

Regulatory Framework and Licensing Process for Nuclear Facilities in Philippines



Outline



Overview of the National Legal Framework for Safety



Licensing Process for Nuclear Installations



Proposed PhilATOM Bill



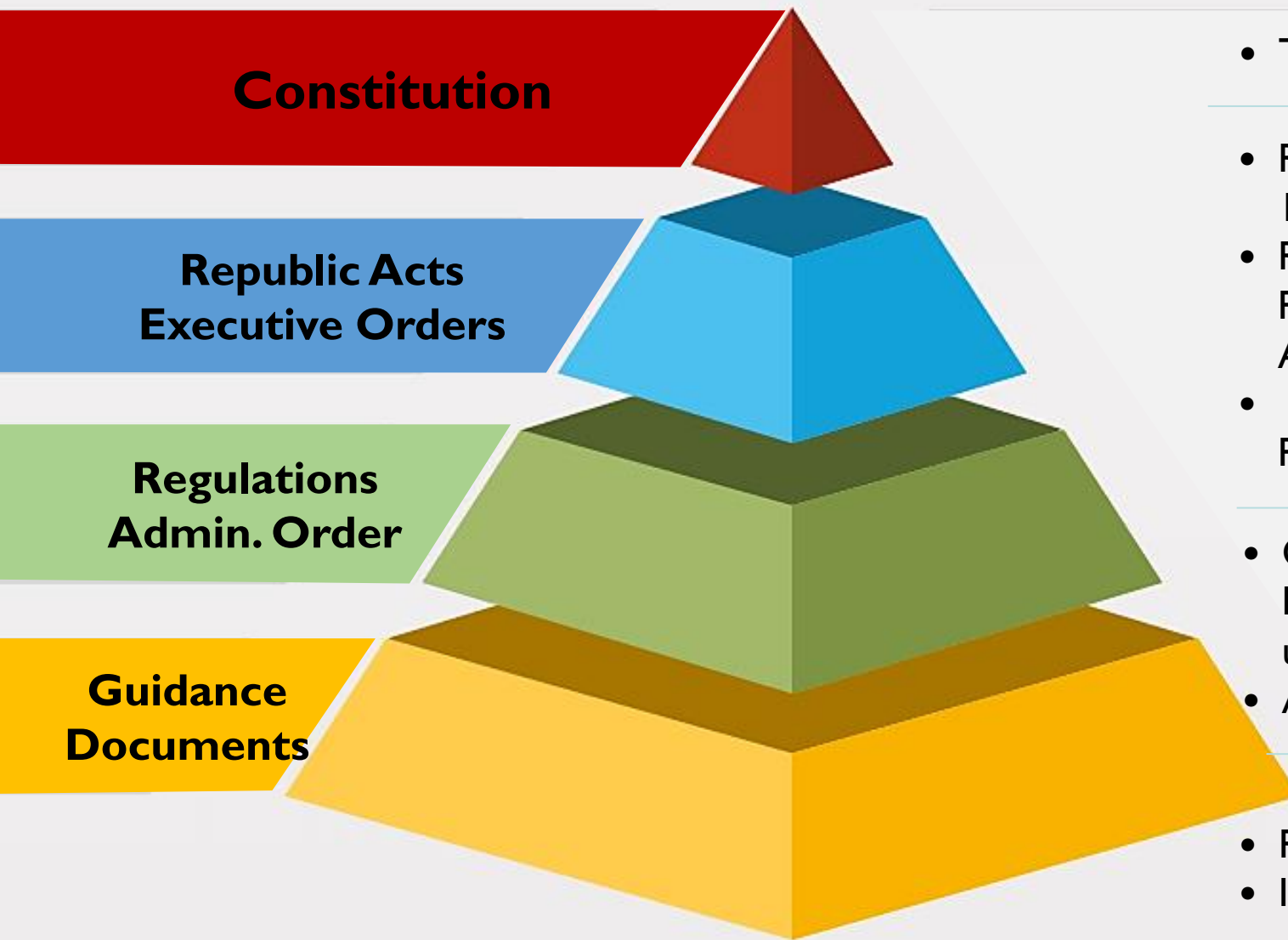


part **1**

Overview of the National Legal Framework



PH Legislative Framework for Safety



- The Philippine 1987 Constitution
- Republic Act 2067 known as the Science Act of 1958, created PAEC
- Republic Act 5207 of 1968 known as An Act Providing for the Licensing and Regulation of Atomic Energy Facilities and Materials
- Executive Order 128 of 1987 reorganizes PAEC to PNRI
- Code of PNRI Regulations Codified from CPR Part 0 – 32 (as of July 2023); 25 published, 7 under development
- Administrative Orders
- Regulatory Guides and Bulletins
- Information Notices; incidents and lessons learned

Nuclear Energy Program Inter-Agency Committee (NEP-IAC)

Executive Order No. 116, Series of 2020

Signed by President Rodrigo Duterte on **28 February 2022**,
“Created the NUCLEAR ENERGY PROGRAM INTER-AGENCY
COMMITTEE (NEP-IAC)”

Executive Order No. 164, Series of 2022

Signed by President Rodrigo Duterte on **28 February 2022**,
“ADOPTING A NATIONAL POSITION FOR A NUCLEAR ENERGY
PROGRAM, AND FOR OTHER PURPOSES



Structure of the NEP-IAC

NEP-IAC Steering Team

(High-level representatives from government agencies)

NEP-IAC Secretariat

(Staff specifically recruited for this NEP-IAC, at least 1 secretariat staff should be assigned to each SC)

NEP-IAC Subcommittees

(TWG with members coming from relevant government agencies)

SC1

Management
, Policies, and
Financing

SC2

Nuclear 3S
and
Radiation
Protection

SC3

Legal and
Regulatory

SC4

Human
Resource
and
Stakeholder
Involvement

SC5

Siting,
Environment
, and
Emergency
Plan

SC6

Nuclear Fuel
and
Radioactive
Waste



Consultants, Contractors, Vendors, Suppliers

(May be requested to provide inputs/information and/or perform specific activities to support activities of SCs)



Composition of the NEP-IAC

Chairperson:

Vice-Chairperson:

Members:

Department of Energy (DOE)

Department of Science and Technology (DOST)

Department of Environment and Natural Resources (DENR)

Department of Finance (DOF)

National Economic and Development Authority (NEDA)

National Transmission Corporation (TransCo)

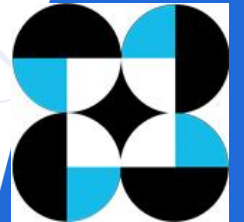
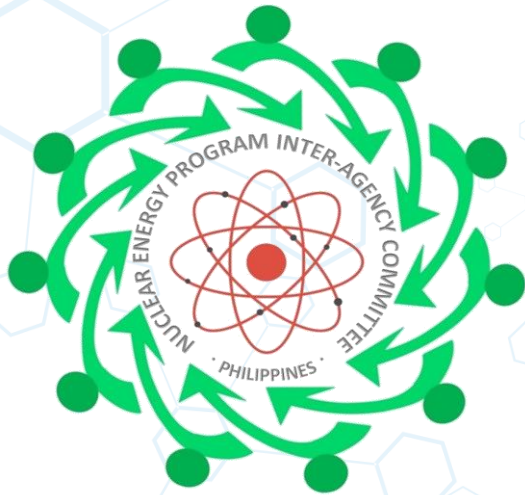
Department of Interior and Local Government (DILG)

Department of Foreign Affairs (DFA)

Philippine Institute of Volcanology and Seismology (PHIVOLCS)

Philippine Nuclear Research Institute (PNRI)

National Power Corporation (NPC)





Promotion



Regulation

PNRI has a Dual Mandate

To promote and regulate the safe and peaceful uses of nuclear science and technology in the country.



PNRI Organizational Structure

Department of Science and Technology

Office of the Director

Office of the Deputy Director

REGULATORY FUNCTION

Planning Section

Atomic Research Division

- Agriculture Research Section
- Biomedical Research Section
- Health Physics Research Section
- Applied Physics Research Section
- Chemistry Research Section
- Nuclear Materials Research Section

Nuclear Services Division

- Nuclear Reactor Operation Section
- Engineering Services Section
- Irradiation Services Section
- Radiation Protection Services
- Nuclear Analytical Techniques Application Section
- Isotope Techniques Section

Technology Diffusion Division

- Nuclear Training Center
- Nuclear Information and Documentation Section
- Business Development Section
- MIS and IT Section
- International Cooperation Section

Nuclear Regulatory Division

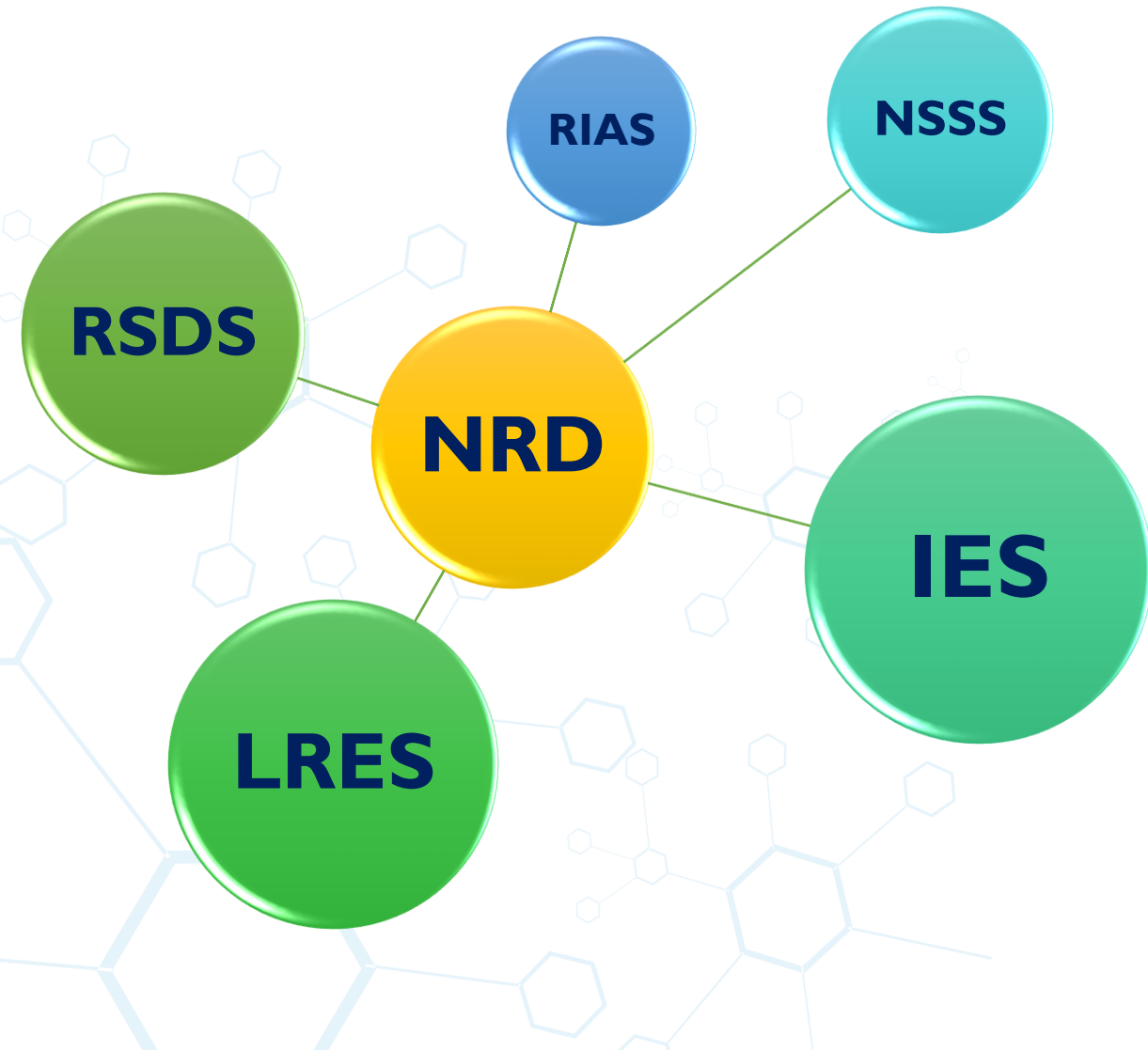
- Regulations and Standards Development Section
- Licensing, Review and Evaluation Section
- Inspection and Enforcement Section
- Nuclear Safeguards and Security Section
- Radiological Impact Assessment Section

Finance and Administrative Division

- Human Resource Management and Records and Communication Section
- Budget Section
- Accounting Section
- Property and Procurement Section
- Cash Section
- General Services Section



PNRI - Nuclear Regulatory Division



- Develop regulations and standards for radiation safety, security and safeguards
- Review and evaluate license applications
- Issue licenses for the use of radioactive materials
- Inspect licensed facilities and enforce corrective actions, as necessary
- Conduct research in support of the regulations
- Conducts projects and inspections for safeguards and the physical protection of nuclear materials and facilities.



Code of PNRI Regulations

PUBLISHED CODE OF PNRI REGULATIONS (CPRs) RELEVANT TO NPP (as of July 2023)

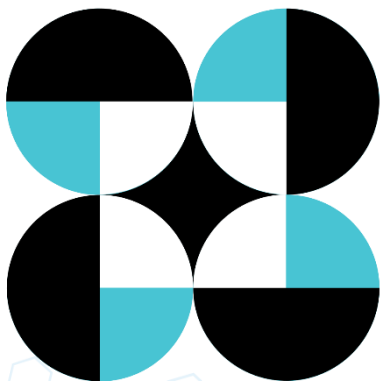
Document Code	Document Title	Revision No.	Date Published in the Official Gazette
CPR PART 0	PNRI as the Regulatory Authority in the Licensing and Regulation of Atomic Energy Facilities and Materials in the Philippines	1	Aug. 10, 2020; Vol. 116, No. 32
CPR PART 3	Standards for Radiation Protection and Safety of Radioactive Material, Rev. 02	2	March 8, 2021; Vol. 117, No. 10
CPR PART 4	Regulations for the Safe Transport of Radioactive Material in the Philippines	2	March 27, 2017 Vol. 113, No. 13
CPR PART 5	Requirements for Siting of Nuclear Installations	0	Aug. 5, 2019; Vol. 115, No. 31
CPR PART 7	Licensing of Nuclear Installations	1	Sept. 16, 2019; Vol. 115, No. 37
CPR PART 10	Requirements for the Physical Protection of Nuclear Materials and Nuclear Installations	0	May 23, 2022; Vol. 118 No. 21
CPR PART 23	Licensing Requirements for Land Disposal of Radioactive Waste	0	May 9, 2005; Vol. 101, No. 19

CODE OF PNRI REGULATIONS (CPRs) UNDER DEVELOPMENT RELEVANT TO NPP

Code	Document Title	Remarks
CPR PART 6	Leadership and Management for Safety	On going
CPR PART 9	Safety Assessment for Facilities and Activities	On going
CPR PART 24	Preparedness and Response for Nuclear and Radiological Emergency	On going

PLANNED CPR DEVELOPMENT / REVISION

Code	Document Title	Remarks
CPR PART 4	Regulations for the Safe Transport of Radioactive Material in the Philippines	To be revised to include nuclear materials
CPR PART 27	Security Requirements in the Transport of Radioactive Material	To be revised to include nuclear materials
CPR PART 8	Safety Requirements of Nuclear Power Plants: Design and Construction	new
CPR PART 9	Safety Requirements of Nuclear Power Plants: Operation	new
CPR PART xx	Requirements on the Implementation of Safeguards (System of Accounting for and Control of Nuclear Material and Application of Additional Protocol)	new



DOST

Philippine Nuclear
Research Institute

PNRI-NRD
regulatory functions
on nuclear and
radioactive
materials

Nuclear
Regulatory
Division(NRD)

DOH

Food and Drug
Administration (FDA)

Center for Device
Regulation Radiation
Health and Research
(CDRRHR) -
**Radiation Regulation
Division**



FDA-CDRRHR
regulatory functions
on electrically
generated ionizing
radiation

Current Regulatory Structure in the Philippines for Ionizing Radiation

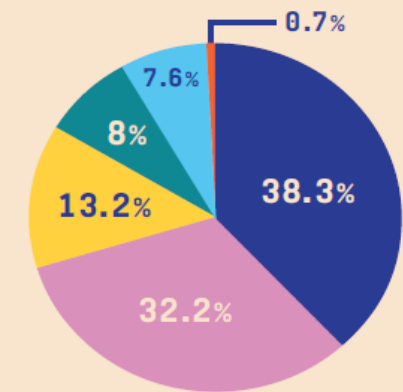


Distribution of Licensees by Region in The Philippines

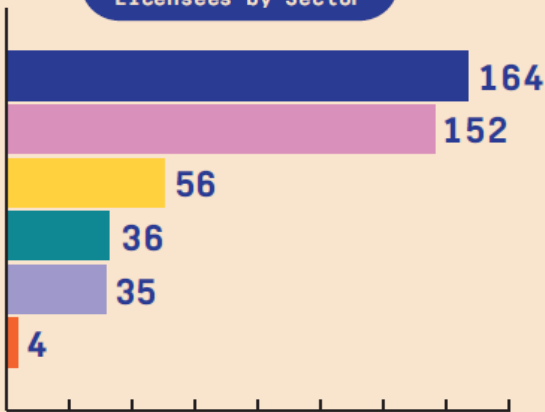
Distribution of Licensees by Region

Region I	9	Region IX	5
Region II	8	Region X	16
Region III	44	Region XI	14
Region IV	75	Region XII	4
Region V	8	Region XIII	4
Region VI	13	CAR	4
Region VII	18	NCR	223
Region VIII	2		
Total			447

Distribution of Licensees by Use

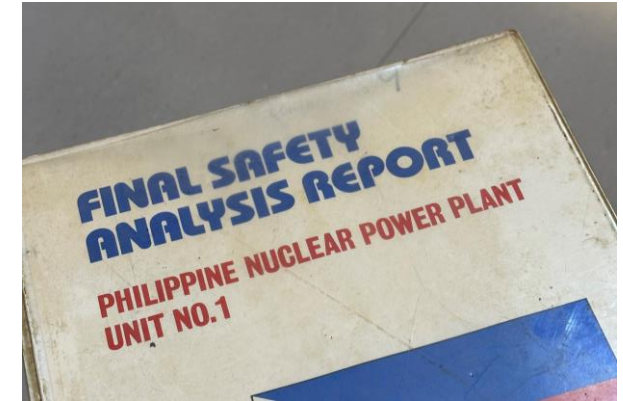


Distribution of Licensees by Sector



Industry Medical Commercial Industrial Radiography Research Particle Accelerator





Nuclear Facilities **REGULATED** by PAEC/PNRI

- Philippine Nuclear Power Plant (PNPP-I)
- Philippine Research Reactor (PRR-I)





Materials/Facilities **REGULATED** by PNRI

- Nuclear Medicine and PET
- Industrial Radiography
- Radiation Therapy
- Research Facilities
- Commercial Sale
- Cyclotron, Irradiation Facilities



Facilities Currently **OPERATED** by PNRI

- Philippine Research Reactor I
- Multi-purpose Gamma Irradiation Facility
- Electron Beam Irradiation Facility
- Secondary Standards Dosimetry Laboratory
- Interim Radioactive Waste Management Facility
- Technetium-99m Generator Production Facility



- Soil Research Testing & Plant Analysis
- Chemistry Research Laboratory
- Nuclear Analytical Techniques Application Laboratory
- Isotope Technique Facility
- Nuclear Materials Research Facility
- Nuclear Training Center/NDT Training Facility



Facilities/Activities currently **REGULATED** by CDRRHR



- Medical devices that use X-rays – CT Scan, Mammography, LINAC, Lithotripsy, Cardiac Catheterization, General Radiography, Fluoroscopy, Dental X-ray
- Industrial Radiography
- Research facilities using X-ray equipment





part **2**

Licensing of Nuclear Installations



Code of PNRI Regulations for NPP

CPR Part 5: Siting of Nuclear Installations

CPR Part 7: Licensing of Nuclear Installations



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

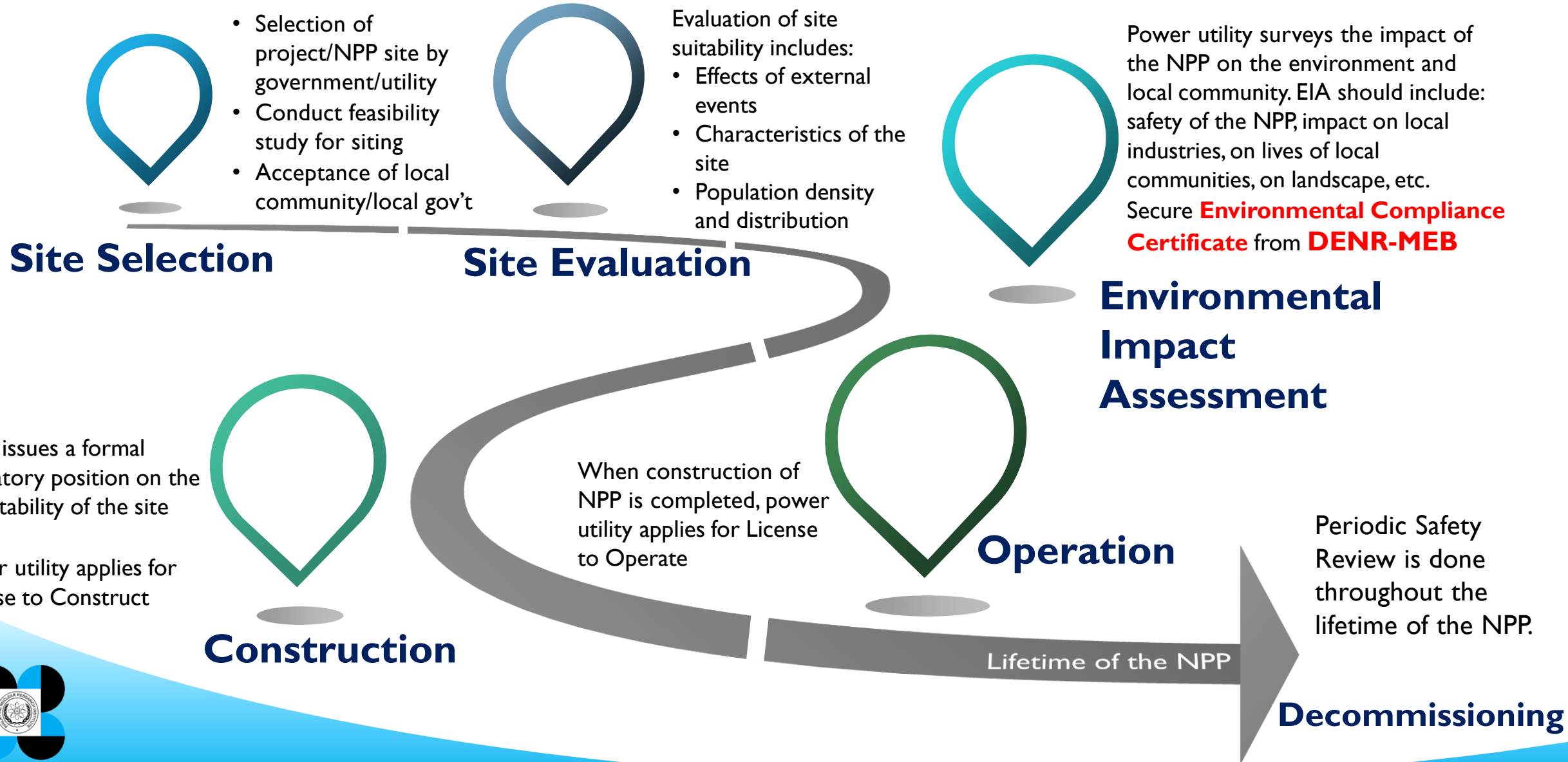
CPR PART 7

LICENSING OF NUCLEAR INSTALLATIONS, Rev. 01

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Overview of the Licensing Process



Regulatory Considerations for Site Selection Process

Hazards Associated with External Natural and Human Induced Events

Frequency and severity of external natural and human-induced events

Foreseeable significant changes in land use shall be considered

Potential Radiological impact of the nuclear installation on the region

Impacts that could lead to emergency measures, on people in the region, of the nuclear power reactor in operational states and in accident conditions, shall be evaluated

Considerations of Population and Emergency Planning

To evaluate the present and foreseeable future characteristics and the distribution of the population of the region



Site Characteristics and Potential Effects of the NPP

Dispersion of Radioactive Materials in the Atmosphere

Dispersion of Radioactive Material through Surface Water

Dispersion of Radioactive Material through Ground Water

Population Density and Distribution

Use of Land and Water in the Region

Ambient Radioactivity



Evaluation of External Events

Seismological and Geological Conditions

- Earthquakes
- Surface Faulting
- Volcanoes

Meteorological

- Extreme values of meteorological phenomena
- Rare meteorological events

Tsunami/Flood Hazards

- Tsunami
- Flood

Geotechnical

- Slope instability
- Collapse, subsidence or uplift
- Soil liquefaction
- Behavior of foundation materials

External Human Induced

- Aircraft crashes



Fundamental Safety Objective



To protect **people**
and the
environment
from harmful
effects of ionizing
radiation

Constitute the basis on which
to establish safety requirements

General Requirements



Applicant's
proof of
business



Applicant's
citizenship
(60/40)



Site plan



Technical
qualifications



HRD Plan



Acquisition of structure,
systems and components



Projected financial
resource



Strategies for public
involvement



Specific Requirements | License to Construct

Standardized Design Certification

Construction program and timeline

Quality Assurance Program

Preliminary Safety Analysis Report

Environmental Compliance Certificate

Physical Protection Plan

Safeguards Measures

Initial Decommissioning Plan



**From DENR – Environmental
Management Bureau**

Specific Requirements | License to Operate

Final Construction Report

Final Safety Analysis Report

Commissioning Program

Radiation Protection Program

Environmental Monitoring Program

Emergency Preparedness Plan

Training Program

Radioactive Waste Management Program

Ageing Management Program

Physical Protection Plan Nuclear

Safeguards Transport of Nuclear Fuel

Operation and Maintenance

License to Construct

- No person may begin the construction of a nuclear installation on a site until that person has been issued a License to Construct
- May request for Provisional Permit for non-safety related works
- Valid for ten (10) years

License to Operate

- Required before fuel loading and the beginning of the hot commissioning.
- Valid for forty (40) years





part **3**

Proposed PhilATOM Bill





Proposed PhilATOM Bill

“An Act Establishing the **Philippine Atomic Energy Regulatory Authority** and Providing For A Comprehensive Legal Framework for Radiation Protection, Nuclear Safety, Security and Safeguards, in the Utilization of Nuclear Energy in the Philippines, And Appropriating Funds Therefor.”

To be known as the

“Philippine National Nuclear Safety Act”



Issues Being Addressed by the Bill



The Philippine Nuclear Research Institute has a **dual mandate** – to promote and regulate the use of ionizing radiation from nuclear and radioactive materials.



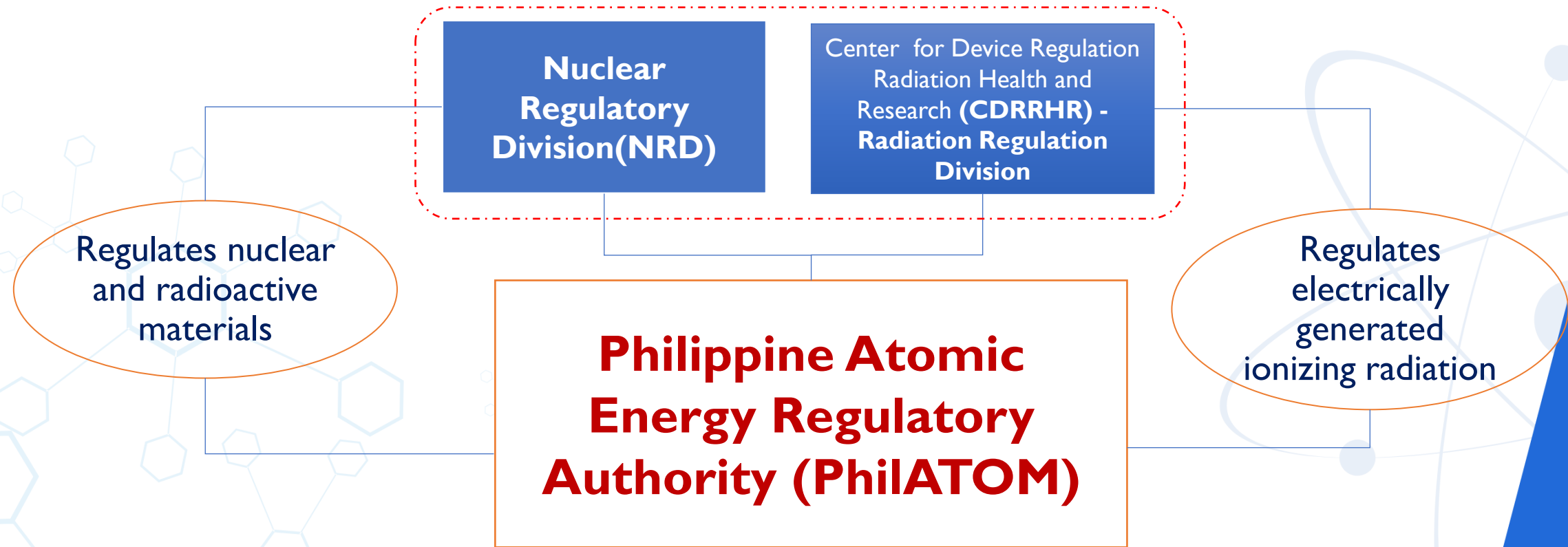
There are **two regulatory agencies** regulating the use of ionizing radiation for medical and non-medical applications – the DOST-PNRI and DOH-FDA CDRRHR.



Gaps are identified in the existing law RA 5207, as amended, on **nuclear security, and safeguards** to meet obligations under relevant international legal instruments acceded by the Republic of the Philippines



Creation of an Independent Regulatory Body



To synchronize all regulatory activities on ionizing radiation under one organization



