QUALITY MANAGEMENT PROGRAM FOR HUMAN RESEARCH SUBJECTS
UNIVERSITY OF CINCINNATI

Effective July 18, 1995
Modified: September 23, 1997, January 19, 1999

I. Purpose

1. This program is established in compliance with 10 CFR 35.32 to demonstrate, with high confidence, that radioactive (byproduct) 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 (NRC Type A Broad scope License # 34-06903-05).

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 member in Nuclear Medicine or in Radiation Oncology at University Hospital, Inc. or at Children's Hospital Medical Center) prior to the administration to human research subjects of either:

a. Quantities of Sodium Iodide I-131 or I-125 in excess of 30 uCi; or

b. Any human therapeutic administration of a radiopharmaceutical other than Sodium Iodide I-125 or I-131; or

c. Any conventional brachytherapy treatment; or

d. Any high dose rate brachytherapy using afterloader treatment.

2. For emergencies which 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 and a written directive is prepared within 24 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 within 24 hours. All changes to a written directive must be signed and dated by the Authorized User.

4. For high dose rate brachytherapy using afterloader, if delaying treatment to perform the checks of dose calculations would jeopardize the human research subject's health because of emergent medical conditions, the dose calculation checks may be delayed, but must be performed within two working days.

5. For written directives involving radiopharmaceuticals, the written directive must specify:

a. The radiopharmaceutical
b. The dosage
c. The route of administration
d. The human research subject's name.

6. For written directives involving conventional brachytherapy, the written directive must specify:

a. The radioisotope
b. The number of sources
c. Source strengths, (planned activity) to be administered
d. The human research subject's name.

7. For written directives involving a high dose rate brachytherapy using afterloader, the written directive must specify:

a. The prescribed radioisotope
b. The treatment site
c. The total dose
d. The human research subject's name.

8. Each written directive will be retained by the appropriate medical division (Nuclear Medicine or Radiation Oncology at University Hospital, Inc.; or Nuclear Medicine at Children's Hospital Medical Center) 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. Identification of the human research subject by an employee (i.e. physician, technologist, nurse or other staff member) who can positively identify the human research subject (exclusive of b below)

b. Requesting and confirming the human research subject's name from the human research subject

c. Requesting from the human research subject 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 will be recorded on an appropriate Radiation Oncology or Nuclear Medicine Quality Management Program form.

IV. Staff Physician Responsibilities for Conventional and High dose rate brachytherapy using afterloader

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

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.

e. For research studies where the physician Authorized User caring for the human research subject is "blinded" to the type and/or amount of radiation to be administered, it is acceptable for any two technologists to verify the dosage and 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)

b. Comparing the results with 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.

e. For research studies where the physician Authorized User caring for the human research subject is "blinded" to the type and/or amount of radiation to be administered, it is acceptable for any two technologists to verify the dosage and sign-off the dosage in the dose book.

4. For beta- or alpha-emitting radiopharmaceuticals in unit dosages this requires:

a. Using the manufacturer's calibration of specific activity to determine the activity (dosage) by volume or weight

b. Comparing the results with the written directive

c. Documenting the activity (dosage) to be administered in either the dose book or on the written directive

d. Having both the physician and the technologist sign-off the dosage in the dose book or on the written directive.

e. For research studies where the physician Authorized User caring for the human research subject is "blinded" to the type and/or amount of radiation to be administered, it is acceptable for any two technologists to verify the dosage and sign-off the dosage in the dose book or on the written directive.

5. For conventional brachytherapy this requires:

a. The Authorized User documenting the radioisotope, the number of sources, the source strengths, and if applicable loading sequence prior to implant (Planned Activity)

b. 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 radioisotope, number of sources, source strengths, treatment site, loading sequence and total dose) are in accordance with the written directive

c. After implant, but prior to completion of the procedure; recording the radioisotope, treatment site, and total source strength and exposure time, (or, equivalently, the total dose (Prescribed Dose))

d. Using radiographs or other imaging techniques to verify implant location

e. Comparing final radioisotope, treatment site, and total dose (Delivered Dose) to the Prescribed Dose.

6. For high dose rate brachytherapy using afterloader this requires:

a. The Authorized User documenting the radioisotope, the treatment site and the prescribed total dose prior to treatment

b. Verifying the dose calculations are correct. Whenever possible, this check will be made by an individual who did not do the original calculations

c. If delaying treatment to perform the checks of dose calculations would jeopardize the human research subject's health because of emergent medical conditions, the dose calculation checks may be delayed, but must be performed within two working days

d. Using radiographs or other imaging techniques to verify the location of nonradioactive dummy sources prior to radiation administration

e. Calculating the administered dose expected from the location of the dummy sources and comparing this to the prescribed total dose

f. After administering the treatment, an Authorized User documenting the calculated administered dose with a verification signature and date

g. Comparing the total administered dose to the prescribed dose.

7. For temporary conventional brachytherapy implants which 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 preformed 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.

8. Computer programs may be used to perform dose calculations for brachytherapy (conventional and high dose rate) procedures; however, prior to use of a new computer program, acceptance testing of dose calculations must be performed.

9. 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. Misadministration; Recordable Event

1. Any unintended deviation from the written directive, shall be identified, evaluated and corrected by appropriate action to prevent recurrence.

2. After discovery of a Misadministration or Recordable Event, the Authorized User must insure proper notification. For misadministrations this will include:

a. (during normal working hours) Immediately notifying the Radiation Safety Officer who will then notify the NRC no later than the next calendar day after discovery

b. (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 NRC no later than the next calendar day after discovery.

3. The Radiation Safety Officer will evaluate all misadministrations and recordable events and insure any written response and/or documentation is submitted within the NRC time frame and contains the information required by the NRC for such events. The documentation for all misadministrations and recordable events will include the following.

a. The cause

b. The identification of corrective action which could prevent recurrence.

4. All records for misadministrations and recordable events 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 which required a written directive to determine that the directives had been followed; and will evaluate all Recordable Events or Misadministrations which have occurred since the last review. The Review will be expanded to include additional cases if the following two conditions are met.

a. A misadministration or recordable event 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 at University Hospital; and to the Division of Nuclear Medicine at Children's Hospital Medical Center.

VIII. Modifications

1. Only modifications of the Quality Management Program which increases the Program's efficiency will be made.

2. Copies of such changes will be furnished to the appropriate NRC Regional Office within thirty days after the modification has been made.