QUALITY MANAGEMENT PROGRAM

William Beaumont Hospital
License # 21-01333-01

September 9, 1996

24pp

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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 remote afterloading (LDR-RAL) 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 HDR and LDR-RAL Devices
Section V: Procedures Specific for HDR
Section VI: Procedures for all other 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-RAL devices
Section VI.A. All other 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, in the judgement of the physician, a delay 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 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-RAL 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 herself, confirmation of proper identity by a relative or friend.
   f. Confirmation that the patient matches the photograph in the patient's chart.
   g. Physician/nurse identification of the patient.

3. If the patient is an inpatient:

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

E. Confirmation of Written Directive Prior to Administration

1. Prior to administration, the specific details of the administration shall be verified to be in accordance with the written directive.

2. Specific verification procedures are listed as follows in this document.
   Section IV.B. HDR and LDR-RAL devices
   Section VI.B. All other 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-RAL devices
Section VI.C. All other 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 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 (see definition in Appendix D) of remote afterloading devices that has the potential for causing a misadministration or recordable event 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, 30% of all similar patient cases from the previous 12 months shall be reviewed.

6. Any possible variance shall be reported to the Radiation Safety Designate up discovery.

7. Any malfunction of remote afterloading devices that has the potential for causing a possible variance shall be reported to the Radiation Safety Designate upon discovery.

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 administration 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 in this document.

III. SPECIFIC POLICIES FOR RADIATION ONCOLOGY

These policies apply to the administration of radiation from byproduct material in Radiation Oncology: HDR, LDR-RAL, and all other brachytherapy applications. These administrations are also referred to in this document as "treatments" or "brachytherapy doses".

A. Oral Directives

An oral revision to a written directive is permitted only if, in the judgement of the physician, a delay 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 the 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.

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-RAL and all other 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-RAL 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-RAL device therapy are: (a) Radionuclide; (b) Treatment Site; (c) Total Dose; (d) for HDR, number of fractions, and for LDR, 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-RAL 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 at the beginning of each treatment day. Prior to each treatment fraction the applicator position and security are verified.

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

4. Prior to administering the brachytherapy 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.

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, reference 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.

6. If the HDR or LDR-RAL 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-RAL 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.

   (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 or within audible distance.

B. Training

All physician authorized users and individuals approved by the Radiation Safety Committee to serve as medical physicist, or Radiation Safety Officer designate 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 annually.

The HDR manufacturer, Nucletron, 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 Mcnitor

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 the daily HDR dosimetry and quality control tests. If the area monitor fails the check source test, a second survey meter will be used.

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, Intracavitary 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 technique will be implemented if the applicator, in the event of a decoupled or jammed source, cannot be expeditiously removed from the patient and placed in a shielded container.

VI. PROCEDURES FOR ALL OTHER 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-RAL device treatments (Section IV), and Sr-90 eye applications (Section VII) are as follows:

1. Prior to insertion of radioactive sources, 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 insertion of radioactive sources, 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 insertion of radioactive sources, 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 insertion of radioactive sources 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 authorized user's written order on the front of the patient's Treatment Record and "Worksheet".

2. For temporary brachytherapy implants, as part of the treatment planning, applicators are radiographed prior to insertion of radioactive sources. The radiographs are retained in the Treatment Record or Radiation Oncology Film File. For temporary eye plaque implants, the applicator position is verified intraoperatively.

3. For permanent brachytherapy implants, radiographs of "dummy" sources or applicators may not be possible prior to insertion of radioactive sources. 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.

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 insertion of radioactive sources), 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 the 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.A1. 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 and initials the radiopharmaceutical label.

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: (a) 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-RAL 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 insertion of radioactive sources: the radioisotope, number of sources, and source strengths; and

(ii) After insertion of radioactive sources 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 radiopharmaceutical, 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 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"

16.4

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		
Initials		
Administered By:		
Returned the Sr-90 Radiation Oncology	Yes No	Yes No

*If no is circled, please explain:

Appendix C

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

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

APPENDIX D

"Malfunction of remote afterloading devices that has the potential for causing a misadministration or recordable event" means that one of the following has occurred:

- The machine has failed to retract the active source into the safe for any reason. This includes separation of the source from the drive cable, complete power loss, mechanical seizure or obstruction, or software errors.
- The machine loses information necessary to complete a treatment.
- The machine fails to make an accurate record of a treatment delivered.
- The machine fails to detect an applicator assembly that is missing, improperly connected or obstructed.
- The machine derives an incorrect value for the current source activity (error > 10%).
- The machine fails to detect improper source positioning of >4mm.
- The machine fails to terminate or prevent treatment if door, keyswitch or emergency stop interlocks are activated. This includes service overrides which are not reset to clinical operation conditions when the machine is returned to service.
- The machine experiences complete power failure (i.e. backup power failure).
- The machine is unable to complete a treatment for any reason, once irradiation has begun.