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**PNRI Administrative Order No. 02**  
**Series of 2011**

## **REGULATORY CRITERIA IN DETERMINING SEVERITY OF VIOLATION(S)**

### **I. INTRODUCTION AND PURPOSE**

Republic Act No. 5207, otherwise known as “*The Atomic Energy Regulatory and Liability Act of 1968*”, authorizes the Philippine Nuclear Research Institute (PNRI) to “*conduct inspections, as may be necessary, at the premises where the atomic energy facility is located and the atomic energy material is stored, to issue orders where situations and conditions endangering life, health or property are found to exist, and to adopt such measures that would eliminate or protect against such situations or conditions*”, for the purpose of determining whether the application for a license should be granted or denied or whether a license should be modified, amended, suspended or revoked, under certain circumstances and of otherwise implementing its licensing and regulatory responsibilities under the said Act.

In the performance of its said licensing and regulatory authority, the PNRI undertakes an enforcement program in support of its overall safety mission to protect the workers, the public and the environment against the hazards of radiation and the need to ensure the security of radioactive sources so as to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of radioactive sources. It likewise emphasizes the importance of compliance with regulatory requirements and identification of violations and correction of such violations.

### **II. THE ENFORCEMENT PROGRAM**

The enforcement program applies to all persons who acquire, possess, use and transfer radioactive material. It consists of activities governing the process to grant or deny an application for a license and the conduct of inspection of licensed facilities to determine whether or not the licensee performs in accordance with the conditions of the license. The **Nuclear Regulatory Division (NRD)** shall determine the level of enforcement actions that, with the approval of the Director, will be taken when dealing with licensees and workers who do not achieve the necessary standard of compliance expected of them, and other persons who may be found to possess or use radioactive materials without the appropriate authorization from PNRI. **Appendix A** enumerates violations identified for each level of severity, which may include such other violations as may be determined by the PNRI, to guide the NRD in determining the enforcement action that will be imposed. Each enforcement action is dependent on the circumstances affecting the violation and requires the exercise of discretion after consideration of applicable safety and security criteria and other regulatory policies established by the PNRI.

Upon a determination of an applicant’s compliance with regulatory requirements, sans any finding(s) of materially false statements, the NRD recommends to the PNRI Director the issuance of a license which would authorize the licensee to engage in all activities stated therein. The conditions of the license may also specify those special requirements that the

licensee needs to follow in addition to the established regulatory requirements. The licensee is required to submit its programs and procedures to the NRD as a commitment on how to comply with the requirements of the regulation.

To determine if the licensee complies with regulatory requirements and the conditions of the license, the Inspection and Enforcement Section (IES) inspectors shall undertake planned inspections that may either be announced or unannounced based on a graded approach and on an annual inspection program of the NRD. These inspections and audit of existing licensed facilities and radioactive materials, usually at specified frequencies, are undertaken to monitor compliance with applicable Sections of the Code of PNRI Regulations and the general and specific conditions of the license, and to provide proofs of implementation of the Radiation Safety Program and commitment in the license application. These inspection activities may consist of the following:

- (a) inspection and audit of records of licensed activities to verify compliance with quality assurance requirements, PNRI rules and regulations, the conditions of the license, and other regulatory requirements;
- (b) interviews with authorized users of licensed radioactive material(s), radiation safety officers, and operating personnel of the licensed facility;
- (c) walk-through at locations where radioactive materials are located, handled, and used;
- (d) radiation area monitoring in the licensed facility;
- (e) actual observation of performance of licensed activities; and
- (f) follow-up inspection of the previous inspection findings based on the licensee's commitments in its response to the PNRI Official Inspection Report.

After the actual inspection and audit, an Exit Meeting is held to discuss major findings with the licensee. The lead inspector discusses the initial results written in the Preliminary Inspection Report. Agreements or disagreements to the findings are discussed, after which the licensee affixes his signature as a sign of accepting the presented results of inspection.

Thereafter, a written PNRI Official Inspection Report is promptly prepared and sent to the licensee to formally inform of the results of the inspection and audit. The report discusses the significance of inspection finding(s), putting emphasis on the regulatory provisions and requirements against which the violation and infractions were committed. The report also requires the licensee to respond within the established deadline, citing the appropriate corrective actions undertaken to prevent recurrence of the non-compliance, if there is any.

The licensee's response to the PNRI Official Inspection Report should contain his concurrence or disagreements with the inspector's findings and report. Each inspection finding of noncompliance is evaluated to determine the enforcement actions to be imposed and whether or not it can be categorized under a level of severity.

### **III. ENFORCEMENT ACTIONS AND RELATED ADMINISTRATIVE SANCTIONS**

The PNRI imposes enforcement actions to licensees who are found to have violated any rule or regulation issued by the PNRI. These enforcement actions are issued in the form of:

**(a) Notice of Violation**

A Notice of Violation is a written notice that sets forth one or more violations to PNRI requirements and requires the licensee to submit a written reply containing:

- (1) An explanation why or how the violation occurred or, if contested, the basis for disputing the violation;
- (2) Corrective actions that have been taken and the results achieved;
- (3) Corrective actions to be taken to prevent recurrence; and
- (4) The date when full compliance will be achieved.

The PNRI issues a Notice of Violation to formalize the existence of a violation, except in cases where the issuance of Orders is necessary. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved.

The purpose of the corrective action is to direct the licensee to:

- (1) Take the immediate necessary actions that would restore safety, security and compliance with the license conditions, regulation(s), or other requirement(s), and
- (2) Develop and implement (in a timely manner) lasting actions that will not only prevent recurrence of the subject violation, but will be appropriately comprehensive, given the significance and complexity of the violation to prevent occurrence of violations with similar root causes.

Regardless of other circumstances (e.g., past enforcement history, identification of enforcement action), the licensee's corrective actions should always be evaluated as part of the process of assessing potential administrative sanctions against the licensee.

In assessing this factor, consideration will be given to the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the adequacy of the licensee's root cause analysis for the violation and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern).

**(b) Orders**

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

Orders are also used when the PNRI has identified deliberate misconduct that may cause a licensee to violate a PNRI requirement, or where incomplete or inaccurate information is deliberately submitted, or where the PNRI is not assured that the licensee, or any of its authorized personnel, will meet PNRI requirements.

Orders may also be issued as appropriate for Severity levels I, II, or III violations, as follows:

- (1) **License Modification Orders** are issued when change in licensee equipment, procedures, personnel or management controls are necessary. This type of Order may be issued by reason of addition or withdrawal of specific authority in the license, or amendment of rules or regulations, or as a result of a determination of a significant violation requiring such directive.
- (2) **Suspension Orders** may be used:
  - (i) To remove a threat to public health and safety, security of radioactive sources, the environment or the national interest;

- (ii) To stop the construction of a facility when:
  - Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component; or
  - The licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;
- (iii) When the licensee has not responded adequately to a previous enforcement action;
- (iv) When the licensee interferes with the conduct of an inspection or investigation; or
- (v) For any reason not mentioned above for which license suspension is legally authorized under Section 27 of RA 5207

Suspension orders may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken. A Suspension Order may last until the PNRI is satisfied that there is a reasonable assurance that the licensee can operate in compliance with applicable regulatory requirements.

- (3) **Cease and Desist Orders** may be used to stop an unauthorized or unsafe activity that has continued after notification by the PNRI that the activity is unauthorized or unsafe, and/or a suspension order has not been followed.
- (4) **Revocation Orders** may be used:
  - (i) When a licensee refuses to correct a violation;
  - (ii) When a licensee does not respond to a Notice of Violation where a response was required;
  - (iii) When a licensee refuses to pay any prescribed fee under the PNRI regulations; or
  - (iv) For any other reason for which revocation is authorized under Section 27 of the Atomic Energy Regulatory and Liability Act of 1958, "R.A No. 5207".

A Revocation Order will be issued upon repeated violation of at least three (3) times, as determined by the PNRI.

Upon the suspension or revocation of a license, pursuant to a PNRI order, the PNRI shall take, or shall require the licensee to take, such measures as may be necessary to protect the health, safety and security of the public or the national interest. The PNRI may, if necessary to protect the public health, safety and security or the national interest, take temporary custody of any atomic energy material or facilities held by the licensee pending full compliance with regulatory requirements at which time, the suspension or revocation may be lifted or a new license, upon due application, is issued.

Orders are made effective immediately whenever it is determined that the interest of public health, safety, or security so requires, or when the order is responding to a violation involving willfulness.

### (c) Administrative Sanctions

In addition to Notices of Violations and Orders, the PNRI also uses administrative regulatory actions, such as Confirmatory Action Letters, Letters of Reprimand, and Demand for Information to supplement its enforcement program. The PNRI expects licensees to adhere to

any obligations and commitments resulting from these actions and will not hesitate to issue appropriate Orders and/or sanctions to ensure that these obligations and commitments are met.

- (1) **Confirmatory Action Letters** are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety or the environment.
- (2) **Letters of Reprimand** are letters addressed to individuals named in the license identifying a significant deficiency in their performance of licensed activities.
- (3) **Demand for Information** are demand letters to the licensee for information for the purpose of enabling the PNRI to determine whether or not an order or other enforcement action should be issued.

Some mechanisms employed by the PNRI to aid enforcement are regulatory conferences with licensees and issuance of regulatory bulletins or information notices. Regulatory conferences are meetings organized by the PNRI with licensee management to discuss safety, security or environmental issues, licensee's compliance with regulatory requirements, licensee's proposed corrective measures and enforcement options available to the PNRI. Regulatory bulletins or information notices are written notifications to licensees identifying specific problems and recommending specific actions.

#### IV. DETERMINATION OF SEVERITY LEVELS

The regulations and licensing requirements have varying degrees of importance and significance with respect to radiation safety, security of radioactive material and its impact on the environment. An important step in the enforcement process is the proper identification and classification of violation with respect to its seriousness or severity. The assignment of severity level to the identified violation shows the significance of established radiation protection standards and other regulatory requirements to the level of enforcement action. For purposes of determining the appropriate enforcement action, violations are normally categorized in terms of four levels of severity to show their relative importance or significance within areas described in the license. Severity **Level I** is assigned to violations that are the **most significant** while **Severity Level IV** is assigned to violations that are the **least significant**.

The PNRI recognizes that there are other violations of minor safety concern that may be considered to be below the level of significance of Severity Level IV violations; thus, these minor violations don't warrant documentation in inspection reports or inspection records and do not warrant enforcement action.

The significance of each regulatory enforcement action varies according to its impact to public health and safety, safety and security of radioactive sources, and to environmental safety. Therefore, the first step in the enforcement process is determining the relative importance or significance of each violation or noncompliance. In assessing the significance of a noncompliance, the PNRI considers the following specific issues:

(a) **Actual Safety Consequences.**

In evaluating actual safety consequences, the PNRI considers issues such as actual onsite or offsite releases of radiation, onsite or offsite radiation exposures, loss of significant radiation shielding, loss of control of radioactive material or radiological emergencies.

(b) **Potential Safety Consequences.**

In evaluating potential safety consequences, the PNRI considers the **realistic** likelihood of the violation affecting safety, i.e., the existence of credible scenarios with potentially significant actual consequences. The PNRI may use risk information wherever possible in

assessing the significance of the violation and assigning severity levels. A higher severity level may be warranted for violations that have greater risk significance and a lower severity level may be appropriate for issues that have low risk significance. Duration of occurrence is an appropriate consideration in assessing the significance of violations.

**(c) Actual and Potential Security Consequences.**

In evaluating security consequences, the PNRI considers the security threats specific to the licensee or evaluates changes to previously determined threats. The PNRI assesses the security vulnerabilities in light of these threats and the quality and extent of the security provisions. The level of security noncompliance will be based on the threat and vulnerability assessments which depend on the Security Group to which a radioactive source has been categorized and assigned in accordance with **Section 19 of CPR Part 26**. Assessment of the significance of violations affecting security will also take into consideration applicable provisions in other CPRs, orders, or rules issued by the PNRI.

**(d) Impact on the Regulatory Process.**

The PNRI considers the safety and security implications of a violation that may impact the ability of the PNRI to carry out its statutory mission. Noncompliance to PNRI regulations may be significant because it may challenge the regulatory criteria upon which certain activities were licensed.

**(e) Willfulness.**

Willful violations pose serious concern to the PNRI regulatory programs and therefore carry a severe sanction than for a mere noncompliance. The term "willfulness" embraces a spectrum of violations ranging from deliberate intent to violate or falsify to, including, careless disregard for requirements.

In determining the significance of a violation involving willfulness, consideration will be given to such factors as:

- (1) the position and responsibilities of the person involved in the violation (e.g., licensee official or non-supervisory employee); and
- (2) the intent of the violator (i.e. blatant disregard or deliberateness).

**V. DETERMINATION OF ENFORCEMENT SANCTION AND PROPOSED ESCALATED ACTIONS**

<b>Level I:</b>	First Offense	= a + b
	Second Offense	= a + b + c
	Third Offense	= d
<b>Level II:</b>	First Offense	= a
	Second Offense	= a + b
	Third Offense	= a + b + c
<b>Level III:</b>	First Offense	= a
	Second Offense	= b
	Third Offense	= a + b
<b>Level IV:</b>	First Offense	= a
	Second Offense	= a
	Third Offense	= b

- Where:**
- a =** Notice of Violation
  - b =** Issuance of Cease and Desist Order on affected operation until the PNRI is satisfied that there is a reasonable assurance that the licensee can operate in compliance with applicable requirements
  - c =** Show cause why an Order to Modify, Suspend or Revoke the license or other regulatory sanctions should not be imposed
  - d =** Issuance of Order to Modify, Suspend or Revoke the license, without prejudice to the institution of criminal prosecution as provided for under Section 65 of RA 5207.

**NOTE:** *Repetitive occurrence of the same violation for at least three (3) times in the lower categories of severity may be cause for upgrading the violation to the next higher severity level.*

## **VI. EFFECTIVITY**

This Administrative Order shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation.

**APPROVED:**

**(Sgd) ALUMANDA M. DELA ROSA, Ph.D.**  
Director

Date: 19 February 2013

## APPENDIX A

### IDENTIFIED VIOLATIONS FOR EACH SEVERITY LEVEL

#### A. Severity Level I - Violations involving, but not limited to:

- Possession, ownership, storage, use or handling of radioactive materials without a PNRI license or possessing an expired or invalid license.
- Deliberate noncompliance with PNRI rules, regulations, orders, and license conditions regarding authorized use, authorized users or personnel, and authorized place of use of the radioactive materials.
- Failure to secure written approval from the PNRI for the transfer of radioactive materials.
- A system designed to prevent or mitigate a serious safety event was not able to perform its intended safety function when actually called upon to work.
- The theft or loss of radioactive sources in which the security system did not function.
- Actual unauthorized use of radioactive materials.
- Conduct of licensed activities by a technically unqualified or unauthorized person.
- Disposal of licensed radioactive materials in quantities or concentrations in excess of 10 times the limits of CPR Part 3.
- Significant injury or loss of life due to a loss of control over licensed or certified activities whether radioactive material is released or not.
- Inaccurate or incomplete information that is provided to the PNRI deliberately with the knowledge of the licensee representative that the information is incomplete or inaccurate.
- Incomplete or inaccurate information that the PNRI requires be kept by a licensee because of falsification by or with the knowledge of a licensee representative.
- Deliberately withholding of information from the PNRI that the licensee has identified as having significant implications for public health and safety, security, or the national interest.
- Radiation overexposures of personnel as a result of mishandling or mismanagement of radioactive materials and facilities for the following end-results or probable end-results:
  1. Personnel dose equivalent exposures will exceed ten (10) times the annual dose equivalent limits for radiation workers.
  2. Annual whole body exposures of a member of the public will exceed ten (10) times the annual dose equivalent limits for the public.
  3. Release of radioactive materials to unrestricted areas will exceed ten (10) times the PNRI limits set forth under Part 3 of the CPR.
  4. Breach of transport package integrity that will result in 1 or 2 or 3 of the above.
  5. Loss of radioactive material that will result in 1 or 2 or 3 of the above.
- Misadministration of medical procedures resulting in 1 or 2 or 3 of the above.
- Failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by CPR Part 13 that results in a death or serious injury (e.g., substantial organ impairment);
- Deliberate failure to possess radiation monitoring instruments (survey meters, pocket dosimeters) to monitor work area radiation dose rates, and personnel exposures.
- A radiation exposure during any year of a worker in excess of 250 mSv (25 rems) total effective dose equivalent, 750 mSv (75 rems) to the lens of the eye, or 2.5 gray (250 rads) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.
- A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 25 mSv (2.5 rems) total effective dose equivalent
- A radiation exposure during any year of a minor in excess of 25 mSv (2.5 rems) total effective dose equivalent, 750 mSv (7.5 rems) to the lens of the eye, or 250 mSv (25



rems) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.

- An annual exposure of a member of the public in excess of 10 mSv (1.0 rem) total effective dose equivalent.
- A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public.
- Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that the material caused a radiation exposure to a member of the public and there was clear potential for the public to receive more than 10mSv (1rem) to the whole body.
- Surface contamination in excess of 50 times the regulatory limit.
- External radiation levels in excess of 10 times the regulatory limit.
- Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license.

**B. Severity Level II - Violations involving, but not limited to:**

- Structures or systems that are completed or accepted by the licensee in such a manner that they would not have satisfied their intended safety related purpose.
- An act of radiological sabotage in which the security system did not function as required resulting in a breach of the safety and security of radioactive sources.
- A breakdown in the Quality Assurance (QA) program as exemplified by deficiencies in construction-QA related to more than one work activity (e.g.. structural, piping, electrical, foundations). These deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation.
- A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.
- A system designed to prevent or mitigate a serious safety event being inoperable.
- The entry into a vital area from outside the protected area of an unauthorized individual who represents a threat.
- Actual unauthorized production or distribution of radioactive material that is not authorized in the license.
- Failure to provide corrective actions or measures on the officially reported PNRI inspection findings of non-compliance.
- Use of radioactive material on humans where such use is not authorized.
- Failure to use a properly prepared written directive as required by CPR Part 13.
- Disposal of licensed material in quantities or concentrations in excess of five times the limits in CPR Part 3.
- A failure to make an immediate or 24-hour notification as required by the CPRs.
- Surface contamination in excess of ten (10), but not more than fifty (50) times the regulatory limit;
- External radiation levels in excess of five (5), but not more than ten (10) times the regulatory limit.
- Radiation levels, contamination levels, or releases that exceed five (5) times the limits specified in the license.
- A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, or a failure to train personnel in those procedures, that result in a medical event.
- Failure, during radiographic operations, to have at least two (2) qualified individuals present.
- Failure, during radiographic operations, to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by CPR Part 11.

- A failure to receive required PNRI approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet the safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance.
- Inaccurate or incomplete information that is provided to the PNRI by a licensee representative because of careless disregard for the completeness or accuracy of the information.
- Radiation overexposures of personnel as a result of the mishandling or mismanagement of radioactive materials and facilities for the following end-result or probable end-results:
  1. Personnel dose equivalent exposures will exceed five (5) times the annual dose equivalent limit for radiation workers.
  2. Annual whole body exposures of a member of the public will exceed five (5) times the annual dose equivalent limit for members of the public
  3. Release of radioactive material to unrestricted areas will exceed five (5) times the PNRI limits set forth under Part 3 of the CPR.
  4. Breach of transport package integrity that will result in 1 or 2 or 3 above.
  5. Loss of radioactive materials that will result in 1 or 2 or 3 above.
- Medical procedures misadministration whether in diagnostic or therapy resulting in 1 or 2 or 3 above.
- Deliberate failure to report to the PNRI incidents or accidents involving the handling of radioactive materials.
- A radiation exposure during any year of a worker in excess of 100mSv (10 rems) total effective dose equivalent, 300 mSv (30 rems) to the lens of the eye, or 1 Sv (100 rems) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.
- A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 10 mSv (1.0 rem) total effective dose equivalent.
- A radiation exposure during any year of a minor in excess of 10 mSv (1 rem) total effective dose equivalent; 30 mSv (3.0 rems) to the lens of the eye, or 100 mSv (10 rems) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.
- An annual exposure of a member of the public in excess of 5 mSv (0.5 rem) total effective dose equivalent.
- A release of radioactive material to an unrestricted area at concentrations in excess of ten (10) times the limits for members of the public.

**C. Severity Level III - Violations involving, but not limited to:**

- A failure or inability of established systems or procedures to control access to protected area such that an unauthorized individual could easily gain undetected access into a vital area from outside the protected area.
- A release of radioactive material to an unrestricted area at concentrations in excess of two (2) times the effluent concentration limits allowed for individual members of the public.
- A failure to make an immediate notification as required in the license for lost, missing or stolen radioactive sources or other incidents.
- A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public.
- Failure to secure, or maintain surveillance over, licensed materials that, where such failure is accompanied by the absence of a functional program to detect and deter

security violations that includes training, staff awareness, detection and corrective action.

- Surface contamination in excess of five (5), but not more than ten (10) times the regulatory limit.
- External radiation in excess of not more than five (5) times the regulatory limit.
- Any noncompliance with labeling, marking, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:
  - A significant failure to identify the type, quantity, or form of material;
  - A failure of the carrier or recipient to exercise adequate controls;
  - A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of radioactive material.
- Possession or use of unauthorized equipment or radioactive material in the conduct of licensed activities that degrades safety.
- A substantial potential for exposures, radiation levels, contamination levels, or releases, including releases of toxic material caused by a failure to comply with PNRI regulations, from licensed activities in excess of regulatory limits;
- A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, which does not result in a medical event.
- Failure to report a medical event.
- A programmatic weakness in the implementation of written directives or procedures for administrations requiring a written directive, whether or not a medical event occurs.
- A significant failure to meet decommissioning requirements including a failure to notify the PNRI as required by regulation or license condition, substantial failure to meet decommissioning standards, failure to conduct and/or complete decommissioning activities in accordance with regulation or license condition, or failure to meet required schedules without adequate justification.
- Equipment failures caused by inadequate or improper maintenance that substantially complicates recovery from an abnormal condition.
- A failure, during radiographic operations, to stop work after a pocket dosimeter is found to have gone off-scale, or after an electronic dosimeter reads greater than 2 mSv (200 mrem), and before a determination is made of the individual's actual radiation exposure.
- Incomplete or inaccurate information that is provided to the PNRI because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation.
- Incomplete or inaccurate information that the PNRI requires to be kept by a licensee because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation.
- Deliberate non-compliance with PNRI rules, regulations, orders, and license conditions on the requirement to have available written programs, procedures, reports, or records of relevant activities for the PNRI regulatory inspection.
- Deliberate failure to provide corrective actions or measures on the officially reported PNRI inspection findings of non-compliance.
- Radiation overexposures of personnel as a result of the mishandling or mismanagement of radioactive materials and facilities for the following end-result or probable end-result:
  1. Personnel dose equivalent exposures which exceeds the annual dose equivalent limit for radiation workers;
  2. Annual whole body exposures of a member of the public which exceeds the annual dose equivalent limit for members of the public; and
  3. Release of radioactive material to unrestricted areas which exceeds the PNRI limits set forth under Part 3 of the CPR.
- Medical procedures misadministration whether in diagnostic or therapeutic use resulting in 1 or 2 or 3 above.

- Breakdown in the radiation protection programs and procedures which may result in 1 or 2 or 3 above.
- Loss of radioactive sources which may result in 1 or 2 or 3 above.
- A radiation exposure during any year of a worker in excess of 50 mSv (5 rems) total effective dose equivalent, 150 mSv (15 rems) to the lens of the eye, or 500 mSv (50 rems) to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue.
- A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 5 mSv (0.5 rem) total effective dose equivalent.
- A radiation exposure during any year of a minor in excess of 5 mSv (0.5 rem) total effective dose equivalent; 15 mSv (1.5 rems) to the lens of the eye, or 50 mSv (5 rems) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.
- An annual exposure of a member of the public in excess of 1 mSv (0.1 rem) total effective dose equivalent.

**D. Severity Level IV - Violations involving, but not limited to:**

- Failure to meet regulatory requirements, i.e., QA Criterion, not amounting to Severity Level II or III violations that have more than minor safety, security, or environmental significance.
- A failure to conduct any search at the access control point or conducting an inadequate search that resulted in the introduction to the protected area of firearms, explosives, or incendiary devices that could significantly assist radiological sabotage or theft of radioactive material.
- A significant failure of the protection systems designed or used to prevent or detect the theft, loss, or diversion radioactive materials
- A failure to respond to a suspected event in either a timely manner or with an adequate response force.
- A failure to maintain patients hospitalized who have Cobalt-60, Cesium-137, or Iridium-192 implants.
- A failure to conduct required leakage or contamination tests, or to use properly calibrated equipment.
- A failure to keep the records required by the CPRs.
- Failure to maintain and implement radiation safety programs to keep radiation exposures as low as is reasonably achievable.
- A failure to make the required thirty (30) day notification.
- A failure to make a timely written report as required after the occurrence of any incident.
- A breach of package integrity without external radiation levels exceeding the regulatory limit or without contamination levels exceeding five (5) times the regulatory limits.
- Surface contamination in excess of but not more than five times the regulatory limit.
- A noncompliance with shipping papers, marking, labeling, placarding, packaging or loading not amounting to a Severity Level I, II, or III violation.
- Incomplete or inaccurate information that is provided to the PNRI but not amounting to a Severity Level I, II, or III violation.
- Failure to respond to a PNRI Official Inspection Report within the prescribed period of time indicated in the report.
- Deliberate failure to meet commitments or commitment dates as submitted to the PNRI.
- Possession of uncalibrated radiation instruments.
- Failure to comply with PNRI rules, regulations, orders, and license conditions on the requirement to have available written programs, procedures, reports, or records of relevant activities for the PNRI regulatory inspection.