

**PHILIPPINE NUCLEAR RESEARCH INSTITUTE**  
**Commonwealth Avenue, Diliman, Quezon City**

**ADMINISTRATIVE ORDER NO. 3**  
**Series of 2004**

**PROCEDURE FOR THE IMPOSITION OF REGULATORY SANCTIONS FOR VIOLATIONS OF  
PNRI LICENSING AND REGULATORY REQUIREMENTS RELATIVE TO THE ACQUISITION,  
POSSESSION AND USE OF RADIOACTIVE MATERIALS**

Pursuant to the authority granted to the Philippine Nuclear Research Institute under the provisions of RA 5207, as amended, the following procedure for the imposition of licensing and regulatory sanctions for violations of PNRI licensing and regulatory requirements is hereby promulgated.

Section 1. **Scope and Coverage**

The procedure adopted herein governs the conduct of proceedings for the imposition of administrative sanctions against persons or entity(ies) subject to the licensing and regulatory jurisdiction of the PNRI. Administrative sanctions consist of modification, suspension, and revocation of licenses. PNRI shall apply this procedure to all the stages of regulatory proceedings, including the evaluation of an application for a license and in the assessment of the licensee's performance as may be reflected in the regulatory inspection and audit of licensee's facilities and radioactive material by PNRI regulatory inspectors.

Section 2. **Definition of Terms**

As used in this Order:

- a. **ACT** means RA 5207, otherwise known as the "Atomic Energy Regulatory and Liability Act of 1968", as amended;
- b. **CEASE AND DESIST ORDER** means a PNRI order ordering the licensee to stop using the licensed radioactive facility and/or material, or the performance of a particular activity authorized in the license;
- c. **CODE** means the Code of PNRI Regulations;
- d. **DIRECTOR** means the Director of the Philippine Nuclear Research Institute;
- e. **INSPECTION REPORT** refers to official written report prepared by PNRI regulatory inspectors after every regulatory inspection conducted on the licensee's facility and/or radioactive material;
- f. **LICENSEE** means a person or entity authorized to conduct activity(ies) under a license issued by PNRI pursuant to the Act;
- g. **LICENSED ACTIVITY** refers to any activity described in the license that involves handling or use of radioactive facility and/or materials;
- h. **LICENSE MODIFICATION** means the act of changing or modifying any authority granted under the license to ensure that the regulations and conditions imposed on the license are adequately complied with;
- i. **LICENSE SUSPENSION** means the suspension of a portion or all of the licensed activities granted or authorized in the license arising from violations of regulatory requirements and/or conditions which pose risk to the health and safety of the workers and the general public;
- j. **LICENSE REVOCATION** means the termination, recall, and withdrawal of the authority granted on a person or entity to acquire, possess or use radioactive facility and/or material;
- k. **LIFT ORDER** means a PNRI order lifting the effectivity of the Cease and Desist Order issued;

1. **NOTICE OF VIOLATION** means the official written notification issued to a licensee informing him of the existence of one or more violations which notification may also require him for a formal written response describing:
  1. The reasons for the violation and, if contested by him, the basis for disputing the finding(s) of violation;
  2. Corrective steps that have been taken on the findings of violations and the results obtained;
  3. Corrective steps that will be taken to prevent recurrence of the findings of violations; and
  4. The date when full compliance to the corrective measures can be achieved.

Section 3. **Inspection and Investigation**

A licensee shall allow PNRI regulatory inspector(s) to enter, at all reasonable times, the facility of the licensee where the licensed radioactive material is stored or used, to perform such inspection or investigation, as may be necessary to determine whether or not the licensee complies with the requirements of the Code and the conditions of the license. Additional inspection or investigation may be conducted to resolve any outstanding safety issues. Inspection results, including findings of non-compliance and violation, are reviewed and consolidated in an Inspection Report a copy of which shall be furnished to the licensee. The licensee, if required, shall submit to the PNRI a formal written response within ten (10) days from receipt of the inspection report. The response shall contain the licensee's explanation of the findings of non-compliance or violation and the corrective measure taken to comply with the requirements of the Code and conditions of the license issued.

Section 4. **Notice of Violation**

- 4.1 A Notice of Violation is a written notice issued to the licensee setting forth one or more findings of violation on the requirements of the Code and conditions of the license. The Notice of Violation requires the licensee to provide a formal written statement or response describing:

- a. The reasons for the violation and, if contested, the basis for disputing the findings of violation(s);
- b. Corrective steps that have been taken on the findings of violation(s) and the results achieved;
- c. Corrective steps that will be taken to prevent recurrence of the finding(s) of violations; and
- d. The date when full compliance to the corrective measures can be achieved.

PNRI may waive all or portions of a written response to the extent that relevant information has already been provided to PNRI in writing or documented in the inspection report or record. PNRI may require responses to Notices of Violation to be made under oath.

- 4.2. If PNRI has determined one or more violations of the requirements of the Code and the conditions of the license, after evaluating the licensee's response to the Inspection Report, or if under certain circumstances, the same violations are reported by the licensee to the PNRI, a written Notice of Violation is served to the licensee. The licensee is required to respond to the PNRI in writing within ten (10) days from receipt of the Notice of Violation.
- 4.3. If the licensee shall contest the finding(s) of the Notice of Violation, its response shall contain the reasons and basis for disputing the findings of violation.
- 4.4. If the licensee shall fail to submit its response to the Notice of Violation within the specified period of ten (10) days, or if PNRI determines that the answer or response is not satisfactory, it may send a final demand letter requiring the licensee to explain in writing why appropriate administrative sanctions, as provided herein, shall not be imposed against said licensee.
- 4.5 PNRI may also direct the licensee, to whom a Notice of violation issued, to cease and desist from undertaking a licensed activity while the required corrective actions are being carried out. The cease and desist order shall:
  - a. State the particular requirements of the Code violated and/or the conditions of the license not complied with;
  - b. Indicate the specific restriction with respect to the use of radioactive materials or the licensed facility; and

- c. Require the licensee to file a response in writing within ten (10) days from receipt of the Notice of Violation, or in a shorter period of time as the circumstance(s) or situation may require.
- 4.6 To protect the health and safety of the public, PNRI may take temporary custody of any or all radioactive materials held by the licensee pending their appropriate and lawful disposition and/or the satisfactory compliance by the licensee to take the required corrective action.

Section 5. **Issuance of Orders of Modification, Suspension or Revocation**

PNRI may issue order(s) to modify, suspend or revoke a license, or take other actions(s) as may be proper against the licensee if the following circumstances exist, thus:

- 5.1 A license Modification Order shall be issued:
- a. When the licensee takes upon itself to implement changes in its equipment, program, procedures, or management control without prior approval from the PNRI; and
  - b. When PNRI determines that the licensee can no longer comply with the safety requirements specified in the license, or, on any privilege granted in the license.
- 5.2 A License Suspension Order shall be issued:
- a. When PNRI determines that the performance of the activity allowed under the license shall pose a threat to public health and safety, the environment and the national interest;
  - b. When PNRI determines that the performance of activities allowed under the license could prevent or hinder the identification or correction of a safety problem;
  - c. When PNRI determines that the implementation of the licensee's quality assurance or radiation safety program is not adequate to provide the needed confidence that safety measures can be properly carried out;
  - d. When the licensee interferes with the conduct of PNRI inspection or investigation activity(ies);
  - e. When the licensee fails to respond adequately to PNRI regulatory action; and
  - f. For other reasons not mentioned above, for which the suspension of the license shall still be appropriate and tenable under certain circumstances.

A License Suspension Order shall cause the suspension of the performance of activities involving the licensed radioactive facility or materials, and shall only be lifted when corrective actions described in the order are satisfactorily complied with.

- 5.3 A License Revocation Order shall be issued:
- a. When the licensee has willfully made a material false statement or willfully made misrepresentations in its application for a license;
  - b. When the licensee is unwilling or unable to comply with the conditions under which the license is issued;
  - c. When the licensee has refused to correct a violation or an unsafe operating condition;
  - d. When the licensee has refused to pay the required licensing and regulatory fees; and
  - e. For any other reasons for which the revocation of the license shall be appropriate and tenable under certain circumstance(s).

A license that is revoked shall not relieve the licensee from its obligation to undertake the decommissioning of its facility and the complete removal of residual radioactivity before the facility is released for unrestricted use.

Section 6. **Order and Decision**

- 6.1 All Notices of Violations, Orders, Decisions and other regulatory sanctions issued pursuant to the provisions of this Procedure shall be signed by the PNRI Director. Except in cases where the Order otherwise so provides, to protect the health and safety of the public or the national interest, no Order for the modification, suspension, or revocation of a license shall become effective until the licensee shall have been given the opportunity to be heard.

- 6.2 Motions for Reconsideration filed by a licensee to any Order issued by the PNRI Director pursuant to the provisions of this Procedure, shall be acted upon accordingly.
- 6.3 If a licensee shall request for a formal hearing in support of its stand in the motion for reconsideration, the PNRI Director shall form a Hearing Committee composed of two technical senior personnel and a lawyer, for the reception of evidence and argument of the licensee. Such Committee shall submit a report to the PNRI Director within thirty (30) days after the termination of the hearing requested.
- 6.4 All Orders and Decisions issued by the PNRI Director pursuant to the provisions of this Procedure shall be in writing, stating clearly and distinctly the facts and issues involved and the reasons upon which the Order or Decision is based, and the same shall be made available to the public.
- 6.5 Appeals from any final Order and/or Decision of the PNRI Director may be reviewed on appeal by the Courts of Appeals within thirty (30) days from receipt of said final Order or Decision.
- 6.6 On questions of law only such Order or Decision of the PNRI Director may be reviewed by the Supreme Court.

Section 7. **Repealing Clause**

All issuances, rules and regulations, inconsistent with this Order are hereby deemed repealed or modified accordingly.

**APPROVED:**

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

Date: 12 July 2004