



# Passaic General Hospital

350 Boulevard, Passaic, New Jersey 07055 • (201) 365-4300

Charles B. Vanderberg  
Chairman, Board of Governors

George J. Dunphey  
President and  
Chief Executive Officer

Nuclear Regulatory Commission  
Nuclear Materials Section B  
631 Park Ave.  
King of Prussia, P.A.  
19406

8/10/83

Gentlemen:

Passaic General Hospital, license #29-01040-03, wishes to amend its license as follows:

- (1) Include the use of Iodine 125 seeds for interstitial implants as as described in 10CFR 35.100, with the maximum quantity of possession of 100 millicuries.
- (2) Authorize Samuel Brown, M.D., to use Iodine 125 for interstitial treatment of cancer. He is presently licensed to work at Beth Israel Hospital in Passiac, N.J. under license # 29-03047-01.

Enclosed is the information required pertaining to the use of Iodine 125 and a check payable to the NRC for the sum of \$40.00 as required as per 10 CFR 170. If you have any questions about this amendment request, please contact me.

Sincerely,

*James B. Makos*  
James B. Makos  
Administrator

RECEIVED BY LFMB	
Date...	9/7/83
Log...	Sept 31
By...	<i>[Signature]</i>
Orig. To...	
Action Date...	9/13/83

Applicant...	500.72
Check No...	40.78
Amount/Fee Category...	Amendment
Type of Fee...	9/7/83
Date Check Rec'd...	
Received By...	Brown

"OFFICIAL RECORD COPY"

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8512040081 850815  
REQ1 LIC30  
29-01040-03 PDR

ML10

22 AUG 1983

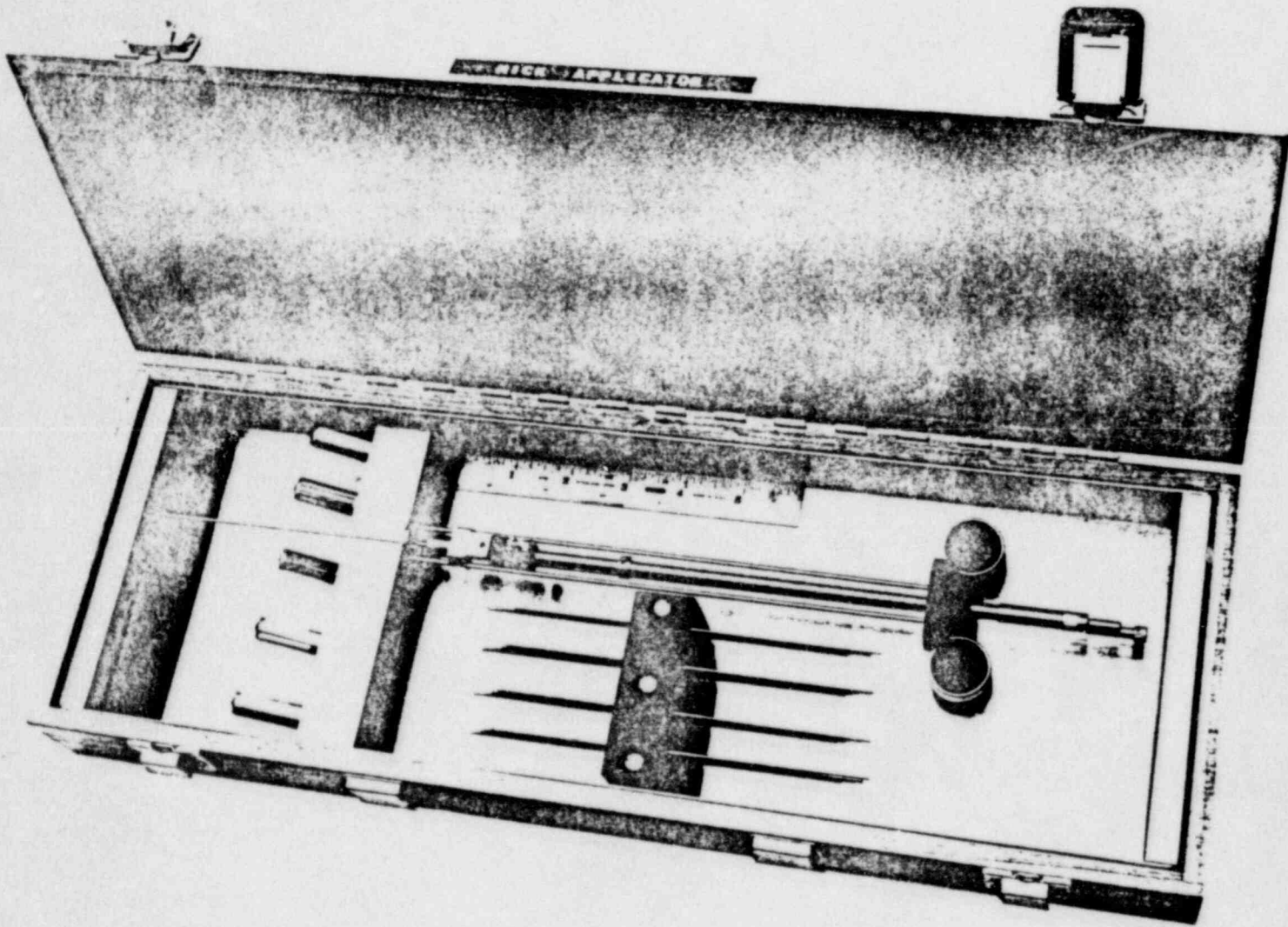
ADDITIONAL : IODINE 125 INFORMATION

The additional information is supplied as required in Appendix N of Regulatory Guide 10.8, Item d, and Contents of an application, Item 20 a-g.

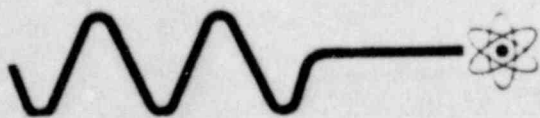
- (a) The Iodine 125 seed will be stored in their respective shielded shipping container in the radioactive storage area. It will be placed inside a lead fort and stored there until used.
- (b) The Iodine 125 seeds will be loaded into the MICK APPLICATOR cartridge in the nuclear medicine hotlab behind a L shield. The MICK APPLICATOR specifications are on a supplement sheet. All sealed source I 125 seeds will be handled with forceps and will loaded as per the MICK APPLICATOR instruction manual. Additional precautions will be used as listed on supplement page A-1
- (c) The radiotherapist, Samuel Brown, M.D., will be the principle user of the I-125 seeds and will be wearing a ring badge on his right hand index finger.
- (d) The I-125 seeds loaded in the MICK APPLICATOR will be shielded by its magazine and cartridge and additional shielding will be used during transport as needed.
- (e) The I-125 sources are to be wiped tested for contamination semiannually and inventoried immediately following each use. To maintain source accountability, a sign-in and sign-out log is to be kept. Please see the attached sample copy.
- (f) Radiation protection surveys are to performed during treatment and at the conclusion of treatment. Before cleaning the applicator and its used needles, a check for possible remaining I-125 seed will be conducted using survey meter.
- (g) Special instructions to the nurses as specified in Appendix L of the NRC Regulatory Guide 10.8 will be followed, and a copy of the instructions and survey will be placed in the patient's chart.

# MICK APPLICATOR

FOR IMPLANTATION OF IODINE -125 SEEDS

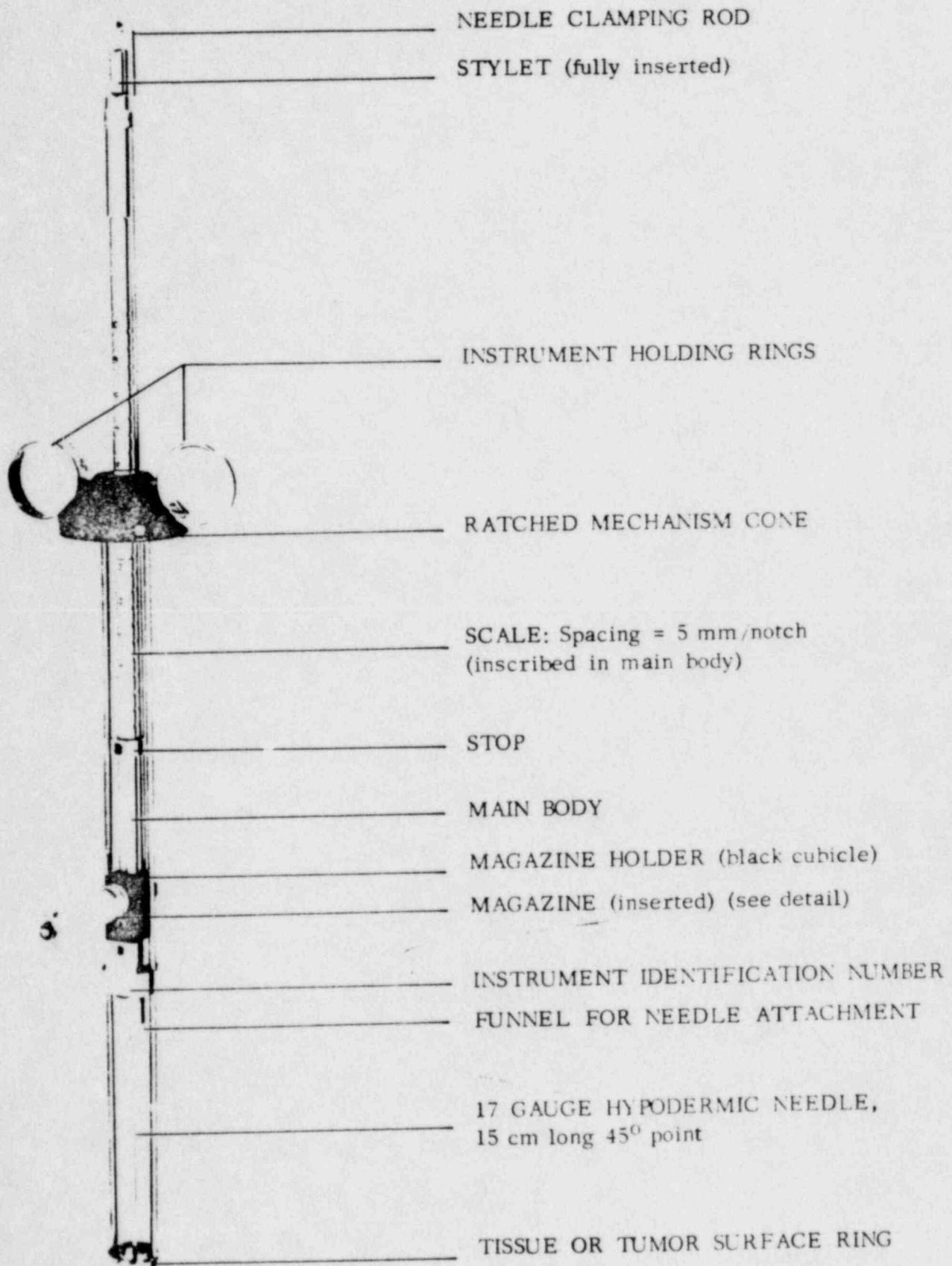


**Mick Radio-Nuclear Instruments, Inc.**



1470 Outlook Avenue, Bronx, N. Y. 10465  
(212) 597-3999

# DESCRIPTION



# INSTRUCTIONS

## Case preparation

The first step in preparing the instrument for implantation of Iodine-125 seeds is loading the magazines (cartridges). The magazines are located in a permanently mounted square chrome-plated brass rod in the stainless steel lift-out tray. Within this square body are five magazines placed at a 30° angle. To remove the magazines turn them clockwise (counterclockwise for storage).

## Loading of magazines

The magazine consists of two components: magazine head and cartridge. The head is a hexagonal body containing a round plunger under spring tension. The cartridge is of rectangular shape and contains a slot to accommodate an Iodine-125 seed. The front of the cartridge is open for easy loading. The cartridge is best loaded by clamping it securely into a V-block (available through Mick Radio-Nuclear Instruments, Inc.). Pick up the seed with a pair of thin-nosed needle clamps (the nose must fit into cartridge opening) and feed it into the slot from top to bottom. It is important that the seed is not dropped into the cavity but placed carefully at the bottom of the cartridge. The next seed is picked up and fed into the same slot until it lays parallel on top of the first seed. This procedure is repeated until the cartridge contains 10 seeds.

When the cartridge is loaded to capacity, clamp the hexagonal magazine head and with a pair of intestinal forceps with rubber jaws twist clockwise until the magazine head comes to a stop. The plunger will stick out of the magazine head by approximately 7½ mm. The magazine can now be put back into the stainless steel tray.

Next lift the tray out of the wooden case and autoclave the entire contents.

## Afterloading technique

Insert hollow 17 gauge stainless steel needles, 15 cm long and ground to a 45° point, around the periphery of the tumor mass. (For implants through the intact skin, needles with sharp points are preferable; but for intrathoracic and intraabdominal implants, it is better to use less sharp needles that do not penetrate and change their position as easily.) They are usually spaced 1 cm apart for tumors up to 4 cm in diameter, 1.5 cm apart for tumors from 4 to 8 cm, and 2 cm apart for larger tumors. All needles should be inserted parallel to each other. The direction of the needles must be considered carefully before starting so that their position may be palpated and the maximum number of seeds inserted through one needle.

## Attaching applicator to needle

After all needles have been inserted into the tumor to the required depth remove instrument from the stainless steel tray.

With one hand hold the instrument in vertical position by inserting thumb and index finger through the instrument holding rings, and with the other hand pull stylet out to its extreme end. Attach clamp to needle to avoid deeper penetration and lower instrument as far as it will go over protruding part of needle. By turning the needle clamping rod firmly clockwise the needle is securely fastened. To establish the depth of the inserted needle lower the tissue ring to the tumor surface and remove the needle clamp. The distance can now be read off the scale on top of the black ratched mechanism cone. (It is advisable to protect the stylet by inserting a needle into the instrument. This protective needle is removed by turning the needle clamping rod counterclockwise not more than two turns).

## Insertion of magazine

Take loaded magazine out of storage and insert all the way into black cubicle. Push the magazine into the cubicle with the cartridge slot facing in the same direction as the slot in the cubicle. To insert or remove magazine stylet must be pulled out completely.

## Implantation

The first of the 10 seeds in the cartridge is deposited into the needle by pushing the stylet forward. In order to penetrate hard tissue it may be necessary to apply extra pressure to the stylet as it reaches its end. If the stylet is not completely depressed the seed will remain in the needle. To insert the next seed - usually spaced 1 cm apart from the previous one - first hold the main body like a pencil, simultaneously resting the middle and ring fingers against the black cone, and raise the main body by two notches. Again the stylet is depressed completely and another seed is transferred. Observe the extended plunger of the hexagonal magazine head as the stylet is pulled back all the way to give space for the following seed to be pushed automatically into position. After the insertion of each seed the plunger in the hexagonal magazine head will be shortened by the thickness of the seed. This is an excellent indication that a seed has been transferred into the needle. Should it occur that the plunger does not move a slight amount of pressure with the finger tip to the plunger will place the seed in proper position. Should the stylet still not go through exchange magazine and check for oversized seed. Never force stylet. After plunger has dropped completely the magazine is empty and the stylet is locked.

## Radiation safety

Before cleaning, place instrument and used needles on a towel and check with Geiger counter for possible remaining seeds.

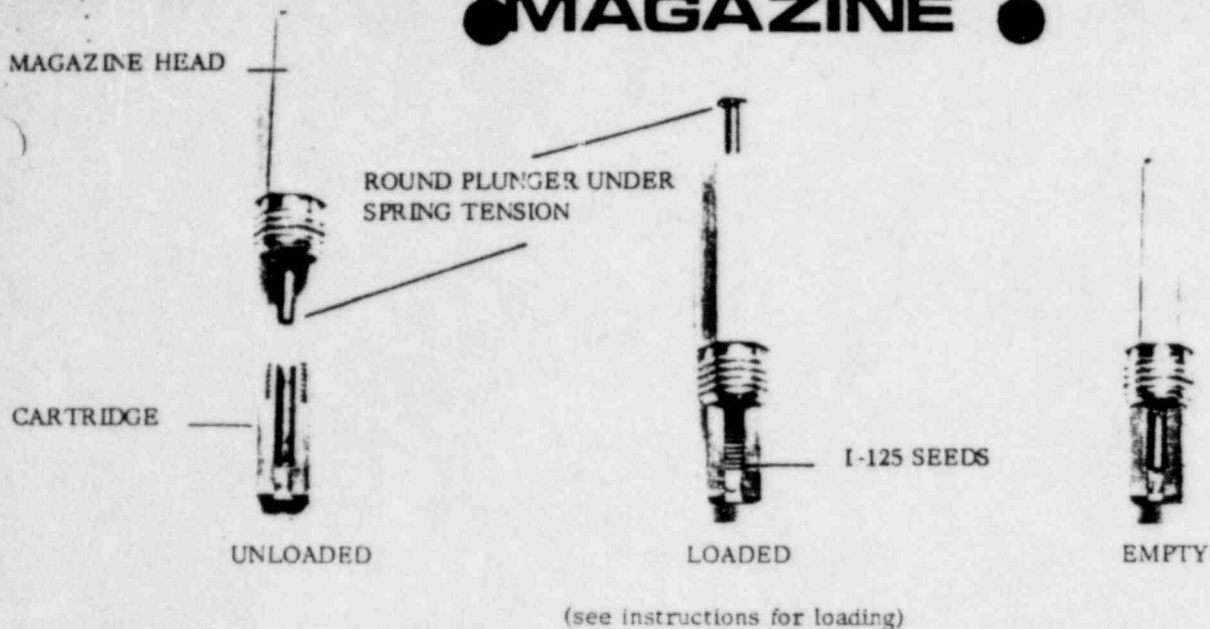
## Cleaning

Remove tissue or clotted blood from instrument immediately after use. Even during implantation the instrument should be rinsed in an Alconox solution during the change of needles. We recommend our TUC-150 Ultrasonic Cleaner. Keeping the instrument clean and in good condition insures a precise and efficient implantation.

Mick Radio-Nuclear Instruments, Inc. provides a yearly maintenance agreement to all our interstitial or intracavitary instruments. For any further advice or assistance please feel free to contact us.

# Mick Radio-Nuclear Instruments, Inc.

# MAGAZINE



## THE MICK APPLICATOR

is based on the same afterloading principle as the Henschke Implant Instrument and the I-125 Gun. These instruments are provided with a ratched mechanism assuring accurate placement of seeds at any desired depth up to 12 cm. Needles can be withdrawn at 5 mm steps and seeds are manually transferred by means of a stylett into the tumor.

## FEATURES

- LIGHTWEIGHT
- EASY HANDLING DUE TO SIMPLICITY OF INSTRUMENT
- QUICK EXCHANGE OF NEEDLES WITHOUT REMOVAL OF MAGAZINE
- SUITABLE FOR SINGLE SEED OR SUPERFICIAL IMPLANTS
- IDEAL FOR IMPLANTS OF THE PROSTATE
- FAST INSERTION OF SEEDS
- ACCURATE PLACEMENT OF SEEDS UP TO 12 CM
- MINIMUM EXPOSURE DUE TO HIGH DENSITY MATERIAL IN MAGAZINE
- RUGGED CONSTRUCTION
- ALL MATERIAL STAINLESS STEEL OR SURFACE TREATED
- EASY CLEANING

## SET INCLUDES:

- 7308 - Mick Applicator (complete)
  - 7308-2 - magazines (5)
  - 7308-3 - hypodermic stainless steel needles (15 cm long)(32)
  - 7308-4 - stainless steel ruler (1)
  - 7308-5 - needle holder (1)
  - 7308-6 - magazine holder (1)
  - 7308-7 - stainless steel lift out tray for sterilization (1)
  - 7308-8 - wooden carrying case (1)
- Cartridge or magazine loading accessories available

HOSPITAL

DEPARTMENT OF RADIOLOGY

SEALED SOURCE ACCOUNTABILITY LOG

PATIENT	NUCLIDE ADMINISTERED	QUANTITY ADMINISTERED*	INSERTION DATE & TIME	QUANTITY RETRIEVED	RETRIEVAL DATE & TIME	SURVEY OF PATIENT AFTER RETRIEVAL (mR/HR)
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						

\* NOTE: Number of sources, quantity of each source, and total quantity.

NURSE INSTRUCTIONS FOR PATIENTS TREATED WITH

BRACHYTHERAPY SOURCES

Patient's Name: \_\_\_\_\_

Room No.: \_\_\_\_\_ Physician's Name: \_\_\_\_\_

Radioisotope Administered: \_\_\_\_\_

Date and Time of Administration: \_\_\_\_\_

Date and Time Sources are to be removed: \_\_\_\_\_

Exposure Rates in mR/hr

Illustration of room and surrounding areas:

Location

Exposure (mR/hr)

Maximum  
Attendance Time

1. 3 feet from bed

2. 10 feet from bed

3. Doorway

4. Hallway

5.

6.

7.

8.

(Comply with all checked Items)

- \_\_\_\_ 1. Visiting time permitted: \_\_\_\_\_
- \_\_\_\_ 2. Visitors must remain \_\_\_\_\_ from patient.
- \_\_\_\_ 3. Patient may not leave room.
- \_\_\_\_ 4. Visitors under 18 not permitted.
- \_\_\_\_ 5. Pregnant visitors not permitted.
- \_\_\_\_ 6. Film badges must be worn. (If required, only personnel who have been issued a film badge may enter the room).
- \_\_\_\_ 7. Use and complete the following tags:
- \_\_\_\_ door
- \_\_\_\_ bed
- \_\_\_\_ chart
- \_\_\_\_ wrist
- \_\_\_\_ 8. Housekeeper, may not enter room.
- \_\_\_\_ 9. Patient must use disposable utensils.
- \_\_\_\_ 10. All items must remain in room until OK'd by Radiation Safety.
- \_\_\_\_ 11. Patient must have a private room.
- \_\_\_\_ 12. Do not release room to admitting until OK'd by Radiation Safety.
- \_\_\_\_ 13. Other instructions

In case of an emergency contact:

RSO  
Name\_\_\_\_\_  
on/off duty telephone number

## THERAPEUTIC USE OR SEALED SOURCES

1. All patients treated with brachytherapy sources will be placed in a private room with toilet.
2. The patient's room will be properly posted in accordance with §20.203 of 10 CFR Part 20.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, 3 feet (or 1 meter) from the patient, 3 feet (or 1 meter) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 meter) from the patient on the patient's chart.
4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and placed on the patient's chart.
5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.
6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient.\*
7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected.

\* Not necessary for Iodine-125 implants.

## 8. Instructions to Nurses

- a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. Call the Radiation Safety Office or his designee with any questions about the care of these patients in regard to radiation safety precautions.
- b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film badge.
- c. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.
- d. Pregnant nurses should not be assigned to the personal care of these patients.
- e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department, at once.
- f. Bed bath given by the nurse should be omitted while the sources are in place.
- g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

- h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Officer or his designee.

Special orders will be written for oral hygiene for patients with oral implants.

- i. No special precautions are needed sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.
- j. All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.
- k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.
- l. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet on the patient's chart.
- m. Visitors should sit at least 3 feet (or 1 meter) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.
- n. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. Emergency Procedures

- (1) If an implanted source becomes loose or separated from the patient, or
- (2) If the patient dies, or
- (3) If the patient requires emergency surgery, immediately call \_\_\_\_\_

Telephone No. (days) \_\_\_\_\_  
(nights) \_\_\_\_\_

- p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room and (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.

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PRECAUTIONS TO BE EMPLOYED WHILE HANDLING BRACHYTHERAPY SOURCES

1. Preparation and loading of applicators should take place before the time of insertion of the sources.
2. Load applicator behind the L-block employing long tongs or forceps. Do not pick up sources by hand.
3. Sources of the same size with different activities should be marked for easy identification.
4. Lead rubber gloves or aprons designed for diagnostic x-rays do not provide protection and may prove to be cumbersome and increase the time of operation.
5. Log the use of sources as they leave the storage facility.
6. Transport sources to and from storage room in shielded carrier only.
7. Employ portable barriers where practical during application and treatment.
8. In general, minimize your time spent handling sources and maximum your distance from sources when possible.