



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

CPR PART 15

REGULATIONS FOR THE DESIGN AND SAFE OPERATION OF GAMMA IRRADIATION FACILITIES, REV. 02

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I. GENERAL PROVISIONS

Section 1. Purpose and Scope.

- (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 requirements in this Part provide for the radiation safety and security requirements for the operation of gamma irradiation facility, and for the protection and safety of the workers, the general public, and the environment from the harmful effects of ionizing radiation.
- (c) This Part applies to the following types of gamma irradiator:
 - (1) Category II (Panoramic dry source storage irradiators);
 - (2) Category III (Underwater irradiators); and
 - (3) Category IV (Panoramic wet source storage irradiators).
- (d) This Part does not apply to Category I self-contained dry-source-storage irradiators, medical radiology or teletherapy, radiography, gauging, or open-field (agricultural) irradiations.

Section 2. Definitions

As used in this Part:

- (a) **"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;
- (b) **"ALARA"** means As Low As Reasonably Achievable, making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

- (1) Consistent with the purpose for which the licensed activity is undertaken; and
 - (2) Taking into account the state of the technology, the economics of improvement in relation to benefits to the health and safety of the public and the radiation workers and other societal and socio-economic considerations;
- (c) **“Authorized Personnel”** means those individuals, other than the Irradiator Operator, authorized in the license to:
- (1) Work with ionizing radiation;
 - (2) Perform operational inspection and maintenance checks on the irradiator; and
 - (3) Perform periodic contamination detection tests on the irradiator;
- (d) **“Code or CPR”** means the Code of PNRI Regulations;
- (e) **“Construction”** means the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks.
- (f) **“Decommissioning”** means removing a facility or site safely from service and reducing residual radioactivity to a level that permits:
- (1) Release of the property for unrestricted use and termination of the license; or
 - (2) Release of the property under restricted conditions and termination of the license.
- (g) **“Facility Manager or Supervisor”** refers to the individual directly supervising the operation of the radiation facility;
- (h) **“Fully shielded”** means the condition in which the source is stored such that dose rates in the radiation room are optimized, allowing the room to be occupied by workers;
- (i) **“Inventory”** means a physical check of all sources possessed, by specifically and uniquely identifying each individual source using appropriate means such as serial numbers;
- (j) **“Irradiator”** means a facility that uses radioactive sources for the irradiation of objects or materials and are designed for industrial and large-scale applications which contain more than 3.70×10^{14} becquerels (Bq) of radioactive material and is not self-shielded;
- (k) **“Irradiator Operator”** means an individual who meets the qualification required in accordance with this Part and is authorized in the license to operate the irradiator;
- (l) **“License”** 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;
- (m) **“Licensee”** means a holder of a valid license issued by the PNRI pursuant to this Part. The licensee is the person or organization having overall responsibility for the operation of a gamma irradiation facility;
- (n) **“Non-routine operations”** means activities that are not performed on a regular basis, which may include the following:
- (1) Source loading, unloading, and repositioning
 - (2) Troubleshooting the control console

- (3) Clearing stuck source racks
 - (4) Investigating/remediating removable contamination/leaking sources
 - (5) (Re)installing source cables
 - (6) Any other activity during which personnel could receive radiation doses exceeding PNRI limits;
- (o) **“Panoramic dry-source storage irradiator or Category II”** means a panoramic irradiator in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations;
 - (p) **“Panoramic irradiator”** means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel, including panoramic dry-source storage irradiator (Category II) and panoramic wet-source storage irradiators (Category IV);
 - (q) **“Panoramic wet-source storage irradiator or Category IV”** means a panoramic irradiator in which the sources are stored under water in a storage pool;
 - (r) **“PNRI”** means the Philippine Nuclear Research Institute and/or its duly authorized representatives;
 - (s) **“Pool irradiator”** means any irradiator at which the sources are stored or used in a pool of water, including panoramic wet-source storage irradiators (Category IV) and underwater irradiators (Category III);
 - (t) **“Product”** means the object or item being irradiated;
 - (u) **“Product conveyor system”** means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place;
 - (v) **“Qualified expert”** means an individual who, by virtue of certification by appropriate boards, professional licenses or academic qualifications and experience, is duly recognized by PNRI as having expertise in a relevant field of specialization, including radiation protection, or design and operation of irradiation facilities;
 - (w) **“Radiation room”** means that region of the irradiator that is enclosed by radiation shields and is made prohibited and inaccessible when the source is in use;
 - (x) **“Radioactive source or 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;
 - (y) **“Radiation Protection Officer (RPO)”** means an individual who is trained and qualified in accordance with this Part and identified as the RPO in the license;
 - (z) **“Regulatory body (PNRI)”** means an authority or a system of authorities designated by the government of a State as having legal authority to conduct the regulatory process, including issuing a license;
 - (aa) **“Safety”** means measures intended to minimize the likelihood of accidents with radioactive sources and, should such an accident occur, to mitigate its consequences;
 - (bb) **“Safety analysis”** means an evaluation of the potential hazards associated with the operation of a facility or the conduct of an activity;

- (cc) **“Safety Assessment Report”** means a consistent safety document or integrated set of documents constituting the licensing basis of the radiation facility and updated under supervision of the regulatory body;
- (dd) **“Security”** means measures to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources;
- (ee) **“Senior management”** means the person who, or group of people which, directs, controls and assesses an organization at the highest level;
- (ff) **“Underwater irradiator or Category III”** means an irradiator in which the radioactive source is stored in a pool of water, the source is shielded at all times, and human access to the source and to the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use;
- (gg) **“Vehicle”** means a conveyance used for land, sea, or air transport; and
- (hh) **“Worker(s)”** means any person who works full-time, part-time or on a temporary basis for a licensee and who has recognised rights and duties in relation to occupational Radiation Protection.

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 3. **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 4. **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 5. **Applicability of other Regulations and Resolution of Conflicts.**

- (a) The requirements in this Part shall be applied in conjunction with CPR Part 3 – “Standards for Protection against Radiation”, CPR Part 4 – “Regulations for the Safe Transport of Radioactive Material in the Philippines”, CPR Part 26 – “Security of Radioactive Sources”, and CPR Part 27 – “Security Requirements in the Transport of Radioactive Materials” and other applicable regulations. 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.
- (b) The sanitary and phytosanitary aspects of processing of food products with ionizing radiation and its quality management is covered under the Bureau of Philippine Standards (BPS) in its *Code of Practice for Radiation Processing of Food* (PNS/ BAFS 151:2015)

- (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.
- (d) 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 6. *Additional Regulatory Requirements.*

The PNRI may impose upon the applicant or 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. ADMINISTRATIVE REQUIREMENTS

Section 7. *Notification and Licensing Requirements.*

- (a) A person or organization intending to build or operate a gamma irradiation facility shall notify the PNRI of this intention and submit an application for a License to Operate in accordance with CPR Part 2, Rev. 01. The applicant for a License to Operate shall provide information in its application which demonstrates that the facility will be operated in compliance with the applicable laws of the Republic of the Philippines and the regulations of the PNRI.
- (b) No person may begin the commissioning or operation of a gamma irradiation facility until that person has been issued a License to Operate.
- (c) The licensee shall obtain prior approval from PNRI before conducting any of the following activities:
 - (1) Import, export, transfer, or disposal of radioactive sources;
 - (2) Transport of radioactive sources; and
 - (3) Source loading and unloading.
- (d) The licensee shall obtain an amended license in accordance with CPR Part 2 before:
 - (1) Acquiring a radioactive source other than what is permitted in the license;
 - (2) Permitting anyone to work as RPO, ARPO, Irradiator Operator, or Authorized Personnel other than those permitted under the license;
 - (3) Replacing the RPO, ARPO, Irradiator Operator, or Authorized Personnel;
 - (4) Receiving radioactive sources in excess of the activity authorized in the license;
 - (5) Making any major modification of the irradiator;
 - (6) Making any change in the radiation room shielding;
 - (7) Implementing any major change in the approved Radiation Protection and Safety Program; or

- (8) Implementing any substantial change in any condition of the license, in consultation with PNRI.
- (e) The licensee shall engage PNRI licensed or recognized organizations for any of the following services:
 - (1) Dosimetry;
 - (2) Calibration of survey instruments;
 - (3) Leak testing;
 - (4) Source change and loading; and
 - (5) Training of Radiation Protection Officers and Irradiator Operators.

Section 8. Commencement of Construction.

- (a) The applicant may not begin construction of a new gamma irradiation facility prior to the submission of an application for a license. A Provisional Permit may be issued by the PNRI upon the request of the applicant to allow commencement of construction. Such permit may only be issued upon the approval of the shielding design and all radiation safety and security features of the proposed facility.
- (b) Any construction activities undertaken prior to the issuance of a License to Operate are entirely at the risk of the applicant and have no bearing on the issuance of a License to Operate with respect to the requirements of the Act, the regulations and orders issued in accordance with the Act.

Section 9. Responsibilities of the Licensee.

- (a) The licensee shall be responsible for obtaining and making available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation.
- (b) The licensee shall be responsible for the operation of the irradiator and for the safety and security of sources in accordance with the regulatory requirements and the conditions of the license.
- (c) The licensee shall ensure that the facility is designed to meet the radiation safety and security requirements pertaining to site selection and evaluation, construction, operation, maintenance, and decommissioning.
- (d) The licensee shall demonstrate to the regulatory body how the design of the irradiation facility and the related operational procedures will contribute to the prevention of accidents or to the mitigation of the effects of accidents.
- (e) The licensee shall ensure that construction and installation work does not compromise the safety of the facility. On completion of the installation, or at appropriate stages during construction, the licensee shall ensure that a Qualified Expert thoroughly and critically reviews the facility and any component part before it is commissioned to ensure that:
 - (1) Safety features and warning signals and alarms have been properly installed and operate correctly; and
 - (2) Radiation protection for workers and members of the public and protection of the environment are adequate.
- (f) The licensee shall ensure that radiation protection and safety measures are being observed in accordance with regulatory requirements and approved procedures.

- (g) The licensee shall ensure the availability of adequate number of Irradiator Operators and Authorized Personnel for the operation of the facility.
- (h) The licensee shall provide the necessary facilities and equipment to all workers in the facility to carry out their functions effectively in conformity with the regulatory requirements.
- (i) The licensee shall provide personnel monitoring devices to workers, and ensure that they are worn as required, and shall ensure that individual dose records are maintained as prescribed.
- (j) The licensee shall ensure that all documents provided by the manufacturer, supplier and installer are available in the language understandable to the users.
- (k) The licensee shall ensure that information on both normal and abnormal operations significant to protection and safety is disseminated or made available, as appropriate, to the PNRI and to manufacturers and/or suppliers.
- (l) The licensee shall ensure that the constructor or installer has provided adequate information about the proper operation, maintenance, and decommissioning of the facility.
- (m) The licensee shall ensure that the supplier of the gamma irradiator provides the necessary theoretical and practical training to the staff to enable them to work in a safe manner.
- (n) The licensee shall notify the PNRI of any proposed modifications of the irradiator that may have radiological protection implications or changes to key personnel, in particular senior managers, the Radiation Protection Officers, Qualified Experts, and Irradiator Operators.
- (o) The licensee shall notify the PNRI of, and shall submit a plan for the transfer or disposal of radioactive sources when they are no longer in use.
- (p) The licensee shall permit inspection of its facilities and records by the regulatory body.

Section 10. Responsibilities of the Senior Management.

- (a) The Senior Management shall provide the human and material resources necessary to ensure safe working conditions and compliance with regulatory requirements.
- (b) The Senior Management shall ensure that all aspects of protection and safety are provided for in a systematic manner by establishing and implementing a management system for safety that is commensurate with the complexity of, and the radiation risks associated with the facility.
- (c) The Senior Management shall demonstrate its commitment to developing and promoting a safety culture that encourages a questioning and learning attitude to protection and safety, and that discourages complacency.
- (d) The Senior Management shall appoint a qualified Radiation Protection Officer (RPO), and shall give the RPO sufficient authority to allow him to exercise close supervision on authorized activities to ensure that the work is done in accordance with the written administrative procedures. The RPO shall report directly to the Senior Management.

Section 11. ***Radiation Protection and Safety Program.***

11.1. General Requirements

- (a) The applicant or licensee shall establish and maintain a Radiation Protection and Safety Program in accordance with CPR Part 3.
- (b) The licensee shall review and assess the Radiation Protection and Safety Program and its implementation at least annually to ensure that reasonable effort is made to maintain individual and collective occupational doses As Low As Reasonably Achievable (ALARA).

11.2. Scope and Structure of the Radiation Protection and Safety Program

The Radiation Protection and Safety Program shall consist of the following:

- (a) Policy Statement:
 - (1) Objectives;
 - (2) Responsibilities;
 - (3) Training;
 - (4) Safety assessment;
 - (5) Quality Assurance Program.
- (b) Procedures and Local Rules:
 - (1) Operation (access control, startup and shutdown procedures);
 - (2) Maintenance and loading and unloading of radioactive sources;
 - (3) Transport of radioactive sources;
 - (4) Individual monitoring;
 - (5) Workplace monitoring;
 - (6) Training;
 - (7) Leak testing of radioactive sources;
 - (8) Testing of radiation monitors;
 - (9) Routine checks by a Radiation Protection Officer;
 - (10) Audits and safety assessments by a Qualified Expert;
 - (11) Response to visible and audible alarms;
 - (12) Incident reporting and investigation;
 - (13) Emergency response.
- (c) System of Records:
 - (1) Documentation of license and any correspondence between the licensee and the regulatory body;
 - (2) Name of the authorized person responsible for the Radiation Protection and Safety Program;
 - (3) Safety assessment reports;
 - (4) Operation logbook;
 - (5) Routine checks of safety systems by a Radiation Protection Officer;
 - (6) Individual doses (current and prior work history);
 - (7) Results of workplace monitoring;
 - (8) Radiation monitor test reports;
 - (9) Results of leakage tests of radioactive sources;

- (10) Inventory of radioactive sources;
- (11) Records of movements of radioactive sources;
- (12) Reports on investigations of incidents and accidents;
- (13) Audits and reviews of the Radiation Protection and Safety Program;
- (14) Installation, maintenance and repair work;
- (15) Facility modifications;
- (16) Training provided (initial and refresher);
- (17) Transport of radioactive sources:
 - (i) Transport documentation;
 - (ii) Contamination surveys and radiation level surveys;
- (18) Disposal or return of radioactive sources;
- (19) Records of training, which shall include the following information:
 - (i) Name of the person who received the instruction or training;
 - (ii) Name of the institution or person who provided the instruction or training;
 - (iii) Date and duration of the instruction or training;
 - (iv) A summary or list of the topics addressed;
 - (v) Results of examinations taken;
 - (vi) Copies of training certificates.

Section 12. Safety Assessment.

- (a) The licensee shall demonstrate to the regulatory body how the design of the irradiation facility and the related operational procedures will contribute to the prevention of accidents or to the mitigation of the effects of accidents. This information shall be documented in a Safety Assessment Report (SAR) which specifies the conditions under which the facility will be constructed and operated.
- (b) The licensee shall update the SAR originally submitted as part of the application for a license to reflect the amendments made as a result of the regulatory safety review and assessment and assure that the information included in the report describes accurately the current status and conditions of the facility.
- (c) The safety assessment shall include, but shall not be limited to, the following issues -
 - (1) Loss of access control;
 - (2) Malfunctions and failures of structures, systems and components;
 - (3) Loss of control over the system for the movement of radioactive sources, including a source rack becoming stuck in the unshielded position;
 - (4) Loss of integrity of systems or components, including shielding integrity, encapsulation of sealed sources and pool integrity;
 - (5) Electrical distribution faults, from localized faults to complete loss of external energy sources;
 - (6) Failures of safety systems caused by fires within the facility;
 - (7) Failures of safety systems resulting from external causes such as storms, floods, earthquakes, or explosions;
 - (8) Failures of personnel to observe proper and safe procedures;
 - (9) Breakdown of procedures for preventing access to the facility by unauthorized persons;
 - (10) Breakdown of administrative procedures, leading to unsafe practices;
 - (11) Detection of contamination; and

- (12) High radiation levels in unexpected locations.

Section 13. **Verification of Safety.**

- (a) The licensee shall conduct periodic audits to verify compliance with the Code of PNRI Regulations.
- (b) All equipment used for this purpose shall be properly maintained, and shall be tested and calibrated at appropriate intervals against standards that are traceable to national or international reference standards.

Section 14. **Radiation Protection Officer.**

14.1. Designation and Authority of RPO and ARPO

- (a) A Radiation Protection Officer (RPO) shall be a person technically competent in radiation protection matters of relevance for a given type of irradiator who is designated by the licensee's Senior Management. He/she shall have consented and accepted in writing to be responsible for implementing the Radiation Protection and Safety Program of the facility.
- (b) The Radiation Protection Officer shall be a full-time staff supported by one or more Assistant RPO. At least one RPO shall be present at the facility during different work shifts throughout the day.
- (c) The RPO shall have sufficient authority, organizational freedom, time, resources, and management prerogative to:
- (1) Stop unsafe activities;
 - (2) Identify radiation safety and security problems;
 - (3) Initiate, recommend, or provide corrective actions; and
 - (4) Verify implementation of corrective actions.

14.2. Qualification of the RPO

- (a) The RPO shall have any of the following qualifications:
- (1) A Bachelor of Science Degree, preferably in Engineering or Physical Science or related degrees, with Physics as one of the subjects; or
 - (2) A Diploma in Engineering from a recognized university/institution with a minimum of five (5) years of relevant experience.
- (b) The RPO shall have successfully completed at least 40 hours radiation safety course conducted by an organization licensed or recognized by the PNRI. The training course shall cover practical radiation protection and regulatory requirements with respect to the irradiation facility for which they are appointed.
- (c) The RPO shall have at least three (3) months of full-time work experience at the applicant's irradiator or at another irradiator of a similar type, which may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

14.3. Responsibilities of the RPO

- (a) The licensee shall establish and state in writing the duties and responsibilities of the

RPO. At a minimum, the RPO's duties and responsibilities shall include the following:

- (1) Ensuring that all Irradiator Operators, maintenance staff, contractors and other relevant workers and organizations are provided with copies of the operating instructions, and that they have read and understood and are complying with these instructions;
- (2) Identifying controlled areas and supervised areas;
- (3) Controlling access to controlled areas;
- (4) Optimizing exposure controls and maintaining engineering features and other equipment that contributes to controlling exposure of workers and members of the public;
- (5) Deciding whether any special restrictions are needed with regard to the exposure of female employees who might be pregnant;
- (6) Arranging for testing of fixed radiation monitors, and for calibration and testing of radiation survey meters;
- (7) Maintaining records of the radioactive source and relevant training and safety records;
- (8) Performing routine radiation surveys and environmental monitoring;
- (9) Arranging statutory tests for leakage of radioactive source;
- (10) Undertaking a program of periodic safety checks of safety systems and warning signals and alarms, and of general conditions at the facility;
- (11) Liaising with contractors, designers and suppliers with regard to radiation protection matters and significant changes to physical or operational aspects of the facility;
- (12) Arranging radiation protection training for Irradiator Operators, maintenance staff, contractors and other staff, as appropriate;
- (13) Ensuring that non-routine operations for irradiators are consistent with the limitations in the license, the Radioactive Source and Device Registration Certificate or its equivalent, and the manufacturer's written recommendations and instructions;
- (14) Analyzing potential safety consequences or non-routine operations before conducting any such activities that have not been previously analyzed;
- (15) Ensuring non-routine operations are performed by the manufacturer or person specifically authorized by the PNRI to perform those operations;
- (16) Ensuring the adequacy of safety assessments and emergency plans for any reasonably foreseeable incidents with consequences for radiation protection;
- (17) Arranging periodic exercises to test the effective implementation of these emergency plans;
- (18) Investigating any incidents including near misses at the facility such as:
 - (i) Any of the operational parameters subject to periodic quality control being out of the normal ranges established for operational conditions;
 - (ii) Any equipment failures, accidents, errors, unusual events or circumstances that cause, or have the potential to cause, doses in excess of regulatory dose limits (e.g. failure of the radioactive source to return to the shielded position).
- (19) Ensuring that personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained by the licensee;
- (20) Notifying proper authorities of incidents such as damage to or malfunction of irradiators, fire, loss or theft of licensed materials;

- (21) Investigating emergencies and abnormal events involving the irradiators (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s);
- (22) Performing radiation protection and safety program audits at least every 12 months and developing, implementing, and documenting timely corrective actions;
- (23) Ensuring the security of radioactive sources in accordance with CPR Part 26;
- (24) Ensuring transport of radioactive sources in accordance with CPR Part 4;
- (25) Ensuring proper disposal of disused sources;
- (26) Maintaining appropriate records associated with irradiator operations;
- (27) Maintaining an up-to-date license and timely submission of amendment and renewal applications; and
- (28) Ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.

Section 15. ***Irradiator Operator.***

- (a) The Irradiator Operator shall be:
 - (1) A graduate with a Bachelor of Science Degree, preferably in Engineering or Physical Science from a recognized university/institution; or
 - (2) If undergraduate, a holder of a certificate of competence for an appropriate training and work experience.
- (b) The Irradiator Operator shall have successfully completed at least 40 hours radiation safety course conducted by an organization licensed or recognized by the PNRI. The training course shall cover practical radiation protection and regulatory requirements with respect to the irradiation facility.
- (c) The Irradiator Operator shall have completed the irradiator manufacturer's course for operators specific to the irradiator to be used or received instructions in:
 - (1) The operation of the irradiator;
 - (2) Operating and emergency procedures that the operator is responsible for performing;
 - (3) Radiation safety at irradiators with respect to practical and operational matters; and
 - (4) Case histories of accidents or problems involving irradiators.
- (d) The Irradiator Operator shall have received on-the-job training or simulator training in the operation of the irradiator. The Irradiator Operator shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he is to perform.
- (e) The Irradiator Operator shall have completed a Security Awareness Training course in accordance with Section 16 of CPR Part 26.
- (f) The licensee shall evaluate the safety performance of each Irradiator Operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the Irradiator Operator and shall instruct the Irradiator Operator on how to correct any mistakes or deficiencies observed.

Section 16. ***Qualified Expert in Radiation Protection.***

- (a) A Radiation Protection Qualified Expert is a person:
- (1) Having education and/or experience equivalent to a graduate or master's degree from a recognized university/institution in radiation protection, radiation safety, biology, chemistry, engineering, physics or a closely related physical or biological science; and
 - (2) Has acquired competence in radiation protection, by virtue of special studies, training and practical experience.
- (b) The Qualified Expert shall have acquired competence in radiation protection matters and shall have:
- (1) Theoretical training that includes training in the properties of radiation as used in the irradiator;
 - (2) A thorough knowledge of the hazards associated with the radiation present and the ways in which these hazards can be controlled and minimized;
 - (3) An understanding and detailed knowledge of the working practices used in the facility, as well as a general knowledge of the working practices in other similar facilities;
 - (4) A detailed working knowledge of all regulatory provisions, relevant codes of practice and protection standards, guidance materials and other information necessary for giving advice in connection with the work with radiation undertaken by the licensee;
 - (5) An awareness of legislation that could affect the work with radiation on which the qualified expert gives advice;
 - (6) The ability to give advice so that the licensee can comply with regulations and follow good radiation protection practices;
 - (7) The ability to communicate with workers and their representatives;
 - (8) The ability to keep up to date with developments in the use of radiation in the field in which the Qualified Expert gives advice and with developments in radiation protection.
- (c) The licensee shall provide the Qualified Expert with the information and resources necessary for the expert to work effectively. The information shall include a clear statement of the scope of the advice that the expert is expected to give.

Section 17. ***Training and Retraining in Radiation Protection and Safety.***

- (a) The licensee shall ensure that appropriate training in protection and safety are provided for all workers who could be subject to occupational exposures, as well as periodic retraining and updating as required in order to ensure the necessary level of competence.
- (b) An in-house training program shall be developed for the following workers commensurate with the duties and responsibilities of their jobs with respect to the operation of the irradiator.
- (1) Senior managers having line responsibility;
 - (2) Radiation Protection Officers;
 - (3) Irradiator Operators;
 - (4) Authorized Personnel;

- (5) Other workers who may be required to enter controlled areas from time to time to perform specific duties; and
 - (6) Personnel who may be required to render assistance in emergencies.
- (c) The in-house training program shall include the following topics:
- (1) The nature of radiation;
 - (2) Health hazards due to exposure to radiation;
 - (3) Basic principles and methods of protection (e.g. time, distance, shielding);
 - (4) Measurement of radiation fields and the units of measurement;
 - (5) Actions to be taken in response to visible and audible warning signals and alarms;
 - (6) Actions to be taken in emergencies.
- (d) In addition to the topics described above, the licensee shall also ensure that Irradiator Operators and Radiation Protection Officers know about and understand the following:
- (1) The functioning of the irradiator, including safety features;
 - (2) Applicable regulations;
 - (3) License conditions;
 - (4) The radiation protection and safety program;
 - (5) Requirements for individual monitoring and workplace monitoring;
 - (6) Requirements for accountability for and control and security of radioactive sources;
 - (7) Hazards identified in the safety assessment;
 - (8) Local rules;
 - (9) Procedures to be followed in emergencies;
 - (10) Case histories of accidents or problems involving irradiators.
- (e) The licensee shall ensure that the training program is reviewed annually and reinforced when necessary. Arrangements shall be made to ensure that all new staff receive the required training and that the training needs of staff affected by any internal reorganization are reviewed and effected.
- (f) The licensee shall ensure that women who may enter controlled areas or supervised areas are provided with information regarding the risks to an embryo or fetus from exposure to radiation and the importance of notifying their employer as soon as pregnancy is suspected.
- (g) The licensee shall prepare and maintain records of the initial and ongoing training of all workers. These training records shall include the following information:
- (1) Name of the person who received the instruction or training;
 - (2) Name of the institution or person who provided the instruction or training;
 - (3) Date and duration of the instruction or training;
 - (4) A summary or list of the topics addressed;
 - (5) Results of examinations taken;
 - (6) Copies of training certificates.
- (h) The Radiation Protection Officers and Irradiator Operators shall undertake a refresher course on radiation safety and security, conducted by a PNRI licensed or recognized organization, every five (5) years.

Section 18. ***Incident Notification and Reporting.***

- (a) The licensee shall notify the PNRI within 24 hours, by telephone or by any similarly fast means of communication, and shall submit a written report to the PNRI within 30 days from the occurrence of the following events:
- (1) Theft or loss of radioactive source; and
 - (2) Events involving radioactive source possessed by the licensee that may have caused or threaten to cause radiation overexposure, excessive concentrations or levels of radiation, loss of one day or more of operation of the irradiator, or property damage.
 - (3) Leaking radioactive sources, damaged radioactive sources, and pool water contamination;
 - (4) Sources stuck in an unshielded position;
 - (5) Fire or explosion in a radiation room;
 - (6) Damage to radioactive source racks;
 - (7) Failure of the cable or drive mechanism used to move the source racks;
 - (8) Inoperability of the access control system;
 - (9) Detection of radiation by the product exit portal monitor;
 - (10) Abnormal or unusual radioactive contamination;
 - (11) Structural damage to the pool liner or walls; and
 - (12) Abnormal water loss or leakage from the source storage pool.
- (b) After carrying out investigations, the licensee shall submit a detailed report to the PNRI including relevant details such as:
- (1) Date and time of occurrence;
 - (2) Status of irradiator at the time of incident;
 - (3) Source activity at the time of incident;
 - (4) Brief description of the event;
 - (5) Names of individuals who have received exposure to radiation and other persons involved in the incident;
 - (6) Action implemented; and
 - (7) Probable cause of the incident.

III. DESIGN AND PERFORMANCE REQUIREMENTS

Section 19. *Design of Radioactive Sources.*

- (a) Radioactive sources used in gamma irradiation facilities shall meet the design requirements for sealed sources and satisfy the performance and safety testing standards specified in the International Organization for Standardization (ISO) Standard 2919. Certifications related to these performance tests shall be maintained by the licensee.
- (b) For wet storage conditions, radioactive sources shall meet the following design requirements:
- (1) Be doubly encapsulated, and the outer capsule shall be of a material that does not corrode under the conditions of storage; and
 - (2) Contain radioactive material that is non-dispersible and substantially insoluble in water.
- (c) The licensee shall also take account of the possible effects of fire, explosion, corrosion, and any aspects related to the continuous use of the sealed source.

- (d) The licensee shall maintain records relating to the radioactive source, including the following:
 - (1) Model number, serial number and identification number of the source;
 - (2) Radionuclide, source activity and reference date;
 - (3) ISO Standard 2919 Certificate;
 - (4) Special Form Radioactive Material Approval Certificate;
 - (5) Leak test certificate; and
 - (6) Contamination test certificate.

Section 20. ***Requirements for Internal Design.***

All equipment inside the radiation room of an irradiation facility, including wiring, electrical equipment, notices and lighting, shall be selected so as to minimize failure due to prolonged exposure to radiation.

20.1. Source Holder and Rack

- (a) The source rack shall be designed so that there are no crevices in the source holder, or between the radioactive source and the source holder, that would promote corrosion.
- (b) The sealed source shall be firmly fixed within its source holder and source rack such that it cannot be readily discharged.
- (c) Devices used for the purpose of positioning and removing sources shall be capable of being safely operated from outside the radiation shields.
- (d) In the event of failure of the source module or source rack, it shall not be possible for the sources to move into a position that may cause a radiation hazard. In the event of power failure, the sources and source rack shall be able to return to the fully shielded position without damage to either. Failure of hoist cables (or of alternative means of support) shall not result in the source rack's moving in such a way that damage is caused to the sealed sources. If the source rack sticks in the exposed position, there shall be a means of freeing it with minimal risk to personnel.

20.2. Source Guard

- (a) The source rack shall be provided with a source guard for adequate mechanical protection against interference and damage by items such as product boxes or carriers. Product positioning mechanisms shall be designed to prevent product from coming into contact either directly or indirectly with the source rack.
- (b) A mechanical device shall be employed to prevent product collisions. When actuated, this device shall automatically stop the product carrier, return the source rack to the fully shielded position, and generate a fault signal on the control console.

20.3. Emergency Core Cooling System

Category IV irradiators shall use an emergency source cooling system to spray water onto the source rack to control the heat generated when there is a malfunction that leaves the source rack in an unshielded position.

20.4. Source Travel Timer

A source travel timer shall be connected to the 'source up' and 'source down' switches to ensure that the source travel time (when moving either up or down) is not in excess of a

preset level. If the preset level is exceeded, the control system shall indicate a fault, shut down the irradiator, and actuate visible and audible alarms.

20.5. Emergency Access Ports

Emergency access ports shall be employed to allow access to the radiation room through the shield if there is a malfunction that leaves the radioactive source in an exposed position. Emergency access ports shall only be used by Authorized Personnel for emergency action and recovery.

20.6. Source Rack Position Indicators

- (a) The switches of the source rack position indicators shall be hardwired directly to the control system. Defence in depth shall be employed to ensure that indicator switches are installed at different locations. There shall also be supplementary means of confirming the position of the source rack, in addition to the indicator switches.
- (b) If the indicator switches malfunction or do not respond to the presence of the source rack, visible and audible alarms shall be actuated to alert personnel in the area and to prevent access to the radiation room.

20.7. Product Positioning System

The product conveyor mechanism shall be monitored for correct operation, and any malfunction shall cause the radioactive source rack to return automatically to the fully shielded position.

20.8. Product Movement Timer

A timer shall be used to monitor movement of the product past the radiation source. The design of the irradiator shall ensure that if the product fails to move in the predetermined time interval, the source rack automatically returns to the fully shielded position, the product positioning system stops, and visible and audible alarm generate signals to alert the Irradiator Operator to the malfunction.

Section 21. Access Control in Panoramic Gamma Irradiators.

21.1. Access to the Radiation Source

- (a) The licensee shall ensure that persons cannot gain access to the irradiation room while the radioactive source is in the exposed position.
- (b) The licensee shall incorporate a series of sequential safety interlocks and controls such that any attempt to pre-empt the controls or to apply them out of sequence will automatically prevent the intended operation. The sequential control operations shall cover the following:
 - (1) Access by personnel to the radiation room following an irradiation;
 - (2) Securing of the radiation room prior to initiating an irradiation; and
 - (3) Start procedure for irradiation.
- (c) Each entrance to the radiation room of a panoramic irradiator shall have a sign bearing the radiation symbol and the words, "**CAUTION (or DANGER) RADIOACTIVE MATERIAL**". Panoramic irradiators shall also have a sign stating, "**VERY HIGH RADIATION AREA**," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

21.2. Safety Interlock for the Personnel Access Door

The safety interlocks for the access door shall be integrated into the master control system so that violation of the safety interlock system or use of the door will cause irradiation to be automatically terminated. Any violation or failure of the safety interlock for the access door shall actuate visible and audible alarms. Opening the personnel access door shall disable the means of producing radiation.

21.3. Backup Access Control — Personnel Entry

- (a) Each entrance to a radiation room shall have an independent backup access control to detect personnel entry while the sources are exposed.
- (b) Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also alert at least one other Authorised Personnel who is trained on how to respond to the alarm and prepared to promptly render or summon assistance.

21.4. Safety Interlocks for Product Entry and Exit Ports

- (a) Suitable means shall be provided at the product entry and exit ports to prevent inadvertent entry of personnel into high radiation areas. The ports shall be interlocked so that a visible or audible alarm indicates when the control mechanism for the entry or exit port has malfunctioned or has been overridden or tampered with.
- (b) It shall be arranged that any violation of the safety interlock system disables the means of producing radiation.
- (c) In addition to the safety interlocks for the product entry and exit ports, each product entry and exit port shall have an independent backup control to detect entry of personnel while the radioactive sources are unshielded. Detection of the entry of personnel when radiation levels are high must disable the means of producing radiation and actuate visible and audible alarms.

21.5. Removable Radiation Room Shield Plugs

If the radiation room of a panoramic irradiator has removable radiation room shield plugs, they shall be interlocked with the control system to disable the means of producing radiation if a plug is not in its proper location. To prevent tampering, the safety interlock must not be accessible from outside the radiation shield.

21.6. Fixed Radiation Monitor with Alarms

- (a) A radiation monitor shall be provided and integrated with the safety interlocks of the personnel access door to prevent access to the radiation room when the monitor detects radiation above a pre-set level, malfunctions, or is switched off. The pre-set alarm level shall be set as low as practicable, but high enough to avoid false alarms.
- (b) Before the personnel access door is opened, the Irradiator Operator shall verify that the radiation monitor is operating and that its reading corresponds to background levels of radiation.
- (c) The radiation monitor shall actuate visible and audible alarms if the radiation level exceeds the pre-set level.

21.7. Backup System for Lowering the Source Rack

A backup system shall be provided for lowering the source rack to the fully shielded position in the event of a failure of the source rack hoist mechanism. Failure of the primary means of lowering the source rack shall create a fault condition and actuate visible and audible alarms.

21.8. Product Exit Radiation Monitor

A fixed radiation monitoring system shall be located such that monitors will detect any radioactive material being brought out of the radiation room. These monitors shall be interlocked with the irradiator controls so that if radiation levels at the exit port exceed a predetermined level, the product positioning system carrying product from the radiation room to the exit port will stop, the radioactive source will automatically be returned to the fully shielded position, and visible and audible alarms will be actuated.

Section 22. *Access Control in Underwater Gamma Irradiators.*

22.1. Access to Storage Pools

- (a) Underwater irradiators shall have a personnel access barrier around the pool that is locked to prevent access when the irradiator is unattended. Only Irradiator Operators or facility manager/supervisor shall have access to keys that operate the personnel access barrier.
- (b) An intrusion alarm shall be able to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an Authorized Personnel who is prepared to respond or summon assistance.
- (c) Each entrance to the area within the personnel access barrier of an underwater irradiator shall have a sign bearing the radiation symbol and the words, "**Caution (or Danger) Radioactive Material**".

22.2. Removable Radiation Room Shield Plugs

Roof plugs designed for access for moving transport packages of radioactive material to the source storage pool shall be located such that a shipping package, if dropped, will not fall on the source rack.

22.3. Fixed Radiation Monitor with Alarms

- (a) Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the source storage pool to detect abnormal radiation levels.
- (b) The radiation monitor shall be able to generate visible and audible alarms at entrances to the access barrier around the source storage pool.

Section 23. *Wet Source Storage Irradiators.*

23.1. General Requirements

- (a) An automatic water level control shall be provided to maintain the water at a level that provides adequate shielding while radioactive sources are in the fully shielded position.
- (b) All components of the automatic water level control system that are below water level, except for float switches, shall be made of a material that will not float in water. If hollow tubing is used, it shall be fully vented to allow water to flood the tubing to eliminate the

risk of a beam of high-level radiation up the tube.

- (c) The source storage pool shall be cleaned regularly to remove foreign matter that has accumulated at the bottom.
- (d) Any vacuum system used for cleaning the source storage pool shall be fitted with an in-line filter. The filter shall be continuously checked for the presence of radioactive material during the vacuum cleaning operation. If radioactive material is detected, the vacuuming operation shall be terminated. All sediment collected in the filter shall only be disposed of if it meets the relevant criteria before its disposal.
- (e) To ensure that there is no inadvertent release of contaminated storage pool water, the vacuum system shall be designed to recirculate the storage pool water back into the storage pool after filtering.
- (f) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools shall not exceed 0.02 millisievert per hour.

23.2. Radiation Monitor of the Water Treatment System

- (a) There shall be a fixed radiation monitor on the water treatment system to detect contamination that may arise if a radioactive source leaks.
- (b) If radiation levels exceed a predetermined value, the fixed radiation monitor shall actuate visible and audible alarms. The monitor shall be interlocked with the irradiator controls so that the source rack is returned to the fully shielded position and the normal circulation of water is stopped if the alarm is actuated.

23.3. Storage Pool Integrity

- (a) The source storage pool shall have a water-tight stainless-steel liner or a liner metallurgically compatible with other components in the pool. It shall be constructed so that there is a low likelihood of substantial leakage and is easily decontaminated.
- (b) The storage pool shall be designed to support the transport containers used during operations for the loading and unloading of sources without compromising the integrity of the pool.
- (c) There shall be no penetration through the bottom of the storage pool. Any penetration through the pool liner shall be no more than 30 cm below the normal water level.

23.4. Materials of Pool Components

All permanent storage pool components shall be made of corrosion resistant materials. Where practicable, stainless-steel components (such as brackets or pulleys) shall be passivated, in particular after fabrication.

23.5. Water Level Control — Level Normal

- (a) Means shall be provided to replenish water losses from the storage pool. The system shall be capable of maintaining the pool water above a level sufficient to maintain adequate radiation shielding.
- (b) A water level control shall cause make-up water to flow into the storage pool through a water treatment system when the level reaches the normal low water level position, and shall cause water to stop flowing when the level reaches the normal high water level position.

- (c) A metering device shall be installed to record the use of replenishment water, changes in which may be associated with pool leakage.
- (d) The storage pool water shall be prevented from migrating into municipal water supplies.

23.6. Water Level Control Abnormal — Level Low

- (a) If the storage pool water falls to a level that would compromise radiation shielding, typically approximately 30 cm below the normal low water level, visible and audible signals shall be generated to alert an Authorized Personnel to investigate and to take corrective action.
- (b) If the storage pool water continues to rise above the normal high water level cut-off point, visible and audible signals shall be generated to alert an Authorized Personnel to investigate and to take corrective action to prevent the pool water from overflowing.

23.7. Water Conditioning

- (a) The storage pool shall be equipped with a water conditioning system capable of keeping the water clean and at a level of conductivity not exceeding 1000 microsiemens per meter ($\mu\text{S}/\text{m}$) for routine operation and not exceeding 2000 $\mu\text{S}/\text{m}$ for temporary excursions not exceeding 90 days. The conductivity of the storage pool water shall be monitored continuously.
- (b) Care shall be exercised to avoid the introduction of contaminants into the pool water system. The licensee shall follow the sealed sources manufacturers' recommendations for acceptable levels and testing frequencies for water quality indicators such as conductivity, pH and chloride concentrations.
- (c) All filters and resin beds in water treatment systems shall be tested for contamination before the removal, backwashing or regeneration of the system. Fluids resulting from backwashing or regeneration shall only be released if the level of contamination is below authorized limits established in CPR Part 3.

23.8. Cooling of Storage Pool Water

A pool water cooling system shall be provided in wet storage irradiators to remove heat produced by the radioactive decay process of the radioactive sources.

23.9. In-Pool Piping

Since pipes are used in the source storage pool for the water level and water quality control systems, suitable siphon breakers shall be provided to prevent the siphoning of storage pool water down to levels that could compromise radiation shielding, typically levels more than 30 cm below the normal make-up water level. Suction pipes for providing circulation of the pool water shall have intakes no lower than 30 cm below the normal make-up water level.

23.10. Storage Pool Guard and Cover

A physical barrier shall be installed to prevent personnel from falling into the source storage pool. The barrier may be removed during maintenance, inspection, and service operations.

Section 24. Shielding.

- (a) The licensee shall design shielding walls to meet generally accepted building code

requirements for reinforced concrete and shall design the walls, wall penetrations, and entranceways to meet the following radiation shielding requirements:

- (1) Radiation dose rates in the following areas shall not exceed 0.02 millisievert (mSv) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed or at 30 cm over the edge of the pool of an underwater irradiator when the source is in the fully shielded position;
 - (2) Areas where the radiation dose rate exceeds 0.02 mSv per hour shall be locked, roped off, or posted to prevent access.
- (b) If the irradiator will use more than 2×10^{17} becquerels (Bq) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
 - (c) The licensee shall ensure that all shielding calculations carried out for the purposes of design are undertaken by a Qualified Expert.
 - (d) Once the shield has been designed, no subsequent changes shall be made unless they have been carefully considered and agreed to by the PNRI.

Section 25. Fire Protection.

- (a) The radiation room shall have heat and smoke detectors equipped with visible and audible alarms. The alarm must be capable of alerting an Authorized Personnel who is prepared to summon assistance promptly.
- (b) The radiation room shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.
- (c) If fire is detected, the radioactive source rack shall automatically return to the fully shielded position and the product positioning system and ventilation systems shall be shut down if either the heat or the smoke detector is actuated.

Section 26. Radiation Monitors.

- (a) The licensee shall provide a fixed radiation monitor with an audible alarm located at the product exit to detect loose radioactive sources that could be carried out of the radiation room. If the monitor detects a source, an alarm must sound, and product conveyors must stop automatically. The alarm must be capable of alerting an Authorized Personnel in the facility who is prepared to summon assistance.
- (b) Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the storage pool to detect abnormal radiation levels. The monitor must have a visible and audible alarm at entrances to the personnel access barrier around the pool. The alarm must be capable of alerting an Authorized Personnel who is prepared to respond promptly.
- (c) A fixed radiation monitor shall be installed on the water treatment system to detect contamination that may arise if a radioactive source leaks. If radiation levels exceed a predetermined value, the fixed radiation monitor must actuate visible and audible alarms. The monitor shall be interlocked with the irradiator controls so that the source rack is returned to the fully shielded position and the normal circulation of water is stopped if the alarm is actuated.

Section 27. Control Console.

27.1. Access key

- (a) Irradiator controls shall be designed so that a single multipurpose key can be used to operate the irradiator in normal use, including:
- (1) Actuation of the mechanism that moves the sources;
 - (2) Gaining access to the radiation room; and
 - (3) Actuation of the safety delay timer.
- Only one key shall be in use at any time, and only Irradiator Operators or facility manager/supervisor may possess it.
- (b) The access key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. An audible signal shall be used to indicate that the sources are leaving the shielded position. Only one multipurpose key must be available to all Authorized Personnel.
- (c) The control console shall –
- (1) Be clearly labelled as to its function
 - (2) Have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when they are exposed; and
 - (3) Have a control that promptly returns the sources to the shielded position.

27.2. Emergency stop device at the control console

In addition to any other means normally available at the control console to shut down the irradiator, a clearly labelled emergency stop device shall be provided at the control console for preventing, quickly interrupting or aborting irradiator operations and disabling the means of producing radiation.

27.3. Disabling the radiation source

For the purpose of servicing the irradiator, a method shall be provided for disabling the means of producing radiation so that irradiation cannot be started while servicing operations are being carried out.

Section 28. *Radiation Room.*

28.1. Safety delay timer with alarms

- (a) The irradiator shall be equipped with a safety delay timer inside the radiation room that is actuated to begin the irradiator startup sequence. The timer shall be placed in a location such that, to actuate the timer, the Irradiator Operator needs to pass through all areas of the radiation room where a person might be present.
- (b) The safety timer shall automatically actuate visible and audible warning signals and alarms to alert any personnel who may be in the radiation room that the irradiator start-up sequence has begun. The alarms shall provide personnel sufficient time to leave the area or to operate a clearly identified emergency stop device that will abort the startup sequence.
- (c) The safety timer shall be integrated with the control system so that operation of the radiation source cannot be initiated unless the startup sequence has been completed within the preset time and the control console indicates that it is safe to start the irradiator.

28.2. Emergency stop device

- (a) An emergency stop device shall be provided within the radiation room for promptly aborting irradiator operations and disabling the means of producing radiation at any time.
- (b) The emergency stop device shall be clearly labelled and be readily accessible to personnel in the radiation room. It shall cause a visible or audible alarm to be generated outside the radiation room.

28.3. Emergency exit

- (a) For the safety of anyone inadvertently shut inside the radiation room, a means shall be provided to ensure that personnel can leave the radiation room at any time.
- (b) The individual shall first actuate the emergency stop device and then leave the radiation room. In case the emergency stop device does not actuate before the person leaves the radiation room, the most direct exit route that avoids the area near the radiation source must be taken.

Section 29. *Power Failure.*

29.1. Electrical power

- (a) If an electrical power failure of longer than ten (10) seconds occurs, the radioactive source rack shall automatically be returned to the fully shielded position.
- (b) Critical electronic components used in the irradiator control system shall be connected to an uninterruptible power supply capable of providing the necessary electrical power for a controlled shutdown of the irradiator. The radiation room monitor, safety interlocks for access control and source rack position indicators shall also be powered by the uninterruptible power supply to ensure safe system shutdown.
- (c) During a power failure, the area of any irradiator where sources are located may be entered only using an operable and calibrated radiation survey meter.

29.2. Non-electrical power

Failure of non-electrical power, such as pneumatic power or hydraulic power, used to control or to operate any safety feature of the irradiator shall cause the radioactive source rack to be automatically returned to the fully shielded position.

Section 30. *Considerations With Regard to External Events.*

- (a) External natural events such as events relating to geological and extreme meteorological phenomena and human induced events that could adversely affect the integrity of radiation shielding shall be evaluated in accordance with specific characteristics of the irradiation facility and the local site.
- (b) Conventional norms, codes or standards that address hazards due to external events may be used for assessing the potential hazards, and for designing facilities that can withstand such hazards, the radiation risks associated with the facility being taken into account.
- (c) In seismic areas, the gamma irradiation facility shall be equipped with instrumentation to warn of the occurrence of a seismic event and to disable the means of producing radiation. The seismic instrumentation shall be firmly anchored to a concrete shield wall and is set to actuate at the lowest practicable level that will not generate false alarms.

- (d) During the process of site selection and evaluation, particular consideration shall be given to potential hazards that cannot be addressed by means of engineering measures, such as hazards relating to flooding and hazards relating to geological phenomena in areas of potential or actual subsidence, uplift, collapse or faulting.

Section 31. Ventilation.

- (a) The licensee shall assess the levels of ozone produced by the irradiator and shall protect personnel against exposure to ozone in concentrations above the limits established by the competent health authority.
- (b) Personnel shall be prevented from entering any area where concentrations of ozone may be high. Irradiation facilities shall be designed so that ozone will not migrate to occupied areas.
- (c) The following control measures for ozone shall be used:
- (1) A ventilation system to exhaust ozone and to maintain a low pressure differential in the irradiator, to prevent the migration of ozone to occupied areas;
 - (2) A safety interlock with entry delay to allow for reduction in ozone levels by reversion to diatomic oxygen or removal of ozone by the ventilation system.
- (d) The irradiator control system shall be designed to monitor the ventilation system to ensure that it is operating. If the ventilation system fails, the source rack shall be returned to the fully shielded position. Entry to the radiation room shall not be permitted until ozone levels have fallen.

Section 32. Notices and Symbols.

- (a) The radiation symbol (Fig. 1) and other notices shall be placed at entrances to the radiation room and in proximity to the radioactive source. Any notices and symbols placed inside the radiation room shall be made from materials that will resist damage due to high radiation levels and that are durable under the ambient conditions.
- (b) In addition to the radiation symbol (trefoil), the ionizing radiation supplementary warning symbol (Fig. 2) shall also be used on Category II, III and IV gamma irradiators. The supplementary symbol shall be placed in close proximity to the source.



Fig. 1 Basic ionizing radiation symbol (trefoil)



Fig. 2 Ionizing radiation supplementary symbol

Section 33. Irradiation Status Indicators.

- (a) Irradiation status indicators shall be provided to show:
- (1) When the irradiation has been terminated;
 - (2) When the irradiation is in progress;
 - (3) When either the radioactive source is in transit (An audible signal shall also be used to indicate this condition.)
- (b) An irradiation status indicator shall be clearly visible at the control console and at each access door for personnel and product entry and exit port.
- (c) When illuminated or color-coded controls are used, the following colours shall be considered for indicating the specified conditions:

Condition	Color
Emergency (stop buttons or warning lights)	Red
Warning or hazard	International trefoil or red
Critical information (irradiator malfunction)	Red
Caution (not an emergency but heightened awareness is called for)	Yellow or orange
Normal (irradiator is not in use or is functioning safely)	Green
Information	Blue

Section 34. Audible Signals.

- (a) Each audible signal used in the irradiator control system shall be distinct and loud enough to immediately gain the attention of persons in the area. It shall not be capable of being confused with any other signals in use in the area.
- (b) An audible signal shall be used to indicate when a radioactive source is in transit.

Section 35. Labelling and Posting.

- (a) Indicators and visual signals used to alert individuals shall be clearly labelled as to the conditions that prompt actuation of the indicator. Visual warning signals and alarms,

such as flashing lights or messages on the control console, shall provide the Irradiator Operator with unambiguous information that is adequate to determine the cause of the warning signal or the alarm so that the appropriate corrective actions can be initiated.

- (b) In addition to notices and symbols, certain information relevant to the operation of the irradiation facility shall be posted in clearly visible locations within the facility. This information shall include:
- (1) A copy of the license from the regulatory body authorizing operation of the irradiator.
 - (2) Emergency contact information, including the names and telephone numbers (or other means of immediate contact) of individuals to be contacted in an emergency.

Section 36. *Commissioning and Acceptance Testing*

Commissioning and acceptance testing shall be carried out following installation of the irradiator to verify that it conforms to the technical specifications certified by the manufacturer and the requirements of this Part.

Section 37. *Facility Modifications.*

The licensee shall consult a Qualified Expert and shall seek the approval of the PNRI before carrying out any modifications that have the potential to cause a radiation hazard, including:

- (1) Modifications of operating procedures;
- (2) Modifications of the safety control system;
- (3) Major modifications of the irradiator;
- (4) Loading, replenishment, removal or redistribution of radioactive sources, in any way at variance with what was approved by the regulatory body;
- (5) Changes in key personnel.

IV. OPERATIONAL SAFETY REQUIREMENTS

Section 38. *Local Rules and Operating Procedures.*

- (a) The licensee shall ensure that local rules are fully understood by the Radiation Protection Officers, Irradiator Operators and other workers. Operational instructions shall, at a minimum, include:
- (1) A description of the nature of the hazards posed by the facility and the safety features used to minimize the risks.
 - (2) A reference to the existence and the location of the written emergency procedures.
 - (3) A description of the functions, duties and responsibilities with regard to radiation safety of key individuals within the operating organization.
 - (4) The method of implementing the operating instructions and ensuring that the facility is being operated safely, including:

- (i) A description and schedule of the inspections and test procedures for ensuring that all safety interlock systems and components associated with the irradiator are functioning properly. Each safety item and the appropriate test, check and inspection for it shall be specified.
 - (ii) A requirement for the operating procedures to be available at the control console and for the emergency procedures to be conspicuously posted.
- (5) The method of ensuring that persons entering the controlled area are wearing appropriate radiation monitoring devices and that the results of the monitoring are recorded.
 - (6) The method of controlling access to the controlled area and ensuring that only qualified Irradiator Operators can use the irradiator at appropriate times.
 - (7) Written instructions covering actions to be taken in the event of malfunctions.
 - (8) Written instructions to ensure that the irradiator is maintained as prescribed by the manufacturer, with particular attention paid to ensuring that all components of the product positioning system, product boxes and carriers continue to meet design specifications.
 - (9) Written instructions to require that the Irradiator Operator carry a portable radiation survey meter when entering the radiation room.
 - (10) Written instructions to require that the Irradiator Operator check that all visual indicators of the facility conditions show that it is safe to enter the radiation room. In addition, procedures shall be established for the continuous monitoring of radiation levels with a portable radiation survey meter when a person enters the radiation room.
- (a) The licensee shall establish and implement written operating procedures for:
 - (1) Operation of the irradiator, including the sequential control operations in entering and leaving the radiation room;
 - (2) Use of personnel dosimeters;
 - (3) Surveying the shielding of panoramic irradiators;
 - (4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
 - (5) Leak testing of sources;
 - (6) Operational inspection and maintenance checks;
 - (7) Loading, unloading, and repositioning sources if the operations will be performed by the licensee; and
 - (8) Inspection of movable shielding, if applicable.

Section 39. ***Individual Monitoring of Workers.***

39.1. Designation of Controlled and Supervised Areas

- (a) The licensee shall designate controlled and supervised areas in accordance with CPR Part 3.
 - (1) The following shall be designated as controlled areas:
 - (i) Underwater gamma irradiators (Category III): the room in which the irradiator is housed;
 - (ii) Panoramic gamma irradiators (Categories II and IV): the radiation room and roof of the radiation room;
 - (2) The following areas shall be designated as supervised areas, unless circumstances warrant their designation as controlled areas:

- (i) Underwater gamma irradiators (Category III): control room;
 - (ii) Panoramic gamma irradiators (Categories II and IV): product entry and exit areas and service areas such as where the source rack hoist is located, water treatment rooms and control room;
- (b) The designation of these areas shall be reviewed regularly, and may be changed or extended during initial installation, maintenance and operations for the loading and unloading of radioactive sources.
 - (c) All controlled areas shall be identified by physical barriers, such as doors, where practicable, or by other means such as marking on the floor. Access points to controlled areas shall be clearly labelled with signs including the radiation warning symbol, the statement "Radiation Controlled Area".
 - (d) Access to controlled areas shall be restricted to Irradiator Operators, Radiation Protection Officers and Authorized Personnel only.

39.2. Individual Dose Assessment and Monitoring

- (a) Individuals who routinely enter controlled areas shall be subject to individual dose monitoring. These individuals shall wear an appropriate personal dosimeter that can detect high energy photons in the normal and accident dose ranges.
- (b) Occupational exposure of other workers who are regularly employed in a supervised area shall be assessed on the basis of the results of monitoring of the workplace or individual monitoring.
- (c) Other individuals who are permitted to enter the radiation room of a panoramic irradiator on special circumstances shall wear direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters.
- (d) Personal dosimeters shall be provided and processed by a laboratory that has been recognized by the PNRI and is traceable to a standards dosimetry laboratory approved by the PNRI.
- (e) The licensee shall prepare procedures describing the way in which individual dosimeters are to be administered, including the following:
 - (1) Ordering and receipt of dosimeters from the dosimetry laboratory;
 - (2) Distribution of dosimeters to monitored workers;
 - (3) Collection and dispatch of dosimeters to the dosimetry laboratory for processing;
 - (4) Review and maintenance of dose records.
- (f) The licensee shall maintain records of exposures of all individuals required to wear dose monitoring devices. Such records shall be made available to PNRI during inspections. The licensee shall ensure that personal dose records are available to individuals at all times and will be provided to workers upon termination of their employment.

39.3. Care and Use of Dosimeters

- (a) Each personal dosimeter shall be assigned to and worn by only one individual. Personal dosimeters shall be worn on the front of the body, in the area of the main torso.
- (b) Monitored workers shall take precautions to protect their dosimeters from loss, theft,

tampering or damage and from inadvertent exposure to radiation. They shall inform the Radiation Protection Officer without delay if a dosimeter is missing or damaged, or if it has been exposed to radiation when it was not being worn.

- (c) If a dosimeter is lost, the licensee shall take all reasonable steps to recover it. If the dosimeter cannot be located, the licensee shall carry out an investigation and prepare a report that includes an estimate of the dose received by the worker for the relevant period of time, subject to the approval of the PNRI prior to the entry of such estimates into a person's dose record.
- (d) When not in use, personal dosimeters shall be kept in suitable storage facilities located in a low-radiation background area. Personal dosimeters shall also be protected from inadvertent exposure to radiation and from direct light and heat.
- (e) Direct reading dosimeters shall be read, and the exposures recorded at the beginning and end of each use, and records shall be maintained. Calibration of direct reading dosimeters shall be done at least annually and shall read within ± 20 percent of the true radiation dose.

39.4. Investigation of Doses

- (a) The licensee shall instruct workers to notify a Radiation Protection Officer immediately if they know or suspect that they have been exposed to high level radiation. If the individual concerned was wearing a personal dosimeter, it shall be sent to the dosimetry laboratory immediately, and the laboratory shall be informed of the urgency of the case.
- (b) The Radiation Protection Officer shall inspect the results of personal dosimeter readings promptly to determine whether any unexpectedly high doses have been reported and to determine whether individuals are keeping their doses as low as reasonably achievable, taking into account their workload and any dose constraints.
- (c) The licensee shall conduct a formal investigation whenever the recorded dose exceeds the investigation level. The investigation shall be initiated as soon as possible following the event, and a written report shall be prepared concerning its cause. This report shall include –
 - (1) A determination or verification of any doses received,
 - (2) Details of corrective or mitigating actions, and
 - (3) Instructions or recommendations on how to avoid a recurrence.
- (d) The licensee shall provide a copy of this report to the PNRI and to all concerned parties within the appropriate time frame as required by the regulations.

Section 40. **Workplace Monitoring.**

40.1. Monitoring of the Workplace

- (a) The licensee shall establish, maintain, and keep under review a program for the monitoring of the workplace under the supervision of the Radiation Protection Officer.
- (b) The nature and frequency of monitoring of workplaces shall be sufficient to enable:
 - (1) Evaluation of the radiological conditions in all workplaces;

- (2) Exposure assessment in controlled areas and supervised areas; and
 - (3) Review of the classification of controlled and supervised areas; and
- (c) The workplace monitoring program shall specify:
- (1) The quantities to be measured;
 - (2) Where and when the measurements are to be made and at what frequency;
 - (3) The most appropriate measurement methods and procedures; and
 - (4) The investigation levels and the actions to be taken if they are exceeded.
- (d) If the radiation levels specified in the shielding criteria under this Part are exceeded, the facility shall be modified to comply with the requirements.

40.2. Radiation Survey Meters and Radiation Monitors

- (a) Portable radiation survey meters shall be capable of clearly indicating the dose rates encountered during normal operation of the irradiator and shall have a satisfactory overload performance. They shall be of a type that does not saturate and read zero at high radiation dose rates.
- (b) The licensee shall calibrate or cause the calibration of its radiation survey instruments before first use, annually, and following repair to an accuracy of ± 20 percent for the gamma energy of the sources in use.
- (c) Fixed radiation monitors and contamination monitors for storage pool water shall be used to detect radiation levels and trigger an alarm when a preset point is reached. Fixed radiation monitors shall be of a type that does not read zero on saturation and shall be subject to periodic operational testing to ensure that they retain the capability to respond to relevant radiation levels. Contamination monitor shall be sensitive in detecting contamination at the lowest practicable level to minimize the potential spread of contamination.

40.3. Maintenance And Calibration

- (a) Portable radiation survey meters shall be calibrated before their first use, after repair and at least annually to an accuracy of ± 20 percent for the gamma energy of the sources in use.
- (b) The pre-use test shall include a test of the instrument's overload performance; that is, the instrument shall be tested to verify that it will operate correctly up to the maximum foreseeable dose rate.
- (c) Following calibration, a sticker shall be attached to the instrument to provide information, including the name of the organization performing the test, the test certificate number and the date of the test or the date when the next test is due, as appropriate. Tests shall be carried out by an organization recognized by the PNRI and is traceable to a standards dosimetry laboratory approved by the PNRI.

40.4. Use of Radiation Survey Meters

- (a) Before operation of the facility is started, a radiation survey of the area outside the shielding of the radiation room shall be performed, with the radioactive sources in the exposed position for a panoramic irradiator. Additional surveys of the area outside the shielding shall be performed at intervals not exceeding three (3) years, and before the resumption of operations following the introduction of new radioactive sources or any modification of the structure of the radiation room shielding.

- (b) For pool irradiators, an initial radiation survey of the area above the source storage pool or the dry source storage container shall be performed. The survey shall be conducted after the radioactive sources have been loaded but before operation of the facility is started.
- (c) In the event of any apparent change in contamination levels that cannot be attributed to known causes, an evaluation shall be performed to determine the cause, which include:
 - (1) Verifying that the survey instrumentation is functioning properly;
 - (2) Repeating the survey to verify the apparent change in contamination levels;
 - (3) Performing more frequent surveys;
 - (4) Consulting with the supplier of the radioactive source.
- (d) Surveys shall be undertaken at positions around the facility to confirm the status of controlled areas and supervised areas and to indicate any failure in the control of the radiation source.
- (e) When making an initial entry to the radiation room, the Irradiator Operator shall use a portable radiation survey meter to determine the ambient radiation levels. The portable meter shall be tested for proper functioning prior to each entry into the radiation room by using a check source located near the radiation room door.
- (f) When visitors are permitted to enter the radiation room, they shall be issued with a personal dosimeter and an authorized Irradiator Operator who has surveyed the area immediately prior to the visit shall escort all visitors.

40.5. Records of Radiation Surveys

- (a) The licensee shall keep appropriate records of the findings of the workplace monitoring programme and shall be made available to workers. Reports on radiation levels shall include the following information:
 - (1) Survey date;
 - (2) Irradiator identification (manufacturer, model number and serial number);
 - (3) Irradiator location;
 - (4) Information on the irradiator's radiation source, including its calculated activity;
 - (5) Information on the survey instrument (manufacturer, model number and serial number);
 - (6) Calibration date of the survey instrument;
 - (7) Correction factors, background subtraction, conversions or other calculations for the survey instrument if used;
 - (8) Name of the person or organization performing the survey;
 - (9) Radiation levels and the corresponding locations outside the shield both when the irradiator is in use and when the radioactive source is fully shielded;
 - (10) Radiation levels and the corresponding locations inside the radiation room when the radioactive source is fully shielded;
 - (11) Any actions taken on the basis of information yielded by the survey.
- (b) The licensee shall maintain records of contamination at the facility and records of which shall be made available for inspection by the PNRI. Contamination surveys shall be performed routinely where neutron fields could give rise to activation products. Contamination reports shall include the following information:
 - (1) Survey date;

- (2) Irradiator identification (manufacturer, model number and serial number);
- (3) Irradiator location;
- (4) Information on the irradiator's radiation source, including its calculated activity;
- (5) Information on the survey instrument (manufacturer, model number and serial number);
- (6) Calibration date of the survey instrument;
- (7) Correction factors, background subtraction, conversions or other calculations for the survey instrument if used;
- (8) Name of the person or organization performing the survey and/or analysis;
- (9) Contamination levels and the corresponding locations;
- (10) Cause of the contamination, if known;
- (11) Any actions taken on the basis of the information yielded by the survey.

Section 41. *Testing and Maintenance of Equipment.*

- (a) To ensure the continued safe operation of the irradiation facility, the licensee shall develop and implement a formal program of maintenance and testing to test all safety functions regularly. The following actions shall be performed periodically:
 - (1) Regular testing of components of the safety interlock system for correct operation, in accordance with the instructions of the equipment manufacturer. These tests shall be carried out by a Qualified Expert in the presence of a Radiation Protection Officer.
 - (2) Calibration of portable radiation survey meters before their first use, after repair and at least annually.
 - (3) Periodic examination of the source rack hoist cable and guide cables. The cables shall be replaced at the intervals recommended by the manufacturer.
 - (4) Periodic leak tests of radioactive sources as recommended by the source supplier and in accordance with the requirements of this Part.

41.1. Weekly Tests

- (a) The following tests shall be carried out weekly:
 - (1) Category II and IV gamma irradiators. If air filtration is provided for the irradiation room exhaust system, a portable survey meter shall be used to check radiation levels at the air filter banks. All readings shall be recorded.
 - (2) Category III and IV gamma irradiators. A portable survey meter shall be used to check radiation levels at the deionizer filter and resin beds. All readings shall be recorded. If the deionizer resin bed has a continuous monitor to check for contamination of the storage pool water, additional surveys are not necessary.
 - (3) Category III and IV gamma irradiators. The water deionizer system shall be checked for correct operation.
 - (4) Category III and IV gamma irradiators. The storage pool water cooler shall be checked, and the temperature of the storage pool water shall be within authorized limits.
 - (5) The access control system, the emergency stop device inside the radiation room and the system for the detection of entry by personnel shall be checked if

functioning. This test may be carried out when each component is tested or actuated during the irradiator startup sequence.

41.2. Monthly Tests

- (a) The following additional tests shall be carried out on a monthly basis:
- (1) Test that the radiation room radiation monitor is functioning properly; This can be done by exposing the monitor probe to a check source until the alarm sounds.
 - (2) Check, in accordance with the manufacturer's instructions, that access to the radiation room is prevented when the radiation room monitor alarm sounds upon exposing the monitor probe to a check source. Check the emergency exit procedure by ensuring that the personnel access door can be opened from the inside and that other means of exit in an emergency are operating properly.
 - (3) Test that the product exit radiation monitor is functioning properly; the test shall be carried out with the irradiator operating by exposing the monitor probe to a check source until the alarm sounds. The product positioning system must stop, and the means of producing radiation is disabled.
 - (4) Category III and IV gamma irradiators. Check that the continuous radiation monitoring device on the circulation system for the storage pool water is functioning correctly.
 - (5) Test irradiator shutdown controls during operation where possible. Check the high temperature switch, the source rack position switches, the backup access control and the earthquake detector.
 - (6) Test the source rack hoist mechanism, the ventilation system and any similar hardware that contributes to the safe operation of the irradiator, and the product positioning mechanism.
 - (7) Check that other main items of equipment associated with the means of producing radiation function properly and show no signs of excessive wear or potential failure.
 - (8) Check that all product containers are undamaged and in good condition.
 - (9) Category III and IV irradiators. Check the water level control switches (normal level and abnormal level) for correct operation.
 - (10) Check for correct functioning of the emergency stop device on the control console and at any other locations.
 - (11) Check all visual warning signals and alarms for correct operation. Check all control indicator lights to ensure that they illuminate.
 - (12) Attempt to operate the irradiator after deliberately violating the approved startup procedure, to ensure that the safety interlocks and sequential controls are functioning correctly.
 - (13) Verify that the uninterruptible power supply is functioning properly and is capable of providing adequate electrical power to allow safe shutdown of the irradiator.
 - (14) Verify that the heat detectors and smoke detectors are operating properly.
 - (15) Verify that safety interlocks on removable shield plugs in the radiation room are operating properly.

- (16) Category III and IV gamma irradiators. Evaluate the amount of water added to the source storage pool to determine whether the amount of makeup water added is abnormal (too high or too low). If the amount of water added to the storage pool is abnormally high, investigate whether water is leaking from the pool. If the amount of water added to the storage pool is abnormally low, investigate the operation of the supply system for make-up water.
 - (17) Verify that posted notices (e.g. emergency call lists) and symbols are still present, legible and clearly visible.
 - (18) Test the safety delay timer by actuating the timer, waiting until the time limit has expired and then attempting startup to verify that the system cannot be started.
- (b) If any of the checks indicate a fault or if safety interlocks do not function properly, the irradiator shall not be used until repairs have been made. The return of the irradiator to normal operation shall be subject to approval by a Radiation Protection Officer.

41.3. Semi-annual Tests

- (a) For Categories II and IV gamma irradiators, an inspection of the entire length of the cables in the source rack hoist and suspension system shall be carried out. Cables showing signs of excessive wear shall be replaced.
- (b) The source guard shall be visually inspected to ensure that its integrity is maintained.

41.4. Recordkeeping

The results of all tests described in this Section shall be recorded on a formal checklist signed by the Radiation Protection Officer who has witnessed the tests.

Section 42. *Leak Testing of Radioactive Sources.*

- (a) Each sealed source shall be tested for leakage at intervals not to exceed six (6) months using a leak test or method approved by the PNRI. The test must be capable of detecting the presence of 200 Bq of radioactive material and must be performed by a person approved by the PNRI to perform the test.
- (b) For storage pool type irradiators, sources shall not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within six (6) months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water.
- (c) If the leak tests do not show activity above the established action level, the test results shall be documented and retained for future reference. Leak test records shall include:
 - (1) Identification of the irradiator;
 - (2) Date of the test;
 - (3) Leak test method;
 - (4) Identification of the measuring instrument by manufacturer, and model and serial number;
 - (5) Date of the most recent calibration of the measuring instrument;
 - (6) Calculation of the activity detected;
 - (7) Evaluation of test results;
 - (8) Name of the person or organization responsible for the test.

- (d) If a leaking source is detected, the licensee shall immediately withdraw the irradiator from operation and appropriate actions shall be taken to prevent exposure of personnel and further dispersal of radioactive material, including stopping operation of the radiation room ventilation system and stopping circulation of the storage pool water. The licensee shall immediately isolate the area and notify the PNRI, the manufacturer of the equipment and the supplier of the radioactive source.
- (e) The licensee shall request for a special permit from the PNRI for the removal of a damaged or leaking radioactive source and its transfer to an authorized recipient. The source shall be removed promptly once the decision to remove it has been made. Removal shall be performed by, or under the supervision and in the physical presence of, an individual who is qualified and specifically authorized to perform such activities. Unauthorized or untrained persons shall not attempt to examine or decontaminate the irradiator under any circumstances.
- (f) The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a service provider authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until found free of contamination.

Section 43. Facility Maintenance.

- (a) The licensee shall ensure that maintenance operations at the facility are coordinated with the manufacturer of both the irradiator and the radiation source to ensure that appropriate repairs, modifications and system upgrades are instituted at the facility.
- (b) Regular maintenance of all components of the irradiation facility shall be performed in accordance with the manufacturer's instructions.
- (c) The licensee shall ensure that they are advised by manufacturers of any previously unforeseen conditions that could cause accidents, or that have given rise to hazards or potential hazards, including the corrective actions to be taken. The licensee shall ensure that the corrective actions are implemented.
- (d) If in certain situations it may be necessary to bypass a safety interlock to repair components of irradiator systems, a written approval of the Radiation Protection Officer shall be obtained. This shall be documented with a description of the circumstances and the actions taken, and with the specific approval of the Radiation Protection Officer.
- (e) If it becomes necessary to bypass or disable a safety interlock, independent verification shall be obtained that the radioactive source is in the fully shielded position.
- (f) The affected component of the safety interlock system shall be bypassed or disabled only long enough to allow entry into the radiation room to remedy the, during which time the irradiator will not be in operation. Entry into the radiation room shall be accomplished by following routine procedures, including the use of a portable survey meter to monitor radiation levels on entry.
- (g) If it is necessary to bypass or disable a component of a safety system, the affected

component shall be tested for proper operation upon being reinstated. After verifying that the safety interlocks have been restored to their design function, approval of the Radiation Protection Officer shall be obtained for a return to normal operations.

- (h) The licensee shall maintain a record of the maintenance and repair performed on the irradiator for the duration that it is in use.

V. CONTROL AND SECURITY OF RADIOACTIVE SOURCES

Section 44. Control Over Radioactive Sources.

- (a) The licensee shall ensure that all radioactive sources are properly shielded and are kept secure so as to prevent unauthorized access or use.
- (b) The licensee shall make arrangements to control access of visitors to the irradiation facility and shall provide information and instruction to these individuals before entering the facility.
- (c) The licensee shall perform physical inventory of radioactive sources on an annual basis. Records of source inventory shall be kept until the license is terminated.
- (d) A radioactive source shall not be transferred unless the receiver possesses a valid license issued by the PNRI.

Section 45. Security of Radioactive Sources.

- (a) The licensee shall establish and implement administrative and technical measures for ensuring the security of radioactive sources and the facility in compliance with CPR Part 26 and the conditions of the license. These measures shall be documented in a Security Plan approved by the PNRI.
- (b) The licensee shall control and restrict access to controlled areas to Radiation Protection Officers, Irradiator Operators and Authorized Personnel. The licensee shall implement the following key control measures:
 - (1) A record shall be kept of all individuals having access to, or possession of, keys concerned with the management of radioactive sources; and
 - (2) Arrangements shall be made for:
 - (i) Checking and custody of keys, particularly to minimize the possibility of duplication;
 - (ii) Changing of combination settings at suitable intervals; and
 - (iii) Changing of locks, keys, or combination whenever there is evidence or suspicion that they have been compromised or when a staff that has held access is no longer allowed to have access.
- (c) The licensee shall conduct background checks to ensure that persons engaged in the management of sources are trustworthy and reliable.
- (d) The licensee shall establish measures to prevent theft, loss, unauthorized withdrawal, damage to or tampering with sources and equipment.
- (e) The irradiator room shall be subject to continuous detection of unauthorized intrusion

attempt, either by personal surveillance or a remotely monitored intruder alarm. Every unauthorized access to the source shall be detected in a timely manner.

- (f) The licensee shall ensure the confidentiality of information, the unauthorized disclosure of which could compromise the security measures.
- (g) The licensee shall have pre-arranged procedures with law enforcers regarding intelligence information and use of secure communications as well as the reactions to an increased threat.
- (h) The licensee shall prepare and appropriately exercise emergency plans to respond to the loss of authorized control of radioactive sources.

Section 46. *Management of Disused Radioactive Sources and Radioactive Wastes.*

- (a) The licensee shall establish and implement a radioactive waste management program to ensure an effective control and disposal of radioactive wastes generated under the license for the protection of the public and the environment.
- (b) Disused radioactive sources that are to be returned to the original supplier or manufacturer shall comply with the requirements on the export of radioactive sources in CPR Part 27.

Section 47. *Decommissioning and Disposal of Radioactive Sources.*

- (a) At the end of the operating lifetime of the facility, the licensee shall ensure that:
 - (1) Buildings and equipment are free from radioactive material and contamination before disposal or resale;
 - (2) All radioactive sources are properly accounted for before they are returned to the supplier or disposed of in accordance with the applicable national regulations; and
 - (3) Any radioactive waste resulting from decontamination is disposed of in accordance with regulatory requirements.
- (b) The licensee shall submit to PNRI, upon completion of decommissioning, a report of the results of the radiation survey performed.
- (c) The licensee shall demonstrate that the premises are suitable for unrestricted use and occupancy after decommissioning.

VI. TRANSPORT, LOADING AND UNLOADING OF RADIOACTIVE SOURCES

Section 48. *Transport of Radioactive Sources.*

- (a) The transport of radioactive sources is subject to the requirements of CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines".
- (b) Measures shall be taken to ensure that the radioactive source is kept secure during transport in accordance with CPR Part 27, "Security Requirements in the Transport of Radioactive Material" so as to prevent theft or damage and to ensure that control over the radioactive source is not relinquished inappropriately.
- (c) The import or export of Categories 1 and 2 radioactive sources shall be conducted in a

manner consistent with CPR Part 4 and Part 27, the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA Guidance Document on the Import and Export of Radioactive Sources.

Section 49. *Receipt of Radioactive Source.*

- (a) The licensee shall have a detailed exchange of information with the source supplier prior to each shipment of radioactive source to be dispatched to the licensee. For each package, this information shall include:
 - (1) The nuclide, number and activity of sources;
 - (2) A description of the source construction and performance tests, including leakage tests;
 - (3) Special form approval certificate;
 - (4) A description of the container;
 - (5) Approval certificate for Type B container or statement of compliance with CPR Part 4 for other containers;
 - (6) Details of any special arrangements required, including multilateral approvals, where necessary; and
 - (7) A copy of the transport documents, to be sent to the licensee by fax or e-mail before dispatch.
- (b) The licensee shall have an agreement with the supplier on the transport route and responsibility for each stage of the journey.
- (c) Arrangements shall be made, where necessary, for:
 - (1) Special handling equipment during transfer from one mode of transport to another, or between vehicles;
 - (2) Checking radiation dose rates from the package or container;
 - (3) Checking that correct transport labels are attached to the package or container;
 - (4) Ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labeled; and
 - (5) Dealing with Bureau of Customs controls; and security of the consignment during transport, particularly during delays or overnight stops.

Section 50. *Loading and Unloading of Sources.*

50.1. Handling of Radioactive Sources

- (a) The licensee shall make an evaluation of source loading and unloading procedures to ensure that the exposure of individuals is kept as low as reasonably achievable.
- (b) The licensee shall assess all hazards associated with the loading, unloading and handling of radioactive sources. For these activities, the licensee shall ensure the optimization of protection and safety and shall ensure that the safety interlocks and control system of the irradiator are not compromised. Any necessary contingency plans shall be incorporated into the written instructions for operation of the facility.
- (c) The loading and unloading of the radioactive sources on arrival at the facility or on dispatch from shall only be undertaken under close radiation protection supervision in accordance with the PNRI approved plan for such activity.
- (d) For wet source storage irradiator, the transport package shall be placed at the bottom

of the storage pool and fully vented. Long handled instruments shall be used to manipulate radioactive sources under water. For dry source storage irradiator, remote instruments shall be used to manipulate radioactive sources.

50.2. Survey of Transport Packages

- (a) The licensee shall perform radiation surveys of transport packages including radioactive sources when they are received at the facility. The following surveys shall be performed by appropriately trained individuals:
 - (1) *External radiation survey.* Prior to performing the contamination surveys, the licensee shall verify that dose rates due to the transport package do not exceed the limits in CPR Part 4. This shall be done by means of measurements made at the surface of the package and at one meter from its surface. A survey of the transport vehicle, including occupied areas, shall be performed to verify that any shifting of the package that may have occurred during transport has not resulted in high radiation levels in and around the vehicle.
 - (2) *External removable contamination survey.* The licensee shall perform a contamination survey of the external surface of the radioactive source transport package, which must consist of a series of wipes to check for the presence of removable contamination.
 - (3) *Internal removable contamination survey.* The licensee shall perform tests to determine whether source integrity has been compromised during transport by checking for the presence of removable contamination inside the transport package.
- (b) If exposure rates or contamination levels exceed authorized limits, including those specified in transport documentation, or exceed the limits set by the supplier, actions shall be taken to protect workers and members of the public from the hazard. The licensee shall notify the consignor of the shipment and the PNRI. The licensee shall also conduct an investigation into the cause of the elevated dose rates and/or the contamination, and corrective actions shall be taken before the source loading procedure is started.
- (c) For returning empty transport packaging following the loading of a source, the same series of surveys shall be performed, except that the internal contamination survey consists of taking wipe samples from inside the packaging cavity, in place of the test described above. If sealed sources are being returned to the manufacturer, the same series of surveys shall be performed as described for the receipt of radioactive sources at the facility, except for the internal removable contamination survey.

Section 51. ***Security in the Transport of Radioactive Sources.***

- (a) The licensee shall establish a Transport Security Plan in accordance with CPR Part 27, "Security Requirements in the Transport of Radioactive Material".
- (b) The licensee shall conduct background checks, verify, and document that the carrier:
 - (1) Use package tracking systems;
 - (2) Implement methods to assure trustworthiness and reliability of transport personnel;
 - (3) Maintain constant control and/or surveillance during transit; and

- (4) Have the capability for immediate communication to summon appropriate response or assistance.
- (c) The licensee shall ensure that each radioactive source is stored at all times during transport in a secure container that is locked and sealed and transported in an enclosed and secured vehicle.
- (d) The licensee shall ensure timely detection of unauthorized access to the source through:
 - (1) A security device equipped in the transport vehicle which will be activated to prevent theft; and
 - (2) An audible and visible alarm that will sound upon detection of unauthorized entry or attack to the vehicle.
- (e) The licensee shall ensure response to a security threat through:
 - (1) Radio communication between the personnel in the conveyance and a security office or organization;
 - (2) Security-trained transport operatives; and
 - (3) Additional guards or a response force, as appropriate, depending on the threat assessment.
- (f) The licensee shall ensure that before undertaking the transport of radioactive sources, carriers are fully aware of the procedures to be followed in the event of an accident.

VII. EMERGENCY PLANNING, PREPAREDNESS AND RESPONSE

Section 52. *Emergency Planning.*

- (a) The licensee shall prepare an Emergency Plan for the protection of people and the environment in accordance with Chapter VIII, "Requirements for Emergency Preparedness and Response", of CPR Part 3.
- (b) In specifying actions to be taken in response to an emergency, the emergency plan shall provide for minimizing radiation exposure, regaining control of the situation to restore the site to its normal conditions, and treating any persons who have been injured or overexposed. The possibility of contamination shall be considered in specifying immediate actions that may be taken in response to an emergency involving a gamma irradiator.
- (c) Immediate actions in response to an emergency involving a gamma irradiator shall include the following, depending on the circumstances:
 - (1) Evacuating the area in the proximity of the hazard;
 - (2) Informing persons in the immediate vicinity of the accident;
 - (3) Rendering first aid to any injured persons;
 - (4) Notifying the Radiation Protection Officer;
 - (5) Evaluating the cause and extent of the hazard;
 - (6) Setting up appropriate notices and barriers to secure the area against unauthorized entry, including the construction of temporary shielding in the event that shielding integrity has been compromised, until post-accident recovery operations have been completed.

Section 53. ***Development of Emergency Plans.***

- (a) The licensee shall draw up an emergency plan on the basis of the safety assessment performed for the facility. Emergency planning shall incorporate measures for defence in depth to cope with identified events. The reliability of safety systems (including administrative and operational procedures and design of the facility and equipment) shall be evaluated.
- (b) The Emergency Plan shall be made available to mitigate any consequences of emergencies and shall address the following events, appropriate for the irradiator type for:
 - (1) Malfunction or deliberate defeat of the safety interlock system and access control systems;
 - (2) Fire or explosion inside the radiation room;
 - (3) Jamming of automatic conveyor systems;
 - (4) Natural phenomena, including earthquakes, tornadoes, floods or other phenomena as appropriate for the location of the facility;
 - (5) Radioactive source rack stuck in an unshielded position;
 - (6) Radiation alarm from the product exit port monitor or the radiation monitor for the storage pool water;
 - (7) Detection of leaking radioactive sources or contamination of the source storage pool, or an alarm caused by contamination of pool water;
 - (8) Abnormal (low or high) water level indicator, an abnormal water loss or leakage from the source storage pool;
 - (9) Breach of security or an alarm indicating unauthorized entry into radiation room, area around pool, or another alarmed area;
 - (10) Prolonged loss of electrical power.
- (c) The licensee shall include planning for emergency response to an accident during transport of radioactive sources. The licensee shall coordinate with the radioactive source supplier and the carrier to ensure that emergency planning for the transport of radioactive sources to and from the facility is adequately addressed.
- (d) The Emergency Plan shall be specific to each situation and shall include the following, as appropriate:
 - (1) Identification of the reasonably foreseeable accidents, incidents or occurrences and their predicted consequences;
 - (2) Communication procedures, including an emergency call-out list;
 - (3) Recommended actions for specified situations; including the identification of persons able to implement and take responsibility for stated parts of the plan, and positive identification of situations requiring evacuation together with the procedures for implementation;
 - (4) A statement regarding immediate life-saving actions, statutory responsibilities and the names of persons identified for implementing actions to discharge them;
 - (5) Availability of emergency equipment, including a list of equipment that must be available, and their locations;
 - (6) Availability of first aid equipment, including a list of equipment available, and their locations, and the names of persons trained to use them; and
 - (7) An outline of the post-emergency procedures designed to restore normal operating conditions.

- (e) Emergency procedures shall be described in concise, easily followed instructions. They shall identify situations requiring emergency action, specify the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator, and foresee the development of a written contingency plan for effecting entry to the radiation room.
- (f) The plan shall contain the names and telephone numbers of the responsible individuals to be contacted. Notices shall be clearly visible inside the facility at locations where they might be needed, showing the following information:
 - (1) How to contact a Radiation Protection Officer or an alternative person, who must be notified immediately of any emergency;
 - (2) How to call the fire brigade and medical services;
 - (3) Where to find emergency equipment.
- (g) In an emergency, liaison shall be maintained with relevant off-site services or agencies including, as appropriate, ambulance, fire, police and hospital services, and local and national authorities. In the event of an accident, the licensee shall initiate the emergency procedures, coordinate the initial response of the emergency services and other bodies, and inform the PNRI and all relevant parties.
- (h) For emergencies in which follow-up action is required to remedy the situation, such as a stuck source rack, the manufacturer or equipment supplier shall be contacted, along with the PNRI.

Section 54. *Emergency Equipment.*

- (a) The licensee shall ensure that all necessary equipment is readily available to deal with foreseeable emergencies. The following items shall be included:
 - (1) Appropriate and functioning survey meters to measure both dose rates and contamination;
 - (2) Personal alarm and direct reading dosimeters (preferably electronic);
 - (3) Additional personal dosimeters;
 - (4) Barrier materials and notices;
 - (5) Communication equipment (e.g. mobile phones, walkie-talkies);
 - (6) Spare batteries for survey meters, personal electronic dosimeters, mobile phones and torches;
 - (7) Suitable stationery supplies, including an incident logbook;
 - (8) Equipment manuals;
 - (9) First aid equipment;
 - (10) A copy of the emergency procedures.
- (b) Emergency equipment shall be kept in a clearly labelled cabinet in a readily accessible place, with a list of the emergency equipment affixed to the cabinet. Audits shall be made periodically and immediately after use of the equipment to ensure that all items are present and functioning correctly, or that they are replaced as necessary.

Section 55. *Training for Emergencies.*

- (a) All persons with a role in the emergency plans shall be adequately trained to ensure efficient and effective performance of their roles. Training shall include both familiarization with and understanding of the emergency plans, together with training in the use of the emergency equipment. Training shall be reviewed and recorded at appropriate intervals.

- (b) The licensee shall inform staff of any emergency plan that might affect their area of work, and of their role if the plan has to be implemented, and it shall arrange for staff training and emergency drills appropriate to each situation. Training shall include the review of lessons learned from previous emergencies.
- (c) Emergency exercises shall be held at least annually to test critical components of the emergency plans. In addition to personnel training, these exercises serve as an evaluation of the adequacy of the emergency plan. Any lessons learned from the conduct of emergency exercises shall be reviewed, documented and incorporated into the training program or emergency plans as appropriate.

Section 56. ***Periodic Reviews of Emergency Plans.***

- (a) The licensee shall review the emergency plan at least annually to ensure that:
 - (1) Names of persons and contact details (telephone and fax numbers, email addresses, etc.) are up to date;
 - (2) Emergency equipment is readily available and is maintained;
 - (3) Contingency planning is still adequate to address reasonably foreseeable events.
- (b) Emergency plans shall always be reviewed following relevant operational changes and in conjunction with analysis of and lessons learned from accidents in similar facilities or with similar radiation sources.

VIII. EFFECTIVITY

Section 57. ***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:



CARLO A. ARCILLA, Ph. D.
Director

Date of Approval:

1 December 2022