10A NCAC 15 .0364 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 at the address listed in Rule .0111 of this Chapter within 15 days of the discovery of the medical event. The written report must include:

(1) The licensee's name;
(2) The name of the prescribing physician;
(3) A brief description of the event;
(4) Why the event occurred;
(5) The effect, if any, on the individual(s) who received the administration;
(6) What actions, if any, have been taken or are planned to prevent recurrence; and
(7) 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.

(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.

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;*
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