641—37.13(136C) Reports.

37.13(1) *Reports; stolen, lost, or missing licensed or registered sources of radiation.*

a. Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

(1) Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20, Appendix C, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas.

(2) Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in quantity greater than ten times the quantity specified in 10 CFR Part 20, Appendix C, that is still missing.

(3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

b. Written reports. Each licensee or registrant required to make a report pursuant to subrule 37.13(1) shall, within 30 days after making the telephone report, make a written report to the department setting forth the following information:

(1) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) Actions that have been, or will be, taken to recover the source of radiation;

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Additional substantive information. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. Names of individuals. The licensee or registrant shall prepare any report filed with the department pursuant to subrule 37.13(1) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

37.13(2) *Reports; notification of incidents and reporting requirements for licensees.*

a. Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

1. A total effective dose equivalent of 25 rem (0.25 Sv) or more;
2. A lens dose equivalent of 75 rem (0.75 Sv) or more;
3. A shallow dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more;

(2) The release of radioactive material inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) In addition to the requirements of paragraph 37.13(2)*"a,"* each licensee shall notify the department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (e.g., fires, explosions, toxic gas releases, and other such events).

b. Twenty-four-hour notification. Each licensee or registrant shall, within 24 hours of discovery of an event, report to the department each event involving loss of control of a licensed or registered source

of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:

1. A total effective dose equivalent exceeding 5 rem (0.05 Sv);
2. A lens dose equivalent exceeding 15 rem (0.15 Sv);
3. A shallow dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv);

(2) The release of radioactive material inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) In addition to the requirements of paragraphs 37.13(2)*"a,"* and *"b,"* each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

- Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
- Involves a quantity of material greater than five times the lowest annual limit on intake specified in 10 CFR Part 20, Appendix B, for the material;
- Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

- The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
- The equipment is required to be available and operable when it is disabled or fails to function;
- No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

- The quantity of material involved is greater than five times the lowest annual limit on intake specified in 10 CFR Part 20, Appendix B, for the material;
- The damage affects the integrity of the licensed material or its container.

37.13(3) *Reports; notifications and reporting requirements of a reportable radiation incident.*

a. The licensee or registrant shall report any radiation incident involving the administration of ionizing radiation resulted from any of the following to the department, except when the event is the result of intervention by a patient or human research subject.

(1) Therapeutic radiation machines:

1. That involve the wrong patient, wrong treatment modality, or wrong treatment site.
2. For which the weekly administered dose differs from the weekly prescribed dose by more than 30 percent.
3. For which the total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
4. For which the dose differs by 50 percent or greater for any single fraction of a multi-fraction treatment.
5. Any equipment failure, personnel error, accident, mishap or other unusual occurrence that causes or is likely to cause significant physical harm to the patient.

(2) Diagnostic radiation machine:

1. Results in an unintended skin dose to the same area in a single procedure greater than 2 Gy (200 rads).
2. Results in an unintended dose greater than five times the facility's established protocol for a procedure and exceeds any of the following:

- 0.5 Gy (50 rads) to an organ.

- 0.05 Gy (5 rads) total effective dose.

3. Involves the wrong patient or wrong site for the entire diagnostic examination (procedure/service) and exceeds any of the following:

- 0.5 Gy (50 rads) to an organ.
- 0.05 Gy (5 rads) total effective dose for the procedure.

4. Any wrong patient or wrong site imaged, regardless of dose received, shall be reported, documented, and addressed internally in accordance with the facility's established procedures.

(3) CT event investigation and reporting:

1. The cumulative CTDIvol over the course of an individual study at a particular anatomical location exceeds 60 rem (600 mGy) for a pediatric CT procedure or 150 rem (1500 mGy) for an adult CT procedure.

2. Any ionizing radiation exposure from a CT procedure results in unanticipated hair loss, erythema, or functional damage to an organ or physiological system.

3. For each event, the registrant shall conduct a root cause analysis in consultation with a qualified expert, the interpreting physician, and the operator who performed the CT procedure. The registrant shall make appropriate modifications consistent with the corrective action plan to prevent future events.

4. Involves any equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds 0.05 Gy (5 rads) total effective dose.

b. This rule applies to radiation incidents occurring during medical diagnostic and interventional X-ray procedures, as well as any other radiation machine-related incident that meets established reporting criteria. This rule also encompasses any additional incident deemed reportable by the department based on potential or actual deviation from intended use, dose, or safety standards.

c. 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 likely result, in unintended permanent functional damage to an organ or a physiological system, as determined by a physician, shall be reported.

d. The licensee or registrant shall notify the department by telephone no later than the next calendar day after discovery of the reportable radiation incident or medical event or sooner if required under the provisions set forth in this chapter where a more stringent reporting time frame has been established.

e. The licensee or registrant shall notify both the referring physician and the individual who is the subject of the reportable radiation incident or medical event no later than 24 hours after its discovery of the event.

(1) If the referring physician personally notifies the licensee or registrant that they will inform the individual, or determines, based on medical judgment, that informing the individual would be harmful, the licensee or registrant is not required to notify the individual directly.

(2) The licensee or registrant shall consult with the referring physician prior to notifying the individual.

(3) If the referring physician or individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter.

(4) Notification cannot delay any appropriate medical care for the individual, including necessary remedial treatment, resulting from the reportable radiation incident or medical event.

(5) If the individual is a minor or is unable to receive notification directly, notification may be made to a responsible relative or legal guardian.

(6) If notification is provided verbally, the licensee or registrant shall inform the individual, responsible relative, or legal guardian that a written description of the reportable radiation incident or medical event can be obtained from the licensee or registrant. The licensee or registrant shall provide such written description if requested.

37.13(4) *Report by telephone or electronic media.* Licensees or registrants shall make the notification of the incident report required by subrule 37.13(2) to the department by telephone or electronic media.

a. Licensees or registrants making initial reports to the department shall to the extent that the information is available at the time of notification include:

(1) The caller's name and call-back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

b. Each licensee or registrant who makes a notification of incident report required by subrule 37.13(2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all the necessary information. These written reports must be sent to the department at Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. The reports must include the following:

(1) The licensee or registrant name and license or registration number;

(2) Name of the prescribing physician, if applicable;

(3) A description of the event, including:

1. The probable cause;

2. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(4) The exact location of the event;

(5) Date and time of the event;

(6) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(7) Corrective actions taken or planned to prevent recurrence and the results of any evaluations or assessments;

(8) The extent of exposure of individuals to radiation or to radioactive materials, without identification of individuals by name, and the effect, if any, on the individual(s) who received the administration or exposure;

(9) Certification that the licensee or registrant notified the individual or the individual's responsible relative or legal guardian and the referring physician in compliance with the requirements of this chapter and if not, the reason why not.

37.13(5) *Names of individuals in detachable portion.* The licensee or registrant shall prepare each written report to be submitted to the department pursuant to subrule 37.13(2) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

37.13(6) *Rights or duties.* Aside from the notification requirement, nothing in this rule affects any rights or duties of licensees, registrants, and physicians in relation to each other; to individuals affected by the reportable radiation incident or medical event; or to that individual's responsible relatives or legal guardians.

37.13(7) *Doses from planned special exposures.* The provisions of subrule 37.13(2) do not apply to doses that result from planned special exposures provided such doses are within the limits for planned special exposures and are reported pursuant to subrule 37.13(8).

37.13(8) *Reports of planned special exposures.* The licensee or registrant shall submit a written report to the department within 30 days following any planned special exposure conducted in accordance with subrule 37.12(7) informing the department that a planned special exposure was conducted and indicating the date of the planned special exposure and the information required by subrule 37.12(7).

37.13(9) *Notifications and reports to individuals.*

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subrule 37.14(3).

b. When a licensee or registrant is required pursuant to subrule 37.13(8) to report to the department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the department to the individual. Such notice shall be transmitted at a time not later than the transmittal to the department and shall comply with the provisions of subrule 37.14(3).

[**ARC 0387D**, IAB 6/24/26, effective 7/29/26]