

University of Maryland Baltimore

Radiation Safety Procedure

Procedure Number: 4.1

Title: Quality Management Program

Revision Number: 0

Effective Date: October 1, 2001

Technical Review and Approval:

_____ **Date:** _____
Radiation Safety Officer

Radiation Safety Committee Approval:

_____ **Date:** _____
Chair, Radiation Safety Committee

PROCEDURE 4.1, QUALITY MANAGEMENT PROGRAM

1.0 Purpose:

The UMB Quality Management Program has been developed and implemented to provide high confidence that medical uses of radioactive materials and radiation are administered as directed by the Authorized User and unforeseen events are evaluated and reported in accordance with applicable regulatory requirements.

2.0 Scope:

This procedure applies to all medical uses of radiation and radioactive materials for brachytherapy, teletherapy, and radiopharmaceutical use authorized under UMB's radioactive materials licenses.

3.0 Procedure:

3.1 *Quality Management Program Administration*

- 3.1.1 UMB may make modifications to this Quality Management Program provided that the effectiveness of the program is not diminished [G.6(c)(5)].
- 3.1.2 UMB shall provide copies of any Quality Management Program modifications to MDE for approval prior to implementation of the modification [G.6(c)(5)].
- 3.1.3 UMB shall submit to MDE, with the Quality Management Program, a certification that the program has implemented [G.6(c)(6)(ii)].
- 3.1.4 UMB shall conduct a review of the Quality Management Program no less frequently than once every twelve months [G.6(c)(2)]. This review shall include an evaluation of [G.6(c)(2)(i)]:
 - A representative sample of patient and human research subject administrations
 - All recordable events and
 - All misadministrations
- 3.1.5 UMB shall evaluate the annual reviews to determine the effectiveness of the Quality Management Program and make

program modifications as necessary to meet the program objectives [G.6(c)(2)(ii)].

3.2 Training and Compliance

All users of radiation and radioactive materials for medical purposes shall be trained on the content of the Quality Management Program and comply with the UMB Radiation Safety Program related to the use of radioactive materials, including all rules and regulations defined by the Radiological Health Program (RHP) of the Maryland Department of the Environment (MDE). Radiation and radioactive materials will be administered in accordance with approved Department procedures.

3.3 General Requirements for Written Directive Implementation and Verification

3.3.1 A written physician's order shall be confirmed/verified by an Authorized User via signature or initial on the order form prior to administration of [G.6(c)(1)(i)]:

- Any teletherapy radiation dose;
- Any gamma stereotactic radiosurgery radiation dose;
- Any brachytherapy radiation dose;
- Any radiopharmaceutical administration exceeding 30 μCi I-125 or I-131;
- Any therapeutic dose of a radiopharmaceutical other than I-125 or I-131.

3.3.2 If a delay to provide a written directive would jeopardize a patient's health, an oral directive will be acceptable provided that [G.6(c)(Footnote 1)]:

- The information in the oral directive is documented immediately in the patient's record, and
- A written directive is prepared and signed by the Authorized User within 24 hours of the oral directive.

3.3.3 An oral revision to an existing written directive will be acceptable if a delay to provide a written revision would jeopardize the patient's health. If an oral revision is implemented, the oral revisions will be documented immediately in the patient's record and a revised written directive will be signed and dated by the Authorized User within 48 hours of the oral revision [G.6(c)(Footnote 1)].

- 3.3.3 Revisions to written directives may be made provided that the revision is dated and signed by the Authorized User prior to the completion of the procedure or the next fractional dose [G.6(c)(Footnote 1)].

3.4 Specific Requirements for Nuclear Medicine Written Directives

Note: Prescription slips and written orders may be transmitted in hard copy or electronic format.

- 3.4.1 All written orders and prescription slips for therapeutic Nuclear Medicine Procedures shall include the following:
- Patient name
 - Date
 - Name of study and/or radiopharmaceutical for injection
 - Radiopharmaceutical dosages and route(s) of administration, and
 - Ordering physician signature.
- 3.4.2 All requests for specific tests, procedures or exams must be referenced in the Nuclear Medicine Clinical Procedures Manual that includes standard radiopharmaceutical dosages and route(s) of administration.
- 3.4.3 Any and all deviations must be reviewed and authorized by a Nuclear Medicine Physician or Authorized Nuclear Pharmacist.
- 3.4.4 Prior to injection, the technologist must verify the patient identity by at least two means [G.6(c)(1)(ii)]. Acceptable means include:

For inpatients:

- verification of I.D. tag
- verbal verification by patient
- verbal verification by nurse attendant
- patient chart

For outpatients:

- verbal verification, including spelling, by patient or individual accompanying patient
- proof of identity provided by patient
- prescription slip

- 3.4.5 Unless the patient's identity is confirmed, no injection of radiopharmaceutical shall be allowed without authorization of Nuclear Medicine Physician.
- 3.4.6 Prior to administering any byproduct material, the dose (activity), radiopharmaceutical, and route of administration shall be determined/confirmed and verified by the technologist to be in accordance with the written order [G.6(c)(1)(iv)]. An Authorized User must approve all deviations.
- 3.4.7 Immediately following the administration, the technologist performing the injection shall document and/or confirm in the appropriate computer record and/or dose slip, the time, date, radiopharmaceutical, and activity at time of injection, verified by his/her initial or signature.

3.5 Specific Requirements for Brachytherapy Written Directives

- 3.5.1 A written directive shall be obtained prior to the administration of any brachytherapy procedure. The written directives shall include the:
- Patient's name;
 - Date;
 - Treatment site;
 - Radioisotope;
 - Number of fractions;
 - Dose per fraction;
 - Total dose; and
 - Signature of authorized user of radioactive material.
- 3.5.2 A non-authorized user shall be supervised by an Authorized User and his/her signature must be countersigned by the Authorized User on all brachytherapy records.
- 3.5.3 For conventional brachytherapy procedures, the written directive shall also include the:
- Number of sources;
 - Strength of each source; and
 - Loading pattern.

- 3.5.4 Prior to the initiation of any brachytherapy procedure, the following information shall be verified by the individual performing the procedure:
- Patient's identity by two or more means; [G.6(c)(1)(ii)]
 - Treatment site;
 - Radioisotope;
 - Number of sources;
 - strength of each source; and
 - Calculations and dose distribution approved and signed by the Authorized User
- 3.5.5 After implantation but prior to completion of a conventional brachytherapy procedure, the following must be verified:
- time of implantation; and
 - total exposure time or total treatment dose
- 3.5.6 Final plans of treatment and related calculation for brachytherapy shall be prepared according to the written directive.
- Dose calculations shall be computer generated, and a medical physicist, other than the one making the calculations, shall check the calculations against the written directive.
 - The Authorized User shall approve the dose calculations prior to treatment.
- 3.5.7 Acceptance testing of computerized treatment planning programs shall be performed prior to commissioning their use.
- 3.5.8 All brachytherapy procedures shall be conducted in accordance with policies and procedures outlined in the department's Policy and Procedure Book and State of Maryland's RHP/MDE regulations.
- 3.5.9 Upon completion of the total prescribed dose of radiation, the patient's chart will be reviewed by the Medical Physics staff to verify compliance with the Quality Management Program. The results of the review will be reported to the department's Radiation Safety Committee on a semi-annual basis.

3.6 Recordable Events and Misadministrations

Deviations from a planned administration may be classified as either recordable events or misadministrations.

3.6.1 Recordable Events

Recordable events include [G.2]:

- Administration of a radiopharmaceutical or radiation without a written directive/order when required
- Administration of a radiopharmaceutical or radiation without having appropriately documented patient name, isotope, activity (or dose) at time of administration, date and identification of individual administering the dose
- Administration of I-131 or I-125 when:
 - the administered dose differs from prescribed dose by more than 10% and
 - the difference between the administered dosage and prescribed dosage exceeds 15 microcuries
- Administration of a therapy dose other than I-125 or I-131 differing from the prescribed dose by more than 10%

Within 30 days of the discovery of a recordable event, UMB shall [G.6(c)3]:

- Assemble the relevant fact concerning the event, including the cause of the event and
- Identify any corrective actions required to prevent recurrence

3.6.2 Misadministration:

All misadministrations shall be reported to the Radiation Safety Officer immediately upon occurrence, with follow-up written documentation of event within 24 hours.

Misadministrations include [D.1208]:

For radiopharmaceuticals, an administration involving:

- Greater than 30 microcuries of I-125 or I-131 to the wrong patient, or the wrong radioisotope

- Greater than 30 microcuries of I-125 or I-131 which is different from the prescribed dose by more than 20% and greater than 30 microcuries different from the amount prescribed
- A therapy dose other than I-125 or I-131 to the wrong patient, or use of wrong radioisotope or wrong route, or if different by more than 20% from the amount prescribed
- A diagnostic radiopharmaceutical dose other than quantities exceeding 30 microcuries of I-125 or I-131 that is: to the wrong patient; wrong route; wrong radiopharmaceutical; or wrong dose; and results in a dose to the patient which exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

For brachytherapy, an administration involving:

- The wrong individual, wrong radioisotope, or wrong treatment site (not including permanently implanted seeds that migrated from the correct treatment site)
- A leaking sealed source
- The failure to remove one or more temporary implants upon completion of a procedure
- A difference between the calculated administered dose and prescribed dose exceeding 20% of the prescribed dose.

For teletherapy doses, an administration involving:

- The wrong individual, wrong mode of treatment, wrong treatment site, or a dose other than the type intended
- A treatment consisting of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose
- The calculated weekly administered dose is 30% greater than the weekly prescribed dose
- The calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

All misadministrations shall be verbally reported to RHP/MDE. See Procedure 1.3, *Radiation Safety Reporting*.

4.0 Records and Reports:

4.1 Records

- 4.1.1 Each written directive and record of administered radiation dose or radiopharmaceutical dose shall be retained for not less than three years following the administration date [G.6(c)(4)].
- 4.1.2 Documented annual reviews of the Quality Management Program shall be retained for not less than three years [G.6(c)(2)(iii)].
- 4.1.3 All records related to administration of radioisotopes (including recordable events and misadministrations) should be reviewed at least weekly by the Radiation Safety Staff or other assigned individual with results documented in a monthly survey report distributed to the Director of the Nuclear Medicine Division and the Radiation Safety Officer.
- 4.1.4 All records and documentation related to recordable events and/or misadministrations will be retained for not less than three years from the date of occurrence [G.6(c)(3)(iii)].
- 4.1.5 Radiation safety records shall be created and maintained consistent with the requirements of Procedure 1.2, *Radiation Safety Records*.

4.2 Reports

Radiation safety reports shall be created and filed consistent with the requirements of Procedure 1.3, *Radiation Safety Reports*.

5.0 References:

Code of Maryland Regulations (COMAR) 26.12.01.01
State of Maryland License MD-07-014-01
UMB Radiation Safety Program
USNRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs"