

4731.4526 DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND NOTIFICATION.

Subpart 1. **Report required; embryo/fetus.** A licensee must report any dose to an embryo/fetus that is greater than five rems (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant woman unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

Subp. 2. **Report required; nursing child.** A licensee must report a dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding woman that:

A. is greater than five rems (50 mSv) total effective dose equivalent; or

B. has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

Subp. 3. **24-hour notification required.** A licensee must notify the commissioner within 24 hours after discovery of a dose to an embryo/fetus or nursing child that requires a report under subpart 1 or 2.

Subp. 4. **Written report.** A licensee must submit a written report to the commissioner within 15 days after discovery of a dose to an embryo/fetus or nursing child that requires a report under subpart 1 or 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. The 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 woman or mother, or the mother's or child's responsible relative or guardian, and if not, why.

Subp. 5. **Notification of individual.**

A. A licensee must provide notification of an event requiring a report under subpart 1 or 2 to the referring physician and to the pregnant woman or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful.

B. A 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 must make the appropriate notifications as soon as possible thereafter.

C. A 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.

D. To meet the requirements of this subpart, notification may be made to the mother's or child's responsible relative or guardian instead of the mother.

E. If a verbal notification is made, the licensee must inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must provide a written description if requested.

Subp. 6. **Individual identification.** A licensee must:

A. annotate a copy of the report provided to the commissioner with:

(1) the name of the pregnant individual or the nursing child who is the subject of the event; and

(2) the identification number or, if no other identification number is available, the Social Security number of the individual who is the subject of the event; and

B. 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.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 36 SR 74; 46 SR 791*

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