641—38.9(136C) Administrative enforcement actions.

38.9(1) *Scope.*

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term "regulated entity" as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. "Authorization" means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4.

38.9(2) *Notice of violation.*

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) Corrective steps which have been taken by the regulated entity and the results achieved;

(2) Corrective action which will be taken to prevent recurrence; and

(3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

c. Violations are categorized according to five levels of severity, which are:

(1) Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.

(2) Severity Level III: Violations are cause for significant concern.

(3) Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.

(4) Severity Level V: Violations are of minor safety or environmental concern.

d. A group of violations may be evaluated in the aggregate and assigned a single higher severity level if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.

e. The severity level of a violation may be increased if the violation can be considered a repetitive violation. The term "repetitive violation" or "similar violation" means a violation that reasonably could have been prevented by a regulated entity's corrective action for a previous violation normally occurring within the past two years of the inspection at issue or the period within the last two inspections, whichever is longer.

f. The severity level of a violation may be increased if the violation involves casual disregard of requirements, deception, or other indications of willfulness. The term "willfulness" is that characteristic of violations ranging from deliberate intent to violate or falsify to intentional disregard for regulatory requirements.

38.9(3) *Orders.*

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;

(2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;

(3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph *"d"* of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) *Settlement and compromise.* At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty.

38.9(5) *Demand for information.*

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity's answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5)*"a"*(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3)*"d."*

38.9(6) *Civil penalties.*

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a

notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6)*"b,"* an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6)*"a."*

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6)*"c"* or *"f,"* or the expiration of the time for requesting a hearing described in 38.9(6)*"d,"* the agency may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) *Requests for action under this rule.*

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7)*"b."*

b. Within a reasonable time after a request pursuant to 38.9(7)*"a"* has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c. (1) The bureau chief's decisions under this rule will be filed and within 25 days after the date of the bureau chief's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief's decision under this rule will be entertained by the agency.

38.9(8) *Impounding.* The agency may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of Iowa Code chapter 136C, or any rules, license or registration conditions, or orders issued by this agency.

a. If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give to either the owner or the possessor of the source of radiation written notice of the intention to impound the source of radiation.

(1) Either the owner or the possessor shall have 20 days from the date of personal service of certified mailing to request a hearing, except in the case where the regulated entity has consented in writing to the impoundment.

(2) If a hearing is requested, the agency will issue an order designating the time and place of hearing.

b. At the agency's direction, the impounded sources of radiation may be disposed of by:

(1) Returning the source of radiation to a properly licensed or registered owner that did not cause the emergency;

(2) Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or

(3) Selling, destroying, or disposing of the source of radiation in another manner within the agency's discretion.

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