

Republic of the Philippines Department of Science and Technology PHILIPPINE NUCLEAR RESEARCH INSTITUTE Commonwealth Avenue, Diliman, Quezon City

# **CPR PART 7**

## LICENSING OF NUCLEAR INSTALLATIONS, Rev. 01

## TABLE OF CONTENTS

I.	G	ENERAL PROVISIONS	. 1
	Section 1.	Purpose	. 1
	Section 2.	Scope	. 1
	Section 3.	Definitions	. 2
	Section 4.	Interpretation.	. 5
	Section 5.	Communication	. 5
	Section 6.	Applicability of other Regulations and Requirements, and Resolution of Conflicts	. 5
II.	R	EQUIREMENTS FOR LICENSING	. 6
	Section 7.	Pre-requisite to Licensing	. 6
	Section 8.	Licenses Required for Regulated Activities.	. 6
	8.1.	Licence to Construct	. 6
	8.2.	License to Operate	. 7
	Section 9.	General Requirements for License Applications	. 7
	Section 10	Specific Requirements for the Application for License to Construct	. 9
	Section 11	Specific Requirements for the Application for License to Operate	. 9
	Section 12	Requirements for the Safety Analysis Report	11
	Section 13	Filing of Applications	13
	Section 14	Completeness, Accuracy and Withholding of Information	13
Ш	. 18	SUANCE AND CONDITIONS OF LICENSES/PERMITS	14
	Section 15	Issuance and Conditions of Provisional Permit.	14
	Section 16	Issuance and Conditions of License to Construct	14
	Section 17	Issuance and Conditions of License to Operate	16
IV	′. A	MENDMENT; RENEWAL AND TERMINATION OF LICENSES	17
	Section 18	Amendment of License.	17

	Section 19. Renewal of License to Operate.	18
	Section 20. Termination of License	18
	Section 21. Periodic Safety Review	19
V	7. RECORDS, REPORTS, AND NOTIFICATIONS	20
	Section 22. Maintenance of Records, Making of Reports.	20
	Section 23. Immediate Notification Requirements.	21
	Section 24. Reporting of Events.	22
	Section 25. Inspections.	23
	Section 26. Violations	23
	Section 27. Modification, Suspension and Revocation of License.	23
۷	/I. EFFECTIVITY	24
	Section 28. Effective Date.	24



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# **CPR PART 7**

#### LICENSING OF NUCLEAR INSTALLATIONS, Rev. 01

## I. GENERAL PROVISIONS

#### Section 1. Purpose

- (a) This Part is promulgated pursuant to Republic Act No. 5207, otherwise known as the "Atomic Energy Regulatory and Liability Act of 1968", as amended, to establish the licensing and regulation of atomic energy facilities and materials in the Republic of the Philippines.
- (b) This Part provides for the licensing requirements for an application for a license to construct a new nuclear installation or to undertake major modifications and refurbishments of an existing nuclear installation; and for an application for a license to operate a nuclear installation including nuclear commissioning tests.

#### Section 2. Scope

- (a) This Part shall apply to application of License to Construct in order to begin the construction of a new nuclear installation; or modification or refurbishment of an existing nuclear installation, and to carry out non-nuclear commissioning tests at the end of the construction phase.
- (b) This Part shall also apply to application of License to Operate in order to begin the nuclear commissioning tests and operation of the nuclear installation.
- (c) This Part shall apply to license applications for the following nuclear installations:
  - (1) Nuclear power plants;
  - (2) Research reactors, including subcritical and critical assemblies, and any adjoining radioisotope production facilities;
  - (3) Storage facilities for spent fuel;
  - (4) Facilities for the predisposal management of radioactive waste arising from nuclear installations; and
  - (5) Nuclear fuel cycle related research and development facilities.

### Section 3. *Definitions*

As used in this Part:

- (a) **"Accident conditions"** means deviations from normal operation more severe than anticipated operational occurrences, including design basis accidents and design extension conditions. Examples of such deviations include a major fuel failure or a loss of coolant accident (LOCA).
- (b) **"Act"** means the Republic Act No. 2067, otherwise known as the Science Act of 1958, as amended by Republic Act No. 3589, and the Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484.
- (c) **"Anticipated operational occurrence"** means a deviation of an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety nor lead to accident conditions.
- (d) **"Applicant"** means a person or an organization who applies to a regulatory body for a license to construct or operate a nuclear installation, or parts of a nuclear installation, or to undertake specified activities.
- (e) **"Atomic energy facility"** means any equipment or device which the PNRI may determine from time to time, by regulation, to be capable of producing or utilizing energy material in such quantity or in such manner as to be significance to the national interest or to the health and safety of the public.
- (f) "Code" or "CPR" means Code of PNRI Regulations.
- (g) **"Commissioning**" means the process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria. Commissioning may include both non-nuclear testing (before the introduction of nuclear material) and nuclear testing (after the introduction of nuclear material).
- (h) **"Construction or constructing**" means the process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment and the performance of associated tests.
- (i) "Contractor" means any individual or organization that provides items or renders services in accordance with a contract or a procurement document. Contractors may include designers, architects, engineers, manufacturers, assemblers, installers, distributors, importers, suppliers, technical support organizations and other consultants and their subcontractors or subsidiaries.
- (j) "Decommissioning" means the administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for a repository or for certain nuclear facilities used for the disposal of residues from the mining and processing of radioactive material, which are 'closed' and not 'decommissioned') to ensure the long term protection of the public and the environment, and typically include reducing the levels of residual radionuclides in the materials and on the site of the facility so that the materials can be safely recycled, reused or disposed of as exempt waste or as radioactive waste and the site can be released for unrestricted use or otherwise reused;

- (k) "Design basis" means the range of conditions and events taken explicitly into account in the design of structures, systems and components and equipment of a facility, according to established criteria, such that the facility can withstand them without exceeding authorized limits.
- (I) "Design basis accident (DBA)" means a postulated accident leading to accident conditions for which a facility is designed in accordance with established design criteria and conservative methodology, and for which releases of radioactive material are kept within acceptable limits.
- (m) "Design extension conditions (DEC)" means postulated accident conditions that are not considered for design basis accidents, but that are considered in the design process of the facility in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits. Design extension conditions comprise conditions in events without significant fuel degradation and conditions in events with melting of the reactor core.
- (n) "Emergency" means a non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.
- (o) **"Emergency plan"** means a description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists.
- (p) **"Emergency preparedness"** means a description of the on-site emergency preparedness arrangements and the liaison and coordination with off-site organizations involved in the response to an emergency, covering the full range of accidents in particular design extension conditions.
- (q) **"License**" means legal document issued by the regulatory body to the applicant granting authorization to construct or operate a nuclear installation and to perform specified activities relating to a facility or activity.
- (r) "Licensee" means a holder of a current and valid license issued by the PNRI pursuant to this Part. The licensee is the person or organization having overall responsibility for a nuclear installation or activities and possessing all necessary licenses for the nuclear installation and its activities.
- (s) **"Normal operation"** means operation within specified operational limits and conditions. For a nuclear power plant, this includes startup, power operation, shutting down, shutdown, maintenance, testing and refuelling.
- (t) "Nuclear installation" means any nuclear facility subject to licensing that is part of the nuclear fuel cycle, except, for the purpose of this Part, facilities for the mining, processing of uranium ores or thorium ores, refining, conversion, enrichment and fabrication of fuel, including mixed oxide (MOX) fuel and radioactive waste disposal facilities.
- (u) **"Nuclear material"** means plutonium except that with isotopic concentration exceeding 80% in plutonium-238; uranium-233; uranium enriched in the isotope 235

or 233; uranium containing the mixture of isotopes as occurring in nature other than in the form of ore or ore residue; any material containing one or more of the foregoing; and such other fissionable material.

- (v) **"Operation"** means all activities performed to achieve the purpose for which an authorized facility was constructed. For a nuclear power plant, this includes maintenance, refuelling, in-service inspection and other associated activities.
- (w) "Optimization (of protection and safety)" means the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable (ALARA), economic and social factors being taken into account.
- (x) **"Periodic safety review"** means a systematic reassessment of the safety of an operational facility or activity carried out at regular intervals to deal with the cumulative effects of ageing, modifications, operating experience and technical developments, and aimed at ensuring a high level of safety throughout the operating lifetime of the facility or activity.
- (y) **"Person"** means:
  - (1) Any individual, corporation, firm, partnership, association, trust, estate, private or public body, whether corporate or not, group, or any government agency other than the PNRI, any province, city, municipality, or any political entity within the Philippines; and
  - (2) Any legal successor, representative, agent or agency of the foregoing.
- (z) **"Postulated initiating event (PIE)"** means an event identified during design as capable of leading to anticipated operational occurrences or accident conditions. The primary causes of postulated initiating events may be credible equipment failures and operator errors (both within and external to the facility) or human induced or natural events.
- (aa) **"Provisional Permit"** means a permission issued by the PNRI to the applicant of a License to Construct, on the basis of the technical information and data so far made available, to allow the conduct of activities prior to the issuance of a License to Construct.
- (bb) **"Radioactive material**" means material designated in national law or by a regulatory body as being subject to regulatory control because of its radioactivity;
- (cc) **"Regulatory body (PNRI)"** means an authority or a system of authorities designated by the government of a State as having legal authority to conduct the regulatory process, including issuing a license.
- (dd) **"Safety analysis"** means an evaluation of the potential hazards associated with the operation of a facility or the conduct of an activity.
- (ee) **"Safety Analysis Report"** means a consistent safety document or integrated set of documents constituting the licensing basis of the nuclear installation and updated under supervision of the regulatory body.
- (ff) **"Safety-related Structures, Systems and Components (SSC)"** means a general term encompassing all of the elements (items) of a facility or activity that contribute to protection and safety, except human factors.

- (1) Structures are the passive elements: buildings, vessels, shielding, etc.
- (2) A system comprises several components, assembled in such a way as to perform a specific (active) function.
- (3) A component is a discrete element of a system. Examples of components are wires, transistors, integrated circuits, motors, relays, solenoids, pipes, fittings, pumps, tanks and valves.

**NOTE**: Terms defined in the Act and in other Parts of the CPR shall have the same meaning when used in this Part unless such terms are specifically defined otherwise in this Part.

#### Section 4. Interpretation.

Except as specifically authorized by the PNRI Director in writing, no interpretation of the meaning of the requirements in this Part shall be recognized to be binding upon PNRI.

#### Section 5. *Communication.*

All communication and reports concerning this code shall be addressed to:

Office of the Director Philippine Nuclear Research Institute Commonwealth Avenue, Diliman, Quezon City

# Section 6. Applicability of other Regulations and Requirements, and Resolution of Conflicts.

- (a) The requirements in this Part shall be applied in conjunction with the radiation protection and safety requirements of CPR Part 3 – "Standards for Protection against Radiation", the safe transport requirements of CPR Part 4 – "Regulations on the Safe Transport of Radioactive Material in the Philippines", and the security requirements of CPR Part 26 – "Security of Radioactive Sources" and CPR Part 27 – "Security Requirements in the Transport of Radioactive Materials" and other applicable regulations.
- (b) This Part are in addition to, and not in place of, other applicable national and local laws and regulations.
- (c) This Part does not relieve the applicant or licensee from complying with the applicable laws of the Republic of the Philippines and regulations of other responsible government agencies.
- (d) If a conflict exists between requirements contained herein and other laws or regulations, the PNRI shall be notified of such conflict in order to initiate steps towards resolution.
- (e) Nothing in this Part shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

## II. REQUIREMENTS FOR LICENSING

#### Section 7. *Pre-requisite to Licensing.*

- (a) Any person who intends to construct and/or operate a nuclear installation shall, after selecting a suitable site in accordance with CPR Part 5 – "Requirements for Siting of Nuclear Installations",
  - (1) Notify the PNRI in writing and provide a description of the proposed activities and the proposed design of the nuclear installation;
  - (2) Provide a Site Evaluation Report which contains the results of the site evaluation performed in accordance with CPR Part 5 – " Requirements for Siting of Nuclear Installations".
- (b) The PNRI shall assess the acceptability of the proposed site and shall have the authority to establish conditions for the site or to reject a proposed site on the basis of safety concerns.
- (c) If the PNRI has found that the proposed site is suitable for construction and operation of a nuclear installation, the PNRI shall issue a formal regulatory position on the acceptability of the site, coming with possible additional requirements and information in accordance with CPR Part 5, which should address how appropriate participation of all interested parties and authorities is to be ensured.

#### Section 8. Licenses Required for Regulated Activities.

#### 8.1. Licence to Construct

- (a) No person may begin the construction of a nuclear installation on a site on which the nuclear installation is to be operated until that person has been issued a License to Construct in accordance with this Part.
- (b) Activities constituting construction shall include the following:
  - (1) Driving of piles;
  - (2) Subsurface preparation;
  - (3) Placement of backfill, concrete, or permanent retaining walls within an excavation;
  - (4) Installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:
    - (i) Safety-related structures, systems, or components (SSCs) of a nuclear installation;
    - (ii) SSCs relied upon to mitigate accidents or transients or used in emergency operating procedures;
    - (iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;
    - (iv) SSCs whose failure could cause an actuation of a safety-related system;
    - (v) SSCs necessary to comply with physical protection measures; and

- (vi) Onsite emergency facilities, such as technical support and operations support centers.
- (c) Upon the request of the applicant and subject to the conditions set forth in Section 15 of this Part, the PNRI may issue a Provisional Permit to the applicant prior to the issuance of a License to Construct if the application is otherwise acceptable, to allow the applicant to perform non-SSC related activities not constituting construction, in accordance with Subsection 8.1 (b).
- (d) The following activities may be allowed under the Provisional Permit:
  - (1) Changes for temporary use of the land for public recreational purposes;
  - (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
  - (3) Preparation of a site for construction of a nuclear installation, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
  - (4) Erection of fences and other access control measures;
  - (5) Excavation;
  - (6) Erection of support buildings, such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings, for use in connection with the construction of the nuclear installation;
  - (7) Building of service facilities, such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;
  - (8) Procurement or fabrication of components or portions of the proposed nuclear installation occurring at other than the final, in-place location at the nuclear installation; or
  - (9) The erection of buildings which will be used for activities other than operation of a nuclear installation and which may also be used to house a nuclear installation (e.g., the construction of a college laboratory building with space for installation of a training reactor).

## 8.2. License to Operate.

- (a) No person may begin the commissioning or operation of a nuclear installation until that person has been issued a License to Operate in accordance with this Part.
- (b) In respect to nuclear power reactors, the term "operation" shall be deemed to include all activities starting with the initial core loading and throughout the lifetime of such nuclear installation.

## Section 9. General Requirements for License Applications.

(a) An application for a license shall include the following general information:

- (1) Name of the applicant, business address, description of business or occupation of applicant, citizenship (if the applicant is an individual), and the names, addresses and citizenship of its directors and of its principal officers;
- (2) Description of business of the applicant, including information establishing that it is a juridical entity registered in the Securities and Exchange Commission;
- (3) The type of license applied for, and a list of other licenses, issued or applied for in connection with the proposed nuclear installation;
- (4) Brief description of the nature of the nuclear installation, its technical characteristics, the operating principles, the operations to be performed in it and the various phases;
- (5) A map of the location of the nuclear installation to be licensed, including the location of any exclusion zone, and any structures within that zone;
- (6) A site plan indicating the areas, structures, systems and perimeter of the nuclear installation, including the buildings, if any, with their current uses, the public highways or railways, water sources, as well as electricity transmission networks around its perimeter.
- (7) Information sufficient to demonstrate the technical qualification of the applicant to carry out, in accordance with the Code of PNRI Regulations, the activities for which a license is sought;
- (8) Information describing its human resource requirements for the proposed nuclear installation;
- (9) Information on the acquisition of the structures, systems and components and their origin, and, as applicable, details of the manufacturing process for structures, systems and components important to safety;
- (10) Information on the contractors and a description of responsibilities between the applicant and any contractors responsible for the siting, design, construction and operation of the nuclear installation;
- (11) Information describing the applicant's projected financial resource requirements necessary to, as applicable:
  - (i) Cover estimated construction costs and related fuel cycle costs; or
  - (ii) Cover estimated operation costs for the period of the license; and
  - (iii) Cover estimated decommissioning costs of the nuclear installation, including the management of the resulting radioactive waste and spent fuel; and
  - (iv) Cover the applicant's liability for nuclear damage.
- (b) The applicant shall describe the Management System of the operating organization, including its projected financial and human resource requirements for the proposed nuclear installation.
- (c) The applicant shall describe its strategic plans for public involvement, including the proposed programs for the consultation processes, information sharing to persons living in the vicinity of the site, and other communications, as applicable.
- (d) The applicant shall provide information of the strategic plan for the licensing process, including the set of requirements, guides, codes and standards to comply with, which may be partly adopted from the vendor State (if any).

### Section 10. Specific Requirements for the Application for License to Construct.

The applicant for a License to Construct shall provide information in its application which demonstrates that the proposed nuclear installation will be designed and constructed in compliance with the applicable laws of the Republic of the Philippines and the regulations of the PNRI. In addition to the information required in Section 9, the application for a License to Construct shall have the following:

- (1) A certification of a standardized design for a nuclear installation, or if not available, a design verified and validated by individuals or groups separate from those who originally performed the design work;
- (2) The proposed Quality Assurance Program for implementing or modifying the design of the nuclear installation;
- (3) A detailed demonstration of safety, which shall be presented in the form of a Preliminary Safety Analysis Report (PSAR) in accordance with Section 12 of this Part;
- (4) The proposed Construction Program and a timeline of the anticipated commencement of construction and completion dates, outlining the major construction phases;
- (5) The Environmental Compliance Certificate issued by the Department of Environment and Natural Resources (DENR), including a copy of the Environment Impact Assessment report that describes the effects on the environment and the health and safety of persons that may result from the construction, operation and decommissioning of the nuclear installation, and the measures that will be taken to prevent or mitigate those effects;
- (6) The Physical Protection Plan for the construction phase to describe how the applicant will protect the construction site against unauthorized intrusions, theft and sabotage. In addition, the applicant shall also submit preliminary information on the physical protection of the nuclear installation during the operation phase. This plan and other related information shall be protected against unauthorized disclosure;
- (7) Measures necessary to implement the Philippine Safeguards agreement with the International Atomic Energy Agency. (All safeguards related information shall be protected against unauthorized disclosure); and
- (8) The initial Decommissioning Plan, which presents the methodological principles and the steps envisaged for decommissioning of the nuclear installation and rehabilitation and subsequent supervision of the site.

#### Section 11. Specific Requirements for the Application for License to Operate.

The applicant for a License to Operate shall provide information in its application which demonstrates that the nuclear installation will be commissioned and operated in compliance with the applicable laws of the Republic of the Philippines and the regulations of the PNRI. In addition to the information required in Section 9, the applicant shall provide the following:

- (1) The updated schedule outlining the nuclear commissioning tests and the commencement of operation and other operation phases and milestones and an outline of the major operation phases;
- (2) The Final Construction Report, including a summary of the results of the nonnuclear commissioning tests carried out, which demonstrates that the proposed nuclear installation has been designed and constructed in accordance with the License to Construct and in compliance with the applicable laws and the regulations of the PNRI;
- (3) The Final Safety Analysis Report in accordance with Section 12 of this Part, which provides an update or revision on the information that was included in the Preliminary Safety Analysis Report (PSAR) and additional or new information describing the final design and operation of the nuclear installation;
- (4) The Commissioning Program, to demonstrate that the nuclear installation as built is consistent with the provisions of the Safety Analysis Report and in compliance with the Act and this Code;
- (5) The Radiation Protection Program, commensurate with the scope and extent of licensed activities and sufficient to show compliance with the requirements of CPR Part 3, "Standards for Protection against Radiation".
- (6) The Environmental Monitoring Program, including measures to control releases of nuclear substances and hazardous substances into the environment and the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear installation, and the measures that will be taken to prevent or mitigate those effects;
- (7) The Emergency Preparedness Plan, including arrangements for the emergency preparedness and response to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security;
- (8) The Training Program for all staff with tasks important to safety, including the initial training in order to qualify for a certain position and regular refresher training or requalification of workers;
- (9) The Radioactive Waste Management Program and an updated Decommissioning Plan, including technical solutions, the policy framework for disposal and funding;
- (10) The Aging Management Program, to identify all aging mechanisms relevant to structures, systems and components (SSCs) important to safety, their possible consequences, and necessary activities in order to maintain the operability and reliability of these SSCs.
- (11) The Physical Protection Plan, which contains effective measures to prevent, detect and respond to unauthorized acts involving ionizing radiation sources that may cause injury to persons, property or the environment in the Philippines or otherwise jeopardize national security;
- (12) The proposed measures necessary to implement the Philippine Safeguards agreement with the International Atomic Energy Agency;
- (13) Procedures for handling, storing, loading and transporting nuclear and radioactive materials in accordance with applicable regulations; and

(14) Policies, methods and procedures for the operation and maintenance, testing, surveillance and inspection of structures, systems and components important to safety.

#### Section 12. Requirements for the Safety Analysis Report.

The Safety Analysis Report shall include the following information, but shall not be limited to -

- (1) A statement of the main purpose of the SAR, a description of the existing license status and the identification of the designer, vendor, constructor and operating organization of the nuclear installation, information on the preparation of the SAR, its structure, objectives and scope of each of its sections and the intended connections between them.
- (2) General description of the site and of the nuclear installation, including the basic technical characteristics of the proposed installation, information on the layout and other related aspects, description of the operating modes of the proposed nuclear installation, including startup, normal operation, shutdown, refueling and any other allowable modes of operation.
- (3) Identification of any reference nuclear installation, evidence of approval of the reference nuclear installation by the authorized regulatory authority in the country of origin, a list of proposed departures or changes to the submitted reference design, an independent safety verification report describing all proposed departures from or changes to the reference design, and a list of all country of origin safety information incorporated by reference in the SAR.
- (4) Description and evaluation the operating organization's management system that will be implemented, including its structure, procedures and processes to assure satisfactory control of all aspects of safety, security and safeguards throughout the operating lifetime of the nuclear installation, and its strategy for the development, maintenance and enhancement of a strong safety culture, and the principal aspects of the quality assurance system developed for the nuclear installation.
- (5) Description of the site evaluation including site reference data, evaluation of site specific hazards and information on the proximity of industrial, transport and military facilities and other activities at or near the site that may influence the safety of the proposed nuclear installation, information on the hydrology, meteorology and seismology conditions of the proposed nuclear installation and the surrounding site shall also be included, description of the radiological conditions due to external sources, site-related issues in emergency planning and accident management, radiological and non-radiological impacts of the proposed nuclear installation during operation and accident conditions, and monitoring of site related parameters and an emergency plan during construction, including consideration of fire, flooding, and security violations.
- (6) Description of the general design of the proposed nuclear installation including safety objectives and criteria, design principles, applicable codes and standards, the classification of SSCs, descriptions of the civil engineering works, structures and equipment qualification, and environmental factors relating to nuclear safety, provisions for human factors engineering and proposed nuclear installation protection against internal and external hazards.

- (7) Description of the structures, systems and components (SSCs) of the nuclear installation that are important to safety, including a discussion of their safety objectives, design bases, safety classification, design and construction codes and the inspection, tests and analysis that provide reasonable assurance that the system will meet its design objectives. The level of detail of each description should be commensurate with the safety importance of the item described. Regardless of the type of nuclear installation and design, this chapter in the SAR shall be organized into three subsections: system description, engineering evaluation and safety assessment.
- (8) Description of the results of the safety analyses performed to assess the safety of a nuclear installation on the basis of safety criteria and authorized limits on radioactive releases including safety objectives and acceptance criteria, identification and classification of postulated initiating events (PIE), deterministic safety analyses in support of normal operation, analyses of anticipated operational occurrences, design basis accidents, design extension conditions, and probabilistic safety analyses (PSAs). Safety margins shall be described.
- (9) Description of the commissioning program to be adopted prior to entering the operational phase, including the tests intended to validate the installation's performance against the design prior to the operation of the nuclear installation. In the FSAR, a summary of the results of the non-nuclear commissioning tests carried out at the end of the construction phase and a commitment to a nuclear commissioning test program to be conducted.
- (10) Description of operational aspects relevant to safety including a description of the arrangements of the operating organization and specify the functions and responsibilities of the different components within it.
- (11) Description of operational limits and conditions (OLCs) in the form of controls, limits, conditions, rules and required actions, based on the safety analyses of the nuclear installation and its environment in accordance with the provisions made in the design.
- (12) Description of the policy, strategy, methods, and provisions for radiation protection, including a description of all on-site radiation sources, the application of the "as low as reasonably achievable" (ALARA) principle for the optimization of protection and safety, and design features for radiation protection of personnel and the nuclear installation in accordance with CPR Part 3.
- (13) Description of the on-site emergency preparedness, demonstrating in a reasonable manner that, in the event of an accident, all actions necessary for the protection of the public, workers and the nuclear installation could be taken, and that the decision making process for implementation of these actions would be timely, disciplined, coordinated and effective.
- (14) Description of the approach taken to assess the impact on the environment of the construction of the nuclear installation, its operation under normal conditions and its decommissioning.
- (15) Description of the on-site radioactive waste management provisions, including as applicable, arrangements for identification and control of radioactive waste streams, proposals for authorized discharges of radioactive waste, and

arrangements for pre-treatment, treatment, conditioning and storage of residual radioactive waste prior to final disposal.

(16) Description of how the relevant decommissioning and end-of-life aspects are taken into account, including the relevant design aspects that support safe decommissioning.

#### Section 13. Filing of Applications.

- (a) Applications for a License to Construct shall be filed at least three (3) years prior to the planned commencement of construction for nuclear power plants and at least one (1) year for non-power nuclear installations.
- (b) Applications for a License to Operate shall be filed at least one (1) year prior to the proposed starting date of nuclear commissioning tests for nuclear power plants and at least six (6) months for non-power nuclear installations.
- (c) Each filing of an application for license, including whenever appropriate any amendments thereof, correspondence, reports or other written communications from the applicant pertaining to such application shall be submitted to the PNRI in accordance with Section 5 of this Part.
- (d) Each application for a license and each amendment of each application shall be executed in twenty (20) copies, at least ten (10) of which shall be hard copies, duly signed by the applicant or an authorized officer thereof under oath or affirmation.
- (e) The applicant shall maintain the capability to generate additional copies of the documents submitted during the application, or part thereof or amendment thereto, for subsequent distribution in accordance with the written instructions of the PNRI.
- (f) The PNRI may, by rule, order, or regulation impose upon any applicant/licensee such requirements, in addition to those established in this Part, as it deems appropriate or necessary to protect the health and safety of the public or to minimize danger to life, property, and the environment.
- (g) Each application for a nuclear installation license shall be accompanied by such fee as prescribed in the regulations.

#### Section 14. Completeness, Accuracy and Withholding of Information.

- (a) Information provided to the PNRI by an applicant or by a licensee or information required by the regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.
- (b) An applicant seeking to withhold certain information in its application from public disclosure shall prominently mark the document with "**Restricted Information**" and provide statement that identifies which part of the application the applicant seeks to withhold. The applicant shall provide basis for restricting this information from public disclosure and a statement of the effects that would result if the information sought to be withheld is disclosed to the public. The applicant's request to withhold certain information from public disclosure is subject to approval by the PNRI.

(c) All Safeguards and Physical Protection related information shall be protected against unauthorized disclosure.

# **III. ISSUANCE AND CONDITIONS OF LICENSES/PERMITS**

## Section 15. Issuance and Conditions of Provisional Permit.

- (a) Upon the formal request of the applicant, the PNRI may issue a Provisional Permit to the applicant only after:
  - (1) The PNRI has found that the proposed site is suitable for the construction and operation of the nuclear installation in accordance with CPR Part 5, "Requirements for Siting of Nuclear Installations".
  - (2) The PNRI determines that the applicable standards and requirements of the Act, and the PNRI regulations applicable to the activities to be conducted under the License to Construct, can be met and the applicant is technically qualified to engage in the activities authorized; and
  - (3) The PNRI finds that there are no unresolved safety issues relating to the activities to be conducted under the Provisional Permit that would constitute good cause for withholding the permit.
- (b) The Provisional Permit shall specify the activities that the holder is authorized to perform.
- (c) Any activities undertaken under a Provisional Permit shall entirely be at the risk of the applicant and the issuance of the Provisional Permit has no bearing on the issuance of a License to Construct with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.
- (d) If the underlying application for License to Construct is withdrawn by the applicant or denied by the PNRI, or the Provisional Permit is revoked by the PNRI, then the holder shall begin implementation of the redress plan in a reasonable time. The holder shall also complete the redress of the site no later than **18 months** after the withdrawal of the application or revocation of the Provisional Permit, or upon effectivity of the PNRI's final decision denying the associated application for License to Construct, as applicable.

## Section 16. Issuance and Conditions of License to Construct.

- (a) The PNRI shall issue a License to Construct in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:
  - (1) The application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to ensure the health and safety of workers, members of the public and the environment;

- (2) The applicant has established, maintained and will continue to improve its management system to achieve and enhance nuclear safety by ensuring that other demands on the operating organization are not considered separately from nuclear safety requirements;
- (3) The applicant has and will continue to maintain adequate financial resources for regulatory fees and liability insurance for nuclear damage, and for funding of the construction and of maintenance of a nuclear installation;
- (4) The applicant has adequate human resources to safely construct and maintain the nuclear installation, and to ensure that regulatory requirements and safety standards are met and will continue to be met;
- (5) The framework and schedule for construction and acquisition of structures, systems and components are adequate;
- (6) The nuclear installation will be designed and constructed in accordance with the relevant site parameters identified by the applicant and agreed with the PNRI, and in an adequate manner;
- (7) The basic design of the proposed nuclear installation is such that safety requirements can be met in accordance with the design basis;
- (8) Planned deviations from the approved design will be fully analyzed in relation to the original design intentions and submitted to the PNRI for assessment and approval;
- (9) Radiological monitoring equipment and devices are clearly defined, and will be installed and operational before the nuclear or radioactive material is brought onto the site;
- (10) Provisions are made in the design to account for security aspects to minimize potential conflicts between safety and physical protection considerations;
- (11) Provisions are made in the design for requirements concerning the installation of the IAEA's safeguards equipment for non-proliferation control purposes;
- (12) There are no unresolved safety issues relating to the activities to be conducted under the License to Construct that would constitute good cause for withholding the license; and
- (13) The application meets the standards and requirements of the Act and the regulations of the PNRI applicable to the activities to be conducted under the License to Construct, and that notifications, if any, to other agencies or bodies have been duly made.
- (b) The License to Construct shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the PNRI.
- (c) The License to Construct shall be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.
- (d) The License to Construct shall be valid for a maximum of ten (10) years or for period specified by the PNRI in the license depending on the type of nuclear installation.
- (e) The License to Construct shall state the earliest and latest dates for completion of the construction or modification.

- (f) If the proposed construction or modification of the nuclear installation is not completed by the latest completion date, the License to Construct shall expire and all rights are forfeited. However, upon good cause shown, the PNRI may extend the completion date for a reasonable period of time.
- (g) The License to Construct shall be cancelled in the event that the licensee is unable to start the construction of the nuclear installation within five (5) years after the issuance of the License to Construct.

#### Section 17. Issuance and Conditions of License to Operate.

- (a) The PNRI shall issue a License to Operate to the applicant in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:
  - (1) The construction of the nuclear installation has been substantially completed, and in conformity with the License to Construct;
  - (2) The nuclear installation will operate in conformity with the application as amended, and with the provisions of the Act, and the rules and regulations of the PNRI;
  - (3) The applicant has established, maintained and will continue to improve its management system to achieve and enhance nuclear safety by ensuring that other demands on the operating organization are not considered separately from nuclear safety requirements;
  - (4) There is reasonable assurance that the activities authorized by the license can be conducted without endangering the health and safety of the public and the environment, and that such activities will be conducted in compliance with the PNRI regulations;
  - (5) The applicant has adequate human resources to maintain, operate and decommission the nuclear installation, and to ensure that regulatory requirements and safety standards are met and will continue to be met;
  - (6) The applicant has and will continue to maintain adequate financial resources for regulatory fees and liability insurance for nuclear damage, and for funding of the operation and decommissioning stages and of maintenance of a nuclear installation;
  - (7) The applicant has adequate physical protection measures to prevent unauthorized intrusions, theft and acts of sabotage or attempted sabotage at the nuclear installation;
  - (8) The applicant has adequate measures necessary to implement the Philippine safeguards agreement with the International Atomic Energy Agency;
  - (9) The proposed activities will serve a useful purpose proportionate to the quantities of special fissionable or source material to be utilized and are consistent with the policies set forth in the Act;
  - (10) There is reasonable assurance that adequate protective measures, both onsite and off-site, can and will be taken in the event of a radiological emergency;

- (11) The issuance of the license will not be inimical to the common defense and security or to the health and safety of the public and the environment;
- (12) There are no unresolved safety issues relating to the activities to be conducted under the License to Operate that would constitute good cause for withholding the license; and
- (13) The application meets the standards and requirements of the Act and the PNRI regulations applicable to the activities to be conducted under the License to Operate, and that notifications, if any, to other agencies or bodies have been duly made.
- (b) The License to Operate shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the PNRI.
- (c) The License to Operate shall be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms provided by the Act and regulations.
- (d) The License to Operate, including any right thereunder, shall not be transferred, assigned or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the PNRI, after securing full information finds that the transfer or disposition is in accordance with the purposes and provisions of the Act and gives its license in writing.
- (e) The licensee that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the nuclear installation, until the PNRI notifies the licensee in writing that the license is terminated. During such period of continued effectivity, the licensee shall:
  - (1) Take actions necessary to decommission and decontaminate the nuclear installation and continue to maintain the nuclear installation, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition, and
  - (2) Conduct activities in accordance with all other restrictions applicable to the nuclear installation in accordance with the PNRI regulations and the provisions of the specific license for the nuclear installation.
- (f) The License to Operate shall include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety and create unacceptable risks for the environment.
- (g) The License to Operate shall be valid for a maximum of forty (40) years or for period specified by the PNRI in the license depending on the type of nuclear installation. Licenses may be renewed upon the expiration of the validity period taking into account the level of safety required at the time of the renewal.

#### IV. AMENDMENT; RENEWAL AND TERMINATION OF LICENSES

Section 18. Amendment of License.

- (a) A licensee who desires to incorporate any modification in the approved design or licensing basis of the nuclear installation, shall file an application for an amendment in the license, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications and shall specify in what respect the licensee desires his license to be amended, the safety analysis and the justification for such amendment.
- (b) In determining whether an amendment to a license will be issued to the applicant, the PNRI will be guided by the considerations which govern the issuance of initial licenses, to the extent applicable and appropriate.
- (c) The PNRI may make a final determination that a proposed amendment to a License to Operate involves no significant hazards consideration, if operation of the nuclear installation in accordance with the proposed amendment would not:
  - (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or
  - (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or
  - (3) Involve a significant reduction in a margin of safety.
- (d) The corresponding license amendment fee required in the regulations shall be paid upon filing of the application for amendment.

#### Section 19. *Renewal of License to Operate.*

- (a) Each application for license renewal shall include the following:
  - (1) Any changes in the operational limits and conditions or additions necessary to manage the effects of aging during the period of extended operation as part of the renewal application. The justification for changes or additions to the operational limits and conditions shall be contained in the license renewal application.
  - (2) Information that demonstrate that structures, systems, and components important to safety will continue to perform their intended function for the requested period of extended operation; and
  - (3) A description for management of issues associated with aging that could adversely affect structures, systems, and components important to safety.
- (b) Applications for renewal of a license shall be filed at least 2 years before the expiration of the existing license.
- (c) In any case in which a licensee, not less than two years prior to expiration of its existing license, has filed an application in proper form for renewal of a license, the existing license shall not expire until a final decision concerning the application for renewal has been made by the PNRI.

#### Section 20. Termination of License.

(a) A licensee that permanently ceases operations shall make application to terminate the License to Operate within 2 years following permanent cessation of operations,

and in no case later than 1 year prior to expiration of the License to Operate. Each application for termination of a license shall be accompanied by an updated decommissioning plan.

- (b) If the decommissioning plan demonstrates that the decommissioning will be performed in accordance with the regulations and will not be inimical to the common defense and security or to the health and safety of the public and the environment, and after notice to interested parties, the PNRI will approve the plan subject to such conditions and limitations as it deems appropriate and necessary.
- (c) The PNRI will terminate the License to Operate upon the approval of the decommissioning plan. The approved decommissioning plan will be a supplement to the application for a license to decommission in accordance with the applicable regulations.

#### Section 21. Periodic Safety Review

- (a) The licensee shall have the prime responsibility to re-assess systematically and regularly if the nuclear installation remains fit to continue operation. That safety reassessment, hereinafter termed as Periodic Safety Review, shall be done to ensure compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in.
- (b) The Periodic Safety Review shall identify and evaluate the safety significance of deviations from applicable current safety standards and internationally recognized good practices taking into account operating experience, relevant research findings, and the current state of technology.
- (c) All reasonably practicable improvement measures shall be implemented by the licensee as a result of the review, in a timely manner.
- (d) An overall assessment of the safety of the nuclear installation covering the period until the next PSR shall be provided, and adequate confidence in the safety of the nuclear installation for continued operation demonstrated, based on the results of the review in each area. This assessment shall highlight any issues that might limit the future safe operation of the nuclear installation and explain how they will be managed.
- (e) The Periodic Safety Review shall be made periodically, at least every ten years, but a safety review may be carried out at any time at the request of the regulatory body when concerns about safety arise, or may be initiated by the licensee.
- (f) The scope of the review shall be clearly defined and justified. The scope shall be as comprehensive as reasonably practical with regard to significant safety aspects of an operating nuclear installation and, as a minimum the following safety factors shall be covered by the review:
  - (1) Nuclear installation design;
  - (2) Actual condition of structures, systems and components (SSCs) important to safety;
  - (3) Equipment qualification;

- (4) Ageing;
- (5) Deterministic safety analysis;
- (6) Probabilistic safety assessment;
- (7) Hazard analysis;
- (8) Safety performance;
- (9) Use of experience from other nuclear installations and research findings;
- (10) Organization, the management system and safety culture;
- (11) Procedures;
- (12) Human factors;
- (13) Emergency planning;
- (14) Radiological impact on the environment.
- (g) The review shall use an up-to-date, systematic, and documented methodology, taking into account deterministic as well as probabilistic assessments.
- (h) Each area shall be reviewed and the findings compared to the licensing requirements as well as to current safety standards and practices. The safety significance of all findings shall be evaluated using an appropriate approach. A global assessment shall consider all findings (positive and negative) and their cumulative effect on safety, and shall identify what safety improvements are reasonably practicable.

## V. RECORDS, REPORTS, AND NOTIFICATIONS

#### Section 22. Maintenance of Records, Making of Reports.

- (a) The licensee, including the holder of a Provisional Permit, shall maintain all records and make all reports, in connection with the licensed activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the PNRI in effectuating the purposes of the Act. Reports shall be submitted to the PNRI in accordance with Section 5 of this Part.
- (b) Records that are required by the provisions of this Part or by license conditions shall be retained for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified, these records shall be retained until the PNRI terminates the license. In addition, the records may also be needed longer for historical, future decommissioning or liability reasons.
- (c) The licensee shall submit its annual financial report, including the certified financial statements, to the PNRI upon issuance of the report.
- (d) The licensee shall update periodically the safety analysis report (SAR) originally submitted as part of the application for the license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the PNRI by the applicant or licensee or prepared by the applicant or licensee

pursuant to PNRI requirement since the submittal of the original SAR, or as appropriate, the last update to the SAR under this section.

- (1) The licensee shall submit revisions containing updated information to the PNRI on a replacement-page basis that is accompanied by a list which identifies the current pages of the SAR following page replacement.
- (2) The submittal shall include a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the PNRI, or that no such changes were made; and an identification of changes made but not previously submitted to the PNRI.
- (3) The updated SAR shall be retained by the licensee until the PNRI terminates the license.
- (e) The licensee shall keep records of the following information important to decommissioning which consists of:
  - (1) Records of spills or other unusual occurrences involving the spread of contamination in and around the nuclear installation, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
  - (2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
- (f) The licensee shall mark all reports made or filed under this Part with an appropriate protection and classification and shall file reports under the appropriate security precautions in accordance with Section 14 of this Part.

#### Section 23. Immediate Notification Requirements.

- (a) The licensee shall immediately notify the PNRI by telephone or by any fast means of communication and after notification of the appropriate local agencies, as applicable, of any of the following situations:
  - (1) Any event requiring initiation of the emergency plan or any section of that plan;
  - (2) An event that is likely to result in the exposure of persons to radiation in excess of the applicable radiation dose limits prescribed in CPR Part 3;
  - (3) A release of a quantity of nuclear or radioactive substance into the environment not authorized by the license;
  - (4) An attempted or actual breach of security or an attempted or actual act of sabotage at the site of the nuclear installation;

- (5) An actual or attempted work disruption by workers;
- (6) A serious injury or illness or death incurred or possibly incurred as a result of the licensed activity; or
- (7) Any event or condition that resulted in the serious degradation of any component or system of the nuclear installation which could have a serious adverse effect on the environment or constitutes or is likely to constitute or contribute to a serious risk to the health and safety of persons or the maintenance of security.
- (b) Follow-up notification. With respect to the telephone notifications made under paragraph (a) of this section, in addition to making the required initial notification, the licensee, shall during the course of the event:
  - (1) Immediately report:
    - Any further degradation in the level of safety of the nuclear installation or other worsening conditions, any change from one type of emergency to another, or termination of an emergency;
    - (ii) The results of ensuing evaluations or assessments of conditions, the effectiveness of response or protective measures taken, and information related to the behavior of the nuclear installation that is not understood.
  - (2) Maintain an open, continuous communication channel with the PNRI, and shall close this channel only when notified by the PNRI.
- (c) The licensee shall submit an event report for any of the events described in par. (a) in accordance with Section 23 of this Part.

#### Section 24. *Reporting of Events.*

- (a) The licensee shall use a safety significance classification system as documented in its management system to determine the safety significance of a situation or event.
- (b) After determining if a situation or event is reportable, the licensee shall file an event report within thirty (30) days after the occurrence or discovery of the event. All events described in Section 23 requiring an immediate notification shall also be filed within this period.
- (c) The event report shall contain, as applicable:
  - (1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence;
  - (2) A clear, specific, narrative description of what occurred so that knowledgeable readers conversant with the design of the nuclear installation, but not familiar with the details of a particular installation, can understand the complete event;
  - (3) An assessment of the safety consequences and implications of the event;
  - (4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future;
  - (5) Reference to any previous similar events at the same installation that are known to the licensee; and

- (6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the nuclear installation's characteristics.
- (d) The PNRI may require the licensee to submit specific additional information beyond that required by paragraph (c) of this section if the PNRI finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee shall submit the requested information as a supplement to the initial event report.

## IV. INSPECTION AND ENFORCEMENT

## Section 25. Inspections.

- (a) The licensee shall permit inspection, by duly authorized PNRI representatives, of his records, premises, activities, and of licensed materials in possession or use, related to the license or Provisional Permit as may be necessary to effectuate the purposes of the Act, as amended.
- (b) The licensee shall afford any PNRI Inspector assigned to that site, or other PNRI inspectors identified as likely to inspect the nuclear installation, immediate unfettered access, equivalent to access provided to regular employees in the nuclear installation, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety.
- (c) The licensee shall ensure that the arrival and presence of a PNRI inspector, who has been properly authorized access to the nuclear installation, is not announced or otherwise communicated by its employees or contractors to other persons at the nuclear installation unless specifically requested by the PNRI inspector.
- (d) The licensee shall permit the duly authorized representative of the IAEA to conduct inspection activities on specified dates and take other action as necessary to implement the Philippines/IAEA Safeguards Agreement.

#### Section 26. Violations.

Any person who willfully violates or attempts to violate any provision of this Part or any order issued thereunder by the PNRI shall be prosecuted and upon conviction, shall be punished in accordance with the penal provision of the Act.

#### Section 27. Modification, Suspension and Revocation of License.

- (a) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application, or for violation of, or failure to observe any of the terms and conditions of the license or any of the requirements and provisions of this Part or of any rule, regulation or order of the PNRI.
- (b) Except in cases of willful violation or those in which the public health and safety requires otherwise, no license shall be modified, suspended or revoked until the

licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

- (c) Upon the suspension, revocation, or expiration of a license which is not renewed, and pursuant to PNRI order, the licensee shall take such measures as may be necessary to protect the health and safety of the public and the environment or the national interest.
- (d) Whenever the PNRI finds that the public convenience and necessity, or that the production program requires continued operation of the nuclear installation, the license for which has been revoked, the PNRI may, after consultation with the appropriate agencies having jurisdiction, order that possession be taken of such facility and that it be operated for a period of time as, in the judgment of the PNRI, the public convenience and necessity or the production program may require, or until a license for operation of the facility shall become effective. Just compensation shall be paid for the use of the facility.

## VI. EFFECTIVITY

#### Section 28. Effective Date.

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

APPROVED:

CARLO A. ARCILLA, Ph. D. Director

Date of Approval: 14 JUNE 2019