

APPENDIX A  
NOTICE OF VIOLATION

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License No. 53-04935-01

As a result of the inspection conducted June 28, 1982, and in accordance with the NRC Enforcement Policy, (10 CFR Part 2, Appendix C), 47 FR 9987 (March 9, 1982), the following violations were identified:

- A. 10 CFR 20.207(a) states that licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, at the time of the inspection, a sealed source containing 50 millicuries of strontium-90 was stored in a utility room inside the Suite 101 Nuclear Medicine Office, an unrestricted area. The inspector determined that the door to the utility room could not be locked, nor was provision made to secure the sealed source within a locked container inside the utility room. Also, the inspector determined that during the night or weekend hours the unoccupied Nuclear Medicine Office is available to building maintenance personnel to clean the facility.

This is a Severity Level IV Violation (Supplement IV).

- B. License Condition 13.A. states, in part, that each sealed source containing licensed materials, other than hydrogen-3, with a half-life greater than thirty days, and in any form other than gas, shall be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above requirement, a sealed source containing 50 millicuries of strontium-90, was leak tested on September 28, 1979 and was not repeated until November 21, 1980, a period in excess of thirteen months. Another leak test was conducted on the same source on June 8, 1981 and was not repeated until March 31, 1982, a period exceeding nine months.

This is a Severity Level IV Violation (Supplement VI).

- C. License Condition 10. states that licensed material shall be used only at 1507 S. King Street, Room 206, Honolulu, Hawaii and 880 Kam Highway, Pearl City, Hawaii.

Contrary to the above requirement, at the time of inspection, licensed material (50 millicuries of strontium-90) was being used at 1507 S. King Street, Room 101, Honolulu, Hawaii. Also, up to 29.6 millicuries of iodine-131 had been used in the Nuclear Medicine Laboratory located at Room 102 of the above address prior to and during the past year.

This is a Severity Level IV Violation (Supplement VI).

- D. License Condition 18. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated March 19, 1979.

1. Item 1 of the attachment, Calibration of Instruments, which was submitted with the application, states that the dose calibrator will be checked for linearity prior to initial use and quarterly thereafter.

Contrary to the above requirement, tests to determine instrument linearity had not been performed on the dose calibrator during the period of use between the date of license issuance on January 9, 1980, and a linearity test that was performed in the second quarter, 1982.

This is a Severity Level IV Violation (Supplement VI).

2. Item 1 of the attachment, Bioassay for I-131, which was submitted with the application, states that thyroid bioassays for iodine-131 will be required for all personnel who handle more than 0.1 millicurie of iodine-131 on an open bench, or more than 1 millicurie of iodine-131 in a fume hood. Items 2 and 3 of the attachment also states that the bioassay will be performed between 24 and 72 hours after exposure to iodine-131 and again within two weeks after the last possible exposure to iodine-131 when the employee is terminating activities involving iodine-131. The bioassay shall consist of a determination of the individual's thyroid burden.

Contrary to the above requirements, no measurements had been made to determine the thyroid burden of certain nuclear medicine personnel following the handling of up to 29.6 millicuries of iodine-131 which was administered to patients on eleven separate occasions between January 26, 1980 and April 7, 1982.

This is a Severity Level IV Violation (Supplement VI).

3. Item 6 of the attachment, Laboratory Rules for the Use of Radioactive Material, which was submitted with the application, states that each patient dose will be assayed in the dose calibrator prior to administration to the patient.

Contrary to the above requirement, at the time of the inspection, patient doses up to 29.6 millicuries of iodine-131 had not been assayed in the dose calibrator prior to administration to patients between the period of license issuance on January 9, 1980 and the date of inspection, June 28, 1982.

This is a Severity Level IV Violation (Supplement VI).

- E. 10 CFR 20.203(f)(1) states that each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents. Also, 10 CFR 20.203(f)(2) states that the required label shall bear the radiation caution symbol and the words "Caution, Radioactive Material" or "Danger, Radioactive Material". It shall also provide sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures.

Contrary to the above requirements, at the time of the inspection, the lead shield containing a 50 millicurie strontium-90 sealed source (Tracerlab Model RA-1A Medical Applicator), which was located in the utility room of the Nuclear Medicine Office (Suite 101), was not labeled to identify the radioactive contents nor was the container labeled with the words "Caution, Radioactive Material" or "Danger, Radioactive Material."

This is a Severity Level V Violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, you are hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

dated July 23, 1982

*B.A. Riedinger*  
for R. D. Thomas, Chief  
Materials Radiation Protection Section

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Act, to the Attorney General as required by section 105c of the Act. Under that section, the Attorney General will, within a reasonable time, but in no event to exceed 180 days after receipt, render such advice to the Commission as is determined to be appropriate in regard to the finding to be made by the Commission as to whether the activities under the license would create or maintain a situation inconsistent with the antitrust laws specified in subsection 105a of the Act.

(2) The review by the Attorney General described in paragraph (c)(1) above is not required for applications for operating licenses for production or utilization facilities under section 103 of the Act for which the construction permit was also issued under section 103, unless the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, determines, after consultation with the Attorney General and in accordance with § 2.101(e), that such review is advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review by the Attorney General and by the Commission under section 105c of the Act in connection with the construction permit.

(d) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will publish the Attorney General's advice in the FEDERAL REGISTER promptly upon receipt, and will make such advice a part of the record in any proceeding on antitrust matters conducted in accordance with subsection 105c(5) and section 189a of the Act. The Director of Regulation will also publish in the FEDERAL REGISTER a notice that the Attorney General has not rendered any such advice. The notice published in the FEDERAL REGISTER will also include a notice of hearing, if appropriate, or, if the Attorney General has not recommended a hearing, will state that any person whose interest may be affected by the proceeding may, pursuant to and in accordance with § 2.714, file a petition for leave to intervene and request a hearing on the antitrust aspects of the application. The notice will state that petitions for leave to intervene and requests for hearing shall be filed within 30 days after publication of the notice.

(e) If a hearing on antitrust aspects of the application is requested, or is recommended by the Attorney General, it will generally be held separately from the hearing held on matters of radiological health and safety and common defense and security described in sections I-VIII of this appendix. The notice of hearing will fix a time for the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with section 189a of the Act and other provisions of this part. However, as permitted by subsection 105c(8) of the Act, with respect to proceedings in which an application for a construction permit was filed prior to December 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust consideration or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the FEDERAL REGISTER of notice of filing of the applica-

tion for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license, provided that the permit or license so issued contains the condition specified in § 50.55b of this chapter.

(f) Hearings on antitrust aspects will be conducted by a presiding officer, either an Administrative Law Judge or an atomic safety and licensing board comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom will have such technical or other qualifications as the Commission deems appropriate to the issues to be decided.

(g) When the Attorney General has advised that there may be adverse antitrust aspects and recommends that a hearing be held, the Attorney General or his designee may participate as a party in the proceedings.

(h) At the hearing, the presiding officer will give due consideration to the advice received from the Attorney General and to evidence pertaining to antitrust aspects received at the hearing.

(i) The presiding officer will, in the initial decision, make a finding as to whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act. If the presiding officer finds that such a situation would be created or maintained, it will consider, in determining whether the permit or license should be issued or continued, such other factors as it deems necessary to protect the public interest, including the need for power in the affected area. The certainty of contravening the antitrust laws or the policies clearly underlying these laws is not intended to be implicit in this standard, nor is mere possibility of inconsistency. The finding will be based on reasonable probability of contravention of the antitrust laws or the policies clearly underlying these laws. The presiding officer will conclude whether, in its judgment, it is reasonably probable that the activities under the license would, when the license is issued or thereafter, be inconsistent with any of the antitrust laws or the policies clearly underlying these laws.

(j) On the basis of the findings in the proceeding on the antitrust aspect of the application, the presiding officer may (i) authorize the issuance of the permit or license after favorable consideration of matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, at the hearing described in sections I-VIII of this appendix; (ii) authorize the continuation of a permit or license already issued; (iii) direct the denial of the application for the permit or license, or the rescission of a permit or license already issued; or (iv) authorize the issuance of a permit or license subject to appropriate conditions, and subject to favorable consideration of matters of radiological health and safety and common defense matters raised under the National Environmental Policy Act of 1969 at the hearing described in sections I-VIII of this appendix.

### Appendix C—General Policy and Procedure for NRC Enforcement Actions

The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions and of presiding officers, the Atomic Safety and Licensing Appeal Boards, and the Commission in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety, the common defense and security, and the environment.<sup>1</sup>

#### I. Introduction and Purpose

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by:

- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of noncompliance;
- Deterring future noncompliance; and
- Encouraging improvement of licensee 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 NRC expects of its licensees.

It is the Commission's intent that noncompliance should be more expensive than compliance.\*

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. Statutory Authority and Procedural Framework

##### A. Statutory Authority

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Section 186 authorizes NRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's failure to build or

<sup>1</sup> Antitrust enforcement matters will be dealt with on a case-by-case basis.

\*Correction 47 FR 16005

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operate a facility in accordance with the terms of the permit or license, and for violation of a NRC regulation). Section 234 authorizes NRC to impose civil penalties not to exceed \$100,000 per violation per day for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. Section 232 authorizes NRC to seek injunctive or other equitable relief for violation of regulatory requirements.

Section 206 of the Energy Reorganization Act authorizes NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

Chapter 18 of the Atomic Energy Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of the act and regulations or orders issued under Sections 65, 161(b), 161(i), or 161(o) of the Act. Section 223 provides that criminal penalties may be imposed on certain individuals employed by firms constructing or supplying basic components of any utilization facility if the individual knowingly and willfully violates NRC requirements such that a basic component could be significantly impaired. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the Atomic Energy Act are referred to the Department of Justice for appropriate action.

### B. Procedural Framework

10 CFR Part 2, Subpart B, of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the appropriate NRC Office 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 10 CFR 2.202. The mechanism for modifying a license by order is set forth in 10 CFR 2.204. These sections of Part 2 provide an opportunity for a hearing to the affected licensee. However, the NRC is authorized to make orders immediately effective if the public health, safety or interest so requires or, in the case of an order to show cause, if the alleged violation is willful.

### III. Severity of Violations

Regulatory requirements<sup>2</sup> have varying degrees of safety, safeguards, or environmental significance. Therefore, it is essential that the relative importance of each violation 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 seven activity areas:

- Reactor Operations;
- Facility Construction;
- Safeguards;
- Health Physics;
- Transportation;
- Fuel Cycle and Materials Operations; and
- 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. For example, while the immediacy of any hazard to the public associated with Severity Level I violations in Reactor Operations is greater than that associated with Severity Level I violations in Reactor Construction, both areas have violations which cover the full range of severity levels. This disparity in relative seriousness of violations in different activity areas is due to the diversity of licensed activities regulated by NRC and the need for continuing improvement in licensee performance of certain activities.

While examples are provided in Supplements I through VII for determining the appropriate severity level for violations in each of the seven 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, e.g., export license activities, will be placed in the activity area most suitable in light of the particular violation involved.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of

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

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 comprehend 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 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 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.

The NRC expects licensees 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 NRC will be based upon the significance of and the circumstances surrounding the matter. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

### IV. Enforcement Actions

This section describes the enforcement sanctions available to NRC 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 are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, NRC 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 NRC 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 an NRC regional office is appropriate in the form of a Notice of Violation requiring a formal response from the licensee describing its 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 operation. These elevated enforcement actions include civil penalties; 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 licensee to provide a

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written statement describing (1) corrective steps which have been taken by the licensee and the results achieved; (2) corrective steps which will be taken to prevent recurrence; and (3) the date when full compliance will be achieved. NRC 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.

NRC 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 IV.B and IV.C respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, NRC will not generally issue a notice of violation for a violation that meets all of the following tests:

- (1) It was identified by the licensee;
- (2) It fits in Severity Level IV or V;
- (3) It was reported, if required;
- (4) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and
- (5) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee 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. Enforcement actions involving individuals, including licensed operators, will be determined on a case-by-case basis.<sup>3</sup>

### B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of (a) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders, (b) any requirement for which a license may be revoked, or (c) reporting requirements under Section 206 of the Energy Reorganization Act. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Generally, civil penalties are imposed for Severity Level I and II violations, are considered and usually imposed for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar

<sup>3</sup>Section 234 of the Atomic Energy Act gives the Commission authority to impose civil penalties for violations on "any person." "Person" is broadly defined in Section 11a of the AEA to include individuals, a variety of organizations, and any representatives or agents. This gives the Commission authority to impose civil penalties on employees of licensees or on separate entities when a violation of a requirement directly imposed on them is committed.

<sup>4</sup>The word "similar," as used in this policy, refers to those violations which could have been

to violations discussed in a previous enforcement conference, and for which the enforcement conference was ineffective in achieving the required corrective action.

In applying this guidance for Severity Level IV violations, NRC normally considers civil penalties only for similar violations that occur after the date of the last inspection or within two years, whichever period is greater. Enforcement conferences are normally conducted for all Severity Level I, II, and III violations and for Severity Level IV violations that are considered symptomatic of program deficiencies, rather than isolated concerns. Licensees will be put on notice when a meeting is an enforcement conference.

Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act, and for any willful violation, including those at any severity level.

NRC 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 reactor, 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 nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the NRC'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, NRC will consider as necessary an increase or decrease on a case-by-case basis.

NRC 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, provided that such violations were not disclosed as a result of overexposures or unplanned releases of radioactivity or other specific, self-disclosing incidents.

reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations or serious breakdown in management controls, NRC 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 \$100,000 per violation, per day.

NRC 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 below:

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 NRC. 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, and the promptness and completeness of any required report. This factor will not be applied to violations which constitute or are identified as a result of overexposures, unplanned releases of radioactivity or other specific, self-disclosing incidents. In addition, 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 25% 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. *Enforcement History.* The base civil penalty may be increased as much as 25% depending on the enforcement history in the general area of concern. Specifically, failure to implement previous corrective action for prior similar problems may increase the civil penalty value.

4. *Prior Notice of Similar Events.* The base civil penalty may be increased as much as 25% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry

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notification, and had failed to take effective preventive steps.

5. *Multiple Occurrences.* The base civil penalty may be increased as much as 25% where multiple examples of a particular violation are identified during the inspection period. This factor is applicable only where NRC identifies the violation, or for violations associated with self-disclosing incidents.

The above factors are additive so that the civil penalty for any severity level may range from plus or minus 100% of the base value. However, in no instance will a civil penalty for any one violation exceed \$100,000 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. Generally, 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.

Generally, for situations where a licensee is unaware of a condition resulting in a continuing violation, 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. Civil penalties in excess of 3.75 times the maximum civil penalty for a single Severity Level I violation for each type of licensee require specific Commission approval in accordance with guidance set forth in Section VI below.

NRC statutory authority permits the assessment of the maximum civil penalty for each violation. The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to emphasize the focus 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 will generally be based on the amount shown in the table, 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 this regard, 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.

(d) When the licensee interferes with the conduct of an inspection or investigation; or  
(e) 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 NRC requirements,
- (b) When a licensee refuses to correct a violation,
- (c) When a licensee does not respond to a notice of violation where a response was required,
- (d) When a licensee refuses to pay a fee required by 10 CFR Part 170, or
- (e) For any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by NRC 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 NRC 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.

*D. Escalation of Enforcement Sanctions*

NRC considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, NRC will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. NRC 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 IV.B and IV.C, above.

Examples of 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. When more than one facility is covered by a single license, 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

TABLE 1A.—BASE CIVIL PENALTIES  
[For Severity I Violations]

	Plant operations <sup>a</sup> construction and health physics	Safeguards		Transportation	
		Category 1 <sup>b</sup>	Noncategory 1	High level waste, spent fuel <sup>c</sup>	Low specific activity <sup>d</sup>
a. Power Reactors	\$80,000	\$80,000	\$40,000	\$80,000	\$5,000
b. Test Reactors	10,000	10,000	5,000	10,000	2,000
c. Research Reactors and Critical Facilities	5,000	5,000	2,500	5,000	1,000
d. Fuel Facilities	40,000	80,000	40,000	40,000	5,000
e. Industrial Users of Material <sup>e</sup>	8,000			5,000	2,000
f. Waste Disposal Licensees	8,000			8,000	3,000
g. Academic or Medical Institutions <sup>f</sup>	4,000			2,500	1,000
h. Other Material Licensees	1,000			2,500	1,000

<sup>1</sup> Category 1 licensees are those authorized to possess formula quantities of strategic special nuclear material (10 CFR 73.2(bb)).

<sup>2</sup> Also \* Type B packages.

<sup>3</sup> Also \* Type A limited quantity packages.

<sup>4</sup> Includes industrial radiographers, nuclear pharmacies, industrial processors and firms engaged in manufacturing or distribution of byproduct or source materials.

<sup>5</sup> This applies to nonprofit institutions not otherwise categorized under a through f in this table.

TABLE 1B.—BASE CIVIL PENALTIES

Severity level	Base civil penalty amount <sup>1</sup>
I	100
II	80
III	50
IV	15
V	5

<sup>1</sup> Percent of amount listed in table 1A.

*C. Orders*

An order is a written NRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity, or to take such other action as may be proper (see 10 CFR 2.202 and 2.204). Orders may be issued as set forth below. Orders may also be

issued in lieu of, or in addition to, civil penalties, as appropriate.

(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, common defense and security, or the environment;

(b) 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 quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

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operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a physical security violation at Unit 2 of a dual unit 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**

Severity of violation	Number of similar violations from the date of the last inspection or within the previous 2 years (whichever period is greater)		
	1st	2d	3d
I	a + b	a + b + c	d
II	a	a + b	a + b + c
III	a <sup>1</sup>	a	a + b

- a. Civil penalty.  
 b. Suspension of affected operations until the Office Director is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements, or modification of the license, as appropriate.  
 c. Show cause for modification or revocation of the license, as appropriate.  
 d. Further action, as appropriate.  
<sup>1</sup> Consideration of.

### E. Related Administrative Actions

In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, NRC also uses administrative mechanisms, such as enforcement conferences, bulletins, circulars, information notices, generic letters, notices of deviation, and confirmatory action letters to supplement its enforcement program. NRC expects licensees to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to make sure that such commitments are met.

(1) Enforcement Conferences are meetings held by NRC with licensee management to discuss safety, safeguards or environmental problems, licensee's compliance with regulatory requirements, a licensee's proposed corrective measures (including schedules for implementation) and enforcement options available to the NRC.

(2) Bulletins, Circulars, Information Notices and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

(3) 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 the 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.

(4) Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

### F. Referrals To Department of Justice

Alleged or suspected criminal violations of the Atomic Energy Act (and of other relevant Federal laws) are referred to the Department of Justice for investigation. Referral to the Department of Justice does not preclude the

NRC from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Department of Justice to the extent practicable.

### V. Public Disclosure of Enforcement Actions

In accordance with 10 CFR 2.790, all enforcement actions, inspection reports, and licensees' responses are publicly available for inspection. In addition, press releases are generally issued 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 issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

### VI. Responsibilities

The Director, Office of Inspection and Enforcement, as the principal enforcement officer of the NRC, has been delegated the authority to issue notices of violations, civil penalties, and orders.<sup>6</sup> In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, the Director must exercise judgement 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 Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will be consulted prior to taking enforcement action in the following situations (unless the urgency of the situation dictates immediate action):

- (1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation;
- (2) Proposals to impose civil penalties in amounts greater than 3.75 times the Severity Level I values shown in Table 1A;
- (3) Any proposed enforcement action on which the Commission asks to be consulted; or
- (4) Any action the Office Director believes warrants Commission involvement.

### Supplement I—Severity Categories

#### Reactor Operations

A. Severity I—Very significant violations involving:

<sup>6</sup> The Directors of the Offices of Nuclear Reactor Regulation and Nuclear Material Safety and Safeguards have also been delegated similar authority, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions necessary in the interest of public health and safety. The Director, Office of Administration, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license fees. It is planned to consider redelegation of some or all of these authorities to the Administrators of the NRC Regional Offices over the next several years.

1. A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications, being exceeded;

2. A system<sup>4</sup> designed to prevent or mitigate a serious safety event not being able to perform its intended safety function<sup>7</sup> when actually called upon to work;

3. An accidental criticality; or

4. Release of radioactivity offsite greater than ten (10) times the Technical Specifications limit.<sup>8</sup>

B. Severity II—Very significant violations involving:

1. A system designed to prevent or mitigate serious safety events not being able to perform its intended safety function; or

2. Release of radioactivity offsite greater than five (5) times the Technical Specifications limit.

C. Severity III—Significant violations involving:

1. A Technical Specification Limiting Condition for Operation being exceeded where the appropriate Action Statement was not satisfied that resulted in:

(a) Loss of a safety function; or

(b) A degraded condition, and sufficient information existed which should have alerted the licensee that he was in an Action Statement condition;

2. A system designed to prevent or mitigate a serious safety event not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available; materials or components not environmentally qualified);

3. Serious dereliction of duty on the part of personnel involved in licensed activities;

4. Changes in reactor parameters which cause unanticipated reductions in margins of safety;

5. Release of radioactivity offsite greater than the Technical Specifications limit; or

6. 10 CFR 50.59 such that a required license amendment was not sought.

D. Severity IV—Violations involving:

1. 10 CFR 50.59 that do not result in a Severity Level I, II, or III violation;

2. Failure to meet regulatory requirements that have more than minor safety or environmental significance; or

3. Failure to make a required Licensee Event Report when the reported matter does not constitute a violation.

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

### Supplement II—Severity Categories

#### Part 50 Facility Construction

A. Severity I—Very significant violations involving a structure or system that is

<sup>4</sup> "System" as used in these supplements, includes administrative and managerial control systems, as well as physical systems.

<sup>7</sup> "Intended safety function" means the total safety function, and is not directed toward a loss of redundancy. For example, considering a BWR's high pressure ECCS capability, the violation must result in complete invalidation of both HPCI and ADS subsystems. A loss of one subsystem does not defeat the intended safety function as long as the other subsystem is operable.

<sup>8</sup> The Technical Specification limit as used in this Supplement (Items A.4, B.2 and C.5) does not apply to the instantaneous release limit.



completed\* in such a manner that it would not have satisfied its intended safety related purpose.

B. Severity II\*—Very significant violations involving:

1. A breakdown in the quality assurance program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). Such deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

C. Severity III—Significant violations involving:

1. A deficiency in a licensee quality assurance program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). Such significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. Failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

3. Failure to make a required 10 CFR 50.55(e) report.

D. Severity IV—Violations involving failure to meet regulatory requirements including one or more Quality Assurance Criteria not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental significance.

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

#### Supplement III—Severity Categories

##### Safeguards

A. Severity I—Very significant violations involving:

1. An act of radiological sabotage or actual theft, loss, or diversion of a formula quantity of strategic special nuclear material<sup>10</sup> (SSNM);

2. Actual entry of an unauthorized individual into a vital area or material access area from outside the protected area (i.e., penetration of both barriers) that was not detected at the time of entry; or

3. Failure to promptly report knowledge of an actual or attempted theft or diversion of SSNM or an act of radiological sabotage.

B. Severity II—Very significant violations involving:

1. Actual theft, loss or diversion of special nuclear material (SNM) of moderate strategic significance.<sup>11</sup>

2. Failure to use established security items (including compensatory measures)

designed or used to prevent any unauthorized individual from entering a vital area or material access area from outside the protected area (i.e., entry through two barriers) so that access could have been gained without detection;

3. Failure to implement approved compensatory measures when the central (or secondary) alarm station is inoperable;

4. Failure to establish or maintain safeguards systems designed or used to prevent or detect the unauthorized removal of a formula quantity of SSNM from areas of authorized use or storage; or

5. Failure to use established transportation security systems designed or used to prevent the theft, loss, or diversion of a formula quantity of SSNM or acts of radiological sabotage.

C. Severity III—Significant violations involving:

1. Failure to control access to a vital area or material access area from inside the protected area or failure to control access to a protected area from outside the protected area; (i.e., such that only a single security element remained);

2. Failure to control access to a transport vehicle or the SNM being transported that does not constitute a Severity I or II violation;

3. Failure to establish or maintain safeguards systems designed or used to detect the unauthorized removal of SNM of moderate strategic significance from areas of authorized use or storage; or

4. Failure to properly secure or protect classified or other sensitive safeguards information.

D. Severity IV—Violations involving:

1. Failure to establish or maintain safeguards systems designed or used to detect the unauthorized removal of SNM of low strategic significance<sup>12</sup> from areas of authorized use or storage;

2. Failure to implement 10 CFR Parts 25 and 95 and information addressed under Section 142 of the Act, and the NRC approved security plan relevant to those parts; or

3. Other violations, such as failure to follow an approved security plan, that have more than minor safeguards significance.

E. Severity V—Violations that have minor safeguards significance.

#### Supplement IV—Severity Categories

##### Health Physics 10 CFR Part 20<sup>13</sup>

A. Severity I—Very significant violations involving:

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;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or

<sup>10</sup> See 10 CFR 73.2(y).

<sup>11</sup> Personnel overexposures and associated violations, incurred during a life saving effort, will be treated on a case-by-case basis.

5. Exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity II—Very significant violations involving:

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;

2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;

4. Failure to make an immediate notification as required by 10 CFR 20.403(a)(1) and 10 CFR 20.403(a)(2);

5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303; or

6. Exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity III—Significant violations involving:

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;

2. A radiation level in an unrestricted area that exceeds 100 millirem/hour for a one hour period;

3. Failure to make a 24-hour notification as required by 10 CFR 20.403(b) or an immediate notification required by 10 CFR 20.402(a);

4. Substantial potential for an exposure or release in excess of 10 CFR 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;

6. Improper disposal of licensed material not covered in Severity Levels I or II;

7. Exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103;

8. 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;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person; or

11. Significant failure to control licensed material.

D. Severity IV—Violations involving:

1. Exposures in excess of the limits of 10 CFR 20.101 not constituting Severity Level I, II, or III violations;

2. 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;

\*"Completed" means completion of construction including review and acceptance by the construction QA organization.

<sup>10</sup> See 10 CFR 73.2(bb).

<sup>11</sup> See 10 CFR 73.2(x).

\*Correction 47 FR 16005

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3. Failure to make a 30-day notification required by 10 CFR 20.405;
  4. Failure to make a followup written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or
  5. Any other matter that has more than minor safety or environmental significance.
- E. Severity V—Violations that have minor safety or environmental significance.

### Supplement V—Severity Categories

#### Transportation<sup>14</sup>

- A. Severity I—Very significant violations of NRC transportation requirements involving:
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 times the NRC limits.
- B. Severity II—Very significant violations of NRC transportation requirements involving:
1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of NRC requirements;
  2. Surface contamination or external radiation levels in excess of three times NRC 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—Significant violations of NRC transportation requirements involving:
1. Breach of package integrity;
  2. Surface contamination or external radiation levels in excess of, but less than a factor of three above NRC requirements, that did not result from a breach of package integrity;
  3. Any noncompliance with labelling, 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 improper transfer of material; or
  4. Failure to make required initial notification associated with Severity Level III violations.
- D. Severity IV—Violations of NRC transportation requirements involving:
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 NRC requirements; or
  2. Other violations that have more than minor safety or environmental significance.
- E. Severity V—Violations that have minor safety or environmental significance.

<sup>14</sup> Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper (10 CFR 73.20) and a carrier (10 CFR 70.20a). 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 VI—Severity Categories

#### Fuel Cycle and Materials Operations

- A. Severity I—Very significant violations involving:
1. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;
  2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function; or
  3. A nuclear criticality accident.
- B. Severity II—Very significant violations involving:
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—Significant violations involving:
1. Failure to control access to licensed materials for radiation purposes as specified by NRC requirements;
  2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities;
  3. Use of radioactive material on humans where such use is not authorized;
  4. Conduct of licensed activities by a technically unqualified person;
  5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or
  6. Medical therapeutic misadministrations.
- D. Severity IV—Violations involving:
1. 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;
  2. Other violations that have more than minor safety or environmental significance; or
  3. Medical diagnostic misadministrations.
- E. Severity V—Violations that have minor safety or environmental significance.

### Supplement VII—Severity Categories

#### Miscellaneous Matters<sup>15</sup>

- A. Severity I—Very significant violations involving:
1. A Material False Statement (MFS)<sup>16</sup> in which the statement made was deliberately false;
  2. A failure to provide the notice required by Part 21 under circumstances for which a civil penalty may be imposed under section 206(b) of the Energy Reorganization Act (ERA); or

<sup>15</sup> 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 (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 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.

<sup>16</sup> In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process.

3. Deliberate action by management to discriminate (in violation of Section 210 of the ERA) against an employee for attempting to communicate or actually communicating with NRC.

B. Severity II—Very significant violations involving:

1. A MFS or a reporting failure, involving information which, had it been available to the NRC and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in NRC seeking further information;

2. A MFS in which the false statement was made with careless disregard;

3. Discrimination (in violation of Section 210 of the ERA) by management at any level above first-line supervision, against an employee for attempting to communicate or actually communicating with NRC; or

4. A failure to provide the notice required by Part 21.

C. Severity III—Significant violations involving:

1. A MFS not amounting to a severity level I or II violation;

2. Discrimination (in violation of Section 210 of the ERA) against an employee for attempting to communicate or actually communicating with the NRC; or

3. Inadequate review or failure to review such that, if an appropriate review had been made as required, a Part 21 report would have been made.

D. Severity IV—Violations involving:

1. Inadequate review or failure to review under Part 21 or other procedural violations associated with Part 21 with more than minor safety significance; or

2. A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to NRC and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or NRC seeking additional information.

- E. Severity V—Violations of minor procedural requirements of Part 21.