IE72
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Yes - 10 CFR 35.33(a)(2)
Therapeutic

Beaumont

William Beaumont Hospital
Royal Oak

April 2, 1996

Mr. John Jones
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

030-02006

Subject: Written Report Concerning High Dose Rate Brachytherapy Misadministration
License Number 21-01333-01

Dear Mr. Jones:

Enclosed is the required written report describing the high dose rate brachytherapy misadministration that occurred on March 19, 1996 at William Beaumont Hospital, Royal Oak, Michigan.

The patient involved in the misadminstration received written notification of the incident on March 28, 1996. The notification was delivered in person to the patient. The patient and the patient's spouse had an opportunity to review the notification with the physician authorized user and Radiation Safety Officer.

The medical consultant assigned to review this incident is Melvin Griem, M.D. of University of Chicago. A copy of this report and the dosimetry used to determine the absorbed dose to the patient's thighs were sent to Dr. Griem on April 2, 1996.

Please contact me at (810) 551-0548 if you need any additional information related to this incident.

Sincerely,

Cheryl Culver Schultz

Cheryl Culver Schultz, M.S.
Radiation Safety Officer

050006

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769 (313) 551-5000

License Number 21-01333-01: Notification of a High Dose Rate Afterloading Brachytherapy Misadministration
Licensee: William Beaumont Hospital, 3601 W. Thirteen Mile Rd., Royal Oak, Michigan

Date/Time of Discovery: March 19, 1996 at 10:12 a.m.

Referring Physician: Sheldon Weiner, M.D.
Authorized User and Attending Physician: Peter Chen, M.D.

A. Description of Event

A patient with Stage I squamous cell carcinoma of the vagina was scheduled for high dose rate afterloading treatment with Ir-192 (7.9 Curie). The vaginal cylinder (i.e., three 3.5 cm diameter and two 2.5 cm diameter rings; all with a height of 2.5 cm) was positioned correctly (as documented by the pre-treatment radiography) and secured in place. The treatment plan specified seven dwell positions within the treatment site (i.e., vagina) and the sequence of dwell positions was distal to proximal inside the treatment site. Prior to start of the first treatment, all of the treatment parameters were entered by the physicist into the treatment console and verified by the dosimetrist. The treatment plan specified a step size of 2.5 mm. This step size, however, was not entered into the console. The step size entered was 5.0 mm instead of 2.5 mm. A length of 12 cm instead of 6 cm was treated. The target volume (i.e., the intended treatment site) has a length of 8 cm. The active length (from the first to the seventh dwell position) is 6 cm. When the treatment length was inadvertently altered to a longer length, the length of the volume treated was also increased, however, the dose delivered was less than the prescribed dose (i.e., 500 cGy per fraction). The increased step length caused the first dwell position to be located outside the treatment site at a distance of approximately 2.54 cm from the patient's perineum.

The first fraction of the treatment began at 10:06 a.m. on March 19, 1996 and the source progressed as programmed from the first dwell position on through the seventh dwell position. At 10:12 a.m., the dosimetrist noticed that the wrong step length had been entered and immediately terminated the treatment. At this time, the source had progressed from the first through the last (seventh) dwell position.

Two courses of treatment were prescribed for this patient. The first written directive prescribed a high dose rate afterloading treatment to the vagina with Ir-192 for a total dose of 3000 cGy at 5 mm from the surface of the applicator. Individual fractions of 500 cGy were prescribed for a total of six fractions. The second written directive was for a boosted high dose rate afterloading treatment to the apex of the vagina for an additional dose of 1500 cGy at a dose of 500 cGy at the same prescription point for three additional fractions.

Prior to the first treatment, the authorized user wrote the written directive on the patient's chart which indicated the radionuclide, the high dose rate fractionated schedule, treatment site, total dose, and dose per fraction. The physicist checked the treatment plan prepared by the dosimetrist

for accuracy and countersigned it. The physicist entered the plan parameters into the treatment console accurately with the exception of the step length. The physicist entered the step length that had previously been the routine for this type of treatment for several years prior to 1993 (5.0 mm). The dosimetrist checked the treatment tape (printed by the treatment console) for accuracy of transcription. The dosimetrist failed to notice that the step length entered on the treatment console was different from the treatment plan.

The Radiation Safety Officer (RSO) was notified by both the Radiation Oncologist authorized user (at 10:20 a.m.) and the Radiation Oncology dosimetrist (at 10:24 a.m.) on Tuesday, March 19, 1996 that a longer step length had been entered into the treatment console for the first fraction of a high dose rate (HDR) vaginal treatment. The Radiation Safety Officer responded immediately and went to High Dose Rate Treatment Area at 10:30 a.m. The "physics worksheet" that is utilized for the treatment planning, the standard treatment plan, the printout from the afterloading device, the patient chart, the isodose distribution curves, and revised dosimetry plans were reviewed by the RSO. The written directive, confirmation of the written directive prior to administration, and the record of confirmation of the written directive after administration were completed in compliance with our Quality Management Program (QMP). All of the other required procedures specific for HDR treatments had been followed.

A new treatment plan was calculated to compensate for the reduction of the dose to the treatment site for the first fraction. The first fraction was compensated (i.e., the patient was retreated) at 12:02 p.m. The final dose for the first fraction that was delivered to the treatment site was as prescribed (500 cGy $\pm$ 5% to a point 5 mm from the surface of the applicator). The patient and referring physician were notified of the event.

On March 19, 1996 at 1:00 p.m.(i.e., the same day as the event), a meeting was called by the Chief of Brachytherapy to discuss the incident and to develop appropriate corrective actions. In attendance from Radiation Oncology were: the Director of Clinical Physics, the brachytherapy physicists, the brachytherapy fellow, the dosimetrist, scheduling clerk and nurse. The Radiation Safety Officer (RSO) also attended the meeting. It was determined that a misadministration had occurred due to the radiation dose from the dwell position that was located outside the treatment site.

B. Why the Event Occurred

It was determined that the procedure utilized to transcribe all of the treatment parameters from the treatment plan to the treatment console was inadequate. The step length was indicated on the standard plan (i.e., an atlas plan) but was not included on the "physics worksheet." The physicist verified the accuracy of all of the treatment parameters on the "physics worksheet" which did not include the step length. The step length that had been used routinely in previous years was inadvertently entered into the console by the physicist. The error was not noticed when the dosimetrist verified the transcription on the treatment tape. The authorized user physician also verified the parameters on the treatment tape prior to the treatment, but did not identify that the

wrong step length had been entered.

C. The Effect on the Patient

The first dwell position was located inside the vaginal cylinder, however, because of the increased step length the first dwell position was located outside the treatment site (vagina) at a distance of approximately 2.54 cm distal from the vaginal entroitus.

We measured the diameter of the perineal bar on the vaginal applicator, and it is approximately 3.5 cm in width. The skin of the patient's thighs was assumed to be in contact with the perineal bar. An isodose distribution was prepared which included this position. The maximum dose to the skin of the patient's thighs from the treatment was calculated to be 500 cGy (isodose distribution calculation). This is not a medically significant dose to the skin or thigh tissue and no adverse effects are expected from this incident. No reddening of the skin and/or soft tissue injury is expected from this dose. Several times and on different days, the Radiation Oncology physician has examined the patient's thighs for signs of skin erythema during the subsequent scheduled HDR fractional treatments. As of April 2, 1996, no erythema or other reactions were noted. It is very unlikely that 15 days after the small radiation exposure, that an acute side effect will occur.

D. What Improvements are Needed to Prevent Recurrence

The treatment plan parameters have all been transcribed from the standard treatment plan to the "physics worksheet," including the step length. The step length of 2.5 mm was written on this patient's "physics worksheet." When the step size of 2.5 mm was entered onto the "physics worksheet," the date and initials of the individual making the entry, was not included. In the future all such changes on the treatment plans will be dated and initialed at the time of the change. In this case, the date of March 29, 1996 and the initials have been entered onto this patient's "physics worksheet" next to the entry of step size. The physicist and dosimetrist will accurately enter the step length of 2.5 mm on the treatment console and this will be verified by check mark and initials on the treatment tape for each subsequent treatment for this patient.

E. Action taken to Prevent Recurrence

The following actions were taken to prevent this from recurrence: (1) As of March 20, 1996, the "physics worksheet" was revised to include the step length, (2) A checklist was developed for the physicist/dosimetrist to verify the treatment plan parameters and is posted directly on the treatment console, (3) A policy was instituted that all plan parameters will be verified directly on the treatment tape and each item checked off prior to each treatment, (4) All brachytherapy physicists and dosimetrists have reviewed the corrective action listed in this report and the physics chart checking procedures for HDR, (5) all of the physicists were given a test for knowledge and comprehension of our Quality Management Program (QMP), and all passed the test with scores greater than 75%, and (6) The corrective action listed in this report and the physics chart checking procedures for HDR will be reviewed annually, (7) A

comprehensive review of our Quality Management Program (QMP) will be conducted with special emphasis on analysis of human factors in the reduction of human errors. The resultant revision to our QMP will be presented for approval by the Radiation Safety Committee at the next scheduled meeting in June 1996, and (8) Effective immediately, our QMP has been modified to add this item on page 6, b, 5:For HDR, prior to the start of each treatment, the following treatment data entries will be double checked for accuracy with the treatment plan: date, time, activity of the source, patient ID#, **step size (step length)**, channel number, **length (offset)**, dwell positions, dwell times, and total treatment time. The treatment data entry double check will be verified by the signatures (or initials) of two authorized individuals on the treatment tape prior to the start of each treatment.

F. Notification of the Patient and Referring Physician

The Radiation Oncology attending physician notified the patient and patient's husband immediately on Tuesday, March 19, 1996. The Radiation Oncology attending physician notified the referring physician on March 19, 1996. The patient received written notification and an oral explanation of this event on March 29, 1996 by the RSO and Radiation Oncology physician.

G. Conclusions

1. The maximum dose to the skin of the patient's thighs from the first fraction that had the incorrect step length (i.e., 5 mm instead of 2.5 mm) was calculated to be 500 cGy (isodose calculation). This event was reported to NRC Operations on March 19, 1996 at 5:30 p.m.

2. It is a requirement of the QMP and departmental policy that the treatment parameters are verified by both the physicist and dosimetrist prior to treatment. This verification was performed and both signatures were recorded on the treatment plan. Due to a deficiency in the procedure for verifying that the proper treatment data entries had been entered correctly, the error in step size (step length) was not identified.

3. All vaginal cylinder patient treatment charts have been reviewed to ensure that the prescribed step size was entered correctly and verified on the treatment tapes from March 1995 through March 1996. The treatment tape for each fraction was checked and the correct step size was utilized in all cases.

4. HDR prostate, breast, bronchus, and esophagus treatments were also reviewed. More than 72 percent of the these HDR patients (representing over 78% of the total number of fractions treated) that utilize a standard step size were reviewed to verify that the correct step size (step length) was utilized for each fraction from March 1995 through March 1996. Included with this review, we also verified that the treatment plans that utilize a standard length (offset) were programmed as prescribed on the treatment plan. No errors were identified for any fractions or treatments.

5. All of the corrective actions stipulated under items D and E of this report have been implemented. We believe that these corrective actions provide high confidence that all HDR treatments will be administered as directed by the authorized user.

Report Prepared by:

Cheryl Culver Schultz

Cheryl Culver Schultz, M.S.
Radiation Safety Officer

License No. 21-01333-01
April 2, 1996

New Form
3/96

ENDOMETRIUM WORKSHEET

Patient _____ ID# _____ Staff _____ Resident _____

Prescribed Dose [ ] 4 fractions of 600 cGy @ 5 mm depth, for treatment length of 4.0 cm. with external beam or:

[ ] 6 fractions of 500 cGy @ 5 mm depth, treatment length of 4.0 cm. without external beam

[ ] Exception: _____fractions of _____cGy @ _____mm depth, treatment length _____cm

First Source: S/N _____ Activity Assay _____ Ci on ____/____/____ Day of Year _____

Second Source: S/N _____ Activity Assay _____ Ci on ____/____/____ Day of Year _____

Fraction 1: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 2: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 3: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 4: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 5: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 6: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Stepsize = 2.5 mm Cylinder Used: _____

	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5	Fraction 6
Length(offset)						
Dwell Position						
TOTAL/SIG.						
CHECK						

EXM 3/96

OLD Form

ENDOMETRIUM WORKSHEET

F ____________ Hospital Number ________________ Staff _____ Resident _____

I ;00 cGy @ 5 mm depth, for treatment length of 4.0 cm. with external beam or:

;00 cGy @ 5 mm depth, treatment length of 4.0 cm. without external beam

[ ] Exception: __ fractions of __ cGy @ __ mm depth, treatment length __ cm

First Source: S/N ______ Activity Assay ________ Ci on ____/____/____ Day of Year ______

Second Source: S/N ______ Activity Assay ________ Ci on ____/____/____ Day of Year ______

Fraction 1: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 2: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 3: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 4: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 5: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Fraction 6: Date ____/____/____ D.O.Y. _____ Elapsed Days _____ Decay Factor _____ Current Activity _____ Ci

Time:	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5	Fraction 6
Length:						
Dwell Position:						
	______	______	______	______	______	______
	______	______	______	______	______	______
	______	______	______	______	______	______
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	______	______	______	______	______	______
	______	______	______	______	______	______
TOTAL	______	______	______	______	______	______
CHECK	______	______	______	______	______	______

BEFORE INITIALIZING TREATMENT VERIFY THE FOLLOWING ON THE TREATMENT TAPE AND MAKE A CHECK MARK NEXT TO EACH ITEM AFTER YOU HAVE DONE SO. PLEASE INITIAL THE TREATMENT TAPE WHEN COMPLETE.

1. DATE
2. TIME
3. ACTIVITY
4. PATIENT ID#
5. STEPSIZE
6. CHANNEL NUMBER
7. LENGTH (OFFSET)
8. DWELL POSITIONS
9. DWELL TIMES
10. TOTAL TREATMENT TIME
11. PHYSICS SIGNATURE
12. PHYSICIAN SIGNATURE

Thursday, March 21, 1996

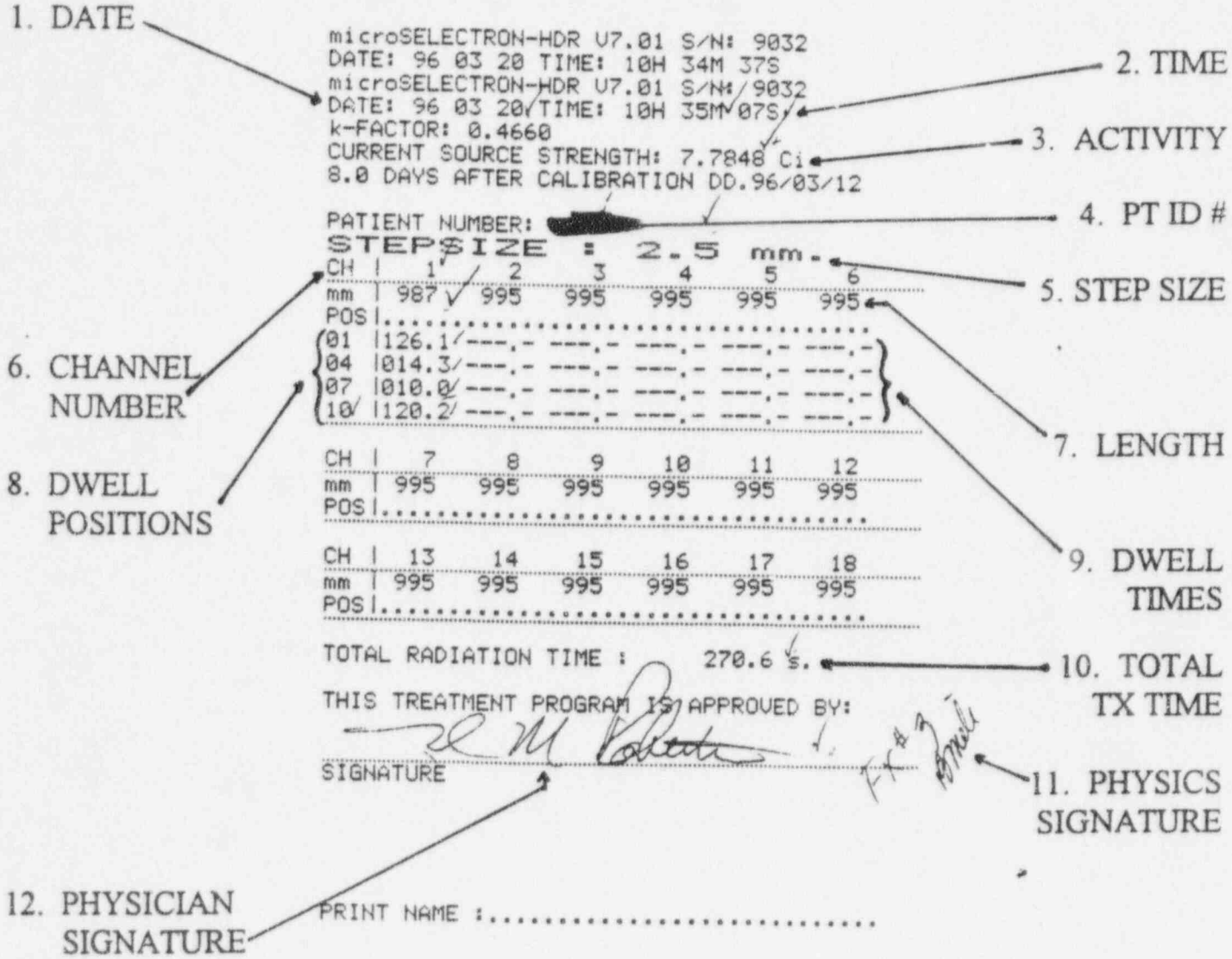
REVIEW OF CHART CHECKING PROCEDURE FOR HDR BRACHYTHERAPY

Verify that all of the following are complete and are correct **prior** to the administration of a radiation dose:

1. Prescription (written directive) signed and dated by the physician and including at a minimum the radioisotope, treatment site, and total dose.
2. Patient identity verified by more than one method.
3. Treatment parameters:
   - date
   - time
   - source activity
   - dose per fraction
   - treatment depth, points, or volume
   - treatment length
   - applicator size and type
   - applicator position (radiograph)
   - step size
   - lenth parameter (offset)
   - channel number and connections
   - dwell positions
   - dwell time at each position
   - total treatment time.
4. Treatment tape:
   1. date
   2. time
   3. activity
   4. patient identification number
   5. stepsize
   6. channel number
   7. length (offset)
   8. dwell positions
   9. dwell times
   10. total treatment time
   11. physics' signature
   12. physician's signature.

Prior to administering the brachytherapy treatment, the responsible personnel must understand the physician's written directive and know how to carry out the treatment procedure and must indicate that this is true by initialling the "DAILY TREATMENT QUALITY MANAGEMENT FORM FOR BRACHYTHERAPY."

Reconstruction of a treament delivered from a standard plan should exactly reflect the above listed treatment parameters and should include dose calculations to anatomical structures (bladder, rectum) as appropriate.



START BUTTON PRESSED :

Beaumont

Inter-department communication

William Beaumont Hospital - RO

Radiation Oncology - Medical Physics

TO: Cheryl Culver Schultz, M.Sc.
Radiation Safety Officer

FROM: Elizabeth Mele, M.Sc.
Clinical Physicist

DATE: March 26, 1996

RE: Vaginal Cylinder Treatment Patients.

All vaginal cylinder patient treatment charts for patients treated March 1995 through March 1996 have been reviewed for use of the correct step size (2.5 mm) during high dose rate treatments. A treatment tape for every fraction was reviewed and a 2.5 mm step size verified.

EM:smg

cc: Dr. Alvaro Martinez
Dr. Gary Gustafson
Dr. John Wong
Mr. P. D. sharma

QUALITY MANAGEMENT PROGRAM

William Beaumont Hospital
License #21-01333-01

MARCH 22, 1996

QUALITY MANAGEMENT PROGRAM
TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

QUALITY MANAGEMENT PROGRAM

I. INTRODUCTION

A. Purpose of Quality Management Program

The purpose of the Quality Management Program (QMP) is to provide a high degree of confidence that byproduct material or radiation from byproduct material is administered as directed by the physician authorized user. The policies and procedures contained in this document comply with 10 CFR Part 35. They are based on existing policies and procedures, Regulatory Guide 8.33 (Quality Management Program), and NRC correspondence dated June 30, 1994.

B. Patient Procedures Included in the Quality Management Program

1. Radiation Oncology Department: any brachytherapy radiation dose including temporary or permanent implants; Sr-90 eye applications; high-dose-rate (HDR) and low-dose-rate (LDR) remote afterloading devices.

2. Nuclear Medicine Department: any administration of quantities greater than 30 microcurie of either sodium iodide I-125 or I-131; or any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

C. General Policies for Radiation Oncology and Nuclear Medicine

General Policies apply to Radiation Oncology AND Nuclear Medicine. See Section II.

D. Specific Policies and Procedures for Radiation Oncology

Section III: Specific Policies for Radiation Oncology
Section IV: Procedures for High-Dose-Rate (HDR) and Low-Dose-Rate (LDR) Remote Afterloading Devices
Section V: Procedures Specific for HDR
Section VI: Procedures for Brachytherapy Applications
Section VII: Procedures for Sr-90 Eye Applications

E. Specific Policies and Procedures for Nuclear Medicine

Specific Procedures for Nuclear Medicine are in Section VIII.

II. GENERAL POLICIES

A. Written Directive (see definitions in Appendix A)

1. A physician authorized user shall date and sign a written directive prior to the administration. This is an order for a specific patient.

2. The required contents for the written directive are specified in the following sections of this document:
Section IV.A. HDR and LDR remote afterloading devices
Section VI.A. Brachytherapy Applications
Section VII.A. Sr-90 Eye Applications
Section VIII.A. Nuclear Medicine.

B. Oral Revision of Written Directive

An oral revision to a written directive is only permitted if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by a physician authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

C. Written Revision of Written Directive

Revisions to written directives may be made provided that the revision is dated and signed by a physician authorized user or physician under the supervision of an authorized user prior to the administration of (a) the diagnostic or therapeutic radiopharmaceutical dosage, (b) the brachytherapy dose (c) the next HDR or LDR remote afterloading device fractional dose, or (d) Sr-90 eye application.

D. Requirements for Patient Identification

1. Prior to administration, more than one method shall be used to verify the identity of the patient as the individual named on the written directive.

At least two of the following methods shall be utilized for confirmation of the patient's identification.

2. If the patient is an outpatient:

   a. The asked birthdate matches information in the patient's chart.
   b. The asked address matches information in the patient's chart.
   c. The asked social security number matches information in the patient's chart.
   d. The name given by the patient matches the name on the written directive.
   e. If the patient cannot speak for him or her self, confirmation of proper identity by a relative or friend.
   f. Confirmation that the patient matches the photograph in the patient's chart.
   g. Physician identification of the patient.

3. If the patient is an inpatient:

   a. Confirmation of the name on the hospital wrist band.
   b. Confirmation by any of the means listed for an outpatient.

E. Confirmation of Written Directive Prior to Administration

1. It shall be verified, prior to administration, that the specific details of the administration are in accordance with the written directive.

2. Specific verification procedures are listed as follows in this document.
   Section IV.B. HDR and LDR remote afterloading devices
   Section VI.B. Brachytherapy Applications
   Section VII.B. Sr-90 Eye Applications
   Section VIII.B. Nuclear Medicine.

F. In Case of Doubt Policy

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

G. Record of Confirmation of Written Directive After Administration

1. A record that confirms that each administered radiation dose or dose fraction was given in accordance with the written directive is required to be made after administering the dose or dose fraction.

2. Specific procedures for making this written record are included in this document as follows.
Section IV.C. HDR and LDR remote afterloading devices
Section VI.C. Brachytherapy Applications
Section VII.C. Sr-90 Eye Applications
Section VIII.C. Nuclear Medicine.

H. Misadministration and Recordable Event Policy (see definitions in Appendix A).

1. Any misadministration, or recordable event or possible variance shall be reported to the Radiation Safety Officer upon discovery.

2. A misadministration shall be reported by telephone to the NRC Operations Center no later than the next calendar day after discovery of the misadministration.

3. Any malfunction of remote afterloading devices that has the potential for causing a misadministration, recordable event, or possible variance shall be reported to the Radiation Safety Officer upon discovery.

4. Each recordable event shall be evaluated within 30 days after discovery by: (1) assembling the relevant facts including the cause, (2) identifying what, if any, corrective action is required to prevent recurrence, and (3) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

5. When a misadministration or recordable event is uncovered during the periodic review of the QMP, all similar patient cases from the previous 12 months shall be reviewed.

I. Modifications to the Quality Management Program

Modifications to the Quality Management Program shall be submitted to the NRC within 30 days after the modification has been made.

J. Training Requirements

All individuals involved in administrations covered by the QMP are required to be instructed in the contents of this document.

K. Commitment to QMP

All individuals involved in administrations covered by the QMP are required to follow the policies and procedures included in this document.

III. SPECIFIC POLICIES FOR RADIATION ONCOLOGY

These policies apply to the administration of radiation from byproduct material in Radiation Oncology: high-dose-rate (HDR), low-dose-rate (LDR) remote afterloading device, and brachytherapy applications. These administrations are also referred to in this document as "treatments" or "brachytherapy doses".

A. Oral Directives

Oral Directives are NOT permitted.

B. Acceptance Testing and Review of Treatment Planning Programs

There shall be a review by a qualified person (i.e. a teletherapy physicist as defined by subpart J of 10 CFR Part 35) of all dose calculating computer programs used for HDR, LDR, and brachytherapy as well as acceptance testing of any new computer systems. The review or acceptance testing must verify the accuracy of the program, the applicability of the program, and that the program is free of any problems that could result in less than accurate treatment plans. A written report of the reviews shall be maintained for three years in the Quality Management Program file.

IV. PROCEDURES FOR HDR AND LDR REMOTE AFTERLOADING DEVICES

A. Written Directive

1. An authorized physician user shall date and sign (or initial) a written directive prior to the administration. This is an order for a specific patient.

   The required contents for the written directive for HDR and LDR remote afterloading device therapy are: (a) Radionuclide, (b) Treatment Site, (c) Total Dose, and (d) Dose rate.

2. This information is written on the front sheet of the Radiation Oncology Treatment Record for that specific patient.

B. Confirmation of Written Directive Prior to Administration

1. Before any treatment is given with the HDR or LDR remote afterloading device, a complete treatment plan utilizing the methods, policies, and procedures of the Radiation Oncology Department is developed for the specific patient to be treated.

2. For HDR administrations, the positional accuracy of the source is verified with a standard check ruler image. Prior to each treatment a radiograph of the applicator position is taken.

3. For LDR remote afterloading administrations, the positional accuracy of the source is verified utilizing a special jig. A radiograph is taken of the applicator to verify the patient position prior to treatment.

4. Prior to administering the "dose", the final completed treatment plan or representative standard plan for the specific patient is checked for accuracy of computation by an individual other than the one who did the treatment plan. Both signatures (or initials) are recorded on the treatment plan and/or "worksheets". This verification of the accuracy must be as thorough as necessary to determine that no errors have been made, and that the plan conforms to the written directive.

Added 3-22-96 CCS

5. For HDR, prior to the start of each treatment, the following treatment data entries will be double checked for accuracy with the treatment plan: date, time, activity of the source, patient ID#, step size **(step length)**, channel number, **length (offset)**, dwell positions, dwell times, and total treatment time. The treatment data entry double check will be verified by the signatures (or initials) of two authorized individuals on the treatment tape prior to the start of each treatment.

5. If the HDR or LDR treatment is an emergency and delay in time to obtain this double check of the treatment plan would jeopardize the patient's health, then the physician authorized user shall note this condition in the patient's chart. This double check of the treatment plan, however, must be performed within two working days of the treatment.

C. Record of Confirmation of Written Directive After Administration

1. After administering the HDR or LDR remote after-loading device treatment, the physician authorized user, or qualified individual under the supervision of the physician authorized user (e.g. oncology resident, radiation therapy physicist, or dosimetrist) makes a record that confirms that each administered radiation dose or dose fraction was given in accordance with the written directive.

2. The dose confirmation record requirement may be fulfilled by one of the following procedures:
   (a) signature (or initials) of the physician authorized user, or qualified individual under the supervision of the physician authorized user on the HDR treatment tape which is saved in the Treatment Record. The HDR treatment tape specifies the source strength and exposure time per dose fraction;
   (b) written confirmation dated and signed (or initialed) by the physician authorized user in the "Progress Notes" section of the patient's Treatment Record or;
   (c) written confirmation dated and signed (or initialed) by a qualified individual under the supervision of the physician authorized user in the "Med/Tech Note" section of the Treatment Record.

3. Each written directive and record of confirmation of the administered dose shall be retained in the patient's chart for three years after the date of administration.

V. PROCEDURES SPECIFIC FOR HDR

A. Staff Whose Presence Is Required During HDR Treatments

During all HDR remote afterloading treatments, both the physician authorized user AND an individual approved by the Radiation Safety Committee to serve as medical physicist, or Radiation Safety Officer designate, are required to be physically present.

B. Training

All personnel are required to have training in both the routine use of the HDR afterloading device and emergency procedures necessary to return the source to a safe condition. This training is provided immediately to new personnel and annually to all personnel.

The HDR manufacturer, Nucleotron, shall provide the Emergency Training. Records of the initial training and annual retraining will be retained for a period of 3 years.

C. Patient Surveys

All patients treated with the HDR remote afterloading devices are surveyed to confirm that all sources have been removed immediately after the completion of the therapy procedure and prior to removal of the patient from the treatment room. The survey shall be performed with a portable radiation measurement survey instrument that is (a) capable of measuring dose rates of 1 millirem per hour to at least 1000 millirem per hour, and (b) calibrated with appropriate sensitivity.

The results of the patient survey are recorded in the "Med/Tech Note" section of the patient's Treatment Record or on the "Survey Log Form".

D. Room Monitor

Inside the HDR treatment room, a wall mounted area monitor displays a red flashing warning light when an exposed or partially exposed source is detected. The operation of the area monitor is directly connected to the Radiation Warning Light located outside the treatment room which also displays the red flashing warning light.

The function of the area monitor is checked in the morning of each patient treatment day with the Ir-192 source incorporated in the HDR remote afterloading device as part of our daily HDR dosimetry and quality control tests. If the area monitor fails the check source test, patient treatments are not performed.

E. Emergency Procedures

1. The "Emergency Procedures for Microselectron-HDR, Ir-192, If the Source Fails to Return to The Safe" are posted. An extended version includes specific instructions applicable to "Endobronchial Esophageal Treatment, Intracavity Applicators, Flexible Interstitial Implants, Rigid Interstitial Implants, and Interstitial Implants with Template". "Surgical Emergency Procedures For Surgical Removal of an Unshielded Source from the Patient's Body" is also posted in the Control Room for the HDR device.

2. These emergency procedures describe actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. No treatment shall be started when a decoupled or jammed source cannot be expeditiously removed from the patient and placed in a shielded container.

VI. PROCEDURES FOR BRACHYTHERAPY APPLICATIONS

A. Written Directive

An authorized physician user shall date and sign (or initial) a written directive. This is an order for a specific patient. The required contents for the written directive for brachytherapy applications other than HDR and LDR remote afterloading device treatments (Section IV), and Sr-90 eye applications (Section VII) are as follows:

1. Prior to implantation, the physician authorized user dates and signs (or initials) a written order on the front of the Radiation Oncology Treatment Record that includes: (a) Radionuclide, (b) Treatment Site, and (c) Total Dose.

2. Prior to implantation, the physician authorized user initials the "Physics Worksheet" as verification that the following information is consistent with the prescribed total dose: (a) the radionuclide, (b) the number of sources, (c) activity per source, (d) source sequence, (e) total activity, and (f) total dose.

3. After implantation, but prior to completion of the procedure, the physician authorized user records the following information in the "Progress Notes" section of the patient's Treatment Record: (a) the radionuclide, (b) treatment site, and (c) total source strength and exposure time (or, equivalently, the total dose).

B. Confirmation of Written Directive Prior to Administration

1. Prior to implantation the medical physicist or brachytherapy dosimetrist must verify that the radionuclide, number of sources, source strengths, and loading sequence of the sources, are consistent with the physician's authorized user written order on the front of the patient's Treatment Record and "Worksheet".

2. For temporary brachytherapy implants, as part of the treatment planning, nonradioactive "dummy" sources or applicators are radiographed prior to implantation. The radiographs are retained in the Treatment Record or Radiation Oncology Film File.

3. For permanent brachytherapy implants, radiographs of "dummy" sources or applicators may not be possible prior to implantation. See Section VI.E.

4. Prior to administration of a temporary or permanent implant, the final completed treatment plan for the specific patient is checked for accuracy of computation by an individual other than the one who did the treatment plan. Both signatures (or initials) are recorded on the treatment plan. This verification of the accuracy must be as thorough as necessary to determine that no errors have been made, and that the plan conforms to the written directive.

5. If the brachytherapy implant is an emergency and delay in time to obtain this double check of the treatment plan would jeopardize the patient's health, then the physician authorized user shall note this condition in the patient's chart. This double check of the treatment plan, however, must be performed within two working days of the treatment.

C. Record of Confirmation of Written Directive After Administration

1. After administering the temporary or permanent implant, the physician authorized user makes a record in the "Progress Notes" section of the patient's Treatment Record that confirms that each administered brachytherapy dose or dose fraction was given in accordance with the written directive. The record consists of (a) radionuclide, (b) treatment site, and (c) total source strength and exposure time (or, equivalently, the total dose).

2. The number of catheters and total activity is also recorded by the qualified individual under the supervision of the physician authorized user in the "Med/Tech Note" section of the patient's chart.

3. Each written directive and record of confirmation of the administered dose shall be retained in the patient's chart for three years after the date of administration.

D. Record of Loading Sequence After Insertion of Implants

1. After insertion of the temporary implant brachytherapy sources, the physician authorized user verifies the actual loading sequence of the radioactive sources implanted and signs (or initials) this record on the "Physics Worksheet" which is part of the patient's Treatment Record.

2. After insertion of the permanent implant brachytherapy sources, the physician authorized user promptly records the actual number of the radioactive sources implanted and signs (or initials) this record in the "Progress Notes" section of the patient's Treatment Record.

E. Radiographs After Insertion of Permanent Implants

After insertion of permanent implants (and when radiographs of "dummy" sources were not made prior to implantation), radiographs of the permanent implant will be taken before the patient is discharged from the hospital to verify the position of the sources and total dose.

VII. PROCEDURES FOR Sr-90 EYE APPLICATIONS

A. Written Directive

1. A physician authorized user shall date and sign a written directive. This is an order for a specific patient. The required contents for the written directive for Sr-90 eye applications are as follows:

   Prior to administration of the eye application, the physician authorized user dates and signs a written order on the "Sr-90 Eye Applicator Quality Management Form" (See Appendix B) which includes: (a) radionuclide, (b) treatment site, (c) source strength, and (d) exposure time (or equivalently, the total dose).

B. Confirmation of Written Directive Prior to Administration

Prior to administration, the authorized physician user, or qualified individual under the supervision of the physician authorized user (e.g. oncology resident, radiation therapy physicist, or dosimetrist), confirms that the final treatment plans and related calculations are in accordance with the written directive.

C. Record of Confirmation of Written Directive After Administration

1. After administering the Sr-90 eye application, the physician authorized user, or qualified individual under the supervision of the physician authorized user makes a record that confirms that administered application was given in accordance with the written directive. This is recorded on the "Sr-90 Eye Applicator Quality Management Form".

2. Each written directive and record of confirmation of the administered dose shall be retained for three years after the date of administration.

D. Oral Directive

Oral Directives Are Not Permitted.

VIII. PROCEDURES FOR NUCLEAR MEDICINE

A. Written Directive

1. A physician authorized user shall date and sign a written directive for any administration of quantities greater than 30 microcurie of either sodium iodide I-125 or I-131; or any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131. This is an order for a specific patient. The required contents for the written directive are as follows:

   Prior to administration of the radiopharmaceutical, the physician authorized user dates and signs the written directive section of the "Nuclear Medicine Quality Management Form" (See Appendix C) which includes: (a) radiopharmaceutical, (b) dosage, and (c) route of administration.

B. Confirmation of Written Directive Prior to Administration

1. Prior to administration of any dosage identified in VIII.A.1. above, the dose shall be measured in the dose calibrator by the radiopharmacy staff and the results compared with the prescribed dosage in the written directive. The measured dose is recorded on the radiopharmaceutical label and initialed.

2. Prior to administration of any dosage identified in VIII.A.1. above, the physician authorized user or qualified individual under the supervision of the physician authorized user (e.g. resident, medical physicist, or nuclear medicine technologist) shall also verify that the dose measured in the dose calibrator is correct.

C. Record of Confirmation of Written Directive After Administration

1. After administration of any dosage identified in VIII.A.1. above, the physician authorized user, or qualified individual under the supervision of the physician authorized user (e.g. resident, medical physicist, or nuclear medicine technologist) dates and initials a record that confirms that administered dosage was given in accordance with the written directive. This is recorded on the "Nuclear Medicine Quality Management Form".

2. Each written directive and record of confirmation of the administered dose shall be retained for three years after the date of administration.

D. Oral Directive

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive may be acceptable provided that: (a) the information provided in the oral directive is documented immediately in the patient's chart, (b) a written directive is prepared within 24 hours of the oral directive, and (c) the Radiation Safety Officer, or Radiation Safety Officer Designate is notified within 24 hours of the oral directive.

IX. PERIODIC REVIEW OF QUALITY MANAGEMENT PROGRAM

A. Annual Review

1. The Radiation Safety Officer shall annually review the Quality Management Program policies and procedures for Nuclear Medicine and Radiation Oncology to determine that the policies and procedures have been followed. The annual review includes an evaluation of: (1) a random sampling of patient charts, (2) the effectiveness of the corrective and follow-up action for all misadministration, and recordable events, and (3) the mechanics of the Quality Management Program to determine if any changes should be instituted.

2. Records of Quality Management Program review and evaluation are retained in an auditable form for three years.

B. Semi-annual Review

1. The Radiation Safety Officer or Radiation Safety Officer Designate shall semi-annually review applicable Treatment Records and/or Forms in Nuclear Medicine and Radiation Oncology to determine that the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive or plan of treatment. The number of records reviewed will be based on the acceptance sampling tables of 10 CFR Part 32.110 assuming an error rate of 2 percent.

2. Any misadministration, or recordable events found shall be reported to the Radiation Safety Officer upon discovery. Any malfunction of either the HDR or LDR remote afterloading devices that is found during the periodic review shall be reported to the Radiation Safety Officer.

3. Records of Quality Management Program review are retained in an auditable form for three years.

C. Access to Patient Charts for Review of QMP

All patient names included in the Quality Management Program shall be compiled and the list provided to the Radiation Safety Officer.

APPENDIX A

1. Written directive

"Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (6) below, containing the following information:

(1) For any administration of quantities greater than 30 microcurie of either sodium iodide I-125 or I-131: the dosage

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration.

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site , and total dose.

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose)."

2. "Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcurie of either sodium iodide I-125 or I-131:

(i) Involving the wrong patient or wrong radiophamaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage exceeds 30 microcurie.

(2) A therapeutic radiopharmaceutical dosage other then sodium iodide I-125 or I-131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration: or

APPENDIX A (continued)

Misadministration (continued)

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(5) A brachytherapy radiation dose:

(i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcurie of either sodium iodide I-125 or I-131, or both:

(i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rem dose equivalent to any individual organ."

3. "Recordable Event means the administration of:

(1) A radiopharmaceutical or radiation without a written directive when a written directive is required:

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

APPENDIX A (continued)

Recordable Event (continued)

(3) A radiopharmaceutical dosage greater than 30 microcurie of either sodium iodide I-125 or I-131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcurie;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose."

Reference: Title 10 Code of Federal Regulation Part 35.2 "Definitions"

Appendix B

WILLIAM BEAUMONT HOSPITAL
Sr-90 EYE APPLICATOR QUALITY MANAGEMENT FORM

Hospital Number: _____

Patient Name: _____

	First Treatment	Second Treatment
Written Directive		
Date		
Radionuclide	Sr-90	Sr-90
Treatment Site		
Source strength (decayed)		
Exposure Time/Total Dose		
Signature (Authorized User		
Patient Confirmation (Must check two)		
Name		
Birthdate		
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before dosing, Confirm:		
Followed Directive	Yes *No	Yes *No
After dosing, Confirm:		
Dose administered within 10% of prescribed	Yes *No	Yes *No
Date		
Inititals		
Administered By:		
Returned the Sr-90 Radiation Oncology	Yes No	Yes No

* If no is circled, please explain:

cc: Quality Management File (cc/sr90eye.494)

Appendix C

WILLIAM BEAUMONT HOSPITAL
NUCLEAR MEDICINE QUALITY MANAGEMENT FORM
(Therapeutic or Radioiodine Doses in Excess of 30 μCi)

Hospital Number: _____

Patient Name: _____

Location: Royal Oak Troy West Bloomfield

Written Directive	
Date	
Radiopharmaceutical	
Dose	
Route of Administration	
Signature (Authorized User)	
Patient Confirmation	
Name	
Birthdate	
Hospital I.D.	
Relative/Friend	
Wrist Band	
Before Dosing, Confirm:	
Followed Directive	Yes No
After Dosing, Confirm:	
Radiopharmaceutical	
Dose	
Route Administration	
Signature	
Date	
Hand Check Negative	Yes No

PLACE LABELS HERE

White: Patient Chart Yellow: Quality Management Folder