

420-3-26-13**ADMINISTRATIVE PROCEDURES**

- (1) **Purpose and Scope.** This Rule establishes the administrative procedures for the Agency as the Radiation Control Agency and describes the organization, methods of conducting business, and interpretations as required by the Alabama Administrative Procedures Act.
- (2) **Organization and Method of Conducting Business.**
 - (a) **Organization.** The State Board of Health is designated in Section 22-14-4, Code of Alabama, 1975 as the State Radiation Control Agency with the State Health Officer as Director. The Director has designated the Division of Radiation Control to implement Chapter 14 of Title 22, Code of Alabama, 1975. The State Health Officer as Director may delegate certain duties to the Division of Radiation Control and its Director. These duties are:
 1. To inspect, process applications to register x-ray facilities, and investigate accidents, incidents, and overexposures as may be required to assure the safe use of x-ray equipment as is defined in these rules.
 2. To inspect, the use of particle accelerators and radioactive material, process applications to register particle accelerators, process applications to license the use of radioactive material(s), and investigate accidents, incidents and overexposures as may be required to assure the safe use of particle accelerators or radioactive materials.
 3. To conduct environmental monitoring around nuclear facilities which have a reasonable potential for releasing radioactive material into the environment.
 4. To develop emergency plans for responding to any radiological emergency in accordance with Memoranda of Understanding and other Agencies.
 5. To respond to, and pursuant to written delegations, issue orders necessary to protect the public health and safety during radiation emergencies, incidents or accidents.
 6. To conduct limited training in the safe use of radiation.
 7. To answer public inquiries, investigate complaints, and provide limited quantities of general information to the public.
 8. To receive, process, and coordinate with other agencies requests for orders for the routing of radioactive material shipments.

9. To determine the compliance of a person's use of radiation as the result of an inspection, investigation, or review of submitted information. This is subject to review and appeal as provided for in this Rule.
10. To issue orders directing compliance with these rules, and when not contested issue orders to suspend, revoke, or modify a license or registration, or sources of radiation.
11. To develop contracts for programs compatible with the Act.
12. To issue orders relating to the routing of radioactive materials as provided for in this Rule.
13. To maintain an index and file of all decisions, opinions, and declaratory rulings issued by the Agency; by subject matter. Copies of these orders are available in the Division of Radiation Control's Office for public review and copying at 25¢ per page.
14. To maintain a file of all licenses, registrations, inspections, investigations and related correspondence for public inspection and copying at 25¢ per page. Certain files may be temporarily unavailable when being used by the Staff or pending determination of compliance or enforcement action. Further, information as determined pursuant to Section 22-14-6(d) Code of Alabama shall not be available for public review or copying.
15. To maintain a list of all forms, statements of policy, instructions, guides, and interpretations available for public review and copying.
16. To maintain copies of all memoranda of understanding or contracts between the Agency and other agencies relating to the radiation program in Alabama, for public inspection and for copying at 25¢ per page.
17. To issue orders suspending a license if the inspection fees are not paid within 45 days of billing the licensee as provided for in the Act.
18. To notify a licensee of any proposed civil penalty as may be determined in accordance to Appendix A of this Rule 420-3-26-.13. Note, the licensee may appeal or provide mitigating information for consideration before a final order is issued.

(b) Applications for Licenses, Registration, or Notice of Registration.

1. All applications for a radioactive materials license shall meet the applicable requirements of Rule 420-3-26-.02 of these rules before being approved. To assist applicants in preparing their applications, the Agency has prepared

instructions and guides which are available on request. In addition, any application for the commercial burial of low-level radioactive wastes must conform with the Agency policy statement, copies of which are available on request. Amendment requests may be submitted by letter but must otherwise meet the requirements of an application prior to approval.

2. All applications for a Notice of Registration shall meet the applicable requirements of Rule 420-3-26-.08 of these rules before being approved. Amendment requests may be submitted by letter but must otherwise meet the requirement of an application prior to approval.
3. All application to register x-ray equipment shall meet the requirements of Rule 420-3-26-.05 of these rules prior to approval. Amendment requests may be by letter but must otherwise meet the requirements for an application prior to approval.
4. Any application may be approved in part, for those proposed activities for which adequate information was supplied. Those proposed portions for which inadequate information was supplied may be approved upon receipt of additional, sufficient information without a reapplication.
5. Any person's application or amendment request which is denied may request a hearing within 30 days of the denial of the application or amendment request in accordance with the hearing procedures of this Rule.
6. Any application or amendment request will be considered abandoned, upon failure of the applicant to supply any additional reasonable information requested to determine whether the application meets the requirements of these rules within 90 days of the written request for supplemental information. This section does not apply if the applicant files for a hearing pursuant to 5 above.
7. Except for the activities listed in 420-3-26-.02(10)(q)4, if the Agency fails to respond to an application by either issuing the appropriate license, amendment, or Notice of Registration; by requesting additional supplemental information; or by denying the request within 90 days of Agency receiving the supplemental information in writing, or the application, if supplemental information was not requested; the applicant may file a petition with the Agency requiring the approval of the request. Such petition only needs to show that the Agency has received, in writing, all of the information requested from the applicant and at least 90 days has elapsed without a request for information and no action has been taken by the Agency. The petition will be granted unless the Agency can show that prior to the filing of the petition,

- (i) the Agency requested in writing sent to the last known address of

the applicant, additional information which has not been received,

- (ii) the Agency denied the application, or
- (iii) the construction, testing, or technical studies have not been completed by the Agency.

(3) **Hearings.**

(a) **Rule Making.**

1. In conformance with Section 5 of the Administrative Procedures Act (Act 81-855), the Agency shall adopt its rules and regulations. Any notice regarding the adoption, repeal or amendment of such rules shall include:
 - (i) The terms or substance of the proposed action.
 - (ii) A description of the subject and issued involved if not included in (i).
 - (iii) The address where written comments or statements may be delivered and the last time and date for delivering such statements.
 - (iv) The date, time, and place for oral statements to be made and any conditions pertaining thereto.
 - (v) Who the hearing officer will be if other than the Division Director or Agency Director.
2. **Petitions for Rulemaking.**
 - (i) Any interested person may petition the Agency to issue, amend, or rescind any rule. The petition should be addressed to the Director, Division of Radiation Control, Alabama Department of Public Health, Montgomery, Al. 36130.
 - (ii) Each petition filed under this section shall:

- (I) Set forth a general solution to the problem or the substance or text of any proposed rule, or amendment or specify the rule which is to be revoked or amended;
- (II) State clearly and concisely the petitioner's grounds for and interest in the action requested;
- (III) Include a statement in support of the petition which shall set

forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonable available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, the petitioner should note any specific cases of which the petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

- (iii) If it is determined that the petition includes the information required by paragraph (ii) of this section and is complete and is probably needed, the Director Division of Radiation Control or his designee through the Agency Secretary will cause a notice of the petition to be published in the Alabama Administrative Monthly in accordance with the rule making provisions of this Rule, within 60 days.
- (iv) If it is determined by the Director of Division of Radiation Control that the petition does not include the information required by paragraph (ii) of this section, or is incomplete or is not needed to protect the health and safety or not authorized by law, the petitioner will be notified of that determination and the respects in which the petition is deficient and will be accorded an opportunity to submit additional data to correct any deficiency within 90 days of the notification to the petitioner of any deficiency, the petition may be returned to the petitioner without prejudice.
- (v) No hearing or rulemaking will be held on the petition unless the Director of the Division of Radiation Control determines that sufficient reason exists, he will initiate rule-making proceeding as provided in this Rule. In any other case he will deny the petition and will notify the petitioner with a simple statement of denial. The petitioner may appeal the denial pursuant to the appeal provisions of this Rule.

(b) **Appeals**

1. All orders, determinations, or denials of the Director, Division of Radiation Control, or of any local Health Departments are appealable to the State Health Officer. All initial determinations, orders, or denials of the State Officer as Agency Director are appealable as described in this section. In addition, this Rule provides for certain informal procedures to resolve contested cases.

2. Any request to appeal an order, determination, or denial shall be filed within 30 days of receiving written notice of such order, determination or denial. Such request should be addressed to:

State Health Officer
Alabama Department of Public Health
Montgomery, Alabama 36130-3017

All appeals should:

- (i) For each exception, separately numbered; state concisely, without supporting argument the single error of fact or law which is being asserted in that exception and identify with particularity the portion of the decision, determination, order or denial to which the exception is addressed. A brief in support of the exception(s) should accompany the exception(s). Within 10 days of receiving the request, the Division Staff, and any other party, shall file their response to the petition.
 - (ii) All documents filed under this section shall be accompanied by a certificate reflecting service upon all parties to the proceeding.
3. Within 5 business days of receiving the Staff's response the State Health Officer shall issue an order designating:
 - (i) The Hearing Officer and any members of a Hearing Board (such as the Radiation Advisory Board of Health);
 - (ii) The date, time, and place for the start of the hearing;
 - (iii) The issues to be resolved;
 - (iv) And other matters appropriate for such an order, such as contained in Section 12(2) of the Alabama Administrative Procedures Act.
4. The Hearing Officer, or Hearing Board, as appropriate, shall submit their recommendations to the State Health Officer, together with the record of the proceeding as described in Section 12(b) of the Alabama Administrative Procedures Act within 10 business days of the close of the hearing.
5. The State Health Officer after reviewing the record and the recommendations shall issue an order upholding, denying or modifying the matter being appealed within 5 business days of receiving the recommendations described in paragraph (4) above. This order will be the final order of the Agency unless the State Committee of Public Health, sua sponte, elects to review the order within 30 days of its issuance.

(c) **Conduct of Hearings**

1. All adjudicatory hearings shall be conducted in accordance with 10CFR Part 2 Sections 2.705; 2.706; 2.707; 2.711; 2.712; except (f); 2.713; 2.714; 2.715; 2.716; 2.718 except (b). (h), (i), (k), (l), and (m); 2.719; 2.730; 2.731; 2.732; 2.733; 2.740; 2.741 except (e); 2.742; 2.743; 2.750; except (c); 2.753; and 2.757 as in effect July 1, 1989. All references to the Commission, Atomic Safety and Licensing Board, and Presiding Officer, are to be replaced with the Hearing Officer.
2. Documents shall be filed with the State Health Officer or the Hearing Officer in adjudication subject to this Rule, either by (1) delivery to the office of the State Health Officer, in the RSA Tower, 201 Monroe Street, Montgomery, or (2) U. S. Mail to the State Health Officer, Alabama Department of Public Health, Montgomery, Alabama 36130-3017.
3. All documents offered for filing shall be accompanied by proof of service upon all parties to the proceeding or their attorney of record, the Hearing Officer and Hearing Board members if any.
4. Filing by U. S. Mail will be deemed to be complete as of the time of deposit in the mail with sufficient postage.
5. Parties to all adjudicatory hearing shall consist of the petitioner or appellant, the Division of Radiation Control and such others as may be admitted by the Hearing Officer.
6. Rulemaking and investigatory hearing shall be conducted in accordance with the procedures outlined in the order established in the hearing. The Hearing Officer has the authority to conduct the hearing in an orderly manner and may require the consolidation of statements and close or adjourn the hearing to another day or time in the event the hearing becomes disorderly. In these hearings the Hearing Officer, Hearing Board members, and the Division of Radiation Control may ask questions of witnesses. If appropriate, they may be placed under oath.

- (4) **Guidance Documents of Division of Radiation Control.** From time to time the Division of Radiation Control may prepare instructions, guidance documents, suggested procedures, etc., to assist persons in complying with these rules. These documents are to provide assistance and are not binding on the Board of Health. Further, other methods may be acceptable and will be approved if the rules are otherwise met. The Board of Health's policy for minimum acceptable training, experience and equipment is to be the same as the U. S. Nuclear Regulatory Commission.

- (5) **The Routing of Radioactive Material Shipments.**

- (a) Applications for designating a route shall contain sufficient information to make the assessment and determination required by 49 CFR 171.8 in effect July 1, 1989. Copies of this regulation and the associated U. S. Department of Transportation guide "Guidelines for Selecting preferred Highway Routes for Large Quantity Shipments of Radioactive Materials" are available from the Agency.
 - (b) Upon receiving a routing request (10 copies) with adequate information to make the necessary assessment and determination, when designated by proper delegation of the Agency Director, the Director, Division of Radiation Control shall notify the Alabama Departments of Public Safety, Highway and Emergency Management and any counties and municipalities along the proposed alternate routes of the request.
 - (c) The Agency Director or the Director, Division of Radiation Control shall also cause a notice to be published in a newspaper of general circulation near the routes under consideration. Such notice shall provide for an investigation hearing to be conducted by the Agency Director or the Director, Division of Radiation Control as the Hearing Officer. Such notice shall provide for receiving written comments and shall indicate the date which comments will be received. This date may be modified at the hearing if appropriate.
 - (d) Within 30 days of the end of the written comment period, the Agency Director or the Director, Division of Radiation Control will issue an order with his decision. This order shall briefly detail the basis for the decision. This is appealable as any other initial order by the Agency Director or order or decision of the Director, Division of Radiation Control.
- (6) **Criteria for Determining Enforcement Action.**
- (a) A major continuing goal of the Agency is to assure that ionizing radiation source facilities are constructed and operated with the necessary degree of safety and reliability. Similarly, it is the responsibility of the Agency to assure a corresponding degree of management controls and safety in the licensed materials processes and programs.

The nuclear industry generally recognizes the necessity for improvements in safety as well as the economic advantages that are derived by extending the management techniques and philosophy of safety to the operations of plants and processes. It is essential that all registrants and licensees meet these high standards.

While broad sanctions are available to the Agency in the event they are necessary, the objectives of safety and reliability should generally be achievable through augmented internal management programs.

Results of Agency inspections and investigations of licensed activities have shown that registrants and licensees have not in all cases complied with regulatory requirements and it has been necessary to take specific enforcement actions

commensurate with the violations. This document sets out the criteria for enforcement actions to be taken with respect to future violations of license conditions relating to health and safety, in accordance with the Alabama Regulations for Control of Radiation and Act 582, Regular Session 1963, Title 22, Chapter 14, Code of Alabama, 1975, as amended.

The enforcement actions available to the agency in the exercise of its regulatory responsibilities may be divided into the following four basic types which are applicable to specific enforcement situations:

1. **Non-Compliance Letters**

This is a letter describing the proposed violations and request to reply within usually thirty (30) days. In his reply, the registrant or licensee may:

- (i) Deny any or all violations
- (ii) Indicate what corrective measures have been instituted and their effect.
- (iii) Indicate proposed corrective actions and the date when compliance will be achieved.

2. **Written Notices of Violations**

Enforcement actions may be written notices to registrants or licensees, citing the proposed violations observed during investigations, inspections, or inquiries. This is a formal notice and requires at least a written response.

3. **Civil Penalties.** The Agency has authority to assess a civil penalty of radioactive material licensees in cases where the noncompliance is serious or repeated. Appendix A details how and when the civil penalties are determined and how they may be reduced.

4. **Orders to Cease and Desist; and Orders for Suspension, Modification or Revocation of a License or to Suspend the Activities of a Registrant.**

The Agency has authority to issue orders to "cease and desist," and orders to suspend, modify, or revoke licenses. Such orders are preceded by certain procedural requirements including a written notice of violation to the licensee or registrant providing him with an opportunity to respond as to the corrective measures being taken. In the event the licensee or registrant fails to respond to the notice or to demonstrate that satisfactory corrective action is being taken, an order to show cause may be issued requiring the licensee or registrant to show why the particular order (either of revocation, or

modification or suspension) should not be made effective. In those instances where the health, safety, or interest of employees or to the public so requires or willful violation of the agency's rules is involved, the notice provision may be dispensed with and, in addition, the particular order may be made immediately effective pending further order. In addition to proceeding by way of order, the Agency may also, pursuant to Section 22-14-12, request the Attorney General to obtain an injunction or other court order to enjoin licensees or registrants from violating the Act or any rules or order issued thereunder.

Authority: §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-11, 22-14-12, 22-14-13, 41-22-4, 41-22-5, 41-22-6, 41-22-7, 41-22-9, 41-22-11, 41-22-12, 41-22-13, 41-22-14, 41-22-15, 41-22-16, 41-22-17, 41-22-18, and 41-22-19, Code of Alabama, 1975.

History: Adopted effective 12-31-83. Revised and Repromulgated effective 1-31-90.

Appendix A

General Statement of Policy and Procedure for Enforcement Actions

The following statement of general policy and procedure explains the enforcement policy and procedures of the Agency and its staff in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.

- (1) **Introduction and Purpose.** The purpose of the Agency enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:
 - (a) Ensuring compliance with Agency rules and license conditions or registration commitments;
 - (b) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
 - (c) Deterring future violations and occurrences of conditions adverse to environmental quality; and
 - (d) Encouraging improvement of licensee or registrant and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or registrants who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees or registrants who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed or registered activities.

- (2) **Procedural Framework.** Rule 420-3-26-.13 of these rules sets forth the procedures the Agency uses in exercising its enforcement authority. This rule sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 420-3-26-.13(2). This rule provides that the Agency Director or Radiation Control Division Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest, in writing, the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed. The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken

is set forth in Rule 420-3-26-.13. The mechanism for modifying a license or registration by order is set forth in the same rule. These sections provide an opportunity for a hearing to the affected licensee. However, the Agency is authorized to make orders immediately effective if the public health, safety or interest so requires.

- (3) **Severity of Violation.** Regulatory requirements¹ have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

- (a) Health Physics;
- (b) Transportation;
- (c) Radioactive Materials Operations;
- (d) Miscellaneous Matters; and
- (e) Emergency Preparedness.

Licensed or registered activities not directly covered by one of the above listed areas, e.g., reciprocity license or registered activities, will be placed in the activity area most suitable in light of the particular violation involved. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public or an individual. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern. Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in nuclear medicine is not directly comparable to that associated with Severity Level I violations in industrial radiography.

While examples are provided in Supplements I through V for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Agency places on a particular type of violation of Agency requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

¹ The term "requirement" as used in this Appendix means a legally binding requirement such as a statute, rule, regulation, license condition, technical specification, or order.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify, to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, i.e., inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The Agency expects licensees or registrants to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee or registrant will not normally be cited for a failure to report a condition or event unless the licensee or registrant was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

- (4) **Enforcement Conferences.** Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, the Agency will normally hold an enforcement conference with the licensee or registrant prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

1. discuss the violations or nonconformance, the significance of each and causes, and the licensee's or registrant's corrective actions;
2. determine whether there are any aggravating or mitigating circumstances; and
3. obtain other information which will help determine the appropriate enforcement action.

In addition, during the enforcement conference, the licensee or registrant will be given an

opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or registrants will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be announced to the public.

When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, terminating, or revoking a license or registration, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

- (5) **Enforcement Actions.** This section describes the enforcement sanctions available to Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the Agency will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by the Radiation Control Division Director is appropriate in the form of a Notice of Violation requiring a formal response from the recipient describing corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's or registrant's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending, terminating, or revoking licenses or registrations; or orders to cease and desist from designated activities.

- (a) **Notice of Violation.** A notice of violation is a written notice setting forth one or more violations of a legally, binding requirement. The notice normally requires the recipient to provide a written statement describing:

1. corrective steps which have been taken and the results achieved;
2. corrective steps which will be taken to prevent recurrence; and
3. the date when full compliance will be achieved.

The Agency may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

The Agency uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement

action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections (5)(b) and (5)(c) respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

Licensees or registrants are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee or registrant quality assurance measures or management controls. Generally, however, licensees or registrants are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

(b) **Civil Penalty.** A civil penalty applies only to radioactive material licensees and is a monetary penalty that may be imposed for violation of:

1. certain specified licensing provisions of the Section 22-14, Code of Alabama, 1975, as amended, or supplementary Agency rule or orders;
2. any requirement for which a license may be revoked; or

Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Civil penalties are imposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar² to previous violations for which the licensee failed to take effective corrective action.

In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for any willful violation of any Agency requirement including those at any severity level.

The Agency imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various fuel cycle, and materials programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees receive higher

² The word "similar" as used in this Rule, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the Agency's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the Agency will consider as necessary an increase or decrease on a case-by-case basis.

The Agency attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant Agency identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$10,000³ per violation, per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

The Agency reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances, adjustments to these values may be made for the factors described in the following table.

TABLE 1A. - BASE CIVIL PENALTIES¹

³ \$1,000 for qualifying small businesses and non-profit entities.

	Plant operations const., health physics and EP	Transportation Greater than type A quantity ²	Type A quantity or less ³
a. Industrial Processors ⁴	\$10,000	\$10,000	\$5,000
b. Mills and Uranium Conversion Facilities	\$10,000	\$5,000	\$2,000
c. Industrial Users of Material ⁵	\$10,000	\$5,000	\$2,000
d. Waste Disposal Licensees	\$10,000	\$5,000	\$2,000
e. Academic or Medical Institutions	\$5,000	\$2,500	\$1,000
f. Other Material Licensees	\$1,000	\$2,500	\$1,000

¹ For qualifying small businesses and non-profit entities use one-tenth the values listed in the table. Civil penalties only apply to radioactive material licensees.

² Includes high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.

³ Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.

⁴ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.

⁵ Includes industrial radiographers, nuclear pharmacies, and other industrial users.

1. **Prompt Identification and Reporting.** Reduction of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

2. **Corrective Action to Prevent Recurrence.** Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 50% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action--such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.
3. **Past Performance.** Reduction by as much as 100% of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100% for prior poor performance in the general area of concern.

In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.
4. **Prior Notice of Similar Events.** The base civil penalty may be increased as much as 50% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific Agency or industry notification, and had failed to take effective preventive steps.
5. **Multiple Occurrences.** The base civil penalty may be increased as much as 50% where multiple examples of a particular violation are identified during the inspection period.

The above factors are additive. However, in no instance will a civil penalty for any one violation exceed \$10,000 per day.

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

- (i) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and as such subject to a separate additional civil penalty.

- (ii) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.
- (iii) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, the focus is on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

TABLE 1B. - BASE CIVIL PENALTIES
Applies only to Radioactive Material Licensees

Severity Level	Base civil penalty amount (percent of amount listed in Table 1A)
I----- -	100%
II----- -	80%
III----- -	50%

IV-----	15%
V-----	5%
-	

(c) **Orders.** An order is a written Agency directive to modify, suspend, terminate, or revoke a license or registration; to cease and desist from a given practice or activity; or to take such other action as may be proper (see 420-3-26-.13). Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate. Orders may be issued as set forth below.

1. License or Registration Modification Orders are issued when some change in a licensee or registrant's equipment, procedures, or management controls is necessary.
2. Suspension Orders may be used:
 - (i) To remove a threat to the public health and safety, or the environment;
 - (ii) To stop facility construction when;
 - (I) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or
 - (II) the licensee's or registrant's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;
 - (iii) When the licensee or registrant has not responded adequately to other enforcement action;
 - (iv) When the licensee or registrant interferes with the conduct of an inspection or investigation; or
 - (v) For any reason not mentioned above for which license revocation or registration termination is legally authorized.

Suspensions may apply to all or part of the licensed or registered activity. Ordinarily, a licensed or registered 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.

3. Revocation Orders may be used:

- (i) When a licensee or registrant is unable or unwilling to comply with Agency requirements,
 - (ii) When a licensee or registrant refuses to correct a violation,
 - (iii) When a licensee or registrant does not respond to a notice of violation where a response was required,
 - (iv) When a licensee refuses to pay a fee or civil penalty required by Act 82-328, as amended, or
 - (v) For any other reason for which revocation is authorized under these rules (e.g., any condition which would warrant refusal of a license or registration on an original application).
4. Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by the Agency that such activity is unauthorized.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the Agency believes a basis could reasonably exist for not taking the action as proposed, the licensee or registrant will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

- (d) **Escalation of Enforcement Sanctions.** The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections (5)(b) and (5)(c) above.

Examples or enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

Normally the progression of enforcement actions for similar violations will be based on violations under a single license or registration. When more than one facility is covered by a single license or registration, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar

violations may be charged even though the second violation occurred at a different facility or under a different license or registration. For example, a survey violation at Unit 2 of a multiunit plant that repeats an earlier violation at Unit 1 might be considered similar.

TABLE 2. - EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE OR REGISTRATION

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
	1st	2nd	3rd
I-----	(^a + ^b)	(^a + ^b + ^c)	(^d)
II-----	(^a)	(^a + ^b)	(^a + ^b + ^c)
III----- -	-----	(^a)	(^a + ^b)

^a Civil penalty, applies only to radioactive material licensees.

^b Suspension of affected operations until the Radiological Health Branch Director is satisfied that there is reasonable assurance that the licensee or registrant can operate in compliance with the applicable requirements; or modification of the license or registration, as appropriate.

^c Show cause for modification or revocation of the license or registration, as appropriate.

^d Further action, as appropriate.

(e) **Enforcement Actions Involving Individuals.** Enforcement actions involving individuals, including licensed users or physicians or registered users, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action will normally be taken only when there is little doubt that the individual fully understood, or should have understood, his or her responsibility: knew, or should have known, the required actions: and knowingly, or with careless disregard (i.e., with more than mere negligence), failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV or V violations will be handled by citing only the facility licensee or registrant.

More serious violations, including those involving the integrity of an individual (e.g., lying to the Agency), concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual. Action against the individual, however, will not be taken if the improper action by

the individual was caused by management failures. The following examples of situations illustrate this concept:

1. Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee or registrant.
2. Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.
3. Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.
4. Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.
5. Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Examples of situations which could result in enforcement actions against individuals include, but are not limited to, violations which involve:

1. Recognizing a violation of procedural requirements and willfully not taking corrective action.
2. Willfully performing unauthorized bypassing or required safety systems.
3. Willfully defeating alarms which have safety significance.
4. Unauthorized abandoning of controls.
5. Inattention to duty such as sleeping or being intoxicated while on duty.
6. Willfully taking actions that violate License or Technical Specification Limiting Conditions for Operation or registration commitments.
7. Falsifying records required for Agency regulations or by the facility licensee or registrant.
8. Willfully failing to take "immediate actions" of emergency procedures.
9. Willfully withholding safety significant information rather than making such

information known to appropriate supervisory or technical personnel.

Any proposed enforcement action against individuals must be done by the Radiation Control Division Director. The opportunity for an Enforcement Conference with the individual will usually be provided.

Examples of sanctions that may be appropriate against Agency licensed or registered operators are:

1. Issuance of a letter of reprimand to be placed in the operator's license file or registration file,
2. Issuance of a Notice of Violation, and
3. Suspension for a specified period, modification, or revocation of the license or registration authorization.

The sanctions are listed in escalating order of significance.⁴ The particular sanction to be used should be determined on a case-by-case basis.

In the case of an unlicensed individual, an Order modifying the facility license to require the removal of the individual from all radioactive material related activities for a specified period of time or indefinitely may be appropriate.

(f) **Reopening Closed Enforcement Actions.** If significant new information is received or obtained by the Agency which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the Radiation Control Division Director.

(g) **Exercise of Discretion.**

1. Because the Agency wants to encourage and support licensee or registrant initiative for self-identification and correction of problems, Agency will not generally issue a notice of violation for a violation that meets all of the following criteria:
 - (i) It was identified by the licensee or registrant;

⁴ Except for individuals subject to civil penalties because they are persons as defined by Section 22-14 et.se., Code of Alabama, 1975, as amended, and are licensed as the named licensee on the licensing document.

- (ii) It fits in Severity Level IV or V;
 - (iii) It was reported, if required;
 - (iv) It was or will be corrected, including to prevent recurrence, within a reasonable time; and
 - (v) It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation.
2. The Agency may also refrain from issuing a Notice of Violation or a proposed civil penalty for violations that meet all of the following criteria:
- (i)
 - (I) The Agency has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of a licensee's or registrant's operations or the licensee or registrant is forced into an extended shutdown or work stoppage related to generally poor performance over a long period;
 - (II) The licensee or registrant has developed and is aggressively implementing during the shutdown a comprehensive program for problem identification and correction; and
 - (III) Agency concurrence is needed by the licensee or registrant prior to restart.
 - (ii) Non-willful violations are identified by the licensee or registrant (as opposed to the Agency) as the result of its comprehensive program, or the violations are identified as a result of an employee allegation to the licensee. If the Agency identifies the violation, the Agency should determine whether enforcement action is necessary to achieve remedial action.
 - (iii) The violations are based upon activities of the licensee or registrant prior to the events leading to the shutdown, and
 - (iv) The non-willful violations would normally not be categorized as higher than Severity Level III violations under the Agency's Enforcement Policy.

Notwithstanding the above, a civil penalty may be proposed in a case where multiple Severity Level III violations are discovered. This action would be

taken when judgment warrants it on the circumstances of the individual case.

- (h) **Related Administrative Actions.** In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licenses to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees or registrants to make sure that such commitments are met.
1. Bulletins, Information Notices and Generic Letters are written notifications to groups of licensees or registrants identifying specific problems and recommending specific actions.
 2. Notices of Deviation are written notices describing a licensee's or registrant's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee or registrant to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.
 3. Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, or the environment.
 4. Notices of Nonconformance are written notices describing non-licensees' or registrant's failures to meet commitments which have not been made legally binding requirements by the Agency. An example is a commitment made in a procurement contract with a licensee or registrant. Notices of Nonconformance request non-licensees or registrants to provide written explanations or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.
- (6) **Referrals to the Attorney General.** Alleged or suspected criminal violations of Section 22-14 et. seq., Code of Alabama, 1975, as amended, are referred to the Attorney General for investigation. Such referral does not preclude the Agency from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Attorney General to the extent practicable.
- (7) **Inaccurate and Incomplete Information.** A violation of the regulations on submitting incomplete and inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information

or the failure to provide significant information identified by a licensee or registrant normally will be categorized based on the guidance herein in (3) of this Appendix, "Severity of Violations", and in Supplement IV.

The Agency recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Agency must be able to rely on oral communications from licensee officials concerning significant information. A licensor registrant or registrant official for purposes of application of the Enforcement Policy means a first line supervisor or above as well as a licensed individual or registered activity, radiation safety officer, or a person listed on a license or registration as an authorized user of licensed material or registered equipment or activity. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as:

- (a) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;
- (b) the opportunity and time available prior to the communication to assure the accuracy or completeness of the information;
- (c) the degree of intent or negligence, if any, involved;
- (d) the formality of the communication;
- (e) the reasonableness of Agency reliance on the information;
- (f) the importance of the information which was wrong or not provided; and
- (g) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee or registrant official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the Agency by a licensee or registrant official or others on behalf of a licensee or registrant, if a record was made of the oral informant, and provided to the licensee or registrant thereby permitting an opportunity to correct the oral informant, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee or registrant and was not subsequently corrected in a timely manner.

When a licensee or registrant has corrected inaccurate or incomplete information, the decision to issue a citation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the case of detection of the error, the timeliness of the correction, whether the Agency or the licensee or registrant identified the problem with the communication, and whether the Agency relied on the information prior

to the correction. Generally, if the matter was promptly identified and corrected by the licensee or registrant prior to reliance by the Agency, or before the Agency raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after the Agency relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information or advance in technology, a citation normally would not be appropriate if, when the new information became available, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee or registrant does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee or registrant later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee or registrant as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's or registrant's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Agency may exercise its authority to issue orders modifying, suspending, or revoking the license or registration. The Agency recognizes that enforcement determinations must be made on a case-by-case basis taking into consideration the issues described above.

- (8) **Public Disclosure of Enforcement Actions.** In accordance with 420-3-26-.01, all enforcement actions and licensees' or registrant's responses are publicly available for inspection. In addition, press releases are generally prepared for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Levels I, II, or III, press releases are prepared at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally prepared for Notices of Violation.
- (9) **Responsibilities.** The Director, Division of Radiation Control, as the principal enforcement officer of the Agency, has been delegated the authority to issue notices of violations, civil penalties, and orders. In recognition that the regulation of radiation related activities in many cases does not lend itself to a mechanistic treatment, the Director, Radiological Health Branch must exercise judgment and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances. The State Committee of Public Health will be provided written notification of all enforcement actions involving civil penalties or orders.

SUPPLEMENT I - SEVERITY CATEGORIES**Health Physics 420-3-26-.03⁵****(1) Severity I. - Violations involving for example:**

- (a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;
- (b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
- (c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 420-3-26-.03(7);
- (d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 420-3-26-.03(18); or
- (e) Exposure of a worker in restricted areas of ten times the limits of 420-3-26-.03(4).

(2) Severity II. - Violations involving for example:

- (a) Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;
- (b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
- (c) Release of radioactive material to an unrestricted area in excess of five times the limits of 420-3-26-.03(7);
- (d) Failure to make an immediate notification as required by 420-3-26-.03(24)(a)1. and 420-3-26-.03(24)(a)2.;
- (e) Disposal of licensed material in quantities or concentrations in excess of five times the limits of 420-3-26-.03(18); or
- (f) Exposure of a worker in restricted areas in excess of five times the limits of 420-3-26-.03(4).

⁵ Personnel overexposures and associated violations, incurred during a life-saving effort, will be treated on a case-by-case basis.

(3) **Severity III.** - Violations involving for example:

- (a) Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 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 100 millirem in a one hour period or 500 millirem in any seven consecutive days;
- (c) Failure to make a 24-hour notification as required by 420-3-26-.03(24)(b) or an immediate notification required by 420-3-26-.03(24)(a);
- (d) Substantial potential for an exposure or release in excess of Rule 420-3-26-.03 whether or not such exposure or release occurs (e.g., entry into high radiation areas in the vicinity of exposed radiographic sources, or operating x-ray equipment without having performed 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 420-3-26-.03(7);
- (f) Improper disposal of licensed material not covered in Severity Level I or II;
- (g) Exposure of a worker in restricted areas in excess of the limits of 420-3-26-.03(4);
- (h) Release for unrestricted 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;
- (i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
- (j) Conduct of licensee or registrant's activities by a technically unqualified person; or
- (k) Significant failure to control licensed material or a registered activity.

(4) **Severity IV.** - Violations involving for example:

- (a) Exposures in excess of the limits of 420-3-26-.03(2) not constituting Severity Level I, II, or III violations;
- (b) A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;

- (c) Failure to make a 30-day notification required by 420-3-26-.03(25);
 - (d) Failure to make a follow-up written report as required by 420-3-26-.03(23)(b), and 420-3-26-.10(4); or
 - (e) Any other matter that has more than minor safety or environmental significance.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT II - Severity Categories

Transportation⁶

- (1) **Severity I.** - Violations of NRC transportation requirements involving for example:
- (a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or
 - (b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the U.S. Department of Transportation limits.
- (2) **Severity II.** - Violations of Agency transportation requirements involving for example:
- (a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of U. S. Department of Transportation requirements;
 - (b) Surface contamination or external radiation levels in excess of five times U. S. Department of Transportation limits that did not result from a breach of package integrity; or
 - (c) Failure to make required initial notification associated with Severity Level I or II violations.
- (3) **Severity III.** - Violations of Agency transportation requirements involving for example:

⁶ Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

- (a) Breach of package integrity;
 - (b) Surface contamination or external radiation levels in excess of, but less than a factor of five above U. S. Department of Transportation requirements, that did not result from a breach of package integrity;
 - (c) Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:
 - 1. Improper identification of the type, quantity, or form of material;
 - 2. Failure of the carrier or recipient to exercise adequate controls; or
 - 3. Substantial potential for personnel exposure or contamination, or improper transfer of material; or
 - (d) Failure to make required initial notification associated with Severity Level III violations.
- (4) **Severity IV.** - Violations of Agency transportation requirements involving for example:
- (a) Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of U. S. Department of Transportation requirements; or
 - (b) Other violations that have more than minor safety or environmental significance.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT III - Severity Categories

Radioactive Materials Operations

- (1) **Severity I.** - Violations involving for example:
- (a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license; or
 - (b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.
- (2) **Severity II.** - Violations involving for example:
- (a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or

- (b) A system designed to prevent or mitigate a serious safety event being inoperable.
- (3) **Severity III.** - Violations involving for example:
- (a) Failure to control access to licensed materials or registered operations for radiation purposes as specified by Agency requirements;
 - (b) Possession or use of unauthorized equipment or materials in the conduct of licensee or registrant activities which degrades safety;
 - (c) Use of radioactive material on humans where such use is not authorized;
 - (d) Conduct licensed or registered activities by a technically unqualified person;
 - (e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or
 - (f) Medical therapeutic misadministrations.
- (4) **Severity IV.** - Violations involving for example:
- (a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;
 - (b) Other violations that have more than minor safety or environmental significance; or
 - (c) Failure to report medical diagnostic misadministrations.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT IV - Severity Categories

Miscellaneous Matters

- (1) **Severity I.** - Violations involving for example:
- (a) Inaccurate or incomplete information ⁷ which is provided to the Agency;

⁷ In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference also should be made to the information in (6) of this Appendix.

1. deliberately with the knowledge of a licensee or registrant official that the information is incomplete or inaccurate, or
 2. if the information, had or been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety.
- (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;
1. incomplete or inaccurate because of falsification by or with the knowledge of a licensee or registrant official, or
 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations;
- (c) Information which the licensee or registrant has identified as having significant implications for public health and safety ("significant information identified by a licensee or registrant") and which is deliberately withheld from the Agency;
- (d) Action by senior corporate management in violation of 420-3-26-.10(7)(c) or similar rule against an employee.
- (2) **Severity II.** - Violations involving for example:
- (a) Inaccurate or incomplete information which is provided to the Agency;
1. by a licensee or registrant official because of careless disregard for the completeness or accuracy of the information, or
 2. if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position.
- (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;
1. incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee or registrant official, or
 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
- (c) "Significant information identified by a licensee or registrant" and not provided to

the Agency because of careless disregard on the part of a licensee or registrant official; or

- (d) Action by plant management above first-line supervision in violation of 420-3-26-.10(7)(c) or similar regulations against an employee;

(3) **Severity III.** - Violations involving for example:

- (a) Incomplete or inaccurate information which is provided to the Agency;

- 1. because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or
- 2. if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection of a formal request for information;

- (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;

- 1. incomplete or inaccurate because of inadequate actions on the part of licensee or registrant officials but not amounting to a Severity Level I or II violation, or
- 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;

- (c) Failure to provide "significant information identified by a licensee or registrant" to the Agency and not amounting to a Severity Level I or II violation", or

- (d) Action by first-line supervision in violation of 420-3-26-.010(7)(c) or similar regulations against an employee.

(4) **Severity IV.** - Violations involving for example:

- (a) Incomplete or inaccurate information of more than minor significance which is provided to the Agency but not amounting to a Severity Level I, II, or III violation;

- (b) Information which the Agency requires be kept by a licensee or registrant and which is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation; or

(5) **Severity V.** - Violations involving for example:

- (a) Incomplete or inaccurate information which is provided to the Agency and the incompleteness or inaccuracy is of minor significance, or
- (b) Information which the Agency requires be kept by a licensee or registrant which is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance.

SUPPLEMENT V - Severity Categories

Emergency Preparedness

- (1) **Severity I.** - Violations involving for example:

In a general emergency, licensee failure to promptly

- (a) correctly classify the event,
- (b) make required notifications to responsible Federal, State, and local agencies, or
- (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

- (2) **Severity II.** - Violations involving for example:

- (a) In a site area emergency, licensee failure to promptly
 - 1. correctly classify the event,
 - 2. make required notifications to responsible Federal, State, and local agencies, or
 - 3. respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or
- (b) Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

- (3) **Severity III.** - Violations involving for example:

- (a) In an alert, licensee failure to promptly
 - 1. correctly classify the event,
 - 2. make required notifications to responsible Federal, State, and local agencies, or

3. respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or
 - (b) Licensee or registrant's failure to meet or implement emergency planning standard involving assessment or notification.
- (4) **Severity IV.** - Violations involving for example:

Licensee or registrant's failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.