Print Form

MEDICAL EVENTS REPORTING FORM

INSTRUCTIONS FOR USE: Read these instructions carefully. Please note that completion and submittal of this form **DOES NOT RELEIVE THE LICENSEE FROM THE 24 HOUR TELEPHONE REPORTING REQUIREMENTS LISTED IN THE REGULATIONS**. The completed form MUST be submitted **within 15 days** of the discovery of the medical event. Please mail the completed report to: ***Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, AZ 85040.*** The completed report may also be faxed to the agency at (602) 437-0705.

The Arizona Radiation Regulatory Agency published this guidance to assist medical use licensees in complying with the reporting requirements regarding Medical Events (R12-1-745). The information contained is subject to change and is **guidance only**. The licensee must evaluate each event carefully and proceed accordingly.

You are strongly encouraged to type the information into the form. This form is posted to the Agency's website (*www.azrra.gov*). You may download the form(s) and save to your local computer.

BACKGROUND and DEFINITIONS

Background:
R12-1-745 "Medical Events" was codified on May 5, 2007. We have included a copy of the regulation within this guidance document for your convenience.

Definitions:
Remember, prescribed dosage and prescribed dose have two very different meanings within the context of the rules.

R12-1-702 "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

In a written directive; or
In accordance with the directions of an authorized user for procedures performed in accordance with the uses described in Exhibit A.

"Prescribed dose" means:

For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
For teletherapy, the total dose and dose per fraction as documented in the written directive;
For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

SECTIONS OF THE FORM

Section I: Use/Procedure/Modality information

This is simply general information gathered about the type of procedure or the modality/equipment being used when the event occurred. The "Other" category should be used for devices such as IVB or Iotrex® systems.

Section II: Type of Medical Event

This portion of the form deals with the language contained within the regulation. The criteria for each of the four "types" or categories of medical events are contained here. This section has four subsections labeled A. through D. Please note that the definition of a medical event is not predicated by the type of administration as was the case with misadministrations. Also, the first three "types" (A. – C.) are related to events that are NOT due to patient intervention. The fourth "type" (D.) is dealing with the issue of patient intervention. Each subsection of the form is explained below.

NOTE: The rule does not differentiate between diagnostic and therapeutic nuclear medicine procedures. Furthermore, the rule does NOT require that a written directive be done – so this rule applies to diagnostic nuclear medicine as well.

A. This "type" is DOSE driven and must have at least one of the subitems in addition to exceeding the dose limits of 5 rem EDE or 50 rem CDE or 50 rem SDE.

1. The dose difference is for 20 percent or more from prescribed. This has been interpreted to mean PLUS or MINUS 20% of the prescribed dose. Again, this relates to radiation from a SOURCE (accelerator, HDR, brachytherapy, etc)

2. Same percentage as No. 1 above or administered dosage falls outside of the prescribed ***dosage*** range

3. If the treatment is prescribed via fractionated dose, then any SINGLE FRACTION that differs from prescribed by 50% or more

B. The same DOSE criteria of 5 rem EDE or 50 rem CDE or 50 rem SDE, and occurs from **ANY** of the following

1. Administration of the **WRONG** radioactive **DRUG** containing radioactive material;
2. Administration of a radioactive drug containing radioactive material by the **WRONG ROUTE** of administration;
3. Administration of a dose or dosage to the **WRONG INDIVIDUAL (patient) or HUMAN RESEARCH SUBJECT;**
4. Administration of a dose or dosage delivered by the **WRONG MODE** of treatment; or
5. A **LEAKING SOURCE**.

C. A dose to the skin (SDE) or an organ or tissue (CDE) ***other than the treatment site*** that exceeds by **50 rem** (0.5 Sv) **and 50 percent** 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).*

D. A event resulting from **patient intervention** in which the administration of radioactive material or radiation from radioactive material ***results or will result*** in an ***unintended permanent functional damage*** to an organ or a physiological system, ***as determined by a physician***. The key pieces of information here are (1) there has to be some form of patient intervention FIRST; secondly, there must be PERMANENT FUNCTIONAL DAMAGE…as determined by a PHYSICIAN. (Note: the rule does not require the authorized user to make the determination. Any person licensed to practice medicine in Arizona can make this determination.)

Section III: Notifications

Three (3) persons are required to be notified with 24 hours of the DISCOVERY of a medical event:

a. The agency
b. The referring physician,
c. The patient (or responsible relative or guardian)

Agency notifications must be made to (602) 255-4845. If calling during normal business hours (M – F, 8 – 5), ask to speak with a member of the Radioactive Materials Program. Otherwise, please leave a message for a member of the Radioactive Materials Program. The message should include the following information:

1. Caller's name
2. Licensee name
3. License Number
4. Date of the medical event
5. Date of DISCOVERY of medical event
6. Date and time of phone call to the agency
7. Brief description of the event

Section IV: Reporting Requirements (To The Agency)

The written report is required to be transmitted to the agency within 15 days of discovery of the medical event. The rule (R12-1-745(d)) requires that seven elements must be contained in the report. The licensee name and the name of the prescribing physician are already listed on the reporting form. The remaining five elements that must be addressed are:

1. Brief description of the event;
2. Licensee's evaluation of why the event occurred;
3. The effect, if any, on the individual(s) who received the administration
4. What action(s), if any, have been taken or are planned to prevent recurrence;
5. Certification that the licensee has notified the individual (or the individual's responsible relative or guardian) and if not, why not.

ALSO NOTE: The rule requires that the licensee furnish an annotated copy of the report ***to the referring physician***

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within 15 days of the discovery of the event. The annotation shall include the name of the individual who is the subject of the event; and the social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event.

Section V: Certification

All medical event reports must be signed by a certifying official before being transmitted to the agency.

Section VI: Supplemental Information

This section is provided for convenience in reporting information to the agency. Attach additional sheets as necessary.

PLEASE REVIEW THE FORM CAREFULLY BEFORE TRANSMITTING

THE FORM MAY BE FAXED TO THE AGENCY [602-437-0705] IF NECESSARY

R12-1-745 MEDICAL EVENTS

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

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

(a) The total dose delivered differs from the prescribed dose by 20 percent or more;

(b) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(c) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(a) An administration of a wrong radioactive drug containing radioactive material;

(b) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) An administration of a dose or dosage to a wrong individual or human research subject;

(d) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent 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).

(B) A licenses 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 an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(C) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of the medical event.

(D) The licensee shall submit a written report to the Agency within 15 days of the 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 responsible relative or guardian) 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 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 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 responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or 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.

(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 responsible relatives or guardians.

(G) A licensee shall:

(1) Annotate a copy of the report provided to the agency 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 medical event; and

(2) Provide a copy of the annotated report to the referring physician if other than the licensee, no later than 15 days after the discovery of the event.

ARRA-ME

ARIZONA RADIATION REGULATORY AGENCY

MEDICAL EVENT REPORTING FORM

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1a. Licensee Name _____ 1b. License No. _____

2. Physical Address _____

3. Mailing Address

4. Event Date _____ 5. Discovery Date _____ 6. Telephone Report Date _____ 7. Written Report Date _____

8. Name of Authorized User or Prescribing Physician _____

9a. Name & Title of Individual to be contacted about this report _____

9b. Telephone No. 9c. Facsimile No. 9d. E-mail

I. USE/PROCEDURE INFORMATION

- ☐ Diagnostic Radiopharmaceutical
- ☐ Iodine-131 greater than 30 microcuries
- ☐ Therapeutic Radiopharmaceutical (other than ^{131}I)
- ☐ Manual Brachytherapy
- ☐ Remote Afterloading Device (HDR, PDR, LDR, etc.)
- ☐ Particle Accelerator
- ☐ Gamma Stereotactic Radiosurgery (gamma knife)
- ☐ Teletherapy
- ☐ Other (explain)

II. TYPE OF MEDICAL EVENT

Events that are NOT the result of patient intervention where…

A. ☐ A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage ***by more than*** 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; **AND**

1. ☐ The total dose delivered differs from the prescribed dose by 20 percent or more; ***or***
2. ☐ The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; ***or***
3. ☐ The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more

B. ☐ A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin **from any of the following**:

1. ☐ An administration of a wrong radioactive drug containing radioactive material;
2. ☐ An administration of a radioactive drug containing radioactive material by the wrong route of administration;
3. ☐ An administration of a dose or dosage to a wrong individual or human research subject;
4. ☐ An administration of a dose or dosage delivered by the wrong mode of treatment; ***or***
5. ☐ A leaking sealed source.

C. ☐ A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent 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).

An Event resulting from patient intervention…

D. ☐ In which the administration of radioactive material or radiation from radioactive material or an accelerator results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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1a. Licensee Name _____ 1b. License No. _____

2. Physical Address _____

3. Mailing Address

4. Event Date 5. Discovery Date 6. Telephone Report Date 7. Written Report Date

III. NOTIFICATIONS [1]

Was the agency notified via telephone within 24 hours of discovery?	☐ Yes	☐ No
Was the referring physician notified of the event within 24 hours of discovery	☐ Yes	☐ No
Was the patient (or patient's responsible relative or guardian) notified of the event within 24 hours of discovery?	☐ Yes	☐ No

If "No" to any question, please explain.

[1] *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 any delay in completing a notification required by this rule*

IV. REPORT REQUIREMENTS (TO THE AGENCY)

DO NOT include patient name or any information IN THIS REPORT that could lead to the identification of the patient.

Provide a written account of the event to include, at a minimum, the following (*Use Supplemental sheet on next page*):

1. Brief description of the event;
2. Licensee's evaluation of why the event occurred;
3. The effect, if any, on the individual(s) who received the administration
4. What actions, if any, have been taken or are planned to prevent recurrence;
5. Certification that the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not

NOTE: *Remember to provide an annotated copy of this report to the referring physician within 15 days of the discovery of the event. R12-1-745 outlines required information for annotated copy.* ***DO NOT SUBMIT ANNOTATED COPY TO THE AGENCY***

V. CERTIFICATION

The licensee, identified in Item 1a., certifies that all information contained in this report has been prepared in conformity with all applicable Arizona Radiation Regulatory Agency rules and regulations and is true and correct to the best of their knowledge and belief.

BY: _____ _____

Signature of Certifying Official Date Signed

_____

Printed Name and Title of Certifying Official

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3. Mailing Address

4. Event Date 5. Discovery Date 6. Telephone Report Date 7. Written Report Date

VI. SUPPLEMENTAL / ADDITIONAL INFORMATION