



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

CPR PART 28

LICENSING REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE FACILITIES AND ACTIVITIES

TABLE OF CONTENTS

I. GENERAL PROVISIONS	1
Section 1. Purpose.....	1
Section 2. Definition of Terms.....	1
Section 3. Interpretation	5
Section 4. Communication	5
Section 6. Application for a License	5
Section 7. Issuance of License	6
Section 8. Terms and Conditions of License.....	7
Section 9. Amendment of License	8
Section 10. Specific Conditions for Expiration of License	9
Section 11. Renewal of License.....	9
Section 12. Termination of License.....	10
Section 13. Specific Exemptions.....	11
Section 14. Additional Regulatory Requirements.....	11
II. ADMINISTRATIVE REQUIREMENTS	11
Section 15. Radiation Safety Program.....	11
Section 16. Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO).....	12
Section 17. Radioactive Waste Management Officer.....	12
III. TECHNICAL REQUIREMENTS.....	13
Section 18. Safety Case	13
Section 19. Classification of Work Areas	14

Section 20. Personnel Monitoring	14
Section 21. Surveys for Contamination and Ambient Radiation Dose Rate.....	14
Section 22. Possession, Use and Calibration of Radiation Detection and Measuring Instruments.....	15
IV. INTEGRATED APPROACH TO SAFETY AND SECURITY	15
Section 23. Management System	15
Section 24. Transport of Radioactive Waste.....	16
Section 25. Emergency Response Plan and Preparedness	16
Section 26. Security of Predisposal Radioactive Waste Management Facility...	17
Section 27. Interdependences	17
V. STEPS IN PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE	18
Section 28. Control of Radioactive Waste Generation	18
Section 29. Radioactive Waste Characterization and Classification	19
Section 30. Radioactive Waste Categorization	20
Section 31. Acceptance Criteria for Radioactive Waste.....	20
Section 32. Processing of Radioactive Waste from Collection up to Treatment	21
Section 33. Conditioning	23
Section 34. Storage of Radioactive Waste.....	24
Section 35. Recycle and Reuse.....	25
Section 36. Discharge or Release of Radioactive Materials to the Environment	26
Section 37. Clearance and its Control	27
VI. DEVELOPMENT AND OPERATION OF PREDISPOSAL RADIOACTIVE WASTE MANAGEMENT FACILITIES AND ACTIVITIES	27
Section 38. Location and Design of Facilities	27
Section 39. Construction and Commissioning of the Facilities.....	27
Section 40. Facility Operation	28
Section 41. Decommissioning.....	29
Section 42. Existing Situations and Past Practices.....	32
VII. EDUCATION, TRAINING AND EXPERIENCE REQUIREMENTS	32
Section 43. Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO).....	32
Section 44. Radioactive Waste Management Officer.....	32
Section 45. Refresher Course.....	33
VIII. RECORDS, REPORTS AND NOTIFICATIONS.....	33
Section 46. Radioactive Waste Records and Reports	33

Section 47. Record System	33
Section 48. Reports of Workers Exposure	35
Section 49. Notification on Specific Changes in the License	35
Section 50. Notification of Incidents/Accidents	35
Section 51. Reporting of Incidents/Accidents.....	35
IX. INSPECTION AND ENFORCEMENT	36
Section 52. Inspections.....	36
Section 53. Violations	36
Section 54. Modification and Revocation of License.....	36
X. EFFECTIVITY	37
Section 55. Effective Date.....	37



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CPR PART 28

LICENSING REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE FACILITIES AND ACTIVITIES

I. GENERAL PROVISIONS

Section 1. Purpose

- (a) This Part prescribes the requirements for the predisposal management of radioactive wastes and development and operation of a predisposal radioactive waste management facility, pursuant to the provisions of Republic Act No. 5207, as amended.
- (b) This Part covers all the steps in the management of radioactive waste prior to disposal, from its generation, pretreatment, treatment conditioning, storage and transport.
- (c) This Part establishes the safety and security requirements that apply to all facilities and activities that are involved in the management of radioactive waste before final disposal.
- (d) The requirements and provisions in this Part provide for the protection of the workers, members of the public and the environment during normal operation and in possible accident conditions, and are in addition to other requirements in the Code of PNRI Regulations (CPR or Code).
- (e) The provisions and requirements of this Part shall be applied in conjunction with the radiation safety requirements of CPR Part 3, radioactive source security requirements of CPR Part 26, safe transport requirements of CPR Part 4 and transport security of radioactive materials requirements of CPR Part 27.
- (f) This Part does not relieve the licensee from complying with the applicable requirements of other responsible agencies of government.

Section 2. Definition of Terms

As used in this Part:

- (a) “**Accident**” means any unintended event, including operating errors, equipment

failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;

- (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;
- (c) “**Applicant**” means any person or organization applying to a regulatory body for authorization or approval to undertake specified activities.
- (d) “**Assistant Radiation Protection Officer**” means the individual who is identified in the license issued pursuant to this Part to perform the duties and responsibilities of the RPO in his/her absence;
- (e) “**CPR**” means the Code of PNRI Regulations;
- (f) “**Characterization**” means the determination of the physical, chemical and radiological properties of the waste to establish the need for further adjustment, treatment, conditioning, or its suitability for further handling, processing, storage or disposal;
- (g) “**Clearance levels**” means a set of values, established by PNRI and expressed in terms of activity concentration and/or total activity, at or below which a source of radiation may be released from regulatory control;
- (h) “**Conditioning**” means those operations that produce a waste package suitable for handling, transport, storage and/or disposal. Conditioning may include the conversion of the waste to a solid waste form, enclosure of the waste in containers and, if necessary, provision of an overpack;
- (i) “**Disused sealed source**” means a radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorization has been granted;
- (j) “**Decommissioning**” means an administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility reducing residual radioactivity that permits:
 - (1) Release of the facility or site for unrestricted use and termination of the license; or
 - (2) Release of the facility or site under restricted conditions and termination of the license.
- (k) “**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;
 - (1) Emergency plans are prepared at several different levels: national, local and facility. They may include all activities planned to be carried out by all

relevant organizations and authorities or may be primarily concerned with the actions to be carried out by a particular organization. The term overall emergency plan is sometimes used for clarification when the former meaning is intended.

- (2) Details regarding the accomplishment of specific tasks outlined in an emergency plan are contained in emergency procedures, a set of procedures to be implemented in the event of an accident.
- (l) “**Interdependence**” means mutual dependence among all steps in the predisposal management;
- (m) “**Licensee**” means the holder of a PNRI license issued pursuant to the Code of PNRI Regulations;
- (n) “**Person**” means:
- (3) any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or government agency other than PNRI, or any province, city, municipality, or any political subdivision or entity within the Philippines; and
- (4) any legal successor, representative, agent or agency of the foregoing.
- (o) “**PNRI**” means the Philippine Nuclear Research Institute and its duly authorized representative;
- (p) “**Predisposal**” means any waste management steps carried out prior to disposal, such as pretreatment, treatment, conditioning, storage and transport activities. Predisposal is used as a contraction of “predisposal radioactive waste management”, not a form of disposal;
- (q) “**Pretreatment**” means any or all of the operations prior to waste treatment, such as collection, segregation, chemical adjustment and decontamination;
- (r) “**Radiation Protection Officer**” means the individual designated in the license issued pursuant to this Part to be responsible for implementing the radiation safety program of the licensee;
- (s) “**Radioactive Source**” means any radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It also means any radioactive material released if the radioactive source is leaking or broken but does not mean source encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research or power reactor;
- (t) “**Radioactive Waste Management Officer**” means a person technically capable of overseeing all the activities, administrative and operational that are involved in the handling, pretreatment, treatment, conditioning, transportation storage and disposal of radioactive waste;
- (u) “**Safety assessment**” means a review of all aspects of a practice that are

relevant to protection and safety; for an authorized facility, this includes siting, design and operation of the facility;

- (v) **“Safety case”** means a collection of arguments and evidence in support of the safety of a facility or activity;
- (w) **“Security”** means measures to prevent unauthorized access or damage to, and loss, theft, or unauthorized transfer of radioactive sources;
- (x) **“Segregation”** means an activity where types of waste or material (radioactive or exempt) are separated or are kept separate on the basis of radiological, chemical and/or physical properties, to facilitate waste handling and/or processing;
- (y) **“Radioactive waste”** means material for which no further use is foreseen that contains, or is contaminated with radionuclides, at activity concentrations greater than clearance levels as established by the PNRI;
- (z) **“Treatment”** means the operations intended to benefit safety and economy by changing the characteristics of waste. Three basic treatment objectives are:
 - (1) volume reduction
 - (2) removal of radionuclides from the waste
 - (3) change of composition
- (aa) **“Waste acceptance criteria”** means quantitative or qualitative criteria specified by the PNRI, or specified by a licensee and approved by the PNRI, for the waste form and waste package to be accepted by the licensed radioactive waste management facility.
- (bb) **“Waste Inventory”** means a detailed, itemized record maintained by the licensee in accordance with the regulations, and may contain data such as physical quantity, the activity of the waste, the radionuclide content, and other characteristics;
- (cc) **“Waste minimization”** means the process of reducing the amount and activity of radioactive waste to a level as low as reasonably achievable, at all stages from the design of a facility or activity to decommissioning, by reducing waste generation and by means such as recycling and reuse, and treatment, with due consideration for secondary as well as primary waste;
- (dd) **“Worker”** means any individual who works, whether full time, part time or temporarily, for a licensee and who has recognized rights and duties in the license in relation to occupational radiation protection;

Section 3. *Interpretation*

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

Section 4. *Communication*

All communications and reports concerning the license and the requirements in this Part shall be addressed to

The Director
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City

Section 5. *Activities Requiring License*

No person shall keep or manage radioactive waste from its generation up to final disposal except in accordance with a license issued by PNRI pursuant to this Part or other applicable Parts.

Section 6. *Application for a License*

- (a) An application for a new license pursuant to this Part shall be filed with the PNRI/NRD Form-028, "Application for a License for the Predisposal Management of Radioactive Waste Facility and Activities", in duplicate copies.
- (b) Each application for a license pursuant to this Part shall be duly affirmed and notarized and shall be signed by the applicant or RPO duly authorized to act for and on his behalf upon submission to PNRI.
- (c) The applicant shall show proof of authenticity of business name issued by the Securities and Exchange Commission and the current business permit or specific authorization issued by the responsible government agency.
- (d) The application shall adequately describe the necessary information required in the application form in accordance with the technical, safety, and security requirements specified in this Part and shall be accepted and processed only when PNRI has determined the completeness of the submitted information, and payment of corresponding fees prescribed in CPR Part 22 has been made.
- (e) PNRI, may, at any time after the filing of the application, require further statements to enable PNRI to determine whether the license should be granted or denied.

Section 7. *Issuance of License*

An application for a license pursuant to this Part shall be approved and license shall be granted if:

- (a) The application is for the purpose authorized by the Act.
- (b) The applicant shall address all the elements of management of radioactive waste that include:
 - (1) Waste generation;
 - (2) Segregation;
 - (3) Pretreatment;
 - (4) Characterization;
 - (5) Treatment;
 - (6) Conditioning;
 - (7) Storage;
 - (8) Control of discharges;
 - (9) Clearance;
 - (10) Packaging strategies;
 - (11) Transport;
 - (12) Design and manufacture of containers;
 - (13) Handling of waste packages; and
 - (14) Site evaluation, design, construction, operation, closure and the post-closure stage of a waste management facility.
- (c) The applicant shall prepare a safety case early in the development of a facility and supporting safety and environmental assessments reflecting the requirements of PNRI and commensurate with the complexity of the facility and its potential impacts. The safety case for a predisposal management of radioactive waste and facility shall:
 - (1) Include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met.
 - (2) The safety case shall address operational safety and all safety aspects of the facility and activities. The safety case shall include considerations for

reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.

- (d) The proposed Radiation Protection Officer, Radioactive Waste Management Officer, and authorized workers shall meet the requirements in Sec. 16, 17, 45 and 46 of this Part.
- (e) The applicant shall designate a Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO) who meet the requirements in Sec. 45 of this Part. The designated RPO and ARPO shall both consent and agree in writing, and shall ensure the effective implementation of the radiation safety and source security programs in accordance with approved procedures and the regulatory requirements.
- (f) The applicant shall designate a Radioactive Waste Management Officer who shall ensure effective and efficient on-site management of radioactive waste.
- (g) The authorities, duties, and responsibilities of the RPO and ARPO on matters affecting radiation safety shall be established and stated in writing.
- (h) The applicant shall have a program for training and retraining of workers.
- (i) The applicant shall possess a calibrated and operable radiation survey instrument required in Sec. 22 of this Part.
- (j) The applicant shall submit a radiation safety program that addresses CPR Part 3 and the technical requirements of this Part.
- (k) The applicant shall establish procedures for the transport of radioactive sources in accordance with the requirements of CPR Part 4 "Regulations for the Safe Transport of Radioactive Material in the Philippines".
- (l) The applicant shall establish a management system that provides assurance that the requirements for safety and environmental protection are met; and that the components of the safety systems are sufficient.
- (m) The applicant shall establish and submit to PNRI an emergency plan in accordance with the requirements of CPR Part 3 and Section 25 of this Part.
- (n) The applicant shall establish a decommissioning plan for a predisposal facility.
- (o) The applicant shall submit proof that it has adequate finances to cover the full costs of the operation of the predisposal management facility.
- (p) The applicant shall pay all applicable fees in accordance with CPR Part 22.

Section 8. *Terms and Conditions of License*

- (a) Each license issued shall be subjected to the applicable provisions of the Act, specific conditions of the license and to all relevant rules, regulations, and orders of PNRI.

- (b) The license shall be valid for a period as may be determined by PNRI.
- (c) PNRI may incorporate in any license issued pursuant to this Part at the time of issuance or thereafter by appropriate notification, rule or order, such additional requirements and conditions with respect to the license as it deems appropriate or necessary in order to protect health and safety, as well as ensure the security of the radioactive source.
- (d) Neither the license issued nor right granted under the license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless PNRI, after securing full information,
 - (1) finds that the proposed transfer, is in accordance with the regulations of the Code and provisions of the Act; and
 - (2) consents in writing to the proposed transfer.
- (e) Upon the approval of PNRI of a proposed transfer, pursuant to (d) of this Section, the transferor shall ensure that the transferee is provided with all the information required by PNRI.
- (f) Each licensee shall confine the activities described in the license to the location and purpose authorized in the license.
- (g) Each licensee shall strictly follow the regulatory requirements regarding the renewal, amendment and expiration of the license.
- (h) Each licensee shall maintain and retain records as required in this Part;
- (i) Each licensee shall keep a copy of the existing license and applicable regulations of the Code and make them available at authorized locations indicated in the license.

Section 9. *Amendment of License*

- (a) An application for amendment of a license shall be filed with the PNRI/NRD Form-028A, "Application for Amendment of License", and shall specify in what respect the licensee desires his license to be amended and the grounds for such amendment. The corresponding license amendment fee required in CPR Part 22 shall be paid upon filing of the application.
- (b) A licensee shall apply for and shall receive an amended license before:
 - (1) it conducts activities other than what are indicated in the license;
 - (2) it permits anyone to work as an authorized workers, RPO, ARPO or RWMO other than those previously authorized in the license;
 - (3) it makes any change in the shielding or structural modification in the licensed facility;

- (4) it changes the location of predisposal of radioactive waste within the premises of the facility identified in the license;
- (5) it implements any major change in the approved radiation safety program;
or
- (6) any substantial change in any conditions of the license takes effect.

Section 10. *Specific Conditions for Expiration of License*

- (a) Each license shall expire at the end of the day of the expiration date specified in the license unless the licensee has filed an application for renewal of the license in accordance with Section 11 of this Part.
- (b) If the license has expired and the licensee fails to renew its license, the licensee shall refrain from undertaking licensed activities involving radioactive waste materials except to keep the radioactive waste materials under safe storage until the applicable provisions of Section 11 are satisfactorily met.
- (c) The expiration of the license shall not relieve the licensee of its responsibility to cause the decommissioning of its facility in accordance with Section 41 of this Part, if the license will be terminated.

Section 11. *Renewal of License*

- (a) A request for license renewal shall be made by submitting an original and one copy of **(PNRI/NRD Form-028)** not less than thirty (30) days before the expiration date of the license.
- (b) An application for license renewal that is filed less than thirty (30) days before the expiration date of the license shall be subjected to a surcharge equivalent to twenty-five (25) percent of the required license renewal fee. In addition to the written application, the licensee shall submit a written explanation about the delay in the filing of application;
- (c) If PNRI determines that the licensee's reasons in (b) of this Section are acceptable and safety has not been compromised, the application will be accepted and processed on the condition that the licensee shall not undertake any principal activity involving the licensed radioactive source after the expiration date of the license.
- (d) An application for license renewal that is filed less than thirty (30) days after the expiration date of the license shall be assessed a surcharge equivalent to fifty (50) percent of the prescribed license renewal fee. In addition to the written application, the licensee is required to.

- (1) Discontinue any licensed activity until the PNRI has issued a new license;

- (2) Ensure that all radioactive wastes are safe and secure in their authorized radioactive waste facility; and
 - (3) Submit a written explanation about the delay in the filing of application and the reason why the PNRI should not impose the appropriate administrative action against the licensee.
- (e) If an application for license renewal is filed more than thirty (30) days after the expiration date stated in the license, the PNRI shall cause the temporary cessation of the activity until the PNRI has determined whether or not the application shall be accepted and processed. Upon such order, the licensee shall not undertake any principal licensed activity.
 - (f) If the license is deemed to have expired and will not be renewed, the licensee shall cease to engage in any licensed activity involving the management of radioactive wastes, except to keep the radioactive waste under safe and secure storage until the disposition of the radioactive waste facility is determined by PNRI.
 - (g) The discontinued management of radioactive waste as a result of the expiration of the license shall not relieve the licensee of the responsibility to cause the decommissioning of the radioactive waste facility and termination of the license.
 - (h) Each application for license renewal must be accompanied by the corresponding license renewal fee and other outstanding regulatory fees in accordance with CPR Part 22, "Fees and Charges for Radioactive Material Licenses and other Related Regulatory Services".

Section 12. *Termination of License*

- (a) The termination of a license shall be initiated at any time at the request of the licensee.
- (b) Before the license can be terminated, the licensee shall:
 - (1) discontinue all activities involving predisposal management of radioactive wastes and facility;
 - (2) dispose of all radioactive wastes which were in the licensee's possession in accordance with the regulations;
 - (3) determine by a survey or other means that no contamination levels in excess of the limits for controlled areas exist in the facility; and
 - (4) assure that the required records are complete and up-to-date.
- (c) To be relieved of the responsibilities for the management of radioactive waste and other conditions in the license, the licensee shall submit to PNRI:
 - (1) his request that the license be terminated;

- (2) a certified statement that the licensee no longer has in his possession any radioactive waste requiring a license; and
 - (3) a listing of the radioactive waste transferred or disposed of and the person to whom the radioactive waste material was transferred or the method of disposal for each item;
 - (4) the statement of a qualified expert that the facility is not contaminated;
 - (5) an agreement that the records and facilities will be available for inspection by PNRI at a mutually agreeable date within the next three months.
- (d) When these procedures have been satisfactorily completed, PNRI will inform the licensee and formally terminates the license.

Section 13. *Specific Exemptions*

The PNRI may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it deems authorized by the Act and will not endanger life, property, and the environment.

Section 14. *Additional Regulatory Requirements*

The PNRI may, by rule, regulation, or order impose upon any 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.

II. ADMINISTRATIVE REQUIREMENTS

Section 15. *Radiation Safety Program*

- (a) Each licensee shall develop and implement a written radiation safety program that includes the provisions of CPR Part 3.
- (b) Each licensee shall develop and implement an ALARA program that shall include the following:
 - (1) Formal commitment of the management to the ALARA philosophy;
 - (2) Periodic review of the radiation safety program and provision of continuing education and training for all workers who work with or in the vicinity of the predisposal radioactive waste management facility;
 - (3) Notice to workers of the program's existence and workers' duties and responsibilities to help keep doses ALARA;

- (4) Establishment of Investigation Levels (IL) and description of actions to be taken if radiation exposure exceeds the IL; and
- (5) Review of the doses received by workers.

Section 16. *Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO)*

- (a) The licensee shall designate RPO and ARPO, to be responsible for implementing the radiation safety program. The licensee, through the RPO, shall ensure that radiation safety activities are being performed in accordance with the licensee's approved procedures and regulatory requirements. The ARPO shall act for and on behalf of RPO in his absence.
- (b) The licensee shall establish and state in writing the authority, duties, and responsibilities of the Radiation Protection Officer.
- (c) The licensee shall provide the Radiation Protection Officer sufficient authority, organizational freedom, time, resources and management prerogative to:
 - (1) identify radiation safety problems;
 - (2) initiate, recommend, or provide corrective actions;
 - (3) stop unsafe practices;
 - (4) verify implementation of corrective actions; and
 - (5) coordinate the establishment, maintenance, drills or exercise of emergency plans and procedures.

Section 17. *Radioactive Waste Management Officer*

- (a) The licensee shall appoint a technically competent person with the appropriate independence and authority to be a Radioactive Waste Management Officer (RWMO) to assist in the safe and efficient on-site management of radioactive waste. The RWMO shall:
 - (1) make and maintain contact with all relevant persons involved with radioactive waste to provide an authoritative point of advice and guidance;
 - (2) liaise as needed with the Radiation Protection Officer and with other radioactive waste management organizations;
 - (3) establish and maintain a detailed record-keeping system for all stages of radioactive waste management, including the inventory of radioactive waste;
 - (4) ensure proper radioactive waste conditioning;

- (5) ensure that on-site transfer of radioactive waste is carried out in accordance with written safety procedures;
- (6) ensure that waste packages for off-site transportation are prepared to be in compliance with transport regulations;
- (7) obtain approval from the PNRI for the transport of radioactive waste;
- (8) ensure appropriate shielding, labelling, physical security and integrity of waste packages;
- (9) ensure that any discharge of effluents is below the limits authorized by the PNRI;
- (10) ensure that solid waste disposed of in a landfill is in accordance with clearance levels established by the PNRI;
- (11) report on accidents and inappropriate waste management practices to the licensees' management; and,
- (12) maintain an up-to-date knowledge of the characteristics of discharge and disposal options.

III. TECHNICAL REQUIREMENTS

Section 18. Safety Case

- (a) The safety case shall be progressively developed and refined as the project proceeds. Such approach ensures the quality of the technical programme and the associated decision making. The licensee shall be responsible to compile the safety assessment as part of the safety case in accordance with the requirements of the PNRI.
- (b) The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for the independent review and approval of the safety case and safety assessment. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of information that is traceable.
- (c) The licensee shall carry out periodic safety reviews and shall implement any safety upgrades required by the PNRI following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.
- (d) The safety assessment and the management systems within which it is conducted shall be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment shall be reviewed and updated:

- (1) when there is any significant change that may affect the safety of the facility or activity;
- (2) when there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);
- (3) when there is an emerging safety issue owing to a regulatory concern or an incident; and
- (4) when there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.

Section 19. *Classification of Work Areas*

The licensee shall classify work areas into controlled and supervised areas and comply with the requirements specified in CPR Part 3.

Section 20. *Personnel Monitoring*

- (a) The licensee shall not allow any worker to perform any licensed activity unless he/she wears a calibrated personnel monitoring device, such as but not necessarily limited to thermoluminescent dosimeter (TLD) or optically stimulated luminescence dosimeter (OSL), in compliance with the requirements specified in CPR Part 3 and Section 20 of this Part.
- (b) All personnel monitoring devices that require processing to determine the radiation dose shall be processed and evaluated by the PNRI, or a PNRI-licensed or PNRI-recognized dosimetry processor.
- (c) The licensee shall ensure that each personnel monitoring device is assigned to, and worn only by one individual for each monitoring period.
- (d) The licensee shall maintain a record of total exposures of all individuals who are required to wear personnel monitoring devices in accordance with Section 47 of this Part.

Section 21. *Surveys for Contamination and Ambient Radiation Dose Rate*

- (a) Each licensee shall perform surveys to ensure that the maximum radiation levels and average radiation levels from the surfaces of radioactive waste packages are met.
- (b) Each licensee shall perform surveys at radioactive waste management facility at least once a week.
- (c) The licensee shall survey for removable contamination with a contamination

meter all areas where activities relevant to the management of radioactive waste are conducted at least once each week.

- (d) The licensee shall retain a record of the radiation surveys made for this Section during the time of the management of radioactive waste.

Section 22. *Possession, Use and Calibration of Radiation Detection and Measuring Instruments*

- (a) The licensee shall have in its possession calibrated and operable radiation detection and measuring instruments to evaluate:
 - (1) The magnitude and extent of radiation levels;
 - (2) Concentrations or quantities of residual radioactivity; and
 - (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.
- (b) The licensee shall calibrate or cause the calibration of the instruments to show compliance with this Part and CPR Part 3 before its first use, annually, and following any repair, unless otherwise recommended by the calibration laboratory. The date of calibration shall be conspicuously noted on the instrument.
- (c) The licensee shall cease to use an instrument if the difference between the indicated exposure rate and the calculated value is more than twenty (20) percent.
- (d) The licensee shall keep records of calibration certificates issued by the service provider subject for inspection by the PNRI.

IV. INTEGRATED APPROACH TO SAFETY AND SECURITY

Section 23. *Management System*

- (a) The licensee shall establish a management system to support the development, implementation and continued enhancement of a practical and strong safety culture. The system shall commensurate with the hazard of the waste management activities and shall be approved by the PNRI. The management system shall contain the following:
 - (1) Policies and procedures that identify safety as being the highest priority;
 - (2) Clear lines of authority for decision on safety and compliance with procedures and processes;

- (3) Organizational arrangements and lines of communications that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the license.
 - (4) Clear specification of safety responsibilities of the RPO, Assistant RPO and workers.
 - (5) Responsibilities for compliance with relevant Parts in the regulations.
 - (6) Clear requirement that problems affecting safety must be promptly identified and corrected in a manner to commensurate with their importance.
 - (7) The RPO, ARPO and workers are suitably trained and qualified.
 - (8) A quality assurance program that provides information on the performance of the radioactive waste management program and equipment and establishes a review regime of the program. This program shall ensure that all necessary records are maintained and are readily retrievable when required.
 - (9) Provisions to ensure that the confidentiality of information that is received in confidence from another party is protected, and only provided to a third party with the consent of the first party.
- (b) The management system shall provide:
- (1) Adequate assurance that the established requirements for safety and environmental protection are being met.
 - (2) Assurance that the components of the safety systems are quality sufficient for their tasks.
- (c) The management system shall be reviewed by the management every three (3) years.

Section 24. *Transport of Radioactive Waste*

The licensee transporting radioactive waste domestically shall comply with the requirements of CPR Part 4, "Regulations on the Safe Transport of Radioactive Materials in the Philippines".

Section 25. *Emergency Response Plan and Preparedness*

- (a) The licensee shall ensure that its emergency plan include radioactive waste management activities and inventory and address environmental aspects. The effectiveness of the plan shall be approved by the PNRI.
- (b) The licensee shall ensure that the emergency plan defines on-site responsibilities and take account of off-site responsibilities of other intervening

organizations appropriate for implementation of the emergency plan. Such emergency plan shall include the following, as appropriate:

- (1) Characterize the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
- (2) Identify the various operating and other conditions of radioactive waste inventory which could lead to the need for intervention;
- (3) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
- (4) Provide for protection and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;
- (5) Provide for rapid and continuous assessment of the accident as it proceeds and determining the need for protective actions;
- (6) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;
- (7) Provide procedures, including communication arrangements for contacting any relevant intervening organization e.g. civil defence and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;
- (8) Provide for training worker involved in implementing emergency plans and shall be rehearsed at suitable intervals, and
- (9) Provide for periodic review and updating of the plan.

Section 26. *Security of Predisposal Radioactive Waste Management Facility*

The licensee shall establish physical security measures for the predisposal radioactive waste management facility in accordance with CPR Part 26 and shall require each person who is authorized to operate the facility to have completed a security awareness training course.

Section 27. *Interdependences*

- (a) Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account.
- (b) The person responsible for a particular step in the predisposal management of radioactive waste, or for an operation in which waste is generated, shall adequately recognize these interactions and relationships so that the safety and the effectiveness of the predisposal management of radioactive waste shall be

considered in an integrated manner. This includes taking into account the identification of waste streams, the characterization of waste, and the implications of transporting and disposing of waste.

- (c) In considering possible options for the processing of waste, care has to be taken to avoid conflicting demands that might compromise safety. It is not consistent with an integrated approach to optimize one step in the predisposal management of radioactive waste in such a way that it imposes significant constraints on the subsequent steps or forecloses viable options.

V. STEPS IN PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

Section 28. *Control of Radioactive Waste Generation*

- (a) The licensee shall ensure that appropriate measures are taken to keep generation of radioactive waste and its environmental impact to the minimum practicable. This can be accomplished by activities such as:
 - (1) applying careful planning to the design, construction, administration, operation and decommissioning planning of facilities so that the generation of radioactive waste is kept to the minimum practicable;
 - (2) using appropriate waste management option and processing procedure with the aim of optimizing the management and reduce the production of secondary waste;
 - (3) reducing the volume and amount of radioactive material that requires further processing by authorized discharge, application of clearance values for release materials from regulatory control, after any appropriate processing and/or a sufficiently long storage period;
 - (4) minimizing the radioactivity by handling the minimum quantity of radioactive waste to be managed;
 - (5) applying the authorized discharge, and its control as well as the clearance of materials from regulatory control could reduce the volume and amount of radioactive waste;
 - (6) wherever possible, when purchasing sealed sources, establishing contractual arrangements for the return of sources to the manufacturer or predetermined waste manager following use;
 - (7) implementing a comprehensive management system for all activities potentially generating radioactive waste, including its processing, handling and storage;
 - (8) applying to the extent possible the reuse and recycling of materials; and

- (9) maintaining consistency with the radioactive management policy and strategy.
- (b) The licensee shall comply with the following in order to keep the generation of radioactive waste to the minimum:
- (1) Careful control of the collecting, segregating, packaging and handling of radioactive materials;
 - (2) Adopting good segregation practices, including clearance of materials, at point of waste generation;
 - (3) Efficient operation of collecting and processing systems for gaseous and liquid radioactive waste;
 - (4) Taking precautions to avoid the contamination of materials, equipment and building surfaces in order to reduce the need of decontamination;
 - (5) Restrictions on taking packaging and other unnecessary material into the controlled area;
 - (6) Planning and performing periodical surface monitoring and maintenance work with due care and with particular emphasis on precautions to avoid the spread of contamination;
 - (7) Creating and maintaining proper record system that would allow the periodical assessment of the effectiveness of measures adopted to minimize radioactive wastes generation. The system shall include the definition of measurable indicators to assess the effectiveness of the applied system.

Section 29. *Radioactive Waste Characterization and Classification*

- (a) The license shall characterize the radioactive waste in terms of its physical, mechanical, radiological and biological properties.
- (b) The characterization shall provide information relevant to process control and assurance that the waste or waste package shall meet the acceptance criteria for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste have to be recorded to facilitate its further management.
- (c) The licensee shall classify the radioactive waste under its responsibility.
- (d) The licensee shall refer to Section 21.5 of CPR Part 23, Licensing Requirements for Land Disposal of Radioactive Waste for the classification of radioactive waste generated.

Section 30. *Radioactive Waste Categorization*

Radioactive waste shall be categorized in accordance with an adequate scheme envisioned to be used for operational waste management purposes.

Section 31. *Acceptance Criteria for Radioactive Waste*

- (a) Exposure of individuals resulting from waste acceptance and disposal shall be subject to dose limits specified in CPR Part 3, Standards for Radiation Protection. If other potential sources of exposure exist, dose constraints shall be established to ensure that the dose to a member of the public from all sources, excluding natural background radiation and medical exposure, does not exceed the specified limit.
- (b) The interdependence among the steps in the management of radioactive waste shall be considered for achieving continuity in operations and consistency of the entire waste management process.
- (c) The licensee of a particular waste predisposal management step or disposal facility shall define its own waste acceptance criteria bearing in mind the criteria established for other steps within the waste management process. Each criterion established by the license of a facility shall be submitted to the PNRI for review, assessment and approval as part of the safety case. It shall include the following elements:
 - (1) The stability of the waste form with respect to mechanical, chemical, structural, radiological and biological characteristics;
 - (2) The maximum content of liquids;
 - (3) Limitations on activity etc, activity per package;
 - (4) Potential for criticality;
 - (5) The extent to which the waste shall be non-pyrophoric, non-explosive or non-reactive;
 - (6) Possibility of generation of toxic gases;
- (d) The waste acceptance criteria defined for each step of the waste management process shall specify the characteristics of waste packages and unpackaged waste, under normal and abnormal conditions, to be processed, stored or disposed of in that step.
- (e) The licensee shall ensure that an appropriate control system is established to provide confidence that the waste under its responsibility meets the applicable waste acceptance criteria.
- (f) The licensee shall ensure that radioactive waste to be transferred to other installations or waste management steps meets the waste acceptance criteria established by the licensed operator of the subsequent step.

- (g) The licensee's procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the waste acceptance criteria; for example, by taking remedial actions or by returning the waste.

Section 32. *Processing of Radioactive Waste from Collection up to Treatment*

- (a) Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste.
- (b) The licensee shall collect, characterize, segregate, pretreat and treat the radioactive waste, as required. Processing of waste may yield materials that are suitable for authorized discharge, authorized use or clearance from regulatory control.
- (c) The licensee shall ensure that waste is processed in such a way that the safety of the operations is appropriately accounted for under normal conditions, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences should accidents occur. Waste shall be rendered into a safe and passive form for storage or disposal as soon as possible.
- (d) The licensee shall ensure that waste is collected, characterized and segregated, at the point of origin in accordance with:
 - (1) the established criteria and categorization scheme;
 - (2) a defined waste management strategy; and
 - (3) the waste acceptance criteria defined for the next step in the waste management process.
- (e) The processing shall be consistent with the type of waste, the possible need for its storage, the anticipated disposal option, and the limits, conditions and controls established in the safety case and in the assessment of environmental impacts. The licensee shall adopt provisions to ensure that after segregation each waste stream is kept in separated, appropriated, and properly identified and labelled containers.
- (f) Radioactive waste shall be processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facility up until its ultimate disposal.
- (g) Provisions shall be established by the licensee for identifying, assessing and dealing with waste and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal.
- (h) Consideration shall be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is created during processing.

- (i) The licensee shall ensure that the waste container shall:
 - (1) be clearly identified;
 - (2) bear a radiation trefoil when in use for radioactive waste;
 - (3) be robust;
 - (4) be compatible with the waste contents; and
 - (5) be able to be filled and emptied safely.
- (j) Waste containers shall be properly identified and labelled so that the required information will be available at all stages of the waste management. The information shall be sufficient to ensure the effectiveness and safety of the next step in the management process. It shall include:
 - (1) Identification number;
 - (2) Radionuclides;
 - (3) Activity (if measured or estimated)/date of measurement;
 - (4) Origin (room, laboratory, individual, etc. if applicable);
 - (5) Potential/actual hazards (chemical, infectious, etc.);
 - (6) Surface dose rate/date of measurement; and
 - (7) Quantity (weight or volume).
- (k) During the waste collection phase, the licensee shall ensure that:
 - (1) Containers for solid wastes shall be lined with a durable plastic bag that can be sealed (tied with plastic adhesive tape, heat-sealed with a radio-frequency welder).
 - (2) Sharps shall be collected separately and stored in rigid, puncture-resistant containers (preferably metal) that have been clearly labelled 'sharps';
 - (3) Damp solid waste and liquid waste shall be collected in suitable containers according to the chemical and radiological characteristics, volume of the waste, handling and storage requirements. Normally double packaging is used;
 - (4) Disused sealed sources shall be kept in their shielding; and
 - (5) Containers shall be checked for radioactive contamination and loose contamination shall be removed before reuse.
- (l) The licensee shall ensure that treatment of waste may be necessary for safety, technical or financial reasons:
 - (1) The wastes are processed only after its precise characterization; and

- (2) The methods for waste treatment are selected based on the waste characteristics and taking into account the generation of secondary radioactive waste.
- (m) The licensee shall include physical or chemical adjustment to make the waste less hazardous or more amenable to further processing in the pretreatment processes of radioactive waste. The treatment processes of radioactive waste may include:
- (1) The reduction in volume of the waste (by incineration of combustible waste, compaction of solid waste and segmentation or disassembly of bulky waste components or equipment);
 - (2) The removal of radionuclides (by evaporation or ion exchange for liquid waste streams and filtration of gaseous waste streams); and
 - (3) Change of form or composition (by chemical processes such as precipitation, flocculation and acid digestion as well as chemical and thermal oxidation);

Section 33. Conditioning

- (a) In selecting a conditioning process, the licensee shall consider the following aspects:
- (1) Whether safety would be improved from the use of a matrix material;
 - (2) Compatibility of the radioactive waste with the selected materials and processes;
 - (3) The waste minimization of the generation of secondary radioactive waste.
- (b) The licensee shall ensure that the waste packages are designed and produced so that radionuclides are confined under both normal conditions and accident conditions that may occur during handling, storage, and disposal.
- (c) The licensee shall ensure that each waste conditioned package is provided with a durable label bearing the identification number and relevant information and that a proper record of each package is kept under the management system.
- (d) The licensee shall include in the conditioning processes provision to ensure the maximum homogeneity and stability of the waste form; minimum free space in the container; low leachability, and maximum container durability.
- (e) The licensee shall consider the quality control of the conditioning process and produced wastes packages since the waste packages may be used for a long time. The quality control shall include, but is not limited to:
- (1) The definition of quality standards applying to waste packages;
 - (2) An unambiguous definition of quality indicators for the conditioning processes as well as for the final packages. The quality indicators shall

- demonstrate that the packages meet specified requirements and waste acceptance criteria;
- (3) The development of a testing program to verify the performance of the packages;
 - (4) Appropriate record keeping; and
 - (5) Making available technical support for radiological and non-radiological measurements and procedures.
- (f) The licensee shall provide each conditioned waste package with a durable label bearing the identification number, and a proper record of each waste package shall be kept under the management system. All records shall be securely stored, easily accessible and retrievable over an extended period. Information shall include as a minimum for each individual package:
- (1) Origin of the waste;
 - (2) Identification number of the package;
 - (3) Type and design details of the package and unloading documentation;
 - (4) Weight of the package;
 - (5) External size and/or volume of the package;
 - (6) Maximum dose rate at contact and 1 m (transport index) and date of measurement;
 - (7) Results of surface contamination measurement;
 - (8) Radionuclide content and activity content;
 - (9) Physical nature; and
 - (10) Presence of potential biological, chemical and other hazards

Section 34. *Storage of Radioactive Waste*

- (a) Prior to generating radioactive waste that may require subsequent management, the licensee shall ensure the availability of an appropriate storage facility within their own organization, or in another authorized facility.
- (b) The licensee shall follow the agreed national policy and strategy, whenever they have to define which type of waste have to be stored for authorized discharge, authorized use or clearance or for processing and/or disposal at a later time.
- (c) The licensee shall have arrangements in place to verify if the waste, collected or received in the storage facility under its responsibility meets the waste acceptance criteria approved by the PNRI in the safety case for this facility.
- (d) In case the waste or sources to be stored do not meet the waste acceptance criteria, the licensee shall establish provisions which compensate for the non-

compliance or refuse the transfer.

- (e) The licensee shall adopt provisions to ensure that radioactive waste and disused sealed sources will be stored in such containers, packages and facilities that meet the requirements approved by the PNRI in the safety case.
- (f) Radioactive waste shall be stored in a manner that ensures proper segregation, and protection of the workers, the public and the environment, and enables its subsequent inspection, monitoring, retrieval and preservation in a condition suitable for movement, handling, transport or disposal. Full traceability of the waste packages by means of record keeping and adequate labelling shall be maintained during the different stages of storage.
- (g) In defining criteria for acceptance of waste packages in a storage facility, the licensee shall take account of the known or likely requirements for subsequent disposal of the radioactive waste.
- (h) The licensee shall ensure that the integrity of waste packages in storage is maintained until it is retrieved for further treatment, conditioning or disposal.
- (i) The licensee shall ensure that the waste package container provides integrity throughout the storage period and permits:
 - (1) Retrieval at the end of the storage period,
 - (2) Enclosure in an overpack if necessary,
 - (3) Transport to and handling at a disposal facility, and
 - (4) Compliance with relevant waste acceptance criteria.
- (j) The adequacy of the storage capacity has to be periodically reviewed, with account taken of the predicted waste arising, both from normal operation and from possible incidents, of the expected lifetime of the storage facility and of the availability of disposal options.

Section 35. *Recycle and Reuse*

- (a) Whenever the option of recycle and reuse implies the transfer of radioactive material to another organization, the licensee shall ensure the compliance with the national safety requirements and standards.
- (b) The licensee for a radioactive waste management facility shall demonstrate that the option of reuse and recycling of radioactive material has been considered.
- (c) Recycling and reuse shall involve the following activities:
 - (1) Before declaring the radioactive material as waste, consider whether the licensee or any other person can make use of the material;
 - (2) Return of radioactive sources to the manufacturer/supplier, when the latter would accept these;

- (3) Decontamination and/or reuse of material such as equipment and protective clothing; and
 - (4) Unconditional or conditional clearance of material that fulfils the conditions for the removal of control from material as defined by the PNRI.
- (d) The licensee shall adopt provisions for possible reuse and recycling of materials as part of the radioactive waste management program, whenever feasible.
 - (e) Recycling and reuse often involve transfer of equipment and materials from one person to another. Such transfer of any radioactive materials shall be carried out according to relevant regulations. In this case, the licensee shall ensure that all information, radiological and non-radiological, concerning the transferred materials are available to the receiving person and that this person is licensed to accept these materials.

Section 36. *Discharge or Release of Radioactive Materials to the Environment*

- (a) Licensees shall ensure that radioactive materials and sources from authorized practices are not discharged to the environment unless:
 - (1) Such discharge is within the limits specified in the license and is carried out in a controlled manner according to the regulation in force and the authorization issued by the Regulatory Body methods; or
 - (2) The activity discharged is confirmed to be below clearance or other disposal levels established by the PNRI.
- (b) Before initiating the discharge to the environment, the licensee shall ensure that the characteristics and activity of radioactive material for release are in accordance with the clearance level specified in CPR Part 3.
- (c) During the operational stage, the licensee, in addition to above mentioned, shall:
 - (1) Keep all radioactive discharges as far below the authorized limits as reasonably achievable;
 - (2) Monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of the representative person;
 - (3) Maintain an appropriate management system for the activities related to effluent or environmental monitoring; and
 - (4) Report discharges to the PNRI at intervals as may be specified in the license; and, promptly when any discharges will exceed the authorized limits.
- (d) The licensee shall review operating experience of discharges, and in

agreement with the PNRI, shall adjust their discharge control measures to ensure optimization of discharges.

Section 37. Clearance and its Control

- (a) In an application for authorization, the licensee shall declare its intention to clear materials from regulatory framework during the operational phase.
- (b) In regard to clearance and its control, the licensee shall adopt provisions to ensure that:
 - (1) The clearance of radioactive waste complies with clearance levels approved by the Regulatory Body;
 - (2) A formal mechanism is in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of clearance;
 - (3) Deliberate dilution of material, other than the dilution that takes place in normal operations shall not be carried out; and
 - (4) Any radiation markings will be removed from any material of which regulatory controls no longer apply.
- (c) Information on material which has been removed from regulatory control shall be recorded, retained within a management system and reported to the PNRI as required.

VI. DEVELOPMENT AND OPERATION OF PREDISPOSAL RADIOACTIVE WASTE MANAGEMENT FACILITIES AND ACTIVITIES

Section 38. Location and Design of Facilities

- (a) Predisposal radioactive waste management facilities shall be located and designed to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning.
- (b) The need for operational maintenance, testing, examination, and inspection has to be addressed from the conceptual design stage onward.

Section 39. Construction and Commissioning of the Facilities

Predisposal radioactive waste management facilities shall be constructed in accordance with the design as described in the safety case and approved by the PNRI. Commissioning of the facility shall be carried out to verify that the equipment, structures, systems and components, and the facility, as a whole, perform as planned.

- (a) In cases when commissioning is carried out in several stages, all of them shall be subject to the review and approval of the PNRI.
- (b) Upon the completion of commissioning, a final commissioning report shall be produced by the licensee. The safety case shall be updated, as necessary, to reflect the as-built status of the facility and the conclusions of the commissioning report.
- (c) A modification of a facility with significant safety implications that requires a revision of the safety case shall be subjected to the same regulatory controls and approvals, as applicable for the new facility.

Section 40. Facility Operation

Predisposal radioactive waste management facilities shall be operated in accordance with provisions of this Part and with the license conditions imposed by the PNRI. Operations shall be based on documented procedures.

- (a) The licensee of facility for predisposal management of radioactive waste shall demonstrate to the PNRI that the conception of the facility is consistent with the radiation safety requirements of CPR Part 3 – “Standards for Protection against Radiation” and the safe transport requirements of CPR Part 4, “Regulations on the Safe Transport of Radioactive Material in the Philippines.
- (b) The licensee shall ensure that the facility for predisposal of radioactive waste has sufficient capacity to process and store all such waste demanded by technological requirements of the installation.
- (c) All operations and activities important to safety shall subject to documented limits, conditions, and controls, and shall be carried out by a trained, qualified, and competent worker. Due consideration shall be given to the maintenance of the facility to ensure its safe performance.
- (d) The licensee of a large and/or centralized storage facility shall design and construct a facility which:
 - (1) has sufficient storage capacity to account for uncertainties in the availability of facilities for treatment, conditioning and disposal. The design of a facility shall take into account the possible need to process waste arising from incidents or accidents.
 - (2) is suitable for the expected period of storage, preferably using passive safety features, considering the potential degradation and with due consideration of natural site characteristics that could impact performance as geology, hydrology, and climate.
 - (3) allows waste to be inspected, monitored and preserved in a condition suitable for release or transport, as appropriate.

- (4) ensures appropriate containment of the waste; for example, on the integrity of the facility's structures and equipment, as well as the integrity of the waste forms and containers over the expected duration of storage. Consideration shall be given to interactions between the waste, the containers, and their environment (e.g. corrosion processes due to chemical or galvanic reactions).
 - (5) makes provision for retrieval of the waste whenever required.
- (e) The licensee of the storage facility shall periodically review and assess the adequacy of the storage capacity, with account taken of the predicted waste arising, the expected lifetime of the facility and the availability of disposal options.

Section 41. *Decommissioning*

- (a) For decommissioning, the most important responsibilities of the licensee shall:
- (1) ensure safety, security and environmental protection during all decommissioning activities, resulting in the workers, the public and the environment being properly protected from radiological and non-radiological hazards;
 - (2) define a decommissioning strategy on which the planning for decommissioning will be based;
 - (3) establish a waste management strategy for decommissioning facilities including the identification of an acceptable destination for all wastes arising from decommissioning;
 - (4) prepare and implement appropriate safety procedures; apply good engineering practice; ensure that staff are properly trained and qualified and are competent; and keep and submit records and reports as required by the regulatory body;
 - (5) perform appropriate radiological surveys, safety assessments and environmental assessments in support of decommissioning;
 - (6) keep records and submit reports to the PNRI, as required;
 - (7) establish a management system including organization and administrative controls, staffing and qualification, project management, documentation and recordkeeping, subcontractor's involvement, and safety management;
 - (8) ensure that end state criteria have been met by performing a final survey; and
 - (9) notify the PNRI prior to shutdown of the facilities permanently or terminating the activity.

- (b) A graded approach shall be applied to the planning, conduct and completion of decommissioning, and release of the site for unrestricted or restricted use.
- (c) The licensee shall prepare and maintain a decommissioning plan throughout the lifetime of the facility, unless otherwise approved by the regulatory body, in order to show that the decommissioning can be accomplished safely to meet the defined end state. In this regard, the licensee shall:
 - (1) Prepare and submit an initial decommissioning plan in support of the license application for the construction of the facility or at the time of applying for an authorization to operate the facility;
 - (2) Review and update periodically the initial decommissioning plan during operation, as prescribed by the regulatory body; and
 - (3) Prepare without undue delay the initial decommissioning plan for facilities where one has not yet been prepared.
- (d) The licensee shall retain the necessary resources, expertise and knowledge for decommissioning and shall keep records and documentation relevant to the design, construction, operation and decommissioning process during transition from operation to decommissioning.
- (e) Prior to the conduct of decommissioning phase, the licensee shall prepare and submit a final decommissioning plan to the regulatory body for approval. In doing so the licensee shall:
 - (1) Not implement the decommissioning plan until the regulatory body has approved it. The licensee shall ensure that the facility is maintained in a safe configuration until approval of the decommissioning plan;
 - (2) Ensure that the decommissioning plan states the methodology and criteria that will be used to demonstrate that the proposed end state has been achieved. For most medical, industrial and research facilities, this end state is typically release for unrestricted use;
 - (3) Define how the project will be managed.
- (f) After shutdown, the responsibility for the facility may be transferred to a different organization which becomes the operating organization of the facility for decommissioning. Knowledge of the operational history of the facility shall be maintained and passed to the new operating organization. For such transfer of responsibility, the new operating organization shall have the necessary resources, expertise and knowledge.
- (g) The licensee shall ensure adequate financial provisions are available to decommissioning the facility including the management of the resulting waste when needed, even in the event of premature shutdown in accordance with the national regulatory framework. The decommissioning cost for the facility shall be calculated.
- (h) Financial assurance for decommissioning shall be included as part of the

license application and needs to be in place prior to initiation of construction or operation of the facility. If financial assurance for decommissioning an existing facility has not been obtained, appropriate funding provisions shall be put in place as soon as possible. In any event, financial assurance shall be in place prior to approval for a license renewal or license extension.

- (i) Decontamination and dismantling techniques shall be chosen such that the protection of workers, the public and the environment is optimized and the generation of waste is minimized. Prior to using any new or untried methods for decommissioning, it shall be demonstrated that the use of such methods is justified and is addressed within the optimization analysis supporting the decommissioning plan. Such analyses shall be subjected to review and approval by the regulatory body.
- (j) On completion of decommissioning, it shall be demonstrated by the licensee that the end state criteria as defined in the decommissioning plan and any additional regulatory requirements have been met. In this regard, the licensee shall consider that:
 - (1) They could only be relieved of further responsibility for the facility after approval by the regulatory body;
 - (2) The facility shall not be released from regulatory control, nor shall authorization be terminated until the licensee has demonstrated that the end state in the decommissioning plan has been reached and that any additional regulatory requirements have been met.
 - (3) On completion of decommissioning, appropriate records should be retained as specified by the regulatory body. A system shall be established to ensure that all records are maintained in accordance with the records retention requirements of the management system and the regulatory requirements.
 - (4) If waste is stored on the site, a revised or new, separate authorization, including requirements for decommissioning, shall be requested by the licensee and issued for the facility.
- (k) A final decommissioning report shall be prepared and submitted to the regulatory body for review and approval. This report shall document, in particular, the end state of the facility or site.
- (l) If a facility cannot be released for unrestricted use, appropriate controls shall be maintained to ensure the protection of human health and the environment. In this case, the licensee shall:
 - (1) Specify these controls which shall be subjected to approval by the regulatory body. Clear responsibility shall be assigned for implementing and maintaining these controls.
 - (2) Ensure that in the case of restricted release of the facility or site from the regulatory control, appropriate arrangements for continuous controls are

established to guarantee the protection of the workers, the public and the environment.

Section 42. *Existing Situations and Past Practices*

- (a) In existing situations, facilities in operation or past practices, where new regulatory requirements are established, the licensee shall cooperate with the PNRI to establish a reasonable time frame to take the necessary measures to come into compliance.
- (b) The safety at existing facilities shall be reviewed to verify compliance with requirements. Safety related upgrades shall be made by the licensee in line with national policies and as required by the regulatory body.

VII. EDUCATION, TRAINING AND EXPERIENCE REQUIREMENTS

Section 43. *Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO)*

The licensee shall require an individual fulfilling the responsibilities of the RPO and ARPO as provided in Section 16 of this Part to be an individual who:

- (a) Holds a Bachelor of Science Degree in Natural Science, Physical Science, or Engineering and is duly licensed by the Philippine Professional Regulations Commission, if applicable;
- (b) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the use of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for the use, radiation biology, and nuclear regulations and licensing; and
- (c) Has at least one (1) year of relevant, fulltime experience on radiation safety in an institution that handles radioactive materials under the supervision of the individual identified as the RPO in a PNRI license that authorizes the use of radioactive material.

Section 44. *Radioactive Waste Management Officer*

The licensee shall require an individual fulfilling the responsibilities of the Radioactive Waste Management Officer (RWMO) as provided in Section 17 of this Part to be an individual who:

- (a) Holds a Bachelor of Science Degree in Natural Science, Physical Science, or Engineering and is duly licensed by the Philippine Professional Regulations

Commission, if applicable;

- (b) Has completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques applicable to the radioactive waste management including, but is not limited to, general classification of waste, waste characterization, waste acceptance criteria, waste conditioning techniques, interim storage of waste, waste transport, radiation physics and instrumentation, mathematics pertaining to the measurement of radioactivity, chemistry of radioactive material, radiation biology, and nuclear regulations and licensing; and
- (c) Has at least one (1) year of relevant, fulltime experience on radioactive waste management at an institution that handles radioactive materials.

Section 45. *Refresher Course*

The licensee shall require the workers to undertake a refresher course on radiation safety as appropriate and approved by PNRI every three (3) years.

VIII. RECORDS, REPORTS AND NOTIFICATIONS

Section 46. *Radioactive Waste Records and Reports*

- (a) The licensee shall develop a suitable and comprehensive recording system for radioactive waste management activities under its responsibility. The recording system shall include discharges and shall allow for traceability of waste from the point of its collection through long term storage and disposal.
- (b) All records related to waste inventory, including disused sources and management activities shall be:
 - (1) Maintained up to date such as changes to waste characteristics during processing;
 - (2) Retained until PNRI authorizes their disposition to ensure that relevant information is accessible in the future, as necessary.
- (c) When waste is being transferred, associated records shall be available to the operator of the subsequent step.

Section 47. *Record System*

- (a) The licensee shall keep a waste characterization record that contains the following information pertaining to the waste:
 - (1) The source or origin;

- (2) The physical and chemical form;
 - (3) The amount in volume and/or mass;
 - (4) The radiological characteristics etc. the activity concentration, the total activity, the radionuclides present and their relative proportions;
 - (5) The categorization in accordance with the categorization scheme for operational purposes;
 - (6) The classification in accordance with the national waste classification system;
 - (7) Any chemical, pathogenic or other hazards associated with the waste and the concentrations of hazardous material; and
 - (8) Any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields.
- (b) The radioactive waste management facility, in order to ensure the proper control under waste management activities, shall maintain records for:
- (1) Generated radioactive waste that includes the date of generation, waste characteristics, etc.;
 - (2) Stored radioactive waste including identification, origin, location, physical and chemical characteristics;
 - (3) Material from which regulatory control has been removed or that has been discharged to the environment including data related to the process;
 - (4) Spent and/or disused radiation sources returned to suppliers;
 - (5) Radioactive waste and disused sources transferred to another user; and
 - (6) Non compliances and action taken in response.
- (c) In case of processing and storage facilities for radioactive waste, the records concerning waste management activities shall include:
- (1) The data of waste and disused sources collected or received from generating facilities;
 - (2) The data needed for a national inventory of waste;
 - (3) The data needed for waste characterization;
 - (4) The records from the control processes for treatment, packaging and conditioning;
 - (5) The documents on the procurement of containers required to provide confinement for a certain period (e.g. in a repository);
 - (6) The specifications for waste packages and audit records for individual containers and packages;

- (7) Trends in operating performance;
- (8) Non-compliances with the specifications for waste packages and the actions taken to rectify them; and
- (9) Discharges.

Section 48. *Reports of Workers Exposure*

- (a) The licensee shall furnish a report referring to worker's total radiation exposure during the period of employment or work assignment in the licensee's facility whenever termination of employment has made. Such report shall be furnished within thirty (30) days after the exposure of the employee has been determined by the licensee or ninety (90) days after the date of termination of employment or work assignment.
- (b) At the request of a worker, each licensee shall furnish a report of that worker's total exposure to radiation as shown in records maintained by the licensee.

Section 49. *Notification on Specific Changes in the License*

- (a) The licensee shall notify the PNRI in writing within thirty (30) days:
 - (1) When a Radiation Protection Officer, operator, or Radioactive Waste Management Officer permanently discontinues performance of duties under the license or has a name change, or
 - (2) When the licensee's mailing address changes.
- (b) The licensee shall mail the report to:

The Director
Philippine Nuclear Research Institute
Commonwealth Avenue, Diliman, Quezon City

Section 50. *Notification of Incidents/Accidents*

The licensee shall notify PNRI within twenty-four (24) hours by telephone or by any other fast means of communications of any incidents or accidents involving radioactive source.

Section 51. *Reporting of Incidents/Accidents*

The licensee shall make a report in writing to PNRI any incidents or accidents involving the management of radioactive waste within thirty (30) days of its occurrence.

IX. INSPECTION AND ENFORCEMENT

Section 52. *Inspections*

- (a) Each licensee shall allow authorized PNRI inspectors to enter its premises at all reasonable times and perform such inspections as may be necessary, announced or unannounced, of the radioactive wastes in possession and the premises, equipment and facilities where radioactive waste are disposed of or stored.
- (b) During such inspections, the licensee shall make available to PNRI inspectors all relevant records kept pursuant to these rules and regulations at the location specified in the license.

Section 53. *Violations*

- (a) A notice of violation shall be issued to any person found to have violated any rule, regulation, or order issued thereunder; or any term, condition, or limitation of any license issued thereunder.
- (b) Any license may be modified, suspended, or revoked, after due process, for any violation which the Institute determines to adversely affect the health and safety of the workers and the public.
- (c) Any person who willfully violates, attempts to violate, or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by **Sections 64 and 65 of Republic Act No. 5207** and **Section 25 of Republic Act No. 2067**, as amended.

Section 54. *Modification and Revocation of License*

- (a) The terms and conditions of each license issued pursuant to the regulations in this Part shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by PNRI in accordance with the terms of the Act.
- (b) 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 by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the PNRI.
- (c) Except in cases of willful violation or where immediate action is required in order to protect public health and safety or the security of the source, no order for the suspension, modification or revocation of the license shall become effective until the licensee have afforded the opportunity to be heard.
- (d) A license maybe modified by PNRI, or upon the request of the licensee, when:

- (1) The licensee decides to discontinue any specific licensed activity authorized in the license or request for another authorization to undertake another licensed activity prescribed in this Part;
 - (2) PNRI determines that the licensee can no longer perform the specific licensed activity authorized in the license; or
 - (3) The licensee has ceased to perform a licensed activity during a two (2) year period.
- (e) Any person who willfully violates, attempts to violate or conspires to violate any rule or regulation or order issued hereunder, may be guilty of a crime, and upon conviction, may be punished by a fine or imprisonment or both as provided by Sec. 64 and 65 of Republic Act No. 5207, as amended.

X. EFFECTIVITY

Section 55. *Effective Date*

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

Approved:

(original signed)

CARLO A. ARCILLA, Ph. D.
Director

Date: 14 December 2020