

Chapter HFS 157

APPENDIX R

EXAMPLES OF SEVERITY LEVELS

The following examples of severity levels apply to licensees or registrants and are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

A. Severity Level 1 – Most Significant Violations.

1. Exposure of a worker in excess of 250 mSv (25 rems) of radiation to the whole body, or 1.50 Sv (150 rems) to the skin of the whole body, or 3.75 Sv (375 rems) to the feet, ankles, hands, or forearms.
2. Annual whole body exposure in excess of 25 mSv (2.5 rems) of radiation to a non-radiation worker or a radiation worker who is a minor.
3. Release of radioactive material to an unrestricted area in excess of 10 times the limits specified in this chapter.
4. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in this chapter or the license.
5. Disposal of licensed material into a sanitary sewerage system in quantities or concentrations which exceed 10 times the limits of s. HFS 157.30 (3).
6. Exposure of a worker in a restricted area to 10 times the limits of s. HFS 157.22 (1).
7. A required system or equipment designed to prevent or mitigate a serious safety event not being operable when actually required to perform its designed function.
8. A material false statement in which the statement made is deliberately false.
9. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the department to report a real or suspected violation of this chapter or license condition.
10. Deliberate exposure of an individual except by or under the supervision of an individual licensed to engage in the healing arts.
11. Refusing authorized department personnel access to facilities, equipment or records necessary to conduct inspections or investigations.
12. Possession of licensable quantities of radioactive material without a license or loss of control of a source of radiation.
13. Falsification of records required by this chapter in which the records were deliberately falsified by or with the knowledge of the licensee or registrant.
14. Licensee or registrant failure to promptly respond to an emergency that has actual or potential offsite consequences.
15. Operating a mammography facility without proper certification.

B. Severity Level 2 – Very Significant Violations.

1. Single exposure of a worker in excess of 50 mSv of radiation to the whole body, 300 mSv to the skin of the whole body, or 750 mSv to the feet, ankles, hands or forearms.
2. Annual whole body exposure in excess of 50 mSv of radiation to a non-radiation worker or radiation worker who is a minor.
3. Release of radioactive material to an unrestricted area in excess of 5 times the limits of s. HFS 157.23 (2).
4. Radiation levels, contamination levels, or releases that exceed 5 times the limits specified in this chapter.
5. Failure to immediately notify the department as required by s. HFS 157.32 (1) and s. HFS 157.32 (2) (a) and (b).

6. Unauthorized disposal of licensed material in quantities or concentrations in excess of 5 times the limits of s. HFS 157.30 (3).
7. Exposure of a worker in a restricted area in excess of 5 times the limits specified in s. HFS 157.22.
8. A required system designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable.
9. Failure to obtain appropriate department approval before moving to a new use or storage location.
10. A material false statement or a reporting failure involving information which, had it been available to the department and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the department seeking further information.
11. Radiation output on fluoroscopic devices which exceed 200 mGy per minute in high rate mode.
12. Failure to register sources of radiation as required by this chapter.
13. Operating a mammography facility without qualified personnel, under 21 CFR Part 900.

C. Severity Level 3 – Significant Violations.

1. Single exposure of a worker in excess of 30 mSv (3 rem) of radiation to the whole body, or 75 mSv (7.5 rem) to the skin of the whole body, or 187.5 mSv (18.75 rem) to the feet, ankles, hands or forearms.
2. A radiation level in an unrestricted area such that an individual could receive greater than 1.0 mSv (100 millirem) in a one-hour period or 5.0 mSv (500 millirem) in any 7 consecutive days.
3. Failure to notify the department immediately as required by s. HFS 157.32 (2) (a) or failure to notify the department within 24 hours as required by s. HFS 157.32 (2) (b).
4. Substantial potential for an exposure or release in excess of the limits of this chapter, such as entry into high radiation areas without performing an adequate survey or operation of a radiation device with a nonfunctioning interlock system, if one is required.
5. Release of radioactive material to an unrestricted area in excess of the limits of s. HFS 157.23 (2).
6. Unauthorized disposal of licensed material not covered in severity levels I or II.
7. Exposure of a worker in restricted areas in excess of the limits of s. HFS 157.22 (1).
8. Release for unrestricted use of radioactive material or contaminated equipment which poses a potential for significant exposure to members of the public, or which reflects a programmatic rather than isolated weakness in the radiation safety program.
9. Cumulative worker exposure in excess of the regulatory limits in this chapter when such exposure reflects a programmatic rather than an isolated weakness in radiation protection.
10. Any noncompliance with posting, labeling, placarding, shipping papers, packaging, loading, or other transportation requirements that could result in the following:
 - a. Improper identification of the type, quantity, or form of material.
 - b. Failure of the carrier or recipient to exercise adequate controls.
 - c. Substantial potential for personnel exposure or contamination.
 - d. Improper transfer of material.
11. Failure to control access to licensed materials as specified by this chapter.
12. Possession or use by a licensee or registrant of a unauthorized radiation machine or radioactive material in conducting registrant or licensee activities.
13. Radiation levels, contamination levels or releases that exceed the limits specified in the license.
14. Failure to use exposure reduction devices properly, such as collimators, filtration or patient shielding.
15. Failure to hospitalize patients who have sealed source implants or therapeutic quantities of radioactive material in accordance with the license or license conditions.

D. Severity Level 4 – Violations.

1. Exposure in excess of the limits of s. HFS 157.22 (1) not constituting severity I, II, or III violations.
2. A radiation level in an unrestricted area such that an individual could receive greater than 0.02 mSv (2 millirems) in any one hour period or 1.0 mSv (100 millirems) in any 7 consecutive days.
3. Failure to notify the department within 30 days as required by s. HFS 157.32 (3).
4. Failure to make a follow-up written report to the department as required by s. HFS 157.32 (1) (b) or s. HFS 157.32 (6).
5. Failure to conduct required leakage or contamination tests or to use properly calibrated equipment.
6. Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the department was not informed, such as change of address, change of person in control or changes in the use of registered or licensed devices.
7. Failure to maintain complete records and forms required by this chapter.
8. Failure to report medical events as required in s. HFS 157.72.
9. Failure to report a dose to a embryo, fetus or nursing child as required by s. HFS 157.72 (2).
10. Fluoroscopic systems where the maximum table top skin entrance exposure rate is 100 mGy (11.5 R) per minute having test values greater than 140 mGy (16.1 R) per minute but less than 200 mGy (23 R) per minute.
11. Radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.
12. Radiation therapy systems in which the registrant fails to maintain proper surveys, calibrations, spot checks or operating procedures.

E. Severity Level 5 – Minor Violations.

1. Failure to maintain a current copy of this chapter and current copies of active licenses or certificates of registration.
2. Failure to post notices required by this chapter.
3. Failure to report leaking sources as required by s. HFS 157.72 (3).
4. Other violations that have minor safety or environmental significance.