


Name of Policy:	<u>Written Directives for Radiopharmaceutical Administration</u>	
Policy Number:	3364-135-090	
Department:	Radiology	
Approving Officer:	Chief Operation Officer- UTMC	
Responsible Agent:	Chairman & Professor, Radiology	
Scope:	Radiology	
		Effective Date: 3/1/2022
		Initial Effective Date: 1/26/1992
<input type="checkbox"/> New policy proposal <input checked="" type="checkbox"/> Minor/technical revision of existing policy <input type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy		

(A) Policy Statement

In accordance with OAC 3701:1-58-15 and OAC 3701: 1-58-16, a written directive is required for all applicable Nuclear Medicine procedures. Written directives pertaining to these administrations will not be executed if there are questions regarding the details of the administration, or the identity of the patient.

(B) Purpose of Policy

To prevent a radiopharmaceutical medical event, by minimizing the possibility of administering the wrong radiopharmaceutical, wrong dosage, wrong route of administration, and to ensure that the intended patient is properly identified prior to the procedure.

(C) Procedure

1. A written directive is required for administrations of sodium I-131 greater than 1.11 megabecquerels (thirty microcuries), or for an administration of a therapeutic dosage of unsealed radioactive material.
2. Only a licensed and Certified Nuclear Medicine Technologist (CNMT) or Authorized Users (AU) granted authority by the Radiation Safety office, will execute a written directive for a therapeutic radiopharmaceutical administration.
3. Prior to the procedure, the AU will sign, date, and time a written directive for the prescribed radiopharmaceutical. The written directive must include the patient's name and one other identification factor (e.g., date of birth, medical record number, SSN, etc.), the radiopharmaceutical, the prescribed activity to administer, and the route of administration.
4. Prior to administration, and in the presence of the AU, the person dosing the patient will properly verify and document the identity of the patient. For outpatients, use the patient's name and DOB. For inpatients, the patient's name, DOB, and MRN will be verified. The written directive will not be executed if proper patient identification cannot be made.
5. Prior to administration, and in the presence of the AU, the person dosing the patient will confirm the radiopharmaceutical, the route of administration, and the activity measured in the dose calibrator, are aligned with the written directive. Revisions to the written directive will be documented, signed, and dated on the original written directive. Oral directives and revisions to written directives are discussed in policy 3364-135-091.

6. The pregnancy and breastfeeding status (as applicable) will be verified with the AU, and all applicable radiation safety instructions and restrictions will be discussed with the patient, prior to administration.
7. If the person performing the administration requires clarification on how to perform the procedure, he/she should obtain guidance from the Chief Nuclear Medicine Technologist and/or the prescribing AU, prior to the administration.
8. If the person performing the administration requires clarification on the radiopharmaceutical, prescribed activity, or route of administration, then guidance from the AU who completed the written directive, or another AU certified for that same administration and route, must be obtained prior to administration.
9. After administration, the Technologist who performed the procedure will document the date of the administration, the time of dosing, and will sign the signature block.
10. If it is discovered that a procedural error has occurred, the administration will be reviewed by the RSO, CRE, and AU to determine if a medical event, as defined in OAC 3701: 1-58-101, has occurred and should be reported. The policy regarding radiopharmaceutical medical events and reporting is outlined in policy 3364-135-092.
11. All administrations requiring a written directive will also be reviewed annually by the Chief Nuclear Medicine Technologist and the RSO to determine if a medical event has occurred as defined in OAC 3701: 1-58-101.
12. Report and Notification of a Medical Event
 - (A) The University of Toledo shall report any event as a medical event, except for an event that results from patient intervention, in which:
 - (1) The administration of radioactive material or radiation from radioactive material, except Permanent implant brachytherapy, results 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 (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty rem) shallow dose equivalent to the skin; and
 - (i) The total dose delivered differs from the prescribed dose by twenty per cent or more;
 - (ii) The total dosage delivered differs from the prescribed dosage by twenty percent cent or more or falls outside the prescribed dosage range; or
 - (iii) The fractionated dose delivered differs from the prescribed dose for a single Fraction, by fifty per cent or more.
 - (b) A dose that exceeds 0.05 sievert (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty 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 (fifty 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) Fifty per cent 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.
- (2) 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 twenty per cent 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 twenty percent 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 (fifty rem) to an organ or tissue.
- (B) The University of Toledo shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- (C) The University of Toledo shall notify by telephone the Ohio department of health, bureau of environmental health and radiation protection no later than the next calendar day after discovery of the medical event.
- (D) The University of Toledo shall submit a written report to the Ohio department of health, bureau of environmental health and radiation protection to the address listed in listed in rule 3701:1-40-04 of the Administrative Code within fifteen days after discovery of the medical event.
- (1) The written report must include:
- (a) The licensee's name;
 - (b) The name of the prescribing physician;
 - (c) A brief description of the event;
 - (d) Why the event occurred;
 - (e) The effect, if any, on the individual(s) who received the administration;
 - (f) What actions, if any, have been taken or are planned to prevent recurrence; and
 - (g) Certification that the licensee notified the individual (or the individual's personal representative), and if not, why not.
- (2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(E) The University of Toledo shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty- four hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful to the individual. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter.

The University of Toledo may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's personal representative. If a verbal notification is made, the licensee shall inform the individual, or appropriate personal representative, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(F) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's personal representative.

(G) The University of Toledo shall:

- (1) Annotate a copy of the report provided to the Ohio department of health, bureau of environmental health and radiation protection with the:
 - (a) Name of the individual who is the subject of the event; and
 - (b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
- (2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

Approved by:		Review/Revision Date: 7/1/1993 10/1/1996 8/20/1999 9/1/2005 5/28/2008 5/1/2011 8/20/2014 8/31/2017 8/1/2020 12/1/2021 3/1/2022
<u>/s/</u> Haitham Elsamaloty, MD Chairman & Professor, Radiology	<u>03/14/2022</u> Date	
<u>/s/</u> Christine Stesney-Ridenour, FACHE Chief Operating Officer - UTMC	<u>03/15/2022</u> Date	
<i>Review/Revision Completed By:</i> Haitham Elsamaloty, MD		Next Review Date: 3/1/2025
Policies Superseded by This Policy:		