QUALITY MANAGEMENT PROGRAM FOR HUMAN RESEARCH SUBJECTS OR CLINICAL HUMAN PATIENTS
UNIVERSITY OF CINCINNATI License No. 02110310010

I. Purpose

This program is established in compliance with OAC 3701:1-58-15 and 3701:1-58-16 to provide high confidence that radiation from radioactive material will be administered to human research subject or patients 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, Interventional Radiology or Radiation Oncology with credentials approved at Children's Hospital Medical Center) prior to the administration to human research subject or patients of either:
    A. Quantities of Sodium Iodide I-131 in excess of 30 uCi;
    B. Any human therapeutic administration of a radiopharmaceutical;
    C. Any conventional brachytherapy treatment; or
    D. Y-90 microspheres (e.g., SIR-Spheres or TheraSpheres).
2. For emergencies that could affect the health of the human research subject or patient, the written directive may be replaced or modified with an oral directive, provided the oral directive is documented in the human research subject or patient'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 or patient'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 or patient'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 or patient’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 or patient's name; and
    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 or patient's name;
    B. The radiopharmaceutical;

C. The dosage; and

D. The route of administration.

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

A. The human research subject or patient's name

B. Before implantation:

i. The radionuclide;

ii. The treatment site;

iii. The prescribed dose; and

iv. The total source strength (permanent implant only).

C. After implantation but before completion of the procedure:

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; and

v. The date when the licensee assessed the patient's implantation.

7. For written directives involving Y-90 microsphere brachytherapy (e.g., SIR-Spheres or TheraSpheres), the written directive must specify:
   A. The patient or human research subject's name;
   B. The treatment site;
   C. The radionuclide (including the physical form [Y-90 microspheres]);
   D. The model of spheres (e.g., SIR-Sphere or TheraSphere) or manufacturer;
   E. The prescribed dose or activity; and
   F. If appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis".
8. Each written directive will be retained by the Radiation Safety Office and appropriate medical division e.g., Nuclear Medicine, Interventional Radiology or Radiation Oncology; in an auditable form for a minimum of three (3) years after the date of administration.

III. Human Research Subject or Patient 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 or patient must be verified by more than one method. The identification of the human research subject or patient may be made by any two of the following methods:

A. Confirming the human research subject or patient's identification by using a photo or other ID;

B. Requesting of, receiving a statement from, and confirming the human research subject or patient's name from the human research subject or patient;

C. Requesting from, receiving a statement from, and confirming the human research subject or patient's name from a companion of the human research subject or patient;

D. Requesting and confirming, using the human research subject or patient's record, the human research subject or patient's date of birth, address, social security number, or signature;

E. Confirming the human research subject or patient's name using ID bracelet, hospital card or medical insurance card; or

F. Confirming with photograph of human research subject or patient's face with appropriate identifier.

2. The methods of identification will be recorded on the written directive or an appropriate Radiation Oncology, Interventional Radiology 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 following:

A. Determining the final plans of treatment; and

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; and

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; and

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; and

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 calculations.

i. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
ii. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
iii. For manually-generated dose calculations, verifying:
1. No arithmetical errors;
2. Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
3. Appropriate use of nomograms (when applicable); and
4. Appropriate use of all pertinent data in the 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 or patient'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 confirming by independent means that the dose calculation methodology is accurate for the brachytherapy source type and model being used.

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. Medical incidents are to be reported to the Director of the appropriate Medical Division, the Authorized User, the RSO and the CRE and/or Authorized Medical Physicist (AMP). The RSO, possibly in conjunction with the appropriate CRE or AMP, will evaluate the specifics of the incident to determine if they meet the criteria to qualify as a Medical Event.

3. With the exception of an event that results from patient intervention, a Medical Event is the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, resulting in:

   A. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 sievert (5 rem) effective dose equivalent, 0.5 sievert (50 rem) shallow dose equivalent to the skin; and
      i. The total dose delivered differs from the prescribed dose by 20% or more;
      ii. The total dosage delivered differs from the prescribed dosage by 20% or more falls outside the prescribed dosage range; or
      iii. The fractioned dose delivered differs from the prescribed dose for a single fraction, by 50% or more.
   B. A dose that exceeds 0.05 sievert (5 rem) effective dose equivalent, 0.5 sievert (50

rem) to an organ or tissue, or 0.5 sievert (50 rem) shallow dose equivalent to the skin from any of the following:

i. An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

ii. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

iii. An administration of a dose or dosage to the wrong individual or human research subject;

iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or

v. A leaking sealed source.

C. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

i. 0.5 sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

ii. 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:
   A. The total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive;
   B. The total source strength administered outside of the treatment site exceeding 20% of the total source strength documented in the post-implantation portion of the written directive; or
   C. An administration that includes any of the following:
      i. The wrong radionuclide;
      ii. The wrong individual or human research subject;
      iii. Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
      iv. A leaking sealed source resulting in a dose that exceeds 0.5 sievert (50 rem) to an organ or tissue.
5. For Y-90 microsphere brachytherapy (e.g., SIR-Sphere or TheraSphere), with exception for an event that is caused by shunting or as a result of patient intervention whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration; the criteria for a medical event are:
   A. The administration of byproduct material resulting in a dose that exceeds 0.05 sieverts (5 rem) effective dose equivalent or 0.5 sievert (50 rem) to an organ or tissue; and
      i. An administration of the wrong radionuclide or type of microsphere;
      ii. An administration to the wrong individual or human research subject;
      iii. An administration by the wrong route of administration; or

iv. An administration by the wrong mode of treatment; or

B. The total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20% or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or

C. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 sievert (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive excluding shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

6. 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 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); and

      ii. Submitting an incident report (RS Form 7 may be used) to the Radiation Safety Officer within seven calendar days.

7. The Radiation Safety Officer will evaluate all medical events and ensure any written response and/or documentation is submitted within the ODH time frame and contains the information required by the ODH for such events as outlined in OAC 3701:1-58-101.

8. 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 Subject or patients will be conducted annually 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; or

   D. Persons delegated by the Radiation Safety Committee.

2. A Review will evaluate a representative sample of the records of human research subject

or patients 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); and

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, Interventional Radiology 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 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.

History
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1/27/92
Revision Date
8/93, 3/94, 8/94, 7/95, 8/97, 11/01, 5/04, 6/06, 11/06, 05/25
Review Date