

STATE OF FLORIDA  
DEPARTMENT OF HEALTH

**GENERAL STATEMENT OF POLICY AND  
PROCEDURE FOR RADIATION  
MACHINE ENFORCEMENT ACTIONS**

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## **General Statement of Policy and Procedure for Radiation Machine Enforcement Actions**

### **Overview:**

The Department of Health (Department) uses notices of violation, civil penalties such as administrative fines, and final orders to assure compliance with program requirements for the safe use of radiation machines. A Notice of Violation identifies a requirement and how it was violated and formalizes a violation. A civil penalty is a monetary fine issued as specified in Ch. 404, Florida Statutes (F.S.), and may be assessed in an amount up to \$1,000 per violation per day. The Department issues Notices of Violation and penalties based on violations or because of a threat to public health and safety.

These procedures apply to registrants, their employees, and contractors who supply registrants with products that relate to licensed activities. Registrants, their employees, nor their contractors may engage in deliberate misconduct that causes a registrant to be in violation of the requirements of Ch. 64E-5, Florida Administrative Code (F.A.C.); or knowingly submit to the Department or to a registrant, information that is incomplete or inaccurate that relates to licensed activities.

### **Criminal Penalties:**

Section 404.161, F.S., states that any person who violates the provisions of Ch. 404, F.S., or Ch. 64E-5, F.A.C.; fails to comply with a lawful order issued within the time frame fixed by the Department, or as provided by Ch. 404, F.S.; or interferes with, hinders, or opposes any agent, officer, or member of the Department in the discharge of his or her duties under Ch. 404, F.S.; is guilty of a felony of the third degree.

### **Administrative Fines:**

The Department has authority to impose different amounts of administrative fines for violations of different severities. The Department considers the gravity of the violation; the registrant's efforts to promptly identify, report, and correct violations; management involvement in the registrant's operations; past performance; the degree to which the violation is repeated during a particular time interval; and the number and type of similar violations.

In general, the Department will impose administrative fines for Severity Level I violations; Severity Level II violations, unless there are mitigating circumstances; and Severity Level IV violations that are similar to previous violations for which the registrant did not take effective corrective action. The Department may consider administrative fines for Severity Levels III, IV and V violations.

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Administrative fines are assessed based on the schedule specified in Table 1, below:

**TABLE 1**  
**ADMINISTRATIVE FINES**

SEVERITY LEVEL	MAXIMUM ADMINISTRATIVE FINE*
I	\$1,000.00
II	\$900.00
III	\$750.00
IV	\$500.00
V	\$250.00

\*The department has statutory authority to assess fines on a per-violation per-day basis.

### **Severity Level I – Examples:**

- Single radiation exposure to a worker in excess of a total effective dose equivalent (TEDE) of 25 rem (0.25 sievert) or more; a lens dose equivalent of 75 rem (0.75 sievert) or more; or a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 gray) or more.
- Annual TEDE exposure of a member of the general public in excess of 100 millirem.
- Failure to make immediate notification as required by Ch. 64E-5.344, F.A.C.
- Deliberate falsification.
- Use of an unregistered machine.

### **Severity Level II – Examples:**

- A TEDE exceeding 5 rem (0.05 sievert); a lens dose equivalent exceeding 15 rem (0.15 sievert); or a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 sievert).
- Failure to make 24-hour notification as required by Rules 64E-5.344, and 64E-5.345, F.A.C.
- Failure to make a written report to the Department as required by Rules 64E-5.343 and 64E-5.345, F.A.C.
- Failure to report to the Department by telephone as required by Rule 64E-5.343, F.A.C.

### **Severity Level III – Examples:**

- Radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period.
- Substantial potential for an exposure or release in excess of Ch. 64E-5, Part III, F.A.C., whether or not the exposure or release occurs.
- Chronic failure to perform a periodic quality control or assurance function during a routine inspection interval.
- Failure to apply for registration of a radiation machine or an additional radiation machine with the Department within 30 days after acquisition and before use.

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### Severity Level IV – Examples:

- Failure to make notification within 30 days as required by Rules 64E-5.343, and 64E-5.345, F.A.C.
- Failure to make a written report within 30 days as required by Rule 64E-5.346.
- Failure to make a follow-up written report within 30 days of initial report required by Rules 64E-5.344, F.A.C.
- Failure to provide personnel monitoring reports to workers as required by 64E-5.903, F.A.C.
- Making an unintentional false statement.

### Severity Level V – Examples:

- Violations that have minor safety or environmental significance.
- Failure to provide documentation of performance of a quality assurance function.
- Failure to maintain records.

The Department considers violations of Severity Levels I, II, and III to be serious. If the registrant does not correct serious violations, the Department will issue orders in conjunction with administrative fines to achieve immediate corrective actions and to deter recurrence of serious violations. Examples of enforcement actions that could be taken for similar Severity Level violations are set forth in Table 2 below. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions normally will escalate for recurring similar violations.

TABLE 2\*\*

### EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS

SEVERITY OF VIOLATION	NUMBER OF SIMILAR VIOLATIONS OR REPEAT OCCURRENCES		
	1 <sup>ST</sup>	2 <sup>ND</sup>	3 <sup>RD</sup>
I	a, b, c	a, b, c	a, b, c
II	a, b	a, b, c, e	a, b, c, e
III	a	a, e	a, b, c, e
IV	---	d, e, f	a, e, f
V	---	d, e, f	a, e, f

a = Administrative Fine

b = Suspension or modification of license

c = Modification or revocation of license

d = Further Action

e = Severity Level may be upgraded

f = Consideration of escalated action

\*\* These are examples only and fines may be assessed according to Table 1 at any time.

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### **Related Enforcement Actions:**

In addition to the enforcement mechanisms of notices of violation, administrative penalties, and orders, it is possible for the Department to use bulletins, information notices, generic letters, and confirmatory action letters or enforcement conferences, and any other legal means to supplement its enforcement program. The Department expects registrants and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders or take other legal means to assure that registrants meet such commitments.

Bulletins, information notices, and generic letters are written notices to groups of registrants identifying specific problems and recommending specific actions. Confirmatory action letters are letters confirming a registrant's agreement to take certain actions to remove significant concerns regarding health and safety, safeguards, or the environment. Enforcement conferences are open meetings between the Department and the registrant or other persons when the department has learned of apparent violations. The enforcement conference does not mean the Department has concluded that a violation has occurred or that enforcement action will be taken. The purpose of the conference is to obtain information that will assist the Department in determining the appropriate enforcement actions, such as:

- A common understanding of the facts, root causes, and missed opportunities to identify the violation sooner;
- A common understanding of corrective actions; and/or
- A common understanding of the significance of the issues and the need for lasting and effective corrective action.

Enforcement conferences normally will be held at the bureau's headquarters and are not meetings to negotiate sanctions. The Department is authorized to take immediate enforcement actions prior to the conference to protect public health, safety, or property. An enforcement conference normally will be held if the registrant requests it.

### **Orders:**

An Order is a written Department directive, signed by the State Surgeon General, to suspend or revoke a registration; to cease and desist from a given practice or activity; or to take such other action as is proper to protect the public health, safety, or interest. Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, safety, or interests so requires, or when the Order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the Order is given. When the Department believes a basis could reasonably exist for not taking the action as proposed, the registrant will ordinarily be given an opportunity to show cause why the Order should not be issued in the proposed manner. Orders are issued in place of or in addition to orders of administrative fines.

Suspension Orders are used:

- To remove a threat to the public health, safety or the environment;
- To stop facility construction when:

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- Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related issue or component; or
- The registrant's quality assurance program is not adequate to assure that construction activities are being properly carried out;
- When the registrant has not responded adequately to other enforcement action; or
- When the registrant interferes with an inspection or investigation.

Suspensions may apply to all or part of the registrant's activity. Ordinarily, an activity is not suspended nor is a suspension prolonged for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

Revocation Orders are used:

- When a registrant is unable or unwilling to comply with departmental requirements;
- When a registrant refuses to correct a violation;
- When a registrant does not respond to a notice of violation where a response is required; or
- When a registrant refuses to pay a fee required by Rule 64E-5.511, F.A.C.

Cease and Desist Orders are used:

- To stop an unauthorized activity that has continued after notification by the Department that such activity is unauthorized.