

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

Section I outlines definitions, reporting, auditing and general requirements of the QMP program while Section II describes the QMP implementation for each therapeutic modality.

Recommendations are expressed in terms of **should and shall**. Use of “**Shall**” indicates that the recommendation is an essential ROC quality assurance guideline, which must be followed. Use of '**should**' in a recommendation implies it is to be followed when practicable. In practice, it is expected that any significant deviation from "**should**" require a justification.

I. Administrative Structure and Monitoring Requirements

This document describes revised quality assurance guidelines and clinical procedures for sealed-source and Radiopharmaceutical therapy intended to supplement the procedures outlined in the Radiation Oncology Center Brachytherapy Quality Assurance and Clinical Procedures Manuals. Their purpose is to assure compliance with NRC regulations regarding quality management and reporting requirements (10 CFR parts 20 and 35)

The Brachytherapy-Radiopharmaceutical and Gamma Knife QMP's stand as independent documents which can be revised independently of one another. The current document applies only to radioisotope procedures performed by Washington University radiation oncologists or supported by Washington University/ROC radiation oncology physicists. This includes all sealed source procedures and therapeutic radiopharmaceutical procedures for malignant disease. Unsealed isotope administrations for diagnosis or for treatment of benign disease are the responsibility of the Division of Nuclear Medicine and are not covered by this document.

We reserve the right to delete, to add, or to modify any of our QA policies, associated forms and documentation without NRC approval and without notifying NRC or the radiation safety committee as long as we satisfy the requirements imposed by our QMP program description, 10 CFR 20 and 35 and our license.

A. Definition of Medical Event

Any event that results in one of the following;

- 1) Delivered Dose/Activity that differs from Prescribed dose/activity by  $> 20\%$  or if it falls outside a Prescribed Dose/Activity Range.
- 2) Delivered fractional Dose/Activity that differs by more than 50% from fractionally prescribed dose/activity.
- 3) A Dose of  $> 5$  rem whole body EDE or  $>50$  rem tissue/organ or skin that results from
  - a. Administration of a wrong Radioactive drug
  - b. Using wrong administration route
  - c. Administration to Wrong individual
  - d. Dose/activity delivered by wrong mode of treatment
  - e. leaky source
- 4) Dose to skin/organ of  $> 50$  rem and 50% different from what it should be expected from the administration.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

- 5) Any unintended permanent functional damage to tissue or organ, as determined by physician, that results from intervention of a patient.

In the following, the term "prescription" is understood to have the same meaning as the term "written directive" used in 10 CFR Part 35. The term "authorized physician" is interchangeable with the term "authorized user".

**B. Quality Management Program**

The term 'licensee' refers to the corporate entity named in the NRC license governing medical use of by-product material within the institutions served by the Radiation Oncology Center Physics Section.

For procedures performed in Barnes-Jewish Hospital, the licensee is Washington University and Barnes Jewish Medical Center.

1. For each treatment modality (radiopharmaceuticals, high dose-rate brachytherapy and all other sealed-source brachytherapy, including <sup>90</sup>Sr eye-plaque therapy), specific policies or procedures shall be documented by each licensee to ensure that the QMP objectives of 10 CFR 35 are met. Specifically each licensee shall have:
  - a. Policies requiring an authorized user date and sign (or initial a written prescription prior to the administration;
  - b. Procedures to identify the patient by more than one method;
  - c. Procedures to confirm that the plans of treatment are in accordance with the written prescription;
  - d. Procedures requiring that, prior to administration, the person responsible for delivering the treatment reviews the specific details of the written prescription (e.g. in radiopharmaceutical therapy, verify the radiopharmaceutical, dosage, and route of administration) and to not initiate administration if discrepancies in the specific details exist;
  - e. Procedures to record the radiopharmaceutical dosage or radiation dose actually administered.
2. Each licensee or designated ROC staff in conjunction with the licensee radiation safety officer shall evaluate and respond to each medical event, within 15 days after discovery of the medical event, by:
  - a. Assembling the relevant facts including the cause;
  - b. Identifying what, if any, corrective action is required to prevent recurrence; and
  - c. Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.
3. Each licensee or designated ROC staff shall retain:

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

- a. Each written prescription; and
  - b. A record of each administered radiation dose or radiopharmaceutical dosage where a written prescription is required, in an auditable form, for three years after the date of administration.
4. Designated ROC staff or Radiation Safety office will review at least annually each applicable program area in behalf of the licensee: (1) radiopharmaceuticals, (2) HDR brachytherapy, and (3) other sealed source brachytherapy.
- a. The review will include:
    - An audit of a representative sample of patient treatments delivered since the previous audit. As a minimum, the licensee shall review at least **20%** of all relevant patient cases for each of the following modalities: therapeutic radiopharmaceutical administrations, high dose-rate brachytherapy courses of treatment and all other sealed-source brachytherapy procedures (including Sr-90 eye plaque courses of treatment) performed in the institution. For each patient case reviewed, a comparison will be made between what was administered versus what was prescribed in the written prescription. If the difference between what was administered and what was prescribed exceeds the criteria for a medical event, the steps outlined in paragraph B.2. or C.1 will be followed.
    - A review of all medical events that were identified in the reporting period.
  - b. To avoid persons reviewing their own work, an Health Physicist from Radiation Safety conducts annual QMP audits. If this is not possible, two people should work together as a team to conduct the review of that work. The Radiation Oncology Center QA and Radiation Safety Committee will regularly review the findings of each licensee's periodic review to ensure that the QM program is effective.
  - c. For each patient case reviewed, each licensee will determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written prescription or plan of treatment, as applicable. For example, were the following correct:
    - For radiopharmaceutical therapy: the radiopharmaceutical, activity, and route of administration prescribed will be compared to those recorded as actually having been administered. In addition, the measured activity of the sample administered to the patient will be checked against the prescribed activity.
    - For each course of HDR brachytherapy the following will be checked:
      - For the entire course of therapy, the radioisotope, treatment site, and total dose (or other relevant treatment specification quantity) recorded in the daily treatment record will be compared to the treatment prescription.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

- For each individual treatment, the prescribed fraction recorded in the daily treatment record will be checked against the prescription and the dwell time calculation and/or graphic treatment plan.
- For each individual treatment, the source strength assumed by the dwell time calculation/graphic treatment plan will be checked against the then-current quarterly source inventory.
- For each individual treatment, the total dwell time recorded on the daily treatment record and the remote-afterloader print-out will be checked against the total dwell time given by the manual calculation/graphic plan
- For all other individual sealed-source brachytherapy treatments, the following will be checked:
  - The recorded number of sources used will be compared to the loading diagram.
  - The strength of the sources, documented as having been used for treatment, will be checked against the appropriate quarterly source inventory and/or the activity verified by the medical physics staff.
  - The recorded total source strength will be verified. For temporary implants, the product of recorded treatment time and total source strength (or, where applicable, prescription dose rate) will be checked against the total quantity of radiation prescribed. For manually loaded temporary implants, the time interval between recorded source removal and recorded source insertion will be checked against the total prescribed time.
  - In the special case of Sr-90 eye plaque therapy, the recorded treatment site, applicator used and total dose administered during the course of therapy, as documented in the treatment record, will be checked against the prescription. The dose rate and fraction size assumed by the treatment-time calculation, will be checked against the appropriate quarterly inventory and prescription, respectively. In addition, for each fraction, the dose delivered will be checked against the prescription and the recorded treatment time checked against the treatment-time calculation.
- d. In addition, the following will be checked:
  - That the patient has been identified by two methods
  - That an authorized user has signed (or initialed), dated and completed the prescription
  - That for HDR brachytherapy, a physicist has reviewed the treatment/dwell time calculations and associated graphic treatment plan, if any. That for other sealed-source brachytherapy, a physicist has reviewed the yellow prescription form and associated treatment plan if any.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

- e. For each patient case reviewed, the licensee will seek to identify any deviations from the written prescription or the above outlined policies, the cause of each deviation, and the actions that would have prevented the deviation.

Any deviations or questions regarding the detailed implementation of the audit will be brought to the attention of the appropriate Physics Staff. Remedial actions to avoid such deviations in the future will be considered. Remedial actions may include, but are not limited to, new or revised policies, new or revised procedures, additional training, increased supervisory review of work or pointing out to personnel the nature of the error made, if any.

The results of the annual QMP audits will be presented to the institutional Radiation Safety Committee for review and action.

- 5. Each licensee will re-evaluate their QMP policies and procedures annually to determine whether the program is still effective or to identify actions required to make the program more effective. The licensee shall provide the NRC Region III Office any revisions to this QMP plan within 30 days of implementation of the revised plan.
- 6. Program review results will be documented and will be available for NRC inspectors for three years. The program review reports will be distributed within each institution to appropriate management and departments. Corrective actions for deficient conditions will be implemented within a reasonable time after identification of the deficiency.

C. Medical Events Procedures

- 1. For a medical event:
  - a. The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the event.
  - b. The licensee shall submit a written report to the NRC Region III Office within 15 days after discovery. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.
  - c. The licensee should notify the referring physician and also notify the patient of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

delay any appropriate medical care for the patient, including any necessary remedial care as a result of the medical event, because of any delay in notification.

- d. If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the medical event, a written report to the patient by sending either:
  - 1) A copy of the report that was submitted to the NRC; or
  - 2) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.
- e. Each licensee shall retain a record of each medical event for five years. The record must contain the names of all individuals involved (including the prescribing 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 medical event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

II. Procedure - Specific Quality Assurance Policies

This section describes revised quality assurance guidelines and clinical procedures for sealed-source and Radiopharmaceutical therapy intended to supplement the procedures outlined in the Barnes-Jewish Radiation Oncology Center Brachytherapy Quality Assurance and Clinical Procedures Manuals. Their purpose is to assure compliance with the new NRC regulations regarding quality management and reporting requirements (10 CFR parts 2 and 35).

Within our program and written documentation, the terms "prescription" and "written directive" are used interchangeably.

A. Radiopharmaceutical Treatments

- 1. Before administering any therapeutic dosage of a radiopharmaceutical, or any dosage of I-125 or I-131 in excess of 30  $\mu\text{Ci}$ , a physician authorized to perform radiopharmaceutical therapy shall sign (or initial) and date a written prescription, i.e., written directive. The isotope, radiopharmaceutical (chemical and physical form), route of administration, and prescribed activity shall be clearly described in the prescription.

If treatment must be delayed in order to obtain a written revision to an existing written directive and such a delay would compromise the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed (or initialed) by an authorized user prior to completion of the treatment.

2. Before administering a radiopharmaceutical treatment the patient's identity shall be verified by at least two of the following methods:

Asking the patient's name, birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, the photograph of the patient's face, or other appropriate method. Other appropriate method may include questioning the Operating Room personnel if the patient was identified prior to being placed under anesthesia in addition to looking at the Operating Room Boards and monitors to make sure that the patient under anesthesia is the correct patient.

Fulfillment of the requirement should be documented on the general radiopharmaceutical QA check off list and any other location where it is required (i.e. "prescription form")

3. Prior to administering the radiopharmaceutical, the brachytherapy technologist shall verify that the pre-treatment checks on the "general radiopharmaceutical administrations check off list" and the "specific radiopharmaceutical administration check off list" if available, are completed.
4. Prior to administering a radiopharmaceutical treatment to a patient, the technologist and/or assisting physician shall review the written prescription to verify that the proposed treatment is in accord with the prescription and other treatment documentation. Specifically, the isotope, radiopharmaceutical (chemical and physical form), proposed route of administration and the recorded measured/verified activity shall be checked against the prescription. The recorded measured/verified activity shall be within 10% of the prescribed activity.
5. *Activity of Record: The Manufacturers/ radiopharmacy supplier activity as documented on the package label and as verified by way of dose calibrator measurements shall be compared to the prescription activity. The activity determined by the dose calibrator assay must agree within better than  $\pm 3-5\%$  of the manufacturer/radiopharmacy stated activity; and the manufacturer/radiopharmacy stated activity must agree within  $\pm 10\%$  of the prescribed activity. **When this is met the Activity of Record is that provided by the manufacturers/radiopharmacy. This is applicable for both photon emitting and beta emitting isotopes..** If this is not met, an investigation on to the cause of discrepancy must be performed before administering the dose. If the explanations for the discrepancy can not be found in a timely manner, and if our dose calibrator daily quality assurance tests are satisfactory, the activity of record shall be that measured by our dose calibrator. The authorized physician must be contacted to inform of occurrence and to provide guidance on whether to proceed with the administration or to postpone. If the authorized physician approves the administration of the amount of drug measured, a prescription modification must be made and documented immediately. An investigation and remedial actions must be undertaken to resolve further issues. Dose*

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

*calibrators used for photon-emitting radiopharmaceuticals will meet the requirements outlined in 10 CFR 35.60.*

For radiopharmaceuticals emitting only  $\beta$  particles for which NIST traceable calibration standards are not readily available, the unit dosages of the manufacturer may be considered. Calibration checks against appropriate historical or vendor-established standards are strongly encouraged.

5. For complex radiopharmaceutical administrations (BEXXAR ,SIRTEX, TMI , MIBG) that requires the involvement of multiple disciplines and departments within our hospital/ institution, specific procedures should be written in order to comply with the requisites of this section; NRC regulatory guidelines and to address specific drug ordering and dispensation procedures, determination of activities to administer, determination of activities post administration, source ordering and receipt, actual drug delivery technique and procedures and logistics.
6. The individual administering the therapy shall seek guidance from a physician authorized to perform brachytherapy or a physicist (as appropriate) if the treatment prescription and/or treatment documentation is not understood before administering treatment.

**B. High-Dose Rate Brachytherapy**

1. Before administering an HDR treatment the brachytherapy technologist (or other operator) shall verify the patient's identity at least by two of the following methods:

Asking the patient's name, birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, the photograph of the patient's face or other appropriate method.

Fulfillment of the requirement should be documented on the HDR QA checkoff list and any other location that is required.

2. Before administering an HDR treatment, a physician authorized to perform brachytherapy procedures shall sign (or initial) and date a prescription. The prescription shall include: the isotope used, site of treatment, number of treatments, prescribed dose (or other prescription quantity) per fraction and total dose (or other prescription quantity).

If treatment must be delayed in order to obtain a written revision to an existing written directive and such a delay would compromise the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and the revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed (or initialed) by an authorized user prior to completion of the course of therapy.



**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

3. Where appropriate, radiographic imaging shall be used to define the dwell positions that are to be treated, anatomic location of the applicators, and/or relative positions of the applicators or dwell positions. Anatomical positioning of fixed-geometry or radio-opaque applicators (e.g., molds or shielded endocavitary applicators) will be confirmed using appropriate surgical, visual or imaging techniques. The accuracy of source positioning within such applicators shall be confirmed by appropriate techniques before initiating their use in patient therapy.
4. Prior to each treatment, a physicist shall review the prescription, simulation films or other localization data, graphic treatment plan (if available before treatment) and/or dwell-time calculations and remote afterloader treatment program print out.

The physicist shall verify:

- data input to the treatment planning computer or manual calculation including prescribed dose, active source positions, and source strength.
- accuracy of dose calculations including dwell-time calculations.
- accuracy of information transfer to HDR remote-afterloading device.

The physicist shall initial the treatment record, the computer treatment plan or manual calculation and the HDR treatment program printout to document this review. Graphic treatment plans are not appropriate or not required for some treatments. If medically appropriate, treatments normally accompanied by graphic treatment plans may be administered on the basis of manual calculations and the plan prepared later.

5. Before administering an HDR treatment, the technologist shall verify that:
  - Patients identity has been confirmed
  - the treatment program agrees with the written prescription, with regard to treatment site, isotope, total dose, dose per fraction and treatment modality (i.e., HDR).
  - that the programmed sequence of source positions and dwell times agrees with the previously-reviewed HDR graphic treatment plan or manual calculation.
  - that the HDR treatment channels are correctly connected to the corresponding applicators.

The technologist shall seek guidance from a physician authorized to perform brachytherapy or a physicist (as appropriate) if the treatment prescription and/or treatment documentation is not understood before administering treatment.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

6. Following completion of each fraction, the technologist shall document the treatment on the daily treatment record. Graphic treatment plans prepared after treatment administration should be promptly reviewed by a physicist.
7. Prior to implementing a previously-unused treatment planning program or any other equipment to support clinical procedures, a brachytherapy physicist will test the software and hardware for safe use and accuracy.

C. Low Dose-Rate (LDR) Brachytherapy (Eye Plaques, Prostates Implants, Lung I-125, IR-192 Implants)

1. Before administering an LDR treatment, the brachytherapy technologist or other operator shall verify the patient's identity by at least two of the following methods:

Asking the patient's name, birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, the photograph of the patient's face or other appropriate method. Other appropriate method may include questioning the Operating Room personnel if the patient was identified prior to being placed under anesthesia in addition to looking at the Operating Room Boards and monitors to make sure that the patient under anesthesia is the correct patient.

Fulfillment of this requirement should be documented on the LDR QA check off list and in any other documents where it is required. (i.e. prescription form)

2. Before administering an LDR brachytherapy treatment, an authorized physician shall sign (or initial) and date a written prescription and if available, treatment plan. If the prescription, and if available, treatment plan, are not signed by the authorized physician at the time of implant, a verbal authorization shall be obtained and the authorized physician must sign the prescription and treatment plan by the next calendar day.
3. Prior to loading sources into the applicators, the prescription and/or treatment plan shall, at minimum, specify the isotope, source strength, number of sources, applicator type (catheters/needles/plaques) and loading patterns.
4. The source strength shall be verified by way of measurement and compared against the prescribed and if available, treatment planned source strength, prior to loading any applicators and/or implanting the sources. Verification of the source strength shall be by way of measurement using the dose calibrator for loose sources and/or calculations based on manufacturer specified activity for sterile sutured sources.
5. Source loading patterns within applicator shall be verified by visual inspection or any other appropriate method before implanting the applicators into the patient.
6. Before completion of the treatment, the prescription shall be completed, including, in addition to the above, the treatment time, total prescribed dose or other prescription quantity (e.g., mg-hrs, total absorbed dose to an isodose surface or reference point, or total treatment time) and the treatment site.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

- a. In the special case of eye plaque brachytherapy, the actual plaque extraction date and time and the actual delivery time, in hours, shall be recorded on the prescription form. The technologist shall determine if the delivered amount of time is within 3% of the prescribed time. If this is not the case, the brachytherapy technologist shall inform physics and the authorized user of the events. The authorized user and physics shall either make the appropriate modifications to the prescription or classify the event as a medical event. If the event is classified as a medical event, then we proceed as indicated above in the medical event section of this manual.
7. In the special case of  $^{90}\text{Sr}$  eye plaque therapy, the prescription shall include the treatment site, radioisotope, activity, and number of fractions, dose (or other quantity) per fraction, and total dose (or other quantity).
8. If treatment must be delayed in order to obtain a written revision to an existing written directive and such a delay would compromise the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is dated and signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed (or initialed) by an authorized user prior to completion of the treatment.
9. Where appropriate, radiographic imaging shall be used to define the dwell positions that are to be treated, anatomic location of the applicators, and/or relative positions of the applicators or dwell positions. Anatomical positioning of fixed-geometry or radio-opaque applicators (e.g., molds or shielded endocavitary applicators) will be confirmed using appropriate surgical visual or imaging techniques. The accuracy of source positioning within such applicators shall be confirmed by appropriate techniques before initiating their use in patient therapy.
10. Prior to completion of treatment, a physicist shall review the prescription, simulation films or other localization data, graphic treatment plan (if available before treatment) and any relevant manual calculations. The physicist should verify:
  - accuracy of data input to the treatment planning computer and/or manual calculations including prescribed dose, prescription quantity, isotope, source type, source strength and source loadings and applicators types used.
  - Any manual or computer-aided dose calculations impacting on the accuracy of dose delivery.
  - Programming of remote afterloading device (if any).

In the case of a permanent implant, treatment calculations, if available and required, shall be reviewed as promptly as possible after source insertion.

**Barnes-Jewish Hospital/Siteman Cancer Center  
Washington University School of Medicine  
Mallinckrodt Institute of Radiology  
Radiation Oncology Department  
Medical Physics Division**

**Brachytherapy-Radiopharmaceutical Therapy Quality Management Program**

**Rev Date: Feb 15 2008**

11. Prior to inserting sources into the patient, the technologist and/or assisting physician shall review the written prescription to verify that the proposed loading is in accord with the prescription and other treatment planning documentation. Specifically, the radioisotope, number of sources, source strength and loading patterns will be confirmed.
12. The technologist and/or assisting physician shall seek guidance from a physician authorized to perform brachytherapy or a physicist (as appropriate) if the treatment prescription, associated treatment documentation or procedure is not understood before administering treatment.
13. Any changes in loading, prescribed dose, or total treatment time deemed advantageous to the medical management of the patient by the authorized physician shall be documented on the treatment record, signed (or initialed) and dated by an authorized physician. Such revisions to the written prescription must be made before completion of the treatment.
14. Prior to implementing a previously-unused treatment planning program or any other equipment to support clinical procedures, a brachytherapy physicist will test the software and hardware for safe use and accuracy.