



Republic of the Philippines
Department of Science and Technology

PHILIPPINE NUCLEAR RESEARCH INSTITUTE



19 April 2021

PNRI INFORMATION NOTICE 2021-03

REVISED REGULATION: CPR PART 3, "STANDARDS FOR PROTECTION AGAINST RADIATION, Rev. 02"

ADDRESSEES

All PNRI radioactive material license holders.

PURPOSE

This Information Notice is issued to inform all PNRI licensees on the publication of CPR Part 3, "Standards for Protection Against Radiation, Rev.2" in the Official Gazette Volume 117, No. 10 on March 8, 2021.

DESCRIPTION OF CIRCUMSTANCES

The previous publication of CPR Part 3, "Standards for Protection Against Radiation, Rev. 1" was on September 6, 2004 under Volume 100, No. 36, was based on the International Atomic Energy Agency (IAEA) Safety Series No. 115 (1996 version) entitled "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources". In 2014, the IAEA issued General Safety Requirements (GSR) Part 3 on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IBSS) which supersedes the IAEA Safety Series No. 115. The IAEA GSR Part 3 provides for the international harmonization of radiation protection and safety standards under the terms of the IAEA Statute and for the Member States to adopt or use, as far as practicable, as the basis for the formulation of national standards for radiation protection and safety. The PNRI adopted IAEA GSR Part 3, whenever practicable, to establish the required standard for protection against the hazards associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure.

DISCUSSION

Considering the relevance of the new IAEA GSR Part 3 in governing the safety of radioactive materials applications, the PNRI issued the PNRI Administrative Order No. 01 Series of 2015, "Adoption of IAEA General Safety Requirements (GSR) Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards" which

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was published on May 18, 2015, Vol. 111 No. 21. The IAEA GSR Part 3 was used as reference, as far as practicable, in the revision of CPR Part 3.

The key changes in the revised CPR Part 3 are the following:

Section 2. Scope.

The scope covers planned exposures due to practices or sources within practices in all categories of exposure such as Occupational Exposure, Medical Exposure and Public Exposure.

Section 3. Definitions.

The following definitions were deleted from the previous version and new terms were defined in the revised CPR Part 3:

DELETED

- Act
- Action Level
- Activity / Radioactivity
- ALARA
- Authorized Worker
- Chronic Exposure
- Exposure
- Guidance Level
- High Radiation Area
- IBSS
- Intervention
- Intervention Level
- License
- Medical Exposure
- Person
- Personnel Monitoring Device
- Pnri
- Protective Action
- Radiation Area
- Radiological Health and Safety Officer
- Remedial Action
- Special Form Radioactive Material
- Survey

DEFINED

- Annual Dose
- Carers and Comforters
- Clearance
- Clearance Level
- Committed Dose
- Consumer Product
- Containment
- Contamination
- Controlled Area
- Decontamination
- Diagnostic Reference Level
- Disposal
- Dose Assessment
- Dose Limit
- Emergency
- Emergency Preparedness
- Emergency Procedures
- Event
- Exemption
- Exemption Level
- Facilities
- Graded Approach
- Investigation Level
- Licensee
- Management System
- Medical Physicist
- Medical Radiological Equipment
- Monitoring
- Planned Exposure Situation
- Qualified Expert
- Radiation Protection Officer

- Radiation Risk
- Radioactive Source
- Safety Assessment
- Waste or Radioactive Waste
- Worker's Health Surveillance

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

This section provides applicable requirements from other CPRs, national laws, relevant binding conventions, and specific provisions of IAEA GSR Part 3, as applicable.

Section 7. Additional Requirements.

This section provides additional requirements that may be imposed by the PNRI by regulation, order, or conditions of an authorization, in addition to those established in this Part, as deemed appropriate or necessary.

Section 8. General Obligations.

This section provides the general responsibility of the licensee before engaging in any activity pursuant to this CPR.

Section 9. Exemption of Practices and Sources.

This provides the exemption of practices and source within a practice. It also states the references and criteria for exemptions.

Section 10. Clearance.

This section provides the criteria for clearance as specified in Appendix A and C.

Section 11. Graded Approach.

This provides the graded approach which shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.

Section 12. General Responsibilities of Licensees.

This section provides requirements for the responsible parties or licensee which is based on the fundamental safety principle which states that the prime responsibility for safety rests on the person or organization responsible for any facility or activity that gives rise to radiation risks.

Section 13. Application of Radiation Protection Principles.

This section provides the application of radiation protection principles such as justification, optimization and dose limits.

Section 14. Radiation Protection and Safety Program.

This section provides the requirements for the radiation protection and safety program which is further explained in detail under the following sub-sections:

- 14.1 Establishment of Radiation Protection and Safety Program.
- 14.2 Radiation Protection Officer (RPO) and Qualified Expert.
- 14.3 Content of Radiation Protection and Safety Program.

Section 15. Management for Protection and Safety.

This section provides the requirements for the establishment of a management system, commensurate with the size and nature of the authorized activity. It also provides the requirements for promoting and maintaining safety culture in the facility taking into account human factors to prevent human and organizational failures.

Section 16. Safety Assessment.

This section provides the requirements for the conduct of safety assessments at different stages – siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities

Section 17. Monitoring, Testing and Verification of Compliance.

This section provides the requirements for the monitoring and measurements of parameters that are performed as necessary for verification of compliance with the requirements of regulations and license conditions.

Section 18. Prevention and Mitigation of Accidents.

This section provides necessary information for the prevention and mitigation of accident through good engineering practice and applying the defence-in-depth principle.

Section 19. Investigations and Feedback of Operating Experience.

This section provides the requirements for feedback mechanism during normal and abnormal conditions. It also provides for the requirements on the conduct of investigation if accident or any incident occurs.

Section 20. Safety Measures and Control of Radioactive Sources.

This section provides requirements for safety measures and control of radioactive sources which includes provisions for importers and suppliers of radioactive sources; use and storage of radioactive sources; and inventory and records of radioactive sources.

Section 24. Special Arrangements for Female Workers.

This section provides the requirements for the licensee to have special arrangements for female workers to ensure protection of the embryo or fetus and breastfed infants.

Section 33. Compliance by Workers and Worker's Health Surveillance.

This section provides the licensee's responsibility for making arrangements and recording of occupational exposures and for workers' health surveillance.

Section 37. Compliance by Workers and Worker's Health Surveillance.

37.5 Diagnostic Reference Levels

This provides the requirement for the establishment of diagnostic reference level for medical exposures incurred in medical imaging, including image guided interventional procedures.

Section 40. Release of Patients after Radionuclide Therapy.

This section provides the requirements to ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

Section 41. Unintended and Accidental Medical Exposures.

This section provides the requirements to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. The licensees are required to promptly investigate unintended or accidental medical exposures and implement corrective actions, as appropriate.

Section 42. Radiological Reviews.

This section provides the requirements to ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.

Section 47. Sources of External Exposure.

This section provides the requirements for the licensee to apply the system of protection and safety to protect members of the public against exposure.

Section 48. Contamination in Areas Accessible to Members of the Public.

This section provides the requirements to ensure that specific provisions for confinement are established for the design and operation of a source that could cause the spread of contamination in areas that are accessible to members of the public.

Section 49. Monitoring and Reporting of Public Exposure.

This section provides the requirements to ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.

Section 50. Consumer Products

This section specifies the requirements for the providers of consumer products to ensure that consumer products are not made available to the public unless the use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized.

The development of the CPR Part 3 undertook thorough review process through series of consultations, discussions, and IAEA expert mission prior to its approval. The CPR Part 3, "Standards for Protection Against Radiation, Rev. 2" was published in the Official Gazette Vol. 117 No. 10 on 8 March 2021 and took effect fifteen (15) days thereafter. The provisions of this order are applicable to all addressees.

The electronic copy of the latest CPR Part 3 is now available and can be downloaded from the PNRI website. (www.pnri.dost.gov.ph).

REQUIRED LICENSEE RESPONSE

The licensee must comply with the requirements of the said CPR.

CONTACT

If you have any question about the information in this notice, please contact:

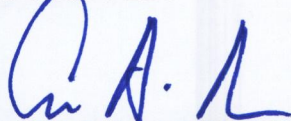
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