is passed, it should be picked up with tweezers and placed in the packet provided.

6. A seed may rarely be passed with the ejaculate during intercourse. Use a condom during intercourse for the first two months following the implant procedure so that any possible seed can be retrieved. It is normal for the ejaculate to be discolored dark brown to black for up to several weeks following the implant procedure. Sexual intercourse may be resumed after two weeks.

Madison Community Hospital

BRACHYTHERAPY SERVICE
Radiation Oncology Quality Assurance Management Program
Written Directive to be used with _____

PART I

Patient Name_____ Room #_____

History Number_____ Date of Treatment_____

Attending Physician_____

Indication(s)_____

Procedure_____

Radiopharmaceutical SR-89 P-32 I-125 Pd-103

Dosage_____mCi or Gy Route_____

Authorized User Signature_____ Date_____

PART II

Ordered for_____MD/DO Date Ordered _____

Assayed by_____ _____ Date Assayed_____

Assayed Value_____ Ordered by _____ (Physicist)

PART III

The patient's identity must be verified by at least two of the following:

- ☐ Patient called by name
- ☐ Patient spelled his/her name
- ☐ Patient stated date of birth
- ☐ Patient stated social security number
- ☐ Patient provided positive identification
- ☐ Is patient pregnant?
- ☐ Is patient breast feeding?
- ☐ Booklet given and reviewed?
- ☐ Consent signed?
- ☐ Wrist bend verified?

PART IV

Dose Administered On (Date)_____ Time:_____

Actual Dose Delivered_____mCi

Bioassay Needed? Yes No

Authorized User_____ Date_____

Medical Physicist_____ Date_____ ☐ ☐ ☐ ☐

(Signature above indicates presence at administration and assurance that this written directive was followed.)

Madison Community Hospital

NURSING CHECKLIST

RADIOACTIVE SEED IMPLANT-PROSTATE

Patient _____

Urologist _____

Consultation Date _____

Simulation _____

CT Scan _____

Ultrasound _____

Surgery Date _____

Patient Teaching: _____

- Video view by Patient _____
- Patient Information Booklet _____
- Discharge Instructions-Surgery _____
- Antibiotic Rx _____

Consents: _____

- Notification of Seed Charge _____
- Iodine-125 Prostate Seed Implant Consent

Surgery Preparation to be Ordered: _____

- (2) Fleets Enemas AM of Surgery _____
- CBC, Electrolyte, PT, PTT _____
- FAT _____

CT Pelvis-Post Surgery _____

- Simulation Post Surgery _____

Appointments: _____

- Dr. Bagne _____
- MCH _____

Madison Community Hospital

WRITTEN DIRECTIVE

IODINE-125 PROSTATE SEED IMPLANT

Patient_____ Date_____

MR_____ Prescribed Dose_____

Number of Needles_____ Number of Seeds_____ Seed Strength_____mCi

Date Ordered_____ Date of Implanation_____

Order_____extra seeds for a total of _____seeds

Clinical Information:

_____

_____

_____

_____

_____

Radiation Oncologist_____

Signature_____

Madison Community Hospital

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH 8-125 IMPLANT SOURCES

Patient Name:_____ Patient No. _____
Attending:_____ Phone: _____
Pager No.:_____ Patient Room:_____
Dose:____mCi of ____ as ____ individual source was implanted on_____

Radiation Exposure Rates

Unrestricted areas: door ____mR/Hr; rm____ ____mR/Hr.; rm____ ____mR/Hr.
Patient supine in bed _____
Date Time Bedside 3 Ft. from Bed Door _____
Release certification: Patient may not be released from the Hospital until the following certification is signed and dated by the RSO or the attending physician.

I have surveyed this patient. A survey of the patient indicated the exposure rate to be within the acceptable limit. Written instructions were provided to patient.
Signature:_____ Date:_____

Instructions

Visitor Restrictions:

- [ ] No visitors under 18 or pregnant
- [ ] _____ minutes each day maximum for each visitor.
- [ ] Visitors must stay behind line on floor at all times.

Nursing Restrictions

- [ ] Patient is restricted to room.
- [ ] Patient is restricted to bed.
- [ ] Patient must not move.
- [ ] No nurses who are pregnant may render care.
- [ ] _____ minutes each day per nurse in the room.

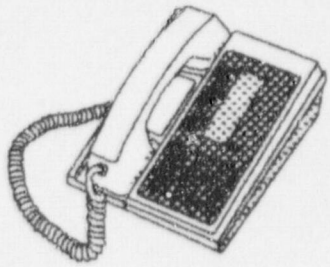
Patient Care

- [ ] Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- [ ] If a source appears dislodged, call the attending physician and the RSO immediately.
- [ ] Omit bed bath.
- [ ] No perineal care. Pad may be changed as necessary.
- [ ] Save surgical dressings for disposal by attending physician or RSO.
- [ ] See special oral hygiene care instructions

In case of emergency, or if you have a question, call:
RSO: Dr. F. Bagne Work: 248-583-7393 Pager: 810-856-1234

c:\madison\bagne\nursing.ins

Madison Community Hospital



FAX TRANSMITTAL SHEET

TO: MICHAEL WEBER

COMPANY: NRC

FAX NO.: 630-515-1259

FROM: F. BAGNE, PhD

TELEPHONE: 248-583-7393

FAX NO.: 248-588-9140

DATE: OCTOBER 12, 1998

NO. PAGES FOLLOWING: 12

Hi Mike:

Per Dr. Bagne's request, I'm faxing you a revised copy of our application for material license. Due to it's size, I'll be sending approximately 10-15 sheets at a time. I'll have a cover sheet for each different set I send.

If you don't get everything, give me a call at the number shown above.

As soon as we get your approval, I'll overnight the signed original to your attention.

Thanks in advance!

Betty Wynn

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION
(5-1997)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 7/31/1999

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-3415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*
   Madison Community Hospital
   30671 Stephenson Highway
   Madison Hts., MI 48071

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Madison Community Hospital
   30671 Stephenson Hwy.
   Madison Hts., MI 48071

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Dr. Farideh R. Bagne
   TELEPHONE NUMBER
   248-588-8000

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL.
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. Dr. Farideh R. Bagne, RSO

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Ezra Shaya, MD/Chairman of the Board		10-12-98

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

Madison Community Hospital

APPLICATION FOR MATERIAL LICENSE
ATTACHMENT A

Item 5 - Radioactive Material

Byproduct Material	Amount:
Materials in 35.400 (Iodine - 125 Seeds)	As needed

Item 6 - Purpose

Brachytherapy prostate implant and other medical uses (therapeutic treatments).

Item 7 - Individuals Responsible for Radiation Safety Program and Their Training Experience.

Radiation Safety Officer: Dr. Farideh R. Bagne

Dr. Bagne is certified by the American Board of Radiology in Radiological Physics (Nuclear Medicine, Radiology and Radiation Therapy). She has been the Radiation Safety Officer for brachytherapy on a number of hospital licenses from NRC, including: St. Joseph Mercy Hospital, License # 21-1165101 (Pontiac, Michigan); Oakland General Hospital, License # 21-11494-01 (Madison Heights, Michigan), and American Oncologic Associates of Michigan, License # 21-26488-01 (Pontiac, Michigan). A copy of her board certification is already on file with NRC.

Item 8 - Training Program

8.1 - Training for Individuals Working in or Frequenting Restricted Areas.

We will establish and implement the model training program that is published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT8.1 that identifies the groups of workers who will receive training and the method and frequency of training.

8.2 N/A

Item 9 - Facilities and Equipment

Item 9.1 - Annotated Drawing - See ATT 9.1 for the annotated drawing of the room and adjacent areas.

Item 9.2 - Survey Instrument Calibration

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to the Regulatory Guide 10.8, Revision 2.

Alternatively calibration of survey meters will be performed by Radiological Physics Service, Inc., License #21-26253-01, or by another licensed service.

Instrumentation

Survey meters:

a. Manufacturer: Victoreen
b. No. of Instruments Available: 1
c. Model No.: 493
d. Maximum Range: 0 to 50 mR/hr.
e. Minimum Range: 0 to 0.5 mR/hr.

a. Manufacturer: Victoreen
b. No. of Instruments Available: 1
c. Model No. 495
d. Maximum Range: 0 to 1000 mR/hr.
e. Minimum Range: 0 to 0.1 mR/hr.

Dose Calibrator:

a. Manufacturer: Capintec
b. Model No. CRC-4

9.3 N/A

9.4 - Radiation Safety Programs

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide, Revision 2.

PROGRAM:

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization changers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

9.5 N/A

9.6 N/A

Item 10 - Radiation Safety Programs

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide, Revision 2.

We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2.

10.1 - Radiation Safety Committee/Radiation Safety Officer

Charge: The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license.

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. identify program problems and solutions.

Responsibilities The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments.;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Office (RSO), and the Teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 11 CFR Part 19;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, action, recommendations, decision, and numerical results of all votes taken; and

10. Ensure that the by-product material license is amended if required prior to any changes in facilities, equipment, policies, procedures and personnel.

Administrative Information:

1. The Committee shall meet as often as necessary to conduct its business but no less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plan, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

DELEGATION OF AUTHORITY

See attached memo regarding delegation of authority to RSO.

3. Radiation Safety Officer

   a. Annual and Quarterly Review

      (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

      (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

      (3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning state before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures to ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

10.2 - ALARA Program

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

ALARA PROGRAM

Madison Community Hospital
September 14, 1998

1. Management Commitment

a. We, the management of this Hospital, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include review of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to

demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

3. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

* The NRC has emphasized that the investigational levels in this program are not new dose limits, but as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

3. The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

Radiation Safety Committee Charter shall be:

10.3 **Procedure for Leak Testing Sources.**
We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

10.4 N/A

10.5 N/A

10.6 **Guidance for Ordering and Receiving Radioactive Material (§ 30.51 and 20.205)**

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulator Guide 10.8, Revision 2.

10.7 Opening Packages

Procedure for safely opening packages containing radioactive material. We will establish and implement the model procedure for opening packages that was published in Appendix X to Regulatory Guide 10.8, Revision 2.

10.8 N/A

10.9 N/A

10.10 N/A

10.11 Implant Source Use Record

We will establish and implement the model procedure for keeping an inventory of implant sources (Section 30.51, 35.21, 35.406) that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

10.12 We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10, Revision 2. See attached procedures.

10.13 N/A

10.14 N/A

10.15 Procedure for Radiation Safety During Implant Therapy

We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2.

10.16 N/A

Item 11 - Waste Management

11.1 Waste Disposal

PROCEDURE FOR RETURNING IODINE-125 SEEDS TO THE MANUFACTURER

Excess or unused iodine will be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.457(8) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

See attached forms.

11.2 N/A

7. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____

Signature

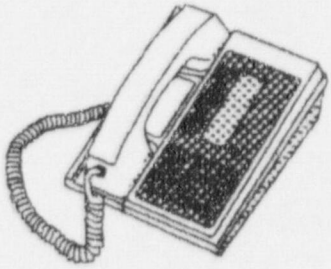
_____

Name (Print or Type)

_____

Madison Community Hospital

2



FAX TRANSMITTAL SHEET

TO: MICHAEL WEBER

COMPANY: NRC

FAX NO.: 630-515-1259

FROM: F. BAGNE, PhD

TELEPHONE: 248-583-7393

FAX NO.: 248-588-9140

DATE: OCTOBER 12, 1998

NO. PAGES FOLLOWING: 12

Hi Mike:

Per Dr. Bagne's request, I'm faxing you a revised copy of our application for material license. Due to it's size, I'll be sending approximately 10-15 sheets at a time. I'll have a cover sheet for each different set I send.

If you don't get everything, give me a call at the number shown above.

As soon as we get your approval, I'll overnight the signed original to your attention.

Thanks in advance!

Betty Wynn

Madison Community Hospital

ATTACHMENT 8.1 - TABLE 8.1

a. Groups of workers who will receive training:

Urologists
Radiation Physicists
Dosimetrists
Technologists
Nursing Staff
O.R. Staff
Recovery Room Staff
Radiation Oncologists
Any other groups who care for patients receiving radioactive material.

b. Method of training:

- Lectures given by RSO and other qualified professional, under RSO's supervision, or
- Video - taped presentations, or
- Demonstrations

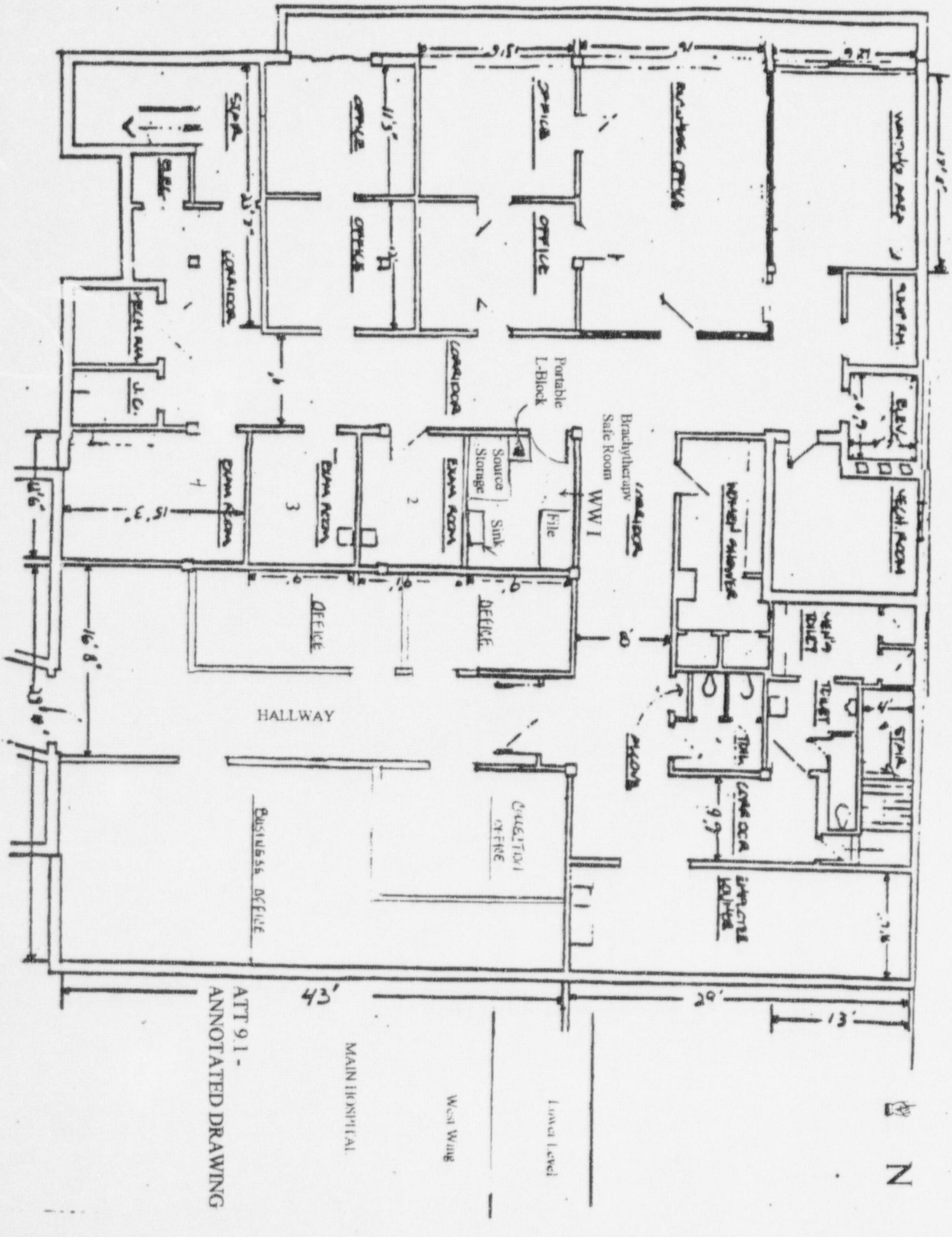
c. Frequency of Training:

- Before assuming duties with, or in the vicinity of, radioactive materials.
- During annual refresher training.
- Whenever there is a significant change in duties regulations, or the terms of the license.

d. Subject matter:

- Applicable regulations and license conditions.
- Areas where radioactive material is used or stored.
- Potential hazards associated with radioactive material in each area where the employees will work.
- Appropriate radiation safety procedures.
- Licensee's in-house work rules.

BUILDING EXTERIOR



ATT 9.1 -
ANNOTATED DRAWING

MADISON COMMUNITY HOSPITAL

MADISON HEIGHTS, MICHIGAN

Madison Community Hospital

QUALITY MANAGEMENT PROGRAM

APPROVED BY: **Radiation Safety Committee** Date:

PURPOSE: To establish an environment which will provide high confidence that ~~radiopharmaceutical and~~ brachytherapy sources will be administered as directed by the authorized user.

SCOPE: The stipulations of this policy shall apply to all authorized uses of ~~radiopharmaceutical and~~ brachytherapy sources as noted in 10 CFR 35.32.

RESPONSIBILITY: The responsibility and authority to establish and implement the Quality Management Program shall be given to the Radiation Safety Officer through the Radiation Safety Committee.

BRACHYTHERAPY SECTION

1. Prior to administration, a written directive will be prepared for any brachytherapy radiation dose.

   With regards to brachytherapy, a written directive means an order in writing for a specific patient dated and signed by an authorized user prior to the administration of radiation, containing the following information:

   a. For all brachytherapy other than Strontium -89 Brachytherapy.

      1. Prior to implantation:

         - Radioisotope
         - Number of Sources
         - Source Strengths

      2. After implantation, but prior to completion of the procedure:

         - Radioisotope
         - Treatment Site
         - Total Source Strength
         - Prescribed Exposure Time or equivalently the Total Dose Prescribed.

2. Prior to administration, the patient's identify is verified by more than one method as the patient named in the written directive.

   If the information obtained from any of these methods does not correspond to the information on the written directive, the radiation shall not be administered until conclusive evidence is obtained that this agent/procedure is intended for the patient in questions.

3. Each administration is in accordance with the written directive. If any portion of the written directive is unclear, the authorized user will be contacted for clarification. The radiation shall not be administered until the intent of the written directive is thoroughly understood.

4. Any clinically significant unintended deviation from the written directive is identified and evaluated, and appropriate action is taken by the authorized user.

5. Final plans of treatment and related calculations for brachytherapy are viewed and signed by the authorized user to ensure accordance with the written directive.

6. Established procedures will ensure the following:

   a. Written directives to include all treatment parameters will be prepared prior to each patient administration.

   b. Verification of the patient's identify by more than one (1) method prior to administration.

   c. Assurance that each administration is in accordance with the written directive.

   d. Identification, evaluation, and corrective action for any clinically significant unintended deviations from the written directive.

   e. Treatment plans will be prepared in accordance with the written directive.

   f. Preparation of dose calculations and treatment plans (i.e., computer generated dose calculations, manual dose calculations, and isodose-distribution).

   g. Verification of the position of dummy sources or fixed geometry applicators prior to insertion of sealed source.

h. Visual confirmation of the radioisotope, number of sources, source strengths, treatment site, loading sequence and total dose by the person administering the brachytherapy treatment for agreement with the written directive and treatment plan.

i. Signing of the calculated time and total dose by the physician before administration of the prescribed brachytherapy dose.

j. Signing the authorized user, after administration of the number of sources, the actual loading sequence of the sources implanted (i.e., location of each sealed source in a tube, tandem, or cylinder).

k. After administration the authorized user must sign or initial the patient's chart or appropriate record.

ANNUAL REVIEW

A review shall be conducted under the supervision of the approved user to determine the effectiveness of the Quality Management Program. After completion an evaluation of the findings will be conducted and resultant actions set in motion to comply with the objectives of Part 35.32. Changes in the Quality Management Program, generated to increase its efficiency, shall be furnished to the Nuclear Regulatory Commission Region III Office within thirty (30) days after the modifications have been made.

This review for the radiopharmaceutical section except Sr-89 brachytherapy twelve (12) month intervals by a member of the consulting medical physicist group and/or the supervisor of Nuclear Medicine, and for the brachytherapy section a medical physicist from Radiation Oncology. Any reportable deviation from the established criteria by the NRC will be reported to the Radiation MCH Committee and maintained for three (3) years.

The audit of a representative sample of radiopharmaceutical and brachytherapy administrations shall evaluate the following items.

1. The compliance rate of having written directives prior to administration of a radiopharmaceutical or radiation in those cases where written directives are required.

2. The content of the written directive is as required.

3. The compliance rate of verifying the patient's identity by two methods.

4. Radiopharmaceutical or radiation administrations are in accordance with the written directive.

5. The compliance of staff in identifying, evaluating, and taking appropriate corrective actions for clinically significant UN-intended deviations from the written directive.

6. The compliance with the requirement to respond to each recordable event. This shall include a brief summary to include cause of event, and identification of corrective action, if any, was taken.

7. The compliance with the requirements to notify and report a misadministration.

8. The instruction of supervised individuals in the principles of radiation safety and in the facility's quality management program.

9. The compliance with the requirements to keep the appropriate records, specifically,

    Annual Reviews (to include findings and evaluations)
    Written Directives
    Radiopharmaceutical and/or Radiation Dosages
    Recordable Events
    Misadministrations

10. The final treatment plans for brachytherapy and related calculations shall be reviewed by the approved user or his/her designee.

Madison Community Hospital

SURVEY METER CALIBRATION REPORT

Owner:_____ Department:_____

Manufacturer:_____ Type: ○ Ion Cahmger ○ GM ○ Nal (T1) ○ _____

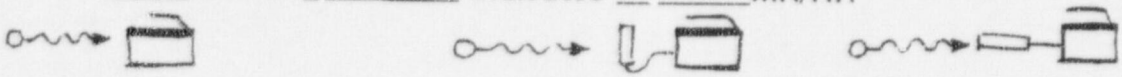
Meter Model:_____ Meter S/N:_____ Probe Model: _____ Probe S/N_____

Calibratrion Source: _____mCi of _____m/R/Hr. at _____ in on _____, 19____

Instrument Checks: Battery Check: _____mR/Hr. or _____

Constancy Check: ○ Integral Chgeck Source Indicates _____mR/Hr.

○ _____mCi of _____ Indicates _____mR/Hr.

Calibration Geometry: 

Window: ○ Open ○ Closed ○ Fixed

Dist. (Feet)	mR/Hr. Today	Scale: Rdng	CorFac	Scale: Rdng.	CorFac	Scale: Rdng.	CorFac	Scale: Rdng.	CorFac

Correction Factors: _____ _____ _____ _____

Name:_____ Date:_____

Calibration Sticker:

Cald____ - ____ - ____ With ____
// _1_ Window:_____

Scale CorFac
____ ____ bat:"_____mR/Hr."

____ ____ _____

____ ____ chk:"_____mR/Hr."

c:\madison\bagne\Calibra.rep

Madison Community Hospital

Memo To: All Employees

From: Ezra Shaya, M.D.
Chief Executive Office/Chairman of the Board

Subject: Delegation of Authority

Date: October 12, 1998

Dr. Farideh R. Bagne has been appointed Radiation Safety Officer for Madison Community Hospital is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibiiities.

The Radiation Safety Office is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

Madison Community Hospital

Radioactive Package Receipt Memorandum

MEMO TO: Chief of Security

FROM: Dr. F.R. Bagne, Radiation Safety Officer

SUBJ: Receipt of Packages Containing Radioactive Material
Madison Community Hospital

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room WW I. Unlock the door, place the package on top of the counter, sign the logbook, and relock the door. Call RSO and notify her of the shipment arrival.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the Hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our Hospital Radiation Officer, Dr. F.R. Bagne, at Ext. 393.

	Name	Office Phone	Home Phone/ Pager
Radiation Safety Officer	Dr. F.R. Bagne	Ext. 393	810-856-1234
Radiology Manager	Sandy Piotrowski	Ext. 391	
Radiology Director	Dr. Nefcy	Ext. 391	
Nuclear Medicine Physician	Dr. R. Gunabalan	(248) 585-5115	

Madison Community Hospital

30671 Stephensen Highway
Madison Heights, MI 48071-1678
Tel. (810) 588-8000
Fax (810) 588-9140

PROCEDURE FOR ORDERING I-125 SEEDS

1. Use standing purchasing order #_____ from Madison Community Hospital.

2. Determine the activity of the I-125 seeks (6711, I-125, Type 109) from the pre-plan _____ mCi of type_____.

3. Determine the total number of seeds _____.

4. Check with the radiation oncologist to ensure the written directive is completed.

5. MCH's NRC License is #_____ _____.

6. MCH's Amersham Account # is _____.

7. Call: Amersham Healthcare
   Medi-Physics, Inc.
   2636 S. Clearbrook Drive
   Arlington Hts., IL 60005
   Customer Service: 1-800-228-0126
   Technical Information: 1-800-554-0157

   Give:
   - Total # of I-125 Seeds_____
   - Type of Seed: ☐ 109 ☐ 6711
   - Activity per Seed _____
   - Date of Insertion: _____
   - Date of Delivery: _____
   - Location of Delivery: Hand deliver to MCH's Radiology Department.
   - Your Name:_____
   - Give Dr. Bagne's Phone No. (248) 583-7393.
   - Refer to MCH's Account and Purchase Order Numbers.

8. Fax a copy of the prescription to MCH to Betty Wynn at 248-588-9140.

9. Amersham's Order No._____

10. File this sheet in nurse's I-125 patient book and a copy in the patient's Hospital chart.

11. Patient_____ Order Date_____

MADISON COMMUNITY HOSPITAL

PACKAGE RECEIPT AND MONITOR LOG

Date Rec'd	Purchase Ord. No.	Packing Slip No.	mCi	iso	Chemical	Supplier	Catalogue Number	Pkg. OK?	mR/Hr Surf	Notes	Init

c:\madison\bagne\monitor.log

Madison Community Hospital

IODINE-125 SOURCE LOG

The following individuals are authorized to handle Iodine-125 Sources:

Dr. F.R. Bagne		

1.) **Receipt** (attach all paperwork)

Date: Time:
No of Sources:
Activity 1) Individual _____ mCi 2) Total _____ mCi

Manufacturer: Type:
Received by: Placed in:

2.) **Removal**

Date: Time:
Number of Sources Removed: Total Activity: _____mCi
Patient Name: Removed:
Location: _____ Room No._____ O.R. No._____

Removed by: _____ Purpose:_____

3.) Returned to Safe:

Date: Time:
No. of Sources: Total Activity:_____ _____mCi

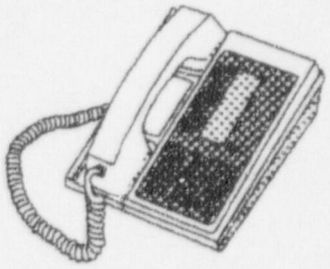
History: _____
Done by: _____

4.) Return to Manufacturer: (Attach all paperwork)

Date: Time:
No. of Sources: _____ Activity:_____mCi
Done by: _____

Madison Community Hospital

3



FAX TRANSMITTAL SHEET

TO: MICHAEL WEBER

COMPANY: NRC

FAX NO.: 630-515-1259

FROM: F. BAGNE, PhD

TELEPHONE: 248-583-7393

FAX NO.: 248-588-9140

DATE: OCTOBER 12, 1998

NO. PAGES FOLLOWING: 10

Hi Mike:

Per Dr. Bagne's request, I'm faxing you a revised copy of our application for material license. Due to it's size, I'll be sending approximately 10-15 sheets at a time. I'll have a cover sheet for each different set I send.

If you don't get everything, give me a call at the number shown above.

As soon as we get your approval, I'll overnight the signed original to your attention.

Thanks in advance!

Betty Wynn

Madison Community Hospital

IMPLANT SOURCE LOG

Only the following individuals may handle threse sources: _____

_____

RSO:_____ Date: _____

	No.	iso	act	
Received On:_____	_____	_____	_____	iso each
	_____	_____	_____	
	_____	_____	_____	

Date	Time	no	mCi	no	mCi	no	mCi	Patient Name	mR/hr	Init.

c:\madison\bagne\impsource.log

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

RADIATION SAFETY SURVEY FORM
IODINE-125 PROSTATE SEED IMPLANT

Patient_____ Date:_____

Activity in mCi per seed _____ # of seeds _____ Total Activity _____

1. Indicate those locations to be surveyed.
2. Record values bellow.
3. Limit nurses and staff to 2.0 mR in any hour.
4. Limit visitors and other patients to 100 mRem total.
5. Make sure some diagnostic equipment isn't interfering with the survey.
6. Upon completion of this form, return to Radiation Safety Office at MADISON COMMUNITY HOSPITAL.

Survey Instrument used_____ Background reading (mR/hr) _____

	Room		Room
1.	OR Floor-	1.	Bedside-
2.	Patient Groin-	2.	1 m from patient-
3.	1 m from patient-	3.	6 ft from patient-
4.	6 ft from patient-	4.	Urine container-
5.	Table tops-	5.	Bathroom-
6.	Urine bag-	6.	Floor-
7.	Urine container-	7.	Bed-
8.	Staff bodies/feet-	8.	Table tops-
9.	Needles-	9.	Trash-
10.	Template/Stepper-	10.	
11.	Trash-		
12.	Done By:_____		Done By:_____

Madison Community Hospital

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH I-125 IMPLANT SOURCES

Patient Name:_____ Patient No. _____
Attending:_____ Phone: _____
Pager No.:_____ Patient Room:_____
Dose:____mCi of ____. as ____ individual source was implanted on_____

Radiation Exposure Rates

Unrestricted areas: door ____mR/Hr; rm____ ____mR/Hr.; rm____ ____mR/Hr.
Patient supine in bed _____
Date Time Bedside 3 Ft. from Bed Door _____

Release certification: Patient may not be released from the Hospital until the following certification is signed and dated by the RSO or the attending physician.

I have surveyed this patient. A survey of the patient indicated the exposure rate to be within the acceptable limit. Written instructions were provided to patient.
Signature:_____ Date:_____

Instructions

Visitor Restrictions:

- [ ] No visitors under 18 or pregnant
- [ ] _____ minutes each day maximum for each visitor.
- [ ] Visitors must stay behind line on floor at all times.

Nursing Restrictions

- [ ] Patient is restricted to room.
- [ ] Patient is restricted to bed.
- [ ] Patient must not move.
- [ ] No nurses who are pregnant may render care.
- [ ] _____ minutes each day per nurse in the room.

Patient Care

- [ ] Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- [ ] If a source appears dislodged, call the attending physician and the RSO immediately.
- [ ] Omit bed bath.
- [ ] No perineal care. Pad may be changed as necessary.
- [ ] Save surgical dressings for disposal by attending physician or RSO.
- [ ] See special oral hygiene care instructions

In case of emergency, or if you have a question, call:

RSO: Dr. F. Bagne Work: 248-583-7393 Pager: 810-856-1234

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL-OPERATING ROOM

CERTIFICATION OF RADIATION HAZARD STATUS

At _____, AM / PM on _____ (date) the brachytherapy implant of _____ (patient) was completed. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any **CAUTION** signs have been left in place, or if you have any questions about the radiation status of this room, please call MADISON COMMUNITY HOSPITAL or the attending Radiation Oncologist.

Please return this form to MADISON COMMUNITY HOSPITAL or call (248) 588-8000.

Madison Community Hospital

PATIENT IDENTIFICATION

IODINE-125 PROSTATE SEED IMPLANT

Patient Name: _____ Date:_____

Prior to the administration of any Seed, identify the patient by two or more of the following methods, then compare to the patient's record.

a. Patient's Name _____

b. Birth Date _____

c. Address _____

_____

_____

d. Social Security # _____

e. ID Wrist Band/Hospital ID_____

f. Name on Patient's Medical Insurance:_____

g. Photo of Patient's Face_____

h. Patient's Signature _____

Done By_____

Signature_____

Madison Community Hospital
30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL

CERTIFICATION OF RADIATION HAZARD STATUS

On _____(date) the patient_____ was permanently implanted with _____mCi total activity of radioactive I-125 seeds. In accordance with 10 CFR 35.75, the patient may be discharged provided **the measured dose rate is at or below 1.0 mR/hr at 1.0 meter**.
Survey instrument used: _____
mR/hr at 1.0 meter: _____

At _____ AM / PM on _____(date) the room was surveyed and the patient was discharged. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any **CAUTION** signs have been left in place, or if you have any questions about the radiation status of this room, please call MADISON COMMUNITY HOSPITAL or the attending Radiation Oncologist.

Please return this form to MADISON COMMUNITY HOSPITAL or call (248) 588-8000.

Madison Community Hospital

BRACHYTHERAPY SERVICE

Brachytherapy Quality Assurance Management Program

Written Directive to be used with _____

PART I

Patient Name_____ Room #_____

History Number_____ Date of Treatment_____

Attending Physician_____

Indication(s)_____

Procedure_____

Radiopharmaceutical SR-89 P-32 I-125 Pd-103

Dosage_____mCi or Gy Route_____

Authorized User Signature_____ Date_____

PART II

Ordered for_____MD/DO Date Ordered _____

Assayed by_____ Date Assayed_____

Assayed Value_____ Ordered by _____ (Physicist)

PART III

The patient's identity must be verified by at least two of the following:

- ☐ Patient called by name
- ☐ Patient spelled his/her name
- ☐ Patient stated date of birth
- ☐ Patient stated social security number
- ☐ Patient provided positive identification
- ☐ Is patient pregnant?
- ☐ Is patient breast feeding?
- ☐ Booklet given and reviewed?
- ☐ Consent signed?
- ☐ Wrist band verified?

PART IV

Dose Administered On (Date)_____ Time:_____

Actual Dose Delivered_____mCi

Bioassay Needed? Yes ☐ No ☐

Authorized User_____ Date_____

Medical Physicist_____ Date_____

(Signature above indicates presence at administration and assurance that this written directive was followed.)

c:\madison\bagne\writdir.frm

Madison Community Hospital

WRITTEN DIRECTIVE

IODINE-125 PROSTATE SEED IMPLANT

Patient_____ Date_____

MR_____ Prescribed Dose_____

Number of Needles_____ Number of Seeds_____ Seed Strength_____mCi

Date Ordered_____ Date of Implanation_____

Order_____extra seeds for a total of _____seeds

Clinical Information:

_____

_____

_____

_____

_____

Radiation Oncologist_____

Signature_____

Madison Community Hospital

DISCHARGE INSTRUCTIONS
RADIOACTIVE SEED IMPLANT
FOR PROSTATE CANCER

1. You may notice some blood in your urine. This is normal and should subside in approximately 24 hours. If after 24 hours the bleeding persists, or you begin to pass blood clots, you should contact your urologist.

   It is common to experience frequent urination, burning with urination, a sense of urgency or a decrease in the force of the urinary stream. These symptoms will gradually decrease as the seeds lose their strength, but may be present to some degree for 6-12 months after the implant. Drink plenty of fluids and void caffeine containing beverages to help relieve the symptoms.

2. If you experience any light-headedness, dizziness or a temperature over 100°, please contact your urologist right away.

3. Avoid heavy lifting or strenuous physical activity for two days. After that, you may return to normal activity.

4. No restriction on your travel or physical contact with other adults. If a child or pregnant woman is in the same room as you for more than 5-10 minutes, they should stay 6 feet or more away. since the radiation is coming from the prostate, children should not sit on your lap during the initial 2 month period following the implant. Do not sleep in the same bed as a pregnant woman or child.

5. Although rare, an occasional seed may be lost via urination within the first week following the implant procedure. if a seed is passed, it should be retrieved and returned to the Madison Community Hospital. Strain your urine for the first week following the implant. If a seed is passed, it should be picked up with tweezers and placed in the packet provided.

6. A seed may rarely be passed with the ejaculate during intercourse. Use a condom during intercourse for the first two months following the implant procedure so that any possible seed can be retrieved. It is normal for the ejaculate to be discolored dark brown to black for up to several weeks following the implant procedure. Sexual intercourse may be resumed after two weeks.

Madison Community Hospital

NURSING CHECKLIST

RADIOACTIVE SEED IMPLANT-PROSTATE

Patient _____

Urologist _____

Consultation Date _____

Simulation _____

CT Scan _____

Ultrasound _____

Surgery Date _____

Patient Teaching: _____

- Video view by Patient _____
- Patient Information Booklet _____
- Discharge Instructions-Surgery _____
- Antibiotic Rx _____

Consents: _____

- Notification of Seed Charge _____
- Iodine-125 Prostate Seed Implant Consent

Surgery Preparation to be Ordered: _____

- (2) Fleets Enemas AM of Surgery _____
- CBC, Electrolyte, PT, PTT _____
- PAT _____

CT Pelvis-Post Surgery _____

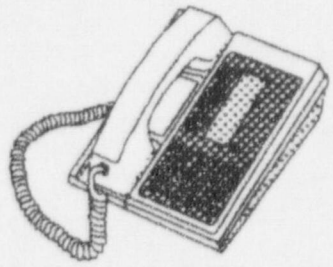
- Simulation Post Surgery _____

Appointments: _____

- Dr. Bagne _____
- MCH _____

Madison Community Hospital

4



FAX TRANSMITTAL SHEET

TO: MICHAEL WEBER

COMPANY: NRC

FAX NO.: 630-515-1259

FROM: F. BAGNE, PhD

TELEPHONE: 248-583-7393

FAX NO.: 248-588-9140

DATE: OCTOBER 12, 1998

NO. PAGES FOLLOWING: 8

Hi Mike:

Per Dr. Bagne's request, I'm faxing you a revised copy of our application for material license. Due to it's size, I'll be sending approximately 10-15 sheets at a time. I'll have a cover sheet for each different set I send.

If you don't get everything, give me a call at the number shown above.

As soon as we get your approval, I'll overnight the signed original to your attention.

Thanks in advance!

Betty Wynn

Madison Community Hospital

U.S. GUIDED IODINE-125 PROSTATE IMPLANT BRACHYTHERAPY
ULTRASOUND INFORMATION SHEET

Patient's Name: _____ Date: _____

Ultrasound: 1st_____ 2nd_____ 3rd_____ Other_____

Number of Contours Outlined _____ Total Volume: _____cc Sagittal Views: _____

Patient Under Hormonal Therapy: _____ Re-Ultrasound Needed: _____

Physician: _____ Tech: _____

Urologist: _____

Special Instructions:

_____

_____

_____

_____

_____

This form is to be filed in the patient's chart immediately.

Madison Community Hospital

PATIENT NAME_____ TOTAL SCORE_____

DATE OF VISIT_____

AUA SYMPTOM CODE

Please fill out this short questionnaire to help us find out more about any urinary problems you might have; for Questions 1 through 5, circle the number. Circle the number in the column that best describes your situation; for Question 6, circle the number in the row which best describes your situation.

	Not At All	Less Than One Time in Five	Less Than Half the Time	About Half The Time	More Than Half The Time	Almost Always
1. Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. Over the past month or so, how often have you had to urinate, less than two hours after you finished urinating?	0	1	2	3	4	5
3. Over the past month or so, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. How often do you find it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month or so, how often have you had a weak urinary stream?	0	1	2	3	4	5

	Not At All	Once Every 8 Hours	Once Every 4 Hours	Once Every 3 Hours	Once Every 2 Hours	At Least Once Every Hour
6. Over the past month or so, how often did you most typically get up at night to urinate?	0	1	2	3	4	5

Madison Community Hospital
Madison Hts., MI
SPECIAL RADIATION ISOLATION ORDERS
Iodine-125 Prostate Seed Implant

Addressograph

Total Activity: _____ mCi Assay Date:_____ Site of Application:_____

Patient Name_____

Attending Physicians:_____

Date of Insertion:_____ Time of Insertion_____

THIS PATIENT IS IN RADIATION ISOLATION UNTIL ORDERS ARE RESCINDED BY RADIATION ONCOLOGIST

1. Nurses - Not more than _____ minutes in any one hour at bedside and not more than _____ minutes in nay one hour at six (6) feet.
2. No pregnant visitors or visitors under 18 years of age.
3. Visitors should sit at least _____ feet from the patient and limit their stay to _____ minutes per hour.
4. Surgical dressings to be changed only by the physician or individual designated by him/her and trained in techniques applicable to such cases.
5. In the event of the patient's death, contact the Radiation Oncologist and Brachytherapy RSO immediately.
6. The room cannot be reused until surveyed and declared radiation free.
7. Additional instructions: _____

EXPOSURE RATES (mR/hr)

Background	Bedside	One Meter	Six Feet	Date	Initials

IN CASE OF EMERGENCY, or for further information, call 248-588-8000, Ext. 391

Name	Title	Office	Pager/Home

AT TIME OF PATIENT DISCHARGE, SEND THIS FORM TO THE RADIATION SAFETY OFFICE AT MCH.

Madison Community Hospital

1-125 PROSTATE SEED IMPLANT
NEEDLE GUIDESHEET

Patient Name_____ ID#_____Date_____Done By:_____

Inferior										Superior
Plane #										
Needle #:										
1.....										
2.....										
3.....										
4.....										
5.....										
6.....										
7.....										
8.....										
9.....										
10.....										
11.....										
12.....										
13.....										
14.....										
15.....										
16.....										
17.....										
18.....										
19.....										
20.....										
21.....										
22.....										
23.....										
24.....										
25.....										
26.....										

c:\madison\bagne\ndlguide.sht

Madison Community Hospital

ULTRASOUND GUIDED PROSTATE IMPLANT FLOWSHEET

Patient:_____ Physician_____ Date:_____ Done By: _____

	Yes	No	Date
I. PRELIMINARY STATUS			
Consult Status			
Initial Simulation Films Taken Complex			
CT Scan for Pubic Arch Study Done			
Ultrasound Volume Study Done			
Ultrasound Images Labeled as to Sequence (Base to Apex)			
Target Volume Indicated on each Image			
Urethra Marked if Sparing Desired			
Target Volume ___ Desired Isotape____ Desired MPD__ GY			
II. PRE-PLAN			
Volume Study Signed by Oncologist & sent to Dosimetry			
Number of Seeds Required by Plan_____ Plus_____ Extra			
Activity of Individual Seeds = _____mCi			
Total Contours Planned _____			
Pre-Plan Reviewed by 2 Physics People			
Pre-Plan Approved & Signed by Radiation Oncologist			
III. ORDERING			
Written Directive Part I & Prescription completed			
Seeds Ordered (Written Directive Part II)			
Delivery Date _____ Implant Date_____			
IV. DAY OF IMPLANTATION			
Patient Identification Completed (Written Direction Part III)			
Needle Loading Verified by 2 Physics People			
All Factors Checked Prior to Treatment			
Treatment Administered without Problems			
O.R. Surveyed After Implantation			
All Seeds Accounted for After Implantation			
Written Directive Part IV and Notice of Treatment Completed			
Patient Given Post-Implant Instructions, Pb Packet & Strainer			
Patient and Room Surveyed Prior to Discharge			
All Radioactive Signs Removed & Stored after Patient Release			
V. POST-IMPLANTATION			
Post-Implant Simulation Films Taken-Complex			
Check Simulation Films taken-Simple			
CT Scan of Pelvis with 0.5 cm cuts done for Post-Plan			
Post-Treatment Verification Plan Done			
Post-Treatment Plan Reviewed by 2 Physics People			
Post-Treatment Plan Approved and Signed by Oncologist			
Final Billing Completed			

Answers of "NO" should be explained if not self-explanatory

c:\madison\bagne\flowsheet.us

Madison Community Hospital

CT-BASED PUBIC ARCH INTERFERENCE STUDY FOR I-125 PROSTATE SEED IMPLANT PATIENTS

Requested by: _____

Patient Name _____

Done By: _____

Date: _____

Utilizing the Treatment Planning CT Scan, I have evaluated the position of the pubic arch in relation to the prostate gland.

_____ The arch should not impede the progress of the Brachytherapy needles.

_____ The arch may interfere with the treatment.

_____ Other: _____

_____

_____

_____

_____

Physician Approval

Madison Community Hospital

30671 Stephenson Highway
Madison Heights, MI 48071-1678
Tel. (248) 588-8000
Fax (248) 588-9140

To Patient:

You have selected to have a radioactive seed implantation to the prostate performed at Madison Community Hospital in Madison Heights, Michigan, for your prostate cancer.

The purpose of this letter is to inform you that, if for any reason, it is necessary for you to cancel your scheduled procedure:

WE MUST RECEIVE WRITTEN NOTIFICATION OF YOUR DESIRE TO CANCEL OR POSTPONE YOUR PROCEDURE AT LEAST THIRTY (30) DAYS PRIOR TO THE SCHEDULED SURGERY. IF WE DO NOT RECEIVE SUCH NOTIFICATION, IT WILL BE NECESSARY TO CHARGE YOU THE COST OF THE RADIOACTIVE SEEDS EVEN THOUGH THEY ARE NOT USED

We regret the necessity for this policy. The seeds are individually ordered for each patient and therefore cannot be easily transferred to another patient; they also have a "limited lifespan" and cannot be held for a significant period of time without being used. When the seed are shipped to Madison Community Hospital, the Hospital is then responsible to the manufacturer for the cost of the seeds, whether or not they are used. Depending on the number and type of seeds ordered, this cost could range from a minimum of $1,200.00 to more than $4,500.00 for which you would be held responsible.

We regret any inconvenience that this policy may cause you and trust that you will understand the necessity for it.

Sincerely,

F.R. Bagne, PhD
President, Chief Executive Officer

Date:_____ Time_____ AM/PM

Patient's Signature_____

Witness: _____

Madison Community Hospital

CONSENT FORM - IODINE-125 PROSTATE SEED IMPLANT

I,_____, know that I have a condition requiring radiation therapy. I have authorized Dr. _____ to perform the radiation therapy procedure known as **Ultrasound-Guided Iodine-125 Prostate Implant Brachytherapy**. I understand that this procedure is for the purpose of **controlling prostate cancer** and, although no specific result has been guaranteed, it is expected to **kill cancer cells in the prostate gland**. I understand that **POSSIBLE** complications are as follows: **Immediately post-op: slight bleeding beneath the scrotum; blood in the urine; bruising and tenderness between the legs. Later: frequent urination; burning with urination; sense of urgency, weakened urinary stream. Possible long-term side effects: narrowing of the urethra; impotence; loss of bladder control; damage to bladder; damage to rectum; rare risk of seed migration into a lung; or, rare risk of seed migration into ejaculatory fluid.**

I understand that an identification photograph of my face will be taken. In addition, photographs may be taken of me or parts of my body to be used for medical records. Also, if in the judgement of my physicians, medical research, education, or science will be benefitted by their use, such photographs and information relating to my case may be published and republished, either separately or in connection with each other, in professional journals or medical books or used for any other purpose which they may deem proper in the interest of medical education, knowledge or research, provided, however, that is specifically understood that, in any such publication or use, I shall not be identified by name.

I acknowledge that the doctors have explained to me the nature and purpose of the procedure and what the procedure is expected to accomplish, together with the known risks. I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees hav been made to me as to the results of the operation or procedure. Possible alternate methods of treatment, if any, have been explained, as have the results likely if I remain untreated.

With a full understanding of all the foregoing, and realizing that no guarantee or assurance has been given by anyone as to the results that may be obtained from this therapy, I do hereby request and authorize Dr. _____ and whomever they may designate to assist them to administer radiation treatments with **Iodine-125** radioisotope therapy to me.

Date_____ Time_____AM/PM

Signature of Patient_____

Signature of Closest Relative or Legal Guardian_____

Physician's Signature_____

Witness:_____

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

October 1, 1998

Farideh R. Bagne, Ph.D.
Radiation Safety Officer
Madison Community Hospital
30671 Stephenson Highwayt
Madison Heights, MI 480[illegible]-1678

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(LETTER DATED 09/28/98)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

__X__ New License _____ Amendment _____ Renewal
_____ Termination _____ Auth User (Amendment not Required)

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 completed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance. You are required to provide your taxpayer identification number to our Fees Department. Please fill out the enclosed NRC Form 531.

2. Renewal actions are normally completed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

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

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

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

Materials Licensing Branch

Mail Control No. 304463
License No. 21-32128-01