

<b>Document:</b> CPR Part 09, Rev. 0	<b>Title:</b> Safety Assessment for Nuclear and Radiation Facilities and Activities	
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Republic of the Philippines  
 Department of Science and Technology  
**PHILIPPINE NUCLEAR RESEARCH INSTITUTE**  
 Commonwealth Avenue, Diliman, Quezon City

**CPR PART 9**  
**SAFETY ASSESSMENT FOR NUCLEAR AND RADIATION FACILITIES AND ACTIVITIES**

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## CPR PART 9 SAFETY ASSESSMENT FOR NUCLEAR AND RADIATION FACILITIES AND ACTIVITIES

### 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) The objective of this regulation is to establish the responsibilities and requirements to perform and manage the safety assessment of nuclear and radiation facilities and their associated activities in order to determine whether adequate measures are in place to ensure compliance with the Act and the Code of PNRI Regulations (CPR).

#### Section 2. **Scope.**

- (a) The requirements of this regulation apply as such to an applicant for, or a holder of, a License to Construct or License to Operate for nuclear and radiation facilities and their associated activities.
- (b) This Part does not apply to an applicant for, or a holder of, a Radioactive Material License pursuant to CPR Part 2.
- (c) Nothing in this Part shall be construed as restricting any actions that may otherwise be necessary to ensure protection and safety of the workers, the general public, and the environment.

#### Section 3. **Definitions.**

As used in this Part:

- (a) **"Accident condition"** means a deviation from normal operation that are less frequent and more severe than abnormal operations;

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- (b) **“Act”** means Republic Act No. 2067, otherwise known as the Science Act of 1958, as amended by Republic Act No. 3589, and 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”**, also called abnormal operation, means a deviation of an operational process from normal operation that 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 or lead to accident conditions;
- (d) **“Associated activities”** means the possession, production, processing, use, handling, storage, import, export, decommissioning or dismantling, radioactive waste management activities, disposal or transport of radioactive material and for which a specific authorization under a License to Operate is required;
- (e) **“Code or CPR”** means the Code of PNRI Regulations;
- (f) **“Failure”** means a failure of a system, structure, or component (item) to maintain its capability or perform its function as intended in the design by any of the relevant failure modes, including inadvertent or spurious operation;
- (g) **“Graded approach”** means an application of safety requirements that is commensurate with the characteristics of the facilities and activities or the source and with the magnitude and likelihood of the exposures;
- (h) **“Human factors”** means the environmental, organizational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety;
- (i) **“License to Operate”** means legal document issued by the PNRI to the applicant granting authorization to operate a radiation facility and to perform specified activities relating to a facility or activity.
- (j) **“Licensee”** means a holder of a valid license issued by the PNRI pursuant to this CPR Part 2, and having overall responsibility for the conduct of authorized activities involving a licensed radioactive material or the operation of a radiation facility;
- (k) **“Nuclear facility”** means a facility (including associated buildings and equipment) in which nuclear material is produced, processed, used, handled, stored or disposed of;
- (l) **“Normal operation”** means operation within specified operational limits and conditions, or when the facility is operating normally, or the activity is being carried out normally;
- (m) **“Person”** means any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity, or any government agency other than the PNRI who or which has responsibility and authority for any action having implications for protection and safety:
- (n) **“Philippine Nuclear Research Institute or (PNRI)”** means the body designated by the government as having legal authority to conduct the regulatory processes, including the issuance of a license, conduct of inspection and enforcement;

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- (o) **“Radiation facility”** means a facility, other than nuclear installations, where radioactive material is produced, processed, used, handled, stored or disposed of on such a scale that consideration of protection and safety is required within the entire premises, and is likely to cause overexposure of individuals and release of radioactive substances in the environment;
- (p) **“Safety analysis”** means the evaluation of the potential hazards associated with a facility or an activity. The formal safety analysis is part of the overall safety assessment; i.e. it is part of the systematic process that is carried out throughout the design process (and throughout the lifetime of the facility or the activity) to ensure that all the relevant safety requirements are met by the proposed (or actual) design;
- (q) **“Safety assessment”** means the systematic process that is carried out throughout the design process and throughout the lifetime of the facility or the activity to ensure that all the relevant safety requirements are met by the proposed or actual design; and
- (r) **“Safety functions”** means functions that are necessary to be performed for the facility or activity to prevent or to mitigate radiological consequences of normal operation, abnormal operations and accident conditions.

**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 **PNRI** in writing, no interpretation of the meaning of the regulations by any officer or employee of PNRI, other than a written interpretation by the **Director**, will be recognized to be binding upon the PNRI.

#### Section 5. ***Communication.***

All communications 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 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”, and with the administrative and technical requirements of other applicable regulations for specific facilities and activities.
- (b) 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.

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- (c) If a conflict exists between requirements contained herein and other laws or regulations, the PNRI shall be notified of such conflict to initiate steps towards resolution.

#### Section 7. ***Additional Regulatory Requirements.***

The PNRI may impose upon the licensee, by appropriate rule, regulation, or order after due process or consultation, such requirements in addition to those established in this Part as it deems appropriate or necessary to protect the health and safety of the workers, public and the environment, or minimize danger to life or property and ensure the security of radioactive sources.

## II. GENERAL REQUIREMENTS FOR SAFETY ASSESSMENT

#### Section 8. ***Purpose of the Safety Assessment.***

- (a) The primary purpose of the safety assessment shall be to determine whether an adequate level of safety has been achieved **by the proposed (or actual) design** for a facility or activity in relation to the safety objectives and safety criteria as established in the Code of PNRI Regulations.
- (b) The safety assessment shall be able to address the following:
- (1) All radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.
  - (2) All the radiation risks to individuals and the local population groups that arise from operation of the facility or conduct of the activity, including those that are geographically remote from the facility or activity.
  - (3) All radiation risks in the present and in the long term, in particular, the management of radioactive waste whose effects could span many generations.
- (c) The results of the safety assessment shall be used to --
- (1) Determine appropriate safety related improvements to the design and operation of the facility or the conduct of the activity;
  - (2) Specify the operational limits and conditions for the facility;
  - (3) Specify the program for maintenance, surveillance, and inspection to be established;
  - (4) Outline the procedures for abnormal conditions and on-site and off-site emergency response;
  - (5) Specify the necessary competences of staff in nuclear and radiological safety issues;
  - (6) Make decisions that ensure the safety of and minimize the risks to the facility and related activities.

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- (d) The safety assessment shall be updated throughout the lifetime of the facility whenever a design modification, operational experience, or new knowledge makes it necessary to revise the assumptions, models, or data used in the assessment.

### Section 9. ***Responsibility for the Safety Assessment.***

- (a) An applicant for, or a holder of, a license shall be responsible for carrying out the safety assessment. In particular, the applicant or licensee is required to:
- (1) Conduct safety assessment and document the results;
  - (2) Identify any additional safety requirements to be included;
  - (3) Ensure that the safety assessment is independently verified before submission to the PNRI as part of the licensing process;
  - (4) Conduct periodic review of the safety assessment;
  - (5) Ensure that all safety provisions are implemented; and
  - (6) Keep relevant records for the period required by the PNRI.
- (a) The applicant for, or a holder of, a license shall ensure that the safety assessment covers the full life cycle of the facility. The stages of the facility life cycle shall include the following:
- (1) Site evaluation for the facility;
  - (2) Development of the design of the facility;
  - (3) Construction of the facility;
  - (4) Commissioning the facility or activity;
  - (5) Commencement of operation of the facility or conduct of the activity;
  - (6) Modification of the design or operation; (that requires license amendment)
  - (7) Periodic safety reviews;
  - (8) Life extension of the facility beyond its original design life;
  - (9) Changes in ownership or management of the facility;
  - (10) Decommissioning and dismantling of the facility;
  - (11) Closure of a disposal facility for radioactive waste, and the post-closure phase; and
  - (12) Remediation of a site and release from regulatory control.
- (b) The applicant or licensee shall ensure that the following are available to carry out the safety assessment:
- (1) Sufficient number of people with the necessary skills and expertise available to conduct the safety assessment;
  - (2) Access to a Qualified Expert to conduct an independent review the safety assessment;



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- (3) Background information relating to the location, design, construction, commissioning, operation, decommissioning and dismantling (or closure) of the facility, as relevant, together with any other evidence that is required to support the safety assessment;
- (4) Adequate funding;
- (5) The necessary tools for carrying out the safety assessment;
- (6) The safety criteria defined in the regulations or standards adopted or approved by the regulatory body to be used for judging whether the safety of the facility is adequate.

Section 10. ***Graded Approach to Safety Assessment.***

- (a) Before starting the safety assessment, **the applicant or licensee shall determine** the scope and level of detail of the safety assessment, and the resources that need to be directed to it, and these shall be agreed with the PNRI.
- (b) The application of the graded approach shall be reassessed as the safety assessment progresses and a better understanding is obtained of the radiation risks arising from the facility or activity. The scope and level of detail of the safety assessment shall be modified as necessary and the level of resources to be applied is adjusted accordingly.

Section 11. ***Scope of the Safety Assessment.***

**11.1. Considerations Applicable to All Types of Facilities and Activities**

- (a) The safety assessment shall address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions. The safety assessment for anticipated operational occurrences and accident conditions shall also address failures that might occur and the consequences of any failures.
- (b) The safety assessment shall include an assessment of the provisions in place for radiation protection, to determine whether radiation risks are being controlled within specified limits and constraints, and whether they have been reduced to a level that is as low as reasonably achievable.
- (c) The **safety assessment shall review and analyze** the design of the facility, items important to safety, and human interactions to identify and correct design deficiencies, to assess and justify the final design solutions, and to ensure the fulfillment of the safety objectives and design basis requirements in operational states as well as in accident conditions.
- (d) It shall be determined in the safety assessment whether requirements relating to human factors were addressed in the design and operation of a facility or in the way in which an activity is conducted. This includes those human factors relating to ergonomic design in all areas and to human-machine interfaces where activities are carried out.
- (e) It shall be evaluated in the safety assessment whether personnel competences, the associated training programs, and the specified minimum staffing levels for maintaining safety are adequate.

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- (f) It shall be determined in the safety assessment whether any time related aspects, such as ageing and wear, or life limiting factors, such as cumulative fatigue, embrittlement, corrosion, chemical decomposition and radiation induced damage, have been adequately addressed.

### **11.2. Additional Considerations Applicable to Large Scale Radiation Facility and Nuclear Facility**

- (a) The requirements of this Sub-section shall be applicable to the following facilities and their associated activities:
- (1) Particle therapy facility;
  - (2) Gamma irradiation facility;
  - (3) Cyclotron facility for radiopharmaceuticals production;
  - (4) Radioactive waste management and disposal facility;
  - (5) Nuclear installations; and
  - (6) Other high-risk facilities as will be determined by PNRI.
- (b) The site characteristics relating to the safety of the facility shall be assessed to ensure that the radiological impact assumptions are correct, that the facility is sufficiently protected against external hazards, and that the potential effects on a nuclear facility with multiple units, if relevant, are appropriately covered by the facility design and emergency measures. An assessment of the site characteristics shall cover:
- (1) The physical, chemical, and radiological characteristics that will affect the dispersion or migration of radioactive material released in normal operation or as a result of anticipated operational occurrences or accident conditions;
  - (2) Identification of natural and human induced external events in the region that have the potential to affect the safety of facilities and activities; and
  - (3) The distribution of the population around the site and its characteristics with regard to any siting policy established by the Department of Environment and Natural Resources (DENR), and the requirement to develop an emergency plan.
- (c) All structures, systems and components important to safety shall be assessed to determine whether they are of a robust and proven design and are suitable for their purpose. It shall be addressed in the safety assessment whether preference has been given to a fail-safe design or, if this is not practicable, whether an effective means of detecting failures that occur has been incorporated wherever appropriate.
- (d) Human interactions with the facility or a specific activity shall be addressed to determine whether the procedures and measures for operational states and accident conditions ensure an adequate level of safety and whether sufficient design features, administrative procedures, and control measures have been provided to prevent and mitigate the influence of human errors on the safety of the facility.
- (e) The external and internal events that could arise for a facility or activity shall be addressed in the safety assessment, and it has to be determined whether an adequate level of protection against their consequences is provided.

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- (f) For facilities on a site that would share resources (whether human resources or material resources) in accident conditions, the safety assessment shall demonstrate that the required safety functions can be fulfilled at each facility in accident conditions.
- (g) The provisions made for the decommissioning and dismantling of a facility or for the closure of a disposal facility for radioactive waste shall be specified, and it shall be determined in the safety assessment whether they are adequate.
- (h) In the case of a disposal facility for radioactive waste in significant quantities, radiation risks shall be considered for the post-closure phase, including the degradation of barriers, and from discrete events that could affect isolation of the waste, such as inadvertent human intrusion or abrupt changes in geological conditions.

### **11.3. Additional Considerations Applicable to Nuclear Facilities**

- (a) The safety functions shall be reviewed, analyzed, and assessed to determine whether their failure tolerance and reliability are at a level commensurate with their importance for the defense in depth and the fundamental safety function objectives of the facility. The reviews, analyses, and assessments performed for a specific safety function shall cover the relevant operational states and the accident, design extension, and hazard conditions.
- (b) It shall be determined in the safety assessment whether equipment essential to safety has been qualified to a sufficiently high level that it will be able to perform its safety function in the conditions that would be encountered in normal operation, and following anticipated operational occurrences and accident conditions that were taken into account in the design, and in conditions that may arise as a result of external events that were taken into account in the design.
- (c) The defense in depth features of the nuclear facility shall be reviewed, analyzed, and assessed to determine whether adequate provisions have been made at each level of defense in depth, whether there exist such dependencies between the levels that several levels of defense could be coincidentally or consequentially lost, and whether the final design can be considered compliant with the defense in depth principle.
- (d) It shall be determined in the safety assessment whether there are adequate safety margins in the design and operation of the facility, or in the conduct of the activity, in normal operation and in anticipated operational occurrences or accident conditions such that there is a wide margin to failure of any structures, systems and components for any of the anticipated operational occurrences or any possible accident conditions.
- (e) For sites with multiple facilities or multiple activities, account shall be taken in the safety assessment of the effects of external events on all facilities and activities, including the possibility of concurrent events affecting different facilities and activities, and of the potential hazards presented by each facility or activity to the others.
- (f) The safety assessment shall include a safety analysis, which consists of a set of different quantitative analyses for evaluating and assessing challenges to safety by means of deterministic and also probabilistic methods. The scope and level of detail of the safety analysis are determined by use of a graded approach.
- (g) The calculational methods and computer codes that are used to carry out the safety analysis shall be verified, tested, and benchmarked as appropriate to build confidence

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in their use and their suitability for the intended application. This will form part of the supporting evidence presented in the documentation. As part of the management system, the operating organization and the regulatory body shall seek improvements to the tools and data that are used.

### **III. SAFETY ANALYSIS**

#### **Section 12. *Scope of the Safety Analysis***

- (a) The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.
- (b) The consequences arising from all conditions in normal operation and the frequencies and consequences associated with all anticipated operational occurrences and accident conditions shall be addressed in the safety analysis. The analysis shall be performed to a scope and level of detail that correspond to the magnitude of the radiation risks associated with the facility or activity, the frequency of the events included in the safety analysis, the complexity of the facility or activity, and the uncertainties inherent in the processes that are included in the safety analysis. The analysis of accidents shall also be made for the purposes of emergency preparedness.
- (c) The anticipated operational occurrences and accident conditions that challenge safety shall be identified in the safety analysis, including all internal and external events and processes that may have consequences for physical barriers for confining radioactive material or that otherwise give rise to radiation risks. The features, events and processes to be considered in the safety analysis shall be selected on the basis of a systematic, logical and structured approach, and justification shall be provided that the identification of all scenarios relevant for safety is sufficiently comprehensive. The analysis shall be based on an appropriate grouping and bounding of the events and processes, and partial failures of components or barriers as well as complete failures shall be considered.
- (d) The safety analysis shall take into account any relevant operating experience from the actual facility or activity, where available, and operating experience from similar facilities and activities, including consideration of the anticipated operational occurrences and accident conditions that have arisen during operation of the facility or conduct of the activity.
- (e) The safety analysis shall include both deterministic and probabilistic approaches, the extent of which shall be consistent with the graded approach.

#### **Section 13. *Deterministic Safety Analysis***

- (a) A deterministic safety analysis of the design of the nuclear facility shall be made to predict the behavior of the facility in, and following, all operational states and accident conditions and to ensure that the safety criteria are met.
- (b) Acceptance criteria shall be specified for the deterministic safety analyses to judge the safety based on the key facility parameters and the radiological impact, as analysed for regular operation, anticipated operational occurrences, and accident conditions.

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- (c) A comprehensive list of postulated initiating events shall be prepared so that the analysis of the facility response provides an envelope of all foreseeable events challenging the integrity of physical release barriers and the performance of safety functions.
- (d) Calculational methods and computer codes used in the safety analysis shall undergo verification and validation with appropriate experimental data and research. Uncertainty and sensitivity analyses shall be performed and accounted for when applying the results.
- (e) The facility's response to postulated initiating events shall be analyzed to determine whether the acceptance criteria and the safety criteria are met even with unfavorable combinations of initial conditions, equipment failures, and operator actions, as specified for the design basis and features as well as the operational limits and conditions of the facility.

#### Section 14. ***Probabilistic Safety Analysis.***

- (a) A probabilistic safety analysis shall be made to determine whether the radiation risks are as low as reasonably achievable and to guide the decisions for improving the safety of the design and management of a facility throughout the life cycle.
- (b) All initiating events caused by failures, errors, or hazards that could challenge regular operation and require mitigation to prevent, or events that could lead directly to severe damage to fuel, the reactor core, or other radiologically risk-significant items of the nuclear facility, shall be identified and grouped to establish the starting point of the probabilistic safety analysis.
- (c) The response of the nuclear facility to each group of initiating events shall be analyzed to model the alternative sequences in which the initiating events could develop further, as they are affected by the reliability of items performing their safety functions and of the operators taking correct actions.
- (d) Based on initiating event identification, accident sequence modelling, and detailed reliability analyses, the probabilistic safety analysis shall present the quantitative results in the form of different facility damage states and their frequencies. The total frequency of damage states involving severe damage, with appropriate uncertainty considerations, shall be viewed as a quantitative estimate of the effectiveness of the defense in depth levels and the safety functions in preventing severe accidents. The results shall be used to identify the most significant contributors to the severe damage frequency and the subsequent opportunities for safety improvements and a more balanced design.
- (e) The probabilistic safety analysis shall be completed by further analyzing the progress and management of severe accidents, the effectiveness of the confinement of radioactive materials released, and the consequences in terms of radioactive releases into the environment. The frequencies and characteristics of these radioactive source terms and their radiological impact, with appropriate uncertainty considerations, shall be viewed as quantitative estimates of the radiation risks associated with the nuclear facility. The assessment results shall be factored to identify the largest risk contributors and opportunities for risk reduction.

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**Section 15. *Criteria for Judging Safety.***

- (a) Criteria for judging safety shall be defined for the safety analysis.
- (b) The safety criteria shall be sufficient to meet the requirements of the designer, the operating organization and the regulatory body.

**Section 16. *Uncertainty and Sensitivity Analysis.***

- (a) Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.
- (b) Uncertainties in the safety analysis shall be characterized with respect to their source, nature and degree, using quantitative methods, professional judgement or both. Uncertainties that may have implications for the outcome of the safety analysis and for decisions made on that basis shall be addressed in uncertainty and sensitivity analyses.

**Section 17. *Use of Operating Experience Data.***

- (a) If warranted by the possible radiation risks associated with a facility or activity, data on operational safety performance shall be collected and assessed, including records of incidents such as human errors, the performance of safety systems, radiation doses, and the generation of radioactive waste and effluents. The scope of the data to be collected for facilities and activities shall be in accordance with the graded approach.
- (b) Data on operating experience shall be used, as appropriate, to update the safety assessment and to review the management systems.

**IV. MANAGEMENT AND MAINTENANCE OF THE SAFETY ASSESSMENT**

**Section 18. *Documentation of the Safety Assessment.***

- (a) The results and findings of the safety assessment shall be documented, as appropriate, in the form of a safety report that reflects the complexity of the facility or activity and the radiation risks associated with it.
- (b) The quantitative and qualitative outcomes of the safety assessment shall form the basis for the safety report. The outcomes of the safety assessment are supplemented by supporting evidence for and reasoning about the robustness and reliability of the safety assessment and its assumptions, including information on the performance of individual components of systems as appropriate.
- (c) The safety report shall document the safety assessment in sufficient scope and detail to support the conclusions reached and to provide an adequate input into independent verification and regulatory review. The safety report includes:
  - (1) A justification for the selection of the anticipated operational occurrences and accident conditions considered in the analysis;

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- (2) An overview and necessary details of the collection of data, the modelling, the computer codes and the assumptions made;
  - (3) Criteria used for the evaluation of the modelling results;
  - (4) Results of the analysis covering the performance of the facility or activity, the radiation risks incurred and a discussion of the underlying uncertainties;
  - (5) Conclusions on the acceptability of the level of safety achieved and the identification of necessary improvements and additional measures.
- (d) The safety report shall be updated as necessary. The safety report shall be retained until the facility has been fully decommissioned and dismantled or the activity has been terminated and released from regulatory control. For a disposal facility for radioactive waste, the safety report shall be retained for an extended period of time after closure of the disposal facility.

#### Section 19. ***Independent Verification.***

- (a) The operating organization shall ensure that safety assessment undergoes appropriate verification controls and a formal approval process before it is submitted to the regulatory body as part of its license application.
- (b) The independent verification shall be performed by a Qualified Expert or a PNRI-approved Technical Service Provider, who are independent of the original team who performed the safety assessment and those directly responsible for the facility's operations.
- (c) The decisions made on the scope and level of detail of the independent verification shall be reviewed in the independent verification itself, to ensure that they are consistent with the graded approach and reflect the possible radiation risks associated with the facility or activity, and its maturity and complexity.
- (d) The independent verification shall combine an overall review, to determine whether the safety assessment carried out is comprehensive, with spot checks in which a much more detailed review is carried out that focuses on those aspects of the safety assessment that have the highest impact on the radiation risks arising from the facility or activity. It shall be considered in the independent verification whether there are any contributions to radiation risks that have not been taken into account.
- (e) In addition, the PNRI shall carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are being met.

#### Section 20. ***Periodic Safety Reviews.***

- (a) The safety of the facility shall be periodically reviewed to determine whether an adequate level of safety is maintained during operation.

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- (b) The periodic safety reviews shall be performed with a broad scope covering the design and development, condition and aging, operational performance, radiological effects, and management of the facility.
- (c) The following circumstances shall be taken into account in the review and updating of the safety assessment:
  - (1) Any changes that may significantly affect the safety of the facility or activity;
  - (2) Significant developments in knowledge and understanding;
  - (3) New safety-related information and standards;
  - (4) Emerging safety issues due to a regulatory concern or a significant incident; and
  - (5) Safety significant modifications to the design or operation.
- (d) The results of the periodic safety review of the nuclear facility shall be used to --
  - (1) Create an integrated view of the facility safety status and necessary improvements;
  - (2) Steer the allocation of resources for issues and actions of safety significance; and
  - (3) Support the safe use of the facility throughout its lifetime.
- (e) The periodic safety reviews shall be performed with a maximum interval of ten (10) years or as prescribed by the PNRI for specific facilities.

## V. EFFECTIVITY

### Section 21. *Transitory Provision.*

- (a) For facilities and activities already licensed or authorized by PNRI, all the requirements of this Part shall be fulfilled within two (2) years after the promulgation of these regulations.
- (b) For a new facility, a safety assessment shall be conducted at the design stage as part of the requirements to apply for a license. For existing facilities, a safety assessment shall be carried out as early as possible. A new safety assessment may not be necessary for the replacement of one source with an identical one.
- (c) For facilities under construction and no safety assessment has been previously conducted, a retrospective safety assessment shall be carried out to confirm or identify any additional measures required.

### Section 22. *Effective Date.*

The regulations in this Part shall take effect 15 days following the publication in the Official Gazette or in a newspaper of general circulation.

**APPROVED:**



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**CARLO A. ARCILLA, Ph. D.**

Director

Date of Approval: \_\_\_\_\_