

RADIOACTIVE MATERIALS SECTION
RADIATION HEALTH BRANCH
Inspection and Enforcement Manual

TITLE 300

SECTION 301

Enforcement Actions

I. Purpose

The purpose of the Radiation Health Branch (RHB) enforcement program is to promote and protect the public health and safety and property including employee's health and safety and the environment from unnecessary exposure to ionizing radiation. The purpose is achieved by:

- A. Ensuring compliance with Cabinet for Health and Family Services regulations 902 KAR 100 and license conditions and commitments;
- B. Obtaining prompt correction of violations;
- C. Deterring future violations; and
- D. Encouraging improvement of the licensee.

The purpose of the RHB enforcement program is achieved by prompt and vigorous enforcement actions as appropriate to achieve and maintain compliance by licensees. Each enforcement action is dependent upon specific circumstances. These circumstances will be evaluated for the appropriate enforcement action(s).

II. Severity of Violations

The requirements of 902 KAR 100 have varying degrees of severity based on health and safety, security or environmental impact. The type of enforcement action is determined by the severity of the violation(s) either individually or as an aggregate. Therefore, violations must be identified as their importance in a determination.

The violations are rated in Appendix A as to the degree of severity for use in the determination of the appropriate enforcement action. The violations are compiled in category areas and are given a severity level from I to IV. Severity I has been assigned to violations that are the most serious with Severity IV being the least serious.

Severity I violations are considered as having immediate significant health and safety or environmental concern. Severity II violations are considered as having potential health and safety or environmental concern. Severity III violations are cause for concern in that if uncorrected could result in potential or immediate health and safety or environmental concern. Severity IV violations are of minor concern regarding health and safety or environmental concern.

III. Enforcement Actions

The enforcement actions available to RHB are described in this section. The basic action is in the form of a Notice of Violation which requires a written response. Any enforcement action beyond the Notice of Violation is considered as an escalated enforcement action.

A. Notice of Violation

A Notice of Violation is a written notice setting forth one or more alleged violations of the regulations, statutes or the conditions and/or terms of the license found during an inspection, incident, investigation, etc. The licensee shall be served with a written Notice of Violation prior to the institution of any proceedings except where in the opinion of the Cabinet the public health, interest, or safety so requires or the violation is willful. The Notice of Violation shall state the alleged violation and will require that the licensee submit, within fifteen (15) days of the date of the receipt of the notice or other time as specified in the notice, a written explanation or statement in reply including:

- (1) corrective steps which have been taken by the licensee and the results achieved;
- (2) corrective steps which will be taken;
- (3) the date when such correction and compliance will be achieved; and
- (4) an admission or denial of the violation and the reason(s) for the violation(s) if admitted and required in the notice in accordance with 902 KAR 100:170, Section 5.

Normally, the Notice of Violation may require an admission or denial when Severity I or II violations are involved. The Notice of Violation is normally the only enforcement action taken by the RHB unless a reply is not received or is warranted by the nature of the violation(s).

B. Informal Hearings

An informal hearing, as specified in 902 KAR 100:170, Section 15 is a hearing whereby RHB directs the licensee to appear to discuss violations or other matters related to the license. The purpose of the informal hearing is: (1) to discuss the violations or nonconformance with health physics practices, their significance and causes, and the licensee's corrective action; (2) determine whether there are any aggravating or mitigating circumstances; and (3) obtain other information which will help determine the appropriate enforcement action. During the informal hearing, the licensee will be given an opportunity to explain to the Cabinet what corrective actions (if any) were taken or will be taken following discovery of the violation or nonconformance. The procedure to be followed in informal hearings shall be as best serve the purpose of the hearing. An informal

hearing may consist of the submission of written data, views, or arguments with or without oral argument, or may partake of the nature of a conference or may assume some of the aspects of a formal hearing in which the subpoena of witnesses and the production of evidence may be permitted or directed.

Informal hearings will normally be held in each of the following cases:

1. Those involving Severity 1 violations
2. Repeated violations that were the subject of a previous informal hearing
3. The third occurrence of a repetition of a violation or multiple repetitive violations. (The second occurrence of a violation will normally be brought to the attention of the licensee in the "Notice of Violation.")
4. Failure to respond to a "Notice of Violation."
5. Violations resulting in a threat to public health and safety.

Failure of the person to whom the notice of informal hearing was sent to appear at the informal hearing may result in: (1) the license being modified, suspended or revoked; (2) the recapture, quarantine or seizure of the radiation source; or (3) other appropriate action deemed necessary by the Cabinet to protect public health and safety in accordance with 902 KAR 100:170, Section 6.

C. Notices and Orders

A notice or order is a written directive to:

1. comply with Cabinet rules and regulations;
2. modify, suspend or revoke a license;
3. to cease and desist from a given practice or activity; or
4. to take such other action as deemed necessary by the Cabinet to protect the public health and safety.

The following are types of notices and order.

- (a) License Modification Notice or Order are issued when some change in licensee equipment, procedures, or management controls is necessary.
- (b) Suspension Notice or Order may be used:
 - 1) To remove a threat to the public health and safety or the environment.
 - 2) When the licensee has not responded adequately to other enforcement action;
 - 3) When the licensee interferes with the conduct of an inspection or investigation;
 - 4) For any reason not mentioned above for which license revocation is authorized.
- (c) Revocation Notice or Order may be used:
 - 1) When a licensee is unable or unwilling to comply with RHB requirements;

- 2) When a licensee refuses to correct a violation;
 - 3) When a licensee does not respond to a Notice of Violation where a response was required;
 - 4) When a licensee refuses to pay a fee required by 902 KAR 100:012; or
 - 5) For any other reason for which revocation is authorized.
- (d) Cease and Desist Notice or Order are typically used to stop an unauthorized activity that has continued after notification by RHB that such activity is unauthorized.

The terms of the notice or order may be effective immediately or at a time specified in the notice or order. The licensee shall be afforded a hearing if such request is made within thirty (30) days in writing to the Cabinet in accordance with 902 KAR 100:170, Section 7.

- (e) Emergency Notices and Orders are issued whenever the Cabinet finds that a condition exists requiring immediate action to protect the public health or welfare in accordance with 902 KAR 100:170, Section 8.

The terms of the emergency notice or order shall be effective immediately. The licensee shall be afforded a hearing for the basis if the Cabinet shall continue, revoke, or modify such notice or order.

If the failure on the part of a person to comply with a lawful order of the Cabinet or with process or if the refusal of a witness to testify concerning a matter on which he may be lawfully interrogated, the circuit court or a judge thereof having jurisdiction may, on application of the cabinet, compel obedience by proceedings as in contempt cases as provided by KRS 211.230 in accordance with 902 KAR 100:170, Section 9.

4. Recapture. Quarantine or Seizure of Sources of Radiation

In cases which is extreme importance to the health and safety of the public, the Cabinet may recapture, quarantine or seize any source or sources of radiation in accordance with 902 KAR 100:170, Section 10. The person from whom such sources were recaptured, quarantined, or seized shall be served an appropriate order depriving that person of possession or use of the sources together with a notice which shall give that person the right to request a hearing pursuant to 902 KAR 1:400.

5. Penalties

Any person who violates any provision of KRS 211.842 to 211.852 or any regulation or any order issued by the Cabinet to comply shall be subject to additional non-routine inspections in accordance with 902 KAR 100:012, Section 3. The fee for each additional non-routine inspection shall be \$500. One or more additional non-routine inspections shall be conducted as determined by the Cabinet to ensure ongoing public health and safety if any of the following conditions exist:

- (a) Willful neglect or careless disregard that has, or could lead to, a threat to public health and safety;
- (b) Failure to take appropriate and timely action to correct documented violations of statutes, regulations, or conditions of the license or permit;
- (c) A substantiated violation that indicates a lack of management oversight or that the radiation safety officer is not adequately performing duties; or
- (d) Repeated violations from the previous inspection.

IV. Responsibility

The Supervisor, Radioactive Materials Section has authority for the issuance of Notice of Violations though typically those notices are issued under the authority of the Manager. The Manager, Radiation Health Branch has authority for the issuance of notices to comply, modify, suspend or revoke a license, to cease or desist, emergency notice or order or other action as deemed necessary and to authorize the recapture, quarantine or seize sources of radiation. The Director, Division for Public Health Protection and Safety shall be advised of escalated enforcement actions and informal hearings by the Manager. The Secretary, Cabinet for Health and Family Services has authority to issue orders to comply, petition the court for a restraining order or an injunction or the assessment of a penalty by the courts.