

EFFECTIVE DATE
September 1, 2021

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ENFORCEMENT MANUAL

ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING PROCEDURES
FOR LICENSEES AND REGISTRANTS; PENALTIES

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001. SCOPE AND AUTHORITY

This manual addresses the conduct of proceeding under the Radiation Control Act, the administrative procedures of the Department and the Formal Hearing Procedures of the Department of Health and Human Services, for the issuing, denying, renewing, transferring, amending, suspending, revoking of any license, registration or certification of persons to use radiation sources and for determining compliance with or granting of exemptions from Department rule, order, or condition of license or certification of persons; for assessing administrative penalties; and for determining content of other Department orders. Proceedings held under the Radiation Control Act will be governed by 184 NAC 1, except as provided below. This manual provides guidance for the implementation of the Nebraska Radiation Control Act (the Act), Neb. Stat. Rev. §§ 71-3501 to 71-3520.

002. DEFINITIONS

Terms used in this manual have the following definitions:

Applicant. A person seeking a license or certificate of registration or a person's certification to use radiation sources issued under the provisions of the Act and these rules.

Certificate of Registration. A document issued according to the Act and 180 NAC.

Civil Penalty. A monetary penalty levied on a licensee or registrant because of statute, rule, regulation, license, or registration certificate violations not including criminal penalties.

Deliberate Misconduct. An intentional act or omission by a person that (a) would intentionally cause a licensee, registrant, or applicant for a license or registration to be in violation of any rule, regulation, or order of or any term, condition or limitation of any license or registration issued by the Department under the Radiation Control Act or (b) constitutes an intentional violation of a requirement, procedure, instruction, contract, purchase order, or policy under the Radiation Control Act of a licensee, a registrant, an applicant for a license or registration, or contractor or subcontractor of a licensee, registrant or applicant for a license or registration.

Enforcement Conference. A meeting held by the Department with licensee/registrant management to discuss safety, safeguards, or environmental problems; the licensee's/registrant's compliance with regulatory, license condition, or registration condition requirements; a licensee's/registrant's proposed corrective measures (including, but not limited to, schedules for implementation); and enforcement options available to the Department.

Hearing. A proceeding to examine an application or other matter before the Department in order to receive information or to adjudicate rights, duties, or privileges.

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Notice of Violation. A written statement of one or more infringements of a legally binding requirement. The notice normally requires the licensee/registrant to provide a written statement describing:

- (A) Corrective steps taken by the licensee/registrant, and the results achieved;
- (B) Corrective steps to be taken to prevent recurrence; and
- (C) The projected date for achieving full compliance.

Order. A specific directive contained in a legal document issued by the Department.

Severity Level. A classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

Violation. An infringement of any rule, license or registration condition, order of the Department, or any provision of the Act.

003. PUBLIC HEARINGS

The Department will hold a proceeding open to the public for the issuance or modification of rules or regulations relating to control of sources of radiation; and provide an opportunity for public participation through written comments and a public hearing. The purpose of the public hearing is to hear testimony or receive written statements from any person who chooses to offer information on the subject matter set for hearing, conducted according to the Nebraska Open Meetings Act, Neb. Rev. Stat. §§ 84-1407 through 84-1414.

004. RIGHT TO A HEARING

When the Department:

- (A) Denies:
 - (i) An application for a license or registration; or
 - (ii) An amendment to a license or registration; or
 - (iii) An application for an exemption from license or registration requirements; or
- (B) Revokes, suspends, modifies, conditions, or limits a license or registration; or
- (C) Imposes a civil penalty or appropriate order;

The Department will provide the applicant or licensee an opportunity for a hearing according to the Department's Rules of Practice and Procedures for Administrative Hearings, adopted pursuant to the Administrative Procedures Act, currently 184 NAC 1.

005. DISCIPLINE

005.01 Sanctions. Any person who violates any provision of the Radiation Control Act, or any rule, regulation, or order issued pursuant to such Act, or any term, condition, or limitation of any license, registration, or certificate issued pursuant to such Act or has engaged in deliberate misconduct is subject to:

- (A) Revocation, denial, suspension, modification, condition or limitation;
- (B) The imposition of a civil penalty; or
- (C) The terms of an appropriate order issued by the Department.

005.02 Compliance.

- (A) In all instances other than the issuance of emergency sanctions pursuant to Section 008, the Department may give the licensee, registrant, or certificate holder the opportunity to:
 - (i) Correct violations and show compliance with applicable provisions of the Act, or the rules and regulations, license or registration requirements, and any orders of the Department issued thereunder, or
 - (ii) Attend an enforcement conference to discuss with the Department methods and schedules for correcting the violation(s) or to show compliance with the Act, rules and regulations and license conditions. Notice of any enforcement conference will be sent by personal service or certified mail, return receipt requested. An enforcement conference is not a prerequisite for any action.
- (B) The Department may permit the licensee or registrant, or certified individual to respond in writing to the alleged violation of the Act, rule, regulation, order, or any term, conditions of limitation of license or registration.
- (C) Failure of a licensee or registrant to respond is cause for the Department to proceed with disciplinary action.

006. HEARINGS

Whenever the Department proposes to subject a licensee or registrant to the provisions of 005.01, the Department will notify the person in writing, of the following:

- (A) The date, facts, and nature of each act or omission with which the person is charged;
- (B) The chapter, rule, regulation, order, license or registration certificate involved in the violation; and
- (C) The sanction or order to be imposed.

If a civil penalty is imposed, the notice will include a statement that it can be collected by civil action. The notice will be delivered to each alleged violator by personal service, by certified or registered mail to the individual's last known address, or by publication. Notice by publication will only be made if personal service or service by mail is not possible. The sanction or order in the notice will become final 30 days after the mailing of the notice unless the applicant, registrant, or licensee, within the 30-day period, requests, in writing, a hearing before the Department. If the notice is served by personal service or publication, the sanction order will become final 30 days after completion of the service unless the applicant, registrant, or licensee, within the 30-day period, requests, in writing, a hearing before the Department.

007. SANCTIONS

007.01 Consideration. The Department may consider the following:

- (A) Criteria in determining appropriate sanctions:
 - (i) Previous history of noncompliance;
 - (ii) Action necessary to deter future violations;
 - (iii) Lack of reasonable efforts to correct the violation(s);
 - (iv) Willfulness; and
 - (v) Any other aggravating factors.
- (B) Severity levels. The seriousness of violations will be categorized by one of the following severity levels:
 - (i) Severity Level I - Violations that are most significant and have a direct negative impact on occupational and/or public health and safety or on the environment.
 - (ii) Severity Level II - Violations that are very significant and have an impact on occupational and/or public health and safety or on the environment.
 - (iii) Severity Level III - Violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.
 - (iv) Severity Level IV - Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances affecting public health and safety.
 - (v) Severity Level V - Violations that are of minor public health and safety or environmental significance.
- (C) Examples of violations in each severity level are set out in Appendix A of this manual.

007.02 Civil Penalties. The department may impose a civil penalty in an amount not to exceed \$10,000 for each violation. If any violation is a continuing one, each day a violation continues may be considered a separate violation for purposes of penalty assessment. Table 1 provides examples for civil penalties.

TABLE I

Examples of Civil Penalty Base Amounts Based on Severity Level of Violations

| Severity Level | Amount |
|----------------|---------|
| I | \$5,000 |
| II | \$3,000 |
| III | \$1,500 |
| IV | \$ 500 |
| V | \$ 100 |

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Adjustments to the amounts in Table I may be made for the presence of the criteria set out in Section 007.01, item (A).

007.03 Suspension and Revocation of a License or Registration. In addition to the other factors set out in Section 007 used by the Department to determine appropriateness of license revocation or suspension, the Department may act to suspend or revoke a license or a registration if a person:

- (A) Knowingly causes a material misstatement or misrepresentation to be made in the application for license or registration if such misstatement would impair the Department's ability to evaluate the applicant's qualifications; or
- (B) Willfully aids another person in violating the Act or Title 180.

008. EMERGENCY SANCTIONS

In the event of an emergency requiring immediate action to protect the occupational or public health and safety, or the environment, the Department may immediately, without prior notice or hearing:

- (A) Issue a regulation or order citing the existence of such emergency and require that certain actions be taken to meet the emergency:
 - (i) An emergency regulation or order takes effect immediately upon service on the person to whom the order is directed.
 - (ii) Any person receiving such emergency regulation or order must comply immediately.
- (B) If the Department determines that a person possessing sources of radiation is not equipped to observe or fails to observe the provisions of the Act or 180 NAC, then the Department may impound or order the impounding of the sources of radiation. Any person receiving an order of impoundment will comply immediately.
- (C) Service of any regulation order, or other notice or pleading under this manual will be made by personal service or by certified mail, return receipt requested. Affidavit of service, proof of mailing to the proper address, or the return receipt is evidence of service.
- (D) Hearings on Emergency Sanctions:
 - (i) A hearing will be held on an emergency regulation or order pursuant to Section 008, item (A) or upon an impoundment or order of impoundment pursuant to Section 008, item (B) if the person to whom the regulation or order or impoundment is directed makes a written application to the Department for a hearing; said application must be filed within 15 days of receipt of the emergency regulation or order of impoundment or notice of impoundment.
 - (ii) The hearing will be held not less than 15 days nor more than 30 days after filing the written application for hearing, unless waived by the person requesting the hearing.
 - (iii) On the basis of the evidence presented at the hearing, the Department will, within 30 days after such hearing, continue, modify or revoke the emergency regulation or order or impoundment or order of impoundment that was the subject of the hearing, and the Department will send the applicant a copy of its findings of fact and determination.
- (E) Any final department action on emergency regulations or orders or impoundment of sources of radiation is subject to judicial review pursuant to the Administrative Procedure Act.

009. DISPOSITION OF AN IMPOUNDED SOURCE OF RADIATION

Any source of radiation impounded by the Department is declared to be a common nuisance and cannot be subject to a replevin action. Disposal of an impounded source of radiation will be determined by Section 009 and Neb. Rev. Stat. §71-3516.01.

009.01 The Department will keep any source of radiation impounded under Neb. Rev. Stat. §71-3516 for as long as it is needed as evidence for any hearing.

009.02 Prior to the issuance of an order of disposition for an impounded source of radiation, the Department will notify in writing any person, known by the Department to claim an interest in the source of radiation, that the Department intends to dispose of the source of radiation. Notice will be served by personal service, by certified or registered mail to the last-known address of the person, or by publication. Notice by publication will only be made if personal service or service by mail is not possible.

009.03 Within 15 days after service of the notice under Section 009.02, any person claiming an interest in the impounded source of radiation may request, in writing, a hearing before the Department to determine possession of the source of radiation. The hearing will be held in accordance with rules and regulations adopted and promulgated by the Department. If the Department determines that the person claiming an interest in the source of radiation has proven by a preponderance of the evidence that such person:

- (A) Had not used or intended to use the source of radiation in violation of the Radiation Control Act,
- (B) Has an interest in the source of radiation acquired in good faith as an owner, a lien holder, or otherwise, and
- (C) Has the authority under the Radiation Control Act to possess such source of radiation, the Department will order that possession of the source of radiation be given to such person. If possession of the impounded source of radiation is not given to the person requesting the hearing, the person may appeal the decision of the Department, and the appeal will be in accordance with the Administrative Procedure Act. If possession of the impounded source of radiation is not given to the person appealing, the Department will order the person to pay for the costs of the hearing, storage fees, and any other reasonable and necessary expenses related to the impounded source of radiation.

009.04 If possession of the impounded source of radiation is not given to the person requesting the hearing under Section 009.03, the Department will issue an order of disposition for the source of radiation and will dispose of the source of radiation as directed in the order. Disposition methods are at the discretion of the Department and may include, but are not limited to:

- (A) Sale of the source of radiation to a person authorized to possess the source of radiation under the act; or
- (B) Transfer to the manufacturer of the source of radiation; or
- (C) Destruction of the source of radiation.

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The order of disposition will be considered a transfer of title of the source of radiation.

- 009.05** If expenses related to the impounded source of radiation are not paid under Section 009.03, the Department will pay such expenses from:
- (A) Proceeds from the sale of the source of radiation, if sold; or
 - (B) Available funds in the Department of Health and Human Services Cash Fund.

010. DELIBERATE MISCONDUCT

- 010.01** Any licensee, registrant, applicant for a license or registration, employee of a licensee or registrant, contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, or employee of any contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, who knowingly provides to any licensee, registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities covered by the Radiation Control Act, must not:
- (A) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the Department; or
 - (B) Intentionally submit to the Department, a licensee, a registrant, an applicant, or a licensee's, registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

- 010.02** Any person who violates Section 010, is subject to the provisions of Section 005.

APPENDIX A

EXAMPLES OF SEVERITY LEVELS

The following provides examples of each severity level as guidance in determining the appropriate severity level for violations that may apply to licensees or registrants. They reflect 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.

Severity I - Most Significant Violations

- (A) Exposure of a worker in excess of 250 mSv (25 rems) of radiation to the whole body, or 1500 mSv (150 rems) to the skin of the whole body, or 3750 mSv (375 rems) to the feet, ankles, hands, or forearms;
- (B) 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;
- (C) Release of radioactive material to an unrestricted area(s) in excess of ten times the limits specified in 180 NAC;
- (D) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in 180 NAC;
- (E) Disposal of licensed material into a sanitary sewage system in quantities or concentrations which exceed ten times the limits of 180 NAC 4-041;
- (F) Exposure of a worker in a restricted area(s) to ten times the limits of 180 NAC 4-005;
- (G) A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or not operable due to a deliberate act by the licensee or registrant (e.g., bypassing an interlock);
- (H) A material false statement. This is a written or sworn statement that is false and is relevant to the regulatory process;
- (I) Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Department pursuant to 180 NAC 10-007.03;
- (J) Deliberate exposure of an individual except by or under the supervision of an individual licensed to engage in the healing arts;
- (K) Refusing authorized Department personnel access to facilities and/or equipment to conduct inspections or investigations; or
- (L) Possession of licensable quantities of radioactive material without a license.

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Severity II - Very Significant Violations

- (A) Single exposure of a worker in excess of 50 mSv (5 rems) of radiation to the whole body, 300 mSv (30 rems) to the skin of the whole body, or 750 mSv (75 rems) to the feet, ankles, hands or forearms;
- (B) Annual whole body exposure in excess of 5 mSv (0.5 rem) of radiation to a non-radiation worker or radiation worker who is a minor;
- (C) Release of radioactive material to an unrestricted area in excess of five times the limits of 180 NAC 4-014;
- (D) Radiation levels, contamination levels, or releases that exceed five times the limits specified in 180 NAC;
- (E) Failure to immediately notify the Department as required by 180 NAC 4-057.01, item (A) and (C), 4-058.01 item (A) and (B);
- (F) Unauthorized disposal of licensed material in quantities or concentrations in excess of five times the limits of 180 NAC 4-041;
- (G) Exposure of a worker in a restricted area in excess of five times the limits 180 NAC 4-005;
- (H) A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable;
- (I) Failure to obtain appropriate Department approval before moving to a new use and/or storage location;
- (J) A material false statement. This is a statement that is false by omission and is relevant to the regulatory process;
- (K) Radiation output on fluoroscopic devices which exceed the limits in 180 NAC 6-005.
- (L) Absence of patient exposure reduction equipment required by 180 NAC.
- (M) Refusing authorized Department personnel access to records during an inspection or investigation upon reasonable notice;
- (N) Loss of control of a source of radiation; or
- (O) Failure to register sources of radiation or services as required by 180 NAC.

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Severity III - Significant Violations

- (A) Single exposure of a worker in excess of 30 mSv (3 rems) of radiation to the whole body, or 75 mSv (7.5 rems) to the skin of the whole body, or 187.5 mSv (18.75 rems) to the feet, ankles, hands or forearms;
- (B) A radiation level in an unrestricted area such that an individual could receive greater than 1.0 mSv (100 millirems) in a one-hour period or 5.0 mSv (500 millirems) in any seven consecutive days;
- (C) Failure to notify the Department within 24 hours as required by 180 NAC 4-058.02 or failure to notify the Department within 30 days as required by 180 NAC 4-057.01 (B) or 4-059;
- (D) Substantial potential for an exposure or release in excess of the limits of 180 NAC 4 (e.g., entry into high radiation areas without performing an adequate survey; operation of a radiation facility with a nonfunctioning interlock system);
- (E) Release of radioactive material to an unrestricted area in excess of the limits of 180 NAC 4-014;
- (F) Unauthorized disposal of licensed material not covered in Severity Levels I or II;
- (G) Exposure of a worker in restricted areas in excess of the limits of 180 NAC 4-005;
- (H) 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;
- (I) Cumulative worker exposure above 180 NAC limits when such exposure reflects a programmatic rather than an isolated weakness in the radiation safety program;
- (J) Conduct of licensee or registrant activities by an unauthorized or an unqualified person;
- (K) Any noncompliance with posting, labeling, placarding, shipping papers, packaging loading, or other transporting requirements that could result in the following:
 - (i) Improper identification of the type, quantity, or form of material,
 - (ii) Failure of the carrier or recipient to exercise adequate controls, or
 - (iii) Substantial potential for personnel exposure or contamination, or improper transfer of material;
- (L) Failure to control access to licensed materials as specified by Department rules;
- (M) Possession or use by a licensee or registrant of unauthorized radiation machine or radioactive material in conducting registrant or licensee activities;

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- (N) Radiation levels, contamination levels, or releases that exceed the limits specified in the license;
- (O) Failure to use exposure reduction devices properly (e.g., collimators, filtration); or
- (P) Failure to hospitalize patients who have sealed source implants or therapeutic quantities of radioactive material in accordance with the license or license conditions;

Severity IV - Violations

- (A) Exposure in excess of the limits of 180 NAC 4-005 not constituting Severity I, II, or III violations;
- (B) 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 year;
- (C) Failure to notify the Department within 30 days as required by 180 NAC 4-059.
- (D) Failure to make a follow-up written report to the Department as required by 180 NAC 4-057.02, 4-063 or 10-004.
- (E) Failure to conduct required leakage or contamination tests or to use properly calibrated equipment.
- (F) 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 (e.g., change of address, expiration of certificate of registration); or
- (G) Failure to maintain complete records and/or forms required by Nebraska's Regulations for Control of Radiation - Ionizing.

Severity V - Minor Violations

- (A) Failure to maintain a current copy of 180 NAC and current copies of active licenses and/or certificates of registration;
- (B) Failure to post 180 NAC notices required by 180 NAC 10-002; or
- (C) Other violations that have minor safety or environmental significance.