

10A NCAC 15 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by that authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of administration of radioactive material to a breast-feeding individual, that:

- (1) Is greater than 5 rem (50 mSv) total effective dose equivalent; or
- (2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) of this Rule.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) in this Rule.

- (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 embryo/fetus or the nursing child;
 - (F) What actions, if any, have been taken or are planned to prevent recurrence; and
 - (G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
- (2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under Paragraphs (a) or (b) of this Rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this Paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible 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) A licensee shall:

- (1) Annotate a copy of the report provided to the agency with the:
 - (A) Name of the pregnant individual or the nursing child who is the subject of the event; and
 - (B) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child 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 15 days after the discovery of the event.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0365 Eff. February 1, 2015.