Lic No: 13-17073-01 DCD

Wiley N. Carr, FACHE
President
and
Chief Executive Officer

PORTER MEMORIAL HOSPITAL

814 LaPorte Avenue • Valparaiso, Indiana 46383
Telephone (219) 465-4600

December 27, 1990

A. Bert Davis
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mr. Davis:

Enclosed is a copy of the audit of the Brachytherapy Program performed by Drs. Bernard Aron and Howard Elson as well as a proposed "Procedures and Quality Review Guidelines for Brachytherapy Program." This report is being submitted per the instructions contained in your letter of December 3, 1990.

If you have any questions regarding this report, please feel free to call me.

Sincerely,

Gregg A. Bechtold
Vice President
Professional/Support Services

GAB/ks
Enclosures

cc: Robert Welsh
Richard Boyd, M.D.
Wiley Carr
Glen Janssen

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REGION III

University of Cincinnati
Medical Center

University of Cincinnati Hospital

Radiation Oncology
Charles M. Barrett Center

234 Goodman Street
Cincinnati, Ohio 45267-0757
Phone: (513) 558-5668

December 26, 1990

Gregg Bechtold
Assistant Administrator
Porter Memorial Hospital
Valparaiso, In. 46383

Dear Mr. Bechtold:

Please find enclosed a copy of the report of the audit of the brachytherapy program of Porter Memorial Hospital as required by the May 2, 1990 Confirmatory Letter regarding the authorization to perform brachytherapy procedures under NRC License No. 13-17073-01. This report should fulfill the requirements as set forth in the Confirmatory Letter as to an independent review of the five brachytherapy procedures performed under the NRC License and the review of the revised program to prevent any such difficulties. As such a copy of the present brachytherapy procedures are attached for transmission to the NRC.

We would like to take this opportunity thank yourself and please thank your staff for their cooperation during the audit.

If we might be of any further assistance, please do not hesitate to contact us.

Sincerely,

Bernard S. Aron, M.D.

Howard R. Elson, Ph.D.

Brachytherapy Audit
for Porter Memorial Hospital
Valparaiso, Indiana 46383

Licensee: Porter Memorial Hospital, 814 LaPort Avenue, Valparaiso, In. 46383

USNRC License No.: 13-17073-01

Preparation Date: December 21,1990

Prepared By: Bernard S. Aron, M.D.
Howard R. Elson, Ph.D.

Persons Contacted: Richard Boyd, M.D., Radiation Safety Officer, Porter Memorial Hospital, Valparaiso, Indiana
Koppolu Sarma, M.D., Radiation Oncologist
Diana Painton, Supervisor, Nuclear Medicine, Porter Memorial Hospital, Valparaiso, Indiana
Gregg Bechtold, Assistant Administrator, Porter Memorial Hospital, Valparaiso, Indiana

1. Scope of Audit

This audit of the brachytherapy program at Porter Memorial Hospital, Valparaiso, Indiana, was performed to: evaluate the brachytherapy cases performed under the USNRC license 13-17073-01 to determine if any misadministrations had occurred, and to review the present brachytherapy program with regard to safeguards to prevent a reoccurrence of difficulties discovered.

2. Review of brachytherapy cases (records)

Copies of all pertinent records, radiographs and dosimetry records for the five brachytherapy cases performs under the USNRC license were furnished to the auditors by the licensee. Based on the information furnished the following was determined:

Case No. 1

Prescribed Dose: 2600 cGy stated however no documented prescription prior to completion of the treatment.
Delivered Dose: 2600 cGy
Total treatment time: 64 hours
Implant date and time: 8/4/87 at 3:00 p.m.
Explant date and time: 8/7/87 at 7:00 a.m.

Case No. 2

Prescribed Dose: 2000-2400 cGy
Delivered Dose: 2100 cGy
Total treatment time: 47 hours
Implant date and time: 10/3/87 at 1:00 p.m.
Explant date and time: 10/5/87 at 12:00 p.m.

Case No. 3

Prescribed Dose: 3000-3500 cGy
Delivered Dose: 3500 cGy
Total treatment time: 47.5 hours
Implant date and time: 2/19/89 at 9:15
Explant date and time: 2/21/89 at 8:45

Case No. 4

Prescribed Dose: 3000-3500 cGy
Delivered Dose: 3500 cGy
Total treatment time: 34 hours
Implant date and time: 4/25/89 at 9:15 p.m.
Explant date and time: 4/27/89 at 7:15 a.m.

Case No. 5

Prescribed Dose: 43 cGy at 1/2 cm, 23 cGy at 1 cm
Delivered Dose: 3100 cGy at 1/2 cm
Total treatment time: 72.3 hours
Implant date and time: 12/19/89 at 1:00 p.m.
Explant date and time: 12/22/89 at 1:15 p.m.

Upon review of the patient treatment records, the auditors feel Cases No. 2, 3, 4 and 5, do not represent misadministrations as the Delivered Doses are within the range of the Prescribed Dose. For Case No. 1, no conclusions as to the potential misadministration status can be drawn as no Prescribed Dose is available.

3. Review of the brachytherapy cases (medical)

Case No. 1
Delivered Dose: 2600 cGy
Evaluation of Treatment Dose: Within range of standard and customary dose.
Expected result to normal tissue: Local Fibrosis

Case No. 2
Delivered Dose: 2100 cGy
Evaluation of Treatment Dose: Within range of standard and customary dose.
Expected result to normal tissue: Local Fibrosis

Case No. 3
Delivered Dose: 3500cGy
Evaluation of Treatment: Toward the higher end of standard and customary dose, but necessary in view of patient's refusal of surgery.
Expected result to normal tissue: Extensive local fibrosis

Case No. 4
Delivered dose: 3500 cGy
Evaluation of treatment dose: Within range of standard and customary dose.
Expected result to normal tissue: Local fibrosis

Case No. 5
Delivered dose 3100 cGy
Evaluation of treatment dose: Within range of standard and customary dose.
Expected result to normal tissue: Local fibrosis

4. Review of the present brachytherapy program

The licensee furnished the auditors a copy of proposed brachytherapy procedures for Porter Memorial Hospital. Upon review, modification and approval by the Radiation Safety Committee for Porter Memorial Hospital, it is our understanding that these procedures will become policy for the institution. These procedures detail the various aspects of the brachytherapy program including 1)scheduling of radioactive implants 2)duties and responsibilities of the various individuals involved in accomplishing a brachytherapy procedure 3)procedure for ordering radioactive material 4)patient monitoring requirements 5)requirements prior to, during and post patient implantation the establishment of a quality assurance committee for brachytherapy 6)establishment of a brachytherapy quality assurance committee 7)rules covering a therapeutic misadministration and 8)required documentation for the dosimetry involved in brachytherapy procedures.

The program detailed in the materials furnished (Appendix A), if strictly administered by the Porter Memorial Hospital administration, the institution Radiation Safety Committee, and the newly formed Quality Assurance Committee should prevent the reoccurrence of any oversights as required for the proper use of brachytherapy sources. To this end the auditors would like to suggest an annual review of the brachytherapy program by the Quality Assurance Committee by the hospital administration.

PORTER MEMORIAL HOSPITAL

PROCEDURES AND QUALITY REVIEW GUIDELINES FOR BRACHYTHERAPY PROGRAM

SCHEDULING AN IMPLANT

The authorized user must submit the following documentation to the Nuclear Medicine Department before an implant is scheduled:

1. Pathology Report;
2. Consult Report (which includes reason for implant);
3. Pertinent information including any H&P and operative report.

PRIOR TO IMPLANT
(INSERTION OF APPLICATOR OR CATHETERS)

The following material is needed in the Nuclear Medicine Department:

1. All the needles or catheters needed for the implant.

2. Any pre-treatment planning done with a "model implant."*

3. Pre-treatment estimation of # of seeds needed will be ordered before the implant. However, if there is a possibility of postponing or any question of feasibility of the implant being done, the radioactive seeds will not be ordered until the implant (insertion of applicator or catheters) is performed.

4. Consent is to be signed by the patient, which includes:
   a. Possible complications.
   b. Other alternatives (a videotape can be used for explanation).

5. Physician to explain implant to the patient.

6. Physician to explain to the family the restrictions of visits during the implant.

7. Nursing Station is to have the following:
   a. Nature of the implant.
   b. Possible precautions to be taken during the procedure (hospital stay).
   c. Radiation Safety Procedures to be followed during the implant.

*For example: If a brain implant or a prostate implant is to be done, Pre-implant Isodose curves are generated using a CT scan or Ultrasound.

DAY OF IMPLANT

1. The implant is either performed by the Radiation Oncologist by himself/herself or in association with another surgeon depending upon the disease, that is, if an implant has to be performed in the head and neck, the Radiation Oncologist may use the services of a head and neck surgeon.

2. After the surgical procedure is completed, i.e., insertion of catheters, the patient will be shifted to the recovery room.

3. Depending upon the nature of the surgery, the patient will either go to Radiology for AP and orthogonal films, or the patient will go to the appropriate unit, i.e., intensive care or regular unit depending upon the surgery.

4. When the patient's condition permits, the patient will go for x-ray of the area by using regular orthogonal films or by using x-ray unit in the cath lab or, if needed, a simulator. The time delay between the appropriate films and the surgery depends upon the patient's condition. At no time is the patient's condition compromised to obtain the films as well as to insert the radioactive material soon.

ORDERING THE RADIOACTIVE SOURCES AND INSERTION OF SOURCES

Prior to the implant, an appropriate treatment volume will be determined by the physicist and Radiation Oncologist and if the procedure is definite and the Dr.'s are confident of the tumor estimation, the radioactive material can be ordered before the implant. The radioactive material takes approximately 24 hours to reach the facility.

2. If the radioactive material is not ordered prior to surgery, in the following circumstances:

    a. The tumor volume could not be successfully estimated prior to the implant.
    b. In the teamwork of surgery and radiation, there is a question if the implant will be placed or not

    In these cases, obtaining the radioactive material before surgery will drain the resources as well as causing unnecessary exposure of handling radioactive material.

3. After the implant is performed, the number of seeds could be estimated by counting the number of catheters as well as the number of seeds required in each catheter. A portable film is to be obtained and if possible both AP and lateral. These preliminary films could be used to estimate the strength of the seeds and the number of seeds needed, then the order for the radioactive material should be placed.

4. Once the radioactive material arrives, the Radiation Physicist along with the Nuclear Medicine Department will inspect the radioactive material and make sure that the activity prescribed matches the activity needed. The standards of the calibration needed prescribed by the American Association of Medical Physicists will be performed prior to insertion of any radioactive seeds. A computerized treatment plan is performed on each implant, i.e., a volume calculation should be done, which includes:

    a. Minimal dose encompassing all of the tumor.
    b. Dose encompassing at least 80% of the tumor area.
    c. Any hot spots.
    d. The minimal tumor dose or the minimal dose to any area surrounding the implant.
    e. Dose to critical organs (ex., if implant is close to the spinal cord, spinal cord dose, or renal tissue or liver, etc.).

5. Once the port films and the Isodose curves are verified and signed by both the Physicist and the authorized user, the radioactive material will be inserted.

ORDERING THE RADIOACTIVE SOURCES AND INSERTION OF SOURCES
(CONTINUED)

6. The Physicist or associate will assist the authorized user in the insertion of radioactive material.

7. The proposed rules of N.R.C. of January 16, 1990, suggest that before 50% of the desired dose is delivered, an independent person (other than those who calculated initially) under the supervision of the authorized user, will verify the calculations and computerized plans generated by dosimetrist or physicist. This person can be either: radiation Oncologist, physicist, technologist, or dosimetrist. This is to avoid any mathematical error. This is also recommended by ACR in the meeting of October, 1990 (ASTRO).

8. Department will survey the room and disposed material to make certain that no source is lost. Dose meter rates will be recorded at:

    Bedside
    Three (3) feet from patient
    Six (6) feet from patient
    Hallway of patient's room
    Adjoining room
    Room above patient's room
    Room below patient's room

9. A detailed inventory form is made during the time of insertion of Radioactive sources. This form is helpful to counter check and balance at time of explanation of radioactive sources.

MONITORING OF THE PATIENT DURING THE IMPLANT

The Radiation Oncologist, or the physician covering the Radiation Oncologist, shall see the patient every day during the implant procedure. That coverage includes the verification of the correct placement of the applicators and to monitor any side effects which include: nausea, vomiting, diarrhea, respiratory problems, respiratory distress, difficulty in swallowing and mucosal secretions (when a head and neck is done). The monitor also will be done along with the surgeon, if a surgeon is involved with an implant.

The care of the patient should also include, if needed, monitoring of the blood counts, patient's electrolytes, and nutrition.

A primary care physician will also follow the patient during hospitalization and any medical management needed will be initiated through him/her.

Nursing instructions are given prior to insertion of the seeds. The nursing instructions should include generalized principles of radiation safety and any specific instructions depending on the nature of the implant.

REMOVAL OF IMPLANT

The day of the removal of the implant is determined when the treatment plan is obtained and prior to the insertion of the radioactive sources. The Nuclear Medicine Department is notified the day of the insertion of the sources, when the implant is coming out.

If for medical reasons, the implant has to be taken out earlier, or if the implant needs to be left for more time, it should be documented on an appropriate form and the reasons stated, and the Nuclear Medicine will be notified.

The Nuclear Medicine Department and/or a Radiation Physicist is needed at the time of removal, the Radiation Oncologist is to be there at the time of removal.

During the removal of the radioactive material by the Radiation Oncologist, the nursing staff will provide necessary instruments and dressings.

The detailed radioactive material inventory form (i.e., type and number of radioactive materials inserted is documented on form at the time of insertion) is readily available at the time of the radioactive material explanation so when the sources are taken out this can be checked and balanced.

STORAGE OF RADIOACTIVE SOURCES (AFTER THE REMOVAL OF THE IMPLANT)

1. The patient is monitored after all sources are removed. All the radioactive material removed are carefully monitored and accounted for and matched with the number of seeds taken before and signed by the appropriate personnel in the Nuclear Medicine Department.

2. They will immediately be sent back to the place where the sources were obtained.

MODIFICATION IN THE PROCEDURE FOR PERMANENT SEED IMPLANT

When a permanent seed implant, i.e., I-125 or pallidium, is desired:

1. The treatment volume and all of the films needed including ultrasound or CT scan are to be obtained prior to ordering any I-125 or pallidium seeds.

2. After the appropriateness of the procedure is determined and documented and submitted to the Nuclear Medicine Department, the permanent radioactive material, i.e., I-125 or pallidium, will be ordered and at least 3-5% more seeds will be ordered to make sure that all of the tumor is implanted adequately during surgery.

3. After the seeds are implanted, the patient will go to the appropriate unit, depending upon the medical condition. Room and urine will be monitored for dislodged seeds.

4. Once the patient improves, the patient will have preliminary arthogonal films for record keeping and a good x-ray unit which might include the x-ray unit in cath lab or a simulator will be used for permanent record keeping and dose calculation.

5. Once good orthogonal or stereo-shift films are obtained, computerized treatment plans are generated which includes (but is not limited to) the dose to:

    1. Target volume - minimal dose
    2. Tumor volume - minimal dose
    3. Dose to 80% of target volume
    4. Hot spots

BRACHYTHERAPY QUALITY ASSURANCE AUDIT

The purpose of the Brachytherapy Quality Assurance Audit is to monitor the Brachytherapy Program at Porter Memorial Hospital and to ensure that high quality care is given to the patient and to ensure that the Radiation Safety Guidelines, set by the NRC, are followed for the safety of the hospital personnel and patients.

The brachytherapy program will be added to the Radiation Safety Committee agenda.

The functions of the Committee are:

I. Review Brachytherapy records and identify any problems, including:

   a. Quality of care for the patient during hospitalization.
   b. Identify any violations of the Radiation Safety Guidelines set by the Radiation Safety Committee.
   c. Audit the Brachytherapy charts and forms which includes:
      1. Appropriateness of therapy.
      2. Any variation of Initial and Final doses.
      3. Timely completion of records including appropriate forms and Isodose curves.
      4. To check whether timely inventory of radioactive sources is done.
      5. To ensure that the proper procedures are followed in handling of radioactive material at the time of arrival and disposal.
      6. Handling of the patients during implantation and to ensure that proper radiation safety procedures are followed.

The Radiation Safety Committee meets once every three (3) months and compiles a report form to all the members.

IDENTIFICATION OF A THERAPEUTIC MISADMINISTRATION

I. Difference of prescribed dose and delivered dose. With the forms attached, once the final delivered dose is entered, the percentage of difference between prescribed dose and delivered dose is calculated. If the variance is greater than 10% (present guidelines) and greater than 20% (for the future), appropriate steps should be taken.

II. Source dislodged or came out of applicator.

III. Loss of sources.

IV. Sources with wrong activities loaded.

V. Incorrect number of sources loaded.

VI. Leaking sources are discovered.

RECORDS AND REPORTS OF MISADMINISTRATIONS

A. When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian) unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician. However, the licensee shall not delay medical care for the patient because of this.

B. Within 15 days after an initial therapy misadministration report of NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (A). The written report must include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative (or guardian) and, if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

D. Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient and the action taken, if any, to prevent recurrence.

E. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardian).

ADMINISTRATION _____

DATE _____

CHAIRMAN OF RADIATION SAFETY COMMITTEE

_____

DATE _____