



Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

**Hazardous Materials and Waste Management Division,
Radiation Control**

6 CCR 1007-1, Part 13

**STATE BOARD OF HEALTH
PENALTIES FOR VIOLATIONS**

(Amended September 15, 1993, effective October 30, 1993)

PART 13

PENALTIES FOR VIOLATIONS

RH 13.1 Purpose and Scope

13.1.1 The regulations in this Part set the criteria and specific procedures for notification of violations and the imposition of civil penalties under 25-11-107(5), CRS 1973 as amended.

RH 13.2 Definitions

13.2.1 "Civil Penalty" means any monetary penalty levied against a licensee or registrant because of violations of statutes, regulations, licenses, registration provision or order issued thereunder. Civil penalty does not include any criminal penalty levied under 25-1-114 or 25-11-107, C.R.S. 1973 as amended.

13.2.2 "Material False Statement" means a statement that is false by omission or commission and is relevant to the regulatory process.

RH 13.3 Penalties and Severity Levels

13.3.1 Any person who violates any license or registration provision of 25-11-103 or 25-11-104, CRS 1973 as amended, regulation, or any license or registration certificate condition, regulation or order issued thereunder shall be subject to these civil penalty regulations except as provided for under 13.4.

13.3.2 Violations are categorized in six levels of severity to reflect their public health or worker safety or environmental significance. Severity Level I represents the most significant actual or potential hazard; Severity Level VI represents the least significant actual or potential hazard.

13.3.2.1 Examples are provided in Appendix A for determining the appropriate severity level and will be presumptively correct. However, the severity level of a violation will be determined based upon the criteria in 13.3.2, above. The examples are not and do not create new requirements, but are predicated on existing regulatory requirements.

13.3.2.2 For violations not listed in Appendix A, the severity of a violation will be characterized at the severity level best-suited to the significance of the particular violation.

RH 13.4 Exemptions

13.4.1 A civil penalty will not generally be assessed for a violation which was unavoidable to prevent loss of life, personal injury or severe property damage or there were no feasible alternatives, and provided that proper notification was provided to the Department.

- 13.4.2 A civil penalty will not generally be assessed for violations resulting from matters beyond the control of the licensee or registrant, such as equipment failures that were unavoidable by reasonable quality assurance measures or management controls.
- 13.4.3 A civil penalty will not generally be assessed if interlocks are bypassed for short periods for maintenance or for quality control procedures provided that alternative safety procedures are implemented.

RH 13.5 Notification and Imposition

- 13.5.1 If the Department has reason to believe, based upon facts available to the Department, that a person has committed any violation of any licensing or registration provision of 25-11-103 or 25-11-104, CRS 1973 as amended, regulation, any license or registration certificate, or order issued thereunder, it shall notify such person within a reasonable time specifying:
 - 13.5.1.1 The date and factual basis of each act or omission with which such person is charged;
 - 13.5.1.2 The particular provision of the statute, rule, regulation, order, license, or registration certificate violated; and
 - 13.5.1.3 Necessary actions required to bring the licensee or registrant into compliance.
- 13.5.2 The notification required by RH 13.5.1 shall be sent by the Department by certified or registered mail, return receipt requested, to the last known address of the alleged violator. Any notice may be served by the Department by publication in a newspaper of general circulation in the area of the licensed facility or activity that is the subject of the notice, if the Department's efforts to serve by mail are unsuccessful. Service shall not be incomplete due to any refusal to accept service.
- 13.5.3 The alleged violator shall have thirty (30) days following the receipt of publication of the notice to submit a written response containing data, views, and arguments concerning the alleged violations and proposing a reasonable time for abatement. In addition, the alleged violator may request an informal conference with Department personnel to discuss the alleged violations. Such conference is to be held within the thirty (30) days allowed for a written response.
- 13.5.4 Within thirty (30) days after the time allowed for the written response and informal conference, the Department shall issue an order affirming or dismissing or otherwise disposing of the violation and, if the violation is affirmed, setting a time for abatement.
 - 13.5.4.1 The time for abatement shall be that reasonably necessary to achieve compliance given the severity of the violation and the actions necessary to correct the violation.
 - 13.5.4.2 The order may be modified and the time for abatement extended for good cause shown.

13.5.4.3 Immediate abatement may be ordered to the extent necessary to remove an imminent danger to public health, worker safety or the environment.

13.5.5 Any person failing to comply with an order issued pursuant to RH 13.5.4 shall be subject to a civil penalty of not more than five thousand dollars (\$5,000.00) for each violation specified in the order.

13.5.5.1 The amount will be based on the following Severity Level Table as adjusted in the discretion of the Department based on consideration of willfulness of the violation and good faith of the alleged violator in achieving compliance, but in no event may the penalty exceed \$5,000 for a single violation.

Dollar Amounts of Civil Penalties

| <u>Severity Level</u> | <u>Penalty</u> |
|-----------------------|----------------|
| I | \$5,000 |
| II | \$2,500 |
| III | \$1,250 |
| IV | \$ 625 |
| V | \$ 300 |
| VI | NONE |

13.5.5.2 The Department may compromise, mitigate, or remit any such civil penalty as justified by written documentation.

13.5.6 Upon determining that a person has failed to comply with an order issued pursuant to RH 13.5.4, the Department shall notify the person within ten (10) days by certified or registered mail, return receipt requested, of the proposed amount of any civil penalty. Such person shall have ten (10) days after receipt of the notification of the proposed penalty within which to request, in writing, an informal conference in which all relevant information concerning the violation and penalty, including all information which the alleged violator may submit, shall be reviewed by the alleged violator and an authorized representative of the Department. If such conference is requested, the alleged violator shall provide the Department with all relevant information, in writing, at least three (3) days prior the conference.

13.5.7 Following the conference pursuant to RH 13.5.6, or upon the expiration of time allowed for requesting the conference if no conference is requested, the Department shall either dismiss the penalty or order the penalty fixed and shall cause the order to be served personally on the alleged violator or his designated agent within forty-five (45) days of the mailing of the proposed penalty pursuant to RH 13.5.1. The order shall notify the alleged violator of the right to request a hearing within thirty (30) days, such hearing to be held in accordance with 24-4-105, C.R.S. 1973 as amended, to determine all of the following:

- 13.5.7.1 Whether the alleged violation exists or did exist;
- 13.5.7.2 Whether the actions taken or to be taken are or will be adequate to correct the violation;
- 13.5.7.3 Whether the time set for abatement was reasonable; and
- 13.5.7.4 Whether the civil penalty is reasonable in light of the statutory criteria upon which it is based.
- 13.5.8 Upon the request for such a hearing, the order shall be stayed pending the results of the hearing and any subsequent judicial review.
- 13.5.9 At the request of the Department, the Attorney General may institute a civil action to collect any civil penalty imposed pursuant to these regulations.

APPENDIX A
SEVERITY LEVEL EXAMPLES

Severity Level I

1. Single exposure of a worker in excess of 25 rem to the whole body, 150 rem to the skin of the whole body, or 375 rem to the hands, forearms, feet or ankles.
2. Annual whole body exposure of a member of the public in excess of 0.5 rem.
3. Release of radioactive material to an uncontrolled area in excess of ten times the limits of RH 4.35.1.2 of these regulations.
4. Exposure of workers in controlled areas in excess of ten times the limits of RH 4.6.1.1 of these regulations.
5. Violation of Department of Transportation (DOT) requirements pursuant to RH 17.15.10 of these regulations resulting in whole body radiation exposure of a member of the public in excess of 0.5 rem.
6. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times DOT limits.
7. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license.
8. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.
9. A Material False Statement in which the statement made was deliberately false.
10. Deliberate action by management to discriminate against an employee for attempting to communicate or actually communicating with the Department as specified in RH 10.5, RH 10.6, and RH 10.7 of these regulations.

Severity Level II

1. Single exposure of a worker in excess of 5 rem to the whole body, 30 rem to the skin of the whole body, or 75 rem to hands, forearms, feet or ankles.
2. Annual whole body exposure of a member of the public in excess of 0.1 rem.
3. Release of radioactive material to an uncontrolled area in excess of five times the limits of RH 4.35.1.2 of these regulations.
4. Failure to make an immediate notification as required by RH 4.35.1.2 of these regulations.
5. Exposure of a worker in controlled areas in excess of five times the limits of RH 4.6.1.1 of these regulations.

6. Exposure of a worker in controlled areas in excess of five times the limits of RH 4.4 of these regulations.
7. Breach of package integrity resulting in surface contamination or external radiation levels in excess of DOT limits.
8. Surface contamination or external radiation levels in excess of three times DOT limits that did not result from a breach of package integrity.
9. Failure to make required initial notifications associated with Severity Level I or II violations.
10. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license or regulations.
11. A system designed to prevent or mitigate a serious safety event being inoperable.
12. 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 the Department seeking further information.
13. A Material False Statement in which the false statement was made with careless disregard.

Severity Level III

1. Single exposure of a worker in excess of 3 rem to the whole body, 7.5 rem to the skin of the whole body, or 18.75 rem to the hands, forearms, feet or ankles.
2. A radiation level in an uncontrolled area that exceeds 100 millirem/hour for a one-hour period.
3. Failure to make a 24-hour notification as required by RH 4.52.2 these regulations.
4. Substantial potential for an exposure or release in excess of Part IV of these regulations whether or not such exposure or release occurs.
5. Release of radioactive material to an uncontrolled area in excess of limits of RH 4.35.1.2 these regulations.
6. Improper disposal of licensed material not covered in Severity Levels I or II.
7. Exposure of a worker in controlled areas in excess of limits of RH 4.6.1.1 of these regulations.
8. Release for uncontrolled use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program.

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic rather than an isolated weakness in radiation protection.
10. Conduct of activities by a technically unqualified person.
11. Significant failure to control licensed material.
12. Breach of package integrity.
13. Surface contamination or external radiation levels in excess of, but less than a factor of three above DOT requirements, that did not result from a breach of transport container.
14. Any noncompliance with labeling, placarding, shipping paper, packaging, loading or other requirements that could reasonably result in the following:
 - a. Improper identifications 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, or improper transfer of material.
15. Failure to control access to licensed materials for radiation purposes as specified by Department regulations, license conditions and orders.
16. Possession or use of unauthorized materials or equipment in the conduct of licensee activities.
17. Use of radioactive material on humans where such use is not authorized.
18. Radiation levels, contamination levels, or releases that exceed the limits specified in the license or regulations.
19. Medical therapeutic misadministrations.
20. A Material False Statement not amounting to a Severity Level I or II Violation.

Severity Level IV

1. Exposure in excess of the limits of Part 4 of these regulations not constituting Severity Level I, II, or III violations.
2. A radiation level in an uncontrolled area such that an individual could receive greater than 2 millirem in a one hour period or 100 millirem in any seven consecutive days.
3. Failure to make a 30-day notification as required by RH 4.53.1 of these regulations.
4. Failure to make a written report as required by RH 4.54 or 4.59 of these regulations.
5. Package selection or preparation which does not meet DOT requirements, but does not result in a breach of package integrity or surface contamination or external radiation levels in excess of DOT requirements.
6. Failure to maintain patients hospitalized who have had cobalt-60, cesium-137, or iridium-192 implants.
7. Medical diagnostic misadministrations.
8. Failure to conduct required leakage or contamination tests.
9. Failure to use properly calibrated equipment.
10. Other violations that have more than minor safety or environmental significance.

Severity Level V

1. Public health or worker safety or environmental items of minor significance.

Severity Level VI

1. No public health or worker safety or environmental items of significance.