

# CHAPTER 8

## MISCELLANEOUS MATERIALS ENFORCEMENT ACTIVITIES

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Chapter 8 provides specific guidance regarding various enforcement activities, including:


- ▶ dispositioning of violations involving sealed sources and devices containing NRC-licensed material
- ▶ transportation
- ▶ fuel cycle and materials operations
- ▶ use of material in areas under exclusive federal jurisdiction within an Agreement State
- ▶ actions involving written directive requirements
- ▶ reporting requirements for the Healthcare Integrity and Protection Data Bank

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## 8.1 Loss, Abandonment, or Improper Transfer or Disposal of Licensed Material

- a. The guidance in this section applies to violations that involve loss, abandonment, or improper transfer or disposal of sealed source and devices (SSDs). It does not apply to violations that involve security and control of licensed material unless the failure to secure or control results in loss, abandonment, improper transfer or disposal, or other unauthorized release of SSDs containing NRC-licensed material.
- b. Violations of NRC requirements involving loss, abandonment, or improper transfer or disposal of SSDs containing NRC-licensed material will be considered for escalated enforcement action as follows:
  1. Such violations, in accordance with the [Enforcement Policy](#), “are treated separately, regardless of the use or the type of licensee.”
  2. The staff should assign a severity level to the violation that appropriately reflects the normal factors for considering significance, including:
    - (a) A consideration of the chemical and physical characteristics of the radioactive material;
    - (b) Safety and environmental significance;
    - (c) Whether the circumstances surrounding the violation, represents an isolated, rather than programmatic, weakness; and
    - (d) Whether the staff should increase the significance when a violation is willful.
- c. Consultation with OE is required for all cases involving loss, abandonment, or improper transfer or disposal of licensed material.
- d. The following are examples of Severity Level III violations involving the loss, abandonment, or improper transfer or disposal of SSDs:

 If the licensee exercises adequate security and control but the source/device is still lost (e.g., stolen), there is no violation and, therefore, no enforcement issues.

### Example 1:

A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 and 40 mCi of Am-241 resulting in the loss of the gauge. The gauge was recovered eight hours later at the same time that the licensee was reporting the loss to the NRC. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

Example 2:

A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 resulting in the gauge being stolen. The amount of the radioactive material was less than 1000 times the 10 CFR Part 20, Appendix C value and the licensee had a functional program to detect and deter security violations that included training, staff awareness, detection, and corrective action; however, the violation was significant since the gauge contained more than a nominal amount of material. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.


Example 3:

A licensee failed to maintain control of brachytherapy sources containing 7.7 mCi of Ir-192 resulting in the loss of the material. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

- e. The following are examples of Severity Level IV Violations:

Example 1:

A licensee lost a static eliminator containing 10 mCi of Po-210. Due to the low actual safety significance associated with the isotope and small amount of material and the difficulty in gaining access to material, the NRC issued a Severity Level IV violation.

 All cases being considered for disposition at Severity Level IV should be coordinated with OE (normally by phone or e-mail) and should receive an EA number.

Example 2:

A licensee lost a sealed source containing 0.7 mCi of I-125. Due to the low actual safety significance associated with the small amount of material, the fact that the quantity was less than 1000 times the 10 CFR Part 20, Appendix C value, and the licensee had a functional program, the NRC issued a Severity Level IV violation.


### **8.1.1 Base Civil Penalties for Violations Involving Loss, Abandonment of Improper Transfer or Disposal of a SSD**

- a. Civil penalties for violations that involve loss, abandonment, or improper transfer or disposal of a SSD are assessed:
1. Under Table 1A.f, of the Enforcement Policy; or
  2. By considering the actual cost of proper disposal, regardless of the type of licensee or the use of the SSD.


- b. The three levels of civil penalties listed in Table 1A.f are intended to correlate the civil penalty amount to the costs of properly disposing of the SSD.
1. SSDs containing small amounts of radioactive material, such as gas chromatographs, and devices containing hydrogen-3 (tritium) have a base civil penalty in the amount of \$6,500 for a severity level I violation, \$5,200 for a severity level II violation, and \$3,250 for a severity level III violation.
  2. SSDs containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, and 37 MBq (1mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)) are considered to present a higher risk for potential exposure to the public and for loss of property (due to contamination) if the device is lost, abandoned, or improperly transferred or disposed of. Based on the higher risk, violations involving loss, abandonment, or improper transfer or disposal of SSDs in this category have been assigned a base civil penalty amount of \$16,500 for a Severity Level I violation, \$13,200 for a Severity Level II violation, and \$8,250 for a Severity Level III violation.
  3. With the exception of SSDs containing hydrogen-3 (tritium), the highest activity SSDs (i.e., those with activities greater than  $3.7 \times 10^4$  MBq (1 Curie)) have been assigned a base civil penalty amount of \$50,000 for a Severity Level I violation, \$40,000 for a Severity Level II violation, and \$25,000 for a Severity Level III violation.
- c. Adjustment of Civil Penalty Amounts Based on Disposal Costs:
1. In assessing the amount of a civil penalty, the NRC may consider information concerning the actual expected cost of authorized disposal instead of using the civil penalty amounts in Tables 1.A.f and 1B of the Enforcement Policy.
    - (a) The actual expected cost of authorized disposal would be the expected cost for an individual or organization that found and took possession of the SSD.
    - (b) Normally, the burden of determining the actual expected cost of authorized disposal rests with the licensee.

§ The December 18, 2000, (65 FR 79139) change to the base civil penalty structure considers both the cost of proper disposal and the relative risk to the public from sources that are lost, abandoned, or improperly transferred or disposed of. The Commission believes that a base civil penalty equivalent to three times the cost of proper disposal will provide for sufficient deterrence and an economic incentive for licensees to expend the necessary resources to ensure compliance.

- (1) If a licensee requests that the civil penalty amount be reduced based on the actual expected cost of disposal, the licensee should provide a copy of a written estimate from a waste disposal site, waste broker, or the SSD manufacturer.
  - (2) The licensee may provide the information in (1) above, in its response to a choice letter, a proposed action, or at a pre-decisional enforcement conference (PEC).
  - (3) NRC may increase or decrease the value of the civil penalty if it has reliable specific information on the expected cost of disposal (e.g., assessment of a civil penalty amount for a similar case).
  - (4) Based on current information and recent cases, the NRC has determined that the expected authorized costs of disposal of portable moisture density gauges containing approximately 10 mCi of Cs-137 and 40 mCi of Am-241 is less than \$1000. Therefore, rather than have licensees provide disposal information for such cases, the NRC will typically propose imposition of civil penalties in the amount \$3000 for Severity Level III violations involving the loss, abandonment, or improper transfer or disposal of these types of devices.
2. The NRC will evaluate the merits of each specific case and may reduce or increase the amount of a civil penalty based on other information, such as the actual consequences of the loss, abandonment, or improper transfer or disposal.
- (a) While NRC may adjust the civil penalty based on actual consequences (e.g., cost of recovery, decontamination, etc.). NRC will not normally reduce the amount of the civil penalty because there was a quick recovery or some other fortuitous event.


 NRC will typically adjust the civil penalty amount to correlate to one of the base civil penalty amounts for violations involving loss, abandonment, or improper transfer or disposal. For example, if the base civil penalty amount is \$22,500, based on the violation being at Severity Level III and involving material described in Table 1A.f.1., and a licensee provides adequate information demonstrating that three times the cost of authorized disposal is \$6,000, the NRC would likely assess a \$7,500 civil penalty (the amount a Severity Level III violation for material described in Table 1A.f.2.). In cases that the NRC decides to mitigate a civil penalty, the NRC will only mitigate the civil penalty down to the lowest base civil penalty in Tables 1A.f and 1B, currently \$3000.

- (b) NRC would typically only consider reducing the amount of a civil penalty for identification or corrective action if such actions were extraordinary.
- d. Choice Letters: In some cases, NRC may have sufficient information to make an enforcement decision and does not need to hold a PEC. In such cases, NRC may send a choice letter to the licensee.
1. If the staff is considering a civil penalty, the choice letter should explicitly state that NRC is considering the use of discretion in accordance with the Enforcement Policy to issue a civil penalty.
  2. The standard choice letter may include an optional paragraph that informs the licensee that the licensee may submit information regarding the expected costs of authorized disposal.
- e. Conference Letters: If the staff chooses to invite the licensee for a conference, the licensee should be informed that the NRC:
1. Should normally proposes imposition of a civil penalty of at least the base amount for violations involving the loss, abandonment, or improper transfer or disposal of a SSD; and
  2. May consider adjusting the civil penalty amount to a more appropriate base amount if a licensee can demonstrate that three times the actual cost of disposal would be significantly less than the base amount.
- f. Cover letters for NOV with civil penalties typically discuss the complete civil penalty assessment process, including:
1. How NRC considered credit for identification and corrective action; and
  2. If applicable, the use of discretion in consideration of the actual costs of disposal in determining the civil penalty.

 The license may provide information regarding the actual expected costs of authorized disposal in its response to a choice letter, a proposed action, or as part of a PEC.

## 8.2 Transportation

- a. 10 CFR Part 71 establishes the requirements for:
1. Packaging;
  2. Preparation for shipment;

 Supplement V of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

3. Transportation of licensed material; and
  4. The standards for NRC approval of packaging and shipping procedures for fissile material and for quantities of other licensed material in excess of Type A quantity.
- b. The packaging and transport of licensed material is also subject to:
1. Other parts of Title 10 (e.g., Parts 20, 21, 30, 39, 40, 70, and 73);
  2. The regulations of other agencies (e.g., U.S. Department of Transportation (DOT) and the U.S. Postal Service (USPS)) or Agreement States having jurisdiction over means of transport; and
  3. The jurisdiction of individual states which may take enforcement action for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements.
- c. Reactor transportation cases are normally addressed under the Significance Determination Process (SDP).

### 8.2.1 Memorandum of Understanding (MOU) Between NRC and DOT

- a. The MOU between the NRC and DOT, is included on the **Enforcement** Web site, at <http://www.nrc.gov/what-we-do/regulatory/enforcement/moudot.pdf>.
- b. In accordance with the MOU:
1. DOT is required to regulate safety in the transportation of hazardous materials, including radioactive materials;
  2. NRC is authorized to license and regulate the receipt, possession, use, and transfer of "byproduct material," "source material," and "special nuclear material."
  3. Each agency has its own inspection and enforcement programs within its jurisdiction to assure compliance with its requirements.
    - (a) The NRC will assist DOT, as appropriate, in inspecting shippers of fissile materials and other radioactive materials exceeding Type A limits.
    - (b) The DOT and the NRC will consult with each other on the results of their respective inspections in the areas where the results are related to the other agency's requirements.
    - (c) Each agency will take enforcement action, within the limits of its authority, as it believes appropriate.



4. In accordance with Section IV of the MOU regarding formalized working arrangements:
  - (a) The NRC normally carries out enforcement actions for violations of the requirements of 10 CFR 71 and 49 CFR (except 49 CFR Parts 390 through 397) by NRC licensees.
  - (b) DOT normally carries out enforcement actions for violations of 49 CFR (including Parts 390 through 397) by carriers of radioactive materials and shippers of radioactive materials from Agreement States, or any other shippers otherwise not subject to NRC requirements (shippers of radium, for example).

### 8.2.2 NRC Action in Conjunction With State Action

- a. When a State takes an enforcement action (e.g., the imposition of a civil penalty or suspension or revocation of the licensee's burial permit or both) against a licensee for activities that also represent violations of NRC requirements, the following guidance should be used:
  1. Individual States may take enforcement action against shippers for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements.
  2. Notwithstanding the severity level of a violation, the NRC will not normally propose a civil penalty in cases where a State issues a civil penalty.
    - (a) Even if a State has taken enforcement action for the violation, the NRC may consider enforcement action beyond an NOV, such as the issuance of a civil penalty or order, if the violation is repetitive.
    - (b) If the region believes that a civil penalty should be assessed in a particular case, the region should submit a recommendation to the Director, OE.
  3. The region should submit NOV with Severity Level I, II, or III violations to OE for review and approval prior to issuance.
  4. The region may issue NOV with Severity Level IV violations without prior review and approval by the Director, OE, or the DEDOs.
  5. Regardless of the severity level, all NOVs and accompanying documents should require the licensee to submit to the office issuing the NOV a description of the corrective action taken or planned to prevent similar future violations.
    - (a) This corrective action will be reviewed by the region.



- (b) If the region determines that the corrective action is unsatisfactory, the region should consider further enforcement action to ensure compliance with NRC regulations.
  - (c) A PEC does not need to be held if:
    - (1) The licensee understands the significance of the violation; and
    - (2) The region is satisfied with the corrective action.
  - (d) NOVs including Severity Level III violations should:
    - (1) Be coordinated with OE;
    - (2) Have an EA number;
    - (3) Be signed by the Regional Administrator; and
    - (4) Be sent subsequently to OE for information.
- b. Violations that are discovered by the NRC at the licensee's facility, or in other cases where the State has not taken action, will continue to be processed in accordance with normal NRC policy and practice.

### 8.2.3 Inaccessible Areas With Excessive Radiation Levels

When the area of a transport vehicle with excessive radiation levels is not easily accessible, consideration may be given to categorizing the violation at a lower severity level.

### 8.2.4 Exercise of Enforcement Discretion Involving Transportation Casks

- a. Enforcement may not be warranted for certain cask contamination issues.
- b. Enforcement of the removable contamination limits in 10 CFR 71.87(i)(2) may not be appropriate where the licensee had taken comprehensive steps to ensure compliance, i.e., the licensee had decontaminated the cask several times before providing it for transportation and the staff is not aware of any further reasonable actions that the licensee could have taken to prevent the violation (see EA-93-306).

✓ The Enforcement Policy provides that "...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."

- c. Exercise of this discretion:
  - 1. Requires an EA number; and
  - 2. Should be coordinated with OE.

### 8.3 Fuel Cycle and Materials Operations

This section provides specific guidance concerning enforcement practices for fuel cycle and materials operations.

#### 8.3.1 Activities of Unqualified Persons

- a. When taking escalated enforcement action for violations involving unauthorized and potentially unqualified persons using material or performing licensed activities, consideration should be given as to whether the individual in question is, in fact, unqualified to use the materials or perform the activities.

☞ Supplement VI of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in the area of fuel cycle and materials operations.

- b. An inspector may ask the materials licensee to explain whether or not the current unauthorized user is technically qualified.
  - 1. If the **user is not qualified**, a Severity Level III violation should be cited and the user should be precluded from further licensed activity without appropriate supervision.
  - 2. If the **user is qualified**, the violation may be categorized at a Severity Level IV.
    - (a) OE concurrence is not required.
    - (b) The licensee should take corrective action to preclude further unsupervised activity by the unauthorized user of licensed material until the license has been amended.

☞ An individual may be technically qualified to perform the activities in question but does not have, e.g., the appropriate certification to perform these activities. In that case, the violation may be categorized as a Severity Level IV. This stands in marked contrast to the individual who has neither the appropriate training or certification to perform the activities in question. In that case, the violation may be categorized as a Severity Level III.

3. If the **only user of licensed material is not qualified**:
  - (a) In cases involving more hazardous materials, e.g., materials used in medical programs, an order suspending the license until an authorized, qualified user is obtained may be appropriate.
  - (b) If radiation hazards are minimal, e.g., materials used in stationary liquid-level-measuring gauges or stationary thickness-measuring gauges, a Confirmatory Action Letter (CAL) suspending the user or preventing the user from using licensed material until becoming qualified may be appropriate.
    - (1) The CAL could also state, at the licensee's option, that the licensee will suspend further activities until it finds another qualified user and amends its license to reflect this change.
    - (2) If the CAL is ineffective, an order suspending the license should be considered.

### 8.3.2 NRC Action Against Agreement State Licensee

- a. An **Agreement State** is defined as any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (AEA), by which those States have assumed regulatory responsibility over byproduct and source materials and small quantities of special nuclear material.
- b. A **non-Agreement State** is defined as any other State. The materials programs in such states are subject to NRC jurisdiction.
- c. Under **reciprocity**, the provisions of 10 CFR 150.20 establish a general license authorizing any person who holds a specific license from an Agreement State to conduct the same activity in areas under NRC jurisdiction provided that the specific license does not limit the activity authorized by the general license to specified installations or locations.

☞ Regulations addressing the activities of Agreement State licensees in areas of NRC jurisdiction are located in 10 CFR Part 150.

☞ In accordance with 10 CFR 150.20, a licensee must submit an NRC Form-241 at least 3 days before engaging in the activities permitted under the general license. The NRC considers failure to submit this form to be significant because without this information, the NRC is not aware of the licensed activities being conducted in NRC jurisdiction and, therefore, cannot inspect these activities. This impedes the agency's ability carry out its mission to protect the public health and safety and ensure the common defense and

- d. Areas under NRC jurisdiction are:
- Areas within non-Agreement States
  - Areas under exclusive Federal jurisdiction within Agreement States
  - Offshore waters
- e. The NRC can take enforcement action against an Agreement State licensee if:
1. It is improperly conducting activities in areas under NRC jurisdiction in conjunction with the general license in 10 CFR 150.20;
  2. It is improperly conducting activities in areas under NRC jurisdiction in conjunction with an NRC specific license; or
  3. It failed to submit an NRC Form-241 in accordance with 10 CFR 150.20.
- ☞ Currently, approximately 34 Agreement States administer approximately 17,600 radioactive materials licenses (i.e., approximately 80 percent of all radioactive materials licensees issued in the U.S.).
- f. For those cases where the NRC identifies issues involving or concerning the Agreement State licensee that may have an immediate impact on the public health and safety or the common defense and security, the office that identified the issue should provide immediate notification of the concern to the Agreement State that issued the license.
- g. For those cases where the NRC proposes enforcement action against an Agreement State licensee:
1. For proposed escalated enforcement actions, the office issuing the enforcement action should discuss the enforcement action with the Agreement State before the enforcement action is issued to ensure that the Agreement State understands the NRC's rationale for issuing the action.
  2. The office proposing enforcement action should ensure that the Agreement State that issued the specific license receives copies of any enforcement correspondence.
  3. If the staff proposes to conduct a PEC, the office proposing the conference should notify the Agreement State and forward a copy of the meeting notice for the conference.
- ✓ For proposed escalated enforcement actions, the office issuing the enforcement action should discuss the enforcement action with the Agreement State before the enforcement action is issued.

### 8.3.2.1 Use of Byproduct Material in Areas Under Exclusive Federal Jurisdiction Within Agreement State

- a. The AEA and NRC regulations require that, in order to use byproduct material, a person must obtain a license either from:
1. The NRC, for those areas under NRC jurisdiction; or
  2. An Agreement State, for those areas under Agreement State jurisdiction.
- b. In order for an Agreement State licensee to use material in areas of exclusive Federal jurisdiction within the Agreement State, the Agreement State licensee must either:
1. Obtain a license from the NRC as required by 10 CFR 30.3; or
  2. File an NRC Form-241 pursuant to 10 CFR 150.20 at least 3 days before engaging in the activities permitted under the general license, as long as the Agreement State license does not limit the activity it authorizes to specified installations or locations.
- c. Notwithstanding its location within an Agreement State, there are areas that are under exclusive federal jurisdiction, including:
1. Areas under NRC jurisdiction, e.g., Federal facilities; and
  2. Areas not under the jurisdiction of the Agreement State, e.g., Tribal lands.
- d. Each case involving the failure to file an NRC Form-241 or obtain an NRC license prior to using materials in areas of exclusive Federal jurisdiction, will need to be reviewed on a case-by-case basis to determine the appropriate enforcement action.
- e. Enforcement discretion in accordance with the Enforcement Policy may be appropriate:

Information indicating that the Agreement State licensee was given erroneous information concerning the status of the Federal property may be contained in a written statement from the Federal agency or a written statement signed and dated by the licensee documenting the name and title of the person at the Federal agency who provided the determination that the work site was not in an area of "Exclusive Federal Jurisdiction" and the date the determination was provided.

In February 27, 1997, an amendment to 10 CFR 150.20 (62 FR 1662) was implemented which requires licensees to file NRC Form-241 prior to using byproduct material in areas under exclusive Federal jurisdiction within Agreement States. Special consideration should be given for violations that occurred prior to this date.

1. If the Agreement State licensee was not aware that it was operating within NRC jurisdiction; or
  2. If the Agreement State licensee was given erroneous information concerning the status of the Federal property.
    - (a) When enforcement discretion is exercised in this case, an enforcement panel with OE is not required, however:
      - (1) The region needs to obtain an EA number for tracking purposes; and
      - (2) Coordination with OE staff is warranted given the exercise of discretion.
  3. If other violations of NRC requirements exist, the region should issue an NOV for these failures and the "contrary to" paragraph and cover letter should indicate that the location was an area under exclusive Federal jurisdiction.
    - (a) Enforcement action for other violations should only be taken in accordance with the provisions in 10 CFR 150.20.
    - (b) The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION." The cover letter to the licensee should include the following:

"If, in the future, you operate at a temporary job site that is a Federally controlled site in an Agreement State and which may be subject to exclusive Federal jurisdiction (e.g., a military facility, or VA hospital) you should obtain a written jurisdictional determination from the Federal agency which controls the facility or land in question. If possible, obtain this determination in writing. If that is not available, you should keep a written record, signed and dated, that reflects the name and title of the person at the Federal agency who provided the information that the work site was not in an area of exclusive Federal jurisdiction and the date that the determination was provided. Absent this documentation, the NRC would expect to take enforcement action for future violations of this nature."
- f. Any proposed enforcement action should be prepared using the standard citation in Appendix C for failure to comply with 10 CFR 30.3, "Activities requiring license." The violation should normally be categorized at Severity Level III.
1. The cover letter transmitting the enforcement action should specifically state that the licensee conducted NRC-licensed activities in an area under exclusive Federal jurisdiction.

2. If additional violations of NRC requirements exist, the "contrary to" paragraph should also indicate that the location was an area under exclusive Federal jurisdiction.
3. In addition to the action against the Agreement State licensee, the head of the Federal facility should be informed in writing (see forms in Appendix B).


### 8.3.3 Information Copies to Outside Organizations

The following office is to be sent a copy of every inspection report, CAL, NOV, or order that is issued concerning an individual radiographer:

American Society for Nondestructive Testing, Inc.; ATTN: Technical Services Manager  
1711 Arlingate Lane  
P.O. Box 28518  
Columbus, OH 43228-0518

### 8.3.4 Actions Involving Written Directive Requirements

- a. On April 24, 2002, Supplement VI of the Enforcement Policy was modified ([67 FR 20187](#)) to revise the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material.
  1. For any administration that requires a written directive to be prepared in accordance with 10 CFR 35.40, licensees must develop, implement, and maintain written procedures in accordance with 10 CFR 35.41.
  2. The written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.
- b. The Enforcement Policy places greater emphasis, and attaches greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature.
  1. Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events that is more widespread than simple occasional human error.

 **Substantial programmatic weaknesses** applies in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. **Programmatic weakness** indicates that the failure is more widespread than simple occasional human error, e.g., a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions resulted in a medical event.



Examples include, but are not limited to:

- Failure to develop and implement adequate written procedures for administrations that require a written directive
  - Failure to train personnel on the procedures
  - Failure to follow procedures
2. Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.
  3. A decision on whether to categorize a violation resulting in a medical event at Severity Level I, II, III or IV must consider both the consequences and the isolated or programmatic nature of the violation.
    - (a) If the medical event was caused by an isolated failure and there were only limited medical consequences based on a medical consultant's report, then the violation would be categorized at Severity Level IV, e.g., the administration of a dosage of greater than 30 microcuries of sodium iodine I-131, that was not within 20% of the dosage prescribed by the authorized user, would meet the criteria for a medical event.
    - (b) If the medical event was caused by a one-time failure to determine the activity of the dosage prior to the administration, and the medical consultant expected limited consequences, the violation would be categorized at severity level IV.
    - (c) If the medical consultant found that the consequences were not limited, or if the violation appeared to result from a substantial programmatic failure or a programmatic weakness, then the violation would be categorized at Severity Level III or greater.

### 8.3.5 Actions Involving Radiation Safety Officers (RSOs)

- a. The following examples provide additional clarification on when it may be appropriate to consider the lack of an RSO or replacement of an RSO with an unqualified individual as a Severity Level III violation.
  1. If the RSO leaves the facility and no RSO is appointed, a Severity Level III violation is appropriate.
  2. If the RSO leaves the facility and the individual assigned as a replacement RSO is not qualified under applicable NRC criteria, a Severity Level III violation is appropriate.
- b. If, on the other hand, the RSO leaves the facility and the individual assigned as a replacement RSO is qualified under the applicable NRC criteria, but the license has not been amended to name the new RSO, a Severity Level IV violation is appropriate.

- c. For some small materials licensees, there are no special qualification requirements or duties for the RSO position because of the limited types and quantities of material authorized on the license. For this type of licensee, a violation involving a change of RSO without receiving required NRC approval, or an absent RSO, is more appropriately categorized at Severity Level IV, unless other concurrent violations indicate the existence of a programmatic breakdown.

### 8.3.6 Severity Level For Failure To Report A Medical Event

- a. 10 CFR 35.3045 requires that medical events be reported to the NRC. When there is a failure to report a medical event to the NRC, the following considerations apply:
  - 1. Failure to report a medical event is normally categorized at Severity Level III.
  - 2. If no report has been made to NRC at the time that NRC becomes aware of the medical event, the violation normally should be categorized at Severity Level III.
  - 3. If the report to NRC is late or incomplete, but is nonetheless the vehicle by which NRC becomes aware of the medical event, the violation may be categorized at Severity Level IV provided that the late or incomplete nature of the report did not substantially diminish the NRC's ability to determine the significant facts of the medical event once the NRC became aware of it.
- b. 10 CFR 35.3045 requires that medical events be reported to:
  - (a) The referring physician; and
  - (b) Either the patient, or the patient's responsible relative or guardian.
- c. An exception in 10 CFR 35.3045(e) provides that the patient need not be notified if the referring physician informs the licensee that, based on medical judgement, telling the patient would be harmful.
- d. When there is a failure to report a medical event to the referring physician or the patient or the patient's responsible relative or guardian, the following considerations apply:
  - 1. If no report has been made to the referring physician, the violation normally should be categorized at Severity Level III. (The regulation does not specify that the report to the referring physician needs to be in writing; therefore, an oral report to the referring physician is sufficient.)
  - 2. If neither an oral nor a written report has been made to the patient or the patient's responsible relative or guardian, and the referring physician did not invoke the exception in 10 CFR 35.3045(e) as it applies to the patient, the violation normally should be categorized at Severity Level III.

3. If the licensee made an oral report to the patient or the patient's responsible relative or guardian, but failed to make a written report as required by 10 CFR 35.3045(d), the violation may be categorized at Severity Level IV provided that the licensee promptly provides the written report once the matter is brought to the licensee's attention.


#### 8.4 Guidance for Dispositioning Violations of the Clarification of Decommissioning Funding Assurance Rule

- a. On July 26, 1995, the NRC issued a rulemaking on "Clarification of Decommissioning Funding Requirements" for materials licenses, (Clarification Rule) (60 FR 38235).
    1. The [Clarification Rule](#) requires licensees to have:
      - (a) Adequate financial assurance for decommissioning during licensed operations; and
      - (b) Updated financial assurance for decommissioning when the licensee decides to cease operations and begin decommissioning.

✓ Licensees were required to provide adequate financial assurance for decommissioning by November 24, 1995, the effective date of the Clarification Rule.

  - 2. The Clarification Rule was intended to address those licensees who have been in timely renewal since the promulgation of an earlier Decommissioning Rule, or who have ceased operations without having adequate decommissioning funding arrangements in place.
  - 3. Licensees were required to provide adequate financial assurance for decommissioning by November 24, 1995, when the Clarification Rule became effective.
- b. Violations of the Clarification Rule are normally identified during records reviews conducted to determine compliance with the rule, and enforcement action should be taken if the licensee is currently not in compliance with the requirements of the rule.
  1. The staff will provide the licensee with a letter indicating that an apparent violation has been identified as a result of a records review (see forms in Appendix B).
  2. The licensee can request a PEC within 7 days or can provide a written response within 30 days.
  3. Since an inspection report is not issued for a violation identified during a records review, the letter needs to clearly identify and document the specific apparent violation.

- (a) The language used in the letter to identify and document the apparent violation may be adapted from the standard citations for 10 CFR 30.35 and 30.36.
  - (b) Although the text of these standard citations focuses on violations of 10 CFR Part 30, the text can be adapted for violations of the identical regulation in 10 CFR Parts 40, 70, or 72.
4. In addition to sending the letter, the region should contact the licensee's management by telephone to assure that the licensee has an opportunity to ask questions in order to fully understand the apparent violation.
- c. The Enforcement Policy provides that violations involving significant failure to meet decommissioning requirements should be categorized at Severity Level III.
- d. Violations involving significant failure to meet decommissioning requirements may be treated by issuing a Severity Level IV violation if the licensee:
- 1. Responds to the apparent violation within 30 days;
  - 2. Provides an acceptable plan for meeting the decommissioning financial assurance requirements; and
  - 3. Fully implements the plan according to an agreed-upon schedule.
- e. Where the NOV is not issued until the corrective action is completed, a response to the NOV normally would not be required.
- f. Escalated enforcement action in the form of an NOV, civil penalty and/or Order is appropriate, if the licensee:
- 1. Is not responsive;
  - 2. Does not provide an acceptable plan for meeting the decommissioning financial requirements; or
  - 3. Is not implementing the plan according to an agreed-upon schedule.
- g. Enforcement decisions will be made on a case-by-case basis.
- h. In processing cases involving significant failure to meet decommissioning requirements:

 Corrective action is not considered in determining the severity level of a violation; however, the significance of a violation is increased if the licensee has notice of the violation but is either unwilling or unable to achieve compliance.

1. An enforcement action (EA) number is required to track the action.
  2. Following the licensee's response, the determination of the severity level and sanction, if appropriate, is to be discussed during the weekly OE panel for the respective region.


✓ In addition to the normal Commission notification for Orders and Civil Penalties, the staff in accordance with NMSS policy, should notify the Commission of denials of license renewal applications in the weekly highlights.
  3. Appropriate regional and Division of Waste Management and Environmental Protection staff will participate in weekly OE panels involving escalated enforcement action in response to Clarification Rule violations.
- i. In the event an application for renewal of a license is outstanding under these circumstances, the staff may deny the license renewal application and require the licensee to begin decontamination and decommissioning activities.
  - j. As the staff considers escalated enforcement action, it should also consider matters, on a case-by-case basis, such as:
    - The licensee's financial status
    - The types and levels of contamination at the site
    - The steps needed to ensure protection of the public health and safety if the licensee should declare bankruptcy, abandon the site, or both

## 8.5 Guidance for Dispositioning Violations of the Timeliness in Decommissioning of Material Facilities Rule

- a. On July 15, 1994, the NRC issued a rulemaking entitled "Timeliness in Decommissioning of Material Facilities" for materials licensees (Timeliness Rule, 59 FR 36026-36040).
- b. The [Timeliness Rule](#) amended 10 CFR Parts 30, 40, 70, and 72, and established definitive criteria for timely decommissioning upon termination of operations.
  1. The rule establishes requirements for notifying the NRC of pending decommissioning actions and cessation in licensee operations, establishes requirements for when decommissioning plans need to be submitted, and establishes requirements for completing decommissioning activities.
  2. The rule allows licensees to request relief from the timing of requirements where justified.
- c. Violations of the Timeliness Rule are normally identified during inspections of records or records reviews conducted to determine compliance with the regulation.

### 8.5.1 Failure to Notify NRC pursuant to 10 CFR 30.36(d)

- a. If the failure is not willful and there are no other decommissioning violations for which escalated enforcement action may be taken, the violation should be dispositioned as a Severity Level IV violation.
  - 1. Use standard citation **30.36a**.
  - 2. If the licensee is not responsive to the NOV, the issue should be paneled with OE to determine a further course of action.
- b. If the failure to notify may be willful or if there are additional decommissioning violations for which escalated enforcement action may be taken, refer to the following section.

 Licensees are not required to notify NRC when a decision is made to permanently cease principal activities in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

### 8.5.2 Processing Other Violations

- a. Violations of the Timeliness Rule are dispositioned similarly to the manner in which violations of the Clarification Rule are dispositioned
  - 1. For violations of the Timeliness Rule that may involve escalated enforcement action, the guidance for the Clarification Rule for contacting the licensee, providing notice of the apparent violation(s) in a letter to the licensee, and paneling the enforcement sanction with OE should be followed.
  - 2. Appropriate regional and NMSS Division of Waste Management and Environmental Protection staff should participate during the panel.
- b. If the violation was identified as a result of an inspection, as opposed to a records review, the cover letter should be modified accordingly.
- c. The Timeliness Rule should be consulted to determine compliance requirements for certain specific situations.

### 8.5.3 Storage Only Licenses

- a. There are two types of licenses that authorize “storage only.” The Timeliness Rule applies differently depending on the type of “storage only” license, as follows:

1. For the first type of license, storage historically was not a principal activity authorized by the license; however, the license has been amended to authorize “storage only” because as a result of some difficulty regarding the transfer or disposal of the material, the material remains on the licensee’s site.
  - (a) Storage under these circumstances is not a "principal activity" as defined in 10 CFR 30.4.
  - (b) The requirements to notify NRC and undertake decommissioning in 10 CFR 30.36(d)(2)-(4) are not triggered, because there is no principal activity to cease.
  - (c) For these licensees, decommissioning issues should be addressed when the license comes up for renewal.
  - (d) Concerns about such licensees also may be addressed through Demands for Information, CALs, Orders, etc.
  - (e) Concerns, which may involve insolvency, lack of security and control, etc., should be discussed on the weekly OE panel for the respective region which should be attended by the NMSS Division of Waste Management and Environmental Protection staff.
2. For the second type of license, storage of material historically has been the principal activity conducted by the licensee, who did not engage in an activity that produced or used the material in storage.
  - (a) In such cases, storage should be treated as the principal activity under the license, and the notification and decommissioning requirements in 10 CFR 30.36(d)(2)-(4) are applicable.
  - (b) The requirements to notify NRC and undertake decommissioning in 10 CFR 30.36(d)(2)-(4) are triggered when the licensee ceases to store the material (i.e., the material is transferred).
- b. Questions concerning an NRC position on the Timeliness Rule should be referred to the NMSS Division of Waste Management and Environmental Protection staff.

## 8.6 Severity Levels of Violations at Fuel Facilities

- a. The severity levels in the examples in Supplement VI that are applicable to fuel facilities are based on the relationship of the loss of criticality safety control(s) to the availability (or likely availability) of a sufficient amount of fissile material for a nuclear criticality accident.



The examples in Supplement VI also address events that involve chemical processes integral to licensed activities, whether or not radioactive material is released. The following examples from Supplement VI are illustrative:

1. Example VI.A.6, concerning significant injury or loss of life to site personnel, addresses a very significant regulatory concern because, in addition to the radiation, contamination and releases defined in VI.A.1. of the Supplement, the NRC is concerned about the actual impact of any occurrence from a portion of a licensed fuel cycle activity, including chemical processes, that has been reviewed and approved as part of the NRC licensing process.
  2. Example VI.B.4 indicates that the absence of all the criticality safety controls for a single anticipated or unanticipated nuclear criticality scenario is a very significant safety concern when the availability of fissile material makes a nuclear criticality accident possible.
  3. Example VI.B.5 indicates that events which do not involve actual significant injuries or loss of life, but reasonably could have, had circumstances been different, are considered very significant safety concerns that do not amount to a Severity Level I threshold specified in Example VI.A.5.
  4. Example VI.C.4 reflects the view that more than minor release of toxic material caused by the failure to comply with NRC regulations, including licensee procedures established to comply with license conditions, is a significant regulatory concern because, if not adequately corrected, it could have serious consequences to the public and licensee employees.
  5. Example VI.C.8, addressing changes of significance, also considers the "lack of a nuclear criticality specialist or replacement of a nuclear criticality specialist with an unqualified individual." This highlights the importance that the NRC places on the nuclear criticality specialist's position in a licensee's organization because this key position is responsible for conducting NCS evaluations and final reviews of changes or modifications to licensed processes. The failure to staff this position with an individual meeting the qualifications specified in the license could result in inadequate safety evaluations.
- b. In considering whether a violation should be categorized at Severity Level III, example VI.C.16 provides guidance indicating that a failure to establish, maintain, or implement all but one criticality safety control for a single nuclear criticality scenario when a critical mass of fissile material was present or reasonably available such that a nuclear criticality accident was possible, should be viewed as a significant regulatory concern.

- c. In considering whether a violation should be categorized at Severity Level IV, example VI.D.8 indicates that the absence of one or more criticality safety controls for a single anticipated or unanticipated nuclear criticality scenario is a regulatory concern of lesser significance when a critical mass is not, but could have been, present.

## 8.7 Material False Statements and Completeness and Accuracy of Information

- a. Supplement VII of the Enforcement Policy provides examples of violations involving inaccurate or incomplete information or the failure to provide significant information.
- b. Submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions.

☞ The decision to view a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations.
- c. The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review; however, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as:
  - 1. The degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;
  - 2. The opportunity and time available prior to the communication to ensure the accuracy or completeness of the information;
  - 3. The degree of intent or negligence, if any, involved;
  - 4. The formality of the communication;
  - 5. The reasonableness of NRC reliance on the information;
  - 6. The importance of the information that was wrong or not provided; and
  - 7. The reasonableness of the explanation for not providing complete and accurate information.
- d. Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official.

1. Enforcement action may be taken, e.g., for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, or if a record of the oral information such as a transcript of the communication or meeting summary containing the error was provided to the licensee, thereby giving an opportunity to correct the oral information, and was not subsequently corrected in a timely manner.
  2. When a licensee has corrected inaccurate or incomplete information, the decision to issue an NOV will consider:
    - (a) The ease of detecting the error;
    - (b) The timeliness of the correction;
    - (c) Whether the NRC or the licensee identified the communication problem; and
    - (d) Whether the NRC relied on the information prior to the correction.
  3. If the matter was promptly identified and corrected by the licensee prior to reliance by the NRC, or before the NRC raised a question about the information, normally no enforcement action will be taken for the inaccurate or incomplete information.
  4. If the misinformation is identified after the NRC relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken.
  5. If the initial submittal was thought to be accurate when made but later turned out to be erroneous because of newly discovered information or an advance in technology, a citation would not normally be appropriate (if, when the new information became available, the initial submittal was corrected).
- e. The circumstances surrounding the failure to correct may be relevant to determining enforcement action for the initial inaccurate or incomplete statement.
1. The failure to correct inaccurate or incomplete information which the licensee knew of, but did not regard as significant, normally will not constitute a separate violation.
  2. An unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error.
  3. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information.

4. In serious cases where the licensee's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.
- 10 CFR 150.20 provides that when an Agreement State licensee is operating within the NRC's jurisdiction under the general license granted by Section 150.20, the licensee is also subject to the completeness and accuracy requirements.
- f. If enforcement action appears warranted for incomplete and inaccurate information, the region should prepare the appropriate enforcement action cited against the applicable regulation (e.g., 10 CFR 30.9, 40.9, 50.9, 55.9, 60.10, 61.9a, 70.9, 71.6a, 72.11, and 110.7a).
- The provisions in 10 CFR Part 55 contains the first element only, i.e., that all information provided to the Commission by an applicant or licensee or required by the Commission to be maintained by the applicant or licensee shall be complete and accurate in all material respects.
- g. The provisions of the applicable regulation address two elements:
1. A general provision that requires that all information provided to the Commission by an applicant or licensee or required by the Commission to be maintained by the applicant or licensee shall be complete and accurate in all material respects (violations are most commonly cited against this element); and
  2. A reporting requirement that requires applicants and licensees to report to the NRC information identified by the applicant or licensee as having a significant implication for the public health and safety or common defense and security.
- h. If the inaccurate or incomplete information was provided to the NRC, after citing the requirement paragraph, the "contrary to" paragraph should establish:
1. When the information was provided to the NRC;
  2. How the information was provided and to whom in the NRC, (e.g., oral presentation to the NRC staff in the NRC Region IV office; letter to the Director, NRR);

3. What the specific information was that the licensee provided (use direct quote if possible);
  4. How the information was either inaccurate or incomplete; and
  5. How the inaccuracy or incompleteness was material (e.g., the inaccuracy was material in that the NRC relied on the information in granting a license amendment, the incompleteness was material in that the NRC subsequently requested the licensee to make a submittal clarifying the information).
- i. If the inaccurate information was required by the Commission to be maintained, the requirement section should include the requirement for maintaining the information and the “contrary to” paragraph should establish:
1. When the inaccurate or incomplete information was identified;
  2. That the information was required to be maintained by the Commission;
  3. How the information was either inaccurate or incomplete; and
  4. How the inaccuracy or incompleteness was material.

✓ It is important to note that information provided to the NRC relating to a licensee’s commitment to perform or complete an activity in the future is normally not a violation of 10 CFR 50.9 if it turns out that the licensee subsequently did not perform or complete the activity. This is because at the time the commitment was made, the licensee intended to perform or complete the activity; therefore, the information was accurate at the time.

## 8.8 Violations of Reporting Requirements


- a. A licensee may be cited for violating reporting requirements if the licensee:
1. Did not file a required report;
  2. Filed an incomplete or incorrect report; or
  3. Filed a report late.
- b. A licensee normally will not be cited for failing to report an issue if the licensee was not aware of the information that was reportable; however, a licensee should be cited for failure to report an issue if the licensee knew of the information to be reported, but did not recognize that a report was required.

✗ Ignorance of a reporting requirement is not an excuse.

- c. The severity level assigned to the licensee's failure to submit a required, acceptable, and timely report on a violation that occurred at the licensee's facility is normally the same as would be assigned to the violation that should have been reported; however, the severity level for submitting a late report may be reduced, depending on the individual circumstances.

## 8.9 Violations of Record-Keeping Requirements

- a. When a licensee is required to perform a task and to keep a record of having performed it, but cannot produce that record:
  - 1. An NOV may be issued for failing to keep the record.
  - 2. The citation may be considered supporting evidence that a licensee did not perform a required task.
- b. Without additional evidence that the task was, indeed, not performed, the absence of the record is normally insufficient to support an NOV for "failure to perform" the task.

 Collaborating information, such as interviews or other evidence, should be used to determine whether the licensee **failed to perform** the task or merely **failed to record** that the task was performed.

## 8.10 Meetings With Licensees on NRC Enforcement Action

- a. In a few escalated enforcement cases, licensees have requested that a meeting be held after an enforcement action has been issued but before the enforcement process has been completed.
  - 1. From the time an enforcement action is issued through the hearing process, the NRC is considered to be in the enforcement process.
  - 2. Throughout the enforcement process, the licensee is given numerous opportunities to discuss in detail the inspection findings, i.e., during the inspection, at the inspection exit interview, after receipt of the inspection report, during the PEC, in the formal response to the NOV, in the reply to the Order Imposing Civil Monetary Penalty, and in a hearing, if requested.
  - 3. Unless new information has been discovered which has a significant effect on the outcome of the NRC enforcement action, additional discussion beyond those described in the preceding paragraph normally would not be useful.
- b. If the licensee insists on holding a meeting with the NRC, the following guidelines should normally apply. The licensee is to be informed that:

1. An official transcript of the meeting will be made in order to have a complete record of the meeting should the staff desire to rely on it in the event that the licensee provides information that had not been provided previously in a written submittal; and
2. The transcript (absent exempt information) will be made a public record and will be made available to the Public, except when:
  - (a) The meeting occurs after a hearing request has been made, in which case, the decision to have a transcript should be made in consultation with OGC; and
  - (b) When a meeting will need to be closed because the new information involves privacy, safeguards, or proprietary information, in which case, the transcript will not be made available to the Public.
- c. If, after consultation with the Regional Administrator, the Director, OE, concludes that such a meeting should be held, it is to be conducted with the Director or Deputy Director, OE, present.

### 8.11 Deliberate Misuse of Licensed Material


- a. This section provides guidance as to the extent to which an NRC licensee should be held liable for deliberate, frivolous or malicious misuse of NRC-licensed material at its facility.
- b. NRC licensees are required to control and limit their use of byproduct material to that authorized by the license or by regulation.
  1. In general, licensees are accountable for the use of their licensed material by their employees and should normally receive at least a citation for violations involving deliberate misuse of their licensed material by their employees or agents.
  2. Since the underlying issue of misuse normally would be categorized at Severity Level IV or higher, and since the Enforcement Policy states that the severity level of a willful violation may be increased, these violations normally would be categorized at Severity Level III or above and an NOV should be issued at Severity Level III or above.

☛ Recently, there have been cases involving, e.g., medical technicians injecting other medical technicians with diagnostic doses of NRC-licensed materials without the authority to do so. These individuals are aware that they require authorization to engage in these activities. In such cases, while the types and doses of licensed materials may not create a safety concern, the activities of these individuals reflects a careless disregard of NRC regulations addressing the use of these materials and, in general, degrades the NRC's confidence in the licensee's ability to conduct a safe nuclear medicine program.



- c. Although there may be cases where the ownership of the material and/or the identity of the perpetrator cannot be established definitively, in the absence of reasonable evidence to the contrary, normally the NRC will presume that:
  1. The NRC-licensed material used in the incident belonged to the licensee, assuming that the licensee has possessed the type, quantity and form of the material involved;
  2. The individual who perpetrated the act was an employee or agent of the licensee; and
  3. The individual obtained the material while acting in the capacity of employee or agent.
- d. Enforcement discretion should be considered for each case involving deliberate misuse of licensed material by licensee employees; however, it is not necessarily appropriate to seek a civil penalty against the licensee in every case.
  1. NRC should encourage licensees to prevent, investigate, report, and correct violations involving deliberate misuse of licensed material.
    - (a) If civil penalties were automatic imposed for deliberate misuse, licensees would have a disincentive to conclude that the misuse was a result of a deliberate action.
    - (b) Where there is a need to convey a specific message about some particular facet of the case, a civil penalty may be assessed based on enforcement discretion, notwithstanding the normal application of the civil penalty factors.
  2. The following are examples where it may be appropriate to use discretion to highlight a concern such as:
    - Inadequate actions to prevent deliberate misuse
    - The effort put forth by the licensee in investigating the deliberate misuse
    - Whether deliberate misuse has occurred previously
    - Whether the licensee had some basis to suspect that deliberate misuse might occur
    - The corrective actions taken by the licensee
    - The past performance of the licensee in controlling the use of licensed material, including training, labeling, posting, surveys, and security
    - The actual and potential consequences of the deliberate misuse
- e. In accordance with the Enforcement Policy, if the individual responsible for the deliberate misuse of licensed material is identified, enforcement action also may be taken directly against that individual.

## 8.12 Enforcement Actions Involving Master Materials Licenses

- a. A **Master Materials License** (MML) is a materials license (byproduct, source, and/or special nuclear material), issued to a Federal organization, authorizing use of radioactive material at multiple sites.
1. The MML authorizes the licensee to issue permits to multiple user sites (permittees) for the possession and use of licensed material under the master license.
  2. The MML obligates the licensee to have a centralized program that provides oversight and internal licensee inspection of the MML permittees.
- b. Where responsibilities are divided between the MML management and NRC, the division of responsibilities and requirements for coordination are clearly defined and documented in a Letter of Understanding (LOU) between NRC and the MML.
-  The MML remains an NRC licensee, and is required to meet NRC regulatory requirements.
1. Responsibility for allegations and enforcement are activities that are divided between the NRC and the MML.
  2. Inspection activities, including reactive inspections and/or inspection frequencies are not within the purview of the Office of Enforcement (OE), and will not be addressed here.
- c. The MML must have an enforcement program that commits to following NRC's Enforcement Policy to ensure that enforcement actions are consistent with the Policy and regulations, and are uniformly applied between the MML and its permittees.

### 8.12.1 Process for Dispositioning Violations

- a. The MML
1. Based on the NRC Enforcement Policy, when the MML identifies permittee violations of NRC or license requirements that could result in escalated enforcement (SL III, SLII, or SL I), the facts related to the case are provided to the appropriate NRC Regional MML Project Manager(PM).
  2. An MML is an NRC licensee. Reports and notifications, as described in the regulations, must be made to NRC within the time frames specified in the regulation (e.g., 20.2201 Reports of theft or loss of material). Reports and notifications from permittees to the MML does not fulfill the responsibility of reporting to NRC.

3. The outcome of any NRC enforcement action against the MML depends, among other things, on appropriate corrective actions implemented at the permittee level; therefore, the MML is expected to ensure that permittees provide corrective actions appropriate to their violations.
  4. The MML may take whatever enforcement action it deems appropriate against its permittee for violations of NRC regulations, license conditions, or conditions of the permit. However, the MML may not issue a civil penalty to its permittee.
- b. The NRC Project Manager (PM)
1. The PM coordinates any needed Regional Office follow-up of events or incidents using the appropriate inspection guidance for MML licenses (at whatever frequency the region and Program Office believes is appropriate).
    - (a) Once the information has been gathered and reviewed, and potential violations that may result in escalated action are identified, the region should disposition potential escalated violations through the normal enforcement process.
    - (b) An Enforcement Action Worksheet is prepared and an enforcement panel is scheduled. The worksheet should include the MML and/or the permittees short and long term corrective actions appropriate to the violation(s).
  2. Enforcement actions taken by NRC against the MML do not preclude the MML from taking any action it deems necessary against its permittee for those violations. NRC may issue a CP to the MML, but will normally not take action against a MML permittee.
- c. NRC Enforcement Discretion
1. Exercise of Discretion to either escalate or mitigate enforcement sanctions is addressed in Chapter VII of the Enforcement Policy.
  2. Discretion to mitigate an escalated enforcement action regarding an MML may be considered when:
    - The violation was not willful
    - The MML has done a thorough investigation, and has reported their findings to the MML PM
    - A source is lost

3. Although these cases normally should result in a civil penalty of at least the base amount, for MMLs, discretion to mitigate the enforcement sanction may be considered when:
  - Based on the source activity/dose rate the violation would normally be dispositioned as Severity Level III or Severity Level IV
  - During the period of time that the location of the source was not known, workers or members of the public were not likely to exceed the radiation dose described in 10 CFR 20.1201 or 20.1301
  - The final location of the source is believed to be in an area where it would be unlikely for workers or members of the public to exceed the radiation dose described in 10 CFR 20.1201 or 20.1301
4. NRC discretion to either mitigate or escalate an enforcement sanction would be considered on a case-by-case basis when:
  - A source is lost, and the underlying violation was willful
  - There was an over-exposure of a worker or a member of the public; or
  - Based on the source activity/dose rate, the violation would normally be dispositioned as SL I or SL II

### 8.13 Liability of Former and Successor Licensees

- a. The termination of an NRC license does not invalidate the former licensee's liability for actions taken under the license.
  1. Depending on the circumstances of a particular case (i.e., former licensees not in bankruptcy or out of business), escalated action may be taken against a former licensee for actions occurring during the time it held its license.
    - (a) The NRC's philosophy is that civil penalties should deter future violations not only for the involved licensee but also for other licensees conducting similar activities.
    - (b) For a particularly significant violation, it may be appropriate to issue a civil penalty to a licensee who is terminating licensed activities, to deter future violations by other licensees.
- b. OE should be notified before a license is terminated for cases where:
  1. An OI investigation or inspection is ongoing, since, in such cases, enforcement action could still be taken based on the results of that investigation or inspection; and
  2. Enforcement action is pending and the licensee has not been responsive.

- c. The transfer of control of a license to a new individual or business is a matter requiring NRC consent.
  - 1. Enforcement action should be taken if a person is found to have obtained a business or commenced operations under these conditions without obtaining NRC approval.
  - 2. The NRC considers the successor licensee to have assumed responsibility for violations occurring under the previous license, if these violations are not resolved when transfer of control occurs.

### 8.14 Enforcement Action Against Non-Licensees

- a. The Enforcement Policy is also applicable to non-licensees, including:
  - 1. Contractors and subcontractors;
  - 2. Holders of NRC approvals, e.g., certificates of compliance (CoCs), early site permits, standard design certificates, quality assurance program approvals, or applicants for any of them; and
  - 3. Employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation.
- b. Prohibitions and sanctions for any of the persons included in the preceding paragraph, who engage in deliberate misconduct or knowing submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct, e.g., 10 CFR 30.10 and 50.5.
- c. Contractors who supply products or services provided for use in nuclear activities are subject to certain requirements designed to ensure that the products or services supplied that could affect safety are of high quality.
  - 1. Contractors supplying certain products or services to licensees are subject to 10 CFR Part 21 requirements regarding the reporting of defects in basic components.
    - (a) NOVs will be issued for contractors who violate 10 CFR Part 21.
    - (b) Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(d)(1).
  - 2. Through procurement contracts with licensees, suppliers may be required to have quality assurance programs that meet applicable requirements, e.g., 10 CFR Part 50, Appendix B, and 10 CFR Part 71, Subpart H.

- d. When inspections determine that violations of NRC requirements have occurred, or that contractors have failed to fulfill contractual commitments (e.g., 10 CFR Part 50, Appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken.
  - 1. NOVs and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements.
  - 2. NOVs and civil penalties will be used against non-licensees who are subject to the specific requirements of 10 CFR Part 72.
  - 3. Notices of nonconformance or orders will be used against non-licensees who are subject to the specific requirements of 10 CFR Part 72 (see additional discussion in the FRN for the Policy revision in 1999 at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/history/fr101599.html>.)
- e. Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.

### 8.15 Reopening Closed Enforcement Actions


- a. Under special circumstances, i.e., where significant new information is received or obtained by NRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, on a case-by-case basis, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record.

✓ Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the DEDO.

  - 1. Special circumstances include, e.g., a situation in which individuals lied to the NRC about information that would have been considered material to the NRC's disposition of the case.
  - 2. Special circumstances do not include the discovery of additional information that was reasonably available at the time the agency made its initial decision.
- b. In cases where the severity of an original enforcement sanction was inappropriately low, consideration may be given to issuing a separate sanction against a different applicable requirement, categorized at the appropriate severity level to reflect the level of NRC concern and convey the appropriate message to the licensee.

- c. Even where special circumstances exist, the passage of time must be considered as well for very old violations.

### 8.16 Reporting Final Adverse Actions Against Healthcare Practitioners, Providers or Suppliers to the Healthcare Integrity and Protection Data Bank

- a. "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners (HIPDB)," found in 45 CFR Part 61, requires federal agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the HIPDB.
1. The regulations in 45 CFR 61 define the types of final adverse actions that are reportable to the HIPDB.
  2. The reportable actions must be formal or official actions such as the revocation or suspension of a license, reprimands, censure, probation, other negative actions or findings that limit the scope of practice, and other adjudicated actions or decisions.
- b. The following final adverse actions taken by the NRC must be reported to the HIPDB:
- Orders suspending or revoking a license, excluding Orders suspending a license due to non-payment of fees
  - Orders modifying a license that limit the scope of practice of the licensee
  - NOVs with associated civil monetary penalties
  - CALs that limit the scope of practice of the licensee
  - Orders to individuals prohibiting involvement in NRC-licensed activities
  - Termination of a license by a licensee for the purpose of avoiding enforcement actions
-  The scope of actions that must be reported to the HIPDB, is defined in very broad terms.
- c. The following actions do not need to be reported to the HIPDB:
- NOVs with no associated civil penalty
  - Licensee corrective action plans
  - Non-publically available final adverse actions
- d. For those actions where the reportability of the action is questionable, the action and the associated background information should be provided to OGC for the final determination of reportability.



### **8.16.1 Entities that are Considered Healthcare Practitioners, Providers, or Suppliers**

- a. The reportability of the actions described in the previous section is limited to those actions taken against NRC licensees, and individuals employed or contracted by licensees, that satisfy the definition of a healthcare practitioner, provider, or supplier as prescribed in 45 CFR Part 61.
- b. NRC licensees and individuals that satisfy the definitions prescribed in 45 CFR Part 61 are categorized as follows:
  1. Healthcare practitioners:
    - Physicians
    - Technologists/technicians
    - Pharmacists
    - Nurses
    - Medical Physicists
    - Health Physicists
  2. Healthcare providers:
    - Hospitals
    - Clinics
    - Mobile Medical Units
  3. Healthcare suppliers:
    - Radiopharmaceutical Manufacturers
    - Radiopharmacies
    - Medical Source Replacement Contractors
    - Source Providers (E.g. Seeds)

### **8.16.2 Information to be Reported**

- a. 45 CFR Part 61 specifies the information that must be reported.
  1. This information is dependent on the entity involved and the type of action reported.
  2. Optional information will be reported only if readily available.
- b. HIPDB requires the NRC to provide certain information, such as birth date, gender, Social Security number, school attendance with dates, State license numbers, and medical specialties, that NRC may not normally collect.

1. For final adverse actions resulting from enforcement actions, OE will collect the additional information that is required as part of the final enforcement action.
2. The proposed action, e.g., NOV/CP or Order, will contain a paragraph requesting the information to be provided as part of the response to the action.
  - (a) The action will not be closed until the required information is received.
  - (b) NMSS and/or the Regional Office will be responsible for collecting the data for other reportable final adverse actions that did not result from an enforcement action, and providing it to OE for entry into the database.
  - (c) The required information must be forwarded to the OE Office Director within 10 calendar days of those actions being final.

### 8.16.3 Information that must be reported

- a. Mandatory information that must be reported for an Individual includes:
  - Name, sex, date of birth
  - Social Security Number, Home address or address of record
  - Organization name and type
  - Occupation and specialty, if applicable
  - National Provider Identifier (NPI), when issued by the Health Care Financing Administration (HCFA)
  - Name of each professional school attended and years of graduation
  - NRC license number, including field of licensure
  - With respect to the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held
- b. Mandatory information that must be reported for an organization includes:
  - Name and business address of the organization
  - Federal Employer Identification Number (FEIN), or Social Security Number when it is used by the subject as a Taxpayer Identification Number (TIN)
  - The NPI, when issued by HCFA
  - Type of organization
  - With respect to the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held

- c. Mandatory information that must be reported for both an individual and an organization includes:
- A narrative description of the acts or omissions and injuries upon which the reported action is based
  - Classification of the acts or omissions in accordance with reporting codes provided in the database
  - Classification of the action taken in accordance with the reporting code in the database, and the amount of any monetary penalty resulting from the reported action
  - The date the action was taken, its effective date and duration
  - If the action is on appeal
  - Name, title, address, and telephone number of the responsible official submitting the report

#### 8.16.4. Information Collection

- a. To request the information that the HIPDB requires but that the NRC does not normally collect, one of the following paragraphs should be inserted in the proposed final adverse action document after the paragraph that requires the licensee to submit a response:

1. For an individual, include:

“In addition, 45 CFR Part 61, “Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners,” requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services’ Healthcare Integrity and Protection Data Bank. Since the HHS Databank requires information that the NRC does not normally collect, you are required to submit the following information with your response: your date of birth; Social Security Number; sex; employment organization name and type; Occupation and/or specialty; National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); name of each professional school attended and years of graduation; professional certification and/or registration; your State license number; your field of licensure; and the name of the State or territory in which your license is held. This information should be provided on a separate sheet of paper since it will not be publically released. This enforcement action will not be closed until this information is received.”

2. For an organization, i.e., a licensee, include:

“In addition, 45 CFR Part 61, “Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners,” requires

✓ Information the NRC receives that is required by HIPDB but not the NRC, must be profiled in ADAMS as not publicly available.

Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services' Healthcare Integrity and Protection Data Bank. Since the HHS Databank requires information that the NRC does not normally collect, you are required to submit the following information with your response: Federal Employer Identification Number (FEIN), or Social Security Number (when it is used as a Taxpayer Identification Number (TIN)); the National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); the type of organization; and the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held. This information should be provided on a separate sheet of paper since it will not be publically released. This enforcement action will not be closed until this information is received."

- b. When the NRC receives the response containing the information that the HIPDB requires but that the NRC does not normally collect, the information should be scanned into ADAMS; however, this information must be profiled as not publically available.
- c. A copy of the response containing the information that the HIPDB requires but that the NRC does not normally collect, must be provided to the Office Director, OE, for entry into the databank.