U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-31379/91001(DRSS); 030-01615/91001(DRSS)

Docket Nos. 030-31379; 030-01615

License No. 13-03459-03 Category G Priority III

License No. 13-03459-02 Category G Priority III

Licensee: St. Mary Medical Center - Hobart and Gary
1500 South Lake Park Avenue
Hobart, IN 46342

Inspection Conducted: February 7, 1991 and February 22, 1991

Inspectors: John A. Grobe, Chief
Nuclear Materials Safety
Branch, Region III
3-15-91
Date

James R. Mullauer, M.H.S.
Radiation Specialist
Nuclear Materials Safety
Section 1, Region III
3/15/91
Date

for Janet R. Schlueter, Health Physicist
Office of Nuclear Materials
Safety and Safeguards
3-15-91
Date

Also Present: Carl J. Paperiello, Ph.D.
Deputy Regional Administrator,
Region III
4/19/91
Date

for Eugene Holler, Attorney, NRC
Office of General Counsel
3-15-91
Date

Approved By: Charles E. Norelius, Director
Division of Nuclear Materials
Safety and Safeguards, Region III
3/15/91
Date

Inspection Summary

Inspection conducted on February 7, and 22, 1991 (Report Nos.030-31379/91001(DRSS); 030-01615/90001(DRSS)

Areas Inspected: This was an announced special inspection to evaluate the results of the licensees' independent audit of their brachytherapy programs. The licensees' audit report received by the NRC January 16, 1991, concluded that no misadministrations occurred in the 71 brachytherapy cases reviewed. However, the report also shows that in 29 of the 71 cases reviewed by the licensees' audit team, prescribed dose information could not be determined. In addition, the report showed in 1 case that the final treatment dose exceeded the documented final prescribed treatment dose by more than 10 percent (Inspection Report paragraph 4, Case No. 8). 10 CFR 35.2 defines a therapeutic misadministration as a therapy radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent. The NRC reviewed records of three brachytherapy cases identified as apparent misadministrations in NRC Inspection Report Nos. 030-31379/90001(DRSS); 030/01615/90001(DRSS) and the records on 6 additional cases to assure a full understanding of the licensee's audit team's conclusion. Results: After review of all available records for the 9 specific cases, interviews with licensee and Diagnostic Outpatient (DOC) personnel, and discussions with independent audit team members, the NRC agrees with the licensees' audit team that no misadministrations occurred in 5 cases (Inspection Report paragraph 4, Cases No. 2, 5, 7, 8, 9). However, 3 cases remain indeterminate with respect to whether misadministrations occurred since prescribed dose information could not be determined (Inspection Report paragraph 4, Cases No. 3, 4, 6). One additional case remains indeterminate with respect to whether a misadministration occurred because there was disagreement between the medical professionals regarding the final dose delivered to the patient (Inspection Report paragraph 4, Case No. 1).

Based on the NRC review of the overall audit team report concerning 71 brachytherapy cases, the NRC concludes that no misadministrations occurred in 41 of the cases and concludes that 30 cases remain indeterminate with regard to whether misadministrations occurred.

DETAILS

1. Persons Contacted

NRC Representatives

*Carl Paperiello, Ph.D., Deputy Regional Administrator, Region III
+*John A. Grobe, Chief, Nuclear Materials Safety Branch, Region III
*Eugene Holler, Attorney, Office of General Counsel,
+*James R. Mullauer, Nuclear Materials Safety, Section 1, Region III
*Janet Schlueter, Nuclear Materials Safety and Safeguards,
+William L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards

*Denotes those present at the exit meeting on February 7, 1991.
+Denotes those present at the telephone conference on February 22, 1991.

Licensee Representatives

*Milton Triana, Vice President of Operations
*Ken Vanderhye, Regional Director, Nuclear Medicine
Tom Torabi, Ph.D., Radiation Safety Officer and Medical Physicist
*Alice Nale, Quality Assurance Officer
+*Kappolu Sarma, M.D., Radiation Oncologist, Authorized User
+Ned Hornback, M.D., Radiation Oncologist, member of St.Mary Medical Center's Audit Team
+Richard A. Steeves, M.D., Ph.D., Radiation Oncologist, member of Dr. Sarma's Audit Team
+*Steve Pratt, Attorney for St. Mary Medical Center
*Allen F. Hrejsa, Ph.D., Director of Medical Physics, Lutheran General Hospital and Consultant for Dr. Sarma
+*J. Paige Clousson, Attorney for Dr. Sarma
*Kevin O'Grady, Medical Physicist formerly employed by Dr. Sarma
*Rene Darnell, Secretary at the Diagnostic Outpatient Clinic

*Denotes those persons present at the NRC exit meeting on February 7, 1991.
+Denotes those persons present at the telephone conference on February 22, 1991.

2. Purpose of Special Inspection

As a result of allegations received by the NRC Region III office on March 28, 1990, concerning the licensees' brachytherapy program, an inspection was conducted involving NRC inspectors and a medical consultant on March 30, 1990, through April 19, 1990. The inspection disclosed three apparent misadministrations as defined in 10 CFR 35.2 and that the licensees did not implement effective oversight of the brachytherapy program to assure safe use of NRC licensed materials and compliance with 10 CFR 35.33. In addition, when records were available to indicate the occurrence of apparent misadministrations, the licensees failed to evaluate in a timely manner those occurrences to: (1) determine

whether misadministrations occurred; (2) implement corrective actions; and (3) determine whether there was a basis to notify the NRC in accordance with the NRC's misadministration reporting requirements.

As a result of these findings, on April 27, 1990, the licensees were ordered to suspend brachytherapy activities and assemble an independent brachytherapy audit team to review all brachytherapy cases since the inception of licensed brachytherapy activity and to determine whether therapeutic misadministrations occurred as defined by 10 CFR 35.2.

On April 18, 1990, St. Mary Medical Center - Hobart notified the NRC Region III office by telephone of 4 possible misadministrations. In a letter dated May 3, 1990, the 15-day report concerning the 4 possible misadministrations was submitted from St. Mary Medical Center - Hobart. The letter addressed the six items required for a 15-day report in 10 CFR 35.33(b). The letter also reported that no misadministratons had occurred and the brachytherapy treatments had no adverse effect on the patients. The letter further stated that St. Mary Medical Center - Hobart was continuing the investigation of these four cases. After NRC review of the 15-day report, a question was raised by the NRC whether the licensee fully considered the 10 CFR 35.2 definition of a misadministration. In a letter dated May 17, 1990, to the NRC Region III office, the licensee stated that, while they considered the 10 CFR 35.2 definition for misadministrations, the clear focus of the previous review was whether any of the possible misadministrations had any adverse medical effect on the patients. The licensee also clarified that the independent audit required by the April 27, 1990 Order would fully consider whether misadministrations as defined by 10 CFR 35.2 had occurred.

On January 16, 1991, NRC Region III received the licensees' final audit report. The audit team concluded that no misadministrations occurred. However, in 29 out of 71 brachytherapy treatments, the audit report stated that a prescribed radiation dose could not be determined and, in one case, the audit report documented that the delivered dose exceeded the prescribed dose by more than ten percent.

To understand the audit team's conclusions and address any differences between those conclusions and the previous NRC inspection findings, the NRC determined an onsite inspection would be conducted to: (1) re-examine three brachytherapy treatments originally identified by the NRC as apparent misadministrations; and (2) to examine the records on at least six additional brachytherapy cases.

3. Organization

John Birdzell is the President of Lakeshore Health Systems, Milton Triana is the Vice President of Operations, Hobart, Beth Kaminski is the Chief of Operations for the Hobart Facility, Sam Turner is the Chief of Operations for the Gary Facility, Earl Mason, M.D., is the Chairman of the Radiation Safety Committee, K-ppolu Sarma, M. D. is the Chairman of the Radiation Oncology Department, Ken Vanderhye is the Regional Director of Nuclear Medicine, Tom Torabi, Ph.D., is the Radiation Safety Officer and Medical Physicist and Alice Nale is the Regional Radiology - Radiation Therapy Quality Assurance Coordinator.

4. Review of Brachytherapy Cases

The NRC inspection team selected nine brachytherapy cases performed at the St. Mary Medical Centers for detailed review. This review was performed by a thorough examination of all available records for those cases in the St. Mary Medical Centers' files and the DOC files. The record review concentrated on any information that would identify the authorized users' prescribed radiation dose made either prior to, during, or after treatment and any information that would identify the actual final dose delivered to the patient. This specific information is necessary to determine if any misadministrations occurred as defined by 10 CFR 35.2. The cases and records were extensively discussed with the radiation oncologist, medical physicists and the licensees' quality control officer. In addition, those denoted in Section 1 were contacted on February 22, 1991, for final clarification concerning certain cases.

Since the inception of the brachytherapy program at St. Mary Medical Centers, various records, forms, and charts were developed and used. Therefore, the types of forms used in specific cases depend on when the procedure was performed. In general, the following forms are referenced in this report and examples of the forms can be found in the attachments to this report. Form A is the Dosimetry and Computerized Treatment Planning form (Attachment 1) which is used to document what sources are to be used and the specific planned source configuration, to document the magnification factors derived from x-rays taken prior to afterloading the sources and to document the anticipated dose to various points of interest. The dose information is taken from the computer generated treatment plan that shows the dose distribution (isodose curves) around the area of interest. Form B is the Implant Dosimetry Form (Attachment 2) and contains two sections. The top section is used to document the actual date and time of implant, source type, number of sources, source configuration and desired dose. The bottom section of Form B is filled out after the sources are explanted from the patient documenting the actual explant time and date, total treatment time and delivered dose. Form C is the Brachytherapy Sources Inventory Form (Attachment 3) which is used to document the dates when sources are in storage, removed from storage for therapy, and returned to storage at the completion of therapy. Attachment 4 is an updated version of Form A, Dosimetry and Computerized Treatment Planning Form. Attachment 5 is the most recent version of Form A which is a combination of the old Form A and B. Attachment 6 is an actual example of a computer generated treatment plan showing the dose distribution around the area of interest. Progress notes are lined blank forms typically found in the patient's chart during hospital stay. These forms are filled out either by attending nurses and/or physicians to document the condition of the patient, medications ordered and given, examination results, and other information regarding patient progress.

The combined hospital and DOC records of brachytherapy cases were found to be a major problem when attempting to evaluate compliance with NRC requirements during administration of the brachytherapy treatments. Some information was missing from records and other information was contained in cryptic margin notes that could only be interpreted after extensive discussion with the involved persons. In addition, several records contained conflicting information. Computer generated dates on treatment

plans were incorrect over 50 percent of the time; therefore, it was decided that this information was unreliable and the computer generated dates were not used in any NRC conclusions unless those dates agreed with other treatment date information. Hospital and DOC personnel stated that those errors likely occurred during data entry on computer system startup.

Review of Case No. 1 - Gynecologic implant on August 2, 1989

NRC Review in April 1990

Based on the NRC review in April 1990, this case was determined to be an apparent misadministration.

The initial NRC review of Case No. 1 on April 4, 1990, revealed the following information. The Implant Dosimetry form (Form B) showed the desired radiation dose to be 3000 rads which was changed to 3500 rads. The change was not signed, initialed or dated. A second record, the Dosimetry and Computerized Treatment Planning form (Form A) showed the prescribed dose as 3000 rads, an apparent conflict between the records. In addition, the original computer treatment plan indicated the prescribed radiation dose was 3000 rads. The final delivered dose indicated in the hospital record (forms A and B) was 3550 rads. It was also noted that the authorized user signed and dated both forms A and B when the forms were initially filled out. Other information noted in these records included a total treatment time of 65.5 hours, implant and explant time and date and treatment plan time and date. According to the date on the computer treatment plan, the plan was performed during treatment three days after the radioactive sources were implanted.

On April 11, 1990, the NRC medical consultant reviewed this case and determined that the prescribed radiation dose was 3500-3600 rads. This was determined from progress notes found in the patient's medical records which indicated that the dose was changed by the authorized user two days after implant. The consultant determined that the final dose to a designated reference point (point A) was 70 rads/hour rather than the indicated dose rate of 54 rads/hour. Since the records indicated that the total time of treatment was 65.5 hours, the final delivered dose was determined to be 4590 rads instead of the prescribed dose of 3500 - 3600 rads.

Licensees' Audit Team's Finding

Due to the large discrepancy between the prescribed dose and the final dose as noted in the NRC medical consultant report, the audit team chose to repeat the calculation of this plan on the Theraplan treatment planning system used at Indiana University Medical Center. The team found that the radiographs were not optimal for calculations because the patient position was not the same in the supine and lateral radiographs. The team also determined that the ovoids as shown on the lateral radiograph had slipped inferiorly about 2 cm with respect to the tandem and bladder from their position in the supine radiograph. The team, therefore, computed their treatment plan on the basis that the position of the sources on the lateral radiograph were correct and the position of the sources on the supine radiograph were shifted to match the lateral radiograph. Based on

the above information, the team determined that the delivered dose to point A was 3706 rads. The variance of the total delivered dose from the prescribed dose of 3500 rads (as indicated on form B) was 5.9% and on this basis the audit team concluded this case did not constitute a misadministration.

The audit team report also states that if the position of the ovoids in the supine radiograph were assumed correct and the position of the sources in the lateral radiograph shifted, then the average dose rate at point A would have been 74.45 rads/hour. Also, if the mean position of the sources between the supine and lateral radiographs were selected, then the average dose rate at point A would have been 63.47 rads/hour. In either of these two situations, the audit team states that the dose delivered would have constituted a misadministration.

NRC Final Review of Case No. 1

In reviewing all relevant hospital records and DOC records, it was determined that no new information could be ascertained when compared to the initial NRC record review. The authorized user was questioned about the change in the recorded prescribed dose. The authorized user explained that during treatment, he decided that one brachytherapy treatment would be given to this patient rather than two treatments which he had originally contemplated. Therefore, the prescribed dose was increased from 3000 rads to 3500 rads. A hospital progress report shows that two days after implant, the authorized user prescribed a radiation dose of 3500 - 3600 rads. The authorized user stated that his thought at that time was to deliver a single treatment with a dose between 3500 - 3600 rads; however, his final prescribed dose was to deliver 3500 rads as documented on hospital Form B. (See Attachment 2)

The authorized user and licensee personnel discussed the audit team's method of reviewing this case and it became apparent that the definition of points on a radiograph vary depending on the medical opinion of the reviewer. The dose rate also varies to a large degree depending on what points are being considered. This is apparent since the delivered dose as recorded by the authorized user was 3550 rads, the delivered dose according to the NRC medical consultant was 4590 rads and the licensees' audit team determined the final delivered dose was 3706 rads.

Conclusion

Since the medical interpretation varied between the medical reviewers and three different delivered doses were determined, the NRC review concluded that the final delivered dose is indeterminate and it cannot be concluded whether a misadministration occurred as defined by 10 CFR 35.2.

Review of Case No. 2 - Gynecologic implant on December 11, 1989

NRC Initial Review in April 1990

The initial NRC review of Case No. 2 on April 4, 1990, revealed the following information. Hospital staff indicated on the computer treatment plan a prescribed radiation dose of 3500 rads and the final delivered dose

at 0.5 centimeters was 3937 rads as indicated on Form A. Other information on Form A indicated implant and explant dates and times, and 52.5 (hours of treatment assumed). The treatment plan was dated in writing because the computer printed date appeared to be incorrect. It should be noted that Form A documented an implant date of 12/11/89 and time of 11:30 a.m. and an explant date of 12/13/89 and time of 4:45 p.m.. This would equal an actual treatment time of 53.25 hours rather than the documented 52.5 (see Attachment 6, page 2).

On April 11, 1990, the NRC medical consultant reviewed this case and determined that the physician prescribed a radiation dose of 3500 rads to a depth of 0.5 centimeters 24 hours after implant. The radioactive material was left implanted 52.5 hours, and the actual dose delivered was 3940 rads to a depth of 0.5 centimeters.

Licensees' Audit Team Findings

The audit team determined that the prescribed radiation dose was 7875 rads to the surface and documented the final delivered dose in its report was 7875 rads to the surface. However, the audit team stated there was a typographical error in its report. The audit team confirmed that the total treatment time was 53.25 hours at a dose rate of 150 rads/hour and the final dose delivered to the patient was 7988 rads. The audit team derived this prescription and delivered dose using information that was documented on the treatment plan after explant.

NRC Final Review of Case No. 2

In reviewing all relevant hospital records and DOC records, it was determined that no new information could be ascertained when compared to the initial NRC record review except as noted below. The authorized user indicated that the documented 3500 (no units are indicated) as originally noted on the computer treatment plan was only a preliminary notation made by the physicist and was not intended to be the prescribed dose. He referred the inspection team to another computer treatment plan which contained an annotation for a treatment time of 52.5 hours. Although it is not clear whether the documented treatment time of 52.5 hours was actually documented at the time the treatment plan was generated or after treatment occurred, the authorized user stated that this treatment time of 52.5 hours was his prescription. The dose rate of 75 rads/hour at 0.5 centimeters depth for 52.5 hours was his intended dose. Hospital personnel stated they had no knowledge of this apparent prescribed dose.

The audit team based its calculations on a prescribed and delivered ovoid surface dose instead of the 0.5 centimeter depth dose generally referred to in the records by Dr. Sarma.

Conclusion

It is unclear what the prescribed dose actually was since two treatment plans performed within minutes of each other show two different sets of numbers (3500 rads and 52.5 hours at 75 rads per hour). In addition, one treatment plan shows a treatment time of 47 (hours assumed) and another 52.5 (hours assumed). None of these records identify information as the

prescribed dose. Based on statements made by the authorized user that the documented 3500 (rads assumed) on the computer treatment plan was not intended to be the prescribed dose and he intended to deliver a dose of 75 rads/hour at 52.5 hours, the NRC agrees with the licensees' audit team's conclusion that no misadministration occurred.

Review of Case No. 3 - Gynecologic implant on December 5, 1988

NRC Initial Review in April 1990

This case was initially determined by the NRC to be an apparent misadministration. On April 11, 1990, the NRC medical consultant reviewed this case and determined that the prescribed radiation dose was 2500 - 3000 rads at the surface and the total treatment time was 20 hours for a final delivered dose of 1840 rads to the surface treatment area as documented in the hospital records. The consultant also noted that the applicator and radioactive material were removed prematurely for undocumented reasons.

Licensees' Audit Team Findings

The audit team determined that the prescribed radiation dose was 1740 rads and the final delivered dose was 1760 rads.

NRC Final Review of Case No. 3

Hospital personnel informed the NRC inspection team that the forms being reviewed were new forms and sometime after treatment, Dr. Sarma filled these forms out, signed and back dated the forms to the date of actual treatment. Dr. Sarma stated that he did this to consolidate the records.

The actual prescribed dose is unclear in that doses are indicated as follows:

1. History and physical form (Form used when patients are admitted) presented by the hospital staff dictated by Dr. Sarma on 12/5/88, signed by Dr. Rajbhandari and transcribed 12/8/88 references in its text that only 5000 rads was given (external) and 7500 rads are needed to the area of interest.

2. An operative report (Form which is filled out after surgery) in the hospital record dated 12/5/88, which was dictated by Dr. Sarma after implant on 12/5/88, and signed by Dr. Rajbhandari references in its text that about 2500 - 3000 rads will be given.

3. A nuclear medicine record signed by Dr. Sarma on 12/5/88 indicates 2500 - 3000 rads to the surface.

4. A progress record signed by Dr. Sarma and dated 12/6/88 indicates a treatment duration of 46 hours.

5. A nuclear medicine source log-out, log-in inventory shows that the sources were out of the safe for 20 hours.

6. A computer treatment plan dated 12/4/88 (NOTE: This date was determined to be incorrect as the computer treatment plan was actually performed on 12/5/88 at 10:25 a.m.) indicates in the right hand corner that based on 27 hours, a dose of 2500 rads would be delivered to the surface, and based on 33 hours, 3000 rads would be delivered to the surface. At the bottom of the treatment plan, the following information is indicated: the dose rate at 2 centimeter away from the surface would be 24 rads/hour, the dose rate at 1 centimeter away from the surface would be 41 rads/hour and the dose rate at the surface would be 92 rads/hour.

7. An implant dosimetry form (Form B) signed by Dr. Sarma and back dated to 12/8/88 indicates the insertion of Cs-137 on 12/5/88 at 5 p.m. and removal on 12/6/88 at 1 p.m. for a total of 20 hours which was signed by Dr. Sarma and back dated 12/6/88.

8. The audit team determined the prescribed dose was 1740 rads. The audit team stated this was determined from information in records. The NRC inspection team could not identify a record that contained this information.

Dr. Sarma explained that the original prescribed dose of 1700 rads was derived from an initial plan of treatment which included both external beam and internal beam treatment. According to Dr. Sarma, the desired total external-internal dose was planned to be 7500 rads. A dose of 5800 rads would be delivered by external beam treatment and the final 1700 rads would be delivered by internal treatment.

Based on other hospital progress notes, the treatment lasted 22 hours at a dose rate of 75 rads/hours as indicated on the treatment plan. Based on this information, the final delivered dose should be 1650 rads.

According to the licensees' audit team, a dose rate of 80 rads/hour for 22 hours was used to arrive at a delivered dose of 1760 rads.

Conclusion

While the NRC understands the basis for the audit team's conclusion that this was not a misadministration, the NRC was unable to replicate the audit team's findings that the prescribed dose was 1740 rads. Dr. Sarma stated that he originally thought 5000 rads was given by external beam which would support the documented prescribed dose of 2500 - 3000 rads since the combination of this external-internal treatment would equal approximately 7500 rads. However, at some time Dr. Sarma discovered that 5800 rads were delivered by external treatment. Dr. Sarma presented a document which indicated that the difference between 7500 and 5800 was 1700 and his intent was to deliver 1700 rads; however, it is unclear when this decision was made. Therefore, due to the conflicting information between hospital and DOC records, the NRC is unable to draw a conclusion and this case is considered to be indeterminate.

Review of Case No. 4 - Gynecologic Implant on December 18, 1989

NRC Initial Review

No determination by the NRC could be made on this case in April 1990 due to the absence of a prescribed dose. The initial NRC review of Case No. 4 on April 4, 1990, revealed the following information. Hospital forms did not show the desired radiation dose; however, the recorded final delivered dose was 2760 rads. Other information indicated in hospital records were as follows; total treatment time was 46 hours, the implant and explant dates and times, dose rate was 60 rads/hour and the treatment plan date and time.

On April 11, 1990, the NRC medical consultant reviewed this case and could not determine if the physician prescribed a radiation dose. The final delivered dose was determined to be 5060 rads to the surface and 2760 rads at 0.5 cm.

Licensees' Audit Team Findings

The audit team determined that the prescribed radiation dose was 2760 rads and the final delivered dose was 2760 rads. The audit team stated that the prescribed dose of 2760 rads was found in the patient medical records.

NRC Final Review of Case No. 4

In reviewing all relevant hospital records and DOC records, no prescribed radiation dose could be found by the NRC. The progress notes and a nuclear medicine department worksheet indicated a treatment duration of 46 hours. Based on the indicated dose rate of 60 rads/hour, the delivered dose appears to have been 2760 rads.

Conclusion

All persons reviewing this case agree that the final dose delivered to the patient was 2760 rads. According to the licensees' audit team, they determined the prescribed dose of 2760 rads by back calculating from the time of explant to the time of implant. While the NRC understands the audit team's basis for concluding that this case was not a misadministration, no documented prescribed dose could be found. Therefore, the NRC is unable to draw a conclusion and this case is considered to be indeterminate.

Review of Case No. 5 - Breast Implant on September 3, 1986

NRC Initial Review in April 1990

This case was not initially reviewed by the NRC.

Licensees' Audit Team Review

The audit team determined that the prescribed radiation dose was 2000 rads and the final delivered dose was 2115 rads.

NRC Final Review of Case No. 5

Hospital personnel presented medical records that indicated a prescribed

dose of 2000 - 2500 rads which was dictated and signed by Dr. Sarma on 9/2/86. The patient discharge summary which was transcribed on 10/24/86 and signed by Dr. Sarma states that the seeds were inserted on 9/2/86 and were kept in 40 hours which gave 1500-2000 rads. An operative report dictated on 2/27/87 and signed by Dr. Sarma states that "radium" (iridium-192 was actually used) was loaded and kept in place approximately 40 hours and 1500 rads were given to the area. A treatment plan dated 9/3/86 was also presented to the inspection team which indicated a dose rate of 50 rads/hour at 40 hours. Progress notes proved to be the only source of implant and explant information. Based on this information, the total time of treatment appeared to be 42.3 hours at a dose rate of 50 rads/hour, for a total delivered dose of 2115 rads.

Conclusion:

Based on the progress notes that were apparently located in the DOC files, NRC agrees with the audit team's finding of prescribed and final dose and that no misadministration occurred.

Review of Case No. 6 - Breast Implant on August 10, 1987

NRC Initial Review in April 1990

On April 11, 1990, the NRC medical consultant reviewed this case and could not determine by record review a prescribed dose. According to the consultant, a treatment plan was also not available for review. A simple statement in the record documented the final dose delivered to the patient as "about" 1500 rads.

Licensees' Audit Team Findings

It should be noted that the date in the auditors' final report to the NRC was incorrect. The date in the report showed that treatment began on August 8, 1987, when the actual date of implant was August 10, 1987.

The audit team could not determine a prescribed radiation dose; however, reported that the final delivered dose was 2695 rads.

NRC Final Review of Case 6

According to a hospital medical progress record, Dharma Rajbhandari, M.D., an authorized user at the time of this treatment who was not available for interview during this inspection, documented that the final delivered dose was 1500 rads. Dr. Sarma could not comment on this case beyond what the medical records indicated other than the fact that there appeared to be no prescribed dose. This was the only source of documented final dose.

According to a computer treatment plan dated August 19, 1987, (dated 9 days after implant) the dose rate was 55 rads/hour. If this is multiplied by a total treatment time of 49 hours (rounded up from 48.75 hours of actual treatment) as indicated in the hospital progress notes, the delivered dose should have been 2695 rads as determined by the audit team. Dr. Sarma stated that he documented a final delivered dose of 2550 rads on the computer treatment plan; however, could not explain the basis for

entry. No other computer treatment plan prior to August 19, 1987, was available for review. According to the hospital staff, treatment plans used during the actual treatment had been misplaced.

Conclusion

The NRC was able to affirm the audit team's documented final delivered dose. While the NRC understands the audit team's conclusion that this case was not considered to be a misadministration, a prescribed dose could not be determined by the audit team or the NRC. Therefore, the NRC is unable to draw a conclusion and this case is considered to be indeterminate.

Review of Case No. 7 - Breast Implant on August 5, 1987

This case was not reviewed by the NRC during its inspection in 1990.

Licensees' Audit Team Review

The audit team determined that the prescribed radiation dose was 2100 rads and the final delivered dose was 2046 rads.

NRC Final Review of Case No. 7

The hospital medical records showed a prescribed dose of 2100 rads. Dr. Sarma stated that 2100 rads was his prescribed dose. The treatment plan signed and dated August 6, 1987, by Dr. Sarma indicated that a dose rate of 44 rads/hour was delivered for 46 hours. According to the hospital progress notes, the treatment duration was 46 hours resulting in a delivered dose of 2024 rads. However, a hospital transcribed medical record signed and dated by Dr. Sarma showed that the final delivered dose to the patient was 1500 rads. When questioned about this apparent conflict, Dr. Sarma stated that he transcribed this information several months after treatment without reference to his patient records for exact dose information. Dr. Sarma could not explain why he dictated a record that contained specific information several months after treatment without consulting patient records. The audit team stated that the difference between its final delivered dose and the NRC's final delivered dose was due to mathematical differences.

Conclusion

Based on available records and Dr. Sarma's statements, the NRC concurs with the audit team's conclusion that no misadministration occurred.

Review of Case No. 8 - Breast Implant on December 11, 1989

NRC Initial Review in April 1990

Based on NRC review in April 1990, the NRC could not determine whether this case was a misadministration due to the lack of an identifiable prescribed dose. The initial NRC review of Case No. 8 on April 4, 1990, revealed the following information. Hospital records failed to show a

prescribed radiation dose; however, the recorded final dose on Form A was 2640 rads. Other information documented in the hospital records included; implant date and time and computer treatment plan date and time. The treatment plan was performed during treatment 2 days after radioactive source implant.

On April 11, 1990, the NRC medical consultant reviewed this case and was informed by licensee personnel that the catheters were surgically implanted in the patient 4 days prior to source implant because the radioactive sources had not been ordered. Apparently the radioactive sources were implanted 4 days later when they arrived at the hospital. No prescribed radiation dose could be determined from the computer treatment plan or patient's chart. The final delivered radiation dose could not be determined because the physicist could not accurately identify individual seeds for entry into the computer. Therefore, it could not be determined if the dose distribution on the computer treatment plan was correct.

Licensees' Audit Team Findings

The audit team determined that the prescribed radiation dose was 3575 rads and the final delivered dose was 3960 rads.

NRC Final Review of Case No. 8

Through review of all relevant hospital and DOC records and interviews with involved medical personnel, the following information was revealed. Dr. Sarma stated that he was consulting with three other physicians while this patient was being treated. The original prescribed time of treatment was 48 hours at a dose rate of 55 rads per hour as recorded in Form A. According to Dr. Sarma, that original prescription was modified during treatment in a progress note dated December 13, 1989, indicating that the sources would be explanted at 7 a.m. the next morning, December 14, 1989. This change would increase the prescribed time of treatment from 48 hours to 65 hours. Therefore, the modified prescribed dose became 3575 rads as noted in the audit report. The licensees' audit team reported that the final delivered dose was 3960 rads. The NRC inspection team pointed out that this situation represented a misadministration in that the difference between the prescribed dose and the delivered dose was greater than 10 percent.

Dr. Sarma stated that some time after the first treatment modification was made on December 13, 1989, and prior to scheduled explant on December 14, 1989, at 7:00 a.m., Dr. Sarma decided to change the time of treatment again and increased it to 72 hours, the actual explant time. Dr. Sarma stated that this medical decision was based on his evaluation of various blood test results. The NRC inspection team reviewed the patients available blood test results and it was noted that no test results were received between December 10 and 15, 1989. According to Dr. Sarma, this second change in prescription was in his mind. No record was made to indicate this change to 72 hours.

Based on Dr. Sarma's stated final prescribed treatment time equal to the actual treatment time of 72 hours at a dose rate of 55 rads/hour, the final prescribed and delivered dose was 3960 rads. The audit team stated

during the February 22, 1991 telephone conference that they were aware of Dr. Sarma's second prescription change, but did not reflect it in their conclusions because it was not recorded. The audit team further stated that, although the difference between the prescribed and delivered dose calculated by the audit team was greater than 10 percent, due to the inherent inaccuracy in these calculations and the slight exceedance of the 10 percent limit, they concluded that no misadministration occurred.

Conclusion

Based on Dr. Sarma's statement that sometime prior to explant, he made an undocumented medical decision to increase the treatment time from 65 hours to 72 hours; the NRC agrees with the licensees' audit team that no misadministration occurred.

Review of Case No. 9 - Gynecologic Implant on July 22, 1987

NRC Initial Review in April 1990

This case was not reviewed by the NRC during its inspections in 1990.

Licensees' Audit Team Review

The audit team determined that the prescribed radiation dose was 1500 rads and the final delivered dose was 1625 rads.

NRC Final Review of Case No. 9

A prescribed dose of 1500 rads was documented in the hospital patient progress note. The progress notes further indicated that a dose rate of 65 rads/hour was delivered for a total time of 25 hours. This calculates to a final delivered dose of 1625 rads. According to hospital personnel, a computer treatment plan was unavailable for review.

Conclusion

NRC agrees with the audit team's findings that no misadministration occurred.

5. NRC Final Conclusion:

The NRC agrees with the licensees' audit team that records maintained by both DOC and the hospital were incomplete and poorly maintained. It was very difficult to utilize those records when trying to evaluate the program to determine compliance with NRC requirements. Information when available was often conflicting and in some cases incorrect. The NRC also agrees with the licensees' audit team that a great deal of effort will be required in the future by both DOC and hospital personnel to coordinate documents to assure that both facilities have a complete set of documents and that the information contained in the documents is accurate. While the NRC understands the licensee's audit team's conclusion that no misadministrations occurred from a medical viewpoint, the NRC was unable to make a determination in four of the nine cases reviewed whether

misadministrations as defined by 10 CFR 35.2 occurred. These four cases remain indeterminate.

6. Exit Interview

At the conclusion of this special inspection on February 7, 1991, the NRC staff met with those persons listed in Section 1 of this report and summarized the inspection findings for each case reviewed. The attendees were advised that the summary was preliminary and that further information from the licensees' audit team may be needed for the NRC staff to make their final conclusions. The attendees agreed to this suggestion and the meeting was closed.

Attachments:

1. Form A, Dosimetry and Computerized Treatment Planning Form
2. Form B, Implant Dosimetry
3. Form C, Brachytherapy Sources Inventory Form
4. Updated Version of Form A
5. Newest Version of Form A
6. Computer Generated Dose Distribution Curves
7. Audit Report of Brachytherapy Program

ATTACHMENT 1

175

Lakeshore Health System

DOSIMETRY & COMPUTERIZED TREATMENT PLANNING

Patient: [redacted] Date [redacted]-89 Pat. ID# [redacted]

Cs 137 SOURCES

Model		Date of Cal.	Mg Rad Eq.	mCi	Date of Insertion	mg Rad Eq	mCi
1862	Red H-3	5-23-86	11.4	29.1	8-2-89	10.8	27.2
"	" E-1	"	11.4	29.2		10.7	27.2
"	" H-5	"	11.2	28.7		10.5	26.8
1863	Black N-4	"	11.9	29.2		10.7	27.2
"	" L-1	"	16.9	43.3		15.8	40.4
"	" O-9	"	16.7	42.7		15.6	39.8
"	" M-1	"	16.9	43.1		15.8	40.2
"	" M-9	"	17.1	43.6		16.0	40.9
1864	White R-3	"	17.1	43.8		16.0	40.9
"	" T-8	"	22.3	57.0		20.8	53.0
			22.3	56.9		20.8	53.1

OTHER TYPE OF SOURCES:

SOURCE CONFIGURATION

Pulled at 4 P.M. on 8-2-89

AP Magnification: $\frac{45}{38} = 1.2$ Lat. Magnification: $\frac{46}{36} = 1.3$

	Dose per hr.	Total hrs.	Total Dose
Dose to Point A	~~54 Rad/hr~~ 54.20	~~56 hrs~~ 55.35	~~3084 Rad~~ 3000 Rad
Dose to Point B			

Prescribed dose.

Dose to other points of interest:

Dose to Point _____

Dose to Point _____

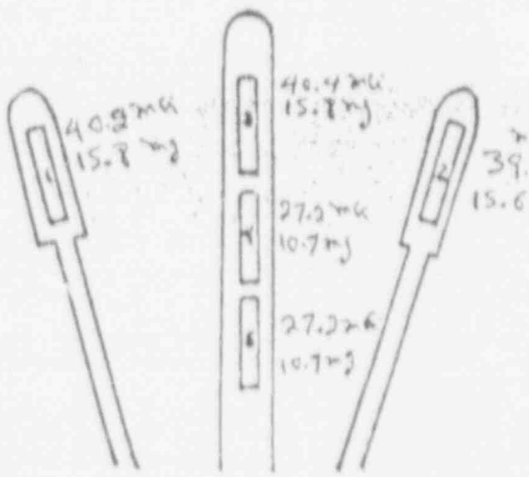
Dose to Point _____

Dose to Point _____

Dose to Point _____

Dose to Point _____

Dose to Point _____



Radiation Oncologist MD [signature] Radiation physicist I. Tonda

Patient at 9:30 A.M. on 8-5-89

LDR hrs 65.5 hrs FORM A

LDR dose 3550 Rad.

ATTACHMENT 2

Lakeshore Health System

IMPLANT DOSIMETRY

This form must be completed by Radiation Oncologist M.D.

ient [redacted] Date [redacted]-89 Room [redacted]

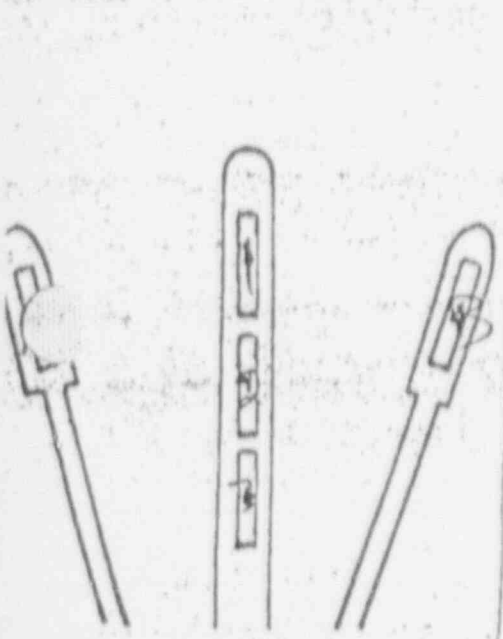
gnosis: Ca of Cervix Area treated: Cervix

ertion Date: [redacted]89 Time: 4 ___AM ___Permanent implant
___PM ✓Not permanent implant

s 137 ___Ir192 ___I-125 Others ___

linear sources ___Seed Sources ___micrad ___Needles ___Other

SOURCE CONFIGURATION. IF NOT FLETCHER PLEASE DRAW



SOURCES STRENGTH

	Mg Rad Eq	mCi
A	15.8	40.2
B	15.6	39.8
3	15.8	40.4
4	10.7	27.2
5	10.7	27.2
6	68.6	174.8
7		
8		
9		
10		

red Dose: 3600 Rad Comment: ___

ant ___ Total 68.6 174.8

✓YES
iterized treatment plan ___NO If yes, the MD must mark both the AP & Lat films, the
ical OSS then 1-point A, 2-point B, 3, 4, 5.....(etc.-all other points of interest)

M.D. signature: [signature] Date: 8/3/89

ered Dose: 3550 Rad Comment: ___

of Removal 8-5-89 Time 9:30 ___AM ___PM Total Hours 65.5

ERT Physician should indicate the radiation exposure to the areas mentioned above
(eg: points A, B, etc.)

M.D. Signature: [signature] Date: 8/5/89

Lakeshore Health System

BRACHYTHERAPY SOURCES INVENTORY FORM

SOURCES IN STORAGE:

DATE OF INVENTORY	SOURCE ACTIVITY MILLIGRAM RADIUM EQUILAVENT	NO. OF SOURCES IN STORAGE	SOURCES INVENTORIED BY:
	5		NAME:
	10		SIGNATURE:
	15		
	20		
	30		

SOURCES REMOVED FROM STORAGE FOR THERAPHY:

DATE	TIME	SOURCE ACTIVITY MILLIGRAM RADIUM EQUIVALENT	No.OF SOURCES REMOVED FROM STORAGE	SOURCES LEFT IN STORAGE	SOURCES REMOVED FROM STORAGE BY:
		5			NAME:
		10			SIGN:
		15			
		20			
		30			

SOURCES RETURNED TO STORAGE AT THE COMPLETION OF THERAPY:

DATE	TIME	SOURCE ACTIVITY MILLIGRAM RADIUM EQUIVALENT	No.OF SOURCES RETURNED TO STORAGE	TOTAL No.OF SOURCES IN STORAGE	SOURCES RETURNED TO STORAGE BY:
		5			NAME:
		10			SIGN:
		15			
		20			
		30			

ARE ALL SOURCES ACCOUNTED FOR ?

yes [ ] no [ ] INITIALS:

FORM C

ATTACHMENT 4

Dosi[illegible] Computerized Treatment Planning

Patient Name: _____ Date In _____ AM PM Date Out _____ AM PM

Patient Computer ID# _____ AP mag _____ = _____ Lat mag _____ = _____

Model	Date of Cal.	Mg Rad Eq.	mCi	Date of Insertion	mg Rad Eq	mCi
1862 Red H-5	5/23/86	11.4	29.1			
" " E-5	"	11.4	29.2			
" " E-1	"	11.2	28.7			
" " H-3	"	11.4	29.2			
1863 Black N-4	"	16.9	43.3			
" " L-1	"	16.7	42.7			
" " O-9	"	16.9	43.1			
" " M-1	"	17.1	43.6			
" " M-9	"	17.1	43.8			
1864 White R-3	"	22.3	57.0			
" " T-8	"	22.3	56.9			

Cs 137 Fletcher Applicator ONLY

Set		Rad/hr	x	hrs	=	Total Dose
1-Point A	[r	_____	x	_____	=	_____
	[l	_____	x	_____	=	_____
2-Point B	[r	_____	x	_____	=	_____
	[l	_____	x	_____	=	_____
3-Bladder	[ant	_____	x	_____	=	_____
	mid	_____	x	_____	=	_____
	[post	_____	x	_____	=	_____
4-Rectum	[ant	_____	x	_____	=	_____
	mid	_____	x	_____	=	_____
	[post	_____	x	_____	=	_____
5-Cervical Os		_____	x	_____	=	_____
6-		_____	x	_____	=	_____
7-		_____	x	_____	=	_____

	mgRaEq	mCi
1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	_____	_____
6	_____	_____
7	_____	_____
Total	_____	_____

Other Type of Brachytherapy Sources / Source Name _____

Set	Rad/hr		hrs		Total Dose
1 _____	_____	x	_____	=	_____
2 _____	_____	x	_____	=	_____
3 _____	_____	x	_____	=	_____
4 _____	_____	x	_____	=	_____
5 _____	_____	x	_____	=	_____
6 _____	_____	x	_____	=	_____
7 _____	_____	x	_____	=	_____

SOURCE CONFIGURATION

# of source	mgRaEq	mCi
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Radiation Oncologist MD Signature _____

Radiation Physicist Signature _____

LAKESHORE HEALTH SYSTEM
SMMC Hobart

ATTACHMENT 5

Dosimetry and Computerized Treatment Planning

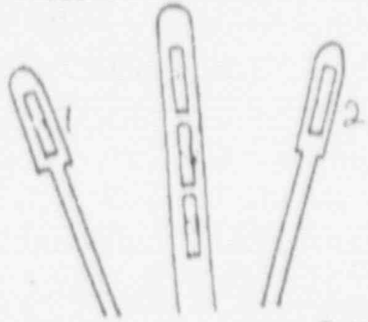
Patient Name: [redacted] Date In [redacted] AM / PM Date Out [redacted] AM / PM 4:43

Patient Computer ID# [redacted] AP mag _____ = _____ Lat mag _____ = _____

Model	Date of Cal.	Mg Rad Eq.	mCi	Date of Insertion	mg Rad Eq	mCi
1862 Red H-5	5/23/86	11.4	29.1			
" " E-5	"	11.4	29.2			
" " E-1	"	11.2	28.7			
" " H-3	"	11.4	29.2			
1863 Black N-4	"	16.9	43.3			
" " L-1	"	16.7	42.7			
" " O-9	"	16.9	43.1			
" " M-1	"	17.1	43.6			
" " M-9	"	17.1	43.8			
864 White R-3	"	22.3	57.0	12-11-89	19.2	52.3
" " T-8	"	22.3	56.9	12-11-89	19.2	52.3

Cs 137 Fletcher Applicator ONLY

et		Rad/hr	x	hrs	=	Total Dose
~~Point A~~ 1Cm R	r	150	x	52.5	=	7875
	l	154	x	52.5	=	7770
~~Point B~~ 15Cm L	r	75	x	52.5	=	3937
	l	75	x	52.5	=	3937
Bladder	ant		x		=	
	mid		x		=	
	post		x		=	
Rectum	ant		x		=	
	mid		x		=	
	post		x		=	
Cervical Os			x		=	
			x		=	
			x		=	



	mg RaEq	mCi
1	19.2	52.3
2	19.2	52.3
3		
4		
5		
6		
7		
Total	39.6	105

Other Type of Brachytherapy Sources / Source Name _____

et	Rad/hr		hrs	=	Total Dose
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	
		x		=	

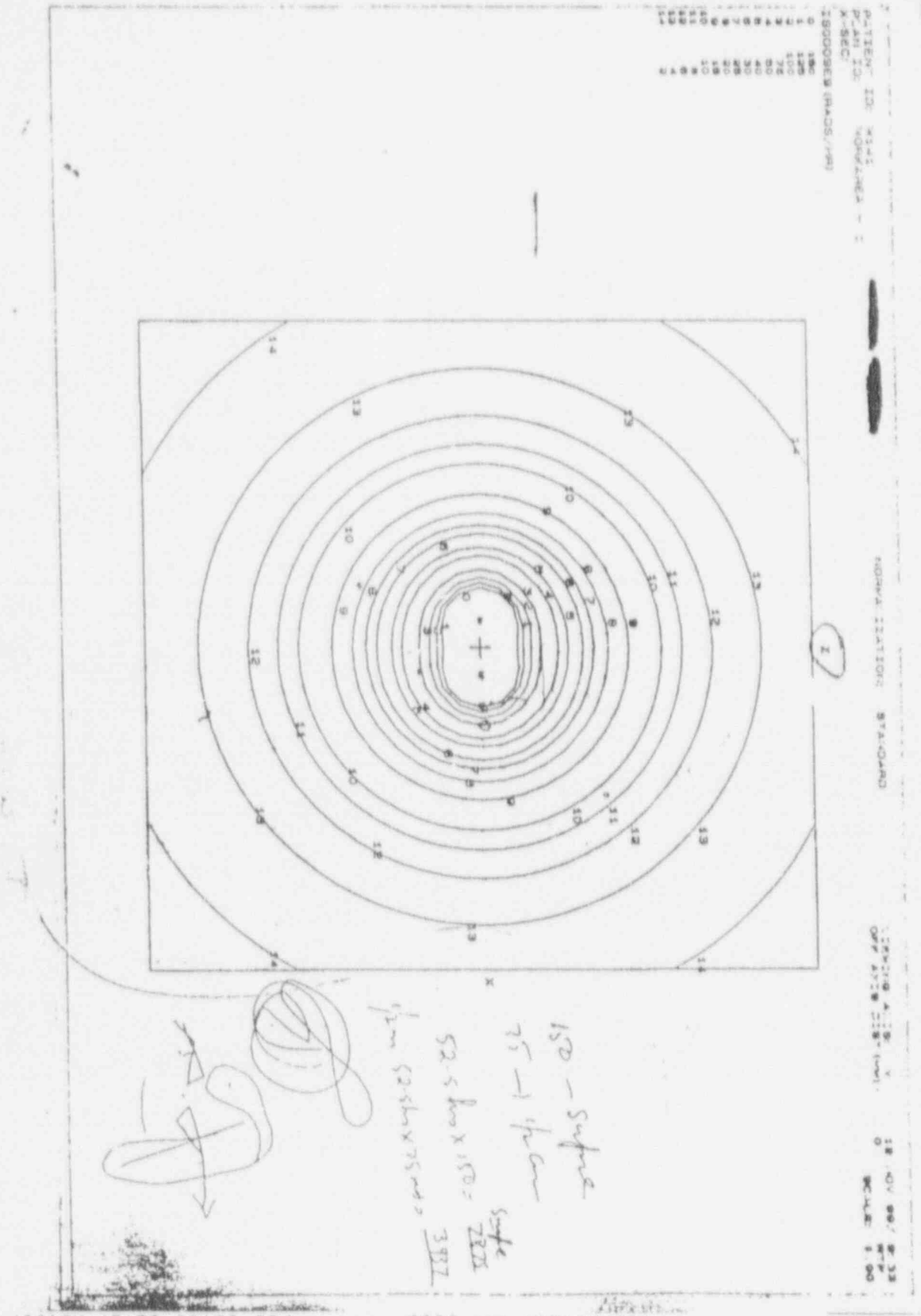
SOURCE CONFIGURATION

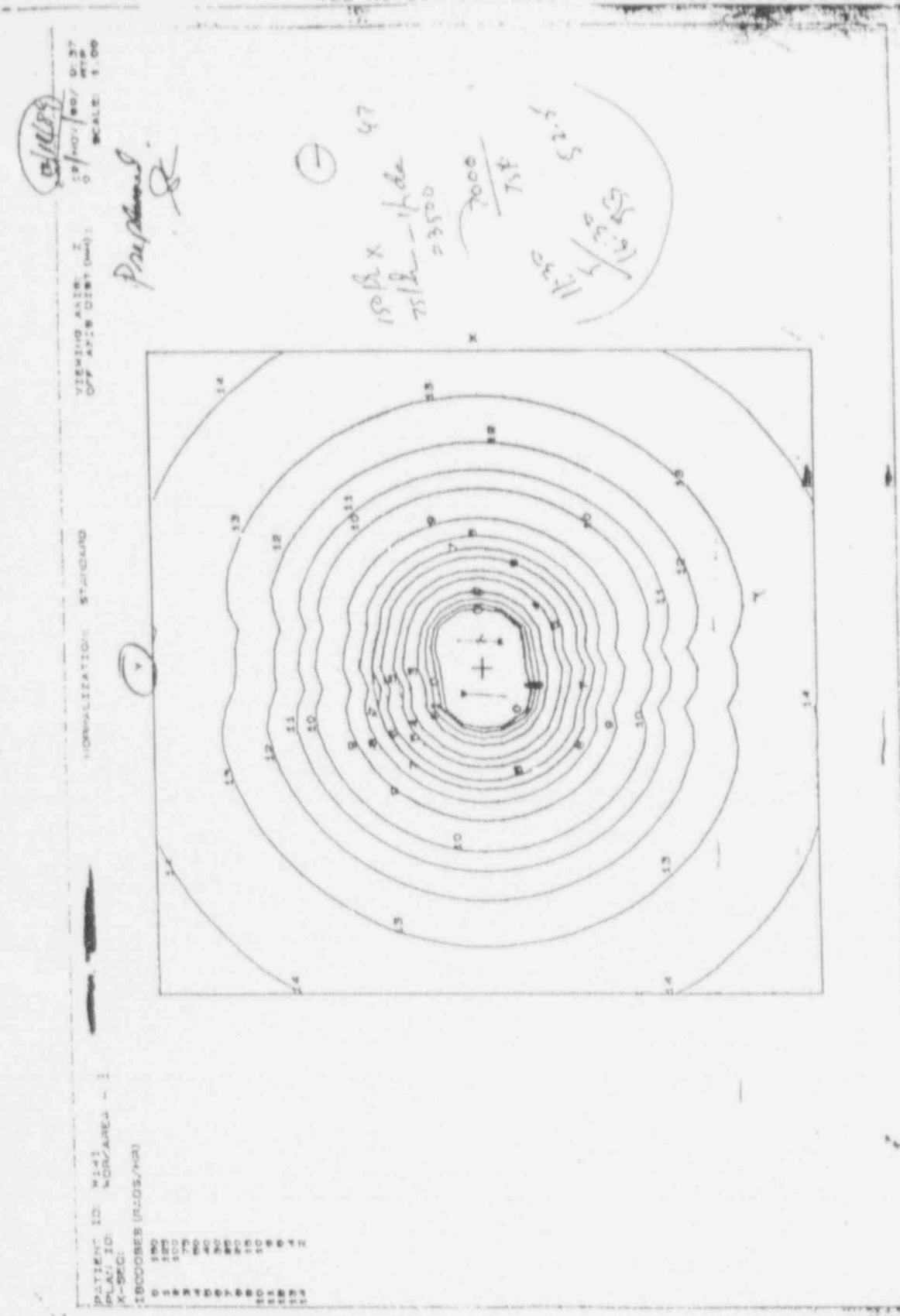
# of source	mg RaEq	mCi

Radiation Oncologist MD Signature [redacted]

Radiation Physicist Signature [redacted]

FORM A





ATTACHMENT 6

UNITED STATES

NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
ST. MARY MEDICAL CENTER-HOBART	)	Docket No. 030-31379
1500 South Lake Park Avenue	)	License No. 13-03459-03
Hobart, Indiana 46342	)	EA No. 90-071
ST MARY MEDICAL CENTER-GARY	)	Docket No. 030-01615
540 Tyler Street	)	License No. 13-03459-02
Gary, Indiana 46402	)	EA No. 90-071

AUDIT REPORT

OF

BRACHYTHERAPY PROGRAM

Information Withholdable under the provisions of 10 CFR 2.790 has been removed from this report

J. W. Foster
5/9/91

Audit of Brachytherapy Programs
at St. Mary Medical Center
Hobart - Gary

Dates of Site Visit: Tuesday, November 27, 1990
Wednesday, November 28, 1990

Members of the Audit Team:

Ned Hornback, M.D., Chairman
Department of Radiation Oncology
Indiana University Medical Center
535 Barnhill Drive
Indianapolis, IN 46202-5289

Richard A. Steeves, M.D., Ph.D.
Section of Radiation Oncology
Department of Human Oncology
University of Wisconsin Hospital
600 Highland Avenue (K4/B100)
Madison, WI 53792

George Anthony Sandison, Ph.D.
Department of Radiation Oncology
Indiana Univerity Medical Center
535 Barnhill Drive
Indianapolis, IN 46202-5289

Bhudatt R. Paliwal, Ph.D.
Section of Radiation Oncology
Clinical Health Science Ctr.
University of Wisconsin Hospital
600 Highland Avenue (K4/B100)
Madison, WI 53792

Purpose of Audit:

In September, 1990, Dr. Ned Hornback was contacted by Mr. Steven Pratt, Attorney for the St. Mary Medical Center, Hobart - Gary for the purpose of conducting an independent audit of radiotherapy procedures utilizing radioactive isotopes performed at St. Mary Hospital - Hobart during the past four years.

This audit was requested based upon an unannounced special inspection done in April, 1990 by the NRC Region III office after they had received allegations of questionable medical procedures performed by the authorized users, including misadministrations in the use of therapeutic radioactive isotopes. Although some of the allegations could not be documented by the inspectors, several cases of possible misadministration were found by the examiners which triggered a more in-depth audit by an NRC physician auditor who reviewed eleven charts in-depth. His findings suggested that a major problem of record keeping existed, as prescribed doses were not available on the chart. In addition, the examiner questioned the user's technique and procedures in placing radioactive sources in patients. He also found evidence of miscalculation of doses which he classified as misadministrations.

As a result of his report, the radioactive material license was suspended at St. Mary Hospitals - Hobart and Gary until an in-depth analysis of the patient material could be reviewed by a disinterested audit team. Dr. George Sandison was contacted by Dr. Hornback to perform the physics part of the audit. Dr. Sarma's attorney felt that the authorized users interest could best be served by engaging a second team of expert auditors, Dr. Richard Steeves and Dr. Bhudatt Paliwal from the Deprtment of Oncology at the University of Wisconsin.

An audit plan along with the list of auditors was submitted to and approved by the Nuclear Regulatory Commission. The audit plan is enclosed and listed as Appendix I.

It was the opinion of the audit team that an on-site review of all brachytherapy patients' files be undertaken at the St. Mary Medical Center and that the team would also interview all medical staff involved in therapeutic radioisotope procedures. Initially, it was the plan of the auditors to return to their respective institutions with the necessary charts and films and redo all treatment plans on Indiana University and University of Wisconsin treatment planning systems. However, once the task of reviewing charts began, it was quite evident that record keeping and data information was a major problem and that the site visit could best be done by all members of the examining team reviewing each chart in the presence of the physician and physicist who could produce the specific items requested. This amounted to a review of 71 separate brachytherapy/interstitial applications performed in 58 patients.

It should be noted that all members of the hospital staff, as well as Dr. Sarma, his colleagues and his physicists cooperated fully with the investigating team, giving a significant advantage over previous auditors in that Dr. Sarma and staff provided complete medical records from his private medical practice.

In addition to the intensive review of each of the patient's medical records, considerable time was spent in interviewing Dr. Sarma, members of Dr. Sarma's staff as well as all hospital staff involved with administration, control and regulation of the radioactive material license.

The audit team interviewed the following persons:

Milton Triana, Regional Vice-President
St. Mary Medical Center
Tom Torabi, Ph.D., Radiation Safety Officer and
Medical Physicist for Lakeshore Health System, Inc.
Ken Vanderhye, Regional Director, Nuclear Medicine Program
Alice Nale, R.T., Radiology Quality Assurance Coordinator
Keith Sauerland, R.T., Nuclear Medicine Technician
Kappolu Sarma, M.D., Radiation Oncologist, Authorized User
Dharma Rajbhandari, M.D., Radiation Oncologist, previous authorized user (Physician left Dr. Sarma's practice and returned especially for site visit.)
J. Sloan, Ph.D., Medical Physicist in Illinois who initially helped calibrate Dr. Sarma's radiation therapy equipment (returned especially for site visit)
Kevin O'Grady, B.S., Medical Physicist (previously with Dr. Sarma and now attending University of Illinois for Master's degree in Health Physics)
(returned especially for site visit)

In addition to the above individuals, the audit team had an opportunity to briefly interview J. Paige Clousson and Steven Pratt. (Mr. Clousson was acting as counsel for the authorized user Dr. Sarma. Mr. Pratt represented the Hospital, the licensee.)

Results of the Interviews:

The initial plan of the audit team was that we would interview very briefly a few individuals to understand the relationship between the hosptial, the Physics staff, Radiation Safety, and Dr. Sarma's practice. Initially, we felt this could be accomplished in less than an hour, however, the interviews actually took several hours. The following information is a condensation of information received during the interviews. Dr. Sarma is a board certified radiation oncologist who practices at the hospital in Valparaiso as well as St. Mary - Hobart and Gary. The majority of Dr. Sarma's radionuclide applications are done at St. Mary Hospital in Hobart. Initially, he was with Methodist Hospital in Merrillville for 12 years and moved to St. Mary Hospital - Hobart to work in a free standing cancer center

known as Diagnostic Outpatient Center (DOC). He has been with the DOC for the past four years, and all external therapy for Hobart St. Mary Hospital is done in this free standing unit which is located on hospital ground less than five minutes away. It should also be noted that in May of 1990 Dr. Sarma underwent open heart surgery which would help explain the unusually long time required for response to NRC's audit.

Dr. Sarma is a respected member of the medical community and holds hospital privileges in both hospitals. He is Chairman of the Oncology Board at St. Mary Hobart and is responsible for planning and implementing educational seminars in oncology. He is on the American Cancer Society Professional Committee and is a regular attendant of the tumor board.

Dr. Sarma felt that the major difficulties with NRC began in March of 1990 when the Indiana State Board of Health contacted him because of two deaths of patients which had occurred soon after implantation with radioactive nuclides. He also had been accused, apparently anonymously, of a complaint that he changed radioactive sources too rapidly and was guilty of "not sterilizing radioactive sources." Dr. Sarma was not informed of the individual who contacted the State Board of Health.

Since some of the alleged cases of misadministration involved Dr. Rajbhandari (Dr. Sarma's colleague, who six months ago accepted a position in Mississippi), Dr. Sarma requested that Dr. Rajbhandari be present to discuss some of the cases when they were reviewed. In addition, Dr. Sarma requested Kevin O'Grady be present. Mr. O'Grady was with Dr. Sarma as his physicist from August 1986 through August 1990, and felt his presence would be helpful concerning questions about the physics calculations. Dr. Sarma informed the audit team that he was aware of problems encountered by the NRC inspectors of locating the prescribed doses and possible misadministrations, but in neither the unscheduled visit by the NRC, nor the scheduled visit by the NRC physician were the records from Dr. Sarma's cancer center allowed to be used for location of prescribed doses. He informed the audit team he was aware that record keeping must be improved. He stated he has been working with the hospital since late 1989 to develop quality assurance procedures which would conform to the standards set by NRC.

Dr. Tom Torabi, Ph.D., who was trained in medical physics at Wayne State University and has a Masters in "pure" physics from the University of Minnesota, felt that the physics staff was adequate at both hospitals. He is licensed in Radiation Therapy, Nuclear Medicine, and Diagnostic Radiology by the Indiana State Board of Health and is the radiation safety officer for St. Mary Hospital - Hobart and Gary. In addition, he also performs radiation physics duties at St. Catherine Hospital which is under a different license. The handling and storage of isotopes is done in the Nuclear Medicine Department which is actually under the direction of the Pathology Department. The training of all

nuclear technologists in the handling of isotopes is done by Dr. Torabi.

Dr. Torabi felt that communication between he and Dr. Sarma had been lacking in the past, but that over the past several months this has improved, and currently there is a strong effort to develop regulations and forms which meet NRC standards. Dr. Torabi felt very strongly that both he and Dr. Sarma needed to follow the quality assurance program set forth by the Radiation Safety Committee.

Kevin O'Grady was interviewed at the request of Dr. Sarma. Mr. O'Grady was very helpful in outlining the history of the physics support at the DOC where external radiation therapy is performed. He was not licensed by the State of Indiana to perform physics testing and was ordered by the Indiana State Board of Health to "cease and desist" performing physics on the external equipment at DOC on March 29, 1990. Mr. O'Grady has since returned to graduate school to obtain his Masters in Medical Physics. The audit team felt Mr. O'Grady to be a very knowledgeable physicist and very helpful in the review of the charts.

Jerry Sloan, who has a Master's degree in Medical Physics, and who is recognized by the State of Indiana as a licensed physicist, initially did the acceptance testing for the Linac at the DOC and completed all annual review forms to Indiana. He assisted Kevin O'Grady in performing calibration of equipment, etc., and was available to Mr. O'Grady for consultation whenever this was required.

Dr. Rajbhandari currently is practicing in Mississippi after leaving Dr. Sarma's practice in July of 1990. Her impression of the situation was that there was difficulty in communication between Dr. Torabi and Dr. Sarma. She felt Dr. Torabi was not readily available for consultation. She also felt that Dr. Sarma had always advised her of the time to pull sources despite the fact prescribed doses were not always written in charts. She had worked very closely with Kevin O'Grady in the past and she felt he was a very competent and capable medical physicist.

Ms. Alice Nale is the radiology quality assurance coordinator for the hospital. Her background is that of a radiologic technologist who works at all three Lakeshore Health Systems Hospitals. One of her primary responsibilities is to develop a quality assurance program when therapeutic radioisotopes are used. Ms. Nale states she was instructed by the inspectors from NRC she could not use Dr. Sarma's private clinic records to substantiate doses received by patients. The audit team felt Ms. Nale was very helpful in the review of the records and was felt to be very capable in her work as Quality Assurance Coordinator. It was the impression of the audit team that because of her expertise and knowledge in quality control procedures, the problem of record keeping could be markedly improved by her input.

Mr. Milton Triana, Regional Vice-President, has only recently taken over his position since July of 1990 and was not completely familiar with all the details of what transpired between the user and licensee prior to July of 1990, but was anxious to resolve the issue and recognized the need for improved records to meet the high standards of NRC.

Keith Sauerland is a nuclear medicine technologist who works with both Dr. Sarma and Dr. Torabi in the removal of isotopes to and from the patient and safe. He appears to be knowledgeable, experienced and capable. It was obvious that he had been well-trained in the handling of therapeutic nuclear isotopes.

With this background, the audit team began an intensive review of the 71 records available to us, which included all patients treated from the inception of the license in 1986 to the last isotope used sometime late in April of 1990. It should be pointed out that following suspension by NRC of the radioactive nuclide license, Dr. Sarma had requested and received approval from NRC to do an isotope procedure on one patient on an emergency basis. The new forms which had been developed by the hospital in cooperation with Dr. Sarma were used for this patient. In this particular patient, the prescribed dose, time of removal, placement of sources, etc., were all well-documented and the records produced would have met the NRC's requirements. The date of this last record was April 2, 1990.

In-Depth Chart Aralysis:

An in-depth chart analysis was conducted on each patient from charts provided us by both the hospital and Dr. Sarma's private records. (Dr. Sarma's charts had not been previously thoroughly reviewed by NRC inspectors.) The complete summary record appears in Appendix II, which includes the name, the date, the treatment plan, milligram equivalents, the R per hour, the hour left in, the total treatment time, whether safety records are complete, and any complications which would have been expected to occur in the event of a misadministration. The patient files reviewed consisted of 71 separate brachytherapy/interstitial treatments in 58 patients.

The medical records in general were extremely disorganized, and considerable time was spent with both Dr. Sarma and representatives of the hospital in locating the information needed. This created a considerable amount of frustration among the auditors, leading to the unanimous agreement of the auditors that Dr. Sarma's record keeping must be dramatically improved.

During this chart review, the patient's isodose curves were examined for accuracy, and all calculations were checked. In addition, the localization films for radioactive isodose instruments and carriers were examined in every case.

Findings of the Audit:

10 CFR 2.790 Withholdable Information Removed 5/14/91

1. Of the 71 separate brachytherapy/interstitial treatment files reviewed, there were no definite cases of misadministration as defined by the NRC. One patient who had initially been felt to have a major misadministration by the physician NRC representative, was studied in great detail. This patient's treatment planning films and isodose curves were recalculated using the therapy planning system of Indiana University. A detailed analysis of this plan is in Appendix III. The computer calculation done on the Indiana University computer was very similar to the calculations done by the physicist at St. Mary Hospital, and it was the consensus of the radiation therapists that this did not necessarily constitute a misadministration. (See Appendix III.)

2. Documentation of the dose, prescription, and treatment aim by the physician was absent in 28 of the 71 treatments. The fact that a prescription was not present on the chart prior to the performance of the radioactive procedure does not necessarily constitute bad medicine. It simply means this procedure does not meet the requirements of NRC. In every instance, details of the complete treatment given, including radioactive source therapy, were written and recorded in Dr. Sarma's files. It should also be pointed out that the doses actually received by patients met the standards of a community-practicing radiation oncologist. This policy of not writing prescribed doses was discussed at great length with Dr. Sarma, and it has been his practice for many years to not write a prescribed dose prior to his examination of the isodose curves. He would then make a decision on the exact dose to be used based upon the amount of radiation given in combination with external therapy and the amount that was going to be received by vital normal structures such as the rectum and the urinary bladder. This has been fairly common practice in the past, and while the prescribed dose prior to use of the isotope is not required for good medicine, it does not meet NRC requirements. No pattern of excessive complication rates were detected in a review of Dr. Sarma's patients charts.

3. The dosimetry calculation procedures were correct, complete, and acceptable.

4. Safety regulations procedures appeared to have been followed with adequate documentation of source control and radiation safety surveys. The only irregularity discovered was the omission of a radiation survey of a patient with a permanent radioactive Iodine 125 implant before leaving the hospital. The newly developed quality assurance forms should eliminate a repeat of the unfortunate, but harmless incident.

5. One of the members of the audit team (NBH) has reviewed several hundred gynecological radioactive instrument implants in ladies who have been placed on national protocol studies (RTOG and GOG). While not all of Dr. Sarma's instrument placements were ideal, they certainly met the standards of the community-practicing radiation oncologist, and it should be realized that there is a great deal of variation in patients' anatomy, tumor size, etc., which all must be taken into consideration before attempting to evaluate GYN instrument implantation. The implication by the NRC physician auditor that several GYN applicators had been misplaced and in poor position was not substantiated, as the ultimate dose received by the patient was within the guidelines of that prescribed by most radiation oncologists.

Conclusions from the Audit:

1. It was the unaminous opinion of the audit team that no administrations as defined by the NRC under 10CFR 35.2. occurred.

2. In general, the hospital staff responsible for nuclear safety and storage appeared to be well-trained and qualified. A physicist previously employed by Dr. Sarma who was responsible for several of the treatment plans had not received formal certification by the Indiana State Board of Health. The examiners did not feel that this led to any misadministrations or problems with developing treatment plans. This individual is no longer with Dr. Sarma, and the audit team met with this young physicist, and he appeared to be quite a knowledgeable, dedicated individual. He is currently in the process of receiving his Masters in medical physics at the University of Illinois.

3. The new radiation safety guidelines and procedures manual relating to brachytherapy activities was quite extensive. (See Appendix IV.) This quality assurance plan is quite extensive and has been developed by Dr. Sarma, Dr. Torabi, and Alice Nale, Quality Assurance Officer for St. Mary Medical Center. If followed, these policies and procedures are satisfactory and will meet the standards set by NRC for the handling and use of therapeutic radioactive sources.

4. Dr. Sarma's medical records were very disorganized and sloppy and must be dramatically improved. It is strongly recommended that hospital records and Dr. Sarma's records be interchanged and dupicated so that both parties have summaries of treatments received at each place. Dr. Sarma is aware that record keeping is a major problem, and he is receptive to learning methods to improve this problem.

5. An identified procedural weakness in the brachytherapy program was a lack of close working relationship between the physician, Dr. Sarma and the physicist, Dr. Torabi. Coordination of brachytherapy activities was problematic due to both parties having duties at several hospitals. It is essential that this conflict of activities which impact upon brachytherapy procedures be resolved. The hospital has an unusual administrative arrangement whereby the radiation physicist answers to the vice-presidents of operations with responsibility for radiation therapy, rather than the customary Department of Radiology, or a Department of Radiation Oncology. This unfortunate administrative relationship allows the hospital to hire a radiation physicist who would be required to work very closely with the radiation oncologist, but not necessarily in harmony. It is absolutely essential that the radiation oncology physician have the maximum support and the full confidence of the radiation physicist, as disagreements and poor working relationships could result in horrendous medical problems for the patients, not the least of which could lead to significant malpractice problems for both the hospital and the doctor.

6. The physicists felt that the radiation physics staffing level for the hospital is inadequate and that if the hospital is to continue in the use of brachytherapy, that the physicist's duties be resolved and perhaps combined with Dr. Sarma's physicist.

Recommendations Following the Audit:

1. An expeienced (ABR [or equivalent] certified radiation physicist) should be employed to work closely with physician Dr. Sarma on brachytherapy procedures to relieve some of Dr. Torabi's duties at St. Mary Hospital - Hobart.

2. It is also recommended that the hospital re-evaluate the administrative relationship between the attending radiation oncologist and Dr. Torabi. In most hospitals, Dr. Torabi would be working either directly under the radiation oncologist, or if not that, under the Director of the Radiology Department.

3. It was a strong recommendation of the audit team that the record-keeping procedures be dramatically improved. A great deal of this has been accomplished by the new quality assurance plan for the brachytherapy program; however, with external radiation therapy being done outside of the hospital, coordination of record keeping must be done, not only to comply to the NRC requirements, but also because the practice of good medicine requires satisfactory medical records.

4. It is strongly recommended that an independent radiation oncologist consultant be brought in as a consultant for the hospital, and Dr. Sarma to develop ways to improve and simplify the record keeping which will meet the NRC requirements. In addition, the consultant could recommend ways of strengthening relationships between the hospital physics staff and the radiation oncologist.

5. It is the recommendation of the audit team that brachytherapy procedures should not be instituted at St. Mary - Hobart until the above recommendations have been completed.

6. If the ban on the radioactive license is lifted, it is recommended that NRC perform an unexpected site visit at approximately six months to ensure compliance with NRC requirements.

Why Independent Audit Report Varies from NRC Report:

This report differs considerably from that which was submitted by the previous NRC report on St. Mary Medical Center - Hobart. There are two major reasons for this:

(1) The independent audit team had a complete set of the patient medical records which had been provided by Dr. Sarma. Much of the required information required for an audit was unavailable to NRC inspectors at the time of their visit.

(2) Dr. Sarma and his staff, as well as St. Mary Medical Center staff were available to the audit team during our visit, which made location of important documentation much easier.

In summary, we were unable to substantiate the initial NRC report of widespread misadministration of radioactive nuclides or poor medical practice techniques; however, we believe that the NRC acted correctly in suspending the radioactive material license because of extremely poor record keeping. It was the opinion of the audit team that both Dr. Sarma and St. Mary Medical Center will benefit by this action by the NRC so that proper records and documentations can be developed which will eventually improve patient care, which after all, is the primary goal of all of the participants.

Ned B. Hornback, M.D.

Bhudatt R. Paliwal, Ph.D.

George A. Sandison, Ph.D.

Richard A. Stephes, M.D., Ph.D.

APPENDIX I

AUDIT PLAN

1. Introduction:

NRC requires the review of all patient files of patients who have undergone brachytherapy treatment at the St. Mary Medical Centers of Hobart and Gary, Indiana. Approximtely 69 patients have received such treatment since the St. Mary Medical Centers received authorization from the NRC to have radioactive sources for brachytherapy use. This review is required because of a concern raised by the NRC that therapeutic misadministrations, as defined under 10CFR 35.2, may have occurred and not been reported as required under 10CFR 35.33. The mandate of the audit group is to determine if brachytherapy misadministrations have occurred and to provide recommendations for improvements to the brachytherapy program to prevent possible future misadministrations. Following the audit, a written report from the audit group will be submitted to the NRC.

2. Audit Procedure:

a) The number of patient files for review is large (approximately 69) and it is estimated that one month will be required to complete the audit.

b) The audit of patient files wil take place in two stages.

Stage I:

On site review of all brachytherapy patient files. This review will consist of the following checks.

1. Prescription
2. Dosimetry calculation procedure
3. Treatment plan
4. Delivered dose
5. Documentation of treatment procedure and delivered dose
6. Safety regulations and procedures

Stage II:

As a result of the above checks, patient files and possible problem areas will be identtified for detailed review. This will involve:

1. The rerun of treatment plans on the University of Indiana or University of Wisconsin planning systems.
2. The calculation of dose to specific sites/organs based on the rerun treatment plans or determination in advance of such doses from the institutions calculations.
3. Assessment of misadministration if any.

To accomplish this task, copies of all information relating to the brachytherapy administrations need to be furnished. This information should include all patient prescriptions, source

activity and loading information, copies of the radiographs used in the brachytherapy examinations and the treatment plans used.

c) To determine if misadministrations have occurred, treatment plans for the patients will be reproduced from the information provided. The treatment plan calculations will be performed on the Theraplan Treatment Planning System located in the Departments of Radiation Oncology, Indiana University Medical Center, or the Treatment Planning System of the University of Wisconsin.

d) The audit group will travel to each of the St. Mary Medical Centers to interview all personnel involved in the dose prescription, tretment planning, source preparation and handling and radiation safety surveys and source storage. It is expected that these personnel will include the prescribing physician, physicists, dosimetrists/treatment planners and the radiation safety officer for the centers. The purpose of these interviews is to determine any procedural weaknesses in the brachytherapy program and possible remedial actions necessary. It is expected that these interviews will last a period of one or two days.

e) The adequacy of staffing levels, qualifications and training of staff will be assessed.

f) The adequacy of documentation, records, and written guidance and procedures relating to brachytherapy activities will be assessed.

December 4-5, 1990

Brachytherapy Audit Summary Data
St. Mary's Medical Center, Hobart, Indiana

Date	Plan	Plan (P) Rads	Rx mg-Eq	D Rate R/hr	Time hr	Given Rx	((G-P)*100/P	Safety Record	Complication (long term)	Notes
8/2/89	Y	3500	68.6	70	65.5	4585	24	Y	N	
12/11/89	Y	7875	39.6	150	52.5	7875	0	Y	N	
12/5/88	Y	1740	40.8	80	22	1760	1	Y	N	
12/7/88	Y	2500	90	62	38	2356	-6	Y	N	
9/3/86	Y	2000	50 mci	50	42.3	2115	5	Y	N	
4/18/99	Y	1600	42.1	39	41.1	1602.9	0	Y	N	
4/22/88	Y	1500	55	71	21	1491	-1	Y	N	
11/2/88	Y	7000	21.4	180	40.8	7335	5	Y	N	
6/27/88	N	5000	30	125	40.8	5093.8	2	Y	N	
6/27/88	Y	2870	93.1	72	41.5	2988	4	Y	N	
8/17/88	Y	5000	78.1	85	31	2635	-90	Y	N	50 Gy/ comm., med comp,stop Rx
4/24/89	Y	1920	60.4	43	48.6	2089.8	8	Y	N	Patient noncompliance
10/26/88	Y	3465	97.3	90	39	3510	1	Y	N	
12/18/89	Y	2760	39.6	60	46	2760	0	Y	N	
4/13/89	Y/N	18000	27.4 mci			17500	-3	Y	N	160-200 Gy total I125, permanent
12/14/89	Y	17500	30.6			18260	4	Y	N	low dose region boosted 5760 EBT
7/8/86	Y	7250	44	117	63	7371	2	Y	N	
6/4/86	Y		18.5	42	48	2016	NA	Y	N; recurred	No prescription
7/1/86	Y		33.3	41	42.5	1742.5	NA	Y	N	No prescription
4/2/90	Y	2600	97.2	65	40.3	2619.5		1	Y	N	Model for future procedures
8/7/86	Y	1640	45.4 mci	25	68	1700		4	Y	N	
2/24/88	Y	5300	83.7 mci	108	50.3	5427		2	Y	N	
4/18/88	Y	3500	43.4	50	72	3600		3	Y	N	
8/14/86	Y		68	49.9	48	2395.2	NA	Y	N	No prescription
9/3/86	Y		51.3	67	44	2948	NA	Y	N	No prescription
9/22/86	Y		73.6	48	47.5	2280	NA	Y	N	No prescription
10/13/86	Y		75	65	42	2730		Y	N	No prescription
11/18/86	Y	4608	33.8	64	70	4480		-3	Y	N	
10/20/86	Y	3045	73	70	46	3220		5	Y	N	
11/11/86	Y		79.3	77	24	1848	NA	Y	N	No prescription
4/21/87	Y		68	70	48	3360	NA	Y	N	No prescrition
5/8/87	Y		68	67	24	1608	NA	Y	N	No prescription
8/8/87	Y		62.4 mci	55	49	2695	NA	Y	N	No prescription

Date	Plan	Plan (P) Rads	Rx mg-Eq	D Rate R/hr	Time hr	Given Rx	((G-P)*100/P	Safety Record	Complication (long term)	Notes
11/15/86	Y		68.2	65	44	2860	NA	Y	N	No prescription
9/14/87	Y	4161	143	110	38	4180	0	Y	N	
2/16/90	Y	18000	20.5mci	perma		18000	0	Y	N	CT/MRI not available
11/4/87	Y	4160	54.4	65	64	4160	0	Y	N	
12/29/87	Y	3200	125 mci	64.2	38	3199.6	0	Y	N	
1/18/88	Y		76.7	82	47.8	3919.6	NA	Y	N	No prescription
2/12/88	Y		40	160	11	1760	NA	Y	N	No prescription
3/1/88	Y	4050	132	113	36.5	4106.3	1	Y	N	
8/3/89	Y	2535	96	65	39	2535	0	Y	N	
8/30/89	Y		73.6	80	38	3040	NA	Y	N	No prescription
8/24/89	Y		100	90	38.3	3442.5	NA	Y	N	No prescription
10/9/89	Y	2500	31	58	43.5	2523	1	Y	N	
10/18/89	Y	2750	73.8	73	40.2	2931.7	6	Y	N	
12/11/89	Y	3575	184 mci	55	72	3960	10	Y	N	
12/21/89	Y		46.28	90	31	2790	NA	Y	N	No prescription
1/22/90	Y	2580	31	62	43	2666	3	Y	N	
2/1/90	Y	3850	60.2 mci	55	72	3960	3	Y	N	RHC
2/19/90	Y	2925	72.2	65	45	2925	0	Y	N	
11/6/89	Y	3000	58.05	70	45.8	3202.5	6	Y	N	
1/17/87	Y		85.3	75	46	3450	NA	Y	N	No prescription
2/5/87	Y		79	75	28.5	2137.5	NA	Y	N	No prescription
2/20/87	Y		73	77	43	3311	NA	Y	N	No prescription
3/11/87	Y		50.7	55	32	1760	NA	Y	N	No prescription
3/16/87	Y		78.9	70	44	3080	NA	Y	N	No prescription
5/20/87	Y		78.7	78	39	3042	NA	Y	N	No prescription
6/17/87	Y	6980	43.5	141	49	6909	-1	Y	N	No prescription
6/18/87	Y	3528	45	72	49	3528	0	Y	N	
7/16/87	Y	3749	20.7	52.8	72	3801.6	1	Y	N	
7/16/87	Y	2897	10.8	40.8	72	2937.6	1	Y	N	
7/22/87	Y	1500	72.1	65	25	1625	8	Y	N	
8/3/87	Y	2992	71.5	68	45	3060	2	Y	N	

Date	Plan	Plan (P) Rads	Rx mg-Eq	D Rate R/hr	Time hr	Given (G) Rx	((G-P)*100/P	Safety Record	Complication (long term)	Notes
8/3/87	Y		33.4	65	47	3055	NA	Y	N	No prescription
8/8/87	Y		134 mci	100	30.5	3050	NA	Y	N	No prescription
8/5/87	Y	2100	113.8 mc	44	46.5	2046	-3	Y	N	
7/7/86	Y		22	100	22.5	2250	NA	Y	N	No prescription
6/4/86	Y		75	80	43	3440	NA	Y	N	No prescription
9/17/86	Y		57	60	56.5	3390	NA	Y	N	No prescription
10/13/86	Y		117 mci	64.6	52	3359.2	NA	Y	N	No prescription

Explanation of titles and terminology

Name: Patient name

Plan: Calculations of radiation distributions/dosages using a computer

Plan (P): Planned course of radiation treatment stratagey as documented in the hospital chart

Rx: Radioactivity in mg-Ra equiv. or mci (if Iodine or Ir)

D Rate: Dose rate (rads/hr) from the computer plan used to calculate tretment time

Time: Duration of hours for which the sources were left in the patient to deliver the treatment.

Given(G): Tolat dose given to the patient

(G-P)*100/P: % variation between given and prescribed dose

Records / safety: Recorded documentation of radioisotope inventory and safety data

Complications: Complications documented in the chart or expected due to if any misadministration

Perm: Permanent

im: Implant

iL: Left implant

iR: Right implant

Appendix II

10 CFR 2.790 Withholding Information Removed
5/9/91

Analysis of _____ Plan

This plan was the only one selected by the audit team for detailed review (i.e., second stage of audit plan). It appeared to be a misadministration at the time of audit because the difference between the prescribed dose to point A (3500 cGy) and the delivered dose to point A (4585 cGy), as determined from the original St. Mary's treatment plan, was 24%.

A repeat calculation of this plan was performed on the Theraplan treatment planning system used at Indiana University. The original AP and lateral radiographs and source loading were used for the calculation. It was immediately apparent that the radiographs were not optimal for calculations because the patient position was not the same in the AP and lateral radiographs. More significant, however, was the finding that the position of the ovoids in the lateral radiograph was different from their position in the AP radiograph. It was determined that the ovoids, as shown in the lateral radiograph, had slipped inferiorly about 2 cm with respect to the tandem and bladder from their position in the AP radiograph. It is most likely that the ovoids remained in the position shown in the lateral radiograph for the whole course of the treatment. The treatment plan was, therefore, computed on the basis that the position of the sources in the lateral radiograph were correct and the position of the sources in the AP radiograph were shifted to match. The computer calculation verified that the average dose rate at point A (left + right /2) was 56.58 cGy/hr resulting in a total delivered dose of 3706 cGy. The variance of the total delivered dose from the prescribed dose of 3500 cGy was only 5.9% on this basis and does not constitute a misadministration.

(It should be noted that if the position of the ovoids in the AP radiograph were assumed correct and the position of the sources in the lateral radiograph shifted, then the average dose rate at point A would have been 74.45 cGy/hr. Also, if the mean position of the sources between the AP and lateral radiographs were selected, then the average dose rate at point A would have been 63.47 cGy/hr. In either of these cases, the dose delivered would have constituted a misadministration.)

Appendix IV

540 Tyler Street
Gary, Indiana 46402
(219) 882-0411

QUALITY ASSURANCE PLAN FOR BRACHYTHERAPY PROGRAM

PURPOSE

The Quality Assurance Program for Brachytherapy provides a documented process for an effective means of objective and systematic monitoring and evaluating of the quality and appropriateness of patient care. The program will pursue opportunities to improve patient care and resolve identified problems associated with the delivery of patient care in a safe environment.

GOALS & OBJECTIVES

1. To provide an organized program that establishes priorities for objective assessment and correction of know or suspected problems that impact directly or indirectly on the patient care.

2. Control costs through idnetification of wasteful or inefficient practice.

3. Promote compliance with accrediting , regulatory, licensing, and hospital standards of care.

4. Prove competency of operations from a medical-legal standpoint.

5. Maintain an ongoing educational program based in part on the findings or review and evaluation of the quality and appropriateness of care provided by the Brachytherapy Program.

QUALITY ASSURANCE COMMITTEE

A Quality Assurance Committee for Brachytherapy has been established for the purpose of reviewing the ongoing monitoring, evaluation of appropriateness, and effectiveness of the quality assurance activities and recommending procedures and solutions to resolve any problems identified.

The Brachytherapy Quality Assurance Committee is a sub-committee of the hospital Radiation Safety Committee.

SUB-COMMITTEE MEMBERS

1. Radiation Safety Committee Chairman
2. Regional Radiation Safety Officer
3. Regional Vice President - Operations
4. Radiation Oncologist
5. Radiologist
6. Regional Nuclear Medicine Director
7. Regional Radiology Q.A. Coordinator

Other members serving on the committee as needed shall be the Vice President of Nursing or her designee from the Hobart facility and the Vice President of Nursing or her designee from the Gary facility.

MEETINGS

Meetings shall be held quarterly or more often if needed.

A quorum shall consist of all seven (7) members present. All decisions shall be made by a majority vote of those members present.

COMMITTEE FUNCTIONS

- Identification of known or suspected problems
- Assessment of cause and scope of problems
- Planning of action and implementation
- Implementation of recommendations
- Monitoring to assure effectiveness of action
- Documentation as to the effectiveness and insure the resolution of the problem

COMPONENTS OF MONITORING AND ASSESSMENT

Review and evaluation shall encompass but not be limited to the following activities:

I. TECHNICAL - all areas of Quality Control, mechanical, or scientific subject matter

II. MEDICAL - all areas related to, or concerned with, the practice of medicine and medical treatment of patients.

III. MANAGERIAL - all areas related to, or concerned with, but not limited to, time, productivity, finance, statistics, and patient satisfaction

For the purpose of clarification, suggested monitoring points, but not all inclusive, shall be:

I. TECHNICAL

A. Quality Control Measures
   1. Instrument response
   2. Calibration of radioactive sources
   3. Calibration of measurement instruments
   4. Integrity of applicators and accessory hardware used in implants

B. Radiation & Safety Measures
   1. USNRC & AAPM recommendations/standards
   2. Patient dose reduction
   3. Personnel radiation monitoring

C. Equipment Calibration Standards
   1. Preventitive maintenance
   2. Equipment repair service
   3. Radiation surveys

D. Risk Management
1. Occurance reports
2. Misdaministrations

II. MEDICAL

A. Review of medical charts/records

B. Appropriateness and justification of procedure

C. Peer review of patient treatment program

III. MANAGERIAL

A. Patient Satisfaction

B. Productivity Program
1. Time studies

C. Financial & Statistical Analysis
1. Cost per procedure
2. Most costly procedures
3. Most frequently ordered procedures

D. Staff Satisfaction
1. Working Conditions
2. Compensation
3. Educational opportunities

IV. Infection Control surveillance using measures to minimize the possibility of contamination and transfer of infection according to policies

V. Policy and porcedure review and update shall be done yearly and whenever deemed necessary through identification.

REPORTING

All reporting for the Brachytherapy quality assurance activities shall be in compliance with the hospital Administrative and Medical Staff Ouality Assurance Committees.

A quarterly report shall be submitted to the Radiation Safety Committee meeting for review and incorporation into the minutes.

Any problem involving another department, service, or committee, that has proven difficult to correct through the normal channels and has a significant impact on the patient care shall be forwarded to the hospital Radiation Safety Committee for assessment and assistance.

ANNUAL REVIEW

In compliance with the hospital wide Quality Assurance Plan an annual evaluation of the quality assurance activities for Brachytherapy shall be done for the past year. The review shall determine the effectiveness of the following:

1. Organization
2. Process of problem identification and solutions
3. Communication
4. Impact - areas of improvement and non-improvement

The completed evaluation, recommended modifications and goals for the coming year shall be presented to the hospital Radiation Safety Committee for use inthe overall evaluation of the quality assurance activities throughout the hospital.

CONFIDENTIALITY

All quality assurance activities shall be considered confidential information. The guideline of the hospital Quality Assurance Plan will be followed to ensure the necessary confidential

This Quality Assurance Plan for the Brachytherapy Program has been approved on April 6 1990 by:

Radiation Safety Committee Chairman: E. Mason, M.D.

Regional Radiation Saftey Officer: T. Torabi, PPhD

Regional Radiology Q.A. Coordinator: A. Nale, R.T.(R)

ST. MARY MEDICAL CENTER
GARY/HOBART, INDIANA

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Calibration of Radiation Measuring Instruments	To ensure that the instruments used in surveys & implant source calibration are operating correctly.	Measure instrument response using a radioactive source	Radiation Physicist or Designee	Every 6 months
Calibration of Radioactive Sources	To ensure that the proper dose of radiation is administered.	Determine the radioactivity of the source used in the patient for Brachytherapy.	Radiation Physicist or Designee	Prior to each Brachytherapy procedure
Personnel Radiation Monitoring	To ensure that radiation dosage received by personnel is as low as possible and within the radiation safety guidelines	Individual radiation monitor badges. Written reports from monitoring company monthly. Review of report upon receipt.	Radiation Physicist or Designee	Monthly
Personnel Dosimeter Monitoring	To ensure that radiation dosage received by personnel is as low as possible and within the radiation safety guidelines.	Log sheet for individual dosimeter readings for each Brachytherapy patient.	Radiation Physicist or Designee	Each Brachytherapy Procedure
Radiation Survey of Radioactive Brachytherapy Patient and hospital room	To ensure that the radiation levels are within acceptable regulatory guidelines.	Measurements of radiation exposure are taken in the patient's room and the surrounding areas.	Radiation Physicist	Each Brachytherapy Patient

ST. MARY MEDICAL CENTER
GARY/HOBART, INDIANA

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Proficiency in Expediting Brachytherapy Procedures	To ensure proper time management of staff during work shifts with adherence to policy and protocol for procedures.	Daily patient schedules Completed Procedure Record	Radiation Oncologist	Monthly
Infection Control	To ensure adherence to the use of appropriate barrier protection methods to prevent exposure to or transmission of infections and/or diseases in the health care setting.	Review of procedure check sheets documented during each Brachytherapy procdure.	Technologists Radiation Oncologist	Each Case Monthly
Appropriateness of Brachytherapy Requests	To evaluate appropriateness of Brachytherapy treatment vs. diagnosis and acceptable standards of practice.	Patient Medical Record Brachytherapy Order	Designated Radiation Oncologist	Monthly
Physician Peer Review	To ensure adherence to policies and protocols, Hospital and Department.	Physician Peer Review of medical records of patient's undergoing Brachytherapy and retrospective review of completed patients.	Designated Radiation Oncologist	Monthly

ST. MARY MEDICAL CENTER
GARY/HOBART, INDIANA

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Chart Review	To ensure adherence to departmental policies and procedures and acceptable standards of practice	Review of each patient's charts currently and retrospectively	Q.A. Coordinator	Each Brachytherapy Procedure
Misadministration of internal beam radiation	To ensure adherence to USNRC rules & regulations with regard to administration of radiactive sources in patients.	Review of each patient's prescribed dose and delivered dose to verify not above or below 10%	Q.A. Coordinator	Each Brachytherapy Procedure
Annual Radiation Safety Inspection	To verify that all radioactive sources are being used in compliance with the USNRC	Complete the Radiation Safety Inspection report of USNRC	Radiation Safety Officer	Annually
Inventory of Brachytherapy Sources	To verify the number of sources and sizes stored within the facility to ensure all sources are present.	Visual inventory count of radioactive sources and sizes in storage cross checked against previous inventory count	Radiation Physicist or designee	Quarterly
Wipe Test	To ensure each shipment of radioactive material received has not been contaminated by radiation.	Monitoring of both the outside and the inside of the package prior to acceptance by the facility	Radiation Safety Officer or designee	Each shipment recieved

St. Mary Medical Center

NO:

TITLE: REQUEST FOR BRACHYTHERAPY PROCEDURE	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90 PAGE 1 OF 1

PURPOSE/STATEMENT:

Brachytherapy consults shall be performed only upon the written request of a qualified Medical Physician to avoid the misuse of radioactive material in clinical treatment.

PROCEUDRE:

1. The referring physician (Family or Consultant) will consult with the Radiation Oncologist.

2. The referring physician will write orders on the In House Patient chart requesting the Radiation Oncologist's consult and treatment.

3. The referring physician will submit a written request with all Out Patients requesting the Radiation Oncologist's consult and treatment, or if request is by phone, the Radiation Oncologist must complete the Radiation Therapy Consultation form.

4. The completed Radiation Therapy Consultation Form or the referring Physician s written request for consultation is to be kept in the patient's chart in in Nuclear Medicine.

5. After the request has been received, the Radiation Oncologist will see the patient within 48 hours of request received excluding Saturday, Sunday, and Holidays.

6. After the Radiation Oncologist has seen the patient, an Appropriateness Form is to be completed and placed in the patient's chart in Nuclear Medicine.

7. The Radiation Oncologist must dictated Consult on patient within 48 hours of the receiving the request for consult. (Original on the patient's medical record and a copy in the patient's chart in Nuclear Medicine).

ST. MARY MEDICAL CENTER
RADIATION ONCOLOGY CONSULTATION

PATIENT NAME: _____ AGE: _____ HOME PHONE #: _____

ROOM #: _____ FACILITY: _____GARY _____ HOBART

REFERRING PHYSICIAN: _____ PHONE #: _____

CONSULTATION APPOINTMENT: _____

TUMOR:

LOCATION: _____

HISTOLOGY: _____

EXTENT: _____

RECOMMENDATIONS: _____

_____

_____

_____
RADIATION ONCOLOGIST

St. Mary Medical Center

NO:	
TITLE: NOTIFICATION FOR BRACHYTHERAPY	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr.T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 2/20/90	DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

All Therapeutic procedures involving the use of radioactive substances will be under the direct supervision of the Nuclear Medicine department.

PROCEDURE:

1.1 Nuclear Medicine MUST be notified at least 48 hours in advance of the therapy procedure. Same day as verbal notification is given, completed Brachytherapy Request Form MUST be delivered to Nuclear Medicine department indicating the date and time of the scheduled implant to be done. If a Surgeon is required, specify the date and time approved for surgery suite. This form is to be kept in the patient's chart in Nuclear Medicine.

1.2 The exact hour of implant MUST be given to the Nuclear Medicine department when scheduling. The scheduled time MUST be honored.

1.3 If there should be a complication which will change the scheduled time, the Physician will call the Nuclear Medicine Department. The Nuclear Medicine Technologist will document on the "Notification of Implant Change" form, the date & time of call, the Physician's name, patient's name & room number, and message received. The technologist will sign the form. Physician will sign form as soon as possible. Completed form is to be kept in the patient's chart in Nuclear Medicine.

1.4 In case of an Emergency, the 48 hour notice will be waived. However, the Physician must call the Nuclear Medicine Department and give reason for the emergency. The technologist will document on the "Notice for Emergency Brachytherapy" form, the date & time of the call, the Physician's name, the patient's name and room number, and the reason for the emergency. The technologist receiving the call will sign the form. Physician will sign the form prior to implant. Completed form is to be kept in the patient's chart in Nuclear Medicine.

1.5 After the Radiation Oncologist has explained the procedure to the patient, the "Consent To Radiation Therapy" form is to be signed by the patient and witnessed. The original consent is placed on the patient's chart and a copy is kept in the patient's chart in the Nuclear Medicine Department.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

NUCLEAR MEDICINE DEPARTMENT
AUTHORIZED USER REQUEST FOR THERAPEUTIC DOSAGES OF RADIOACTIVE MATERIAL & PATIENT SCHEDULING

I _____ authorize the Nuclear Medicine Department to act on
Authorized Physician User

my behalf and order the following radioactive material for _____

to be implanted on _____ at _____ AM PM for treatment

of _____.
(diagnosis & anatomical body part)

PROPOSED TREATMENT PLAN: _____

RADIOISOTOPE: _____ CHEMICAL FORM: _____

RADIOPHARMACEUTICAL: _____ PHYSICAL FORM: ( ) CAPSULE
( ) SEEDS SEALED SOURCE
( ) WIRE SEALED SOURCE

ACTIVITY: _____

SUPPLIER: _____

SURGICAL HARDWARE NEEDED:

_____ _____
AUTHORIZED PHYSICIAN DATE REQUESTED

DATE ORDERED: _____ DATE RECEIVED: _____

TECH. ORDERING: _____ TECH. RECEIVING: _____

I have checked the received order of radioactive material and confirm that the received material is the same as the radioacetive material ordered as indicated above.

_____ _____
AUTHORIZED PHYSICIAN DATE CHECKED

ST. MARY MEDICAL CENTER

NOTIFICATION OF IMPLANT CHANGE

LOCATION: _____GARY _____HOBART

DATE: _____ TIME: _____

PHYSICIAN CALLING: _____

PATIENT'S NAME: _____

PATIENT'S ROOM #: _____

MESSAGE: _____

_____

_____

_____

_____
TECHNOLOGIST SIGNATURE

_____
PHYSICIAN SIGNATURE

ST. MARY MEDICAL CENTER

NOTICE OF EMERGENCY BRACHYTHERAPY

LOCATION: _____GARY _____HOBART

DATE: _____ TIME: _____

PHYSICIAN CALLING: _____

PATIENT'S NAME: _____

PATIENT'S ROOM #: _____

TYPE OF IMPLANT: _____

REASON FOR EMERGENCY: _____

_____

_____

_____

_____
TECHNOLOGIST SIGNATURE

_____
PHYSICIAN SIGNATURE

St. Mary Medical Cente

	NO:
TITLE: PROCEDURE FOR ORDERING RADIOACTIVE MATERIAL	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: KEN VANDERHYE/DR. T. TORABI
CROSS REFERENCE:	SUPERCEDES: 6/6/89
DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90	PAGE 1 OF

PURPOSE/STATEMENT:

PROCEDURE:

The following procedures are to followed when ordering radiopharmaceuticals/ radioactive materials:

1.0 ALL radiopharmaceuticals/radioactive materials are ordered ONLY by the Radiation Safety Officer or by designated Nuclear Medicine personnel as authorized by the Radiation Safety Officer.

1.1 A completed and signed "Authorized User Request for Therapeutic Dosages of Radioactive Material" form must be received in Nuclear Medicine from the Radiation Onoclogist 48 hours prior to the scheduled implant before order is placed for the material.

1.2 All radiopharmaceuticals/radioactive material is ordered from a radiopharmacy in Chicago, Illinois, or Munster, Indiana, which only delivers to the Nuclear Medicine department during routine working hours.

1.3 If an emergency situation arises after routine scheduled work hours, the Nuclear Medicine Technologist on call will phone the radiopharmacy to bring the drugs to the hospital.

1.4 Hospital Security personnel will escort the delivery personnel to the "Hot Lab" and will remain to ensure the "Hot Lab" is locked after receipt.

1.5 ALL Therapy I-131 MUST be approved prior to ordering.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

NUCLEAR MEDICINE DEPARTMENT
AUTHORIZED USER REQUEST FOR THERAPEUTIC DOSAGES OF RADIOACTIVE MATERIAL & PATIENT SCHEDULING

I _____ authorize the Nuclear Medicine Department to act on
(Authorized Physician User)

my behalf and order the following radioactive material for _____

to be implanted on _____ at _____ AM PM for treatment

of _____.
(diagnosis & anatomical body part)

PROPOSED TREATMENT PLAN: _____

RADIOISOTOPE: _____ CHEMICAL FORM: _____

RADIOPHARMACEUTICAL: _____ PHYSICAL FORM: ( ) CAPSULE
( ) SEEDS SEALED SOURCE
( ) WIRE SEALED SOURCE

ACTIVITY: _____

SUPPLIER: _____

SURGICAL HARDWARE NEEDED:

_____ _____
AUTHORIZED PHYSICIAN USER DATE REQUESTED

RSO APPROVAL TO ORDER: _____ DATE: _____

DATE ORDERED: _____ DATE RECEIVED: _____

TECH. ORDERING: _____ TECH. RECEIVING: _____

I have checked the received order of radioactive material and confirm that the received material is the same as the radioactive material ordered as indicated above.

_____ _____
AUTHORIZED PHYSICIAN USER DATE CHECKED

4/90

St. Mary Medical Center

NO:

TITLE: PROCEDURES FOR RECEIVING RADIOACTIVE MATERIALS FROM SUPPLIERS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES: 6/6/89

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

1.1 Wear gloves during package inspection and opening to prevent contamination.

1.2 Inspect and open all packages IMMEDIATELY upon receipt. Should a package arrive when Nuclear Medicine Department is closed, this procedure will receive top priority as soon as the Nuclear Medicine personnel arrive. If visual inspection shows any signs of damage (if wet or crushed, etc.) stop the procedure immediately and notify the Radiation Safety Officer.

1.3 ALL radioactive packages will be surveyed at three (3) feet and at the surface to verify that radiation levels at three feet from the surface are not in excess of 10 millirems per hour or on the surface in excess of 200 millirems per hour. (If the levels are in excess of those indicated, the NRC REgion III Office will be notified by telephone by the Radiation Safety Officer.)

1.4 Open package and verify that the contents are in tact and that the items are in agreement with what was ordered in both name and quantity. Also make sure that the shipment does not exceed the license possession limits.

1.5 If a wipe test of the package is required to be performed as specified in 10CFR 20.205, the wipe test will be performed and analyzed as indicated in one of the "Wipe Test Procedures" as folows.

1.6 Check the possible breakage of seals or loss of liquid from the container's or a change in the color of the absorbing material. Wipe test the final source container to rule out contamination.

1.7 Place the radioactive patient doses in their respective drawers in the storage lab area of the "Hot Lab".

1.8 Monitor the shipment packing material for contamination after removal of the doses.

1.9 Review the labels on the individual patient doses or packages for the type of activity, radionuclide, quantity present, date of calibration, time of calibration, and prescription number.

1.10 If the material is packaged in dry ice, refrigerate immediately.

1.11 If excessive radiation levels, contamination, leakage or shortages are observed, notify the final delivering carrier by telephone or telegraph and the Regional Office of the NRC. Also notfify the Radiation Safety Officer of any damage or leakage resulting in contamination.

2.0 WIPE TEST PROCEDURES

2.1 To be performed on all shipments, specified in Part 10CFR 20.205, and on final containers of radioactive souorces.

2.2 To be performed as soon as practicable after receipt. If receiving during wrok hours, wipe test MUST be performed within three (3) hours; if received at some other time, within eighteen (18) hours after receipt.

2.3 PROCEDURE # 1:

2.3.1 Wipe the surface of the container over its entirety with an alcohol swab or filter paper wipe.

2.3.2 Check the wipe using a low level GM survey meter probe with the window open. The wipe should be held directly over the probe but not touching it and held in place for approximately 10 to 15 seconds. Record the reading in mR/hr.

2.3.3 If the radiation level is higher than the natural background 0.05mR/hr for our department, the item will be considered contaminated and will be stored behind lead and left to decay until reading is 0.05mR/hr.

2.4 ALTERNATE PROCEDURE # 2:

2.4.1 Wipe the surface of the container over its entirety with an alcohol swab or filter paper wipe.

2.4.2 Place the wipe into a plastic 12 x 75 tube and label. After all items are wiped they will be taken to a gamma counter to determine the presence of contamination.

2.4.3 The level for contamination on the gamma counter for the low level gamma radiation is equal to or less than 1760 cpm. If any items have counts per minute greater than this amount, they will be considered contaminated and placed behind lead to decay until the above count is reached or the area will be decomtaminated until the 1760 cpm level is obtained.

St. Mary Medical Center

NO:

TITLE: USE AND INDICATIONS FOR BRACHYTHERAPY

APPLICABLE TO: NUCLEAR MEDICINE

ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi

CROSS REFERENCE:

SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

To achieve maximum local control of CA using radioactive sources directly into the tumor.

EXPLANATION:

1. Higher doses of radiation are delivered to the tumor with a rapid fall off of dose outside of the implanted area and with relative sparing of the normal surrounding tissue.

2. A continuous irradiation may be better biologically due to less oxygen dependency.

3. Cosmetic and functional results may be excellent for local control and maximum palliation.

4. This method can be used for the early stage cancer and with megavoltage, external irradiation, and/or surgery.

INDICATIONS:

HEAD AND NECK CANCER

1. Under surface of the tongue and the floor of the mouth.
2. Posterolateral tongue border.
3. Base of the tongue.

BREAST CANCER

1. Boost therapy to surgical bed for Stage I and II following lumpectomy or segmental mastectomy.
2. Boost therapy to residual tumor following external beam irradiation for Stage III.

UTERINE CANCER

ENDOMETRIAL CANCER

TECHNIQUES

A. REMOVAL AFTER LOADING TECHNIQUES (TEMPORARY):

1. Plastic Tube Technique
   a. Breast
   b. Head and Neck
   c. Esophagus

2. Template technique (Steel Guides)
   a. Cervix and Vagina
   b. Uterus
   c. Prostate and Urethra
   d. Cervix and Peritenium

B. PERMANENT IMPLANTATION TECHNIQUE

C. COMBINATION OF TECHNIQUES

1. Interstitial and Intracavitary
   a. Cervix
   b. Vagina
   c. Urethra

2. Surgery with removable or permanent technique
   a. Soft Tissue Sarcoma
   b. Lung
   c. Prostate
   d. Cervix and Vagina
   e. Anus and Rectum

St. Mary Medical Center

NO:

TITLE: TREATMENT PROCESS FOR BRACHYTHERAPY	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

The clinical use of Brachytherapy should be provided to a patient with cancer to achieve a cure, long term control and palliation.

To assure the best quality care possible, a written request for Consultation is sent to the Radiation Oncologist or Nuclear Medicine Department from the nursing unit, and all steps in the treatment process are to be followed.

PROCEDURE:

1.0 Record the patient's name, age, sex, room number, referring physician and diagnosis on the consultation sheet.

2.0 Records must be obtained for the patient's chart in Nuclear Medicine:

- 2.1 History and physical examination report
- 2.2 Pertinent reports of radiographs, CT scans, MR images and radionuclide scans.
- 2.3 Pertinent laboratory reports
- 2.4 Pathology reports
- 2.5 Operative reports
- 2.6 Nurse's admission history on patient

3.0 The Radiation Oncologist will review all records and may consult with other physicians to determine the best method of treatment.

4.0 If Brachytherapy is selected as the mode of treatment, the Radiation Oncologist will take the following steps:

- 4.1 Complete and sign Appropriateness Form prior to sending written request to Nuclear Medicine for radioactive material. Completed form is to be placed in the patient's chart in Nuclear Medicine.

- 4.2 Discuss with the patient and/or family members the treatment including diagnosis, prognosis, explanation of brachytherapy procedure, length of treatment, possible side effects on specific organs in the field of treatment and possible alternative therapy.

4.3 Obtain informed consent of patient or legal guardian with signature on the "Consent to Radiation Therapy" form prior to actual treatment and other procedures, e.g., photograph of face and tumor site. (Tumor site photo not applicable to intracavitary sites). Have patient's signature on "Consent" witnessed at the time of signing.

Send a copy of the signed consent to Nuclear Medicine and place the original on the patient's hospital medical record.

4.4 Document prescribed treatment plan and patient diagnosis in progress notes prior to sending written request to Nuclear Medicine for radioactive materials.

4.5 Send written orders to Nuclear Medicine a minimum of 48 hours prior to scheduled implant indicating the proposed dose, # of sources to use, total dose required, type of isotope to be used, implant date, time, site, and amount of rads to be given, the supplier to be used, and the type of surgical hardware necessary for implant.

4.7 Physician makes arrangements with surgeon and surgery department. If there is a change in the scheduled date and/or time, the Radiation Oncologist must notify the Nuclear Medicine personnel and complete a "Notification of Change" form for the patient's Nuclear Medicine chart.

4.8 Dictate consult within 48 hours of receipt of consultation request. Original to be placed in the patient's medical chart with a copy in the patient's chart in Nuclear Medicine.

4.9 Receipt of the radioactive materials and surgical hardware by Nuclear Medicine personnel checked by the Radiation Oncologist 24 hours prior to the start of the surgery or scheduled time for implant.

4.10 Identification photo using Polaroid film taken of patient's face - front facing from shoulders up and site of implant, if possible.

4.11 Radiation Oncologist to write orders for Blood Count and patient's weight to be done prior to scheduled implant.

4.12 Radiologist to review the simulation films and mark all appropriate anatomical landmarks as indicated prior to the computerized treatment plan and implanting of radioactive sources.

4.13 Radiation Oncologist to review marked simulation films with Radiation Health Physicist and mark appropriately, sign, date, and time reviewed on the original films. Original simulation films are to be kept in the patient's record in Nuclear Medicine with copies remaining in the Radiology film jacket.

4.15 Radiacion Oncologist to review computerized treatment plan with the Radiation Health Physicist, document radiation dosage to be given, number of hours to remain in the patient, sign, date, and time on on the computerized treatment plan prior to implanting of the radiation sources.

4.16 Radiation Physicist to complete all appropriate physics calculations, review Nursing Instructions with R.N., post appropriate signs, and and perform radiation survey of the patient and the room.

4.17 After reviewing the Nursing Instructions, the R.N. is to sign and date. The original is to be placed inthe patient's medical record and a copy is to be placed in the patient's chart in Nuclear Medicine.

4.18 Radiation Oncologist is to perform a daily examination of the patient and write daily progress notes in in the patient's medical record.

4.19 If any change is made in the prescription for the patient, Radiation Oncologist must document the reason for change in the patient's medical record (Progress Notes) and in the patient's chart in Nuclear Medicine.

4.20 At the time of removal of the radiation sources, the Radiation Oncologist will document removal in the progress notes in the patient's medical record, complete all appropriate forms necessary for the patient's chart in Nuclear Medicine, and give patient any necessary home instructions.

4.21 Following removal of the radiation sources, the Radiation Physicist will remove posted signs, do final radiation survey on patient's room, document necessary physics calculations, complete all appropriate forms for the patient's chart in Nuclear Medicine, and return all radioactive sources to inventory in the safe.

4.22 Radiation Oncologist will dictate a Treatment Summary within 48 hours after removal of the radioactive sources. The original is to be placed in the patient's medical record and a copy is to be placed in the patient's chart in Nuclear Medicine.

St. Mary Medical Center

NO:

TITLE: PROCESS OF RADIATION THERAPY UTILIZING BRACHYTHERAPY	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

PROCEDURE:

1.0 CLINICAL EVALUATION

1.1 Diagnostic Evaluation by the Radiation Oncologist requires a pertinent history, complete physical examination, and review of all diagnostic studies and reports including those from pathology, the imaging services, surgery, and the laboratory.

1.2 Assessment of Pathobiology of Tumor - The Radiation Oncologist must be aware of the biological characteristics of each caancer as a basis for estimating its clinical behavior. The assessment of tumor extent must be considered so that the radiation treatment volume will be adequate.

1.3 Staging - The documented extent of each cancer must be recorded as a basis for staging. This will support an estimation of the prognosis for the individual patient and comparison of treatment performances in different centers.

2.0 THERAPEUTIC DECISION MAKING

2.1 Selection of Treatment Goals

2.2 Choice of radioactive isotopes, applicators

An estimation of whether treatment is likely to help the patient; selection of cure or palliation as the objective; identification of management alternatives; and if ionizing radiation is to be use, selection of the beams and/or radionuclide sources, methods, pattern of delivery, doses, and sequencing with other treatment.

3.0 TARGET VOLUME LOCALIZATION

3.1 Definition of tumor

3.2 Identification of sensitive organs/tissue

A determination of the tumor site and the target volume in relationship to the adjacent normal tissues. This is based on physical examination, endoscopy, visual imaging such as radiography, radionuclide scanning, computerized tomography, magnetic resonance imaging, and findings during surgery.

4.0 TREATMENT PLANNING

4.1 Selection of approximate volume for implantation

4.2 Appraisal of dosimetry

4.3 Estimation of patient tolerance to procedure

4.4 Check off of equipment needed

4.5 Arrangement for surgical suite and anesthesia, when applicable

4.1.5 If a Surgeon is required for the implantation, the Radiation Oncologist will contact the Surgeon. When the Surgeon agrees to the proposed date and time then arrangements are made with the surgery department and the patient.

5.0 TREATMENT

5.1 Review of initial treatment plan

5.2 Implantation of applicator.

6.0 VERIFICATION OF IMPLANTATION

6.1 Orthogonal Xrays of applicator placement

7.0 DOSIMETRY

7.1 Calculations of actual implantation

7.2 Establishment of time for removal

After implantation calculations are performed and documented of the dosage actually implanted. Document at implantation of the radioactive sources the exact date and time for removal of the sources from the patient.

8.0 PATIENT EVALUATION DURING TREATMENT

8.1 Assessment of patient tolerance

8.2 Check of position of implant

A daily examination of the patient and daily written progress notes are written in the patient's chart by the physician.

9.0 REMOVAL OF IMPLANT

10.0 FOLLOW-UP EXAMINATION

10.1 Assessment of early and late sequelae

10.2 Evaluation of tumor control

St. Mary Medical Center

NO:

TITLE: CONSENT FOR BRACHYTHERAPY TREATMENT	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr.T.Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90 PAGE 1 OF 1

PURPOSE/STATEMENT:

Prior to initiation of any treatment program, the patient must give valid informed Consent for actual treatment and other procedures such as photography of the face and tumor site. If the patient is judged to be mentally incompetent, consent must be obtained from a legally qualified guardian.

PROCEDURE:

1. The Radiation Oncologist will speak with the patient and/or family members concerning the type and course of Brachytherapy treatment to be used.

2. During the discussion, the Oncologist will discuss the patient's condition, treatment alternatives, if any, with their reasonable objectives and possible sequalae, the side effects of the Brachytherapy, if any, and the consequences of no treatment.

3. When the patient or guardian decides to pursue the Brachytherapy treatment, a "Consent to Radiation Therapy" form MUST be signed and witnessed.

4. The signed Consent will be filed in the patient's hospital chart with a copy in the patient's chart in Nuclear Medicine.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

CONSENT TO RADIATION THERAPY

1. I, _____, hereby authorize Dr. _____ and such assistants as he may designate to administer _____ therapy to me, and to continue such therapy from time to time as he may deem necessary.

2. The nature of my illnee, the effect and nature of this therapy, possible alternative methods of treatment and the risks of injury despite precautions have been explained to me.

3. This information has been given to me in a manner that I can understand. I have been offered an interpreter if necessary. Those of my family I have designated have been given this information with me. We have had the opportunity to ask questions and all such questions have been answered to complete satisfaction.

4. I acknowledge that no guarantee or assurance have been given by anyone as to the results that may be obtained and I understand that I may discontinue treatments at anytime upon my request.

5. I hereby agree not to hold the Radiation Oncologist, his assistants, attending Physician, or St. Mary Medical Center responsible for any complications which may arise now or later.

6. My signature on this document indicates my desire to receive the therapy proposed by the Radiation Oncologist and explained by him.

_____	_____	_____
Witness	Patient's Signature	Date Time

If the patient is a minor or unable to sign complete one of the following:

A. Patient is a minor of _____ years of age.

B. Patient is unable to sign consent because: _____

_____

The undersigned certifies by his/her signature that he/she is duly authorized to accept the above terms on the patient's behalf.

_____	_____	_____
Witness	Signature of other Responsible Person	Date Time

_____
Relationship to patient

St. Mary Medical Center

TITLE: DOCUMENTATION OF BRACHYTHERAPY TREATMENT AND NUCLEAR MEDICINE CHARTS	NO: APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90	PAGE 1 OF 3

PURPOSE/STATEMENT:

It is the policy of the Nuclear Medicine Department to assure that the appropriate treatment regimen is implemented with each Brachytherapy patient.

The Medical Director and the Department Director will assure that open and frequent communication is maintained between the Radiation Oncologist and the patient's family, referring physician, and other departments regarding the patient's status.

The Medical Director and the Department Director shall assure that the dose given is accurate, the nutritional status is monitored and the facilities and personnel are utilized in an efficient and appropriate manner.

All records of the patient's treatment and management shall be kept in proper order and maintained within the department.

PROCEDURE:

GENERAL

1.0 The Nuclear Medicine Department shall utilize the services of a qualified Radiation Health Physicist to perform timely calibrations, of appropriate calibration equipment. Records of these checks will be kept in the Physicist's office.

2.0 Implants will be performed by a qualified Radiation Oncologist, a Radiation Health Physicist, and with the assistance of a certified Radiologic Technologist or Nuclear Medicine Technologist trained in Brachytherapy.

3.0 All approved policies and procedues pertaining to Brachytherapy patients are to be adhered to.

4.0 All pertinent data generated by the Brachytherapy procedure, e.g. consent, consultation report, radiation prescription, and treatment summary MUST be included on each patient's hospital chart. All records generated by the treatment are to be maintained and secured in the patient's chart in Nuclear Medicine separate from the patient's medical records.

5.0 The records of all current patient's treatment and management are to be reviewed according to the time sequence outlined on "Chart Audit Report" and Criteria/Exceptions Sheet.

6.0 Brachytherapy Chart Audit reviews shall include but not all inclusive of the following items:

6.1 There is a written physician referral for the patient for Brachytherapy treatment.

6.2 Appropriateness form is completed and signed by the Radiation Oncologist

6.3 Patient diagnosis/disease and proposed treatment plan is documented by the Radiation Oncologist

6.4 Written physician orders indicating proposed dose, treatment time, # of sources to use, total dose required, type of isotope to be used, treatment date & site, and supplier is stamped received by the Nuclear Medicine department a minimum of 48 hours prior to implant schedule.

6.5 Written physician orders for surgical hardware necessary for the implant stamped received by the Nuclear Medicine department a minimum of 48 hours prior to the implant schedule.

6.6 All work-up pertinent to patient's clinical situation has been performed and documented.

6.7 Consultation dictated by the Radiation Oncologist, transcribed and charted within specified time periods.

6.8 Consent has been signed by the patient and witnessed prior to treatment beginning.

6.9 Daily examination of the patient with daily progress note written by the Radiation Onocologist.

6.10 All records of physics calculations have been completed, documented, and signed on appropriate forms.

6.11 Simulation Films have been reviewed, marked, signed and dated with time prior to implanting of sources by Radiation Oncologist.

6.12 Computer Plan has been done reviewed, marked, signed and dated with time prior to implanting of sources by the Radiation Oncologist.

A copy of the chart audit will be kept within the patient's chart in Nuclear Medicine.

7.0 The Radiation Oncologist and the Radiation Health Physicist shall be members of the Brachytherapy Quality Assurance Sub-Committee to assist in setting policies and criteria for quality patient care.

8.0 A quarterly report on findings of the chart audits will be submitted to the Brachytherapy O.A. Sub-Committee for review. Report with any recommendations will be submitted to the Radiation Safety Committee quarterly. If any problems are discovered whose cause can not be easily identified, an indepth audit will be conducted

St. Mary Medical Center

NO:

TITLE: BRACHYTHERAPY CHART AUDITS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90 PAGE 1 OF 1

PURPOSE/STATEMENT:

To ensure all pertinent and necessary documentation is contained within the patient's Brachytherapy chart in Nuclear Medicine, three chart audits will be conducted on each chart at specified time frames.

PROCEDURE:

1.0 Chart audits will be conducted in accordance with the items and time frames listed on the pages for Brachytherapy Chart Audit Criteria and Exceptions.

2.0 The first chart audit will be conducted after receipt of the radioactive sources by Nuclear Medicine and prior to implantation of the radioactive sources into the patient.

3.0 The second audit will be conducted immediately following removal of the radioactive sources.

4.0 A third audit will be conducted within 5 working days after the removal of the radioactive sources.

5.0 A copy of the audit will be kept in the patient's Brachytherapy chart in Nuclear Medicine. The original will be sent to the Regional Radiology Quality Assurance Coordinator for review and quarterly summary report to the Radiation Safety Committee.

BRACHYTHERAPY CHART AUDIT CRITERIA

CRITERIA	EXCEPTIONS
1. Physician referral documented on patient medical chart or consultation request form prior to tx.	a) None
2. Appropriateness Form on chart completed & signed by Radiation Oncologist prior to written request to Nuclear Medicine for radioactive material	a) None
3. Proposed treatment plan documented on "Request for Radioactive Materials" sent to Nuclear Medicine prior to ordering materials	a) None
4. Patient diagnosis documented on "Request for Radioactive Materials" sent to Nuclear Medicine prior to ordering of materials	a) None
5. "Request for Radioactive Materials" completed and signed by the Radiation Oncologist sent to Nuclear Medicine a minimum of 48 hours prior to implant indicating the proposed dose, treatment time, # of sources to use, total dose required, type of sources to be used, implant date, time, and site, surgical hardware needed, and supplier to use. Physician written request prior to implant	a) Emergency Cases (48 hr. waived) A written & signed statement from Radiation Oncologist explaining the nature of the emergency delivered immediately to Nuclear Medicine.
6. Radioactive material ordered per Radiation Oncologist written request prior to implant	a) None
7. Surgical hardware necessary for implant ordered per Radiation Oncologist written request prior to implant.	a) None
8. Receipt of radioactive materials and surgical hardware checked by department and checked by Radiation Oncologist 24 hours prior to start of surgery.	a) None
9. Copies of History & Physical, pertinent xray, scans, lab, and operative reports placed in chart prior to implant.	a) None
10. Copy of Nurse's Admission History placed in in chart prior to implant	a) None
11. Copy of consent signed prior to implant	a) None
12. Consent witnessed at time of patient signature	a) None
13. ID photo taken prior to implant	a) Emergency Cases
14. Consult dictated by Radiation Oncologist within 48 hours of Consultation requested	a) Holidays/Saturdays/Sundays
15. Copy of transcribed consult in chart within 24 hours of dictation	a) Holidays/Saturdays/Sundays

BRACHYTHERAPY CHART AUDIT CRITERIA

CRITERIA	EXCEPTIONS
16. Copy of Blood Count of patient prior to implant	a) None
17. Documented weight taken of patient prior to implant	a) None
18. Daily examination after implant by Radiation Oncologist documented in Progress Notes	a) None
19. Daily Progress Notes written after implant by the Radiation Oncologist	a) None
20. Implants done during normal working hours (Mon thru Fri. 7:30AM - 5:00PM)	a) Emergency Cases as documented by Radiation Oncologist
21. Treatment Summary dictated within 48 hours after removal of radioactive materials	a) Holidays/Saturdays/Sunda
22. Appropriate anatomical landmarks marked on Simulation films by Radiologist prior to implant	a) None
23. Simulation films reviewed and signed by Radiation Oncologist prior to impla	a) None
24. Computer Plan completed, reviewed, marked, signed and dated by Radiation Oncologist prior to implant	a) None
25. Implant Dosimetry Form completed by Radiation Oncologist prior to implant	a) None
26. Source Certification documented by RSO or designee prior to implant	a) None
27. Caution Sticker placed on patient's chart	a) None
28. Room Survey Documentation form completed at time of implant of radioactive sources	a) None
29. Nurse Exposure Measurements documented and reviewed by RSO after removal of radioactive sources	a) None
30. Nursing instructions on care of the patient reviewed and signed by RN in patient's chart	a) None
31. Housekeeping instructions posted on patient's door	a) None
32. Family Home Care Instructions given to and discussed with family prior to discharge of pt.	a) None
33. Is prescribed dose and actual delivered dose within + or - 10% of each other?	a) None

ST. MARY MEDICAL CENTER - GARY/HOBART, INDIANA

BRACHYTHERAPY CHART AUDIT REVIEW

TYPE OF IMPLANT: ____________________

PATIENT NAME or ID #: ____________________

CONSULTATION DATE: ____________________
IMPLANT SCHLD. DATE/TIME: ____________________
ACTUAL DATE/TIME IMPLANTED: ____________________
REMOVAL SCHLD. DATED/TIME: ____________________
ACTUAL REMOVAL DATE/TIME: ____________________

CRITERIA	DATE COMPLETED	PRIOR TO TX.	DATE CHART VERIFIED		AUDITOR INITIALS		COMMENTS
PHYSICIAN REFERRAL							
SIGNED APPROPRIATENESS FORM							
PROPOSED TREATMENT PLAN							
PT. DIAGNOSIS							
ONCOLOGIST WRITTEN ORDERS TO SCHEDULE IMPLANT PROCEDURE							
RADIOACTIVE MATERIAL ORDERED PER ONCOLOGIST WRITTEN REQUEST							
SURGICAL HARDWARE ORDERED PER ONCOLOGIST WRITTEN REQUEST							
RECEIPT OF RADIOACTIVE MATERIAL & HARDWARE CHECKED BY DEPARTMENT PERSONNEL AND BY RAD ONCOLOGIST							
HISTORY/PHYSICAL - ONCOLOGIST							
COPIES OF XRAY/LAB/PATH/CT/MRI/NUC.MED/OPERATIVE REPORTS							
COPY OF NURSES ADMISSION HISTORY							
CONSENT SIGNED							
CONSENT WITNESSED							
ID PHOTO							
CONSULT DICTATED							
CONSULT TRANSCRIBED & IN CHART							
BLOOD COUNT (PRIOR TO IMPLANT)							
WEIGHT (PRIOR TO IMPLANT)							
DAILY EXAMINATION BY ONCOLOGIST							
DAILY PROGRESS NOTES WRITTEN							
IMPLANT DURING ROUTINE WORK HRS.							
REMOVAL DURING ROUTINE WORK HRS.							
TREATMENT SUMMARY							
//////////							
SIM. FILM MARKED BY RADIOLOGIST							
SIMULATION FILM REVIEWED							
COMPUTER PLAN REVIEWED & MARKED							
IMPLANT DOSIMETRY FORM							
SOURCE CERTIFICATION							
SOURCE INVENTORY FORM							
CAUTION STICKER FROM CHART							
ROOM SURVEY DOCUMENTATION FORM							
NURSE EXPOSURE MEASUREMENTS							
NURSING INSTRUCTIONS -CARE OF PT							
HOUSEKEEPING INSTRUCTIONS							
FAMILY HOME CARE INSTRUCTIONS							

PRESCRIBED DOSE: ____________________

ACTUAL DOSE RECEIVED: ____________________

DIFFERENCE OF ± 10%: __________

St. Mary Medical Center

NO:	
TITLE: IDENTIFICATION PHOTOGRAPHS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90	PAGE 1 OF 1

PURPOSE/STATEMENT:

Each patient treated with Brachytherapy must have an identification photograph taken for the treatment record. The I.D. photograph will be used by the Nuclear Medicine Department only and will be placed in the patient's Brachytherapy chart.

PROCEDURE:

1.0 I.D. photographs are taken with a polaroid camera

2.0 Full face front view photographs are taken from the shoulder up.

3.0 I.D. photographs MUST be taken prior to implantation of any radioactive sources into the patient.

4.0 I.D. photographs are to be placed in the patient's chart in Nuclear Medicine.

5.0 The photograph is to be used ONLY in the Nuclear Medicine Department for Brachytherapy patients.

St. Mary Medical Center

NO:	
TITLE: BRACHYTHERPAY SIMULATION FILMS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhve/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 2/20/90	DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

Films of Brachytherapy patients should be of sufficient quality to allow the Radiologist to locate appropriate anatomical landmarks or markers and to allow the Radiation Health Physicist to perform the necessary dosimetry required for the patient

PROCEDURE:

1. Radiology department is to be notified prior to patient leaving Recovery Room to allow sufficient time to prepare room.

2. After arrival in Radiology, the patient is to be placed on the table in the supine position.

3. Two films (AP & Lateral) are to be taken with the beam centered in the area of the Brachytherapy site as instructed by the Radiation Health Physicist

4. Both films are to be taken with the same distance between the intended source and the film.

5. If for any reason the film needs adjustment, both films MUST be retaken. For accurate calculations, a true orthogonal pair of films are required.

6. As soon as films are developed and approved by the Radiologist, have the patient transported to their room immediately.

7. The Radiologist will mark all appropriate anatomical landmarks on the original films.

8. A duplicate copy of the marked films will be made and kept in the patient's film folder in Radiology.

9. The original films will be reviewed by the Radiation Oncologist and the Radiation Helath Physicist and stored in the patient's folder in the Nuclear Medicine department.

St. Mary Medical Center

NO:

TITLE: Cs-137 FLETCHER APPLICATOR PROCEDURE	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90 PAGE 1 OF 3

PURPOSE/STATEMENT:

PROCEDURE:

1.0 DAY OF INSERTION

1.1 The Department of Nuclear Medicine MUST be notified when the patient goes to O.R. and when the patient leaves the Recovery Room.

1.2 The Radiology department MUST be notified with sufficient time prior to the patient leaving the Recovery Room to prepare room.

1.3 The Radiation Oncologist and the Regional Health Physicist or designee MUST be available as soon as the patient leaves the Recovery Room:

1.4 The Radiation Oncologist and the Regional Health Physicist or designee will work together in the Simulating Room as follows:

1.3-1 The Radiation Oncologist will place the dummy sources in the applicator, if not previously done in OR.

1.3-2 The Radiation Oncologist or Radiation Health Physicist will determine the location of the applicator and instruct the technologist for placement of the central beams.

1.3-3 After films have been developed and approved by the Radiologist, the Radiologist will mark the AP & Lateral films with the location of the cerival OS, urinary bladder, and rectum.

1.3-4 The Radiation Oncologist will mark point A and B on the films, sign, date and time on each film.

1.3-5 The Radiation Oncologist will provide the Regional Health Physicist with the source configuration on FORM A.

1.3-6 The Regional Health Physicist or designee will do the magnification

1.3-7 The Regional Health Physicist or designee MUST make sure that all of the dummy sources can be seen on the AP and Lateral films.

1.4 While the patient is being transported to his room, the Regional Health Physicist will run the computerized treatment plan.

1.4-1 The Radiation Oncologist with the Radiation Health Physicist will review the computerized treatment plan and make final decision on source configuration prior to implanting the radiation sources.

1.4-2 The Radiation Oncologist will document dosage to be given, number of hours to remain in the patient, sign, date and time on the computerized treatment plan prior to the insertion of the radioactive sources.

1.4-3 The Radiation Oncologist will complete appropriate portion of FORM A and give to the Radiation Health Physicist prior to the insertion of the radioactive sources.

1.5 The Regional Health Physicist or designee will perform inventory on FORM C and will bring the Source Configuration to the patient's room.

1.6 The Radiation Oncologist will then do the insertion of the sources.

1.7 Following the insertion, the Radiation Oncologist MUST complete and sign the top portion of FORM A.

1.8 The Regional Health Physicist or designee will complete the following:

1.8-1 Nursing instructions FORM D.

1.8-2 Room survey on FORM E.

1.8-3 Nurse's exposure document - FORM F.

1.8-4 Complete information on appropriate Radiation Warning signs and post them on patient's room, bed, and chart.

2.0 DAY OF REMOVAL

2.1 The Radiation Oncologist will remove the radiation sources.

2.2 The Radiation Oncologist will complete and sign the remaining portion of FORM A.

2.3 The Regional Health Physicist or designee will:

2.3-1 Perform final room and patient survey on FORM E

2.3-2 Return all sources to storage and perform the source inventory on FORM C.

2.3-3 Take all documents pertaining to Brachytherapy Procedure to the Nuclear Medicine department.

3.0 Within 48 hours of removal of sources, the Radiation Oncologist WILL dictate Treatment Summary on the patient. The Treatment Summary will be transcribed and placed in the medical record and a copy placed in the patient's chart in Nuclear Medicine.

4.0 All documents, including the simulation films & computerized treatment plan, will be kept in the patient's Brachytherapy chart in Nuclear Medicine.

5.0 A copy of all documents will be made available to the Radiation Oncologist and the Regional Radiation Health Physicist. It is their responsibility or a designated individual assigned to pick up the copies after signing a receipt documentation form in Nuclear Medicine.

LAKESHORE HEALTH SYSTEM
DOSIMETRY AND COMPUTERIZED TREATMENT PLANNING

SCH ____ CARY ____ WOBART ____

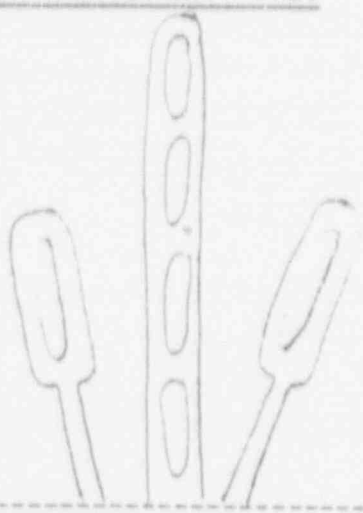
PATIENT NAME: _____ ID #: _____ DATE IN: _____ AM/PM _____ DESIRED DOSE: _____

APPROX. DATE OUT: _____ AM/PM _____ TOTAL HR.: _____ AP MAG: _____ LAT. MAG: _____

MODEL	DATE OF CAL.	Mg. Rad Eq.	mCi	DATE OF INSERTION	mg Rad Eq.	mCi
1862 Red H-5		11.4	29.1			
" " E-5		11.4	29.2			
" " E-1		11.2	28.7			
" " H-3		11.4	29.2			
1863 Black N-4		16.9	43.3			
" " L-1		16.7	42.7			
" " O-9		16.9	43.1			
" " M-1		17.1	43.6			
" " M-9		17.1	43.8			
1864 White R-3		22.3	57.0			
" " T-8		22.3	56.9			

Cs 137 FLETCHER APPLICATOR ONLY

Set		Rad/hr	x	hrs.	=	Total Dose
1-Point A	r		x		=	
	l		x		=	
2-Point B	r		x		=	
	l		x		=	
3-Bladder	ant		x		=	
	mid		x		=	
	post		x		=	
4-Rectum	ant		x		=	
	mid		x		=	
	post		x		=	
5-Cervical OS			x		=	
6-			x		=	
7-			x		=	



	mgRaEq	mCi
1		
2		
3		
4		
5		
6		
7		

OTHER TYPE OF BRACHYTHERAPY SOURCES
SOURCE NAME _____

Set		Rad/hr	x	hrs.	=	Total Dose
1			x		=	
2			x		=	
3			x		=	
4			x		=	
5			x		=	
6			x		=	
7			x		=	

Source Configuration

# of sources	mgRaEq	mCi

PHYSICIST SIGNATURE: _____ DATE: ____

I CERTIFY THAT THE ADMINISTERED DOSE AGREES WITH THE PRESCRIBED DOSE & THE COMPUTER TREATMENT PLAN HAS BEEN VERIFIED.

_____ (RAD. ONCOLOGIST) DATE: _____

DATE OF REMOVAL: _____ AM/PM _____ DELIVERED DOSE: _____ RAD TOTAL HR. _____

IF DELIVERED DOSE AND DESIRED DOSE ARE NOT THE SAME, PLEASE EXPLAIN: _____

_____ (RAD. ONCOLOGIST) DATE: _____

LAKESHORE HEALTH SYSTEM
BRACHYTHERAPY SOURCES INVENTORY FORM

PATIENT NAME: _____ ROOM #: _____

SCH_____ HOBART _____ GARY _____

SOURCES IN STORAGE:

DATE OF INVENTORY	TIME OF INVENTORY	SOURCE ACTIVITY MILLIGRAM RADIUM EQUILVALENT	NUMBER OF SOURCES IN STORAGE	SOURCES INVENTORIED BY:
		5		NAME:
		10		SIGNAURE:
		15		
		20		
		30		

SOURCES REMOVED FROM STORAGE FOR THERAPY:

DATE OF REMOVAL	TIME OF REMOVAL	SOURCE ACTIVITY MILLIGRAM RADIUM EQUILVALENT	# OF SOURCES REMOVED FROM STORAGE	SOURCES LEFT IN STORAGE	SOURCES REMOVED BY:
		5			NAME:
		10			SIGNATURE:
		15			
		20			
		30			

SOURCES RETURNED TO STORAGE AT COMPLETION OF THERAPY:

DATE OF RETURN	TIME OF RETURN	SOURCE ACTIVITY MILLIGRAM RADIUM EQUILVALENT	# OF SOURCES RETURNED TO STORAGE	TOTAL # OF SOURCES IN STORAGE	SOURCES RETURNED TO STORAGE BY:
		5			
		10			
		15			
		20			
		30			

ARE ALL SOURCES ACCOUNTED FOR ? YES [ ] NO [ ]

_____
SIGNATURE

LAKESHORE HEALTH SYSTEM

_____SCH _____HOBART ____GARY

NURSE EXPOSURE MEASUREMENT RECORD

ATTENTION: DO NOT ENTER PATIENT ROOM WITHOUT USING A POCKET DOSIMETER
PRIOR TO ENTERING PATIENT ROOM DOCUMENT READING ON POCKET DOSIMETER.
AFTER LEAVING PATIENT ROOM DOCUMENT READING ON POCKET DOSIMETER.

DATE	NAME	mR READING PRIOR	mR READING OUT	TIME IN ROOM	COMMENTS

RSO SIGNATURE: _____

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

_____ SCH _____ SMMC-GARY _____ SMMC-HOBART

_____ BRACHYTHERAPY RADIATION SURVEY _____ RADIOPHARMACEUTICAL RADIATION SURVEY

PATIENT: _____ BACKGROUND READING: _____ mR/hr. ROOM #: _____

RADIONUCLIDE: _____ ACTIVITY: _____ mCi SURVEY METER: _____ DATE OF CALIB.: _____

DATE IN: _____ TIME: _____ am pm DATE OUT: _____ TIME: _____ am pm

POINTS SURVEYED	EXPOSURE RATE	
A. PT. BEDSIDE	_____ mR/hr	_____
B. 3 FT. FROM PT. FS	_____ mR/hr	ROOM: _____
B. 3 FT. FROM PT. BS	_____ mR/hr	_____
C. 6 FT. FROM PT.	_____ mR/hr	HALL _____
D. AT THE DOOR	_____ mR/hr	_____
E. IN CORRIDOR	_____ mR/hr	ROOM: _____
		_____

OTHER ROOMS AROUND PT. ROOM ARE / ARE NOT SAFE. REMARKS: _____

SURVEYOR: _____

DATE OF SURVEY: _____ RSO SIGNATURE: _____

FINAL RADIATION SURVEY DATE & TIME: _____ SURVEYOR: _____

ROOM: _____ mR/hr PATIENT: _____ mR/hr RSO SIGNATURE: _____

RADIOPHARMACEUTICAL PATIENTS ONLY:

DATE	TIME	READING AT 3 FEET	ESTIMATED ACTIVITY
_____	_____	_____ mR/hr	_____ mCi
_____	_____	_____ mR/hr	_____ mCi
_____	_____	_____ mR/hr	_____ mCi
_____	_____	_____ mR/hr	_____ mCi

FINAL RADIATION SURVEY: ____FLOORS ____WALLS ____SINK ____TOILET ____BED

____PHONE ____DOORS ____TABLES ____TV

ALL ARE DECONTAMINATED: ____YES ____NO ROOM IS RELEASED: ____YES ____NO

SURVEY METER USED: ____YES ____NO WIPE TEST METHOD USED: ____YES ____NO

St. Mary Medical Center

NO:

TITLE: INFECTION CONTROL PROCEDURES DURING BRACHYTHERAPY PROCEDURES	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 2/20/90 DATE EFFECTIVE: 2/20/90	PAGE 1 OF 2

PURPOSE/STATEMENT:

To ensure adherence to the use of appropriate barrier protection methods to prevent exposure to or transmission of infections and/or diseases to personnel involved in providing Brachytherapy to patients.

PROCEDURE:

1. In accordance with hospital policy, Universal Precautions will be followed by all personnel for exposure to all body fluids which represent a potential source for infections.

2. Body Fluids to which strict Universal Precautions apply:

   a. Blood
   b. Fluids with visible blood
   c. Semen
   d. Vaginal Secretions
   e. Cerbrospinal Fluid
   f. Synovial Fluid
   g. Pleural Fluid
   h. Peritoneal Fluid
   i. Pericardial Fluid
   j. Amniotic Fluid

3. The use of protective barriers will be employed to reduce the risk of exposur to blood, body fluids containing visible blood, and other fluids to which universal precautions apply.

   a. Sterile gloves shall be worn for procedures involving contact with normally sterile areas of the body.

   b. Non-sterile gloves shall be worn for procedures involving contact with blood, body fluids, mucous membranes, or non-intact skin of all patients. This includes:

      I. Performing wound or decubitus care, dressing changes, all suctioning, nasogastric tubes, providing oral or perineal care.

      II. Handling items or surfaces soiled with blood or body fluids, such as soiled linen and cleaning up spills.

      III. Performing venipuncture or other vascular access procedures.

      IV. Insertion or removal of applicators into patient's body cavities for Brachytherapy procedures.

4. Gloves should be removed and discarded after contact with each patient, fluid, item or surface.

   a. Hands should be washed before gloving and immediately after gloves are removed. Hands and other skin surfaces should be washed immediately if contaminated with blood and other body fluids.

   b A new set of gloves should be used for contact with each person.

   c. If a glove is torn or punctured it should be removed, hands washed, and a new set of gloves applied.

5. a. Additional appropriate barrier precautions (such as masks, protective eye covers) are to be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of the mucous membranes of the mouth, nose, and eyes.

   b. Gowns should be worn during the procedure if it is likely to generate splashes of blood or other body fluids.

St. Mary Medical Center

NO:

TITLE: SURVEYS OF RADIATION SOURCES	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

All areas where radiation sources are used will be surveyed to ensure that personnel will not exceed MPD limit. To ensure that radiation levels due to the use of these sources are below regulatory limits in the surrounding areas.

PROCEDURE:

1.0 For each use of brachytherapy of radiopharmaceutical source of radiation in the patient's room, the Physicist MUST survey the room and complete the applicable survey form.

2.0 The Physicist will review collected data and issue pertinent instructions to the Nursing personnel for radiation protection for themselves and visitors.

3.0 All surveys will be kept on permanent file in the Physicist's office.

4.0 The Physicist will review the surveys annually to verify that conditions such as workload, occupancy of surrounding areas and facility layouts are still applicable.

5.0 If any of the conditions are no longer applicable, a resurvey must be conducted.

St. Mary Medical Center

NO:

TITLE: CALIBRATION OF SEALED SOURCES	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

To assure that calibrated sources are available for intracavitary applications.

PROCEDURE:

1.0 The Physicist shall obtain for each radiation source in permanent inventory a manufacturer calibration certificate and the date of the calibration.

2.0 All radiation sources should be decayed to the date of the insertion or to ± 3% of the actual value.

3.0 An inventory list shall be kept of all radiation sources on site. This list is to be kept in the Physicist's office.

4.0 Calibration is completed when sealed sources are used.
e.g. - Any implant patient

St. Mary Medical Center

NO:

TITLE: STORAGE, INVENTORY, WIPE TESTS OF SOURCES	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: DATE EFFECTIVE: PAGE 1 OF 1

PURPOSE/STATEMENT:

Storage, inventory and wipe tests shall be done for all brachytherapy sources maintained within the hospital in accordance with US NRC Rules and Regulations.

PROCEDURE:

1.0 The brachytherapy sources, upon receipt, will be assayed in a dose calibrator to insure that each source has the activity certified by the supplier.

2.0 The sources will be stored in a secured room with sufficient lead shielding to insure that the radiation levels from the sources will be as far below 2mR/hr as possible in the unrestricted areas. The storage containers must be locked or stored in a locked cabinet when not in use.

3.0 Quarterly the sources are to be inventoried by the Radiation Safety Officer or designee. The inventory count shall be recorded on approved form, cross checked against previous inventory count to ensure all sources are present. Records will be kept on file by the Radiation Safety Officer.

4.0 An inventory of the sources when removed from storage area for therapy and returned to storage area at the completion of the therapy will be maintained. (See attached inventory form)

5.0 The sources will be wipe tested at intervals required by the NRC Rules and Regulations. The wipe sources will be wipe tested by the Radiation Saftey Officer or his designee. If a designee does the wipe testing all results will be reviewed and signed by the RSO.

St. Mary Medical Center

NO:

TITLE: SOURCE USAGE LOG	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

To maintain accountability for Brachytherapy sources, a Usage Log is to be maintained

PROCEDURE:

1.0 Whenever there is removal of Brachytherapy sources from the storage safe, the approved SOURCE USAGE LOG MUST be filled out and maintained by the Physicist or designee.

2.0 Record the number and type of sources in the sfae and the date of removal for the procedure.

3.0 Record the number and type of sources removed from the storage safe and the date of removal for the procedure.

4.0 Record the number and type of sources in the storage safe after the procedure is completed, whether all unused sources have been returned and the date of return.

5.0 Record the number and type of sources removed from the patient and returned to the storage safe and the date removed.

6.0 Record total number and type of sources in the storage safe. This number should match the recorded number and type of sources prior to removal for the procedure, except for the permanent implants such as I-125.

7.0 Records are to be kept by the storage safe for future use.

St. Mary Medical Center

NO:

TITL	APPLICABLE TO: NUCLEAR MEDICINE
PERONNEL RADIATION MOONITORING	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: DATE EFFECTIVE: PAGE 1 OF 1

PURPOSE/STATEMENT:

Radiation monitoring badges must be worn by all staff personnel who work in radiation areas in order to maintain records of radiation dosages received by the individual personnel.

PROCEDURE:

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

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

3.0 All individuals who are occupationally exposed to radiation on an occassional basis, such as nurses caring for radiopharmaceutical therapy patients, will be issued either a whole body film monitor or a pocket ionizing chamber.

4.0 The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectantly high or low.

5.0 Any abnormal readings will be brought to the attention of the Regional Director of Nuclear Medicine and the Medical Director of Nuclear Medicine for appropriate measures to be taken.

6.0 Other individuals who are exposed to radiation on an occassional basis such as security personnel, housekeeping personnel, secretarial personnel and nurses who occassionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

St. Mary Medical Center

NO:

TITLE: CALIBRATION OF SURVEY INSTRUMENTS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: DATE EFFECTIVE: PAGE 1 OF 1

PURPOSE/STATEMENT:

PROCEDURE:

1.0 METHODS, FREQUENCY AND STANDARDS

1.1 The calibration and repair of survey instruments will be performed annually by the Radiation Safety Officer & Regional Health Physicist, or the Health Physics Consultant.

1.2 The model procedure for callibrating survey instruments published in Appendex B in NRC Regulatory Guide 10.8, Revision 2, August, 1987 will be followed.

1.3 Cs-137 or Ba-133 reference standards will be used as check sources on the instrument prior to use and after battery changing or service. If a reading with the same category is not within ± 20% of the desired reading after the calibration, the instrument will be recalibrated.

1.4 If the survey meter is calibrated by an outside Health Physics Consulting Service, the RAdiation Safety Officer will review all results to make sure they agree with established calibration criteria.

St. Mary Medical Center

NO:

TITLE: LEAK TEST	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: DATE EFFECTIVE: PAGE 1 OF 1

PURPOSE/STATEMENT:

PROCEDURE:

1.0 The sealed sources are required to be wipe tested by NRC Regulations.

2.0 The sealed sources will be wipe tested at semi-annual intervals by the Radiation Safety Officer, a Nuclear Medicine Technologist designated by the RSO, or a Health Physics Consultant.

3.0 The results will be reviewed by the Radiation Safety Officer and kept available for inspection.

St. Mary Medical Center

NO:

TITLE: SAFE HANDLING OF RADIOACTIVE MATERIALS	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

PROCEDURE

1.0 Wear a laboratory coat or other protective clothing at all times in areas where radioactive materials are used.

2.0 Wear disposable gloves while handling radioactive materials.

3.0 Monitor hands and clothing if contamination is suspected after handling radioactive materials.

4.0 ALWAYS use syringe shields for routine preparation of the patient doses and administration to the patient, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g. through use of a b[illegible]erfly valve.)

5.0 Do NOT eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

Do NOT store food, drink or personal effects with radioactive materials.

6.0 Assay each patient dose in the dose calibrator prior to administration. Do NOT use any doses that differ from the prescribed dose by more than 10%.

For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7.0 Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive mateials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated, low background area.

8.0 Wear TLD finger badges during elution of generator and preparation assay and injection of radiopharmaceuticals.

ST. MARY MED. CENTER GARY/HOBART

Lakeshore Health System

ADMINISTRATIVE GUIDELINE

TITLE: RADIATION SAFETY PROCEDURES FOR IMPLANT & THERAPEUTIC USE OF Cs-137 & OTHER BRACHYTHERAPY SOURCES	NO:
	APPLICABLE TO: Nuclear Med. Personnel
	ORIGINATED BY: Ken Vanderhye
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 6/6/89	DATE EFFECTIVE: 6/6/89

PURPOSE/STATEMENT:

To inform Nuclear Medicine personnel in the safe handling and use of Cs-137 sources and other Brachytherapy sources for implants.

1.0 IMPLANT PROCEDURE

1.1 The licensed physician will perform the implants, with the assistance of the radiation physicist and technologist if necessary.

1.2 A record will be maintained of the number of sources implanted and the number of sources not used. Whenever possible, dummy sources should be used in the practice with new applicators, or to determine proper positioning.

1.3 All personnel involved will be provided with pocket dosimeters or film badges.

1.4 X-rays should be taken as soon as practicable to determine sources are placed properly and accounted for.

1.5 Upon completion of the implant procedure, and after the patient has been transferred from the operating room, the room and any containers used (such as containers used in the suction, irrigation, etc.) will be carefully surveyed with a low-level G.M. survey meter.

Reference:

"The Radioactive Patient," Earl Van Rosenbeek.

Earl J. Mason, M.D., Ph.D.
Medical Dir. Nuclear Medicine

Ken Vanderhye
Regional Dir. Nuclear Medicine

ST. MARY MED. CENTER GARY/HOBART

Lakeshore Health System

ADMINISTRATIVE GUIDELINE

NO:

TITLE: PROCEDURES IN CASE OF EMERGENCY SURGERY OR DEATH OF PATIENT TREATED WITH THERAPEUTIC RADIOACTIVE MATERIAL	APPLICABLE TO: Nuclear Med. Personnel
	ORIGINATED BY: Ken Vanderhye
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 5/89 DATE EFFECTIVE: 5/89 PAGE 1 OF 1

PURPOSE/STATEMENT:

1.0 PROCEDURE

1.1 Death of Patient:

1.1-1 Notify Radiation Safety Officer. Phone number is at nursing station and in chart.

1.1-2 Do not release body until Radiation Safety Officer evaluates the radiation hazards associated with handling of the body. An instruction sheet will be issued to either the Funeral Director or to the hospital personnel required to perform work on the patient.

1.2 Emergency Surgery:

1.2-1 Notify Radiation Safety Officer. Phone number is at nursing station and in chart.

1.2-2 An instruction sheet will be issued which will give information concerning the handling of the patient and the preparation of the surgical area.

Earl J. Mason, M.D., Ph.D.
Medical Dir. Nuclear Medicine

Ken Vanderhye
Regional Dir. Nuclear Medicine

ST. MARY MED. CENTER GARY/HOBART — Lakeshore Health Syste

ADMINISTRATIVE GUIDELINE

NO:

TITLE: FUNERAL DIRECTOR INSTRUCTIONS FOR HANDLING A RADIOACTIVE CADAVER	APPLICABLE TO: Nuclear Med. Personnel
	ORIGINATED BY: Ken Vanderhye
CROSS REFERENCE:	SUPERCEDES:

DATE ISSUED: 5/31/89 DATE EFFECTIVE: 5/31/89 PAGE 1 OF

PURPOSE/STATEMENT:

To avoid radioactive contamination of funeral home personnel.

NAME OF DECEASED: _____ DATE DIED: _____

RADIOACTIVE MATERIAL: _____ ACTIVITY: _____ MILLICURIE

MAXIMUM DOSE RATE (measured on body surface): _____ mR/hr

INSTRUMENT USED: _____

PRECAUTIONS FOR STANDARD EMBALMING PROCEDURES

1) Wear rubber gloves.

2) Wear rubber or plastic apron.

3) Do not splash body fluids.

4) Wash all instruments after using.

5) Other instructions:

____ This body measures LESS than 30 mCi in the body. No further precautions are required if standard embalming procedures are used.

____ This body measures MORE than 30 mCi in the body and more than 5 mR/hr at 1 meter. Embalming must be done in hospital.

Earl J. Mason, M.D., Ph.D.
Medical Dir. Nuclear Medicine

Ken Vanderhye
Regional Dir. Nuclear Medicine

527

St. Mary Medical Cente:

TITLE: REPORTING OF MISADMINISTRATION	NO:
	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: KEN VANDERHYE/DR. T. TORABI
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 3/13/90 DATE EFFECTIVE: 3/13/90	PAGE 1 OF 1

PURPOSE/STATEMENT:

To ensure compliance with the regulations of the Nuclear Regulatory Commission concerning misadministration of radioactive sources to a patient.

PROCEDURE:

1.0 Immediately after each explant of radioactive sources, the actual delivered dose and the prescribed dose will be compared.

2.0 If the the two numbers are not the same, calculate the difference between them.

3.0 Divide the prescribed dose by 10%

4.0 If there is a $\pm$ 10% difference between the prescribed dose and the actual delivered dose, check patient's chart for documentation from Radiation Oncologist for reason for change from the prescribed dose.

5.0 If no reason for change in prescribed dose has been documented by the Radiation Oncologist and a misadministration appears to have occured, notify the Radiation Safety Officer immediately.

6.0 Peer Review will be done on each Brachytherapy case at its conclusion. Upon review of the peer review report, if any type of misadministration in accordance with 10 CFR Part 35 of the NRC Rules and Regulations has been noted, it is the responsibility of the Q.A. Coordinator or designee to report such to the Radiation Safety Officer.

7.0 It will be the responsibility of the Radiation Safety Officer to notify the NRC according to regulations if a misadministration has occured. It will also be the responsibility of the Radiation Safety Officer to report the event to the appropriate hospital administration and Medical Staff.

St. Mary Medical Center

TITLE: CODE BLUE PROCEDURE FOR RADIOACTIVE IMPLANT PATIENTS	NO:
	APPLICABLE TO: NUCLEAR MEDICINE/NURSING
	ORIGINATED BY: DR. T. TORABI/A. NALE
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

This policy has been established to ensure that good quality care is maintained for radioactive implant patients in the event of a radioactive patient should have a Cardiac or Respiratory Arrest. The approved hospital Code Blue Procedure is to be followed with the addition of the following procedures.

PROCEDURE:

1.0 In the event the Code Blue Procedure is activated on a radioactive patient the designated nursing staff employee will take to the patient's room the 10 pocket dosimeters and the charging unit located in the Code Blue narcotics box.

2.0 At the same time another designated individual will notify immediately the Radiation Oncologist. The Radiation Oncologist will remain on the phone to provide information or instructions, if necessary, to the responding physician. The Radiation Safety Officer will also be notified immediately.

3.0 At the time the Nursing Instructions are charted for an implant patient, the specific amount of time each person will be allowed to spend in the room during a Code Blue be will recorded by the Radiation Safety Officer.

4.0 Periodic inspections of the pocket dosimeters will be performed by the Radiation Safety Officer or his designee to ensure the dosimeters are zeroed out. It will be the responsibility of the Head Nurse (Supervising Nurse) to zero out all of the pocket dosimeters prior to distributing for use.

5.0 Pregnant employees may NOT enter the radioactive patient's room to assist during the Code Blue.

6.0 Each person entering the patient's room in response to the Code Blue, will be given a pocket dosimeter, which has been zeroed out, to wear during the time spent in the patient's room.

7.0 At the end of each employee's allowed time in the room, the designated nursing employee will record the employees name and their final dosimeter reading on the approved form prior to issuing the dosimeter to the employee who is assuming the responsibilities of the first employee.

i.e, When the first Respiratory Therapy Tech. leaves the room their name and final dosimeter reading is recorded; the name of the second Respiratory Therapy Tech. is recorded and the final reading of the previous Tech. becomes their beginning reading. The dosimeter is then given to the replacement Tech. and he then may enter the room.

8.0 After the Code Blue has ended, all final dosimeter readings are to be recorded next to the appropriate employee's name and all pocket dosimeters are to be zeroed out.

9.0 If the Code Blue should occur on the midnight shift when there is minimum staff and there may not be a replacement for each staff member involved in the procedure, the person may remain in the room for a maximum of _____ hours or _____mR.

10.0 If during the course of providing nursing care to the implant patient, the nurse notices a change in the patient's condition which might result in a possible cardiac or respiratory arrest, the Radiation Oncologist is to be notified immediately to evaluate the patient.

RADIATION SAFETY COMMITTEE CHAIRMAN

RADIATION SAFETY OFFICER

CHAIRMAN - CODE BLUE COMMITTEE

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

___ ST. CATHERINE HOSPITAL Ext. 7319 ___ SMMC-GARY Ext. 8295 ___ SMMC-HOBART Ext. 6280

NURSING INSTRUCTIONS FOR PATIENTS

WITH IMPLANTS OF _____ BRACHYTHERAPY SOURCES

PATIENT NAME: _____ RM. #: _____ DATE: _____

ACTIVITY: _____ TIME OF IMPLANT: _____ AM / PM

DATE OF EXPLANT: _____ TIME OF EXPLANT: _____ AM / PM

BASIC RULES TO FOLLOW:

VISITORS: Visitors should sit at least _____ feet from the patient for no more than _____ hours per day unless Special Permit is issued.

TIME: Every effort should be made by Nursing Staff to spend the least possible amount of time in the patient's room during the course of implant treatment.

DISTANCE: When NOT giving direct care, keep distance of a least 3 feet from the patient

SPECIAL INSTRUCTIONS:

1. Patient must remain in his room at all times. The entrance to the room must have a "CAUTION - RADIATION AREA" sign posted in such a manner that anyone entering the room would immediately notice the CAUTION sign.

2. Pregnant or under 18 years of age employees should NOT be assigned to the personal care of the implant patient. NO PREGNANT EMPLOYEE SHOULD CARE FOR THE IMPLANT PATIENT.

3. Nurses MUST wear a pocket dosimeter or film badge while in the room at all times. One of the dosimeters will be assigned to each Nurse on the shift who will be responsible for the patient's care. Instructions for pocket dosimeters are printed on the top of the Nurse's exposure report.

4. At change of shift or if another Nurse is assigned to this patient, the responsibility of reporting ALL INSTRUCTIONS pertaining to this patient shall be that of the previous Nurse which has been caring for this patient or the Nursing Supervisor of the Unit.

5. Floor and trash CANNOT be cleaned by Housekeeping personnel until the patient is discharged or if the items have been approved by the Radiation Oncologist or the Radiation Safety Officer (RSO) or his disignee.

6. If the implant instrument or source(s) have become dislodged, use the long forceps and place in the lead container. The container and the forceps are left in the patient's room during the course of the implant.

   IMMEDIATELY NOTIFY: The Attending Physician, the Radiation Oncologist, and the Radiation Safety Officer (RSO) or his designee.

7. Surgical dressings and bandages used to cover the area of the implant may NOT be discarded until they have been surveyed with a survey meter by the Radiation Safety Officer (RSO) or his designee. Also all utensils and other such items MUST be checked with a survey meter to ensure that no radioactive source has been inadvertently displaced into them.

8. Visitors will be limited to those 18 years of age or older unless other instructions are noted on the patient's chart. NO PREGNANT VISITORS ARE ALLOWED.

IMPORTANT NOTICE: FOLLOW # 9 thru # 11 FOR ALL GYNECOLOGICAL IMPLANT PATIENTS

9. Perineal care is NOT given during gynecological treatment. The perineal pad MAY be changed when necessary unless orders to the contrary have been written on the chart.

10. Bed baths given by the Nurse should be OMITTED while the radioactive sources are in place.

11. OTHER: _____

_____

12. CHANGES IN PATIENT CONDITION:

    At any time should the patient's condition change or deteriorate, especially the onset of a possible Cardiac Arrest or Respiratory Distress, IMMEDIATELY CALL:

    ATTENDING PHYSICIAN, RADIATION ONCOLOGIST, and follow the established hospital Code Blue Procedue.

13. DISCHARGE OR TRANSFER OF AN IMPLANT PATIENT:

    Before the patient is discharged or transferred to another room or Unit PLEASE FOLLOW THESE INSTRUCTIONS:

    A. Confirm Discharge or Transfer with the Attending Physician and the Radiation Oncologist.

    B. Notify the Radiation Safety Officer (RSO).

    C. Do NOT assign the room to another patient until the Radiation Safety Officer (RSO has surveyed and officially released the room.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

PROCEDURES IN CASE OF EMERGENCY SURGERY OR DEATH
OF A PATIENT TREATED WITH RADIOACTIVE MATERIAL

14. DEATH OF A PATIENT:

A. Immediately notify the Radiation Safety Officer or designee. Phone number is at Nursing station and in patient's chart.

B. Do NOT release the body until the Radiation Safety Officer or designee evaluates the radiation hazards associated with the handling of the body.

C. An Instruction Sheet will be issued to either the Funeral Director or the hospital personnel required to perform work on the patient by the Radiation Safety Officer or designee.

15. EMERGENCY SURGERY:

A. Notify the Radiation Safety Officer or designee. Phone number is at the Nursing station and in the patient's chart.

B. An Instruction Sheet will be issued providing information concerning the handling of the patient and the preparation of the Surgical area.

RADIATION ONCOLOGIST: _____

PHONE #: _____

RADIATION SAFETY OFFICER: _____

PHONE #: _____

NURSING CHECK LIST FOR IMPLANT PATIENTS

_____SCH _____SMMC-GARY _____SMMC-HOBART

PATIENT NAME: _____ ROOM #: _____

_____ 1. Nurse's Exposure Sheet (Posted on door of patient's room)

_____ 2. Nursing Instructions on the patient's chart

_____ 3. Completed Room Survey Form on the patient's chart

_____ 4. Completed Dosimetry Form on the patient's chart

_____ 5. CAUTION SIGN posted on door of patient's room

_____ 6. CAUTION SIGN on patient's chart

_____ 7. CAUTION SIGN on foot of patient's bed

_____ 8. Source Inventory Form on patient's chart

_____ 9. _____ Pocket Dosimeters

_____ 10. _____ Forceps in patient's room

_____ 11. Survey Meter in patient's room

_____ 12. Radiation Lead Safe and Cart

_____ 13. Others: _____

_____

ALL ITEMS CHECKED ARE PRESENT:

_____ RADIATION ONCOLOGIST, MD _____ DATE/TIME

_____ RADIATION SAFETY OFFICER _____ DATE/TIME

_____ NURSING UNIT SUPERVISOR _____ DATE/TIME

3/90

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

___ ST. CATHERINE HOSPITAL Ext. 7319

___ SMMC-GARY Ext. 8295

___ SMMC-HOBART Ext. 6280

NURSING INSTRUCTIONS FOR PATIENTS

WITH IMPLANTS OF _____ RADIOPHARMACEUTICAL SOURCES

PATIENT NAME: _____ RM. #: _____ DATE: _____

ACTIVITY: _____ TIME OF IMPLANT: _____ AM / PM

BASIC RULES TO FOLLOW:

VISITORS: Visitors should sit at least _____ feet from the patient for no more than _____ hours per day unless Special Permit is issued.

TIME: Every effort should be made by Nursing Staff to spend the least possible amount of time in the patient's room during the course of implant treatment.

DISTANCE: When NOT giving direct care, keep distance of a least 3 feet from the patient

SPECIAL INSTRUCTIONS:

1. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes.

2. NO nurse, visitor or attendant who is pregnant or under the age of 18 years, will be permitted in the room of a patient who has receiveed a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors SHOULD be asked if they are pregnant.

3. Attending personnel MUST wear rubber or disposable plastic gloves when handling urinal bedpans, emesis basins or other containers having any material obtained from the body of the patient. The gloves MUST be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

4. Disposable items SHOULD be used in the care of these patients whenever possible. These items SHOULD be placed in the designated waste container. Contact Nuclear Medicine Department for proper disposal of the contents of the designated waste container.

5. All clothing and bed linens used by the patient SHOULD be placed in the laundry bag provided and left in the patient's room to be checked by the Radiation Safety Officer (RSO) or designee.

6. All non-disposable items SHOULD be placed in a plastic bag and left in the patient's room to be checked by the Radiation Safety Officer (RSO) or designee.

7. The patient will be instructed to void in the toilet and flush the toilet at least 3 times after use. If the patient is bedridden a separate urinal or bedpan should be provided. The urinal or bedpan should be flushed several times with hot soapy water after each use.

8. If the Nurse helps to collect the excretia, she SHOULD wear disposable gloves. Afterwards, she SHOULD wash her hands with the gloves on and again when the gloves are removed. The gloves SHOULD be placed in the designated waste container.

9. Disposable plates, cups, and eating utensils WILL be used by patients who are treated with Iodine-131.

10. Vomitting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of the linens and/or floor.

    In any such situations, or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or designee IMMEDIATELY. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

11. All vomitus MUST be kept in the patient's room for disposal by the Nuclear Medicine department. Feces need NOT be routinely saved, unless ordered on the patient's chart. The same toilet SHOULD be used by the patient at all times and it SHOULD be well flushed.

12. Utmost precautions MUST be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or designee IMMEDIATELY.

13. If a Nurse, attendant, or anyone else knows or suspects that his skin or clothing (incluginds shoes) has been contaminated, notify the Radiation Safety Officer or his designee IMMEDIATELY. The person SHOULD remain in the patient's room and NOT walk around the hospital. If the hands SHOULD become contaminated, wash IMMEDIATELY with soap and hot water.

14. At change of shift or if another Nurse is assigned to this patient, the responsibility of reporting ALL INSTRUCTIONS pertaining to this patient shall be that of the previous Nurse which has been caring for this patient or the Nursing Supervisor of the Unit.

15. Other Instructions: _____

_____

_____

16. CHANGES IN PATIENT CONDITION:

At any time should the patient's condition change or deteriorate, especially the onset of a possible Cardiac Arrest or Respiratort Distress, IMMEDIATELY CALL:

ATTENDING PHYSICIAN, RADIATION ONCOLOGIST, and follow the established hospital Code Blue Procedure.

17. DISCHARGE OR TRANSFER OF AN IMPLANT PATIENT:

Before the patient is discharged or transferred to another room or Unit, PLEASE FOLLOW THESE DIRECTIONS:

A. Confirm the Discharge or Transfer with the Attending Physician and the Radiation On logist

B. Notify the Rdiation Safety Officer (RSO).

C. Do NOT assign the room to another patient until the Radiation Safety Officer (RSO has surveyed and officially released the room.

RADIATION ONCOLOGIST: _____

PHONE #: _____

RADIATION SAFETY OFFICER: _____

PHONE #: _____

RADIOPHARMACEUTICAL THERAPY

SAFETY EQUIPMENT, SIGNS, AND FORMS NEEDED

18. THE FOLLOWING ITEMS SHOULD BE IN THE YELLOW CRASH CART OUTSIDE THE PATIENT'S ROOM:

_____ ABsorbent Paper - 1 roll

_____ Roll of Plastic

_____ Plastic Gloves - 1 Box

_____ Plastic Bags - Large & Small Sizes

_____ White Paper Jump Suits - 5

_____ Shoe Covers - 1 Box

_____ Surgeon Masks - 1 Box

_____ Masking Tape - 2 rolls

_____ Test Tubes and Cotton Swabs for Wipe Test

_____ Deion Solution - 1 Bottle

_____ Paper Towels

_____ Labels for Marking Bags

4321 Fir Street
East Chicago, IN 46312
(219) [illegible]-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

PROCEDURES IN CASE OF EMERGENCY SURGERY OR DEATH
OF A PATIENT TREATED WITH RADIOACTIVE MATERIAL

19. DEATH OF A PATIENT:

A. Immediately notify the Radiation Safety Officer or designee. Phone number is at Nursing station and in patient's chart.

B. Do NOT release the body until the Radiation Safety Officer or designee evaluates the radiation hazards associated with the handling of the body.

C. An Instruction Sheet will be issued to either the Funeral Director or the hospital personnel required to perform work on the patient by the Radiation Safety Officer or designee.

20. EMERGENCY SURGERY:

A. Notify the Radiation Safety Officer or designee. Phone number is at the Nursing station and in the patient's chart.

B. An Instruction Sheet will be issued providing information concerning the handling of the patient and the preparation of the Surgical area.

Written: 8/1/83
Revised: 2/90

NURSING CHECK LIST FOR RADIOPHARMACEUTICAL PATIENTS

_____ SCH _____ SMMC-GARY _____ SMMC-HOBART

PATIENT NAME: _____ ROOM #: _____

_____ 1. Nurse's Exposure Sheet (Posted on door of patient's room)

_____ 2. Nursing Instructions on the patient's chart

_____ 3. Completed Room Survey Form on the patient's chart

_____ 4. Completed Dosimetry Form on the patient's chart

_____ 5. CAUTION SIGN posted on door of patient's room

_____ 6. CAUTION SIGN on patient's chart

_____ 7. CAUTION SIGN on foot of patient's bed

_____ 8. Source Inventory Form on patient's chart

_____ 9. _____ Pocket Dosimeters

_____ 10. Survey Meter in patient's room

_____ 11. Yellow Crash Cart with required items

_____ 12. Others: _____

_____

ALL ITEMS CHECKED ARE PRESENT:

_____ RADIATION ONCOLOGIST, MD _____ DATE/TIME

_____ RADIATION SAFETY OFFICER _____ DATE/TIME

_____ NURSING UNIT SUPERVISOR _____ DATE/TIME

3/90

PHYSICIAN PEER REVIEW

1. Brachytherapy was appropriate choice of treatment for patient diagnosis
2. Treatment administered with clinical records and patient history available prior to treatment beginning.
3. Type of Source used was appropriately chosen for the patient diagnosis and tumor site.
4. Treatment Plan was appropriate for patient's diagnosis
5. Prescribed dose documented prior to implant of sources.
5. Simulation Film was marked appropriately for designated tumor treatment site, dated and signed prior to treatment beginning by the Radiation Onocologist.
6. Computer Plan was completed, reviewed, dated and signed by the Oncologist prior to tx. and appropriate for designated tumor treatment.
7. Radiation dosage administered was appropriate for treatment area.
8. Blood counts were taken prior to treatment.
9. Treatment was given with WBC below 2000 minimum.
10. Treatment was given with Platelett count below 50,000
11. Sources were removed at designated date and time
12. If change in scheduled removal time, is there a written reason why
13. Actual radiation dosage received was within $\pm$ 10% of proposed dosage.
14. If designated as an Emergency Case, there was a documented reason by physician.
15. If applicable, was Radiation Oncologist reason for emergency justifiable

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: ORAL CAVITY DATE: _____

PATIENT #: _____ _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Stage I or II
2. Stage III
3. Postoperative irradiation to patient with one of the following:
   a) Positive lymph nodes
   b) Positive surgical margins
   c) Large primary mor
4. Pre-operative irradiation with either Stage II or Stage III
5. Combined chemotherapy and radiotherapy for one of the following:
   a) Stage II
   b) Stage III
   c) Stage IV - No M1
6. Recurrent tumor after previous surgery or moderate irradiation

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Locoregional recurrent tumor after previous curative irradiation
3. Stage IV (advanced disease)

RADIATION ONCOLOGIST SIGNATURE: _____

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatm

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: PROSTATE DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Stage A2
2. Stage B
3. Stage C & D1
4. Postoperative irradiation to patient with either positive lymph nodes or positive surgical margins.

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Locoregionally advanced CA with one of the following:
   a) Pelvic pain
   b) Hematuria
   c) Urinary tract obstruction
   d) Leg edema
3. Prevention of gyneromastia
4. Patient with distant metastasis

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order amd found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: URINARY BLADDER DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Preoperative irradiation to patient with one of the following:
   a) B2
   b) C & D1
   c) Poorly differnetiated CA
2. Postoperative irradiation to patient with eirter positive lymph nodes or positive surgical margins
3. Refused surgery

PALLIATIVE:
1. Patient with pelvic and periaortic lymph node metastasis
2. Locoregionally advanced CA with one of the following:
   a) Pelvic pain
   b) Hematuria
   c) Urinary tract obstruction
   d) Leg edema
3. Patient with distant metastasis

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order amd found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: LUNG DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

PROCEDURE: EBI

CURATIVE:
1. Medically inoperaable patient with tumor limited to the chest
2. Refused surgery for tumor limited to the chest
3. Apical CA
4. Postoperative radiotherapy to the patient with one of the followi
   a) Hilar node metastasis
   b) Mediastinal node metastasis
   c) Positive surgical margins
   d) Parietal pleural invasion
5. Preoperative radiotherapy
6. Locoregional recurrence after previous surgery

PALLIATIVE:
1. Medically intolerable for curative radiotherapy
2. Patient with distant metastasis
3. Bronchial obstruction
4. Bronchial bleeding
5. Superior vena cava syndrome (sometimes without a definitive histologic diagnosis)
6. Locoregional recurrence after previous curative radiotherapy

PROCEDURE: EBI and/or Intrabronchial Brachytherapy

CURATIVE: 1. Boost dose to bronchial tumor

PALLIATIVE: 1. Recurrent obstructive bronchial tumor

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____ _____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: UTERINE CERVIX DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

PROCEDURE: EBI and/or Brachytherapy

CURATIVE:
1. Stage I B
2. Stage II A or B
3. Stage III A or B
4. Stage IV A
5. Postoperative irradiation to patient with one of the following:
   a) Positive pelvic lymph nodes
   b) Positive surgical margins
6. Preoperative irradiation to patient with either Stage IB or Stage
7. Local recurrence after previous surgery

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Stage IV B (distant metastasis)
3. Recurrent CA after previous surgery and/or radiotherapy

PROCEDURE: Brachytherapy

CURATIVE:
1. Stage I A

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: UTERINE CORPUS DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Medically or technically inoperable patient with one of the follo
   a) Stage IA or B
   b) Stage II
   c) Stage III
2. Stage IV - No M1
3. Postoperative irradiation to patient with one of the following:
   a) Stage IA or B with Grade 2 or 3
   b) Stage IB with Grade 1
   c) Stage IA or B with more than 1/3 myometrium invasion.
   d) Stage II
   e) Stage III
4. Preoperative irradiation to patient with one of the following:
   a) Stage IA or B with Grade 2 or 3
   b) Stage IB with Grade 1
   c) Stage II
5. Locoregional recurrence after previous surgery

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Stage IVB (distant metastasis)

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: PHARYNX DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Stage I or II
2. Stage III
3. Postoperative irradiation to patient with one of the following:
   a) Positive lymph nodes
   b) Positive surgical margins
   c) Large primary tumor
4. Preoperative irradiation to patient with either Stage II or III
5. Combined chemotherapy and radiotherapy for one of the following:
   a) Stage II
   b) Stage III
   c) Stage IV - No M1
6. Locoregional recurrent tumor after previous surgery or moderate irradiation

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Locoregional recurrent tuumor after previous curative irradiation
3. Stage IV (advanced tumor)

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatmer

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: BREAST DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Consrvative surgery with one of the following:
   a) Excisional biopsy (Lumpectomy)
   b) Segmental anastectomy (Quadrantectomy)
2. Postoperative irradiation to patient with one of the following:
   a) Total mastectomy
   b) Modified radical mastectomy
3. Preoperative irradiation
4. Combined treatment for locally advanced and inflammatory cancer
5. Locoregional recurrent CA after surgery.

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Patient with distant metastasis.

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: ANUS DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

PROCEDURE: EBI and/or Brachytherapy

CURATIVE:
1. Medically inoperable patient
2. Refused surgery
3. Post-operative irradiation to the patient with one of the followir
   a) Positive lymph nodes
   b) Positive surgical margins
   c) Residual tumor
4. Preoperative irradiation
5. Locoregional recurrance after previous surgery

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Locoregional recurrance after curative irradiation
3. Patient with distant metastasis

PROCEDURE: EBI plus Chemotherapy

CURATIVE:
1. Epidermoid CA

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

__ ____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: ESOPHAGUS DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Intraluminal Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. Tumors up to 10cm in length and limited to the locoregional nodes (no TBF)
2. Combination with chemotherapy and/or surgery.
3. Medically inoperable patient
4. Cervical Esophageal CA
5. Postoperative irradiation to patient with one of the following:
   a) Unresectable tumor
   b) Positive surgical margin
   c) Positive nodes
6. Preoperative irradiation

PALLATIVE:
1. Medically intolerable for curative irradiation.
2. Locoregional recurrance after previous surgery
3. Patient with distant metastasis

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

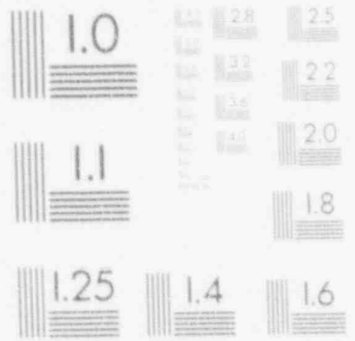
_____ I have reviewed this order and found the order NOT appropriate for treatme

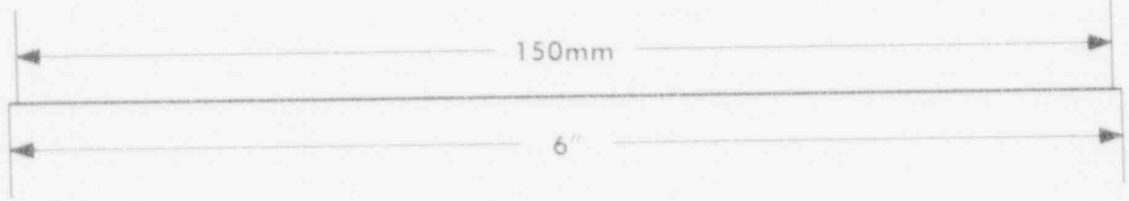
_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

1

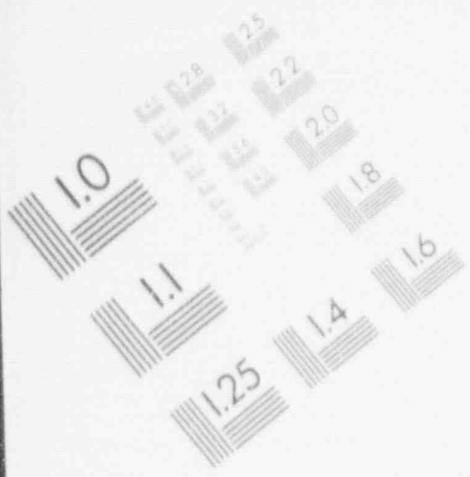
IMAGE EVALUATION TEST TARGET (MT-3)

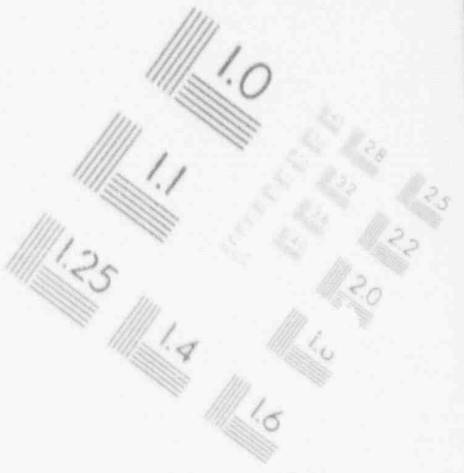


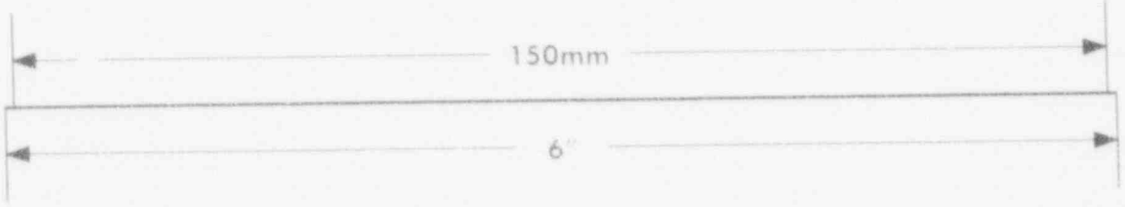


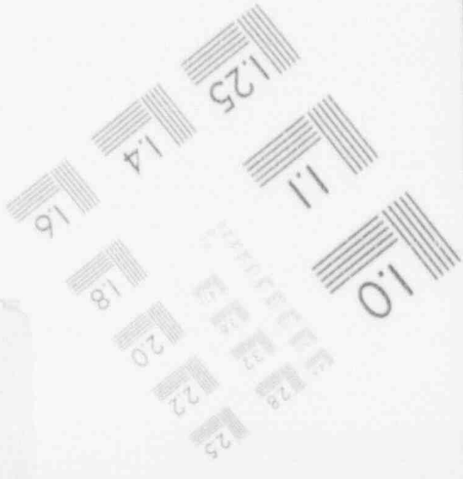
1

IMAGE EVALUATION
TEST TARGET (MT-3)



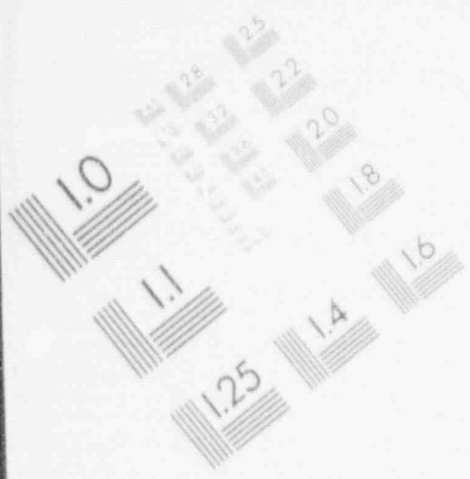


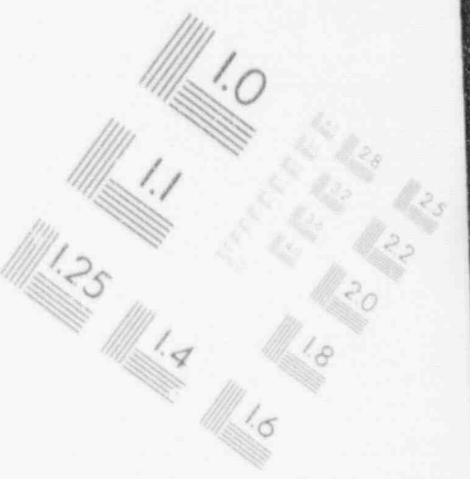


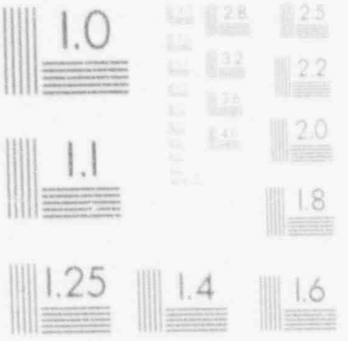


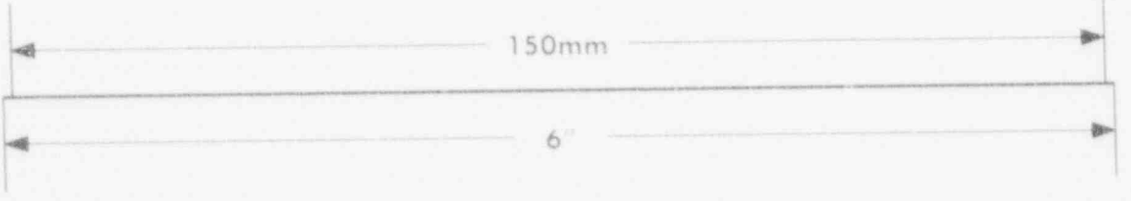
1

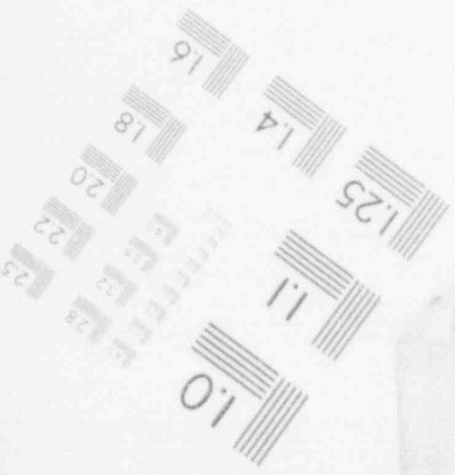
IMAGE EVALUATION
TEST TARGET (MT-3)

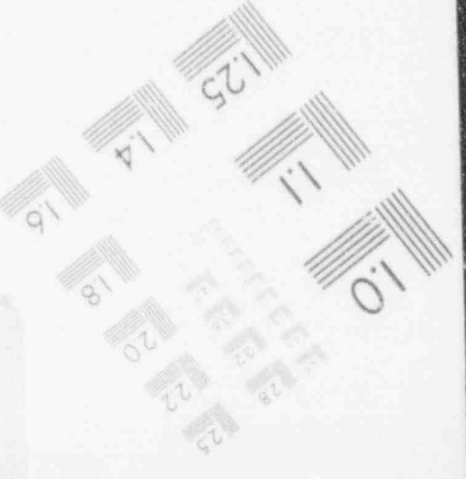












RADIATION ONCOLOGY QUALITY ASSURANCE
APPROPRIATENESS REVIEW

TREATMENT AREA: LARYNX DATE: _____

PATIENT #: _____ AGE: _____

PHYSICIAN REQUESTING CONSULT: _____

DATE CONSULT REQUESTED: _____ DATE CONSULT DONE: _____

APPROPRIATENESS CRITERIA

PROCEDURE: EBI and/or Brachytherapy

ONE OF THE FOLLOWING MUST BE PRESENT: (CIRCLE APPROPRIATE CRITERIA)

CURATIVE:
1. In situ CA
2. Stage I or Stage II
3. Stage III
4. Postoperative irradiation to patient with one of the following:
   a) Positive nodes
   b) Positive surgical margins
   c) Bulky primary tumor
5. Preoperative irradiation to patient with either Stage II or III
6. Combined chemotherapy and radiotherapy to patient with one of the following:
   a) Stage II
   b) Stage III
   c) Stage IV - No M1
7. Locoregional recurrence after previous surgery or moderate irradi

PALLIATIVE:
1. Medically intolerable for curative irradiation
2. Recurrent tumor after previous curative irradiaiton
3. Stage IV (advanced tumor)

COMMENTS: _____

_____

_____ I have reviewed this order and found the order appropriate for treatment.

_____ I have reviewed this order and found the order NOT appropriate for treatme

_____ Follow-up review is indicated regarding orders for the treatment.

_____
Physician Reviewer

1. FORMATION OF A QUALITY ASSURANCE COMMITTEE FOR BRACHYTHERAPY:

A. In accordance with 10 CFR 35.22 a Nursing representative is required as a member of the Radiation Safety Committee, St. Mary Medical Center - Hobart have provided for Nursing representation within the Radiation Safety Committee's composition. This information was provided previously with the application for renewal of license # 13-03459-02 submitted on October 20, 1989 in Item # 10.1 "Radiation Safety Committee".

The Quality Assurance Committee for Brachytherapy as submitted in the Amendment Application is a sub-committee of the full Radiation Safety Committee. This subdivision or sub-committee of the Radiation Safety Committee has been organized from and composed of members from the Radiation Safety Committee for the specific purpose of handling the quality assurance aspects of the Brachytherapy program. Nursing representation is not required nor necessary for all areas of quality assurance, e.g. physics or Physician documentation. However, when items involving nursing aspects of the patient's care and treatment are to be discussed and/or evaluated, representation from Nursing will be provided at the sub-committee meetings, just as Dietary, Housekeeping or any other Ancillary department will be represented when those areas are discussed.

B. As with any sub-committee, the Quality Assurance Committee for Brachytherapy works under the direction of, is responsible to, and reports to the full Radiation Safety Committee. All actions of a sub-committee must be reviewed, approved or disapproved by the members of the committee to which it is a part of.

As with any changes to or implentation of policies or procedures which involves the use of ionizing radiation, those of the Q.A. sub-committee MUST be approved by the members of the Radiation Safety Committee PRIOR to implementation.

Regardless of whether the members of the Radiation Safety Committee approve or disapprove a report and/or recommendations from the Q.A. Committee for Brachythera the Radiation Safety Committee MUST review the report and/or recommendations and incorporate them into the minutes noting the action that was taken by the Radiation Safety Committee members.

C. St. Mary Medical Center Quality Review Committee has developed and implemented certain policies and procedures which delineate the type of forms to be used in reporting quality assurance activities. All committees of the hospital have delineated channels for reporting. There are two main Quality Review Committees within the facility:

1. ADMINISTRATIVE Q.R. COMMITTEE - All quality assurance activities involving the administrative, technical, or clerical areas of departments are assigned to report to this committee.
2. MEDICAL STAFF Q.R. COMMITTEE - All quality assurance activities involving medical physician treatment and care of a patient are assigned to report to this committee.

The Radiation Safety Committee reports to both the Administrative and Medical Staff Quality Review Committees. Both the Administrative and Medical Staff Q.R. Committees report the the Executive Staff and the Board of Directors of the hospital.

D. The Purpose/Statement of a Quality Assurance Plan does not and should not delineate specific duties and tasks or designate the titles of those persons responsible for specific duties.

The purpose, goals and objectives are simply what the titles indicate for the entire quality assurance program and no specific duties or responsibilities.

As indicated in the documentation provided with the amendment application, the "Indicators To Be Monitored" specifies titles of individuals responsible for the monitoring for and documenting of misadministrations and/or incidents are pursuant to 10 CFR Part 35 and 10 CFR Part 20 requirements. (Attachment Item # 1)

A copy of policy and procedure "Reporting of Misadministration" was also attached which delineates the procedure to be used & to whom the repsonsibility for reporting is assigned. (Attachment Item # 2).

E. As with any organization the normal channels generally followed to correct a problem is through direct verbal communication and/or written communication. If these two avenues of communication fail to provide an acceptable resolution to the identified problem, the specific problem with corrective action will be presented to the members of the Radiation Safety Committee for their assessment of the problem and suggested solution(s). The Radiation Safety Committee's assistance and authority through the involvement of the Chairman or designee will be ascertained to correct the problem and implement a solution.

2. NURSING INSTRUCTIONS:

Attached are copies of the "Nursing Instructions for Patients with Implants of Brachytherapy Sources" (Attachment Item # 3) and "Nursing Instructions for Patient with Implants of Radiopharmaceutical Sources" (Attachment Item # 4).

These instructions are completed by the Radiation Safety Officer and the Radiation Oncologist at the time of the source implant.

The final page of each set of instructions is a Checklist Sheet which must be reviewed and verified with the Nursing Unit Supervisor by the Radiation Safety Officer and the Radiation Oncologist and all three individuals must sign and date the checklist.

The signed original checklist and completed Nursing instruction sheets are filed in the patient's chart in Nuclear Medicine. A copy of the signed checklist and completed Nursing instructions sheets are filed on the patient's chart on the Nursing unit.

3. PROCEDURES FOR ORDERING RADIOACTIVE MATERIAL:

As indicated in the documentation provided with the amendment application, the policy "Procedure for Ordering Radioactive Material" (Attachment Item # 5) and from "Authorized User Request For Therapeutic Dosages of Radioactive Material and Patient Scheduling" (Attachment Item # 6), the Radiation Safety Officer must sign and date under the Authorized Physician User signature prior to any radioactive materials are ordered.

4. STORAGE, INVENTORY, WIPE TESTS OF SOURCES:

As indicated in the documentation provided with the amendment application, policy entitled "Storage, Inventory, Wipe Tests of Sources" (Attachment Item # 7 and "Indicators To Be Monitored" (Attachment Item # 1) specifies how it is to be accomplished, when to be done, and who is responsible for completing.

As previously stated in response 1.D., the specific duties and title designation of persons responsible for specific duties do not belong in the purpose of the quality assurance plan. The quality assurance plan is to give an overall view of the quality assurance program. The policies and procedures delineate the responsibilities and specific duties, how to perform the require duties, and to whom the tasks are assigned.

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Calibration of Radiation Measuring Instruments	To ensure that the instruments used in surveys & implant source calibration are operating correctly.	Measure instrument response using a radioactive source	Radiation Physicist or Designee	Every 6 months
Calibration of Radioactive Sources	To ensure that the proper dose of radiation is administered.	Determine the radioactivity of the source used in the patient for Brachytherapy.	Radiation Physicist or Designee	Prior to each Brachytherapy procedure
Personnel Radiation Monitoring	To ensure that radiation dosage received by personnel is as low as possible and within the radiation safety guidelines	Individual radiation monitor badges. Written reports from monitoring company monthly. Review of report upon receipt.	Radiation Physicist or Designee	Monthly
Personnel Dosimeter Monitoring	To ensure that radiation dosage received by personnel is as low as possible and within the radiation safety guidelines.	Log sheet for individual dosimeter readings for each Brachytherapy patient.	Radiation Physicist or Designee	Each Brachytherapy Procedure
Radiation Survey of Radioactive Brachytherapy Patient and hospital room	To ensure that the radiation levels are within acceptable regulatory guidelines.	Measurements of radiation exposure are taken in the patient's room and the surrounding areas.	Radiation Physicist	Each Brachytherapy Patient

ST. MARY MEDICAL CENTER
GARY/HOBART, INDIANA

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Proficiency in Expediting Brachytherapy Procedures	To ensure proper time management of staff during work shifts with adherence to policy and protocol for procedures.	Daily patient schedules Completed Procedure Record	Radiation Oncologist	Monthly
Infection Control	To ensure adherence to the use of appropriate barrier protection methods to prevent exposure to or transmission of infections and/or diseases in the health care setting.	Review of procedure check sheets documented during each Brachytherapy procdure.	Technologists Radiation Oncologist	Each Case Monthly
Appropriateness of Brachytherapy Requests	To evaluate appropriateness of Brachytherapy treatment vs. diagnosis and acceptable standards of practice.	Patient Medical Record Brachytherapy Order	Designated Radiation Oncologist	Monthly
Physician Peer Review	To ensure adherence to policies and protocols, Hospital and Department.	Physician Peer Review of medical records of patient's undergoing Brachytherapy and retrospective review of completed patients.	Designated Radiation Oncologist	Monthly

INDICATORS TO BE MONITORED

INDICATOR	COMMENTS	HOW IT IS MONITORED	BY WHOM	HOW OFTEN
Chart Review	To ensure adherence to departmental policies and procedures and acceptable standards of practice	Review of each patient's charts currently and retrospectively	Q.A. Coordinator	Each Brachytherapy Procedure
Misadministration of internal beam radiation	To ensure adherence to USNRC rules & regulations with regard to administration of radiactive sources in patients.	Review of each patient's prescribed dose and delivered dose to verify not above or below 10% .	Q.A. Coordinator	Each Brachytherapy Procedure
Annual Radiation Safety Inspection	To verify that all radioactive sources are being used in compliance with the USNRC	Complete the Radiation Safety Inspection report of USNRC	Radiation Safety Officer	Annually
Inventory of Brachytherapy Sources	To verify the number of sources and sizes stored within the facility to ensure all sources are present.	Visual inventory count of radioactive sources and sizes in storage cross checked against previous inventory count	Radiation Physicist or designee	Quarterly
Wipe Test	To ensure each shipment of radioactive material received has not been contaminated by radiation.	Monitoring of both the outside and the inside of the package prior to acceptance by the facility	Radiation Safety Officer or designee	Each shipment recieved

St. Mary Medical Cente

TITLE: REPORTING OF MISADMINISTRATION	NO:
	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: KEN VANDERHYE/DR. T. TORAB
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED: 3/13/90	DATE EFFECTIVE: 3/13/90

PURPOSE/STATEMENT:

To ensure compliance with the regulations of the Nuclear Regulatory Commission concerning misadministration of radioactive sources to a patient.

PROCEDURE:

1.0 Immediately after each explant of radioactive sources, the actual delivered dose and the prescribed dose will be compared.

2.0 If the the two numbers are not the same, calculate the difference between them.

3.0 Divide the prescribed dose by 10%

4.0 If there is a $\pm$ 10% difference between the prescribed dose and the actual delivered dose, check patient's chart for documentation from Radiation Oncologist for reason for change from the prescribed dose.

5.0 If no reason for change in prescribed dose has been documented by the Radiation Oncologist and a misadministration appears to have occured, notify the Radiation Safety Officer immediately.

6.0 Peer Review will be done on each Brachytherapy case at its conclusion. Upon review of the peer review report, if any type of misadministration in accordance with 10 CFR Part 35 of the NRC Rules and Regulations has been noted, it is the responsibility of the Q.A. Coordinator or designee to report such to the Radiation Safety Officer.

7.0 It will be the responsibility of the Radiation Safety Officer to notify the NRC according to regulations if a misadministration has occured. It will also be the responsibility of the Radiation Safety Officer to report the event to the appropriate hospital administration and Medical Staff.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health Syster

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Cen
Gary and Hobart, IN

___ ST. CATHERINE HOSPITAL Ext. 7319

____ SMMC-GARY Ext. 8295

___ SMMC-HOBART Ext. 6280

NURSING INSTRUCTIONS FOR PATIENTS

WITH IMPLANTS OF _____ BRACHYTHERAPY SOURCES

PATIENT NAME: _____ RM. #: _____ DATE: _____

ACTIVITY: _____ TIME OF IMPLANT: _____ AM / PM

DATE OF EXPLANT: _____ TIME OF EXPLANT: _____ AM / PM

BASIC RULES TO FOLLOW:

VISITORS: Visitors should sit at least _____ feet from the patient for no more than _____ hours per day unless Special Permit is issued.

TIME: Every effort should be made by Nursing Staff to spend the least possible amount of time in the patient's room during the course of implant treatment.

DISTANCE: When NOT giving direct care, keep distance of a least 3 feet from the patien

SPECIAL INSTRUCTIONS:

1. Patient must remain in his room at all times. The entrance to the rrom must have a "CAUTION - RADIATION AREA" sign posted in such a manner that anyone entering the room would immediately notice the CAUTION sign.

2. Pregnant or under 18 years of age employees should NOT be assigned to the personal care of the implant patient. NO PREGNANT EMPLOYEE SHOULD CARE FOR THE IMPLANT PATIENT.

3. Nurses MUST wear a pocket dosimeter or film badge while in the room at all times. One of the dosimeters will be assigned to each Nurse on the shift who will be responsible for the patient's care. Instructions for pocket dosimeters are printed on the top of the Nurse's exposure report.

4. At change of shift or if another Nurse is assigned to this patient, the responsibility of reporting ALL INSTRUCTIONS pertaining to this patient shall be that of the previous Nurse which has been caring for this patient or the Nursing Supervisor of the Unit.

5. Floor and trash CANNOT be cleaned by Housekeeping personnel until the patient is discharged or if the items have been approved by the Radiation Oncologist or the Radiation Safety Officer (RSO) or his disignee.

6. If the implant instrument or source(s) have become dislodged, use the long forceps and place in the lead container. The container and the forceps are left in the patient's room during the course of the implant.

   IMMEDIATELY NOTIFY: The Attending Physician, the Radiation Oncologist, and the Radiation Safety Officer (RSO) or his designee.

7. Surgical dressings and bandages used to cover the area of the implant may NOT be discarded until they have been surveyed with a survey meter by the Radiation Safety Officer (RSO) or his designee. Also all utensils and other such items MUST be check with a survey meter to ensure that no radioactive source has been inadvertently displaced into them.

8. Visitors will be limited to those 18 years of age or older unless other instruction are noted on the patient's chart. NO PREGNANT VISITORS ARE ALLOWED.

IMPORTANT NOTICE: FOLLOW # 9 thru # 11 FOR ALL GYNECOLOGICAL IMPLANT PATIENTS

9. Perineal care is NOT given during gynecological treatment. The perineal pad MAY be changed when necessary unless orders to the contrary have been written on the chart

10. Bed baths given by the Nurse should be OMITTED while the radioactive sources are in place.

11. OTHER: _____

_____

12. CHANGES IN PATIENT CONDITION:

At any time should the patient's condition change or deteriorate, especially the onset of a possible Cardiac Arrest or Respiratory Distress, IMMEDIATELY CALL:

ATTENDING PHYSICIAN, RADIATION ONCOLOGIST, and follow the established hospital Code Blue Procedue.

13. DISCHARGE OR TRANSFER OF AN IMPLANT PATIENT:

Before the patient is discharged or transferred to another room or Unit PLEASE FOLLOW THESE INSTRUCTIONS:

A. Confirm Discharge or transfer with the Attending Physician and the Radiation Oncologist.

B. Notify the Radiation Safety Officer (RSO).

C. Do NOT assign the room to another patient until the Radiation Safety Officer (R has surveyed and officially releases the room.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

PROCEDURES IN CASE OF EMERGENCY SURGERY OR DEATH
OF A PATIENT TREATED WITH RADIOACTIVE MATERIAL

14. DEATH OF A PATIENT:

A. Immediately notify the Radiation Safety Officer or designee. Phone number is at Nursing station and in patient's chart.

B. Do NOT release the body until the Radiation Safety Officer or designee evaluates the radiation hazards associated with the handling of the body.

C. An Instruction Sheet will be issued to either the Funeral Director or the hospital personnel required to perform work on the patient by the Radiation Safety Officer or designee.

15. EMERGENCY SURGERY:

A. Notify the Radiation Safety Officer or designee. Phone number is at the Nursing station and in the patient's chart.

B. An Instruction Sheet will be issued providing information concerning the handling of the patient and the preparation of the Surgical area.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health Systen

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Cent
Gary and Hobart, IN

NURSING CHECK LIST FOR IMPLANT PATIENTS

_____SCH _____SMMC-GARY _____SMMC-HOBART

PATIENT NAME: _____ ROOM #: _____

_____ 1. Nurse's Exposure Sheet (Posted on door of patient's rrom)

_____ 2. Nursing Instructions on the patient's chart

_____ 3. Completed Room Survey Form on the patient's chart

_____ 4. Completed Dosimetry Form on the patient's chart

_____ 5. CAUTION SIGN posted on door of patient's room

_____ 6. CAUTION SIGN on patient's chart

_____ 7. CAUTION SIGN on foot of patient's bed

_____ 8. Source Inventory Form on patient's chart

_____ 9. _____ Pocket Dosimeters

_____ 10. _____ Forceps in patient's room

_____ 11. Survey Meter in patient's room

_____ 12. Radiation Lead Safe and Cart

_____ 13. Others: _____

_____

ALL ITEMS CHECKED ARE PRESENT:

_____ RADIATION ONCOLOGIST, MD _____ DATE/TI

_____ RADIATION SAFETY OFFICER _____ DATE/TI

_____ NURSING UNIT SUPERVISOR _____ DATE/TI

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

___ ST. CATHERINE HOSPITAL Ext. 7319

____ SMMC-GARY Ext. 8295

____ SMMC-HOBART Ext. 6760

NURSING INSTRUCTIONS FOR PATIENTS

WITH IMPLANTS OF _____ RADIOPHARMACEUTICAL SOURCES

PATIENT NAME: _____ RM. #: _____ DATE: _____

ACTIVITY: _____ TIME OF IMPLANT: _____ AM / PM

BASIC RULES TO FOLLOW:

VISITORS: Visitors should sit at least _____ feet from the patient for no more than _____ hours per day unless Special Permit is issued.

TIME: Every effort should be made by Nursing Staff to spend the least possible amount of time in the patient's room during the course of implant treatment.

DISTANCE: When NOT giving direct care, keep distance of a least 3 feet from the patien

SPECIAL INSTRUCTIONS:

1. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes.

2. NO nurse, visitor or attendant who is pregnant or under the age of 18 years, will be permitted in the room of a patient who has receiveed a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors SHOULD be asked if they are pregnant.

3. Attending personnel MUST wear rubber or disposable plastic gloves when handling urin bedpans, emesis basins or other containers having any materials obtained from the body of the patient. The gloves MUST be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

4. Disposable items SHOULD be used in the care of these patients whenever possible. These items SHOULD be placed in the designated waste container. Contact Nuclear Medicine Department for proper disposal of the contents of the designated waste container.

5. All clothing and bed linens used by the patient SHOULD be placed in the laundry bag provided and left in the patient's room to be checked by the Radiation Safety Officer (RSO) or designee.

6. All non-disposable items SHOULD be placed in a plastic bag and left in the patient' room to be checked by the Radiation Safety Officer (RSO) or designee.

7. The patient will be instructed to void in the toilet and flush the toilet at least 3 times after use. If the patient is bedridden a separate urinal or bedpan should be provided. The urinal or bedpan should be flushed several times with hot soapy water after each use.

8. If the Nurse helps to collect the excretia, she SHOULD wear disposable gloves. Afterwards, she SHOULD wash her hands with the gloves on and again when the gloves are removed. The gloves SHOULD be placed in the designated waste container.

9. Disposable plates, cups, and eating utensils WILL be used by patients who are treated with Iodine-131.

10. Vomitting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of the linens and/or floor.

    In any such situations, or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or designee IMMEDIATELY. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

11. All vomitus MUST be kept in the patient's room for disposal by the Nuclear Medicine department. Feces need NOT be routinely saved, unless ordered on the patient's chart. The same toilet SHOULD be used by the patient at all times and it SHOULD be well flushed.

12. Utmost precautions MUST be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or designee IMMEDIATELY.

13. If a Nurse, attendant, or anyone else knows or suspects that his skin or clothing (inclugind shoes) has been contaminated, notify the Radiation Safety Officer or his designee IMMEDIATELY. The person SHOULD remain in the patient's room and NOT walk around the hospital. If the hands SHOULD become contaminated, wash IMMEDIATELY with soap and hot water.

14. At change of shift or if another Nurse is assigned to this patient, the responsibilit of reporting ALL INSTRUCTIONS pertaining to this patient shall be that of the previous Nurse which has been caring for this patinet or the Nursing Supervisor of the Unit.

15. Other Instructions: _____

_____

_____

16. CHANGES IN PATIENT CONDITION:

At any time should the patient's condition change or deteriorate, especially the onset of a possible Cardiac Arrest or Respiratort Distress, IMMEDIATELY CALL:

ATTENDING PHYSICIAN, RADIATION ONCOLOGIST, and follow the established hospital Code Blue Procedure.

17. DISCHARGE OR TRANSFER OF AN IMPLANT PATIENT:

Before the patient is discharged or transferred to another room or Unit, PLEASE FOLLOW THESE DIRECTIONS:

A. Confirm the Discharge or Transfer with the Attending Physician and the Radiatio: Oncologist

B. Notify the Rdiation Safety Officer (RSO).

C. Do NOT assign the room to another patient until the Radiation Safety Officer (R: has surveyed and officially releases the room.

RADIOPHARMACEUTICAL THERAPY

SAFETY EQUIPMENT, SIGNS, AND FORMS NEEDED

18. THE FOLLOWING ITEMS SHOULD BE IN THE YELLOW CRASH CART OUTSIDE THE PATIENT'S ROOM:

_____ ABsorbent Paper - 1 roll

_____ Roll of Plastic

_____ Plastic Gloves - 1 Box

_____ Plastic Bags - Large & Small Sizes

_____ White Paper Jump Suits - 5

_____ Shoe Covers - 1 Box

_____ Surgeon Masks - 1 Box

_____ Masking Tape - 2 rolls

_____ Test Tubes and Cotton Swabs for Wipe Test

_____ Decon Solution - 1 Bottle

_____ Paper Towels

_____ Labels for Marking Bags

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

PROCEDURES IN CASE OF EMERGENCY SURGERY OR DEATH OF A PATIENT TREATED WITH RADIOACTIVE MATERIAL

19. DEATH OF A PATIENT:

A. Immediately notify the Radiation Safety Officer or designee. Phone number is at Nursing station and in patient's chart.

B. Do NOT release the body until the Radiation Safety Officer or designee evaluates the radiation hazards associated with the handling of the body.

C. An Instruction Sheet will be issued to either the Funeral Director or the hospital personnel required to perform work on the patient by the Radiation Safety Officer or designee.

20. EMERGENCY SURGERY:

A. Notify the Radiation Safety Officer or designee. Phone number is at the Nursing station and in the patient's chart.

B. An Instruction Sheet will be issued providing information concerning the handling of the patient and the preparation of the Surgical area.

Written: 8/1/83
Revised: 2/90

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN
St. Mary Medical Center
Gary and Hobart, IN

NURSING CHECK LIST FOR RADIOPHARMACEUTICAL PATIENTS

_____ SCH _____ SMMC-GARY _____ SMMC-HOBART

PATIENT NAME: _____ ROOM #: _____

_____ 1. Nurse's Exposure Sheet (Posted on door of patient's room)

_____ 2. Nursing Instructions on the patient's chart

_____ 3. Completed Room Survey Form on the patient's chart

_____ 4. Completed Dosimetry Form on the patient's chart

_____ 5. CAUTION SIGN posted on door of patient's room

_____ 6. CAUTION SIGN on patient's chart

_____ 7. CAUTION SIGN on foot of patient's bed

_____ 8. Source Inventory Form on patient's chart

_____ 9. _____ Pocket Dosimeters

_____ 10. Survey Meter in patient's room

_____ 11. Yellow Crash Cart with required items

_____ 12. Others: _____

_____

ALL ITEMS CHECKED ARE PRESENT:

_____ RADIATION ONCOLOGIST, MD _____ DATE/TIME

_____ RADIATION SAFETY OFFICER _____ DATE/TIME

_____ NURSING UNIT SUPERVISOR _____ DATE/TIME

3/90

St. Mary Medical Cent

TITLE: PROCEDURE FOR ORDERING RADIOACTIVE MATERIAL	NO:
	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: KEN VANDERHYE/DR. T. TORABI
CROSS REFERENCE:	SUPERCEDES: 6/6/89
DATE ISSUED: 2/20/90	DATE EFFECTIVE: 2/20/90

PURPOSE/STATEMENT:

PROCEDURE:

The following procedures are to followed when ordering radiopharmaceuticals/ radioactive materials:

1.0 ALL radiopharmaceuticals/radioactive materials are ordered ONLY by the Radiation Safety Officer or by designated Nuclear Medicine personnel as authorized by the Radiation Safety Officer.

1.1 A completed and signed "Authorized User Request for Therapeutic Dosages of Radioactive Material" form must be received in Nuclear Medicine from the Radiation Onoclogist 48 hours prior to the scheduled implant before order is placed for the material.

1.2 All radiopharmaceuticals/radioactive material is ordered from a radiopharmacy in Chicago, Illinois, or Munster, Indiana, which only delivers to the Nuclear Medicine department during routine working hours.

1.3 If an emergency situation arises after routine scheduled work hours, the Nuclear Medicine Technologist on call will phone the radiopharmacy to bring the drugs to the hospital.

1.4 Hospital Security personnel will escort the delivery personnel to the "Hot Lab" and will remain to ensure the "Hot Lab" is locked after receipt

1.5 ALL Therapy I-131 MUST be approved prior to ordering.

4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN

St. Mary Medical Center
Gary and Hobart, IN

NUCLEAR MEDICINE DEPARTMENT
AUTHORIZED USER REQUEST FOR THERAPEUTIC DOSAGES OF RADIOACTIVE MATERIAL & PATIENT SCHEDULING

I _____ authorize the Nuclear Medicine Department to act on
(Authorized Physician User)

my behalf and order the following radioactive material for _____

to be implanted on _____ at _____ AM PM for treatment

of _____.
(diagnosis & anatomical body part)

PROPOSED TREATMENT PLAN: _____

RADIOISOTOPE: _____ CHEMICAL FORM: _____

RADIOPHARMACEUTICAL: _____ PHYSICAL FORM: ( ) CAPSULE
( ) SEEDS SEALED SOUR
( ) WIRE SEALED SOURC

ACTIVITY: _____

SUPPLIER: _____

SURGICAL HARDWARE NEEDED:

_____ _____
AUTHORIZED PHYSICIAN USER DATE REQUESTE

RSO APPROVAL TO ORDER: _____ DATE: _____

DATE ORDERED: _____ DATE RECEIVED: _____

TECH. ORDERING: _____ TECH. RECEIVING: _____

I have checked the received order of radioactive material and confirm that the received material is the same as the radioactive material ordered as indicated above.

_____ _____
AUTHORIZED PHYSICIAN USER DATE CHECKED

St. Mary Medical Cente

NO:

TITLE: STORAGE, INVENTORY, WIPE TESTS OF SOURCES	APPLICABLE TO: NUCLEAR MEDICINE
	ORIGINATED BY: Ken Vanderhye/Dr. T. Torabi
CROSS REFERENCE:	SUPERCEDES:
DATE ISSUED:	DATE EFFECTIVE:

PURPOSE/STATEMENT:

Storage, inventory and wipe tests shall be done for all brachytherapy sources maintained within the hospital in accordance with US NRC Rules and Regulations.

PROCEDURE:

1.0 The brachytherapy sources, upon receipt, will be assayed in a dose calibrator to insure that each source has the activity certified by the supplier.

2.0 The sources will be stored in a secured room with sufficient lead shielding to insure that the radiation levels from the sources will be as far below 2mR/hr as possible in the unrestricted areas. The storage containers must be locked or stored in a locked cabinet when not in use.

3.0 Quarterly the sources are to be inventoried by the Radiation Safety Officer or designee. The inventory count shall be recorded on approved form, cross checked against previous inventory count to ensure all sources are present. Records will be kept on file by the Radiation Safety Officer.

4.0 An inventory of the sources when removed from storage area for therapy and returned to storage area at the completion of the therapy will be maintained. (See attached inventory form)

5.0 The sources will be wipe tested at intervals required by the NRC Rules and Regulations. The wipe sources will be wipe tested by the Radiation Saftey Officer or his designee. If a designee does the wipe testing all results will be reviewed and signed by the RSO.