

**QUALITY MANAGEMENT PROGRAM FOR HUMAN RESEARCH SUBJECT
UNIVERSITY OF CINCINNATI**

Effective January 27, 1992

**Modified: August 10, 1993; March 8, 1994; August 11, 1994;
July 18, 1995; September 23, 1997, November 14, 2001, May 19, 2004, June 17, 2006 and
(November 8, 2006)**

I. Purpose

This program is established in compliance with OAC 3701:1-58-16 to provide high confidence that radiation from radioactive material will be administered to human research subjects as directed by the Human-use Authorized User as authorized by the Radiation Safety Committee under the Radiation Control and Safety Program of the University of Cincinnati (ODH Type A Broad scope License # 02110310010).

II. Written Directive (Prescription)

1. Except for emergencies, a written directive must be signed and dated by a Human-use Authorized User (e.g., physician staff in Nuclear Medicine or Radiation Oncology with credentials approved at Children's Hospital Medical Center or Shriners's Hospital for Children) prior to the administration to human research subjects of either:
 - A. Quantities of Sodium Iodide I-131 in excess of 30 uCi; or
 - B. Any human therapeutic administration of a radiopharmaceutical; or
 - C. Any conventional brachytherapy treatment; or
2. For emergencies that could affect the health of the human research subject, the written directive may be replaced or modified with an oral directive, provided the oral directive is documented in the human research subject's record as soon as possible and a written directive is prepared within 48 hours after the oral directive.
3. Unless due to a medical emergency or change in a human research subject's medical condition, any revision to a written directive must be made prior to administration of the radiation dose or fractional dose. If due to a medical emergency or change in a human research subject's condition the Authorized User concludes a change in the written directive is necessary, the Authorized User must clearly indicate on the written directive why the change was made. If the modification is oral, documentation must be made as soon as possible in the human research subject's record and the revised written directive must be signed by the Authorized User within 48 hours. All changes to a written directive must be signed and dated by the Authorized User.
4. For written directives involving sodium iodine I-131, the written directive must specify:
 - A. The human research subject's name
 - B. The dosage
5. For written directives involving radiopharmaceuticals other than sodium iodine I-131, the written directive must specify:
 - A. The human research subject's name
 - B. The radiopharmaceutical
 - C. The dosage

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- D. The route of administration
- 6. For written directives involving conventional brachytherapy, the written directive must specify:
 - A. The human research subject's name
 - B. Before implantation
 - i. The radionuclide
 - ii. The treatment site
 - iii. The prescribed dose
 - C. After implantation but before completion
 - i. The radionuclide
 - ii. The treatment site
 - iii. The number of sources
 - iv. The total source strength and exposure time, or alternately the total dose
- 7. Each written directive will be retained by the appropriate medical division (Nuclear Medicine or Radiation Oncology) in an auditable form for a minimum of three (3) years after the date of administration.

III. Human Research Subject Identification by Physician, Technologist, Nurse or other Staff Member

- 1. Prior to each administration of radiation requiring a written directive, the identity of the human research subject must be verified by more than one method. The identification of the human research subject may be made by any two of the following methods.
 - A. Confirming the human research subject's identification by using a photo or other ID
 - B. Requesting of, receiving a statement from , and confirming the human research subject's name from the human research subject
 - C. Requesting from, receiving a statement from, and confirming the human research subject's name from a companion of the human research subject
 - D. Requesting and confirming, using the human research subject's record, the human research subject's date of birth, address, social security number, or signature
 - E. Confirming the human research subject's name using ID bracelet, hospital card or medical insurance card
 - F. Confirming with photograph of human research subject's face with appropriate identifier.
- 2. The methods of identification will be recorded on the written directive or an appropriate Radiation Oncology or Nuclear Medicine Quality Management form.

IV. Staff Physician Responsibilities for Conventional Brachytherapy

- 1. The Human-use Authorized User (staff physician) has the responsibility for the

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following.

- A. Determining the final plans of treatment
- B. Assuring that related calculations and administration are in accordance with the written directive.

V. Administration of Radiation under a Written Directive.

1. Prior to each administration of radiation requiring a written directive, the physician, technologist or brachytherapy therapist must verify and document that the radiation is being administered in accordance with the written directive or plan of treatment established from the written directive.
2. For photon-emitting radiopharmaceuticals this requires:
 - A. Measuring the activity (dosage) in a dose calibrator
 - B. Comparing the results with the written directive and documenting the dosage on the written directive
 - C. Documenting the activity (dosage) to be administered in the dose book
 - D. Having both the physician and the technologist sign-off the dosage in the dose book.
3. For beta-or alpha-emitting radiopharmaceuticals other than unit dosages this requires:
 - A. Directly measuring the activity (dosage) using instrumentation that is specifically designed and calibrated to measure beta- or alpha-emitting radionuclides, or combining measurements and calculations to determine activity (dosages) or combining volumetric measurements and calculations to determine activity (dosages)
 - B. Comparing the results with the written directive and documenting the dosage on the written directive
 - C. Documenting the activity (dosage) to be administered in the dose book
 - D. Having both the physician and the technologist sign-off the dosage in the dose book.
4. For beta- or alpha-emitting radiopharmaceuticals in unit dosages this requires:
 - A. Using a direct measurement or a decay correction based on activity or activity concentration determined by licensed manufacturer or licensed preparer
 - B. Comparing the results with the written directive and documenting the dosage on the written directive
 - C. Documenting the activity (dosage) to be administered in the dose book
 - D. Having both the physician and the technologist sign-off the dosage in the dose book.
5. For conventional brachytherapy this requires:
 - A. The Authorized User documenting before implantation the radionuclide, the treatment site, and the dose, and if applicable loading sequence prior to implant (Planned Activity)
 - B. Checking manual and/or computer-generated dose calculations. Whenever possible this check should be made by an individual who did not perform the original

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calculations.

- C. If the implant is not performed by the Authorized User, the individual administering the dose verifying and then the Authorized User confirming, that all applicable items (e.g., the radionuclide, number of sources, source strengths, treatment site, loading sequence and total dose) are in accordance with the written directive
 - D. After implant, but prior to completion of the procedure; recording the radionuclide, the treatment site, the number of sources, and total source strength and exposure time (or, equivalently, the total dose (Prescribed Dose))
 - E. Using radiographs or other imaging techniques to verify implant location
 - F. Comparing final radionuclide, treatment site, and total dose (Delivered Dose) to the Prescribed Dose.
- 6. For temporary conventional brachytherapy implants that include an exposure time greater than 24 hours, the implant site will be visually inspected to ensure sources have not moved. Visual inspections will be performed at least daily. If the visual inspection indicates the sources may have moved, additional radiographs or imaging techniques will be used to verify implant location. The results of the visual inspection will be recorded in the human research subject's chart.
 - 7. Computer programs may be used to perform dose calculations for brachytherapy procedures; however, prior to use of a new computer program, acceptance testing of dose calculations must be performed.
 - 8. If any worker does not understand, has questions concerning, or has doubts regarding a written directive, that worker must immediately seek guidance from the Human-use Authorized User, a physician, a supervisor or other appropriate individual prior to proceeding with the therapy/administration.

VI. Medical Event or Medical Incident

- 1. Any unintended deviation from the written directive, shall be identified, evaluated, and corrected by appropriate action to prevent recurrence. Any significant unintended deviation (i.e., 10% or more difference between administered and prescribed dose) that does not meet the regulatory definition of a medical event shall be handled as a medical incident.
- 2. After discovery of a medical event or medical incident, the Authorized User must insure proper notification.
 - A. For medical events this will include:
 - i. (during normal working hours) Immediately notifying the Radiation Safety Officer who will then notify the ODH no later than the next calendar day after discovery.
 - ii. (during off-hours) Immediately notifying by page the on-call Radiation Safety Technician who will then immediately notify the Radiation Safety Officer (the Assistant Radiation Safety Officer, a Radiation Safety Supervisor or other designated individual) who will notify the ODH no later than the next calendar

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day after discovery.

- B. For medical incidents this will include:
 - i. Notifying the Radiation Safety Officer (or alternatively the Assistant Radiation Safety Officer in absence of the Radiation Safety Officer).
 - ii. Submitting an incident report (RS Form 7 may be used) to the Radiation Safety Officer within seven calendar days.
- 3. The Radiation Safety Officer will evaluate all medical events and insure any written response and/or documentation is submitted within the ODH time frame and contains the information required by the ODH for such events. The documentation for all medical events and medical incidents will include the following.
 - A. The cause
 - B. The identification of corrective action that could prevent recurrence.
- 4. All records for medical events and medical incidents will be retained in an auditable record for five (5) years after the date of the event.

VII. Annual Review

- 1. A review of the Quality Management Program for Human research subjects will be conducted at intervals no greater than 12 months by at least one of the following.
 - A. The medical unit responsible for the radiation (i.e. an internal audit)
 - B. The Radiation Safety Office
 - C. The Radiation Safety Committee
 - D. Persons delegated by the Radiation Safety Committee.
- 2. A Review will evaluate a representative sample of the records of human research subjects receiving radiation that required a written directive to determine that the directives had been followed; and will evaluate all Medical Events or Incidents that have occurred since the last review. The Review will be expanded to include additional cases if the following two conditions are met.
 - A. A medical event or medical incident is uncovered (i.e., unknown until the Review was performed)
 - B. The Review did not include all cases for the time period of the review.
- 3. A record of each Review, including the evaluation and findings of the Review, will be maintained for at least three (3) years.
- 4. A copy of each Review will be presented to the Radiation Safety Committee and to the Divisions of Radiation Oncology and Nuclear Medicine.

VIII. Modifications

- 1. Only modifications of the Quality Management Program that increase the Program's efficiency or are deemed necessary to meet revised regulations will be made.
- 2. All modifications to the Quality Management Program will be reviewed and approved by

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the Radiation Safety Committee in accordance with procedures outlined for Radiation Control and Safety Program changes.

3. Copies of Quality Management Program changes will be maintained for the duration of the license.