

PART B

ENFORCEMENT ACTIONS, PROCEDURES, AND CIVIL PENALTIES

1. Purpose and Scope.

- A. The following statement of general policy and procedure explains the enforcement policy and procedures of the State of Maine Radiation Control Program in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.
- B. The purpose of the enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:
 - (1) Ensuring compliance with regulations and license conditions;
 - (2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
 - (3) Deterring future violations and occurrences of conditions adverse to quality; and
 - (4) Encouraging improvement of licensee and vendor^{1/} performance, and by example, and that of industry, including the prompt identification and reporting of potential safety problems.
- C. Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or vendors who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. It is the state's intent that sanctions should be designed to ensure that a licensee or vendor does not deliberately profit from violations of these requirements. 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.

2. Severity of Violations.

- A. Regulatory requirements have varying degrees of safety or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.
- B. Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:
 - I. Health Physics;
 - II. Transportation;
 - III. Materials Operations
 - IV. Miscellaneous Matters; and
 - V. Emergency Preparedness.
- C. 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 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.
- D. Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency Preparedness.

1/ The term "vendor" means a supplier of products or services to be used by a licensee or registrant in a licensed or registered facility or activity.

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- E. While examples are provided in Appendix 1 for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Radiation Control Program places on a particular type of violation of state requirements. Each of the examples is predicated on a violation of regulatory requirement.
- F. In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.
- G. The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication 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, e.g. inadvertent clerical errors in a document submitted to the Radiation Control Program. 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 or any underlying violation, the intent of the violator (i.e. negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.
- H. The Radiation Control Program expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in Appendix 1, the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event, which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

3. Enforcement Conferences.

- A. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the Agency will normally hold an enforcement conference with the licensee or vendor prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g. Severity Level IV violation, which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:
 - (1) discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor'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.
- B. In addition, during the enforcement conference, the licensee or vendor will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or vendors will be told when a meeting is an enforcement conference.
- C. 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.

4. Enforcement Actions.

- A. This Part describes the enforcement sanctions available to the Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program.
- B. In selecting the enforcement sanctions to be applied, the Agency will consider enforcement actions taken by other State regulatory bodies having concurrent jurisdiction, such as in environmental or transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved.
- C. For the vast majority of violations, action by the Agency is appropriate in the form of a Notice of Violation requiring a formal response from the recipients describing its corrective actions.
- D. In situations involving nonconformance on the part of a vendor, a Notice of Nonconformance will be issued.
- E. Relatively small number of cases involve elevated enforcement actions. These elevated enforcement actions include civil penalties orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

5. Notice of Violation.

- A. Before instituting any proceeding to modify, suspend, or revoke a license or to take other action for alleged violation of any provision of the Radiation Protection Act or these rules or the conditions of the license, the Agency will serve on the licensee or other person subject to the jurisdiction of the Agency a written notice of violation, except as provided in paragraph (3) of this section. The notice of violation will concisely state the alleged violation and will require that the licensee or any other person submit, within twenty (20) working days of the date of the notice or other specified time, a written explanation or statement in reply including:
 - (1) corrective steps which have been taken by the licensee or other person and the results achieved;
 - (2) corrective steps which will be taken; and
 - (3) the date when full compliance will be achieved.
- B. Because the State wants to encourage and support licensee initiative for self-identification and correction of problems, the Radiation Control Program 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.
- C. 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, and must be approved by the Director of the Division of Environmental Health, Department of Health and Human Services.

B.5.D

- D. The notice may require the licensee or other person subject to the jurisdiction of the Agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if any adequate reply is not received within the time specified in the notice, the Agency may issue an order to show cause why the license should not be modified, suspended or revoked or why such other action as may be proper should not be taken.
- E. When the Agency finds that the public health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

6. Civil Penalties

- A. A civil penalty is a monetary penalty that may be imposed for violation of
 - (1) certain specified licensing provisions of the Radiation Protection Act or these rules, or orders, or
 - (2) any requirement for which a license may be revoked. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.
- B. Before instituting any proceeding to impose a civil penalty authorized under 22 MRSA Section 690 of the Radiation Protection Act, the Agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to Part B.5. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and shall state the amount of each penalty which the Agency proposes to impose. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation, or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Agency, if any, the penalty may, unless compromised, remitted or mitigated, be collected by civil action pursuant to the Act.
- C. Generally, civil penalties are imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action.
- D. In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.
- E. Civil penalties will normally be assessed for known and conscious violations of the reporting requirements of these rules and for any willful violation of any Agency requirement including those at any severity level.
- F. Within twenty (20) working days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.
- G. If the person charged with the violation fails to answer within the time specified in paragraph (F) of this Part, the Agency will issue an order imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (B) of this Part.
- H. If the person charged with violation files an answer to the notice of violations, the Agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within twenty (20) working days of the date of the order or other time specified in the order, request a hearing.
- I. If the person charged with violation requests a hearing, the Agency will issue an order designating the time and place of hearing.

- J. If a hearing is held, an order will be issued after the hearing by the Agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.
- K. If the civil penalty is not compromised, or is not remitted and if payment is not made within ten (10) working days following either the service of the order described in paragraph (G) or (J) of this section, or the expiration of the time for requesting a hearing described in paragraph (H) of this section, no such request having been made, the Agency may refer the matter to the Attorney General for collection.
- L. The Agency may impose 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 areas. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees will receive higher civil penalties.
- M. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the State's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the State will consider as necessary an increase or decrease on a case-by-case basis.
- N. The Agency attaches great importance to the 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.
- O. On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to statutory limit. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.
- P. Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.
- Q. The State 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.
- R. Payment of civil penalties imposed under 22 MRSA Section 690 of the Act shall be made by check, draft, or money order payable to the "Treasurer of State of Maine", and mailed to: Radiation Control Program, #11 State House Station, Augusta, Maine 04333-0011.

7. Adjustment Factors.

- A. After considering all relevant circumstances, adjustments to the civil penalty values may be made for the factors described below:

B.7.A(1)

- (1) Prompt Identification and Reporting. Reduction of up to 50 percent of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.
 - (2) Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive correction action may result in reducing the proposed civil penalty as much as 50 percent of the base value shown in Table 1A. On the other hand, the civil penalty may be increased as much as 50 percent of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.
 - (3) Past Performance. Reduction by as much as 100 percent of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100 percent for prior poor performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.
 - (4) Prior Notice of Similar Events. The base civil penalty may be increased as much as 50 percent for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry notification, and had failed to take effective preventive steps.
 - (5) Multiple Occurrences. The base civil penalty may be increased as much as 50 percent where multiple examples of a particular violation are identified during the inspection period.
- B. The above factors are additive. However, in no instance will a civil penalty for any one violation exceed \$10,000 per day.
- C. The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:
- (1) 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.
 - (2) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.
 - (3) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

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

8. Orders.

- A. An order is a written Agency 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. 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.
 - (a) The Agency may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) working days from the date of the notice or such longer period as the notice may provide.
 - (b) The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. If the licensee requests a hearing during this 20-day period, the amendment will become effective on the date specified in an order made following the hearing.
- (2) Suspension Orders may be used:
 - (a) To remove a threat to the public health and safety or the environment;
 - (b) To stop facility construction when: (a) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, to include shielding, or (b) 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;
 - (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 Maine 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 as stated in Appendix 1 to Part C.
 - (e) For any other reason for which revocation is authorized under Section 677 of the Radiation Protection 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 the Agency that such Activity is unauthorized.
- (5) Show Cause Orders.

B. 8.A(5)(a)

- (a) The Agency may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause which will:
 - (i) allege the violations with which the licensee is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action;
 - (ii) provide that the licensee may file a written answer to the order under oath or affirmation within twenty (20) working days of its date, or such other time as may be specified in the order;
 - (iii) inform the licensee of his right, within twenty (20) working days of that date of the order, or such other time as may be specified in the order, to demand a hearing;
 - (iv) specify the issues; and
 - (v) state the effective date of the order.
- (b) A licensee may respond to an order to show cause; by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order to show cause, and may set forth the matters of fact and law on which the licensee relies. The answer may demand a hearing.
- (c) If the answer demands a hearing, the Agency will issue an order designating the time and place of hearing.
- (d) An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order to show cause;.
- (e) The consent of the licensee to the entry of an order shall constitute a waiver by the licensee of a hearing, findings of fact and conclusions of law, and of all right to seek Agency and judicial review or to contest the validity of the order in any forum. The order shall have the same force and effect as an order made after hearing by the Agency.

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

9. Escalation of Enforcement Sanctions

- A. The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in sections 5, 6, 7, and 8 of this Part.
- B. 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.
- C. 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 operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at division 1 of a dual unit hospital that repeats an earlier violation of division 2 might be considered similar.

TABLE 1A - BASE CIVIL PENALTIES

	Health Physics, Operations, EP, and Miscellaneous	Transportation	
		Greater Than Type A Quantity ¹	Type A Quantity or less ²
a. Industrial users of material ³	10,000	5,000	2,000
b. Waste disposal licensees	10,000	5,000	2,000
c. Academic or medical institutions ⁴	5,000	2,500	1,000
d. Other material licenses	2,000	2,500	1,000
e. X-ray facilities	1,000		

- 1 Includes quantities requiring Type B packaging.
- 2 Includes low specific activity waste, low level waste, Type A packages and excepted quantities and articles.
- 3 Includes industrial radiographers, nuclear pharmacies, and other industrial users.
- 4 This applies to nonprofit institutions not otherwise categorized under section "a" through "e" in this table.

TABLE 1B - BASE CIVIL PENALTIES

Severity Level	Base Civil Penalty Amount ¹
I	100
II	80
III	50
IV	15
V	5

¹ Percent of amount listed in table 1A.

TABLE 2 - EXAMPLES OF PROGRESSIONS 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	2nd	3rd
I	a+b	a+b+c	d
II	a	a+b	a+b+c
III	----	a	a+b

- a. Civil penalty.
- b. Suspension of affected operations until the Radiation Control Program Manager 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.

B.10

- 10. Related Administrative Actions.** In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, circulars, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees to make sure that such commitments are met.
- A. Bulletins, Circulars, Information Notices and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.
 - B. Notices of Deviation are written notices describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee to provide a written explanation or statement describing corrective steps taken (or planned), the result achieved, and the date when corrective action will be completed.
 - C. Confirmatory Action Letters are letters confirming a licensee's or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.
 - D. Notices of Nonconformance are written notices describing non-licensees' failure to meet commitments which have not been made legally binding requirements by the Agency. Notices of Non-conformances request non-licensees to provide written explanation or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.
- 11. Referrals to Department of the Attorney General.** Alleged or suspected criminal violations of the Radiation Protection Act (and of other relevant state laws) are referred to the Department of the Attorney General for investigation. Referral to the Attorney General does not preclude the Agency from taking other enforcement action. However, such actions will be coordinated with the Department of the Attorney General to the extent practicable.
- 12. Public Disclosure of Enforcement Actions.** In accordance with the Administrative Procedures Act, all enforcement actions 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 Level 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.

APPENDIX 1

SEVERITY CATEGORIES

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

1. Severity Level I - Most Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 0.25 Sv (25 rems) of radiation to the whole body, 1.5 Sv (150 rems) to the skin of the whole body, or 3.75 Sv (375 rems) to the feet, ankles, hands, or forearms;
2. Annual whole body exposure of a member of the public in excess of 0.025 Sv (2.5 rems) of radiation;
3. Release of radioactive material to an unrestricted area in excess of ten times the limits of section D.1302.;
4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of section D.2001.;
5. Exposure of a worker in restricted areas of ten times the limits of section D.1201.;

B. Transportation.

1. Annual whole body radiation exposure of a member of the public in excess of 0.005 Sv (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 Agency limits.

C. Materials Operations.

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.

D. Miscellaneous Matters.

1. A Material False Statement (MFS)^{2/} in which the statement made was deliberately false;
2. Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or
3. A knowing and intentional failure to provide the notice required by these rules.
4. Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.
5. Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

2./ In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific level of a violation involving material false statements or falsification of records, 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 the information involved, and the intent of the violator (i.e., negligence not amounting to careless disregard, carelessness, or deliberateness). 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.

Appendix 1

- E. Emergency Preparedness. In an emergency, licensee failure to promptly (1) correctly identify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g. assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

2. Severity Level II - Very Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 0.05 Sv (5 rems) of radiation to the whole body, 0.3 Sv (30 rems) to the skin of the whole body or 0.75 Sv (75 rems) to the feet, ankles, hands or forearms;
2. Annual whole body exposure of a member of the public in excess of 0.005 Sv (0.5 rems) of radiation;
3. Release of radioactive material to an unrestricted area in excess of five times the limits of Part D.1302.;
4. Failure to make an immediate notification as required by Part D.2201 and 2202;
5. Disposal of license material in quantities or concentrations in excess of five times the limits of Part D.2001.;
6. Exposure of a worker in restricted areas in excess of five times the limits of Part D.1201.;
7. An x-ray system having a malfunction such that inadvertent exposures could occur e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.
8. A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 0.25 Gy/min (25 R/min) at the point where the center of the useful beam enters the patient, except:
 - (a) During recording of fluoroscopic images, or
 - (b) When an optional high level control is activated.
9. A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier, or
10. Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, etc.
11. Therapy system, with improper operator/patient communication/observation.

B. Transportation.

1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;
2. Surface contamination or external radiation levels in excess of five times Agency 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. Material Operations.

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.

D. Miscellaneous Matters.

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

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

3. Deliberate falsification of records which the Agency requires be kept involving significant information; or
4. A failure to provide the notice required.
5. Failure to register sources of radiation or services as required by these rules.
6. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

E. Emergency Preparedness.

1. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. Severity Level III - Significant Violations.

A. Health Physics.

1. Single exposure of a worker in excess of 3 rems (0.3 Sv) of radiation to the whole body, 0.075 Sv (7.5 rems) to the skin of the whole body, or 0.1875 Sv (18.75 rems) to the feet, ankles, hands or forearms;
2. A radiation level in an unrestricted area such that an individual could received greater than 1 mSv (100 mrem) in a one hour period or 5 mSv (500 mrem) in any seven consecutive days;
3. Failure to make a 24-hour notification or an immediate notification as required by Part D.2202.;
4. Substantial potential for an exposure or release in excess of Part D of these rules, 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 Part D.1302;
6. Improper disposal of licensed material not covered in Severity Level I or II;
7. Exposure of worker in restricted areas in excess of the limits of Part D.1201.;
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;
11. Significant failure to control licensed material;
12. Failure to use exposure reduction devices properly (e.g., collimators, filtration);
13. For a fluoroscopic system where the maximum allowable tabletop exposure rate is 0.05 Gy/min (5 R/min), test values of greater than or equal to 0.07 Gy/min (7 R/min) (uncorrected), but less than 0.25 Gy/min (25 R/min). Correspondingly, for a maximum allowable rate of 0.10 Gy/min (10 R/min), test values of greater than or equal to 0.14 Gy/min (14 R/min) (uncorrected) but less than 0.25 Gy/min (25 R/min) are included;
14. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
15. Intraoral dental systems capable of operations in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters or which exhibit a minimum SSD less than 16 centimeters.

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16. Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.
17. Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.
18. Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.

B. Transportation.

1. Breach of package integrity
2. Surface contamination or external radiation levels in excess of, but less than a factor of five above Agency requirements that did not result from a breach of package integrity;
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;
 - (b) Failure of the carrier or recipient to exercise adequate controls; or
 - (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.

C. Materials Operations.

1. Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;
2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;
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. Therapeutic medical event.
7. Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.

D. Miscellaneous Matters.

1. An MFS not amounting to a Severity Level I or II violation; or
2. Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involved signification information.

E. Emergency Preparedness.

1. Violations of lesser severity than Severity Level II violations.

4. Severity Level IV - Violations.

A. Health Physics

1. Exposures in excess of the limits of Part D. 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 20 μ Sv (2 millirem) in a one-hour period or 1 mSv (100 millirem) in any seven consecutive days;
3. Failure to make a 30-day notification required by Part D.2202.;

4. Failure to make a follow-up written report as required by Parts D.2201., D.2203, and J.4.; or
5. Any other matter that has more than minor safety or environmental significance.

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6. A capacitor storage radiographic system such that the standby radiation is greater than 30 $\mu\text{Gy/hr}$ (3.0 mR/hr), but less than 250 $\mu\text{Gy/hr}$ (25 mR/hr).
7. Systems equipped with positive beam limitation devices which do not allow the field size to be reduced to a size less than that of the image receptor.
8. Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.
9. Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.
10. Mammographic systems manufactured after October 1977 for which the edges of the x-ray field on the right or left sides extend beyond the edges of the image receptor. If manufactured prior to November 1977 and the edges of the x-ray field on either side extend beyond the edge of the image receptor by more than 5 percent of the SID.

B. Transportation.

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 Agency requirements; or
2. Other violations that have more than minor safety or environmental significance.

C. Material Operations.

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. Failure to report diagnostic medical event.

D. Miscellaneous Matters.

1. A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or the Agency seeking additional information.
2. Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (e.g., change of address, expiration of certificate of registration); or

E. Emergency Preparedness.

1. Violations of lesser severity than Severity Level III violations.

5. Severity Level V - Minor Violations.

A. Health Physics.

1. For a fluoroscopic x-ray system where the maximum allowable tabletop exposure rate is 0.05 Gy/min (5 R/min), test values of greater than 0.05 Gy/min (5.0 R/min) (uncorrected), but less than 0.07 Gy/min (7.0 R/min). Correspondingly, if the maximum allowable tabletop exposure rate is 0.10 Gy/min (10 R/min), test values of greater than 0.10 Gy/min (10.0 R/min) (uncorrected) but less than 0.14 Gy/min (14.0 R/min) are included.
2. Other violations that have minor safety or environmental significance.

B. Transportation.

1. Other violations that have minor safety or environmental significance.

C. Materials Operations.

1. Other violations that have minor safety or environmental significance.

D. Miscellaneous Matters.

1. Other violations that have minor safety or environmental significance.

G. Emergency Preparedness.

1. Other violations that have minor safety or environmental significance.