

# Employee Training

## Medical Event vs. Accidental Administration

Accidental administrations can occur in many different situations. They can occur due to technologist error, patient intervention, computer calculation errors, and equipment malfunctions. More serious situations require notification to the Nuclear Regulatory Commission. The NRC has a list of criteria that must be met in order to qualify an accidental administration as an official “Medical Event”. Your physicist will review the circumstances and calculate the dose equivalents to help you determine whether a particular administration issue qualifies.

Following is an overview of the NRC regulations as well as a flow chart to help you determine what constitutes a “Medical Event”. Instructions regarding reporting requirements and notification requirements for physician and patient are explained. Also attached is the dosimetry calculation worksheet that you must fill out as soon as a misadministration occurs and fax it to your physicist for the calculations.

### What constitutes a “Medical Event”?

A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

- A dose that **differs** from the prescribed dose or dose that would have resulted from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; **and**
  - The total dose or dosage delivered differs from the prescribed dose by +/-20% or more or falls outside the prescribed dosage range, or;
  - The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
- A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from **any** of the following:
  - An administration of a wrong radioactive drug containing byproduct material;
  - An administration of a radioactive drug containing byproduct material by the wrong route of administration;
  - An administration of a dose or dosage to the wrong individual or human research subject;
  - An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - A leaking sealed source.
- A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

## Medical Event vs. Accidental Administration

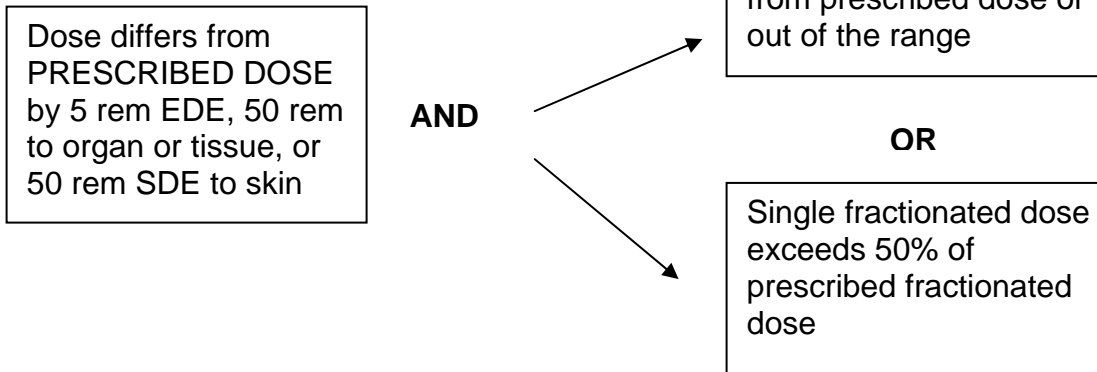
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A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or physiological system, as determined by a physician.

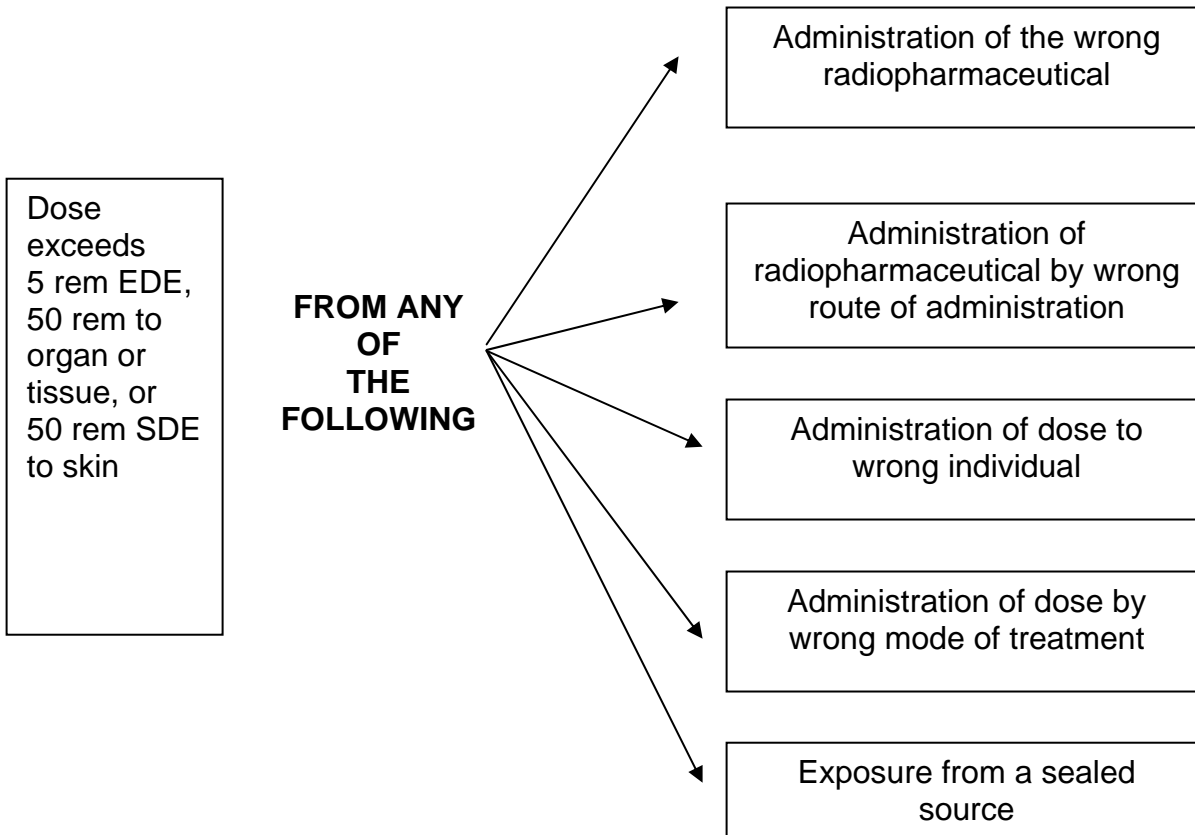
**If you feel you have an accidental administration that may qualify as a Medical Event, please fill out the attached “Worksheet” and fax it to your physicist IMMEDIATELY.**

**Scenarios For Medical Events Reportable to the NRC**

**Scenario 1**



**Scenario 2**



**Scenario 3**

A dose to skin, organ, or tissue other than the treatment site that exceeds 50 rem to an organ or tissue AND 50% or more of the dose expected from the administration defined in the written directive

**Scenario 4**

Any event which results from the intervention of a patient in which the administration of the radiopharmaceutical or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or physiological system, as determined by a physician

## Medical Event vs. Accidental Administration

### Procedures for Notification of the NRC

The licensee shall first notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

The licensee shall submit a written report to the NRC within 15 days after discovery of the medical event. The report must include:

- The licensee's name
- The name of the prescribing physician
- A brief description of the event
- Why the event occurred
- The effect, if any, on the individual(s) who received the administration
- What actions, if any, have been taken or are planned to prevent recurrence
- Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not
- ***The report may not contain the individual's name or any other information that could lead to identification of the individual.***

<b>NRC Notification of Medical Events</b>		
	<b>Telephone notification</b>	<b>Written Notification</b>
<b>Time Frame</b>	Next calendar day	15 days
<b>Region III</b> (Indiana, Ohio, Michigan, Minnesota)	(301) 951-0550	US Nuclear Regulatory Commission Region III, Materials Licensing Section 2443 Warrenville Road Suite 210 Lisle, IL 60532-4351

## **Medical Event vs. Accidental Administration**

### **Procedures for Notification of Referring Physician and Patient**

The licensee 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 24 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. 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 24 hours, the licensee shall notify the individual as soon as possible thereafter.

The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of a 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 instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian 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.

### **Licensee Records**

A licensee shall annotate a copy of the report provided to the NRC with the name and social security number (or other ID number) of the individual who is the subject of the event and keep the annotated report for their records. We have enclosed an "Accidental Radiopharmaceutical Administration" form for your internal use.

A copy of this annotated report must be provided to the referring physician no later than 15 days after the discovery of the event.

### **References:**

1. Title 10 of the Code of Federal Regulations, Part 35.
2. ICRP Report 80, vol. 28, issue 3

# Medical Event vs. Accidental Administration Radiopharmaceutical Dosimetry Calculation Worksheet

Date: \_\_\_\_\_

Institution: \_\_\_\_\_

Facility Address: \_\_\_\_\_  
\_\_\_\_\_

Report should be sent to: \_\_\_\_\_

Title: \_\_\_\_\_

Patient Name: \_\_\_\_\_

Patient Identification Number: \_\_\_\_\_

Patient's Age: \_\_\_\_\_

Intended Radiopharmaceutical and Activity: \_\_\_\_\_

Intended Study: \_\_\_\_\_

Administered Radiopharmaceutical/ Activity: \_\_\_\_\_

Route of Administration: \_\_\_\_\_

## Modifying Factors:

Abnormal Renal Function: Yes/ No

Abnormal Liver Function Yes/No

Occluded Bile Duct Yes/No

Thyroid Uptake: \_\_\_\_\_%

Blocking Agents: \_\_\_\_\_

Please complete this form and fax back to the appropriate office:

Michigan Fax: 734.662.9224

Indiana Fax: 317.581.1931

Wisconsin Fax: 734.662.9224

Utah Fax: 801.467.8774

# Accidental Radiopharmaceutical Administration

<b>Department:</b>		<b>Event Date:</b>		
<b>Root Cause:</b>		<b>Other:</b>		
<input type="checkbox"/> Wrong Radiopharmaceutical <input type="checkbox"/> Wrong Patient <input type="checkbox"/> Dosage Differing From Prescribed Dosage by 20% <input type="checkbox"/> Wrong Route of Administration				
<b>Intended Procedure:</b>		<b>Intended Dose:</b>		
<input type="checkbox"/> No Clinical Procedure <input type="checkbox"/> Nuclear Medicine Procedure <input type="checkbox"/> X-Ray Study <input type="checkbox"/> Ultrasound Study <input type="checkbox"/> No Clinical Procedure <input type="checkbox"/> MRI Study <input type="checkbox"/> Other:		Millicuries	Isotope	Study
		<b>Administered Dose:</b>		
		Millicuries	Isotope	Study

Error Details		
Hot Lab	Referral	Administration
<input type="checkbox"/> Mislabeled Syringe <input type="checkbox"/> Mislabeled Vial or Vial Shield <input type="checkbox"/> Reconstituted Wrong Reagent Kit <input type="checkbox"/> Placed Reconstituted Vial in Wrong Shield <input type="checkbox"/> Other:	<input type="checkbox"/> Selected Wrong Vial When Drawing Dose <input type="checkbox"/> Wrong Setting on Dose Calibrator <input type="checkbox"/> Misread Dose Calibrator <input type="checkbox"/> Misunderstood Radiopharmaceutical or Dosage Order <input type="checkbox"/> Other:	<input type="checkbox"/> Misunderstood Referring Physicians Request <input type="checkbox"/> Requested Wrong Study <input type="checkbox"/> Requested Study for Wrong Patient <input type="checkbox"/> Other:
<input type="checkbox"/> Selected Wrong Patient <input type="checkbox"/> Selected Wrong Isotope <input type="checkbox"/> Other:		

**Contributing Factors: (Check all that apply)**

<input type="checkbox"/> Student Technologist	<input type="checkbox"/> Referring Physician Order Not Checked
<input type="checkbox"/> New Employee	<input type="checkbox"/> Order not Verified in Patient Chart
<input type="checkbox"/> Language Barrier	<input type="checkbox"/> New Procedure
<input type="checkbox"/> Patient Mental Status	<input type="checkbox"/> Heavy Workload
<input type="checkbox"/> Two Patient Identifiers Not Verified	<input type="checkbox"/> Other:

**Action Taken To Prevent Recurrence: (Check all that apply)**

<input type="checkbox"/> Implement New Procedures for:	<input type="checkbox"/> Reprimand Personnel
<input type="checkbox"/> Verification of Request	<input type="checkbox"/> Improve Supervision of Personnel
<input type="checkbox"/> Radiopharmaceutical Labeling and Handling	<input type="checkbox"/> No Action Taken
<input type="checkbox"/> Verification of Patient Identification	<input type="checkbox"/> Other:
<input type="checkbox"/> Reinstruct Personnel	

**Event Details:**

*\*This accidental radiopharmaceutical administration does not meet the criteria of an NRC defined "Medical Event" as per 10 CFR 35.3045.*

<b>Radiation Safety Officer:</b>	<b>Staff Involved:</b>	<b>Witness:</b>
<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>

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