#### U.S. NUCLEAR REGULATORY COMMISSION

## REGION III

Report No. 030-02003/94001(DRSS)

License No. 21-01103-04

Category G

Priority 2

Licensee: Genesys Regional Medical Center 302 Kensington Avenue Flint, MI

Inspection Dates: January 5 and 6, 1994

Inspector:

- Whichard Michael F. Weber Radiation Specialist

Approved By:

John A. Grobe, Chief Nuclear Materials Inspection Section 2

1/21/94 Date

1/21/94 Date

## Inspection Summary

<u>Inspection on January 5 and 6, 1994 (Report No. 030-02003/94001(DRSS))</u> <u>Areas Inspected</u>: This was a special, unannounced safety inspection conducted to review the corrective actions implemented after our inspection at St. Joseph Hospital on April 26 through May 4, 1993. The inspection also included a review of activities at St. Joseph Campus (formerly St. Joseph Hospital) and Flint Osteopathic Campus (formerly Flint Osteopathic Hospital). <u>Results</u>: Of the areas inspected, one violation of NRC requirements was identified, namely the failure to label syringes containing radiopharmaceuticals, 10 CFR 35.60(b) (Sections 9 and 21). One area of concern was also identified regarding the effectiveness of the newly appointed Radiation Safety Officer at Flint Osteopathic Campus (Section 18).

9401280021 940121 PDR ADDCK 03002003 C PDR

#### DETAILS-ST. JOSEPH CAMPUS

## 1. Place of Use

St. Joseph Campus 302 Kensington Avenue Flint, MI

## 2. Persons Contacted

+\*Homer W. Read - Assistant to the President \*Joseph W. Kyle - Vice President, Emergency Services/Diagnostic Center +\*C. V. Prasad, Ph.D. - Medical Physicist and Radiation Safety Officer +\*Mark Gentle - Administrative Director of Radiology Deborah Cook - Lead Nuclear Medicine Technologist Judy Blight - Nuclear Medicine Technologist Diane DuChame - Nuclear Medicine Technologist Joseph Smith - Nuclear Medicine Technologist Karen Dellinger - Nurse Manager Ellie Strubel - Oncology Nurse Kathy Bede - Oncology Nurse

+Present at entrance meeting held on January 5, 1994 \*Present at exit meeting held on January 6, 1994

## 3. Licensed Program

Genesys Regional Medical Center (Genesys or licensee) is authorized to use any byproduct material identified in 10 CFR 35.100-400 for medical use described in 10 CFR 35.100-400, any byproduct material identified in 10 CFR 31.11 for in vitro studies, uranium depleted in uranium-235 for shielding in a linear accelerator, and cesium-137 for survey meter calibration.

The licensee's nuclear medicine program at St. Joseph Campus includes four full-time technologists, and 18 authorized users. The licensee orders unit doses and bulk technetium-99m (Tc-99m) from a local radiopharmacy. Approximately 470 diagnostic procedures are performed per month, primarily bone and heart scans using Tc-99m, and lung scans using xenon-133 (Xe-133). In addition, on average two hyperthyroid therapies using iodine-133 (I-131) are done each month, and one or two thyroid carcinoma therapies using I-131 are done each year. The licensee's brachytherapy program includes one medical physicist, who is also the Radiation Safety Officer (RSO), one dosimetrist, and two authorized users. On average, twenty therapies, using cesium-137 (Cs-137) temporary implants, are performed per year.

## 4. Inspection History

The licensee was last inspected on April 26 through May 4, 1993, in order to review a brachytherapy incident which occurred on April 21, 1993. The inspection also included a review of the nuclear medicine and radiation oncology departments. Seven apparent violations of NRC requirements were identified, namely: (1) failure to instruct nurses in the size and appearance of brachytherapy sources, (2) failure to provide initial and annual radiation safety training, (3) failure to measure the thyroid burden of each individual who helped prepare or administer therapy dosages of I-131 (repeat violation), (4) failure to repair or replace a dose calibrator when the accuracy error exceeded ten percent. (5) failure to survey with a radiation detection instrument the cardiac stress room, (6) failure to survey for removable contamination the cardiac stress room, and (7) failure to apply for and receive a license amendment before using the cardiac stress room as an area of use. Also identified were an area of concern regarding the inadequate management oversight of the radiation safety program, and two unresolved issues regarding the definition of a misadministration as it relates to a brachytherapy incident, and the implementation of the Quality Management Program (OMP).

The next-to-last inspection was conducted December 14, 1990. Three violations were identified, namely: (1) failure to test the dose calibrator for accuracy and geometry dependence upon installation, (2) failure to post clearance times and safety measures in rooms in which radioactive gasses are used, and (3) failure to measure the thyroid burden of individuals who helped prepare or administer therapy dosages of I-131.

## 5. Organization

Young Suh is the President and CEO of Genesys, with Homer Read serving as the Assistant to the President, and Michael Deming serving as the Executive Vice President. Joseph Kyle is the Vice President overseeing the Diagnostic Center, which includes Nuclear Medicine, with Mark Gentle serving as the Administrative Director of Radiology at St. Joseph Campus. C. V. Prasad, Ph.D., is the Radiation Safety Officer (RSO), with John Frederick, D.O., serving as the alternate RSO.

During the inspection, the inspector noted that the management oversight of the radiation safety program appears to have increased markedly since the last inspection. This was especially evident in the nuclear medicine department, where the RSO has increased the time spent in the department and has become very familiar with 10 CFR Part 35, and where the Radiation Safety Committee (RSC) has taken a very active role in assuring that the department operates in a safe manner. Moreover, a lead technologist has now been appointed, and, as a member of the RSC, works closely with the RSO to oversee the day-to-day operation of the department. As will be noted throughout this report, all of the violations identified during the 1993 NRC inspection were effectively corrected.

No violations of NRC requirements were identified.

## 6. <u>Training and Instruction to Workers</u>

During the 1993 inspection, the failure of the licensee to instruct nurses in the size and appearance of brachytherapy sources, and the failure to provide initial and annual radiation safety training to radiation workers, were identified.

During this inspection, the RSO and the Nurse Manager indicated to the inspector that within two weeks following the 1993 NRC inspection, all nurses who worked in the oncology department (main hospital, first floor) received extensive radiation safety training, which included instruction in the size and appearance of brachytherapy sources, emergency procedures, etc. Moreover, nurses who worked in other areas of the hospital where I-131 or brachytherapy patients may be located if the designated rooms are occupied also received this training. The lectures were followed on a different day by an actual drill covering emergency procedures. The above statements were corroborated by the inspector's review of the training records.

The nurse manager also reviewed with the espector a new procedure implemented during the week of the 1993 inspection which requires initial and annual radiation safety training from the RSO for each nurse who may care for an I-131 or brachytherapy patient (see Attachment 1). The training will be followed by a test to prove competency. The inspector's interviews with two oncology nurses, one of which was involved in the 1993 brachytherapy incident, revealed that their knowledge of radiation safety principles, especially relating to I-131 therapy and brachytherapy, appeared to be excellent.

The RSO also indicated that two radiation safety training sessions were provided to the nuclear medicine staff shortly after the 1993 inspection. The first, given during the week of the inspection, covered basic radiation safety, whereas the second, given the next week, covered the licensee's quality management program. Once again, the above statements were corroborated by the inspector's review of the training records. The inspector's interviews with the nuclear medicine technologists revealed that their knowledge of radiation safety principles appeared to be excellent.

No violations of NRC requirements were identified.

## 7. Personnel Radiation Protection - External

During the 1993 inspection, the failure of the licensee's RSO to ensure that nurses caring for brachytherapy patients were supplied with film badges was identified.

During this inspection, the RSO indicated that following the 1993 inspection, a large number of film badges were purchased in order to be able to supply a badge for each nurse caring for an I-131 therapy or brachytherapy patient. The RSO further indicated that the use of the badges was discussed at the radiation safety training sessions. Moreover, the RSO and nurse manager both stated that during I-131 therapies and brachytherapies, they constantly monitor the usage of the film badges by the nurses. The inspector's interviews with two oncology nurses revealed that badges are always available. Moreover, the nurses appeared to understand the use of the badges and agreed with the need to always wear badges when caring for I-131 and brachytherapy patients.

No violations of NRC requirements were identified.

#### 8. Personnel Radiation Protection - Internal

During the 1993 inspection, the failure of the licensee to measure the thyroid burden of each individual who helped prepare or administer therapy dosages of I-131 was identified.

During this inspection, the RSO indicated that the thyroid burden of each individual who helped prepare or administer therapy dosages of I-131 is measured on the day of the therapy. The inspector reviewed the records of each I-131 therapy performed since the last inspection and noted that the thyroid measurements were done as required.

No violations of NRC requirements was identified.

9. Equipment

During the 1993 inspection, the failure of the licensee to repair or replace a dose calibrator when the accuracy error exceeded ten percent was identified.

During this inspection, the RSO and the lead nuclear medicine technologist appeared to understand the requirements concerning the dose calibrator, especially the need to perform and analyze the appropriate tests, and if necessary, complete any repairs, before the first use.

Also during this inspection, several nuclear medicine technologists indicated that syringes, or syringe radiation shields, are not labeled whenever radiopharmaceutical kits are made up from bulk Tc-99m.

10 CFR 35.60(b) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

The failure of the licensee to label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, constitutes a violation of 10 CFR 35.60(b).

Note that the kits were usually made during on-call situations, when only the technologist and patient were present in the department.

One violation of NRC requirements was identified.

#### 10. Area Surveys and Facilities

During the 1993 inspection, the failure of the licensee to perform daily and weekly surveys in the cardiac stress room, and the inadequate surveys of the I-131 therapy rooms, were identified.

During this inspection, the RSO indicated that, immediately following the 1993 inspection, he instructed the nuclear medicine technologists to perform daily and weekly surveys of the cardiac stress room. The survey records revealed that the daily surveys were started the day after the inspection, but the weekly surveys did not begin until two months after the inspection. The daily and weekly surveys have been done regularly as required since the start dates. The RSO and the lead technologist indicated that a misunderstanding resulted in the two month delay with the weekly surveys.

The RSO appeared to understand the survey requirements concerning I-131 therapies, especially the proper way to perform, analyze, and record wipe tests of the patient's room. The inspector reviewed the records of each I-131 therapy performed since the last inspection and noted that the surveys were done and recorded as required.

No violations of NRC requirements was identified.

#### 11. Quality Management Program (QMP)

During the 1993 inspection, the failure of the licensee to include, in the brachytherapy section of the written QMP, procedures for complying with the requirements of the QMP according to 10 CFR 35.32, was identified. No problems regarding the implementation of the QMP were identified.

During this inspection, the RSO indicated that he had attended the Medical Workshop sponsored by Region III, and had subsequently rewritten the brachytherapy section of the QMP to include the required procedures (see Attachment 2). The inspector reviewed the revised QMP, as well as the QMP records of each I-131 therapy and brachytherapy performed since the last inspection and found no deficiencies. However, the inspector made several minor suggestions regarding the QMP records.

No violations of NRC requirements were identified.

## 12. Other Areas Inspected

Other areas inspected include internal audits, radiological protection procedures, materials, waste disposal, notifications and reports, misadministrations, posting and labeling, transportation, record-keeping for decommissioning, independent measurements, and bulletins and information notices.

No violations of NRC requirements were identified.

## 13. Exit Meeting

An exit meeting was held at St. Joseph Campus on January 6, 1994, with those individuals identified in Section 1 of this report. A summary of the areas inspected, the apparent violations and corrective actions from the 1993 inspection, the violation from this inspection, and the NRC enforcement policy were discussed. The licensee did not identify as proprietary any of the materials provided to or reviewed by the inspector.

#### DETAILS-FLINT OSTEOPATHIC CAMPUS

## 14. Place of Use

Flint Osteopathic Campus 3921 Beecher Road Flint, MI

#### 15. Persons Contacted

\*Joseph Kyle - Vice President, Emergency Services/Diagnostic Center \*Jim King - Vice President, Patient Services \*Ronald E. Weigel, D.O. - Authorized User \*Becky Shaw - Radiology Manager \*Tim Washburn - Assistant Radiology Manager \*Sue Baker - Nuclear Medicine Technologist Joyce Eichorn - Nuclear Medicine Technologist Sue Martineau - Nuclear Medicine Technologist William Townsend - Nuclear Medicine Technologist Richie Carter - Nuclear Medicine Technologist

\*Present at exit meeting held on January 6. 1994

## 16. Licensed Program

Genesys Regional Medical Center is authorized to use any byproduct material identified in 10 CFR 35.100-400 for medical use described in 10 CFR 35.100-400, any byproduct material identified in 10 CFR 31.11 for in vitro studies, uranium depleted in uranium-235 for shielding in a linear accelerator, and cesium-137 for survey meter calibration.

The licensee's nuclear medicine program at Flint Osteopathic Campus includes five full-time technologists, two part-time technologists, and 18 authorized users. The licensee orders unit doses and bulk Tc-99m from a local radiopharmacy. Approximately 300 diagnostic procedures are performed per month, primarily bone scans using Tc-99m, heart scans using thallium-201 (Tl-201), and lung scans using Xe-133. In addition, on average six hyperthyroid therapies using less than 30 millicuries (mCi) I-131 are done each year. I-131 therapies using greater than 30 mCi are not performed here, nor are brachytherapies.

#### 17. Inspection History

Flint Osteopathic Hospital, under License No. 21-040074-01, was last inspected on February 27, 1992. No violations of NRC requirements were identified.

The next-to-last inspection was conducted on November 9, 1,89. One violation was identified, namely the failure to perform weekly wipe tests of waste storage areas.

## 18. Organization

Young Suh is the President and CEO of Genesys, with Homer Read serving as the Assistant to the President, and Michael Deming serving as the Executive Vice President. Joseph Kyle is the Vice President overseeing the Diagnostic Center, which includes Nuclear Medicine, with Becky Shaw serving as the Manager of Radiology at Flint Osteopathic Hospital. C. V. Prasad, Ph.D., is the RSO, with John Frederick, D.O., the former RSO of Flint Osteopathic Hospital, serving as the alternate RSO.

During the inspection, the following information provided to the inspector caused him to question the effectiveness of the RSO: (1) Dr. Prasad has been in the department only a few times since the merger took place five months ago, and consequently has not yet become acquainted with the departmental procedures and staff, (2) several nuclear medicine personnel felt uncomfortable reporting minor incidents, asking questions, etc., with Dr. Prasad, and (3) a great deal of confusion exists regarding the division of responsibilities and duties between Drs. Prasad and Frederick. This is an area of concern to the NRC, since the lack of an effective RSO could easily lead to a degradation of safety in the nuclear medicine department.

One area of concern was identified.

## 19. Training and Instruction to Workers

Annual radiation safety training is provided to the nuclear medicine staff, as well as ancillary personnel such as Housekeeping and Security staff. The inspector made several suggestions regarding the training records.

The inspector's interviews with the nuclear medicine technologists revealed that their knowledge of radiation safety principles appeared to be excellent.

No violations of NRC requirements were identified.

## 20. Personnel Radiation Protection - Internal

The licensee performs an average of 30 lung scans per month, using a radioactive gas, Xe-133. The room used for the lung scans is at negative pressure compared to surrounding rooms when all the doors to that room are closed. During the inspection, the inspector was told that sometimes a technologist, unaware that a lung scan is in progress, will open the door to the room, thus possibly negating the negative pressure (depending on the time the door remains open). Solutions to this problem were discussed with the technologists and at the exit meeting.

No violations of NRC requirements was identified.

#### 21. Equipment

During the inspection, several nuclear medicine technologists indicated that syringes, or syringe radiation shields, are not labeled whenever radiopharmaceutical kits are made up from bulk Tc-99m.

10 CFR 35.60(b) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

The failure of the licensee to label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical constitutes a violation of 10 CFR 35.60(b).

It should be noted that he kits were usually made during on-call situations, when only the technologist and patient were present in the department.

One violation of NRC requirements was identified.

## 22. Other Areas Inspected

Other areas inspected include internal audits, radiological protection procedures, materials, personnel radiation protection (internal and external), waste disposal, notifications and reports, misadministrations, posting and labeling, transportation, recordkeeping for decommissioning, quality management program, independent measurements, and bulletins and information notices.

No violations of NRC requirements were identified.

#### 23. Exit Meeting

An exit meeting was held at Flint Osteopathic Campus on January 6, 1994, with those individuals identified in Section 15 of this report. A summary of the areas inspected, the violation, and the NRC enforcement policy were discussed. The licensee did not identify as proprietary any of the materials provided to or reviewed by the inspector.

Enclosures: (1) Corrective Action Plan (2) Brachytherapy Quality Management Policies and Procedures

## ATTACHMENT 1

DATE: April 30, 1993

TO: NRC

FROM: Karen Dellinger, RN, Nurse Manager, Oncology

SUBJECT: Correction Action Plan

#### CORRECTIVE ACTION PLAN

PURPOSE: To assure that every staff nurse caring for either brachy therapy or iodine therapy patients receive yearly education and training from the Hospital Radiation Safety Officer.

ACTION PLAN:

- Every spring, an inservice will be provided by the Radiation Safety Officer.
- The inservice will be coordinated by the Nursing Resource Development Representative and the Oncology Education Committee.
- 3. The inservice will be mandatory for every oncology staff nurse and any other nursing personnel required to care for brachy therapy or iodine therapy patients.
- 4. The Oncology Nurse Manager will maintain a current list of all staff that have attended the inservice. This list will also be kept in the Oncology Guidelines Manual on the Oncology Unit to be accessed whenever necessary.
- A copy of the information provided in this inservice will be kept along with the list of attendees in the Oncology Guidelines Manual.
- 6. An examination will be developed by Nursing Resource Development and completed by each nurse attending the inservice given by the Radiation Safety Officer to prove competency.
- Staff that have not attended the inservice and completed the competency exam will not be assigned to care for patients receiving either brachy therapy or iodine therapy.

4. Workers are instructed to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) should verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources. The verification may be achieved by checking the color-coding of the sealed sources.

6. For temporary brachytherapy implants, radiographs of brachytherapy nonradioactive "dummy" sources in place of the radioactive sources will be used to calculate the exposure time (or, equivalently, the total dose). In some instances, however, "dummy" sources may not be substituted for radioactive sources in certain implant techniques where the actual sources are placed under anesthesia in the operating room (e.g., Cesium 137 needle implants in the tongue or other anatomical structures or organs.) Films of the radioactive source implant geometry will be obtained afterward in the radiation therapy simulator room, radiology, or in the operating room as deemed appropriate.

7. Radiographs or other comparable images of brachytherapy radioactive sources will be used to verify the position of permanently implanted radioactive sources, (e.g., Iodine 125 sealed sources used for interstitial applications), and for calculating the total dose to the area of interest.

8. After insertion of the temporary implant brachytherapy sources, the authorized user will record the actual loading sequence and sign or initial the patient's chart or other appropriate record.

9. After insertion of the permanent implant brachytherapy sources the authorized user will record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

10. Dose calculations will be checked before the total prescribed brachytherapy dose has been administered. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. Manual dose calculations should be checked for:

The term sealed sources includes wires and encapsulated sources.

910 Jes 8048 6'03

10. Manual calculation check parameters (continued).

- (a). Arithmetic errors.
- (b). Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs.
- (c). Appropriate use of nomograms.
- (d). Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Manual calculation of a single key point will be compared to the computer-generated dose calculations to verify agreement to within ±10 percent.

11. A written record will be placed in the patient's chart or other appropriate record of the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

12. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of completion of the brachytherapy treatment.

13. Acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program used for brachytherapy calculations will be done before the first use of a treatment planning computer for patient calculations.

14. Periodic reviews of all brachytherapy procedures will be done and reported annually as required by the QM program.

# QUALITY MANAGEMENT REVIEW Brachytherapy

Review Date:/_/	
Patient Name:	Number:
WRITTEN DI (Y for	IRECTIVE COMPLIANCE yes, N for no)
Pre-implantation:	radioisotope
	number of sources
	source strength(s)
After implant but prior to completion of the procedure:	radioisotope
	treatment site
	total source strength
	exposure time (or total dose)
Comments:	
	ан, на 1. станцията на стануще о то с то с 14. О на станува на полити на станува и с то с о Минтения станува со с
Initials:	

January, 1993

## 35.2 DEFINITIONS

Authorized user means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Misadministration means the administration of:

- (1) A teletherapy radiation dose:
  - (a) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
  - When the treatment consists of three or fewer fractions (b) and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
  - (c) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
  - (d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
- (2) A brachytherapy radiation dose:(a) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
  - (b) Involving a sealed source that is leaking;
  - (c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
  - (d) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

(1) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(2) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Recordable event means the administration of:

- (1) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or
- (2) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified for low-dose-rate brachytherapy, containing the following information:

- For teletherapy: the treatment site, total dose, dose per fraction, and overall treatment period;
- (2) For low-dose-rate blachytherapy:
  - (a) Prior to implantation: the radioisotope, number of sources, and source strengths; and
  - (b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

## St. Joeseph Hospital

# Radiation Oncology Center

Brachy Therapy Implant Treatment Planning Summary Sheet Date: Patient Name : Radio Nuclide: Cs-137 Treatment Site: Type of Implant : No. Of Scurces Used : Source Loading Sequence: No. of Implant Hours: Time In: Time Out: Dose Prescription: Anotomic site & dose (cGy) 1. 4. 2. 5. 3. б. Before Implant After the Implant Aprroved by: Checked By : Treatment Planning done by:

May 1, 1993

#### GUARCERLY GMP REView:

T Dillum pointed but in the yearly review of OMP on January 20,1993, centain difficientles. The present review is done with same in mind and following policies and procedures be adopted as 5/1/03.

A new summary theet will be provided for each patient which identifies the the doos prescription, no. of sources, type of radio nuclide before and after the brachy therapy procedure is done. The physician involved, dosimetrist proplety nurse and physicist all agree on the definitions provided in the OMP.

This will be further reviewed later to the year to identify any short comings.

E.V. Presed Ph.D. S1193

Medical Physiclet

12/8/93

AMP Beview:

This review was done with DR. M.Kim , Dr Dh , the Dosimptrial Oncology Nurse and the physicist to identify if written directive for Brachy therapy procedure should be modified. It was pointed out the summary Rheet itself provides the dose prescription and physician dated signature, to remove any doubt it was decided that a seperate sheet for dose prescription to include Patient name , Implant procedure , radio muchide and the proscribed dose.

Potient Name :

MEDICAL REC #:

Previous Deam if may 1

Site of Implant:

Nadia Nuclide used:

Dose to be given (@ Anatomic site) in cEv:

Physician:

Dates

F.V. Frasho Ph. J. M. P. 18 4)

Medical Physicist