

Appendix A - Severity Level Assignment to Violations

VIOLATION EXAMPLES

The violation examples in this Inspection and Enforcement Policy, Title 300, Section 301 are intentionally broad in scope so as to serve as a set of guiding examples that are neither exhaustive nor controlling for making severity level determinations. Licensed activities are placed in the most appropriate activity area in light of the particular violation involved, including activities not directly covered by one of the listed areas. The violation examples are not intended to address every possible circumstance. However, when an enforcement case scenario very nearly achieves all or some of the criteria set forth in an example, the case should be considered to be at the severity level of that example. For example, when using the examples in Category 2- Health Physics, if the circumstances of a case are such that one or more of the severity levels in an example were very nearly reached, and it was only fortuitous that the limit was not actually met or exceeded, then the severity level for the subject example would be applicable. Additionally, if the circumstances for a case do not squarely fit any particular violation example, a comparable example in the same activity area may be considered to determine the severity (e.g., the case for an industrial licensee presents a set of circumstances and considerations comparable to those for a medical example provided in Category I - Materials Operations"; hence, the severity level for the medical example can be applied).

In general severity level designations reflect different degrees of significance depending on the activity area in which the severity level is designated. For example, the immediacy of any hazard to the public associated with Severity Level I in materials operations is not directly comparable to that associated with Severity Level I violations in materials security.

- a. Severity Level I violations are those that resulted in or could have resulted in serious safety or security consequences (e.g., violations that created the substantial potential for serious safety or security consequences or violations that involved systems failing when actually called on to prevent or mitigate a serious safety or security event).
- b. Severity Level II violations are those that resulted in or could have resulted in significant safety or security consequences (e.g., violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serious safety or security event).
- c. Severity Level III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).

- d. Severity Level IV violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences).
- e. Minor Violations are those that are less significant than a Severity Level IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations must be corrected.

I. MATERIALS OPERATIONS

A. Severity Level I violations involve, for example:

- 1. The loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, results in serious injury or loss of life;
- 2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function, and this results in serious injury or loss of life;
- 3. Failure to use a properly prepared written directive as required by 902 KAR 100:072 Section 13, "Written Directives," or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 902 KAR 100:072 Section 14, "Procedures for Administrations Requiring a Written Directive," results in serious injury or loss of life.

B. Severity Level II violations involve, for example:

- 1. The loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, results in the substantial potential for a significant injury or loss of life, whether or not radioactive material is released;
- 2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function;
- 3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 902 KAR 100:072 Sections 13 or 14, or a failure to train personnel in those procedures, results in a medical event as defined in 902 KAR 100:072, Section 15.

C. Severity Level III violations involve, for example:

- 1. A system designed to prevent or mitigate a serious safety event has one of the following characteristics:
 - (a) It is unable to perform its intended function under certain conditions (e.g., a safety system is not operable unless the required backup power is available), or

- (b) It is outside design specifications to the extent that a detailed evaluation would be required to determine its operability;
2. A programmatic failure occurs to implement written directives or procedures for administrations requiring a written directive, such as the following:
 - (a) A licensee's procedures fail to address one or more of the elements in 902 KAR 100:072 Sections 13 or 14,
 - (b) A licensee fails to train personnel in procedures for administrations requiring a written directive,
 - (c) A non-isolated failure occurs to use and follow written directives or procedures for administrations requiring a written directive; or
 - (d) A licensee fails to have procedures or requirements for written directives or fails to have procedures for administrations that require written directives.
 3. A licensee fails to secure a portable gauge with at least two independent physical controls whenever the gauge is not under the control and constant surveillance of the licensee as required by 902 KAR 100:040 Section 6(4);
 4. A significant failure to implement the requirements of 902 KAR 100:100, "Industrial Radiography," during radiographic operations includes, but is not limited to, the following:
 - (a) During radiographic operations at a location other than a permanent radiographic installation, a licensee fails to have present a radiographer and at least one additional radiographer or qualified individual,
 - (b) A licensee fails, during radiographic operations, to use radiographic equipment, radiation survey instruments, or personnel monitoring devices as required by 902 KAR 100:100, or
 - (c) During radiographic operations, a failure to stop work occurs, after a pocket dosimeter is found to have gone off-scale or after an electronic dosimeter reads greater than 200 millirem (mrem), and before a determination is made of the individual's actual radiation exposure;
 5. An unqualified person conducts licensed activities. The unqualified person is characterized by either of the following:
 - (a) lacking adequate qualifications, experience, or training to safely conduct activities, or
 - (b) lacking the required certification or training for positions such as radiographer or authorized user under 902 KAR 100:072, "Use of Radionuclides in the Health Arts."
 6. Licensed material is used on humans where such use is not authorized;

7. A licensee authorizes the release from its control of an individual who does not meet the release criteria in 902 KAR 100:072 Section 27, "Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material;"
8. A licensee fails to seek required Cabinet approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance, such as the following:
 - (a) a change in ownership,
 - (b) a change in the location where licensed activities are being conducted or where licensed material is being stored,
 - (c) an increase in the quantity or type of radioactive material being processed or used that has radiological significance, or
 - (d) a change in program status with regard to the RSO named on its license (e.g., licensee fails to have an RSO; licensee appoints an unqualified individual as RSO);
9. Failures occur involving decommissioning requirements, such as the following:
 - (a) a significant failure to meet decommissioning as required by regulation or license condition, or
 - (b) failure to meet required schedules without adequate justification

D. Severity Level IV violations involve, for example:

1. A licensee fails to use a properly prepared written directive as required by 902 KAR 100:072 Section 13, or fails to develop, implement, or maintain procedures for administrations requiring a written directive as required by 902 KAR 100:072 Section 14, whether or not a medical event occurs, provided that the failures are characterized by all of the following:
 - (a) are isolated
 - (b) do not demonstrate programmatic weaknesses in implementation
 - (c) have limited consequences if a medical event is involved;
2. A licensee fails to keep the records required by 902 KAR 100:072 Section 13, "Written Directives," and 902 KAR 100:072 Section 14, "Procedures for Administrations Requiring a Written Directive;"
3. A licensee fails to implement procedures including, but not limited to, recordkeeping, surveys, and inventories;

4. A licensee fails to comply with the U.S. Department of Transportation requirement to provide hazardous material (HAZMAT) employee training as required by 902 KAR 100:070 Section 4(1)(a);
5. A licensee fails to seek required Cabinet approval before the implementation of a change in ownership that results in little or no adverse impact on radiological or programmatic activities or on the Cabinet's ability to inspect licensed activities, such that the locations and types of activities are unaffected by the unauthorized license transfer;
6. A licensee fails to seek required Cabinet approval prior to replacement of the RSO, where the RSO was evaluated as qualified; or
7. A licensee fails to seek Cabinet approval, when required, before changing the location where licensed activities are being conducted or where licensed material is being stored that has little or no radiological or programmatic significance, and all other safety and security requirements have been met.

II. HEALTH PHYSICS

Personnel overexposures and associated violations incurred during a lifesaving or other emergency response effort will be treated on a case-by-case basis.

A. Severity Level I violations involve, for example:

1. An adult worker receives a radiation exposure during any year in excess of 25 rem (0.25 sievert (Sv)) total effective dose equivalent; 75 rem (0.75 Sv) to the lens of the eye; or 250 rem (2.5 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus of 2.5 rem (0.025 Sv) total effective dose equivalent;
3. A minor worker (i.e., an individual less than 18 years of age) receives a radiation exposure during any year in excess of 2.5 rem (0.025 Sv) total effective dose equivalent; 7.5 rem (0.075 Sv) to the lens of the eye; or 25 rem (0.25 Sv) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. A member of the public receives an annual exposure in excess of 1 rem (0.01 Sv) total effective dose equivalent;
5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 50 times the limits for members of the public as stated in 902 KAR 100:019 Section 11(2)(b)1.; or
6. Disposal of licensed material occurs in quantities or concentrations in excess of 10 times the limits of 902 KAR 100:021 Section 3, "Disposal by Release into Sanitary Sewerage."

B. Severity Level II Violations involve, for example:

1. An adult worker receives a radiation exposure during any year in excess of violations 10 rem (0.1 Sv) total effective dose equivalent; 30 rem (0.3 Sv) to the lens of the eye; or 100 rem (1.0 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 1.0 rem (0.01 Sv) total effective dose equivalent;
3. A minor worker receives a radiation exposure during any year in excess of 1.0 rem (0.01 Sv) total effective dose equivalent; 3.0 rem (0.03 Sv) to the lens of the eye; or 10 rem (0.1 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
4. A member of the public receives an annual exposure in excess of 0.5 rem (5 millisieverts (mSv)) total effective dose equivalent;
5. Release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 10 times the limits stated in 902 KAR 100:019 Section 11(2)(b)1. (except when the Cabinet has approved operation up to 0.5 rem (5 mSv) per year under 902 KAR 100:019 Section 10(3)); or
6. Disposal of licensed material occurs in quantities or concentrations in excess of 5 times the limits of 902 KAR 100:021 Section 3.

C. Severity Level III Violations involve, for example:

1. An adult worker receives a radiation exposure during any year in excess of 5 rem (0.05 Sv) total effective dose equivalent; 15 rem (0.15 Sv) to the lens of the eye; or 50 rem (0.5 Sv) to the skin of the whole body or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 0.5 rem (5 mSv) total effective dose equivalent (except when doses are in accordance with the provisions of 902 KAR 100:019 Section 9(4));
3. A minor worker receives a radiation exposure during any year in excess of 0.5 rem (5 mSv) total effective dose equivalent; 1.5 rem (0.015 Sv) to the lens of the eye; or 5 rem (0.05 Sv) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 0.1 rem (1 mSv) total effective dose equivalent (except when operation up to 0.5 rem (5 mSv) per year under 902 KAR 100:019 Section 10(3));
5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 2 times the effluent concentration limits referenced in 902 KAR 100:019 Section 11(2)(b)1. (except when the Cabinet has approved operation up to 0.5 rem (5 mSv) per year under 902 KAR 100:019 Section 10(3));

6. A substantial potential exists for exposures or releases in excess of the applicable limits in 902 KAR 100:019, whether or not an exposure or release occurs;
7. Disposal of licensed material occurs in quantities or concentrations in excess of the regulatory limits of 902 KAR 100:021 Section 3;
8. A licensee releases, for unrestricted use, contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public exceeding the annual dose limits for members of the public;
9. A technically unqualified person conducts licensee activities; or
10. A violation involves failure to secure, or maintain surveillance over, licensed material in the following situations:
 - (a) involves licensed material in any aggregate quantity greater than 1,000 times the quantity specified in 902 KAR 100:030, "Quantities of Licensed Material Requiring Labeling,"
 - (b) involves licensed material in any aggregate quantity greater than 10 times the quantity specified in 902 KAR 100:030, where the failure is accompanied by the absence of a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action), or
 - (c) results in a substantial potential for exposures or releases in excess of the applicable limits in 902 KAR 100:019.

D. Severity Level IV violations involve, for example:

1. Intakes exceed those specified in 902 KAR 100:019 Section 3(5) or the equivalent for Section 8. "Occupational Dose Limits for Minors;"
2. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of the limits for members of the public as referenced in 902 KAR 100:019 Section 11(2)(b)1. (except when the Cabinet has approved operation up to 0.5 rem (5 mSv) per year under 902 KAR 100:019 Section 10(3));
3. A radiation dose rate in an unrestricted or controlled area exceeds 0.002 rem (0.02 microsieverts) in any 1 hour (2 mrem/hour) or 50 mrem (0.5 mSv) in a year;
4. A licensee fails to conduct required leakage or contamination tests or to use properly calibrated equipment, although the failure does not contribute to an event;
5. Doses to a member of the public exceed any of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR Part 190, "Environmental

Radiation Protection Standards for Nuclear Power Operations,” as required by 902 KAR 100:019 Section 10(4); or

6. An isolated failure occurs to secure, or maintain surveillance over, licensed material in any aggregate quantity greater than 10 times the quantity specified in 902 KAR 100:030, provided that both of the following apply:
 - (a) The material is labeled as radioactive or located in an area posted as containing radioactive materials, and
 - (b) Such failure occurs despite a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action);

III. **TRANSPORTATION**

Some transportation requirements apply to more than one licensee involved in the same activity (e.g., a shipper and a carrier). When such a violation occurs, the Cabinet will direct enforcement action against the responsible licensee or licensees.

A. Severity Level I violations involve, for example:

1. Failure to meet transportation requirements results in loss of control of radioactive material with a breach in package integrity such that the material causes a radiation exposure to a member of the public in excess of the regulatory limits;
2. Surface contamination exceeds 50 times the Cabinet limit; or
3. External radiation levels exceed 10 times the Cabinet limit.

B. Severity Level II violations involve, for example:

1. Failure to meet transportation requirements results in loss of control of radioactive material with a breach in package integrity such that there is a clear potential for a member of the public to receive a radiation exposure in excess of the regulatory limits;
2. Surface contamination exceeds 10 times, but not more than 50 times, the Cabinet limit;
3. External radiation levels exceed 5 times, but not more than 10 times, the Cabinet limit; or
4. A licensee fails to make required initial notifications associated with SL I or II violations.

C. Severity Level III violations involve, for example:

1. Surface contamination exceeds 5 times, but not more than 10 times, the Cabinet limit;
2. External radiation exceeds 1 times, but not more than 5 times, the Cabinet limit;

3. A violation involves labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result any of the following:
 - (a) a significant failure to identify the type, quantity, or form of material
 - (b) a failure of the carrier or recipient to exercise adequate controls
 - (c) a substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material
4. A licensee fails to make required initial notification associated with Severity Level III violations.

D. Severity Level IV Violations involve, for example:

1. A breach of package integrity occurs without external radiation levels exceeding the Cabinet limit or without contamination levels exceeding the Cabinet limits;
2. Surface contamination is in excess of, but is not more than 5 times, the Cabinet limit;
3. A licensee fails to register as an authorized user of an NRC-Certified Transport package;
4. A licensee fails to demonstrate that packages for special-form radioactive material meet applicable regulatory requirements; or
5. A licensee fails to demonstrate that U.S. Department of Transportation specifications are met for 7A Type A packages as required by 902 KAR 100:070 Section 4, "Transportation of Licensed Material."

IV. **MATERIALS SECURITY**

A. Severity Level I violations involve, for example:

1. The theft, diversion, or sabotage of a Category 1 quantity of radioactive material results from the failure to establish or implement one or more requirements, such as the following:
 - (a) failure to control unescorted access to a Category 1 quantity of radioactive material so that only individuals deemed trustworthy and reliable and having job duties that require unescorted access to the radioactive material are granted such access;
 - (b) failure to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 quantity of radioactive material, including requesting assistance from the local law enforcement agency;
 - (c) failure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material; or
 - (d) failure to implement the Radioactive Material Quantities of Concern (RAM QC) requirements before shipping a consignment containing a Category 1 quantity of radioactive material.

B. Severity Level II violations involve, for example:

1. The theft, diversion, or sabotage of a Category 2 quantity of radioactive material results from the failure to establish or implement one or more increased control requirements, such as the following:
 - (a) failure to control unescorted access to a Category 1 or Category 2¹ quantity of radioactive material so that only individuals deemed trustworthy and reliable and having job duties that require unescorted access to the radioactive material are granted such access;
 - (b) failure to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material, including requesting assistance from the local law enforcement agency;
 - (c) shipping a consignment of a Category 2 quantity of radioactive material by a carrier, other than the licensee, without first verifying that the carrier uses a package tracking system, implements methods to ensure trustworthiness and reliability of drivers, maintains constant control and/or surveillance during transit, and has the capability for immediate communication to summon appropriate response or assistance;
 - (d) failure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material;
 - (e) failure to implement the RAM QC Additional Security Measures before shipping a consignment containing a Category 1 quantity of radioactive material; or
 - (f) failure to use a method to disable a vehicle or trailer, in or on which a Category 1 or Category 2 quantity of radioactive material is stored, when not under direct control and constant surveillance by the licensee.

C. Severity Level III violations involve, for example:

1. A licensee fails to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material, including a failure to request assistance from the local law enforcement agency, but the failure does not result in actual theft, sabotage, or diversion of radioactive material;
2. A licensee fails to determine the trustworthiness and reliability of individuals having unescorted access to radioactive material quantities of concern and devices;

¹ Violation examples 4 b. 1. (a), (b), and (f) recognize that a licensee may possess a total of either Category 1 or Category 2 quantity of radioactive material at the time of the subject incident, but only a Category 2 quantity was actually involved with theft, diversion, or sabotage. Hence, the severity level is determined by the category of material involved in the theft, diversion, or sabotage.

3. A licensee fails to limit access to physical protection information to only those persons with an established need-to-know and who have been determined to be trustworthy and reliable;
4. A licensee fails to verify that a carrier uses package tracking systems, implements methods that ensure trustworthiness and reliability of drivers, maintains constant control and/or surveillance during transit, and has the capability for immediate communication to summon appropriate response or assistance, before shipping a Category 2 quantity of radioactive material, per consignment, by the carrier;
5. A licensee fails to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material;
6. A licensee fails to initiate an investigation to determine the location of a shipment of licensed material containing a Category 2 quantity of radioactive material when the shipment does not arrive on or about the expected arrival time;
7. A licensee fails to notify the Cabinet promptly after initiating a response to any actual or attempted theft, diversion, or sabotage of sources or devices containing a Category 1 or Category 2 quantity of radioactive material;
8. A licensee fails to implement the RAM QC before shipping a Category 1 quantity of radioactive material, per consignment;
9. A licensee fails to use a method to disable a vehicle or trailer, in or on which a Category 1 or Category 2 quantity of radioactive material is stored, when not under direct control and constant surveillance by the licensee;
10. A licensee fails to contact the local law enforcement agency and does not attempt to establish a prearranged response plan with the local law enforcement agency, or a programmatic failure occurs in the implementation of the plan;
11. A licensee fails to establish a program to monitor and immediately detect, assess, and respond to unauthorized access to a Category 1 or Category 2 quantity of radioactive material, or a programmatic failure occurs during implementation;
12. A licensee fails to have a dependable means to transmit information between and among the various components of the intrusion detection system or to summon the appropriate responder; or
13. A licensee fails to verify that a recipient licensee is authorized to possess the material being transferred.

D. Severity Level IV Violations involve, for example:

1. A licensee fails to document the basis for concluding that an individual was determined to be trustworthy and reliable for the purposes of granting unescorted access to a Category 1 or Category 2 quantity of radioactive material;

2. A licensee fails to perform a complete and adequate trustworthiness and reliability determination for an individual, such that information relevant to access approval was not obtained or considered, but the individual would likely have been granted unescorted access if the required information had been obtained or considered;
3. A licensee fails to limit approval for unescorted access with respect to a Category 1 or Category 2 quantity of radioactive material to individuals with job duties requiring unescorted access;
4. A licensee fails to maintain a list of persons approved for unescorted access;
5. A licensee fails to confirm receipt of transferred/shipped radioactive material;
6. A licensee fails to document the prearranged plan with the local law enforcement agency or to update the prearranged plan when changes to the facility design or operation affect the potential vulnerability of sources;
7. An isolated failure occurs in the as-designed operation of the dependable means to transmit information between and among the various components of the intrusion detection system or to summon the appropriate responder. This is a violation if caused by a failure of the licensee in the design, construction, operation, or maintenance of the system. (This example does not include isolated failures caused by means outside the licensee's control, such as service disruptions);
8. A licensee fails to contact the recipient or originator of a shipment to coordinate an expected arrival time for a shipment of a Category 2 quantity of radioactive material;
9. An isolated failure occurs in implementing a portion of the licensee's program to monitor and immediately detect, assess, and respond to unauthorized access to a Category 1 or Category 2 quantity of licensed radioactive material, such that an opportunity exists for unauthorized and undetected access to the material, but the opportunity is neither easily nor likely to be exploitable;
10. An isolated failure occurs in limiting access to physical protection information to only those persons with an established need-to-know and who are considered trustworthy and reliable, where with a high degree of confidence it is determined to be unlikely that an unauthorized individual who represents a predictable threat to circumvent or defeat the licensee's physical protection program could use the information; or
11. A licensee fails to comply with an element of its procedure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material, and this failure does not seriously degrade the enhanced monitoring capability.