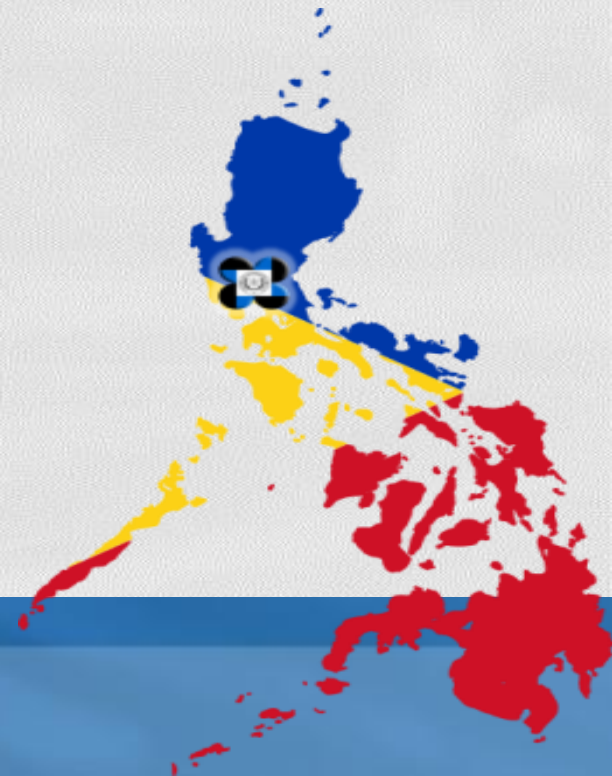


The Philippine Legislative and Regulatory Infrastructure for Nuclear and Radiation Safety

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Department of Science and Technology

Nuclear Energy Forum
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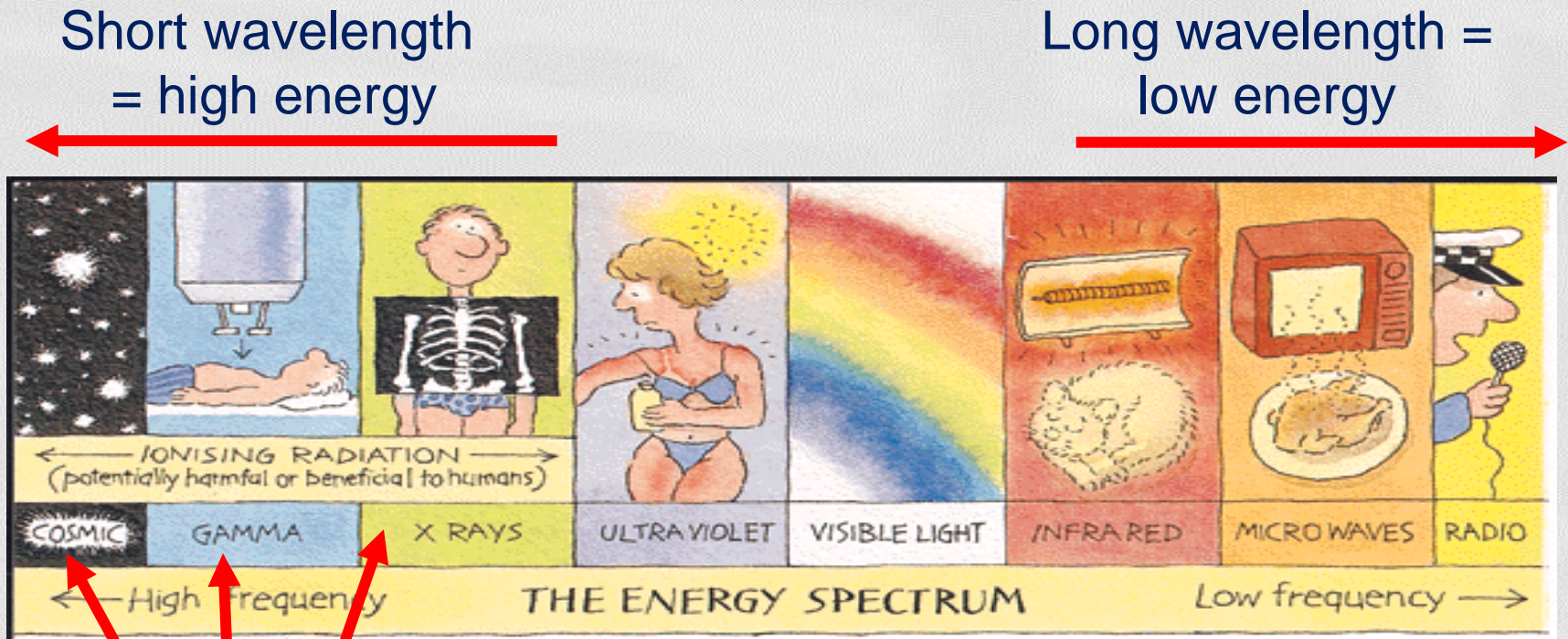
Outline

- Introduction
- Philippine Legislative and regulatory infrastructure for nuclear and radiation safety
- Philippine Regulatory Bodies for sources of ionizing radiation
- Regulated sources of ionizing radiation in the Philippines
- Current PNRI nuclear and radiation S & T Programs
- Overall assessment of Philippine legal and regulatory infrastructure
- Proposed comprehensive nuclear law
- Cooperation and Obligations with Global Safety, Safeguards and Security Regime
- Summary and Conclusion



What is radiation?

Energy emitted from a source is generally referred to as **radiation**.



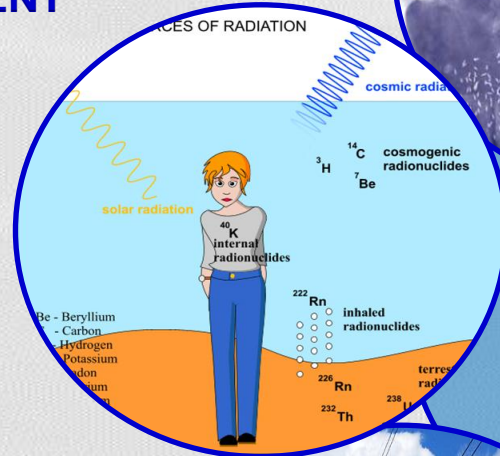
IONIZING RADIATION

Potentially harmful or beneficial to humans...depending on how it is used.



Overview on Sources/Applications of Ionizing Radiation

NATURAL
RADIOACTIVITY
IN FOOD &
ENVIRONMENT



MODERN
HEALTHCARE



INDUSTRIES

IONIZING
RADIATION
is a
FACT OF LIFE

ELECTRICITY
GENERATION
& HEATING



RESEARCH &
DEVELOPMENT



Health effects from exposure to ionizing radiation

- **Stochastic effects** (probabilistic)
 - hereditary effects
 - radiation-induced cancers
- **Deterministic effects**
 - effects on the early radiologists
 - consequences of severe accidents
 - side effects of radiotherapy



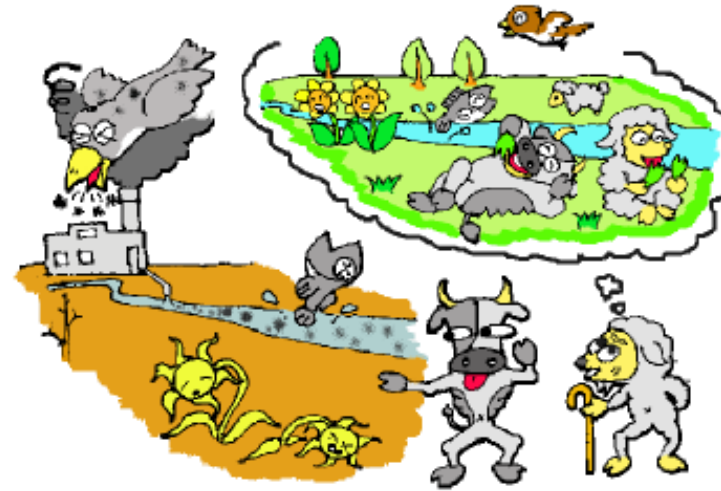
**HOW DO WE KEEP
THE USE OF
IONIZING RADIATION
SAFE AND SECURE?**



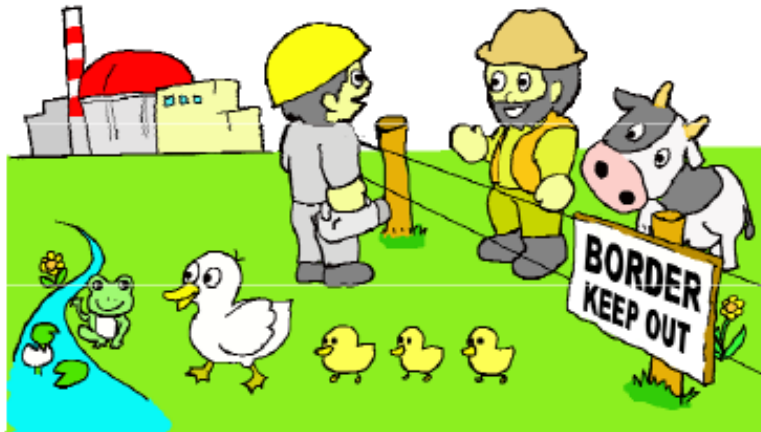
Fundamental Safety Principles



Protection of **Human Health & Future Generations**



Protection of the **Environment**



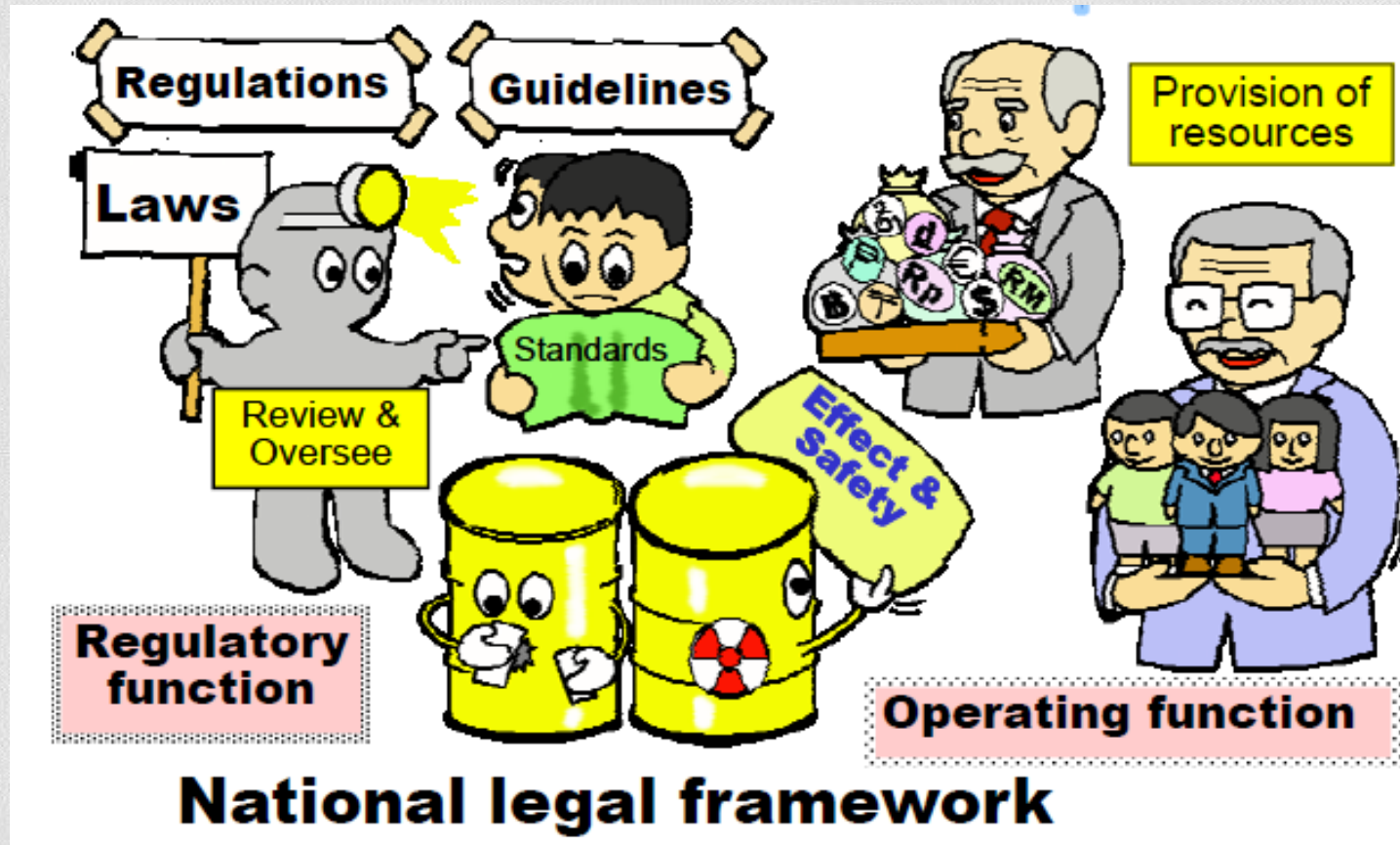
Protection **beyond National Borders**



Burdens on **Future Generations**

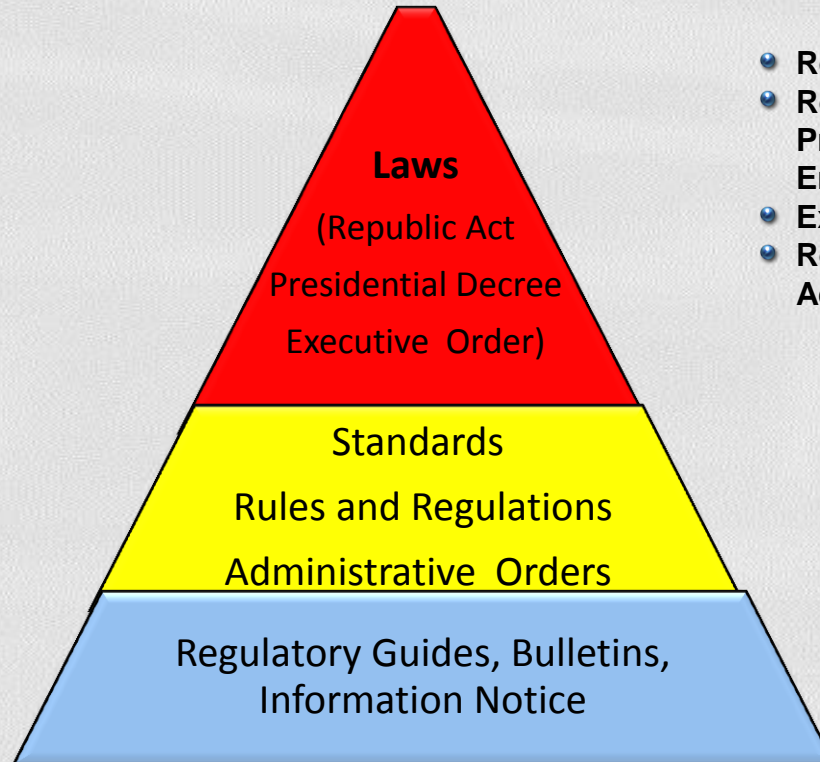


KEY to SAFETY and PROTECTION- National Legal and Regulatory Framework



Philippine Legislative and Regulatory Framework for Nuclear and Radiation Safety

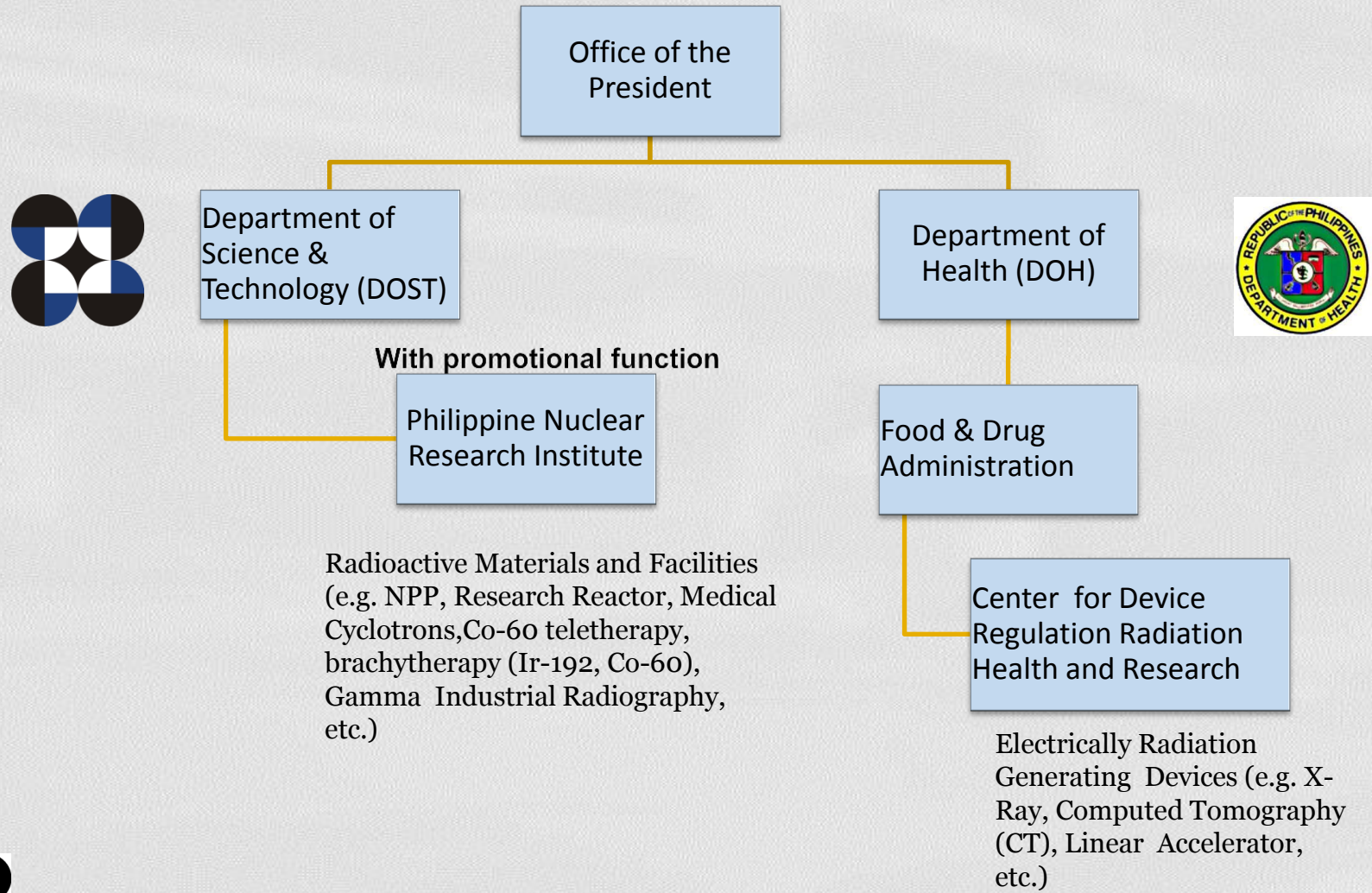
Atomic Energy Facilities, Radioactive Materials and Radiation Generating Devices



- Republic Act 2067 known as the Science Act of 1958
 - Republic Act 5207 of 1968 also known as An Act Providing for the Licensing and Regulation of Atomic Energy Facilities and Materials
 - Executive Order 128 of 1987
 - Republic Act No. 9711 known as the Food and Drug Administration Act of 2009
-
- Covers technical and administrative requirements e.g. radiation protection, import/export control, transport and waste safety, security, fees and charges
-
- Generally based on international best regulatory practices



Current Regulatory Infrastructure for Sources of Ionizing Radiation



Mandates of PNRI (EO 128 of 1987)

- [a] conduct research and development on the application of radiation and nuclear materials, processes and techniques in agriculture, food, health, nutrition and medicine and in industrial or commercial enterprises;
- [b] undertake the transfer of research results to end-users, including technical extension and training services;
- [c] operate and maintain nuclear research reactors and other radiation facilities; and
- [d] license and regulate activities relative to production, transfer, and utilization of nuclear and radioactive substances.



Mandates of CDRRHR – Radiation Regulation Division (IRR of RA 9711, 2011)

- [a] to regulate the use of ionizing and non-ionizing radiation devices in medicine, dentistry, veterinary medicine, commerce and industry, education and training, research, anti-crime, security, household activities, and all other facilities/establishments and activities where radiation devices are used;
- [b] in coordination with the Planning and Policy Office (PPO), to develop policies, standards, regulations, and guidelines for the use of ionizing and non-ionizing radiation devices;
- [c] to conduct radiation protection survey and evaluation of radiation facilities and the activities thereat;
- [d] to issue appropriate authorizations for medical and non-medical radiation facilities;
- [e] to issue certificates of compliance with technical requirements as basis for the issuance of appropriate authorization regarding the use of radiation devices and operation of radiation facilities;
- [f] To conduct compliance monitoring of radiation facilities;
- [g] in coordination with PPO, to provide technical assistance, consultative and advisory services to stakeholders and other government agencies in the implementation of laws, rules and regulations pertaining to radiation facilities; and
- [h] to exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.



REGULATED SOURCES OF IONIZING RADIATION IN THE PHILIPPINES

(as of March 2016)

Practices	No. of facilities and license holders	Types/No. of Sources	Regulatory Body
Medical:			
Linear accelerators	33*	40*	CDRRHR
Teletherapy (gamma)	7	199 Co-60 sources (192 Co-60 sources are for gamma knife)	PNRI
Brachytherapy Manual	7	76 Cs-137 sources I-125 seeds for permanent implants	PNRI
Brachytherapy Remote control	11	10 Ir-192 sources 1 Co-60 source	PNRI
Blood Irradiator	3	3 Cs-137 sources	PNRI
Nuclear Medicine	52	Unsealed sources for therapy & diagnosis: I-131; Tl-201; Tc-99m; Ga-167; Sr-89; Y-90; I-125 (RIA kits)	PNRI
Medical Cyclotron	2	Production of F-18	PNRI



Source:

1. Licensing, Review, and Evaluation Section (LRES), Nuclear Regulatory Division (NRD), Philippine Nuclear Research Institute (PNRI), Department of Science and Technology
2. Ms. Gladys Cabrera, Center for Device Regulations, Radiation Health and Research (CDRRHR), Food and Drug Administration (FDA), Department of Health



REGULATED SOURCES OF IONIZING RADIATION IN THE PHILIPPINES

(as of March 2016)

Practices	No. of facilities/license holders	Types/No. of Sources	Regulatory Body
Gamma industrial radiography	27	97 Ir-192 sources 2 Co-60 sources 3 Se-75 sources (102 devices)	PNRI
X-ray industrial radiography	266	710	CDRRHR
Industrial (nuclear) gauging devices		Am-241:Be & Cs-137, Am-241, Cf-252, Cs-137, Cs-137, Co-60, Kr-85, Am-241; Pm-147; Sr-90; Kr-85, Sr-90, Fe-55, Ni-63, Po-210 & Pu-238, Kr-85 gas, Po-210; Th-232, etc	PNRI
Research and education	31	H-3, Ni-63, Am-241, C-14, Cs-137, Co-60, Fe-55, Sr-90, Tl-204, I-125, Fe-59, Ba-133, Am-241:Be-7, Cl-36, P-32, P-33, S-35, U-238, Ge-68	PNRI

Source:

1. *Licensing, Review, and Evaluation Section (LRES), Nuclear Regulatory Division (NRD), Philippine Nuclear Research Institute (PNRI), Department of Science and Technology*
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REGULATED SOURCES OF IONIZING RADIATION IN THE PHILIPPINES

(as of March 2016)

Practices	No. of facilities/license holders	Types/No. of Sources	Regulatory Body
X-ray fluorescence spectroscopy	31	31	CDRRHR
Security equipment (e.g. baggage x-ray, container inspection)	110	219	CDRRHR
Dental radiology (alone)	146	176	CDRRHR
Diagnostic and interventional radiology	6,123	6,821	CDRRHR
X-ray Diffraction Devices	42	42	CDRRHR



Source:

1. *Licensing, Review, and Evaluation Section (LRES), Nuclear Regulatory Division (NRD), Philippine Nuclear Research Institute (PNRI), Department of Science and Technology*
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REGULATED SOURCES OF IONIZING RADIATION IN THE PHILIPPINES (as of March 2016)

Practices	No. of facilities/license holders	Types/No. of Sources	Regulatory Body
PNRI Facilities			
Co-60 multi-purpose irradiation facility	1	Co-60 pencils (45 units)	PNRI internal regulation
Radioactive waste management facility	1	Various disused/spent radioactive sources	PNRI internal regulation
Electron Beam Facility	1	Specifications: Energy: 1 - 2.5 MeV; Beam current: Maximum 50 mA; Beam power: Maximum 100 kW	CDRRHR
Philippine Research Reactor 1 (shutdown)	1	115 slightly irradiated (General Atomics); 15 fresh (General Atomics) TRIGA fuel rods g; 4 fission chamber neutron detectors containing: Total U – 11.65 g, U-235-10.4 g	PNRI internal regulation
Technetium-99m Generator Production Facility	1	Calibration sources (Cs-137; Ba-133; various radionuclides below exempt level	PNRI internal regulation
Secondary Standard Dosimetry Laboratory	1	Cs-137, Co-60, Sr-90, Ba-133, Co-57, Am-Be-241	PNRI internal regulation
Nuclear Materials Research Laboratory	1	Am-241, Cs-137, U, Th, K pad, U pad, & Th pad	PNRI internal regulation



GEOGRAPHICAL DISTRIBUTION OF PNRI LICENSEES as of Dec. 2016

Region I	7
Region II	5
Region III	40
Region IV	51
Region V	4
Region VI	9
Region VII	8
Region VIII	2
Region IX	3
Region X	14
Region XI	9
Region XII	4
CARAGA	6
CAR	4
NCR	200
TOTAL:	366



Radioactive Material Licensees:

Industry = 158

Medical = 116

Commercial = 31

Industrial radiography = 28

Research = 31

Atomic Energy Facility Licensees:

Medical cyclotron = 2

PNRI Facilities (self-regulated):

- Co-60 multi-purpose irradiation facility
- Radioactive waste management facility
- Phil Research Reactor (for decommissioning)
- Other practices - R&D



CURRENT PNRI NUCLEAR and RADIATION S & T PROGRAMS (1/3)

- Nuclear and Radiation Research and Technology Development

- Food and Agriculture

- Mutation breeding (rice and alternative crops for resilience to impacts of climate change)
- Application of radiotracers and stable isotopes to study agricultural processes (erosion, nutrient and water uptake and utilization)
- Application of radiation to control insect pests
 - successfully applied to mango pulp weevil (protocol approved by USDA) and bunchy top banana virus
- Plant food supplement from radiation-modified carrageenan
 - 30% increase in yield for rice; being tested for more crops and vegetables

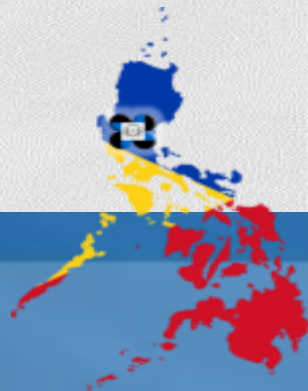


CURRENT PNRI NUCLEAR and RADIATION S & T PROGRAMS (2/3)

- Nuclear and Radiation Research and Technology Development

- Health and Medicine

- Nuclear techniques for harmful algal blooms being transferred to regulatory body
- Production of Tc-99m generator and radiopharmaceutical kits
- Health products from radiation-modified natural products such as carrageenan, alginate, honey (wound dressing, hemostats)
- SIT to combat dengue virus-carrying mosquito



CURRENT PNRI NUCLEAR and RADIATION S & T PROGRAMS (3/3)

- **Nuclear and Radiation Research and Technology Development**

- Environment – results are used in aid of environmental regulation and policies**

- Nuclear spectrometric techniques for identification and source apportionment of air pollutants, marine and coastal pollution and other environmental studies
 - Isotope tracer techniques, radioactive and stable isotopes for water resource management, and for tracing the fate of pollutants from terrestrial sources to aquatic and marine receptors
 - Isotope tracer techniques for understanding terrestrial and marine processes such as erosion, sedimentation
 - Environmental radioactivity measurements and monitoring for nuclear emergency preparedness and response



PNRI Nuclear and Radiation Services

- Gamma irradiation (semi-commercial scale) using the Co-60 Multipurpose Irradiation Facility
- Nationwide personnel radiation dose monitoring
- Radiation instrument calibration
- Radioactive waste management
- Radioanalytical measurement
- Decommissioning of radiation facilities
- Cytogenetic analysis for dose assessment



Stakeholders involvement/Public acceptance

The PNRI-DOST continues to enhance public awareness and appreciation of the peaceful uses of nuclear and radiation technology to build and strengthen competency in the field of safety, safeguards and security through:

- Education and training
 - Radiation Technology
 - Radiation Safety
 - Nuclear S & T program for secondary schools
 - Introduction to Nuclear Power
- Nuclear S & T information dissemination
- Business development and marketing of PNRI technologies



Overall Assessment of Philippine Legal and Regulatory Infrastructure (1/3)

- In view of the complexity of nuclear and radiation applications and greater emphasis on nuclear safety, countries are amending their laws to provide for the creation of an effectively independent radiation and nuclear safety regulatory body.
- In Asia-Pacific region, Australia, China, Indonesia, South Korea, Japan, Malaysia, Thailand, Pakistan, India, New Zealand, Singapore, and Vietnam now have separate nuclear and radiation regulatory bodies from their operating and promotional organizations.

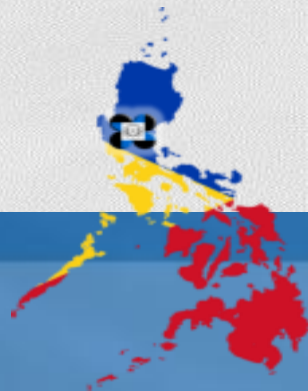


Overall Assessment (2/3)

In the Philippines, there are two (2) separate regulatory authorities for sources ionizing radiation

- PNRI under the Department of Science & Technology for ionizing radiation coming from radioactive materials and facilities
- CDRRHR /FDA under the Department of Health ionizing radiation electrically generated by devices and equipment ionizing

Creates a potential for differing regulatory policies and safety standards governing activities involving the use of ionizing radiation



Overall Assessment (3/3)

- The legislative framework for the control and regulation of sources of ionizing radiation in the country needs to be modernized and rationalized; the primary legal instruments are outdated.
- The primary legal instruments mandated the PNRI with the dual function of promoting and regulating the peaceful applications of nuclear energy.



Title of Proposed Bill

“AN ACT PROVIDING FOR A COMPREHENSIVE NUCLEAR and RADIATION REGULATION, CREATING FOR THE PURPOSE, THE **PHILIPPINE NUCLEAR REGULATORY COMMISSION**, AND APPROPRIATING FUNDS THEREFOR.”

*known as the “**Comprehensive Nuclear Regulation Act**”*

Filed under HB No. [00025/01691/02977/03651/04369](#) 17th Congress



Nuclear Bill: Timeline

PNRI formulated an internal regulatory program where the nuclear regulatory division exercises control over RAMs in PNRI

A draft nuclear law was crafted by the PNRI with the assistance of IAEA legal experts

The draft legislation (HB. 147) was filed by Cong. Gerald Abaya, Cong. Rufus Rodriguez and Cong. Maximo Rodriguez during the 16th Congress.

2004

2007

2008

2009

2013

2016

The Secretaries of Health (Dr. Francisco Duque) and of Science and Technology (Dr. E. Alabastro) agreed to the 2004 IAEA recommendation

Draft legislation was filed by Cong. Joseph Emilio Abaya and Rufus Rodriguez during the 14th Congress. A TWG was created

The draft legislation (HB 00025 by Cong. Francis Abaya/01691 by Cong. Maximo Rodriguez/02977 by Cong. Divina Grace Yu/03651) by Cong. Erico Aristotle Aumentado/04369 by Cong. Joey Salcedo/ 03651 Cong. Seth Frederick Jalosjos/ 04369 by Cong. Joey Salceda was filed during the 17th Congress.

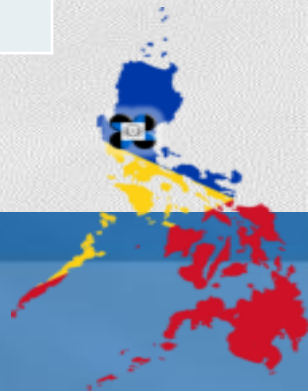


COOPERATION AND OBLIGATION WITH GLOBAL SAFETY, SAFEGUARDS, AND SECURITY REGIME



CONVENTIONS AND TREATIES RATIFIED OR SIGNED (1/5)

SAFETY AND SECURITY	Signature	Instrument	Entry into Force
Convention on Early Notification of a Nuclear Accident		Accession	05 Jun 1997
Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency		Accession	05 Jun 1997
Convention on Nuclear Safety	14 Oct 1994		
Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management	10 Mar 1998		
Convention on Physical Protection of Nuclear Materials	19 May 1980	Ratification	08 Feb 1987
Vienna Convention on Civil Liability for Nuclear Damage	21 May 1963	Ratification	12 Nov 1977



CONVENTIONS AND TREATIES RATIFIED OR SIGNED (2/5)

SAFETY AND SECURITY	Signature	Instrument	Entry into Force
Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage	10 Mar 1998		
Optional Protocol Concerning the Compulsory Settlement of Disputes	21 May 1963	Ratification	13 May 1999
Convention on Supplementary Compensation for Nuclear Damage	10 Mar 1998		
Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention	21 Sept 1988		
International Convention on the Suppression of Acts of Nuclear Terrorism	15 Sept 2005		



CONVENTIONS AND TREATIES RATIFIED OR SIGNED (3/5)

Safeguards and Verification	Signature	Instrument	Entry into Force
Agreement between the Philippines and the IAEA for the Application of Safeguards in connection with the NPT (INFCIRC /216)		Ratification	16 Oct1974
Additional Protocol to Safeguards Agreement	30 Sept 1997	Ratification	26 Feb. 2010
Agreement on the Privileges and Immunities of the IAEA		Acceptance	17 Dec 1962



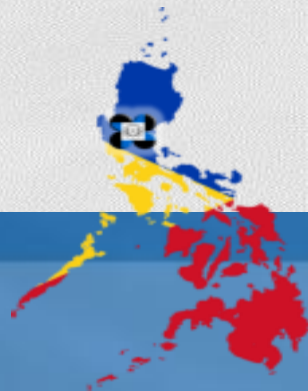
CONVENTIONS AND TREATIES RATIFIED OR SIGNED (4/5)

SCIENCE AND TECHNOLOGY	Signature	Instrument	Entry into Force
Fourth Agreement to Extend the 1987 Regional Co-operative Agreement for Research, Development and Training Related to Nuclear Science & Technology (RCA)		Acceptance	21 Sept 2007
Revised Supplementary Concerning the Provision of Technical Assistance by the IAEA (RSA)	03 Mar 1980		03 Mar 1980



CONVENTIONS AND TREATIES RATIFIED OR SIGNED (5/5)

TREATY	Signature	Instrument	Entry into Force
Treaty on the Non-Proliferation of Nuclear Weapons (NPT)	1 Jul 1968	Ratification	05 Oct 1972
Southeast Asia Nuclear Weapon-Free Zone Treaty (Bangkok Treaty)	15 Dec 1995	Ratification	21 Jun 2001
Comprehensive Test Ban Treaty (CTBT)	24 Sept 1996	Ratification	23 Feb 2001



Regional and International Cooperation

- International Atomic Energy Agency
- European Union
- USNRC International Regulatory Development Program
- Asian Nuclear Safety Network (ANSN)
- Forum for Nuclear Cooperation in Asia (FNCA)
- ASEAN Network of Regulatory Bodies on Atomic Energy (ASEANTOM)



Summary and Conclusions

- Benefits have been derived from the applications of various sources of ionizing radiation in agriculture, industry, medicine, and research
- However, sources of ionizing radiation pose danger if not used safely and securely
- There are two regulatory bodies for sources of ionizing radiation in the Philippines- PNRI-DOST and CDRRHS-FDA-DOH
- There is a need to streamline legal and regulatory infrastructure in compliance with international protection and safety standards for more effective, efficient and harmonized control of sources ionizing radiation
- It is important to strengthen cooperation and meet international obligations for safety, safeguards and security.



THANK YOU FOR YOUR ATTENTION

