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

CPR PART 2

LICENSING OF RADIOACTIVE MATERIALS AND RADIATION FACILITIES, Rev. 01

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LICENSING OF RADIOACTIVE MATERIALS AND RADIATION FACILITIES, Rev. 01

I. GENERAL PROVISIONS

Section 1. ***Purpose and Scope.***

(a) This Part sets forth the regulations applicable to all persons in the Philippines governing the licensing of radioactive materials and atomic energy facilities by the Philippine Nuclear Research Institute (PNRI or Institute) pursuant to Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484.

(b) This Part provides for the general requirements with respect to applications for Radioactive Material License, and to applications for License to Operate for radiation facilities, and for the renewal, amendment, exemption, modification, and termination of these licenses.

(c) This Part also provides for the requirements for the conduct of regulatory inspection and enforcement.

Section 2. ***Definitions.***

As used in this Part:

(a) **"Act"** means Republic Act No. 5207, otherwise known as the Atomic Energy Regulatory and Liability Act of 1968, as amended by Presidential Decree No. 1484;

(b) **"Code or CPR"** means the Code of PNRI Regulations;

(c) **"Construction"** means the process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment, and the performance of associated tests;

(d) **"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;

(e) **"Enforcement"** means the application by a regulatory body of sanctions against a licensee, intended to correct and, as appropriate, penalize non-compliance with any provisions of the

Act, the rules and regulations made thereunder, any of the terms, conditions, limitations of the license, or any of the orders issued by the PNRI;

(f) **"Interested parties"** means a person or company with a concern or interest in the activities and performance of an organization, business, or system;

(g) **"License to Operate**" means a 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;

(h) "**Licensee**" means a holder of a valid license issued by the PNRI pursuant to this Part, and having overall responsibility for the conduct of authorized activities involving a licensed radioactive material or the operation of a radiation facility;

(i) **"Order"** means a written PNRI directive to modify, suspend, or revoke a license, to cease and desist all authorized activities, to lift an order or to take such other action as may be proper;

(j) "**Person**" means:

(1) Any individual, firm, partnership, association, trust, estate, private or public body, whether corporate or not, or any government agency other than the PNRI, any province, city, municipality, or any political entity within the Philippines; and

(2) Any legal successor, representative, agent or agency of the foregoing;

(k) "**Philippine Nuclear Research Institute or PNRI**" means the body designated by the government as having legal authority to conduct the regulatory processes, including the issuance of a license, conduct of inspection and enforcement;

(l) **"Provisional License"** means an authorization issued by the PNRI to the applicant of a License to Operate, on the basis of the technical information and data so far made available, to allow the conduct of a specific activity prior to the issuance of a License to Operate;

(m) **"Radiation facility"** means a facility, other than nuclear installations, where radioactive material is produced, processed, used, handled, stored or disposed of on such a scale that consideration of protection and safety is required within the entire premises, and is likely to cause overexposure of individuals and release of radioactive substances in the environment;

(n) "**Radioactive material**" means a material designated by PNRI as being subject to regulatory control because of its radioactivity;

(o) "**Radioactive Material License**" means a legal document issued by the PNRI to the applicant granting authorization to receive, possess, own, use, transfer, import and export radioactive material and to perform specified activities relating to the authorized activity;

(p) **"Radioactive source or source"** means anything that may cause radiation exposure by releasing radioactive substances or radioactive material and can be treated as a single entity for purposes of protection and safety;

(q) **"Radiation Protection Officer (RPO)"** means a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee or employer to oversee the implementation of the Radiation Protection and Safety Program;

(r) "**Radiation Protection and Safety Program**" means systematic arrangements that are aimed at providing adequate consideration of radiation protection measures in accordance with CPR Part 3;

(s) **"Regulatory inspection"** means an activity undertaken by the regulatory body to determine by investigation, examination and evaluation of objective evidence the adequacy of, and

adherence to, the Act, regulations, standards, administrative or operational programs and other applicable documents, and the effectiveness of their implementation;

(t) **"Safety"** means the achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards;

(u) **"Safety assessment"** means the systematic process that is carried out throughout the design process (and throughout the lifetime of the facility or the activity) to ensure that all the relevant safety requirements are met by the proposed (or actual) design. Safety assessment includes, but is not limited to, the formal safety analysis; that is, it includes the evaluation of the potential hazards associated with the operation of a facility or the conduct of an activity;

(v) **"Sealed source"** means a radioactive source in which the radioactive material is (a) permanently sealed in a capsule or (b) closely bonded and in a solid form;

(w) **"Security"** means the prevention of, detection of, and response to, criminal or intentional unauthorized acts involving or directed at nuclear material, other radioactive material, associated facilities, or associated activities; and

(x) **"Unsealed source"** means a radioactive source in which the radioactive material is neither (a) permanently sealed in a capsule nor (b) closely bonded and in a solid form.

***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", CPR Part 27 – "Security Requirements in the Transport of Radioactive Materials" and with applicable CPRs providing for the administrative and technical requirements of specific practices and facilities.

(b) This Part does not relieve the applicant or licensee from complying with the applicable laws of the Republic of the Philippines and regulations of other responsible government agencies.

(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 the requirements contained herein and other laws or regulations, the PNRI shall be notified to initiate steps towards resolution.

Section 6. ***Activities Subject to License.***

(a) No person shall manufacture, produce, receive, possess, own, use, transfer, import or export any radioactive material, except under a license issued by the PNRI pursuant to this Part.

(b) No person shall operate a radiation facility except under a license issued by the PNRI pursuant to this Part.

Section 7. ***Exemptions.***

7.1. Exempt Quantities.

(a) The following radioactive materials within justified practices are automatically exempted without further consideration from the requirements for licensing set forth in this Part:

(1) Radioactive materials with total activity or activity concentration not exceeding the exemption levels given in Table I.1 of Schedule I;

(2) Radioactive material of artificial origin with activity concentration not exceeding the exemption levels given in Table I.2 of Schedule I; and

(3) Radiation sources, including substances, materials, radioactive waste, and objects within licensed activities that fall under the criteria for clearance or clearance levels given in Schedule II.

(b) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Schedule I.

(c) For radioactive materials of natural origin, exemption of bulk amounts of material is necessarily considered on a case-by-case basis by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation such that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

7.2. Carriers.

Common and contract carriers, freight forwarders, are exempted from the requirements for a license, to the extent that they transport radioactive material in the regular course of carriage for another or storage incident thereto.

7.3. Source Material and Ores Containing Source Material.

(a) Any person is exempt from the requirements for a license set forth in this Part to the extent that such person imports, exports, receives, possesses, uses, transfers, owns or acquires source material (U or Th) in any chemical mixture, compound, solution or alloy in which the source material is less than one-twentieth of one percent (0.05 percent) by weight of the mixture, compound, solution or alloy.

(b) Except as indicated, any person is exempt from the requirements for a license set forth in this Part to the extent that such person imports, exports, receives, possesses, uses, transfers, owns or acquires unrefined and unprocessed ore containing source material; provided,

however, that no person shall refine or process such ore except as authorized to do so in a specific license issued by the PNRI pursuant to the regulations in this Part.

7.4. Consumer Products Containing Radioactive Material.

Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following consumer products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Smoke detectors containing americium-241;

(2) Luminous clocks and watches containing a small quantity of hydrogen-3 (tritium) or promethium-147 or older watches and clocks (made before 1970) which may contain radium-226;

(3) Older camera lenses incorporated with thorium;

(4) Gas lantern mantles that generate light by heating thorium-232;

(5) Ceramics materials such as tiles and pottery that contain elevated levels of naturally occurring uranium, thorium, and/or potassium;

(6) Glassware containing uranium, potassium-40 or thorium-232;

(7) Commercial fertilizers containing varying levels of radioactive potassium, phosphorous, and nitrogen;

(8) EXIT signs containing the radioactive gas tritium; and

(9) Any other consumer products as will be determined by the PNRI.

Section 8. ***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. REQUIREMENTS FOR RADIOACTIVE MATERIAL LICENSE

Section 9. ***Practices Requiring a Radioactive Material License.***

Pursuant to this Part, the following practices and activities shall require a Radioactive Material License:

(1) Blood irradiator;

(2) Field radiography;

(3) Indent sale;

(4) Commercial sale and distribution;

(5) Nuclear technical services;

(6) Education and training;

(7) Fixed gauge;

(8) Portable gauge;

(9) Well logging, dredging and spinning pipe;

(10) Tracer studies;

(11) Radioimmunoassay; and

(12) Any other practices and activities as will be determined by the PNRI.

Section 10. ***Application for Radioactive Material License.***

(a) An application for a Radioactive Material License shall include the following:

(1) Duly accomplished *PNRI/NRD Form – 01, "Application for Radioactive Material License"*, signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) A copy of current business permit issued by the responsible government agency and a proof of authenticity of business name, as applicable, issued by the:

(i) Securities and Exchange Commission, for corporation; or

(ii) Department of Trade and Industry, for single proprietorship.

(3) Payment of license fees and other charges in accordance with CPR Part 22.

(b) The application shall adequately describe the following information required in the application form:

(1) Name, position, and business address of the applicant/responsible person;

(2) Name, title and training of the individual/s who will use and/or directly supervise the use of radioactive material with documentation of qualification, training, and experience requirements;

(3) Name of the Radiation Protection Officer (RPO) and Assistant RPO with documentation of qualification, training, and experience requirements;

(4) Description of the radioactive material and/or associated devices; the purpose for which the radioactive material is to be used; and the location where the radioactive material and/or associated devices will be used; and

(5) Description of the radiation detection instruments; type, use, and sensitivity range; and the method, frequency and standards used in calibrating radiation detection instruments.

(c) The applicant shall submit the following documents along with the application form. The content of these documents shall be commensurate with the complexity and hazards associated with the radioactive material/s for the purpose requested.

(1) Radiation Safety Management Plan;

(2) Radiation Protection and Safety Program;

(3) Radioactive Waste Management Program;

(4) Emergency Preparedness and Response Plan;

(5) Security Plan, as applicable; and

(6) Transport Security Plan, as applicable.

Section 11. ***Review, Evaluation and Verification of License Application.***

(a) The application will be accepted and processed only when it is deemed by PNRI to be complete in substance and form and accompanied by proof of payment of the corresponding application fee.

(b) The PNRI may, at any time after the filing of the application, require further information to enable PNRI to determine whether the license shall be granted or denied.

(c) The PNRI may verify information contained in the application and secure additional information deemed necessary by conducting a pre-licensing inspection on the facility or location.

Section 12. ***Issuance of Radioactive Material License.***

The PNRI shall issue a Radioactive Material License in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:

(1) The application is for a purpose authorized by the Act;

(2) The application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property from the harmful effects of ionizing radiation, as well as to ensure the security of the radioactive sources;

(3) The applicant is qualified by reason of training and experience to use the radioactive material/s for the purpose requested;

(4) The applicant satisfies all the applicable administrative and technical requirements of other practice-specific Code of PNRI Regulations;

(5) The applicant has paid the required license fee and other charges, if any, in accordance with the CPR Part 22.

Section 13. ***Terms and Conditions of Radioactive Material License.***

(a) Each license shall be subject to the provisions of the Act, the general and specific conditions of the license, and to applicable rules, regulations, and orders of PNRI.

(b) The Radioactive Material License shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by the PNRI in accordance with the terms of the Act.

(c) The initial Radioactive Material License issued pursuant to this Part shall be valid for a period of one (1) year and for every three (3) or five (5) years thereafter upon renewal of the license; provided, however, that the PNRI in its discretion may limit the period of validity to less than three (3) or five (5) years if the licensee was found to have recurring non-compliances with safety and security implication. The extended validity period for the renewal of Radioactive Material Licenses is found in Annex I Table I.1.

(d) The Radioactive Material License, including any right thereunder, shall not be transferred nor assigned in any manner, either voluntarily or involuntarily, directly, or indirectly, through transfer of control of the license to any person.

(e) The use, possession, and storage of the radioactive material/s shall be confined to the locations authorized in the license.

(f) The licensee shall maintain a current and valid license at all times. A copy of the license shall be conspicuously posted in the premises where authorized activities are conducted and applicable CPRs shall be kept and be made available at each authorized location.

Section 14. ***Amendment of Radioactive Material License.***

(a) An application for amendment of license shall be made by submitting the following:

(1) Duly accomplished *PNRI/NRD Form – 01, "Application for Radioactive Material License*", signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) The details of the proposed amendment and the assessment of its impact on safety and security, if applicable; and

(3) Payment of applicable amendment fee required in CPR Part 22.

(b) A licensee shall apply for and shall receive the amended license before:

(1) It permits anyone to work as Authorized Users, Radiation Protection Officer (RPO), Assistant Radiation Protection Officer (ARPO), and other personnel other than those previously authorized in the license;

(2) It possesses at any one-time radioactive material in excess of the activity authorized in the license;

(3) It leases, receives and uses radioactive material other than what is authorized in the license;

(4) It uses the radioactive material for purposes other than those specified in the license;

(5) It uses or stores radioactive material in locations other than those specified in the license; or

(6) It implements any major change in the equipment and facilities, or in the approved programs and plans.

(c) In determining whether an application for an amendment of a license will be granted, the PNRI will be guided by the considerations that govern the issuance of the initial license, to the extent applicable and appropriate.

Section 15. ***Renewal of Radioactive Material License.***

(a) An application for license renewal shall be made by submitting the following not less than sixty (60) days before the expiration date of the license:

(1) Duly accomplished *PNRI/NRD Form – 01, "Application for Radioactive Material License*", signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) A complete and up-to-date information and documentation as required in this Part, if many outdated documents are referenced or there had been changes in the regulatory requirements, the licensee's organization, or the required programs and plans; and

(3) Payment of license renewal fee and other outstanding regulatory fees in accordance with CPR Part 22.

(b) An application for license renewal that is filed less than sixty (60) days before the expiration date of the license shall be subject to a surcharge equivalent to twenty-five percent (25%) of the required license renewal fee.

(c) An application for license renewal that is filed after the expiration date of the license shall be assessed a surcharge equivalent to fifty percent (50%) of the prescribed license renewal fee. In addition to the written application, the licensee is required to:

(1) Discontinue the conduct of licensed activities until the PNRI has issued the renewed license;

(2) Ensure that all radioactive sources are safe in their authorized storage locations; and

(3) Submit a written explanation about the delay in the filing of application and a justification on why PNRI should not impose the appropriate enforcement action against the licensee.

Section 16. ***Expiration of Radioactive Material License.***

(a) A Radioactive Material License shall expire at the end of the day, in the month and year stated therein.

(b) Upon expiration of the license, the licensee shall discontinue the conduct of authorized activities and ensure that all radioactive material are safe in their authorized storage locations.

(c) The PNRI may, if necessary to protect the public health and safety or the national interest, take temporary custody of any radioactive material held by the licensee pending its appropriate and lawful disposition by or for the licensee.

(d) If a license has expired and the licensee has not requested a renewal or termination of the license within thirty (30) days after the expiry date, the PNRI shall issue a Notice of Violation and require the licensee to submit a written explanation why an Order to place the radioactive material under temporary regulatory custody should not be issued.

(e) If a licensee decides not to renew its license, the licensee shall request, in writing, the termination of the license in accordance with Section 17 of this Part.

Section 17. ***Termination of Radioactive Material License.***

(a) When a licensee decides to permanently discontinue activities involving a licensed radioactive material, the licensee shall immediately notify the PNRI, in writing, of its intent to terminate. During this time, the licensee shall:

(1) Cease to engage in any authorized activity involving the radioactive material except to keep the radioactive material under safe and secure storage;

(2) Transfer or dispose all radioactive material to an entity licensed to receive and possess the same specified radioactive material, such as the original manufacturer or supplier, another specific licensee, or a licensed radioactive waste management facility. A proof of transfer or disposal from the final recipient of the radioactive material shall be obtained during the transaction; and

(3) Perform a contamination survey of the premises where licensed activities were carried out. If contamination is found, the licensee shall decontaminate the areas until no removable contamination is present. The licensee shall document all wipe assays and decontamination activities.

(b) To be relieved of the responsibility for the radioactive material and the other conditions in the license, the licensee shall submit a written request for termination of the license to PNRI. The letter shall be accompanied by the following:

(1) An inventory of radioactive material transferred or disposed and the method of disposal for each item;

(2) Proof of transfer or disposal of radioactive material;

(3) A final contamination survey report of the premises; and

(4) An agreement that records and facilities will be available for inspection by PNRI at a mutually agreed date within the next six (6) months.

(c) The PNRI may verify information contained in the request for termination and secure additional information deemed necessary by conducting a termination inspection on the facility or location.

(d) The PNRI will officially terminate the license by issuing a formal notice when the following conditions are satisfactorily met:

(1) If the licensee is no longer in possession of any radioactive material that requires a license; and

(2) If the premises are not contaminated and are suitable for release.

(e) The licensee shall cause the proper termination of his license in accordance with this Section within one (1) year after the expiration of the license.

(f) Failure by the licensee to fulfill the provisions of this Section for the proper termination of its Radioactive Material License shall be subject to the penal provisions provided in Section 64 of the Act, as amended.

III. REQUIREMENTS FOR LICENSE TO OPERATE

Section 18. ***Radiation Facilities Requiring a License to Operate.***

Pursuant to this Part, the following radiation facilities shall require a License to Operate:

(1) Nuclear medicine facility;

(2) Positron Emission Tomography (PET) facility;

(3) Teletherapy facility utilizing radioactive sources;

(4) Brachytherapy facility;

(5) Fixed facility radiography;

(6) Gamma irradiation facility;

(7) Radioactive waste management facility;

(8) Particle accelerator facility for the production of radionuclides;

(9) Radiopharmaceutical manufacture and dispensing facility;

(10) Calibration and testing facility used for technical services; and

(11) Any other radiation facility as may be determined by the PNRI.

Section 19. ***Application for License to Operate.***

(a) An application for a License to Operate shall include the following:

(1) Duly accomplished *PNRI/NRD Form – 02, "Application for License to Operate"*, signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) A copy of current business permit issued by the responsible government agency and a proof of authenticity of business name, as applicable issued by the:

(i) Securities and Exchange Commission, for corporation; or

(ii) Department of Trade and Industry, for single proprietorship; and

(3) Environmental Compliance Certificate, and a copy of the Environmental Impact Assessment Report;

(4) Payment of license fees and other charges in accordance with CPR Part 22.

(b) The application shall adequately describe the following information required in the application form:

(1) Name, position, and business address of the applicant/responsible person, citizenship (if the applicant is an individual), and the names, addresses and citizenship of its principal officers;

(2) Name, title and training of the individual/s who will use and/or directly supervise the operation of the radiation facility with documentation of qualification, training, and experience requirements;

(3) Name of the Radiation Protection Officer (RPO) and Assistant RPO with documentation of qualification, training, and experience requirements;

(4) A map of the location and a site plan indicating the areas, structures, systems and perimeter of the proposed facility, including the buildings, if any, with their current uses;

(5) Brief description of the nature of the proposed radiation facility, its technical characteristics and specifications, the operating principles, the operations to be performed in it;

(6) Description of the radioactive material; the maximum activity; the chemical and/or physical form; and purpose for which the radioactive material is to be used;

(7) Description of the radiation detection instruments; type, use, and sensitivity range; and the method, frequency and standards used in calibrating radiation detection instruments;

(8) Information describing its human resource requirements; and

(9) Information on the contractors and a description of responsibilities between the applicant and any contractors responsible for the siting, design, construction, and operation of the proposed radiation facility.

(c) The applicant shall submit the following documents along with the application form. The content of these documents shall be commensurate with the complexity and hazards associated with the radiation facility for the purpose requested.

(1) Radiation Safety Management Plan;

(2) Safety Assessment Report;

(3) Radiation Protection and Safety Program;

(4) Radioactive Waste Management Program;

(5) Emergency Preparedness and Response Plan;

(6) Security Plan;

(7) Transport Security Plan;

(8) Environmental Protection Plan; and

(9) Initial Decommissioning Plan.

Section 20. ***Review, Evaluation and Verification of License Application.***

(a) The application will be accepted and processed only when it is deemed by PNRI to be complete in substance and form and accompanied by proof of payment of the corresponding application fee.

(b) The PNRI may, at any time after the filing of the application, require further information to enable PNRI to determine whether the license shall be granted or denied.

(c) The PNRI may verify information contained in the application and secure additional information deemed necessary by conducting a pre-licensing inspection on the facility or location.

Section 21. ***Issuance of a Provisional License.***

(a) Upon the request of the applicant and subject to the conditions set forth of this Part, the PNRI may issue a Provisional License to the applicant prior to the issuance of a License to Operate if the application is otherwise acceptable, to conduct specific activities prior to operation.

(b) The PNRI shall issue a Provisional License in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:

(1) The application is for the purpose authorized by the Act; and

(2) There is reasonable assurance that the proposed radiation facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(c) Such a Provisional License may be granted even if the health and safety information then available is less than would be needed for a License to Operate provided that the PNRI is satisfied that there is reasonable assurance that questions of health and safety will be so resolved as to warrant the issuance of a License to Operate.

(d) Any activities undertaken prior to the issuance of the 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, as amended, and rules, regulations, and orders issued under the Act.

Section 22. ***Issuance of License to Operate.***

The PNRI shall issue a License to Operate in such form and containing such conditions and limitations, as it deems appropriate and necessary, upon determining that:

(1) The application is for the purpose authorized by the Act;

(2) The application is complete in substance and form and the proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property as well as to ensure the security of the radioactive sources;

(3) The Safety Assessment Report has adequately described all activities with safety significance in appropriate detail and it demonstrates that the facility is safe and can be operated safely;

(4) The applicant has adequate human resources to safely operate and maintain the radiation facility;

(5) Radiological monitoring equipment and devices are clearly defined, and will be installed and operational before the radioactive source is brought onto the facility;

(6) Provisions are made in the design to account for security aspects to minimize potential conflicts between safety and security considerations;

(7) There are no unresolved safety issues relating to the activities to be conducted under the License to Operate that would constitute good cause for withholding the license;

(8) The applicant has satisfied all the applicable administrative and technical requirements provided in other Code of PNRI Regulations specific to the activities to be conducted under the License, and that notifications, if any, to other agencies or bodies have been duly made; and

(9) The applicant has paid the required license fee and other charges, if any, in accordance with the CPR Part 22.

Section 23. ***Terms and Conditions of License to Operate.***

(a) Each license shall be subject to the provisions of the Act, the general and specific conditions of the license, and to applicable rules, regulations, and orders of PNRI.

(b) The License to Operate shall be subject to amendment, revision or modification by reason of amendments to these regulations and the Act, or by reason of rules, regulations and orders issued by the PNRI in accordance with the terms of the Act.

(c) The initial License to Operate issued pursuant to this Part shall be valid for a period of one (1) year and for every three (3) or five (5) years thereafter upon renewal of the license; provided, however, that the PNRI in its discretion may limit the period of validity to less than three (3) or five (5) years if the licensee was found to have recurring non-compliances with safety and security implication. The extended validity period for the renewal of License to Operate is found in Annex I Table I.2.

(d) The License to Operate, including any right thereunder, shall not be transferred nor assigned in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person.

(e) The use, possession and storage of the radioactive sources shall be confined to the location authorized in the license.

(f) The licensee shall maintain a current and valid license at all times. A copy of the license shall be displayed in a conspicuous area within the radiation facility and all applicable regulations of the Code shall be kept and made available.

Section 24. ***Amendment of License to Operate.***

(a) An application for amendment of license shall be made by submitting the following:

(1) Duly accomplished *PNRI/NRD Form – 02, "Application for License to Operate"*, signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) The details of the proposed amendment, the assessment of its impact on safety and security, if applicable, and the justification for such amendment; and

(3) Payment of the applicable amendment fee required in CPR Part 22.

(b) The licensee shall apply for and must receive the amended license before:

(1) It permits anyone to work as Authorized Operators, Radiation Protection Officer (RPO), Assistant Radiation Protection Officer (ARPO), and other personnel other than those previously authorized in the license;

(2) It possesses at any one-time radioactive material in excess of the activity authorized in the license;

(3) It leases, receives and uses radioactive material other than what is authorized in the license;

(4) It uses the radioactive material for purposes other than those specified in the license;

(5) It uses or stores radioactive material in locations other than those specified in the license;

(6) It incorporates any modification in the approved design or licensing basis of the radiation facility;

(7) It implements any major change in the equipment related to safety, or in the approved programs and plans; or

(8) It implements any substantial change in any condition of the license that takes effect, in consultation with PNRI.

(c) In determining whether an application for an amendment of a license will be granted, the PNRI will be guided by the considerations that govern the issuance of the initial license, to the extent applicable and appropriate.

(d) The PNRI may make a final determination that a proposed amendment to a License to Operate involves no significant hazards consideration in the operation of the radiation facility in accordance with the proposed amendment.

Section 25. ***Renewal of License to Operate.***

(a) An application for license renewal shall be made by submitting the following not less than sixty (60) days before the expiration date of the license:

(1) Duly accomplished *PNRI/NRD Form – 02, "Application for License to Operate"*, signed by the Chief Executive Officer or an equivalent head of the company, and notarized;

(2) A complete and up-to-date information and documentation as required in this Part, if many outdated documents are referenced or there had been changes in the regulatory requirements, the licensee's organization, or the required programs and plans; and

(3) Payment of license renewal fee and other outstanding regulatory fees in accordance with CPR Part 22.

(b) An application for license renewal that is filed less than sixty (60) days before the expiration date of the license shall be subject to a surcharge equivalent to twenty-five percent (25%) of the required license renewal fee.

(c) An application for license renewal that is filed after the expiration date of the license shall be assessed a surcharge equivalent to fifty percent (50%) of the prescribed license renewal fee. In addition to the written application, the licensee is required to:

(1) Discontinue the operation of the radiation facility until the PNRI has issued the renewed license;

(2) Ensure that all radioactive sources are safe in their authorized storage locations; and

(3) Submit a written explanation about the delay in the filing of application and the reason why PNRI should not impose the appropriate enforcement action against the licensee.

Section 26. ***Expiration of License to Operate.***

(a) A License to Operate shall expire at the end of the day, in the month and year stated therein.

(b) Upon expiration of the license, the licensee shall discontinue the operation of the radiation facility and shall ensure that all radioactive sources are safe and secure in their authorized storage locations.

(c) The PNRI may, if necessary to protect the public health and safety or the national interest, take temporary custody of any radioactive material or the radiation facility held by the licensee pending their appropriate actions to cause the proper decommissioning of the facility.

(d) If the license has expired and the licensee has not requested a renewal or termination of the license within thirty (30) days after the expiration date, the PNRI shall issue a Notice of Violation and require the licensee to submit a written explanation why an Order to place the radiation facility under temporary regulatory custody should not be issued.

Section 27. ***Termination of License to Operate.***

(a) When a licensee has decided to permanently cease operations, the licensee shall notify the PNRI, in writing, of its intent to terminate and request to amend the license to authorize ownership and possession of the radioactive source/s. During this time, the licensee shall:

(1) Submit an updated Decommissioning Plan, and notify all interested parties of the plan;

(2) Cease to engage in any authorized activity involving the radioactive material except to keep the radioactive material under safe and secure storage;

(3) Continue to control entry to restricted areas; and

(4) Transfer or dispose all radioactive material to an entity licensed to receive and possess the same specified radioactive material, such as the original manufacturer or supplier, another specific licensee, or a licensed radioactive waste management facility. The licensee shall obtain proof of transfer or disposal from the final recipient of the radioactive material.

(b) The Decommissioning Plan shall include:

(1) A description of the controls and limits on procedures and equipment to protect occupational and public health and safety;

(2) A description of the planned final radiation survey;

(3) An updated cost estimate for the decommissioning activities, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning; and

(4) A description of technical specifications, quality assurance provisions and physical security plan provisions in place during decommissioning.

(c) If the Decommissioning Plan demonstrates that the decommissioning will be performed in accordance with the radiation protection and safety requirements, and after notice to interested parties, the PNRI will approve, by amendment, the plan subject to such conditions and limitations as it deems appropriate and necessary.

(d) Within sixty (60) days after the approval of the Decommissioning Plan, the licensee shall begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, including management of radioactive waste, in compliance with applicable regulations.

(e) On the completion of decommissioning activities, the licensee shall submit a written request for termination of the license to PNRI. The letter shall be accompanied by the following:

(1) A final decommissioning report to demonstrate that the end state of the facility as specified in the approved Decommissioning Plan has been reached;

(2) An inventory of radioactive material transferred or disposed, and proof of transfer or disposal of radioactive material; and

(3) An agreement that records and facilities will be available for inspection by PNRI at a mutually agreed date within the next twelve (12) months.

(f) The PNRI may verify information contained in the request for termination and secure additional information deemed necessary by conducting a termination inspection on the facility or site.

(g) The PNRI will officially terminate the license by issuing a formal notice if upon verification —

(1) The licensee is no longer in possession of any radioactive material that requires a license;

(2) The decommissioning has been performed in accordance with the approved decommissioning plan; and

(3) The terminal radiation survey and associated documentation demonstrate that the facility and site are suitable for release.

(h) The licensee shall cause the proper termination of his license in accordance with this Section within two (2) years following permanent cessation of operations or the expiration of the License to Operate.

(i) Failure by the licensee to fulfill the provisions of this Section for the proper termination of its license shall be subject to the penal provisions provided in Section 64 of the Act, as amended.

IV. INSPECTION AND ENFORCEMENT

Section 28. ***Regulatory Inspection.***

(a) The licensee shall afford to PNRI Inspectors the opportunity to enter its premises, at all reasonable times, and to perform inspections as may be necessary, announced or unannounced, of the radioactive materials in possession and the premises, equipment and activities related to the licensed facility as may be necessary to effectuate the purposes of the Act, as amended.

(b) The licensee shall cooperate in the conduct of inspections and shall provide to the PNRI Inspectors, on demand, all kinds of data, information, and full access to all relevant records kept pursuant to these rules and regulations without any obstruction or delay.

(c) In case of any resistance during entry and inspection, or in case of locked premises, the PNRI Inspectors will take reasonable efforts of coordinating with the owner before entering the premises and may seek assistance of the local government unit or the local police upon the approval of the PNRI Director.

Section 29. ***Violations and Issuance of Notice of Violation.***

(a) A licensee shall be issued a Notice of Violation under the following grounds:

(1) Failure to comply with any provisions of the Act, the rules and regulations made thereunder, any of the terms, conditions, limitations of the license, or any of the orders issued by the PNRI;

(2) Action or inaction of the licensee has resulted in the breach of any of the provisions of the Act or the rules and regulations in the Code of PNRI Regulations;

(3) If any of the allegation of possible violations to any of the provisions of the Act, or the rules and regulations in the Code, is determined by the PNRI to be true; or

(4) A default in payment of fee or any other dues imposed by the PNRI.

(b) A licensee who have been served a Notice of Violation shall submit a written reply within ten (10) days from the receipt of the Notice to show cause as to why PNRI should not impose further enforcement action. The letter shall contain the following:

(1) An explanation why or how the violation occurred or, if contested, the basis for disputing the violation;

(2) Corrective actions made and the results achieved;

(3) Corrective measures to be taken to prevent recurrence; and

(4) The date when full compliance will be achieved.

(c) The licensee shall ensure that the corrective actions would restore safety, security and compliance with the license conditions, regulations, or other requirements.

(d) The licensee shall develop and implement, in a timely manner, corrective measures that will not only prevent recurrence of the subject violation, but will be appropriately comprehensive, given the significance and complexity of the violation to prevent occurrence of violations with similar root causes.

(e) The PNRI will evaluate the corrective actions implemented by the licensee as part of the process of assessing further enforcement actions against the licensee.

Section 30. ***Issuance of Orders and Related Administrative Sanctions.***

(a) Any license may be modified, suspended, or revoked, in whole or in part, for any material false statement in the application, or for violation of, or failure by the licensee to observe, any of the terms and conditions of the license or any of the provisions of the Act, or any of the rule, regulation or order of the PNRI.

(b) Any license may be suspended or revoked if the PNRI has identified deliberate misconduct that may cause a licensee to violate a regulatory requirement, or where incomplete or inaccurate information is deliberately submitted, or where the PNRI is not assured that the licensee, or any of its authorized personnel, will meet PNRI requirements.

(c) A License Modification Order shall be issued:

(1) When the licensee takes upon itself to implement changes in its equipment, program, procedures, or management control without prior approval from the PNRI; and

(2) When PNRI determines that the licensee can no longer comply with the safety and security requirements specified in the license, or, on any privilege granted in the license.

(d) A Suspension Order shall be issued:

(1) To remove a threat to public health and safety, security of radioactive sources, the environment or the national interest;

(2) To stop the construction of a facility when further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component;

(3) When the PNRI determines that the implementation of the licensee's Radiation Protection and Safety Program is not adequate to provide the needed confidence that safety measures can be properly carried out;

(4) When the licensee has not responded adequately to a previous enforcement action;

(5) When the licensee interferes with the conduct of an inspection or investigation; or

(6) For any reason not mentioned above for which license suspension is legally authorized under Section 27 of the Act, as amended.

(e) A Cease-and-Desist Order shall be issued to any licensee to stop an unauthorized or unsafe activity that has continued after notification by the PNRI that the activity is unauthorized or unsafe, and/or a suspension order has not been followed.

(f) A Revocation Order shall be issued when:

(1) A licensee refuses to correct a violation;

(2) A licensee does not respond to a Notice of Violation where a response was required;

(3) A certain violation has been repeated at least three (3) times, as determined by the PNRI;

(4) A licensee refuses to pay any prescribed fee under the PNRI regulations; or

(5) For any other reason for which revocation is authorized under Section 27 of the Act, as amended.

(g) An Order to take temporary custody of any radioactive material or radiation facility held by the licensee may be issued to a licensee when the license has been suspended or revoked or when the PNRI has identified a deliberate misconduct or violation of requirements to remove a threat to public health, safety and security.

(h) A Lifting Order shall be issued when the PNRI determines full compliance with regulatory requirements and the licensee's response and corrective actions are deemed acceptable.

Section 31. ***Administrative Sanctions.***

(a) In addition to Notices of Violations and Orders, the PNRI may use administrative regulatory sanctions to supplement its enforcement program in the form of:

(1) Confirmatory Action Letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety or the environment;

(2) Letters of Reprimand addressed to the licensee identifying a significant deficiency in the performance of licensed activities; and

(3) Demand Letters to the licensee for information for the purpose of enabling the PNRI to determine whether an order or other enforcement action should be issued.

(b) The licensee shall adhere to any obligations and commitments resulting from these sanctions and shall ensure that they are met.

Section 32. ***Protective Measures in Cases of Suspension, Revocation or Expiration of License.***

(a) Upon the suspension or revocation of a license, pursuant to an Order, the PNRI shall take, or shall require the licensee to take, such measures as may be necessary to protect the health, safety, and security of the public or the national interest.

(b) The PNRI may, if necessary to protect the public health, safety and security or the national interest, take temporary custody of any radioactive material or radiation facilities held by the licensee pending full compliance with regulatory requirements at which time, the suspension or revocation may be lifted or a new license, upon due application, is issued.

(c) Orders shall take effect immediately whenever it is determined that the interest of public health, safety, or security so requires, or when the order is responding to a violation involving willfulness.

Section 33. ***Right to Withhold or Recall Radioactive Material.***

The PNRI may order the withholding or recalling of radioactive material from any licensee who is not equipped to observe, or fail to observe such safety standards to protect health as may be established by the PNRI, or who uses such materials in violation of law or regulation of the Institute, or in a manner other than as disclosed in the application and approved by the PNRI.

V. EFFECTIVITY

Section 34. ***Effectivity Date.***

The regulations in this Part shall take effect fifteen (15) days following its publication in the Official Gazette or in a newspaper of general circulation. However, licenses in effect of that date shall remain valid until the expiration date given on that license. Application for amendments and renewals of existing licenses received after that date will be considered under this regulation.

APPROVED:

CARLO A. ARCILLA, Ph.D.
Director, PNRI

Date of Approval:

15 July 2022

Schedule I. EXEMPTION

Table I.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}	Ni-63	1×10^{5}	1×10^{8}
Be-7	1×10^{3}	1×10^{7}	Ni-65	1×10^{1}	1×10^{6}
C-14	1×10^{4}	1×10^{7}	Cu-64	1×10^{2}	1×10^{6}
O-15	1×10^{2}	1×10^{9}	Zn-65	1×10^{1}	1×10^{6}
F-18	1×10^{1}	1×10^{6}	Zn-69	1×10^{4}	1×10^{6}
Na-22	1×10^{1}	1×10^{6}	Zn-69m	1×10^{2}	1×10^{6}
Na-24	1×10^{1}	1×10^{5}	Ga-72	1×10^{1}	1×10^{5}
Si-31	1×10^{3}	1×10^{6}	Ge-71	1×10^{4}	1×10^{8}
P-32	1×10^{3}	1×10^{5}	As-73	1×10^{3}	1×10^{7}
P-33	1×10^{5}	1×10^{8}	As-74	1×10^{1}	1×10^{6}
S-35	1×10^{5}	1×10^{8}	As-76	1×10^{2}	1×10^{5}
Cl-36	1×10^{4}	1×10^{6}	As-77	1×10^{3}	1×10^{6}
Cl-38	1×10^{1}	1×10^{5}	Se-75	1×10^{2}	1×10^{6}
Ar-37	1×10^{6}	1×10^{8}	Br-82	1×10^{1}	1×10^{6}
Ar-41	1×10^{2}	1×10^{9}	Kr-74	1×10^{2}	1×10^{9}
K-40	1×10^{2}	1×10^{6}	Kr-76	1×10^{2}	1×10^{9}
K-42	1×10^{2}	1×10^{6}	Kr-77	1×10^{2}	1×10^{9}
K-43	1×10^{1}	1×10^{6}	Kr-79	1×10^{3}	1×10^{5}
Ca-45	1×10^{4}	1×10^{7}	Kr-81	1×10^{4}	1×10^{7}
Ca-47	1×10^{1}	1×10^{6}	Kr-83m	1×10^{5}	1×10^{12}
Sc-46	1×10^{1}	1×10^{6}	Kr-85	1×10^{5}	1×10^{4}
Sc-47	1×10^{2}	1×10^{6}	Kr-85m	1×10^{3}	1×10^{10}
Sc-48	1×10^{1}	1×10^{5}	Kr-87	1×10^{2}	1×10^{9}
V-48	1×10^{1}	1×10^{5}	Kr-88	1×10^{2}	1×10^{9}
Cr-51	1×10^{3}	1×10^{7}	Rb-86	1×10^{2}	1×10^{5}
Mn-51	1×10^{1}	1×10^{5}	Sr-85	1×10^{2}	1×10^{6}
Mn-52	1×10^{1}	1×10^{5}	Sr-85m	1×10^{2}	1×10^{7}
Mn-52m	1×10^{1}	1×10^{5}	Sr-87m	1×10^{2}	1×10^{6}
Mn-53	1×10^{4}	1×10^{9}	Sr-89	1×10^{3}	1×10^{6}
Mn-54	1×10^{1}	1×10^{6}	Sr-90*	1×10^{2}	1×10^{4}
Mn-56	1×10^{1}	1×10^{5}	Sr-91	1×10^{1}	1×10^{5}
Fe-52	1×10^{1}	1×10^{6}	Sr-92	1×10^{1}	1×10^{6}
Fe-55	1×10^{4}	1×10^{6}	Y-90	1×10^{3}	1×10^{5}
Fe-59	1×10^{1}	1×10^{6}	Y-91	1×10^{3}	1×10^{6}
Co-55	1×10^{1}	1×10^{6}	Y-91m	1×10^{2}	1×10^{6}
Co-56	1×10^{1}	1×10^{5}	Y-92	1×10^{2}	1×10^{5}
Co-57	1×10^{2}	1×10^{6}	Y-93	1×10^{2}	1×10^{5}
Co-58	1×10^{1}	1×10^{6}	Zr-93*	1×10^{3}	1×10^{7}
Co-58m	1×10^{4}	1×10^{7}	Zr-95	1×10^{1}	1×10^{6}
Co-60	1×10^{1}	1×10^{5}	Zr-97*	1×10^{1}	1×10^{5}
Co-60m	1×10^{3}	1×10^{6}	Nb-93m	1×10^{4}	1×10^{7}

Co-61	1 x 10^2	1 x 10^6	Nb-94	1 x 10^1	1 x 10^6
Co-62m	1 x 10^1	1 x 10^5	Nb-95	1 x 10^1	1 x 10^6
Ni-59	1 x 10^4	1 x 10^8	Nb-97	1 x 10^1	1 x 10^6

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Nb-98	1 x 10^1	1 x 10^5	I-123	1 x 10^2	1 x 10^7
Mo-90	1 x 10^1	1 x 10^6	I-125	1 x 10^3	1 x 10^6
Mo-93	1 x 10^3	1 x 10^8	I-126	1 x 10^2	1 x 10^6
Mo-99	1 x 10^2	1 x 10^6	I-129	1 x 10^2	1 x 10^5
Mo-101	1 x 10^1	1 x 10^6	I-130	1 x 10^1	1 x 10^6
Tc-96	1 x 10^1	1 x 10^6	I-131	1 x 10^2	1 x 10^6
Tc-96m	1 x 10^3	1 x 10^7	I-132	1 x 10^1	1 x 10^5
Tc-97	1 x 10^3	1 x 10^8	I-133	1 x 10^1	1 x 10^6
Tc-97m	1 x 10^3	1 x 10^7	I-134	1 x 10^1	1 x 10^5
Tc-99	1 x 10^4	1 x 10^7	I-135	1 x 10^1	1 x 10^6
Tc-99m	1 x 10^2	1 x 10^7	Xe131m	1 x 10^4	1 x 10^4
Ru-97	1 x 10^2	1 x 10^7	Xe-133	1 x 10^3	1 x 10^4
Ru-103	1 x 10^2	1 x 10^6	Xe-135	1 x 10^3	1 x 10^{10}
Ru-105	1 x 10^1	1 x 10^6	Cs-129	1 x 10^2	1 x 10^5
Ru-106*	1 x 10^2	1 x 10^5	Cs-131	1 x 10^3	1 x 10^6
Rh-103m	1 x 10^4	1 x 10^8	Cs-132	1 x 10^1	1 x 10^5
Rh-105	1 x 10^2	1 x 10^7	Cs-134m	1 x 10^3	1 x 10^5
Pd-103	1 x 10^3	1 x 10^8	Cs-134	1 x 10^1	1 x 10^4
Pd-109	1 x 10^3	1 x 10^6	Cs-135	1 x 10^4	1 x 10^7
Ag-105	1 x 10^2	1 x 10^6	Cs-136	1 x 10^1	1 x 10^5
Ag-110m	1 x 10^1	1 x 10^6	Cs-137*	1 x 10^1	1 x 10^4
Ag-111	1 x 10^3	1 x 10^6	Cs-138	1 x 10^1	1 x 10^4
Cd-109	1 x 10^4	1 x 10^6	Ba-131	1 x 10^2	1 x 10^6
Cd-115	1 x 10^2	1 x 10^6	Ba-140*	1 x 10^1	1 x 10^5
Cd-115m	1 x 10^3	1 x 10^6	La-140	1 x 10^1	1 x 10^5
In-111	1 x 10^2	1 x 10^6	Ce-139	1 x 10^2	1 x 10^6
In-113m	1 x 10^2	1 x 10^6	Ce-141	1 x 10^2	1 x 10^7
In-114m	1 x 10^2	1 x 10^6	Ce-143	1 x 10^2	1 x 10^6
In-115m	1 x 10^2	1 x 10^6	Ce-144*	1 x 10^2	1 x 10^5
Sn-113	1 x 10^3	1 x 10^7	Pr-142	1 x 10^2	1 x 10^5
Sn-125	1 x 10^2	1 x 10^5	Pr-143	1 x 10^4	1 x 10^6
Sb-122	1 x 10^2	1 x 10^4	Nd-147	1 x 10^2	1 x 10^6
Sb-124	1 x 10^1	1 x 10^6	Nd-149	1 x 10^2	1 x 10^6
Sb-125	1 x 10^2	1 x 10^6	Pm-147	1 x 10^4	1 x 10^7
Te-123m	1 x 10^2	1 x 10^7	Pm-149	1 x 10^3	1 x 10^6
Te-125m	1 x 10^3	1 x 10^7	Sm-151	1 x 10^4	1 x 10^8
Te-127	1 x 10^3	1 x 10^6	Sm-153	1 x 10^2	1 x 10^6
Te-127m	1 x 10^3	1 x 10^7	Eu-152	1 x 10^1	1 x 10^6
Te-129	1 x 10^2	1 x 10^6	Eu-152m	1 x 10^2	1 x 10^6
Te-129m	1 x 10^3	1 x 10^6	Eu-154	1 x 10^1	1 x 10^6
Te-131	1 x 10^2	1 x 10^5	Eu-155	1 x 10^2	1 x 10^7
Te-131m	1 x 10^1	1 x 10^6	Gd-153	1 x 10^2	1 x 10^7
Te-132	1 x 10^2	1 x 10^7	Gd-159	1 x 10^3	1 x 10^6
Te-133	1 x 10^1	1 x 10^5	Tb-160	1 x 10^1	1 x 10^6
Te-133m	1 x 10^1	1 x 10^5	Dy-165	1 x 10^3	1 x 10^6
Te-134	1 x 10^1	1 x 10^6	Dy-166	1 x 10^3	1 x 10^6

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Ho-166	1×10^{3}	1×10^{5}
Er-169	1×10^{4}	1×10^{7}
Er-171	1×10^{2}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}
Yb-175	1×10^{3}	1×10^{7}
Lu-177	1×10^{3}	1×10^{7}
Hf-181	1×10^{1}	1×10^{6}
Ta-182	1×10^{1}	1×10^{4}
W-181	1×10^{3}	1×10^{7}
W-185	1×10^{4}	1×10^{7}
W-187	1×10^{2}	1×10^{6}
Re-186	1×10^{3}	1×10^{6}
Re-188	1×10^{2}	1×10^{5}
Os-185	1×10^{1}	1×10^{6}
Os-191	1×10^{2}	1×10^{7}
Os-191m	1×10^{3}	1×10^{7}
Os-193	1×10^{2}	1×10^{6}
Ir-190	1×10^{1}	1×10^{6}
Ir-192	1×10^{1}	1×10^{4}
Ir-194	1×10^{2}	1×10^{5}
Pt-191	1×10^{2}	1×10^{6}
Pt-193m	1×10^{3}	1×10^{7}
Pt-197	1×10^{3}	1×10^{6}
Pt-197m	1×10^{2}	1×10^{6}
Au-198	1×10^{2}	1×10^{6}
Au-199	1×10^{2}	1×10^{6}
Hg-197	1×10^{2}	1×10^{7}
Hg197m	1×10^{2}	1×10^{6}
Hg-203	1×10^{2}	1×10^{5}
Tl-200	1×10^{1}	1×10^{6}
Tl-201	1×10^{2}	1×10^{6}
Tl-202	1×10^{2}	1×10^{6}
Tl-204	1×10^{4}	1×10^{4}
Pb-203	1×10^{2}	1×10^{6}
Pb-210*	1×10^{1}	1×10^{4}
Pb-212*	1×10^{1}	1×10^{5}
Bi-206	1×10^{1}	1×10^{5}
Bi-207	1×10^{1}	1×10^{6}
Bi-210	1×10^{3}	1×10^{6}
Bi-212*	1×10^{1}	1×10^{5}
Po-203	1×10^{1}	1×10^{6}
Po-205	1×10^{1}	1×10^{6}
Po-207	1×10^{1}	1×10^{6}
Po-210	1×10^{1}	1×10^{4}
At-211	1×10^{3}	1×10^{7}
Rn-220*	1×10^{4}	1×10^{7}
Rn-222*	1×10^{1}	1×10^{8}
Ra-223*	1×10^{2}	1×10^{5}
Ra-224*	1×10^{1}	1×10^{5}
Ra-225	1×10^{2}	1×10^{5}
Ra-226*	1×10^{1}	1×10^{4}
Ra-227	1×10^{2}	1×10^{6}
Ra-228*	1×10^{1}	1×10^{5}
Ac-228	1×10^{1}	1×10^{6}
Th-226*	1×10^{3}	1×10^{7}
Th-227	1×10^{1}	1×10^{4}
Th-228*	1×10^{0}	1×10^{4}
Th-229*	1×10^{0}	1×10^{3}
Th-230	1×10^{0}	1×10^{4}
Th-231	1×10^{3}	1×10^{7}
Th-nat (incl.Th-232)	1×10^{0}	1×10^{3}
Th-234*	1×10^{3}	1×10^{5}
Pa-230	1×10^{1}	1×10^{6}
Pa-231	1×10^{0}	1×10^{3}
Pa-233	1×10^{2}	1×10^{7}
U-230*	1×10^{1}	1×10^{5}
U-231	1×10^{2}	1×10^{7}
U-232*	1×10^{0}	1×10^{3}
U-233	1×10^{1}	1×10^{4}
U-234	1×10^{1}	1×10^{4}
U-235*	1×10^{1}	1×10^{4}
U-236	1×10^{1}	1×10^{4}
U-237	1×10^{2}	1×10^{6}
U-238*	1×10^{1}	1×10^{4}
U-nat	1×10^{0}	1×10^{3}
U-239	1×10^{2}	1×10^{6}
U-240	1×10^{3}	1×10^{7}
U-240*	1×10^{1}	1×10^{6}
Np-237*	1×10^{0}	1×10^{3}
Np-239	1×10^{2}	1×10^{7}
Np-240	1×10^{1}	1×10^{6}
Pu-234	1×10^{2}	1×10^{7}
Pu-235	1×10^{2}	1×10^{7}
Pu-236	1×10^{1}	1×10^{4}
Pu-237	1×10^{3}	1×10^{7}
Pu-238	1×10^{0}	1×10^{4}
Pu-239	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{3}
Pu-241	1×10^{2}	1×10^{5}
Pu-242	1×10^{0}	1×10^{4}

Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)	Radionuclide[a]	Activity concentration (Bq/g)	Activity (Bq)
Pu-243	1×10^3	1×10^7	Cf-246	1×10^3	1×10^6
Pu-244	1×10^0	1×10^4	Cf-248	1×10^1	1×10^4
Am-241	1×10^0	1×10^4	Cf-249	1×10^0	1×10^3
Am-242	1×10^3	1×10^6	Cf-250	1×10^1	1×10^4
Am-242m*	1×10^0	1×10^4	Cf-251	1×10^0	1×10^3
Am-243*	1×10^0	1×10^3	Cf-252	1×10^1	1×10^4
Cm-242	1×10^2	1×10^5	Cf-253	1×10^2	1×10^5
Cm-243	1×10^0	1×10^4	Cf-254	1×10^0	1×10^3
Cm-244	1×10^1	1×10^4	Es-253	1×10^2	1×10^5
Cm-245	1×10^0	1×10^3	Es-254	1×10^1	1×10^4
Cm-246	1×10^0	1×10^3	Es-254m	1×10^2	1×10^6
Cm-247	1×10^0	1×10^4	Fm-254	1×10^4	1×10^7
Cm-248	1×10^0	1×10^3	Fm-255	1×10^3	1×10^6
Bk-249	1×10^3	1×10^6			

* Parent nuclides and their progeny included in secular equilibrium are listed in the following:
Sr-90 Y-90
Zr-93 Nb-93m
Zr-97 Nb-97
Ru-106 Rh-106
Cs-137 Ba-137m
Ba-140 La-140
Ce-134 La-134
Ce-144 Pr-144
Pb-210 Bi-210, Po-210
Pb-212 Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212 Tl-208 (0.36), Po-212 (0.64)
Rn-220 Po-216
Rn-222 Po-218, Pb-214, Bi-214, Po-214
Ra-223 Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224 Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
Ra-226 Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228 Ac-228

Th-226 Ra-222, Rn-218, Po-214
Th-228 Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229 Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212,
Tl-208 (0.36), Po-212 (0.64)
Th-234 Pa-234m
U-230 Th-226, Ra-222, Rn-218, Po-214
U-232 Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36),
Po-212 (0.64)
U-235 Th-231
U-238 Th-234, Pa-234m
U-nat Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214,
Po-214, Pb-210, Bi-210, Po-210
U-240 Np-240m
Np-237 Pa-233
Am-242m Am-242
Am-243 Np-239

Table I.2 LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
H-3	100	Co-58	1
Be-7	10	Co-58m	10 000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1 000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-31	1 000	Ni-59	100
P-32	1 000	Ni-63	100
P-33	1 000	Ni-65	10
S-35	100	Cu-64	100
Cl-36	1	Zn-65	0.1
Cl-38	10	Zn-69	1 000
K-42	100	Zn-69m[a]	10
K-43	10	Ga-72	10
Ca-45	100	Ge-71	10 000
Ca-47	10	As-73	1 000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1 000
V-48	1	Se-75	1
Cr-51	100	Br-82	1
Mn-51	10	Rb-86	100
Mn-52	1	Sr-85	1
Mn-52m	10	Sr-85m	100
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1 000
Mn-56	10	Sr-90a	1
Fe-52a	10	Sr-91a	10
Fe-55	1 000	Sr-92	10
Fe-59	1	Y-90	1 000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
Y-93	100	In-111	10
Zr-93	10	In-113m	100
Zr-95a	1	In-114ma	10
Zr-97a	10	In-115m	100
Nb-93m	10	Sn-113a	1
Nb-94	0.1	Sn-125	10
Nb-95	1	Sb-122	10
Nb-97a	10	Sb-124	1
Nb-98	10	Sb-125a	0.1
Mo-90	10	Te-123m	1
Mo-93	10	Te-125m	1 000
Mo-99a	10	Te-127	1 000
Mo-101a	10	Te-127m[a]	10
Tc-96	1	Te-129	100
Tc-96m	1 000	Te-129ma	10
Tc-97	10	Te-131	100
Tc-97m	100	Te-131ma	10
Tc-99	1	Te-132a	1
Tc-99m	100	Te-133	10
Ru-97	10	Te-133m	10
Ru-103a	1	Te-134	10
Ru-105a	10	I-123	100
Ru-106a	0.1	I-125	100
Rh-103m	10 000	I-126	10
Rh-105	100	I-129	0.01
Pd-103a	1 000	I-130	10
Pd-109a	100	I-131	10
Ag-105	1	I-132	10
Ag-110ma	0.1	I-133	10
Ag-111	100	I-134	10
Cd-109a	1	I-135	10
Cd-115a	10	Cs-129	10
Cd-115ma	100	Cs-131	1 000

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
Cs-132	10	Er-171	100
Cs-134	0.1	Tm-170	100
Cs-134m	1 000	Tm-171	1 000
Cs-135	100	Yb-175	100
Cs-136	1	Lu-177	100
Cs-137a	0.1	Hf-181	1
Cs-138	10	Ta-182	0.1
Ba-131	10	W-181	10
Ba-140	1	W-185	1 000
La-140	1	W-187	10
Ce-139	1	Re-186	1 000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144a	10	Os-191	100
Pr-142	100	Os-191m	1 000
Pr-143	1 000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	Ir-192	1
Pm-147	1 000	Ir-194	100
Pm-149	1 000	Pt-191	10
Sm-151	1 000	Pt-193m	1 000
Sm-153	100	Pt-197	1 000
Eu-152	0.1	Pt-197m	100
Eu-152m	100	Au-198	10
Eu-154	0.1	Au-199	100
Eu-155	1	Hg-197	100
Gd-153	10	Hg-197m	100
Gd-159	100	Hg-203	10
Tb-160	1	Tl-200	10
Dy-165	1 000	Tl-201	100
Dy-166	100	Tl-202	10
Ho-166	100	Tl-204	1
Er-169	1 000	Pb-203	10

Radionuclide	Activity concentration (Bq/g)	Radionuclide[a]	Activity concentration (Bq/g)
Bi-206	1	Pu-241	10
Bi-207	0.1	Pu-242	0.1
Po-203	10	Pu-243	1 000
Po-205	10	Pu-244[a]	0.1
Po-207	10	Am-241	0.1
At-211	1 000	Am-242	1 000
Ra-225	10	Am-242m[a]	0.1
Ra-227	100	Am-243[a]	0.1
Th-226	1 000	Cm-242	10
Th-229	0.1	Cm-243	1
Pa-230	10	Cm-244	1
Pa-233	10	Cm-245	0.1
U-230	10	Cm-246	0.1
U-231	100	Cm-247[a]	0.1
U-232[a]	0.1	Cm-248	0.1
U-233	1	Bk-249	100
U-236	10	Cf-246	1 000
U-237	100	Cf-248	1
U-239	100	Cf-249	0.1
U-240a	100	Cf-250	1
Np-237[a]	1	Cf-251	0.1
Np-239	100	Cf-252	1
Np-240	10	Cf-253	100
Pu-234	100	Cf-254	1
Pu-235	100	Es-253	100
Pu-236	1	Es-254a	0.1
Pu-237	100	Es-254m[a]	10
Pu-238	0.1	Fm-254	10 000
Pu-239	0.1	Fm-255	100
Pu-240	0.1		

[a] Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered), are listed here:

Fe-52	Mn-52m	Sn-113	In-113m
Zn-69m	Zn-69	Sb-125	Te-125m
Sr-90	Y-90	Te-127m	Te-127
Sr-91	Y-91m	Te-129m	Te-129
Zr-95	Nb-95	Te-131m	Te-131
Zr-97	Nb-97m, Nb-97	Te-132	I-132
Nb-97	Nb-97m	Cs-137	Ba-137m
Mo-99	Tc-99m	Ce-144	Pr-144, Pr-144m
Mo-101	Tc-101	U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
Ru-103	Rh-103m		
Ru-105	Rh-105m		
Ru-106	Rh-106	U-240	Np-240m, Np-240
Pd-103	Rh-103m	Np-237	Pa-233
Pd-109	Ag-109m	Pu-244	U-240, Np-240m, Np-240
Ag-110m	Ag-110		
Cd-109	Ag-109m		

Cd-115	In-115m	Am-242m	Np-238
Cd-115m	In-115m	Am-243	Np-239
In-114m	In-114	Cm-247	Pu-243
		Es-254	Bk-250
		Es-254m	Fm-254

Note: The exemption levels set out in Table I.1 and the exemption and clearance levels set out in this table are subject to the following considerations: (a) they were derived using a conservative model based on (i) the criteria of paras I.2 and I.11, respectively, and (ii) a series of limiting (bounding) scenarios for use and disposal; (b) if there is more than one radionuclide, the derived exemption level or derived clearance level for the mixture is determined as specified in paras I.7 and I.14.

Schedule II. CLERANCE LEVELS

Table I.1 DERIVED GENERIC CLEARANCE LEVELS FOR AIRBORNE RELEASES

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways and Limiting Age Group
H-3	1×10^{11}	Ingestion
C-14	1×10^{10}	Ingestion
Na-22	1×10^{6}	External from deposit (Adults and Infants)
Na-24	1×10^{9}	External from deposit (Adults and Infants)
P-32	1×10^{8}	Ingestion (Infants)
S-35	1×10^{8}	Ingestion (Infants)
Cl-36	1×10^{7}	Ingestion (Infants)
K-42	1×10^{10}	External from deposit (Adults and Infants)
Ca-45	1×10^{8}	Ingestion (Infants)
Ca-47	1×10^{9}	External from deposit and ingestion (Adults and Infants)
Cr-51	1×10^{9}	External from deposit (Infants)
Fe-59	1×10^{8}	External from deposit (Adults and Infants)
Co-57	1×10^{9}	Ingestion (infants)
Co-58	1×10^{9}	Ingestion (infants)
Ga-67	1×10^{10}	External from deposit (Adults and Infants)
Se-75	1×10^{8}	External from deposit (Adults and Infants)
Sr-85	1×10^{8}	External from deposit (Adults and Infants)
Sr-89	1×10^{8}	Ingestion (infants)
Y-90	1×10^{10}	Inhalation and Ingestion (Infants)
Mo-99	1×10^{9}	External from deposit (Adults and Infants)
Tc-99	1×10^{7}	Ingestion (infants)
Tc-99m	1×10^{11}	External from deposit (Adults and Infants)
In-111	1×10^{9}	External from deposit (Adults and Infants)
I-123	1×10^{10}	External from deposit (Adults and Infants)
I-125	1×10^{8}	Ingestion (infants)
I-131	1×10^{8}	Ingestion (infants)
Xe-127	1×10^{11}	External from cloud (Adults and Infants)
Xe-133	1×10^{12}	External from cloud (Adults and Infants)
Pm-147	1×10^{10}	Inhalation (Adults and Infants)
Er-169	1×10^{10}	Inhalation and ingestion (Infants)

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways and Limiting Age Group
Au-198	1×10^{9}	External from deposit (Adults and Infants)
Hg-197	1×10^{10}	External from deposit (Adults and Infants)
Hg-203	1×10^{8}	External from deposit and ingestion (Infants)
Tl-201	1×10^{10}	External from deposit (Adults and Infants)
Ra-226	1×10^{6}	Inhalation and Ingestion (Adults and infants)
Th-232	1×10^{5}	Inhalation (Adults)

Reference: IAEA TECDOC 1000

Notes:

(a) The calculations on which these values are based assume releases from a building vent or window. The closest individual is located 20 m from the release point and gets his food, 100 and 800 m from the release point. Doses are evaluated via inhalation, ingestion and external exposure routes.

(b) Significant differences in these values are possible for different source to receptor distances.

Table I.2 DERIVED GENERIC CLEARANCE LEVELS FOR LIQUID RELEASES

Radionuclide	Annual Release Rate (Bq per annum)	Main Exposure Pathways
H-3	1×10^{12}	River - Ingestion
C-14	1×10^{10}	River - Ingestion
Na-22	1×10^{5}	Sewage – External
Na-24	1×10^{8}	Sewage – External
P-32	1×10^{6}	River – Ingestion fish
S-35	1×10^{9}	River – Ingestion fish
Cl-36	1×10^{10}	River – Ingestion fish and water
K-42	1×10^{9}	Sewage – External
Ca-45	1×10^{10}	River – Ingestion fish and water
Ca-47	1×10^{8}	Sewage – External
Cr-51	1×10^{8}	Sewage – External
Fe-59	1×10^{6}	Sewage – External
Co-57	1×10^{9}	Sewage – External
Co-58	1×10^{8}	Sewage – External
Ga-67	1×10^{8}	Sewage – External
Se-75	1×10^{6}	Sewage – External
Sr-85	1×10^{6}	Sewage – External
Sr-89	1×10^{9}	River – Ingestion fish and water
Y-90	1×10^{10}	River – Ingestion fish and water
Mo-99	1×10^{8}	Sewage – External
Tc-99	1×10^{10}	River – Ingestion fish and water
Tc-99m	1×10^{9}	Sewage – External
In-111	1×10^{8}	Sewage – External
I-123	1×10^{9}	Sewage – External
I-125	1×10^{8}	Sewage – External
I-131	1×10^{7}	Sewage – External
Xe-127	Not applicable	
Xe-133	Not applicable	
Pm-147	1×10^{10}	Sewage – External and River - Ingestion fish and water
Er-169	1×10^{10}	River - Ingestion fish and water
Au-198	1×10^{8}	Sewage – External
Hg-197	1×10^{9}	Sewage – External
Hg-203	1×10^{7}	Sewage – External
Tl-201	1×10^{8}	Sewage – External
Ra-226	1×10^{6}	Sewage – External
Th-232	1×10^{6}	Sewage – External

(Reference: IAEA TECDOC 1000)

Note:

The values are the most restrictive of those calculated following discharge to a river or discharge to a sewer.

Table I.3 GENERIC CLEARANCE LEVELS FOR SOLID WASTE (Bq/g)

Radionuclide	Clearance Level for Moderate Quantities (a)	Radionuclide	Clearance Level for Moderate Quantities (a)
H-3	1×10^{6}	Sr-89	1×10^{3}
C-14	1×10^{4}	Y-90	1×10^{3}
Na-22	1×10^{1}	Mo-99	1×10^{2}
Na-24	1×10^{1}	Tc-99	1×10^{4}
P-32	1×10^{3}	Tc-99m	1×10^{2}
S-35	1×10^{5}	In-111	1×10^{2}
Cl-36	1×10^{4}	I-123	1×10^{2}
K-42	1×10^{2}	I-125	1×10^{3}
Ca-45	1×10^{4}	I-131	1×10^{2}
Ca-47	1×10^{1}	Pm-147	1×10^{4}
Cr-51	1×10^{3}	Er-169	1×10^{4}
Fe-59	1×10^{1}	Au-198	1×10^{2}
Co-57	1×10^{2}	Hg-197	1×10^{2}
C0-58	1×10^{1}	Hg-203	1×10^{2}
Ga-67	1×10^{2}	Tl-201	1×10^{2}
Se-75	1×10^{2}	Ra-226	1×10^{1}
Sr-85	1×10^{2}	Th-232	1×10^{0}

(Reference: IAEA TECDOC 1000)

(a) Moderate quantity means less than 3 tonnes per year and per facility. For larger quantities the clearance level is one tenth of the levels in Appendix C - 3.

Note:

The clearance levels for moderate quantities are identical to the BSS (1) exemption levels.

Annex I. EXTENDED VALIDITY OF LICENSES

Table I.1 Radioactive Material License

3-year	5-year
Blood Irradiator	Indent Sale
Field Radiography	Sale
	Sales and Service
	Service
	R & D Class A
	R & D Class B
	Fixed Gauge Class A
	Fixed Gauge Class B
	Portable Gauge Class A
	Portable Gauge Class B
	Well Logging, Dredging and Spinning Pipe
	Tracer Studies
	Radioimmunoassay

Table I.2 LICENSE TO OPERATE

3-year	5-year
Radiopharmaceutical Dispensing Facility	Cyclotron
Fixed Facility Radiography	Radioactive Waste Management Facility
Brachytherapy	Gamma Irradiation Facility
Teletherapy	
I-131 Therapy	
In-Vivo Diagnosis and Therapy Class A	
In-Vivo Diagnosis and Therapy Class B	