

RHODE ISLAND RADIATION CONTROL AGENCY

INFORMATION NOTICE

Enforcement Policy and Procedures

1 May 2001

This notice announces the availability of the document "Enforcement Policy and Procedures", which explains the policies and procedures followed by the Rhode Island Radiation Control Agency for initiating enforcement actions. This document supersedes the document of the same title dated 1 July 1992. The document contains a statement of the enforcement philosophy of the Agency, the legal basis for the Agency's enforcement authority, the enforcement mechanisms available to the Agency and the system for categorizing items of noncompliance found during the Agency's inspections and investigations. The general considerations for initiation of escalated enforcement actions are also described. However, this is a policy statement and not a regulation. The Agency may deviate from this statement of policy and procedure as is appropriate under the circumstances of a particular case.

Under these procedures the Agency classifies items of noncompliance according to five levels of severity. Severity Levels I, II and III comprise violations of the Agency's regulations that are of significant regulatory concern and generally involve actual or high potential impact on the public. Severity Level IV violations include those which, if left uncorrected, could lead to matters of significant concern. Severity Level V violations cover matters of less serious concern. Supplements are included which list criteria for classification of severity levels in five areas of regulatory concern: Health Physics; Transportation; Materials Operations; X-ray Operations; and Miscellaneous Matters.

Enforcement correspondence issued by the Agency will continue to categorize items of noncompliance in conformance with these regulatory areas and severity levels.

For a copy of the document or further information, contact the Agency at (401) 222-2438.

RHODE ISLAND RADIATION CONTROL AGENCY

ENFORCEMENT POLICY AND PROCEDURES

1 May 2001

The following statement of general policy and procedure explains the policies and procedures to be followed by the Rhode Island Radiation Control Agency (RCA) for initiating enforcement actions.

I. Introduction and Purpose

The purpose of the RCA enforcement program is to promote and protect the radiological health and safety of the public, including employee's health and safety, and the environment by:

- Ensuring compliance with RCA regulations and license conditions;
- Obtaining prompt correction of noncompliance;
- Deterring future noncompliance; and
- Encouraging improvement of licensee¹ performance, 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 who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the RCA expects of its licensees. 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 who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

II. Legal Framework

The Rhode Island Radiation Control Agency's enforcement jurisdiction is drawn from Title 23, Chapter 1.3 (Radiation Control Agency) and Title 42, Chapters 35-1 to 35-18 (Administrative Procedures Act) of the General Laws of the State of Rhode Island.

Section 274 of the Atomic Energy Act of 1954, as amended, authorizes the Nuclear Regulatory Commission (NRC) to enter into an agreement with the governor of a state for the purposes of transferring to that state certain functions of licensing and regulatory control of byproduct, source, and less than critical quantities of special nuclear material (SNM). These functions are outlined in 10 CFR, Part 150. Such an agreement has been in effect in Rhode Island since January 1, 1980.

III. Severity of Violations

Regulatory requirements² have varying degrees of safety, public health and environmental significance. Therefore, it is essential that the relative importance of each violation be identified as the first step in the enforcement process.

¹ The term "licensee" in this document should be read to include all X-ray registrants as well as radioactive materials licensees.

² The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

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

- I.** Health Physics (Part A of the RCA Regulations)
- II.** Transportation
- III.** Materials Operations
- IV.** X-ray Operations
- V.** Miscellaneous Matters

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. 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.

The relative seriousness of violations at the several severity levels applies within each activity area, but comparisons between activity areas are inappropriate. This disparity in relative seriousness of violations in different activity areas is due to the diversity of activities regulated by the RCA and the need for continuing improvement in licensee performance of certain activities.

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. They reflect the seriousness of violations of requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. Licensed activities not directly covered by one of the above listed areas will be placed in the activity area most suitable in light of the particular violation involved. 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. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as:

1. The position of the person involved in the violation (e.g., first line supervisor or senior manager),
2. The significance of any underlying violation,
3. The intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and
4. 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 RCA expects licensees and 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 RCA will be based upon the significance of and the circumstances surrounding the matter not reported. The severity level assigned to material false statements may be Severity Level I, II, or III, depending on the circumstances surrounding the statement.

IV. Enforcement Conferences

Whenever the RCA has learned of the existence of a potential violation for which escalated enforcement action may be warranted, the RCA will normally provide an opportunity for an enforcement conference with the licensee, prior to taking enforcement action. The RCA may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violations which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to (1) discuss the violations, their significance and causes, and the licensee'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, an opportunity will be provided to explain to the RCA what corrective actions (if any) were taken or will be taken following discovery of the potential violation.

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

V. Enforcement Actions

This section describes the enforcement sanctions available to RCA and specifies the condition under which each is to be used. The basic sanctions are notices of violation and orders of various types.

Additionally, related administrative mechanisms such as bulletins and confirmatory action letters are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the RCA 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 noncompliance with RCA 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 RCA will be in the form of a Notice of Violation requiring a formal response from the licensee describing its corrective actions. A relatively small number of cases may be expected to involve elevated enforcement action. These elevated enforcement actions include orders modifying, suspending or revoking licenses 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 have been taken to prevent recurrence; and (3) the date when full compliance will be achieved. The RCA may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with orders.

The RCA 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 orders, as set forth in Section V (**B. Orders**), are met. In such cases, the notice of violation will be issued in conjunction with the order.

However, violation findings warranting the exercise of discretion under Section V (**D. Exercise of Discretion**) will generally not result in a notice of violation. In addition, for isolated Severity Level V violations, a notice of violation will not normally be issued regardless of who identifies the violation provided that the licensee has initiated appropriate corrective action before the inspection ends. In these situations, a formal response from the licensee is not required and the inspection report or inspection correspondence serves to document the violations and the corrective actions. However, a notice of violation will normally be issued for willful violations, if past corrective actions for similar violations have not been sufficient to prevent recurrence, or if the circumstances warrant increasing the severity of Level V violations to a higher severity level.

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

B. Orders

An order is a written RCA directive to modify, suspend, or revoke a license³; to cease and desist from a given practice or activity; or to take such other action as may be proper.

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

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed 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:
 - (a) When a licensee is unable or unwilling to comply with RCA requirements;
 - (b) When a licensee refuses to correct a violation;
 - (c) When a licensee does not respond to a notice of violation;
 - (d) When a licensee does not pay a fee required by the RCA;
 - (e) For any other reason for which revocation is legally authorized.
- (4) Cease and Desist Orders are used to stop an unauthorized activity that has continued despite

³ The word "license" in this document should be read to include an X-ray registration as well as a radioactive materials license.

notification by RCA 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 modification is afforded. For cases in which the RCA believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

C. Escalation of Enforcement Sanctions

RCA considers violation of Severity Levels I, II or III to be very serious. If repetitive serious violations occur, RCA will consider issuing orders in conjunction with other enforcement action to achieve immediate corrective actions and to deter further recurrence of serious violations. RCA carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria contained in this document.

The actual progression to be used in a particular case will depend on the circumstances.

Normally the progression of enforcement actions for repetitive violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on repetitive 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, repetitive violations may be charged even though the second violation occurred at a different facility and/or under a different license.

D. Exercise of Discretion

Because the RCA wants to encourage and support licensee initiative for self-identification and correction of problems, the RCA may exercise discretion as follows:

- (1) The RCA may refrain from issuing a notice of violation for a violation described in an inspection report that meets all of the following criteria:
 - (a) It was identified by the licensee;
 - (b) It is normally classified at a Severity Level IV or V;
 - (c) It was reported, if required;
 - (d) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and
 - (e) It was not a willful violation or a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

E. Related Administrative Actions

In addition to the formal enforcement mechanisms of notice of violation and orders, RCA also uses administrative mechanisms, such as bulletins, circulars, information notices, generic letters, notices of deviation, and confirmatory action letters as part of its enforcement and regulatory program. RCA expects licensees to adhere to any obligations and commitments resulting from these processes and will, if necessary, issue appropriate orders to make sure that such commitments are met.

- (1) Bulletins, Circulars, Information Notices and Generic Letters are written notification to

- groups of licensees identifying specific problems and calling for or recommending specific actions on their part. Responses to these notifications may be required.
- (2) Notices of Deviation are written notices describing a licensee's or a vendor's failure to satisfy a commitment. The commitment involved has not been made a legally binding requirement. The notice of deviation requests that licensee or vendor 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.

VI. Inaccurate and Incomplete Information

A violation of the regulations on submitting complete and accurate 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 the licensee normally will be categorized based on the guidance herein, in Section III, "Severity of Violations," and in Supplement V.

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

- (1) The degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;
- (2) The opportunity and time available prior to the communication to assure the accuracy or completeness of the information;
- (3) The degree of intent or negligence, if any, involved;
- (4) The formality of the communication;
- (5) The reasonableness of RCA reliance on the information;
- (6) The importance of the information which was wrong or not provided; and
- (7) 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 would not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the RCA by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee, thereby permitting an opportunity to correct the oral information, such as a transcript of the communication or meeting summary containing the error which was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee 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 ease of detection of the error, the timeliness of the correction, whether the RCA or the licensee identified the problem with the communication, and whether the RCA relied on the information

prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee prior to reliance by the RCA, or before the RCA 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 RCA relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action 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 advances in technology, a citation normally would not be appropriate if, when the new information became available, the submittal was corrected.

The failure to correct inaccurate or incomplete information, which the licensee 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 serious matter if the licensee 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 a licensee recognized information, not corrected, 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 actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the RCA may exercise its authority to issue orders modifying, suspending, or revoking the license. The RCA recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described above.

VII. Responsibilities

The Administrator of the RCA, as the principal enforcement officer of the Agency, has the authority to issue notices of violation or orders. The Administrator exercises judgement and discretion in determining the severity level of the violations and the appropriate enforcement sanctions consistent with the general principles of this statement of policy and the technical merits of the case. In the absence of the Administrator, this authority of the Administrator is delegated within the RCA in accordance with Attachment 1.

The Executive Director for Environmental Health and the Assistant Director of Health (Legal Counsel) of the Department of Health will be consulted prior to taking enforcement action requiring the issuance of an order (unless the urgency of the situation dictates immediate action).

Supplement I. Severity Categories

Health Physics⁴

A. Severity I -- Violations involving for example:

1. 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; or
2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation; or
3. Release of radioactive material to an unrestricted area in excess of 10 times the limits of Section A.2.11 of the RCA regulations; or .
4. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of Section A.4.3 of the RCA regulations; or
5. Exposure of a worker in restricted areas in excess of 10 times the limits of Section A.2.3 of the RCA regulations.

B. Severity II -- Violations involving for example:

1. 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; or
2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation; or
3. Release of radioactive material to an unrestricted area in excess of 5 times the limits of Section A.2.11 of the RCA regulations; or
4. Failure to make an immediate notification as required by Paragraph A.5.13 (a) of the RCA regulations; or
5. Exposure of a worker in restricted areas in excess of 5 times the limits of Section A.2.3 of the RCA regulations.

C. Severity III -- Violations involving for example:

1. 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; or
2. A radiation level in an unrestricted area that exceeds 100 millirems/hour for a one-hour period; or
3. Failure to make a 24-hour notification as required by Paragraph A.5.13(b) or an immediate notification required by Section A.5.12 of the RCA regulations; or
4. Substantial potential for an exposure or release in excess of RCA Part A limits where such exposure or release does not occur (e.g., entry into high radiation area without having performed an adequate survey or operation of a radiation facility with a non-functioning interlock system); or
5. Release of radioactive material to an unrestricted area in excess of the limits of Section A. 4 of the RCA regulations; or
6. Improper disposal of licensed material not covered in Severity Levels I or II; or
7. Exposure of a worker in restricted area in excess of the limits of Section A.2.3 of the RCA regulations; or
8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to member of the public, or which reflects a programmatic (rather than isolated) weakness in radiation control program; or

⁴ Personnel overexposures and associated violations, incurred during a life saving effort, will be treated on a case-by-case basis.

C. Severity III (cont.)

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection; or
10. Conduct of licensee activities by a technically unqualified person; or
11. Significant failure to control licensed material.

D. Severity IV -- Violations involving for example:

1. Exposures in excess of the limits of Section A.2.3 of the RCA regulations not constituting Severity Level I, II, or III violations; or
2. A radiation level in an unrestricted area such that an individual may receive greater than 2 millirem in a one hour period or 100 millirem in any seven consecutive days; or
3. Failure to make notifications required by Sections A.5.12 and 5.13 of the regulations; or
4. Failure to make a follow-up written report as required by Section A 5.14 of the RCA regulations;
or
5. Any other matter, including failure to follow procedures, that has other than minor safety or environmental significant.

E. Severity V -- Violations that have minor safety or environmental significance.

**Supplement II. - Severity-Categories
Transportation⁵
(Part C of the RCA Regulations)**

- A. Severity I -- Violations of RCA transportation requirements involving for example:**
1. Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or
 2. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten (10) times RCA or Department of Transportation (DOT) limits.
- B. Severity II -- Violations of RCA transportation requirements involving for example:**
1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of RCA or DOT requirements; or
 2. Surface contamination or external radiation levels in excess of three times RCA or DOT limits that did not result from a breach of package integrity; or
 3. Failure to make required initial notifications associated with Severity Level I or II violations.
- C. Severity III -- Violations of RCA transportation requirements involving for example:**
1. Breach of package integrity; or
 2. Surface contamination or external radiation levels in excess of, but less than a factor of three above RCA or DOT requirements, that did not result from a breach of package integrity; or
 3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:
 - (a) Improper identification of the type, quantity, or form of material; or
 - (b) Failure of the carrier or recipient to exercise adequate controls; and
 - (c) Substantial potential for personnel exposure or contamination; or
 4. Failure to make required initial notification associated with Severity Level III violations.
- D. Severity IV -- Violations of RCA transportation requirements involving for example:**
1. 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 DOT or RCA requirements; or
 2. Failure to follow procedures; or inadequate procedures, not covered in Severity Level I, II or III violations that reduce the margin of safety.
 3. Other violations that have other than minor safety or environmental significance.
- E. Severity V -- Violations that have minor significance.**

⁵ Some transportation requirements are applied to more than one licensee involved in the same activity. 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.

Supplement III. - Severity Categories
Materials Operations
(Part C of the RCA Regulations)

A. Severity I -- Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license; or
2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

B. Severity II -- Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or
2. A system designed to prevent or mitigate a serious safety event being inoperable.

C. Severity III -- Violations involving for example:

1. Failure to control access to licensed materials for radiation purposes as specified by RCA requirements; or
2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities; or
3. Use of radioactive material on humans where such use is not authorized; or
4. Conduct of licensed activities by a technically unqualified person; or
5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or
6. Failure to report a therapeutic misadministration.

D. Severity IV -- Violations involving for example:

1. Failure to maintain patients containing radium-226, cobalt-60, cesium-137, or iridium-192 implants hospitalized, or to conduct required leakage or contamination tests, or to use properly calibrated equipment; or
2. Other violations that have more than minor safety or environmental significance; or
3. Failure to report a diagnostic misadministration.

E. Severity V -- Violations that have minor safety or environmental significance.

Supplement IV. - Severity Categories
X-Ray Operations

A. Severity I -- Violations involving for example:

1. A technically unqualified or unauthorized person conducting an X-ray procedure that results in (1) a diagnostic skin entrance exposure to a patient that exceeds 5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of a patient's body that exceeds 3 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.5 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of 10R/min; or
2. Use of unauthorized equipment or equipment not meeting the Agency's regulations that results in (1) a diagnostic skin entrance exposure to a patient that exceeds 5 times the median skin entrance exposure for procedure; (2) an exposure to an area of a patient's body that exceeds 3 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.5 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of 10R/min; or
3. Use of unauthorized or improper techniques and/or procedures that result in (1) a diagnostic skin entrance exposure to a patient that exceeds 5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of a patient's body that exceeds 3 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.5 times the prescribed dose; (4) a fluoroscopic skin entrance in excess of 10R/min; or
4. Failure to perform required calibrations, surveys, tests or evaluations, or to implement required safety precautions that result in (1) a diagnostic skin entrance exposure to a patient that exceeds 5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of patient's body that exceeds 3 times the area of clinical interest; (3) a therapeutic dose that exceed 1.5 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess off 10R/min; or
5. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

B. Severity II -- Violations involving for example:

1. A technically unqualified or unauthorized person conducting an X-ray procedure that results in (1) a diagnostic skin entrance exposure to a patient that exceeds 2.5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of a patient's body that exceeds 1.5 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.1 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of manufacturer's specifications or that specified in required facility procedures; or
2. Use of unauthorized equipment or equipment not meeting the Agency's regulations that results in (1) a diagnostic skin entrance exposure to a patient that exceeds 2.5 times the median skin entrance exposure for the procedures; (2) an exposure to an area of a patient's body that exceeds 1.5 times the prescribed dose; (3) a therapeutic dose that exceeds 1.1 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of manufacturer's specifications or that specified in required facility procedures; or
3. Use of unauthorized or improper techniques and/or procedures that result in (1) a diagnostic skin entrance exposure to a patient that exceeds 2.5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of a patient's body that exceeds 1.5 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.1 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of manufacturer's specifications or that specified in required facility procedures; or

B. Severity II (cont.)

4. Failure to perform required calibrations, surveys, tests or evaluations, or institute required safety precautions that result in (1) a diagnostic skin entrance exposure to a patient that exceeds 2.5 times the median skin entrance exposure for the procedure; (2) an exposure to an area of a patient's body that exceeds 1.5 times the area of clinical interest; (3) a therapeutic dose that exceeds 1.1 times the prescribed dose; (4) a fluoroscopic skin entrance exposure in excess of manufacturer's specifications or that specified in required facility procedures; or
5. A system designed to prevent or mitigate a serious safety event being inoperative; or
6. Failure to make a required initial notification associated with Severity Level I or II violations.

C. Severity III --Violations involving for example:

1. Violations resulting in unnecessary patient exposure not constituting Severity Level I or II violations; or
2. Failure to control access to X-ray equipment for radiation purposes as specified in RCA regulations; or
3. Possession of unauthorized X-ray equipment or use of equipment not meeting the RCA regulations; or
4. Use of X-ray equipment by unauthorized or unqualified personnel;
5. Failure to make required initial notifications associated with Severity level III violations; or
6. Degradation of a system designed to prevent or mitigate a serious safety event; or
7. Failure to report a therapeutic misadministration.

D. Severity IV --Violations involving for example:

1. Failure to follow requirements not covered in Severity Level I, II or III violation that reduce the margin of safety (e.g., failure to make a survey required by regulations or procedures) or result in unnecessary radiation exposure to patients, workers or public; or
2. Other violations, such as failure to follow procedure or keep records which have other than minor radiation safety significance; or
3. Violations that alone have minor significance but when combined with others may indicate a pattern of neglect in radiation safety programs or procedures.

E. Severity V -- Violations that have minor safety or environmental significance

Miscellaneous Matters^{6,7}

A. **Severity I --Violations involving for example:**

1. A Material False Statement (MFS)⁸ in which the statement made was deliberately false; or
2. Deliberate action by management to discriminate against an employee for attempting to communicate or actually communicating with the RCA.

B. **Severity II --Violations involving for example:**

1. A MFS or a reporting failure, involving information which, had it been available to the RCA and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the RCA seeking further information; or
2. A MFS in which the false statement was made with careless disregard; or
3. Discrimination by management at any level above first-line supervision, against an employee for attempting to communicate or actually communicating with the RCA.

C. **Severity III --Violations involving for example:**

1. A MFS not amounting to a Severity Level I or II violation; or
2. Discrimination against an employee for attempting to communicate or actually communicating with the RCA.

D. **Severity IV --Violations involving for example:**

1. A false statement caused by an inadvertent clerical or similar error involving information which,

⁶ As noted in Section III, in determining the specific Severity Level of a violation, consideration will be given to such factors as the position of the person involved in the violation (i.e., 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, or deliberateness), and the economic advantage, if any, gained by 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.

⁷ The majority of the violations in this supplement are used by the NRC to deal with 10 CFR 21 requirements. However, Sections A.6.6 and A.6.7 of the RCA regulations also outline the rights of workers at a licensee's or registrant's facility with regard to contacting the Agency.

⁸ In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process.

had it been available to RCA and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or RCA seeking additional information.

E. Severity V - Violations that have minor safety or environmental significance

ATTACHMENT 1

(See Section V. Responsibilities) Delegation of Authority in the Absence of the Administrator

If the Administrator is unavailable, and it becomes necessary to consider the issuance of an order prior to the time when it is anticipated that the Administrator will become available, the authority to issue orders is delegated within the RCA in accordance with the following priority:

1. Supervising Radiological Health Specialist
2. Radiological Health Specialist
3. Industrial Hygienist

Within each classification the priority shall be in accordance with length of service in the position.