

REPORTS

4.51 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

4.51.1 Telephone Reports.

Each licensee or registrant shall report to the Department by telephone as follows:

4.51.1.1 Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix 4C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

4.51.1.2 Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix 4C that is still missing.

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

4.51.2 Written Reports.

Each licensee or registrant required to make a report pursuant to 4.51.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

4.51.2.1 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;

4.51.2.2 A description of the circumstances under which the loss or theft occurred; and

4.51.2.3 A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

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

4.51.2.5 Actions that have been taken, or will be taken, to recover the source of radiation; and

4.51.2.6 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.

4.51.3 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.

4.51.4 The licensee or registrant shall prepare any report filed with the Department pursuant to 4.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

4.52 Notification of Incidents.

4.52.1 Immediate Notification.

Notwithstanding other requirements for notification, each licensee or registrant shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event:

4.52.1.1 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:
 - (a) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
 - (b) A lens dose equivalent of 0.75 Sv (75 rem) or more; or
 - (c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or
- (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 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.

4.52.1.2 That prevents immediate protective actions necessary to avoid exposures to radiation and/or radioactive materials that could exceed regulatory limits, or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

4.52.2 Twenty-Four Hour Notification.

Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department:

4.52.2.1 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:
 - (a) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
 - (b) A lens dose equivalent exceeding 0.15 Sv (15 rem); or
 - (c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
- (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.

- 4.52.2.2 An unplanned contamination event that:
- (1) 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;
 - (2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and
 - (3) 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.
- 4.52.2.3 An event in which equipment is disabled or fails to function as designed when:
- (1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and
 - (2) The equipment is required to be available and operable when it is disabled or fails to function during the event; and
 - (3) No redundant equipment is available and operable to perform the required safety function.
- 4.52.2.4 An event that requires unplanned medical treatment at a medical facility of an individual whose body or clothing is contaminated with spreadable radioactive material.
- 4.52.2.5 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
- (1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and
 - (2) The damage affects the integrity of the licensed material or its container.

4.53 Preparation and Submission of Reports.

- 4.53.1 Reports made by licensees or registrants in response to the requirements of 4.52, must be made as follows:

- 4.53.1.1 Licensees or registrants shall make the reports required by 4.52.1 and 4.52.2 to the Department by telephone. To the extent that the information is available at the time of notification, the information provided in these reports must 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.

4.53.1.2 Each licensee or registrant who makes a report required by 4.52.1 or 4.52.2 shall submit a written follow-up report to the Department pursuant to 4.53.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

4.53.1.3 The provisions of 4.52 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 4.54.

4.53.2 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

In addition to the notification required by 4.52, each licensee or registrant shall submit a written report to the Department within 30 days after learning of any of the following occurrences:

4.53.2.1 Incidents for which notification is required by 4.52; or

4.53.2.2 Doses in excess of any of the following:

- (1) The occupational dose limits for adults in 4.6; or
- (2) The occupational dose limits for a minor in 4.12; or
- (3) The limits for an embryo/fetus of a declared pregnant woman in 4.13; or
- (4) The limits for an individual member of the public in 4.14; or
- (5) Any applicable limit in the license or registration; or
- (6) The ALARA constraints for air emissions established under 4.5.4.

4.53.2.3 Levels of radiation or concentrations of radioactive material in:

- (1) A restricted area in excess of applicable limits in the license or registration; or
- (2) An unrestricted area in excess of 10 times the applicable limit set forth in Part 4 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 4.14; or

4.53.2.4 For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, July 1, 2004, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

4.53.3 Contents of Written Reports.

4.53.3.1 Each report required by 4.53.1.2 or 4.53.2 shall include the following, as appropriate:

- (1) A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (2) The exact location of the event;

- (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (4) Date and time of the event;
- (5) The results of any evaluations or assessments, including:
 - (a) Estimates of each individual's dose;
 - (b) The levels of radiation and concentrations of radioactive material involved;
 - (c) The cause of the elevated exposures, dose rates, or concentrations; and
 - (d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

4.53.3.2 Each report filed pursuant to 4.53 shall include for each occupationally overexposed individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 4.13, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure".

4.54 Reports of Planned Special Exposures.

4.54.1 The licensee or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with 4.11, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 4.45.

4.55 Reports of Transactions Involving Nationally Tracked Sources.

4.55.1 Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in 4.55.1.1 through 4.55.1.5 for each type of transaction.

4.55.1.1 Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Report. The report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
 - (2) The name of the individual preparing the report;
 - (3) The manufacturer, model, and serial number of the source;
 - (4) The radioactive material in the source;
 - (5) The initial source strength in becquerels (curies) at the time of manufacture;
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