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 email the completed report to: travis.cartoski@dhhs.nc.gov, or any inspector listed for the Radioactive Materials Branch: https://radiation.ncdhhs.gov/staff.htm

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This Guide is not intended to, and does not, create any rights or privileges, substantive or procedural, which are enforceable by person. The publication of this guide, or any version thereof, does not place any limitation of the otherwise lawful prerogatives or discretion of the Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

The Radioactive Materials Branch (Branch) published this guidance to assist medical use licensees comply with the reporting requirements regarding Medical Events (10A NCAC 15 .0364). The information contained herein is subject to change and is guidance only. The licensee must evaluate each event carefully and proceed accordingly.

Please TYPE the information into the form. This form is posted to the Branch's website and can be found here:

https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm

Please note that if the information contained in the transmitted report is illegible, the report may be deemed "not timely filed" and the licensee may be subject to compliance and enforcement action(s).

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…)

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. An 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 that the rule does not require the authorized user to make the determination. Any person licensed to practice medicine in N.C. 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 (919) 621-4797 or (919) 602-7151. If calling during normal business hours (M – F, 8 – 5), ask to speak with a member of the Radioactive Materials Branch. Otherwise, please leave a message for a member of the Radioactive Materials Branch. 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

The written report is required to be transmitted to the agency within 15 days of discovery of the medical event. The rule (.0364(d)) requires that seven elements must be contained in the report. The licensee's 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.

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

NORTH CAROLINA
RADIATION PROTECTION

RADIATION PROTECTION SECTION
RADIOACTIVE MATERIAL BRANCH

MEDICAL EVENT REPORTING FORM

Revised December 2023

INSTRUCTIONS: Completion and submittal of this form is required by 10A NCAC 15 .0364. This form **MUST** be submitted within **15 days** of the discovery of the medical event. Completion of this form does **NOT** relieve the licensee of the telephone reporting requirements). This report **SHALL NOT** contain the patient's name or any other information that could lead to the identification of the patient. Records of a medical event must be maintained for agency review. This form may be transmitted via email to travis.cartoski@dhhs.nc.gov, or any inspector listed for the Radioactive Materials Branch: https://radiation.ncdhhs.gov/staff.htm

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
- ☐ Manual Brachytherapy
- ☐ Remote Afterloading Device (HDR, PDR, LDR, etc.)
- ☐ Particle Accelerator
- ☐ Gamma Stereotactic Radiosurgery (gamma knife)
- ☐ Therapeutic Radiopharmaceutical (other than ^{131}I)
- ☐ 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

VI. SUPPLEMENTAL / ADDITIONAL INFORMATION