REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR COMMERCIAL SALE AND DISTRIBUTION OF RADIOACTIVE MATERIALS AND ITS ASSOCIATED DEVICES

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REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR COMMERCIAL SALE AND DISTRIBUTION OF RADIOACTIVE MATERIALS AND ITS ASSOCIATED DEVICES

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE.

This regulatory guide is intended to provide assistance to applicants in the preparation of an application for a license for commercial sale and distribution of radioactive materials and its associated devices. The guide discusses the relevant specific regulatory requirements and provisions that must be addressed by the applicant. This guide provides information and procedures on how applicants/licensees may choose to develop their procedures/programs in order to meet the PNRI regulatory requirements provided in CPR Part 17.

The applicant/licensee may choose to adopt or adapt the guidance and model procedures or modify the model procedures as applicable to comply with the regulatory requirements subject to PNRI approval. Additional information may be required by PNRI as it deems appropriate or necessary.

1.2 MANAGEMENT RESPONSIBILITY.

The PNRI believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely and securely. It also believes that effective management will result in increased safety and security compliance. The management needs to be committed to an effective protection, safety and security policy, particularly at the senior level, and by demonstrable support for those individuals responsible for radiation protection, safety and security. This commitment can be demonstrated by a written policy for the protection of radiation workers, the members of the public, and the environment.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to PNRI;
- Knowledge about the contents of the license and application;
- Compliance with current PNRI regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources for the implementation of the radiation safety program to ensure that public and workers are protected from radiation hazards ;
- Development and maintenance of a radiological emergency procedures; and
- Designation of a qualified individual to serve as the Radiation Protection Officer (RPO) with responsibility for the daily oversight of the radiation safety program.

1.3 APPLICABLE REGULATIONS.

- CPR Part 2, “Licensing of Radioactive Material”, published in the Official Gazette, 1990
- CPR Part 3, "Standards for Protection Against Radiation", published in the Official Gazette, 2021
- CPR Part 4, “Regulations for the Safe Transport of Radioactive Material in the Philippines”, published in the Official Gazette, 2017
- CPR Part 17, "Licenses for Commercial Sale and Distribution of Radioactive Materials”, published in the Official Gazette, 2010
- CPR Part 22, “Fees and Charges for Radioactive Material License and Other Related Regulatory Services”, published in the Official Gazette, 2016
- CPR Part 26, “Security of Radioactive Sources”, published in the Official Gazette, 2014
- CPR Part 27, “Security Requirements in the Transport of Radioactive Material”, published in the Official Gazette, 2013
- Other related PNRI regulations, as necessary and appropriate.

It is the responsibility of applicants and licensees to obtain copies of the regulations specified above and to read and abide by the provisions of these regulations that apply to commercial sale and distribution of radioactive materials and its associated devices.

2. FILING AN APPLICATION FOR A LICENSE

An application for a license must be filed by completing ***PNRI/NRD Form-017, “Application for a License for Commercial Sale and Distribution of Radioactive Materials and Its Associated Devices”*** in duplicate copies. The application must include all the information necessary to support its intended purpose. Completeness of submitted information will be determined by the PNRI reviewer before the application is docketed. The license fee must be paid upon submission of documents in accordance with CPR Part 22, “Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Services”.

For new license applications, submit a copy of the registration with the Securities and Exchange Commission (SEC) or the Department of Trade and Industry (DTI) together with the application form. All applications for a new license must be affirmed or notarized.

3. CONTENTS OF APPLICATION

This portion of the Regulatory Guide explains, item by item, the information requested in the **PNRI/NRD Form-017**. For new license application, check sub-item A. For an amendment to an existing license, check sub-item B. For renewal of an existing license, check sub-item C. Write down the license number if you checked sub-items B and C.

ITEM 1. NAME AND COMPLETE ADDRESS OF APPLICANT.

Enter the applicant’s legal name, mailing address, telephone number, fax number, and email address. The applicant may be an institution, a firm, or government agency. If the applicant is a firm, institution or government agency, the name and signature of the individual who has the authority and responsibility over the radioactive source and the proposed use shall appear in the application, indicating his title or position in the institution.

A section, division or department within a firm, institution, or government agency cannot be an applicant. The address specified in the application should be the mailing address for correspondence. This may or may not be the same as the address at which the radioactive material is stored, as applicable. The telephone number, mobile phone number, facsimile number, and/or e-mail address of the applicant should be provided for easier and faster means of communication. The applicant should demonstrate or provide evidence of authenticity of business name issued by the Securities and Exchange Commission and a copy of business permit issued by the responsible government agency.

ITEM 2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Identify a contact person, usually the Radiation Protection Officer (RPO), who can answer questions about the application. The position or title, address, telephone number, fax number and e-mail address of the contact person must be specified. The PNRI must be notified if the contact person, address, telephone number, fax number or e-mail address changes. Notification of these changes is for information purposes only and would not be considered an application for a license amendment unless the notification involves a change in the contact person who is also the RPO.

ITEM 3. LOCATION(S) OF STORAGE.

Regulations: Section 7 (f) and (g) of CPR Part 17

Specify the location(s) where licensed material will be stored. Indicate the building number, street address, city/town, province, telephone number or other descriptive address (e.g., on South Expressway, 1 kilometer east of the intersection of South Expressway and Bicutan) for each facility to allow the PNRI staff to easily locate the facility. If the licensed activity is performed at more than one location, give the specific address of each location.

Note: *A PNRI-approved license amendment is required before storing licensed material at an address or location not included with the application or already listed on the license.*

ITEM 4. RADIOACTIVE MATERIAL(S) AND ITS ASSOCIATED DEVICE(S) FOR SALE AND DISTRIBUTION.

Regulation: Sections 29 to 36 of CPR Part 17

Licensees will be authorized to sell and distribute only radioactive materials and its associated devices that are specifically approved by PNRI. Each authorized radioactive material must be identified by its element name, chemical and/or physical form, and the maximum possession limit in megabecquerels (MBq) or gigabecquerels (GBq) for each radionuclide. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

A. Sell and Distribute Sealed Sources and Devices for Use in Industrial Gauges and Radiographic Operations.

(a) The applicant shall submit sufficient information relating to the design (identification of the radiographic exposure devices and source changers by manufacturer, model number, serial number, etc), prototype testing, quality

control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the sealed source and device;

(b) The applicant shall assure that each device bears a durable, legible, clearly visible label which contains:
(1) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information); and
(2) The requirements for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, activity, and date of determination of the activity.

(c) The applicant shall assure that a copy of the license or certificate of approval of the design of the sealed source/devices/source changers by the licensing authority of the country of origin shall be submitted to PNRI as evidence of approval of the design.

B. Sell and/or Distribute Radiopharmaceuticals for Medical Use.

(a) The applicant shall submit information on the radionuclide, chemical and physical form, packaging, including maximum activity per package, type, and shielding provided to ensure that it is appropriate for safe handling and storage; and

(b) The applicant shall assure that :
(1) The radiopharmaceuticals meet the requirements imposed by PNRI in accordance with **CPR Part 13**; and
(2) The label affixed to each package of the radiopharmaceutical shall contain information of the radionuclide, activity and date of assay.

C. Sell and/or Distribute Radioactive Materials for Certain In-Vitro Clinical or Laboratory Testing.

(a) The applicant shall assure that the package containing the radioactive material shall bear a clearly visible label:
(1) Identifying the radioactive contents as to chemical form, activity and radionuclide; and
(2) Displaying the radiation caution symbol and the words "CAUTION, RADIOACTIVE MATERIAL" and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS", as appropriate.

(b) The applicant shall assure that the label affixed to the package or the leaflet or brochure which accompanies the package shall contain adequate information as to the precautions to be observed in handling and storing such radioactive material and that the radioactive material will be used only for in-vitro clinical or laboratory tests not involving internal or external use of the material to human beings or animals.

D. Sell and/or Distribute Generators.

(a) The applicant shall submit information of the radionuclide, chemical and physical form and packaging, including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator.
(b) The applicant shall assure that the label affixed to the generator contains information on the radionuclide, activity and date of assay.

(c) The applicant shall assure that the leaflet or brochure which accompanies the generator contains adequate information on the procedures to be followed and on the equipment and shielding to be used with the generator.

(d) The applicant shall assure that a copy of a license or certificate of approval of the generator by the licensing authority of the country of origin shall be submitted to PNRI as evidence of approval of the design.

E. Sell and/or Distribute Sealed Sources and Devices for Medical Use in Teletheraphy and Brachytherapy.

(a) The applicant shall submit sufficient information regarding each type of source and device relevant to an evaluation of its radiation safety, including:
   (1) The radioactive material, its chemical and physical form, and activity;
   (2) Details of design and construction of the source and device;
   (3) Procedures for, and results of, prototype tests to demonstrate that the source and device will maintain its integrity under normal use and accident conditions;
   (4) Details of quality control procedures to assure that production of sources and devices meet the standards of the design and prototype tests;
   (5) Procedures and standards for calibrating sources and devices; and
   (6) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the device or attached to a storage container for the source or device: Provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(b) The applicant shall assure that the label affixed to the device containing the source, or to the storage container for the source or device, contains information on the radionuclide, activity and date of assay.

F. Sell and Distribute Sealed Sources for Large Irradiators.

The applicant shall:

(a) Identify each radionuclide (e.g., Co-60), the chemical or physical form, the number of sources, and the maximum activity;

(b) Identify the manufacturer's name and model number of each sealed source that will be used in gamma irradiator;

(c) Identify the manufacturer's name and model number of the gamma irradiator in which the sealed sources will be housed; and

(d) Specify the purpose for which the licensed material will be used (e.g., food irradiation, etc.), the location where it will be used and the prospective users.

G. Sell and/or Distribute Check, Reference and Calibration Sources.

Each applicant shall:

(a) Specify as to what categories of licensees the check, calibration or reference sources will be used.

(b) Ensure that the check, reference or calibration sources have been obtained from a manufacturer authorized to sell/distribute the sources.

(c) Ensure that the manufacturer's labeling and packaging will not be altered and that the sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet brochure, or other document that provides radiation safety instructions for handling and storing the sources.

H. Sell and/or Distribute Devices Containing Radioactive Material of Exempt Quantity to Persons Exempt from Licensing.

The applicant shall provide sufficient information on the devices containing radioactive material of exempt quantities to persons exempt from licensing relating to the design, manufacture, prototype testing, quality control, labeling, marking and anticipated conditions or handling, storage, use, and disposal of the device to demonstrate that the single exempt unit will meet the safety criteria applicable to that device as established by PNRI, or by the regulatory authority of the country in which the design of the device originated, and can be distributed to persons exempt from licensing without undue hazard.

I. Others

The applicant shall provide sufficient information on other radioactive materials or any devices containing radioactive material that does not fall under the above categories.

ITEM 5. RADIATION MONITORING INSTRUMENTS.

Note: *Personal monitoring devices and radiation survey instruments are not required/applicable to all vendors, only to those selling Ir-192 for Industrial radiography & teletherapy, and other high activity sources as well as in conducting repair and maintenance and this is covered by CPR Part 25.*

Regulation: Section 7 (d) and 24 of CPR Part 17

5.1 Individual Monitoring Devices

Individual monitoring devices are instruments that detect various form of radiation a worker may be exposed to. Individuals who are occupationally exposed are required to wear monitoring devices including direct reading pocket dosimeters or monitoring badges such as thermoluminescent dosimeters (TLD) or optically stimulated luminescence dosimeters (OSL). These devices must be worn in front of the torso, at or above the waist and below the shoulder, at all times when handling radioactive materials. Licensed activities should not be performed if one of the required dosimeters is missing or inoperable. Each monitoring device must be assigned to, and worn only by one individual. It must also be protected from moisture, intense heat or light, and chemicals and must not be stored or placed in close proximity to radiation sources or radiation-emitting devices.

5.2 Radiation Survey Instruments (as applicable)

Applicants are required to possess radiation monitoring instruments to measure radiation levels, radioactive contamination, and radioactivity, as applicable. These instruments must be properly calibrated and available for use at all times in the facility. As a minimum requirement, the applicant should possess survey instruments sufficiently sensitive to measure from 1 uSv/hour through 10 mSv/hour and a contamination meter capable of measuring nanocurie or Becquerel amounts of activity per unit area (Bq/cm^2).

Calibration of radiation detection and measuring instruments must be performed by a PNRI service provider or a PNRI licensee who is qualified to perform calibration in accordance with CPR Part 25, “Licenses for Commercial Providers of Nuclear Technical Services”.

Response from Applicant:

The licensee or applicant shall have, as applicable, the following radiation survey instruments:

1. **Personal Monitoring Devices (as applicable)**

- Specify the type of personnel monitoring device (e.g., film badge, TLD, OSL), the number of units, the type of radiation detected (e.g., gamma, beta, neutron), the type of monitoring (e.g., whole body, extremities), frequency of change (e.g., monthly, quarterly), and the names and addresses of the suppliers.

- Specify the type of direct reading dosimeter (e.g., pocket dosimeter), the quantity or the number of units, the range of pocket dosimeters, the date of last calibration, and the names and addresses of the suppliers.

2. **Radiation Survey Instruments (as applicable)**

- Describe the radiation survey instruments by indicating the type of instrument (e.g. GM counter, beta/gamma probe, etc.), the manufacturer's and distributor's names, the model/serial number, its sensitivity range, and the date of last calibration.
- If instrument calibration will be performed by licensed service provider, identify the organization that will perform the calibration of the survey instruments by stating the name, address and license number.
- If an applicant wishes to calibrate its survey instruments, he should do so in-house and submit the following information:
  (a) Type (radioisotope, manufacturer, model number and serial number) of the source to be used for calibration;
  (b) Activity of the source;
  (c) Specific procedures to be used for calibration, including radiation safety procedures to be followed; and
  (d) Name and pertinent experience of the individual who will perform instrument calibration.

ITEM 6. PROPOSED RADIATION WORKERS.

6.1 RADIATION PROTECTION OFFICER (RPO) AND ASSISTANT RPO.

Regulation: Sections 7(b), 17, 18 and 19 of CPR Part 17

The regulation provides for the appointment of an RPO for the day-to-day oversight of the Radiation Safety Program. The RPO must confirm in writing his acceptance of the appointment. The licensee must provide the RPO sufficient authority to stop any licensed activity that he considers unsafe. He must have sufficient time and commitment from the management to fulfill certain duties and responsibilities to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the course of daily operation. The Assistant RPO will perform the duties and responsibilities of the RPO in his absence.

The individuals designated as RPO or ARPO must have successfully completed the applicable training and experience requirements as described in Section 19 of CPR Part 17. The proposed individual must show proof that he is qualified by training in radiation safety, regulatory issues, and emergency procedures, as applicable. A sample Delegation of Authority of the RPO can be found in **Appendix A**.

Response from Applicant:

- Specify the names of the proposed RPO and, as applicable, the assistant RPO, their telephone numbers and email address, and a brief description of their training and experience;
- Fill out **Attachment A** to the **PNRI/NRD Form-017** "TRAINING AND EXPERIENCE OF PROPOSED RADIATION PROTECTION OFFICER (RPO) AND ASSISTANT RPO"; and
- Attach the following documents in the application:
  1. Delegation of Authority of the RPO and ARPO by the management with their acceptance;
  2. Certificates of relevant training in radiation safety and/or other related training course/s; and
  3. Specific duties and responsibilities of the RPO as applicable to the licensed activity.

***Note**: It is important to notify the PNRI and obtain a license amendment prior to making changes in the designation of the RPO and ARPO responsible for the radiation safety program. If the RPO leaves the organization before an amendment is approved by the PNRI, the ARPO shall be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the license conditions and PNRI regulations.*

6.2 AUTHORIZED PERSONNEL (as applicable).

Regulation: Sections 20, 21, and 22 of CPR Part 17

The licensee shall employ individuals or authorized personnel to undertake the activities as stated in the license and ensure that they have completed the training and instructions on radiation protection and safety principles and practices conducted by the RPO. The training syllabus and modules must be submitted to PNRI for review and evaluation. A refresher course on safety and security must also be undertaken every five (5) years.

Response from Applicant:

- List down the name of the proposed authorized personnel, his telephone number and email address, and a brief description of his training and experience.
- Attach the following documents in the application:
  1. Resume and/or employment record;
  2. Certificates of relevant training and experience relevant to the type of work; and
  3. Certificates of relevant training and experience in radiation safety.

ITEM 7. FACILITIES AND EQUIPMENT. (This is only applicable to applicants who will be storing RAM/device containing RAM)

Regulation: Section 7(f) and 7(g) of CPR Part 17

Applicants/licensees must demonstrate that proposed facilities and equipment provide adequate storage capabilities, appropriate shielding, maintain radiation exposures ALARA, and minimize the possibility of contamination or release of licensed material during normal and emergency situations including fire, flood, and wind damage.

The location or storage area, as discussed in Item No. 3, for the radioactive material indicated in the license application must be adequate to protect health and safety of the workers and the public, minimize danger to life, property or the environment and ensure the security of radioactive material. Licensed materials should be accessible only by authorized

persons and should be secured or locked when the authorize persons are not physically present to ensure the radioactive material and its associated devices are protected from loss, theft, and malicious acts.

Response from Applicant:

- Submit a drawing or sketch of the proposed facility identifying areas where radioactive materials, including radioactive wastes, will be stored. Drawings, sketches, diagrams, etc. should indicate the scale, or include dimensions on each drawing or sketch.
- Show in the drawings the relationship and distance between controlled areas and adjacent uncontrolled areas.
- Specify in the drawings shielding materials (concrete, lead, etc.) and means for securing radioactive materials from unauthorized removal.
- Describe engineered safety systems e.g. area monitors, interlocks, alarms, etc.
- Include a description of the area(s) assigned for the receipt, storage, security, preparation, handling, waste storage and measurement of radioactive materials.

ITEM 8. RADIATION SAFETY PROGRAM.

A radiation safety program must be established and submitted to PNRI as part of the application. Each applicant must develop, document, and implement a radiation safety program which addresses the individual components as described in the following subsections:

8.1 ALARA PROGRAM.

Regulation: Section 16 of CPR Part 17

The applicant/licensee shall use, to the extent practical, procedures and technical controls based upon sound radiation safety principles to achieve occupational doses and doses to the members of the public that are **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA). ALARA is a philosophy of excellence used in one's day-to-day work with radioactive materials and radiation sources. It is when one strives to keep one's radiation exposure ALARA taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest. Some changes in procedures can greatly reduce one's radiation exposure. The ALARA philosophy encourages one to actively seek out these methods of exposure reduction. The success of the ALARA program depends on the cooperation of each individual who works at the facility. The management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. As a minimum, the ALARA program should:

a) Contain management's formal commitment to the ALARA philosophy, recognizing the importance of keeping individual and collective doses ALARA;
b) Include periodic review of the radiation safety program and provide continuing education and training for all personnel who work with or in the vicinity of radioactive sources;
c) Specify the duties and responsibilities of key personnel within the facility's organization as they apply to ALARA;
d) Specify that, at intervals not to exceed six (6) months, record of radiation exposures of all personnel will be reviewed and appropriate actions are to be taken; and

e) Include a formal annual review by the RPO of the entire radiation safety program including ALARA considerations.

A model ALARA program, which can be found in **Appendix B**, contains information and methods to establish radiation safety programs to maintain exposures ALARA in licensed facilities. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

Response from Applicant:
- Submit a copy of the ALARA program.

8.2 DUTIES AND RESPONSIBILITIES OF THE RPO.

Regulation: Sections 17 of CPR Part 17

The applicant/licensee must designate a qualified RPO and an ARPO, who shall be responsible for implementing the radiation safety program. The licensee shall clearly define the duties and responsibilities of the RPO as provided in Section 17 (b) of CPR Part 17 to ensure that radiation safety measures are being observed in accordance with approved procedures and regulatory requirements in the daily performance of the licensee's activities.

Response from Applicant:
- Submit the Delegation of Authority described in Appendix A as affirmation from the RPO/ARPO of his/her acceptance and commitment to his/her designated tasks including the complete list of his/her duties and responsibilities as applicable.

8.3 PERSONNEL MONITORING PROGRAM.

Regulation: Sections 7(d) and 23 of CPR Part 17

The licensee shall establish a personnel monitoring program that requires personnel who enter controlled area to wear adequate personnel monitoring devices (e.g., pocket dosimeter, thermoluminescent dosimeter (TLD), optically stimulated luminescence (OSL), alarm rate meter), as applicable. The program should cover individual dosimetry, including internal radiation monitoring and area monitoring to the extent required for the assessment of individual radiation doses. The responsibilities of the individual (usually the RPO) for monitoring workers who are occupationally exposed, and a description of the monitoring methods should form part of the program. Results of monitoring external and internal contamination must be recorded.

Individual monitoring shall not be required for individuals regularly employed in a supervised area or who enters a controlled area only occasionally. The nature, frequency and precision of individuals monitoring will be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposure.

Periodic reporting of individual and/or collective doses should be done, as required, to the management of the organization. It is considered good practice to inform the radiation workers of the dose they have received over a certain period of time. The management should also report the data, as required and appropriate, to the PNRI and should provide new employers with the data on former employee's radiation dose histories.

Appendix C shows guidance for personnel monitoring program.

Response from Applicant:

- Shall submit, if applicable, a copy of the personnel exposure monitoring program.

8.4 RADIATION MONITORING PROGRAM.

Regulation: Sections 17(b)(6) and 40 of CPR Part 17

The applicant/licensee is required to perform radiation surveys before movement or transport, and storage of licensed radioactive source to ensure safety and compliance with regulatory requirements. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations.

Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

Procedures on conducting radiation surveys should indicate when surveys should be made, what should be surveyed, acceptable radiation levels for the surveys, the steps to be taken if acceptable limits are exceeded, and records of survey results. The acceptable radiation levels for surveys should be expressed in millisievert per hour (mSv/h). Records of radiation measurements should be retained until the PNRI authorizes their disposition. It must include the date of the surveys, a plan of each area that was surveyed, the background dose rate level, the measured dose rate (mSv/hr) at several points in each area, the survey instrument used including its last calibration period, the name and signature of the individuals who made the survey. **Appendix D** shows a model radiation monitoring program.

Response from Applicant:

- Submit a radiation monitoring program that includes survey procedures for each of the items enumerated above, as appropriate and applicable.

8.5 OPERATING AND EMERGENCY PROCEDURES.

Regulation: Section 59 of CPR Part 3; Sections 7(i) and Section 44 of CPR Part 17

The purpose of operating and emergency procedures is to provide personnel with specific guidance for all potential or possible emergencies during movement or transport and storage of radioactive materials and its associated devices. These topics should be included in the operating and emergency procedures and need not be presented in order of importance. Under Section 44 of CPR Part 17, each licensee shall notify PNRI within 24 hours by telephone, or by any other fast means of communication, of any incident involving a licensed activity, licensed facility, source material, or any other radioactive material possessed by the licensee.

Appendix E presents Guidelines for Preparing an Emergency Response and Preparedness Procedures.

Response from Applicant:

- Submit the operating and emergency procedures for evaluation. Copies of PNRI-approved written emergency procedures will be posted at convenient visible locations in the licensed facility. The names and telephone numbers of the persons to be notified within the organization and the responsible person who shall notify the PNRI during an emergency should also be posted.
- For Notification and Reporting of Incidents, please refer to NRD Bulletin No. 94-03 posted in the PNRI website.

8.6 TRAINING PROGRAM.

Regulation: Sections 7(c), 19, 21 and 22 of CPR Part 17

Before working with a licensed material, individuals must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training (or retraining) at no more than five (5) – year intervals.

Topics of the training should depend on the purpose of the training, the participants, and the state of learning (background knowledge). The PNRI will review the outline of the training program to determine if the applicable criteria are met. The name, training and experience of each person who will provide substantial input for the instruction, examination or qualification of all workers should be given in sufficient detail to establish his qualifications to perform these services.

The guidance in **Appendix F** may be used to develop a training program.

Response from Applicant:

- Submit a proposed radiation safety training program, including topics covered, groups of workers, assessment of training, names/qualification of instructors, and the method and frequency of training, as appropriate and applicable.

8.7 TRANSPORT OF RADIOACTIVE MATERIAL.

Regulation: Section 7 (e) of CPR Part 17

The applicant should establish and implement procedures for transport of radioactive material in accordance with CPR Part 4, "Regulations on the Safe Transport of Radioactive Materials in the Philippines" and the rules and regulations of other modal agencies. This is to ensure that radioactive material is safe and secured at all times during transport. Transport documents should be available in the delivery vehicle for proper identification by the driver, police, or civil authorities in case of vehicular accidents or incidents.

Licensees should consider the safety of all individuals who may handle or may come into contact with the transport containers or packages containing licensed material. The primary consideration in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels or removable contamination levels at the package surfaces meet the regulatory requirements. In all cases,

ALARA concerns are addressed prior to, during, and after transporting any radioactive material.

Response from Applicant:

Submit transport procedures specifying the:

(a) Role of the applicant/licensee upon receipt of shipment from the Bureau of Customs to the final destination of the radioactive materials and its associated devices.
(b) Instructions to be followed when delivering packages containing radioactive material and its associated devices.

8.8 PROCEDURE FOR STORAGE OF RADIOACTIVE MATERIAL.

Regulations: Section 7 (f) and (g) of CPR Part 17

If package/(s) will be stored in a facility, the location or storage area for the radioactive material and its associated devices must be provided indicating the description of the facility including control of access and personnel in-charge for the safekeeping and inventory. The licensee shall also comply with the applicable requirements of CPR Part 4 particularly under Section 36 on the transport and storage of radioactive materials during transit.

Response from Applicant:

- Submit, as appropriate and applicable, an adequate storage procedures, location and facility layout of the storage area.

8.9 PROCEDURE FOR CONDUCTING PHYSICAL INVENTORY OF STORED/UNDELIVERED RADIOACTIVE MATERIALS.

Regulations: Section 7 (g), Section 26 of CPR Part 17

The licensee is required to establish adequate security measures to prevent loss or theft of radioactive material and its associated devices while in storage and during transport. To satisfy this requirement, a procedure for conducting physical inventory of stored or undelivered radioactive materials and its associated devices must be in place.

Response from Applicant:

- Provide, as appropriate and applicable, an adequate procedure for conducting physical inventory of stored or undelivered radioactive materials and its associated devices.

8.10 IMPORT AND EXPORT OF RADIOACTIVE MATERIAL.

Regulation: Section 25 of CPR Part 17.

The import and export of radioactive materials in Categories 1 and 2 should conform to the provisions of CPR Parts 4 and 26, 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. The PNRI requires that licensees intending to import or export radioactive sources in these categories should apply for an authorization and must receive such authorization prior to importation or exportation.

Response from Applicant:

- Submit, as appropriate and applicable, the requirements listed in Appendix A, "Requirements on the Import and Export of Radioactive Sources" of CPR Part 17.

8.11 SECURITY AND CONTROL OF RADIOACTIVE SOURCES.

Regulation: Section 7(g), Section 26, and Section 27 of CPR Part 17

Licensees must provide adequate security measures of radioactive sources during transport and storage facility, as applicable. Security requirement involve administrative and technical measures to avoid unauthorized access to storage location(s) of radioactive sources. Security of radioactive sources must be accomplished by complying with the following methods as applicable:

- Keep the source under constant "line of sight" surveillance;
- Lock the room when it is not occupied;
- Place source in locked storage, such as a cabinet; and
- Store source in a locked and fixed container or device.

Appendix G describes the proposed contents of Security Measures.

Response from Applicant:

- Submit a copy of the security measures in accordance with the provisions in CPR Part 26 and Part 27.

ITEM 9. RADIOACTIVE WASTE MANAGEMENT.

Regulation: Sections 7(j) and 28 of CPR Part 17

The licensee shall ensure that its commercial sale agreement with a prospective client provides for the return of disused radioactive sources to the supplier in the country of origin. He shall ensure the return of the disused radioactive sources in accordance with Appendix A, "Requirements on the Import and Export of Radioactive Sources", of CPR Part 17(for Category 1 & 2 sources only). A proof that the disused radioactive source was received by the supplier must be submitted to PNRI.

Appendix H describes the Guidance for Disposal of Disused Radioactive Sources.

Response from Applicant:

- Submit to PNRI:
  (a) a program for the disposal of expired/undelivered/spent radioactive materials; and
  (b) a copy of the agreement with the original supplier or manufacturer for the return of disused radioactive sources.

- Upon disposal/transfer of disused radioactive sources:
  1. Notify and secure the approval of the PNRI before the transfer of radioactive sources to an authorized recipient.
  2. Submit to the PNRI information that includes the name, address and license number; type, form, activity and quantity of material to be transferred; and the name, address and license number of the person to whom the sources will be transferred.
  3. Secure the approval of the PNRI on the design and specifications of the container where the radioactive sources will be packed and shipped, as applicable.

4. Submit to the PNRI plans or other methods of disposition.

Regulation: Sections 29 to 36 of CPR Part 17

Licensees will be authorized to sell and distribute only radioactive materials and its associated devices that are specifically approved by PNRI. Each authorized radioactive material must be identified by its element name, chemical and/or physical form, and the maximum possession limit in megabecquerels (MBq) or gigabecquerels (GBq) for each radionuclide. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

ITEM 10. APPLICATION AND LICENSE FEES.

An application fee normally accompanies the application for a new license. The required license fee will be paid when the initial application is approved or prior to the release of license. License/amendment fee must also accompany application for renewal/amendment of a license. Regulatory and licensing fees are provided in the CPR Part 22, "Fees and Charges for Radioactive Material Licenses and Other Related Regulatory Activities".

ITEM 11. CERTIFICATION.

The application should be signed and dated by a legal entity or a representative of the applicant who is authorized to sign official documents and to certify that the application contains information that are true and correct to the best of their knowledge and belief. Unsigned applications will be returned for proper signature.

ITEM 12. ACKNOWLEDGEMENT.

The license application must be affirmed and notarized.

4. AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: Sections 6 and 9 of CPR Part 17

It is the licensee's obligation to keep the license current. If any of the information in the original application is to be modified or changed, the licensee must submit an application for a license amendment, in accordance with Section 9 of CPR Part 17, before the change takes place. To continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date.

Response from Applicant:

- For license amendments,
  1. Use this guide in preparing an amendment or renewal request;
  2. Submit the Application Form PNRI/NRD-017 or a letter requesting amendment;
  3. Provide the license number; and
  4. Pay the required amendment fee upon filling of amendment or upon the release of written approval from PNRI.
- For license renewals,

1. Provide complete and up-to-date applications if many outdated documents are referenced or there have been significant changes in regulatory requirements, the licensee's organization, or radiation safety program;
2. Describe clearly the exact nature of the changes, additions, and deletions; and
3. Pay the required license fee upon application.

5. TERMINATION OF A LICENSE

Regulations: Section 13 of CPR Part 17

A licensee who decides to cease licensed activities must, before informing PNRI, determine whether residual radioactivity is present at the facility and whether the levels make the building or outdoor area unsuitable for release in accordance with the provisions of CPR Part 3 (Appendix A). A licensee's determination that a facility is not contaminated is subject to verification by PNRI inspection.

A licensee who wishes the termination of his license must do the following:

(a) Before the license can be terminated, the licensee shall:
   (2) Discontinue all activities involving licensed radioactive material;
   (3) Transfer or dispose of all licensed radioactive material which are in his possession in accordance with the regulations;
   (4) Conduct a radiation survey or other means to confirm that the premises are suitable for unrestricted use; and
   (5) Assure that the required records are complete and up-to-date.

(b) To be relieved of the responsibilities for the radioactive material and other conditions in his license, the licensee shall submit to the PNRI:
   (1) His request that the license be terminated;
   (2) A certified statement that he no longer has in his possession any radioactive material requiring a license;
   (3) A listing of the radioactive material transferred or disposed of and to whom the material were transferred or the method of disposal;
   (4) Submit to PNRI information and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
   (5) An agreement that his records and facilities will be available for inspection by the PNRI at a mutually agreeable date.

Response from Applicant:

- The licensee shall inform the PNRI in writing and provide proofs if they will no longer be engaged in the sale and distribution of radioactive materials and its associated devices. Prior to the termination of the license, the licensee must provide information on the results of radiation survey performed at the facility.

APPROVED:

(Original Signed)
DR. CARLOS PRIMO C. DAVID
Officer-in-Charge, PNRI

Date: September 8, 2016

APPENDIX A

SAMPLE DELEGATION OF AUTHORITY FOR THE RADIATION PROTECTION OFFICER

Memo To: Radiation Protection Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, __(*complete name of the RPO*)__, have been appointed Radiation Protection Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Safety Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of unsealed radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Philippine Nuclear Research Institute at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____
Name and signature of Management Representative — Date

I accept the above responsibilities,

_____ _____
Name/Signature of Radiation Protection Officer — Date

cc: Affected department heads

APPENDIX B

GUIDANCE FOR AN ALARA PROGRAM

No matter how low the dose levels are, personnel are required to keep their principle was adopted by international radiation protection agencies to ensure doses received were not only below limits, but only as high as reasonably necessary.

In order to comply with the ALARA policy, certain practices are followed when entering or working in a radiation area:

A worker can limit the dose received in three ways:

a) Maximize the Distance to the source. The dose rate falls as the square of the distance increases. For example, a worker 1.0m from a source receives four times less dose tan if the distance were 0.5m.

$$(D1/D2)^2 = (1.0/0.5)^2 = 4$$

b) Maximize the Shielding. Use lead or bismuth for gamma rays and borated, hydrogen-bearing materials such as polyethylene or water neutrons.

- For gamma rays common to Prompt Gamma Neutron Activation Analysis, PGNAA, the dose rate decreases by approximately a factor of 2 for each 1.25cm (0.5inches) of lead or bismuth used.
- For neutrons, the dose rate decreases by about a factor of 5cm (2inches) of polyethylene or water shielding.

c) Minimize the Time of exposure. Plan and rehearse your work to be time-efficient. Move away from radiation sources when not working directly with them.

It is the worker's responsibility to use Time, Distance, and Shielding to keep dose ALARA.

Dose = Dose Rate x Time Worked

Simple procedures executed very quickly can result in less dose, than more complicated procedures involving auxiliary shielding and/or longer range source handling tools. It is god idea to plan and rehearse the work procedure with dummy source capsules to accomplish the following objectives:

- Plan and organize work with and around sources of radiation.
- Optimize the procedure to minimize dose.
- Practice accomplishing the task quickly and assuredly.

APPENDIX C

GUIDANCE FOR A PERSONNEL MONITORING PROGRAM

1. The RPO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of records is a film badge, or thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, optically stimulated luminescence (OSL) or other approved whole body monitor. The TLD will be processed by PNRI every three months while the film badge will be processed on a monthly basis if they exceed 5 millisievert per quarter. Those licensees whose employees receive exposures of less than 5 millisievert a quarter may request to extend the exchange frequency upon PNRI approval. To receive approval, provide the following information:
   a. Supporting documentation that confirms that no employee will exceed 5 mSv/quarter; and
   b. Proposed frequency of exchange.

3. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, and secretarial personnel who do not work with patients.

4. Submit the name, address, and license number of the company who will process the personnel monitoring devices.

5. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

6. Maintain records of exposure of all individuals required to wear personnel monitoring device. These records should be made available to PNRI during inspections.

APPENDIX D

MODEL RADIATION MONITORING PROGRAM

1. Measure the ambient dose rates quarterly in all areas where sources are stored.

2. Measurements to be performed should include the following:
   a. Radiation levels at external surfaces of the package containing radioactive materials and its associated devices.
   b. Radiation levels in storage room for the radioactive materials and its associated devices.
   c. Radiation levels of containers for shipment of the radioactive materials and its associated devices showing compliance with CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.
   d. Radiation levels in uncontrolled areas.

3. Dosimetry-related calculations should include the following:
   a. Dose received by individuals present in uncontrolled areas, reflecting continuous occupancy.
   b. Dose received by individuals present in controlled areas.
   c. Calculations to demonstrate that the expected dose rates in controlled and uncontrolled areas meet the regulatory requirements.

4. The survey record should include, as applicable:
   a. Date of survey;
   b. Measuring device used (manufacturer, model and serial number, date of last calibration);
   c. Background radiation;
   d. Measured dose rate at several points in each area expressed in millisievert per hour;
   e. Sketch of the industrial device illustrating the points where the survey is conducted;
   f. Sketch of the room surveyed; and
   g. Name and signature of RPO/individual performing the survey.

5. Retain records of radiation measurements for two (2) years.

APPENDIX E

GUIDELINES FOR PREPARING AN EMERGENCY RESPONSE AND PREPAREDNESS PROCEDURES

(1) Preparation of a list of predictable incidents and accidents as well as measures to deal with them;

(2) Designation of persons responsible for taking actions, with complete relevant contact information, including telephone numbers;

(3) Responsibilities of individuals in an emergency defined in procedures;

(4) Set of concise instructions posted in a visible area;

(5) Availability of or quick access to persons responsible for carrying out emergency response actions;

(6) Availability of equipment and tools necessary to carry out the procedures;

(7) Training and periodic rehearsals carried out;

(8) Recording and reporting systems in place;

(9) Immediate measures taken to avoid unnecessary radiation doses to the public;

(10) Measures taken to prevent access of persons to the affected area during the time that the sources are exposed and before normal conditions are restored.

Sample Types of Emergency Situations:

Lost sources

It is critical for this type of event that an up-to-date inventory exists so that it can be determined immediately which source(s) is/are missing, what its type and activity are, when and where it was last known to be, and who last took possession of it. A proactive attitude is important for the case that sources are ordered and not received at the expected time. Making a check for the arrival of a source at the expected receipt time should be part of the procedures. The actions to be part of the contingency plans include:

(1) Obtain assistance from the RPO.
(2) Conduct a local search.
(3) Check and ensure security and control of other sources.
(4) Check all possibilities in the facility.
(5) If still not found, call the company and inform them of the failure so that they can trace the shipment and find out where the radioactive material is.
(6) If not found, report the loss of the material according to the rules given by the PNRI.

Spillage of small amounts of radioactivity

After such a spillage the following actions should be taken:

(1) Use protective clothing and disposable gloves.
(2) Quickly blot the spill with an absorbent pad to keep it from spreading.
(3) Remove the pad from the spill.
(4) Wipe with a towel from the edge of the contaminated area towards the center.
(5) Dry the area and perform a wipe test.

(6) Continue the cycle of cleaning and wipe testing until the wipe sample indicates that the spill has been cleaned.
(7) Use a plastic bag to hold contaminated items. Suitable bags shall be available as well as damp paper towels.

Spillage of large amounts of radioactivity

After such a spillage the following actions should be taken:

(1) The RPO should immediately be informed and directly supervise the clean-up.
(2) Throw absorbent pads over the spill to prevent further spread of contamination.
(3) All people not involved in the spill should leave the area immediately.
(4) Monitor all people involved in the spill for contamination when leaving the room.
(5) If clothing is contaminated, remove and place it in a plastic bag labeled 'RADIOACTIVE'.
(6) If contamination of skin occurs, wash the area immediately.
(7) If contamination of an eye occurs, flush with large quantities of water.

Fires

The normal drill should be observed, with the safe evacuation of the individuals being the most important consideration. When the fire brigade attends, they should be informed of the presence of radioactive material. No one is allowed to re-enter the building/facility until it has been checked for contamination

Transport Accidents

During transport accidents involving radioactive materials, the following action should be taken:

(1) Approach site with caution—look for evidence of hazardous materials.
(2) If radiation hazard is suspected, position personnel, vehicles, and command post at a safe distance (approximately 75 feet) upwind of the site.
(3) Notify proper authorities and hospital.
(4) Put on protective gear and use dosimeters and survey meters if immediately available.
(5) Determine whether injured patient(s) are present.
(6) Assess and treat life-threatening injuries immediately. Do not delay advanced life support if patient cannot be moved, or to assess contamination status. Perform routine emergency care during extrication procedures.
(7) Move patient away from the hazard area, using proper patient transfer techniques to prevent further injury. If contamination is suspected, removing the patient's clothing (gross decon) can remove much of the contamination on patient.
(8) Expose wounds and cover with sterile dressings.
(9) Patient should be monitored at the control line for possible contamination only if they are medically stable. Radiation levels above background indicate the presence of contamination.
(10) Move the ambulance stretcher to the clean side of the control line and unfold a clean sheet or blanket over it. Place the patient on the covered stretcher and package for transport. Do not remove the patient from the backboard if one was used.
(11) Package the patient by folding the stretcher sheet or blanket over and securing him or her in the appropriate manner.
(12) Before leaving the controlled area, rescuers should follow their decontamination procedures and be surveyed at the control line. If possible, the patient should be transported by personnel who have not entered the controlled area. Ambulance personnel attending to patients should wear appropriate PPE.

(13) Transport the patient to the hospital emergency department. The hospital should be given additional appropriate information, and the ambulance crew should ask for any special instructions the hospital may have.
(14) Follow the hospital's radiological protocol upon arrival.
(15) The ambulance and crew should not return to regular service until the crew, vehicle, and equipment have undergone monitoring and necessary decontamination by the radiation safety officer.
(16) Personnel should not eat, drink, smoke, chew, etc., at the accident site, in the ambulance, or at the hospital until they have been released by the radiation safety officer.

APPENDIX F

GUIDANCE FOR A TRAINING PROGRAM

Classroom Training
Classroom training should emphasize practical subject matter important to the safe handling of licensed materials. Duration and technical level of training should be commensurate with the expected hazards encountered during routine and emergency conditions.

Frequency of Training

- Before assuming duties with, or in the vicinity of, radioactive materials;
- Whenever there is a significant change in duties, regulations, or the terms and conditions of the license;
- Refresher training every 5 years.

Suggested Radiation Safety Topics

1) Fundamentals of Radiation Safety:
    - Characteristics of radiation;
    - Units of radiation dose and quantity of radioactivity;
    - Hazards of exposure to radiation;
    - Levels of radiation from licensed material;
    - Methods of controlling radiation dose (time, distance, and shielding);
    - ALARA concept.
2) Radiation Detection Instruments:
    - Operation;
    - Calibration;
    - Limitations of radiation survey instruments;
    - Radiation survey techniques for measuring radiation field;
    - Radiation survey techniques for measuring removable/fixed contamination;
    - Handling and proper use of personnel monitoring equipment.
3) Radiation Protection Equipment and Use:
    - Proper use of protective equipment;
    - Decontamination of contaminated protection equipment.
4) PNRI regulations (CPR Parts 2, 3, 4, 25, 26).
5) Licensee's operating and emergency procedures.
6) Case histories relevant to operations.
7) Course Examination (Didactic):
    - Successful completion of closed-book written/oral examination depending on the complexity and hazards of authorized activities;
    - Review of incorrect answers with student.
8) Discussion and/or drill on emergency procedures.

APPENDIX G

GUIDANCE FOR THE SECURITY OF RADIOACTIVE MATERIALS AND ITS ASSOCIATED DEVICES

1. Licensee shall identify to which category the radioactive material and its associated devices involved in the sale and distribution.
   a. For RAMs in Storage – Security requirements are described in detail under CPR Part 26, “Security of Radioactive Sources”; and
   b. For RAMS in Transport – Security requirements are described in detail under CPR Part 27, “Security Requirements in the Transport of Radioactive Material”.
   c. Conduct quarterly physical inventory to account for all sealed sources and devices received and possessed. Each inventory record should be retained for five years. The inventory records must contain:
      i. Identity of each source radionuclide (element and mass number, chemical and physical form);
      ii. Model and serial number;
      iii. Nominal activity of each source;
      iv. Location of each source; and
      v. Signature of the RPO.

APPENDIX H

GUIDANCE FOR THE RETURN OF DISUSED RADIOACTIVE SOURCES

a) When importing radioactive sources, it should be negotiated that disused radioactive sources should be returned to the original supplier or manufacturer in the country of origin.

b) Prior to the import of a radioactive source:
   1) require the supplier, as a condition of any contract for purchase, to receive the source back after its useful lifetime; and
   2) submit to the PNRI a copy of relevant parts of the contract or acceptance document and obtain its written agreement prior to entering the contract or accepting the source.

c) Do not dismantle any radioactive source.

d) Transfer the source after confirming with PNRI that the organization to which it will be transferred has the necessary authority to possess the source.

e) Disused radioactive sources should be shipped back to the manufacturer in the original transport container or in a properly labeled and shielded transport container whose design is acceptable to PNRI. Export of the disused radioactive sources should be conducted in accordance with **Appendix A of CPR Part 17.** ***(This is applicable to Category 1 & 2 sources)***.

f) Transport of disused radioactive sources should be in accordance with CPR Part 4, “Regulations for the Safe Transport of Radioactive Material in the Philippines”.

g) Submit to the PNRI a proof that the disused radioactive source was received by the original supplier for its management.

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE (COMMERCIAL SALE AND DISTRIBUTION)

INSTRUCTIONS: To complete this application, refer to Part 17 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of an Application for a License for Commercial Sale and Distribution of Radioactive Materials and its Associated Devices. Submit duplicate copies of the completed application form, with the specified application/license fee, and all required attachments, to the Nuclear Regulatory Division, Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City.

This is an application for: (Check appropriate box)

☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NO. _____
☐ C. RENEWAL OF LICENSE NO. _____

1. NAME AND COMPLETE ADDRESS OF APPLICANT/LICENSEE.

Institution/Firm _____

Address _____

Director/Chairman of the Institution _____

Telephone and Fax Number _____

E-mail Address _____

2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Name _____

Position/Title _____

Address _____

Telephone/Fax Number _____

Mobile Phone Number _____

E-mail Address _____

3. LOCATION(S) OF STORAGE (Include facility layout)**.**

Address (Department/Section, Room No., Building): _____
Telephone Number: _____
Fax Number: _____
E-Mail Address: _____

4. RADIOACTIVE MATERIAL(S) AND ITS ASSOCIATED DEVICE(S) FOR SALE AND DISTRIBUTION AND PURPOSE(S) OF USE.

- ☐ **A. Sell and Distribute Sealed Sources and Devices for Use in Industrial Gauges and Radiographic Operations.**
- ☐ **B. Sell and/or Distribute Radiopharmaceuticals for Medical Use.**
- ☐ **C. Sell and/or Distribute Radioactive Materials for Certain In-Vitro Clinical or Laboratory Testing.**
- ☐ **D. Sell and/or Distribute Generators.**
- ☐ **E. Sell and/or Distribute Sealed Sources and Devices for Medical Use in Teletheraphy and Brachytherapy.**
- ☐ **F. Sell and Distribute Sealed Sources for Large Irradiators.**
- ☐ **G. Sell and/or Distribute Check, Reference and Calibration Sources.**
- ☐ **H. Sell and/or Distribute Devices Containing Radioactive Material of Exempt Quantity to Persons Exempt from Licensing.**
- ☐ **I. Others**

4.1 Unsealed Radioactive Materials

Radionuclide (Element/Mass Number)	Chemical/Physical Form	Activity per Unit (MBq)	Max. Amount to be Possessed/Sold at Any One Time (MBq)

4.2 Sealed Sources

Radionuclide (Element-Mass Number)	Manufacturer	Sources Model Number	Source Serial Number	Number of Units (Quantity)	Max. Amount to be Possessed/sold at Any One Time (MBq)

4.3 Device(s)

Device(s)	Manufacturer	Model Number	Serial Number	Purpose(s) of Use

5. RADIATION MONITORING INSTRUMENTS (IF APPLICABLE)

5.1 Individual Monitoring Devices

5.1.1 Passive Dosimeters

Type	Quantity	Type of Radiation Detected	Type of Monitoring	Frequency of Change	Name and Address of Supplier(s)

5.1.2 Direct Reading Dosimeters

Type	Quantity	Range	Date of Last Calibration	Name and Address of Supplier
Pocket Dosimeter				
Others				

5.2 Radiation Survey Instruments

Type of Instrument	Manufacturer/ Distributor	Model	Serial Number	Sensitivity Range (mSv/hr)	Date of Last Calibration	Organization to Perform Calibration

6. PROPOSED RADIATION WORKERS.

Worker	Name	Telephone Number/E-mail Address	Description of Training/Experience
Radiation Protection Officer (RPO)[a]			
Assistant RPO[a]			
Authorized Personnel[b]			

Append: [a]*Delegation of Authority, Certificates, and Specific duties and responsibilities as* ***Attachment 1****.*
[b]*certificates of relevant training and experience (as applicable) as* ***Attachment 2****.*

7. FACILITIES AND EQUIPMENT. (This is only applicable to applicants who will be storing RAM/device containing RAM)

8. RADIATION SAFETY PROGRAM. (As applicable)

8.1 ALARA Program.
8.2 Duties and responsibilities/Role of the RPO.
8.3 Personnel Monitoring Program.
8.4 Radiation Monitoring Program.
8.5 Operating and Emergency Procedures. Actions to be taken in case of accident/incident (e.g. vehicular accident, loss/theft) of radioactive material.
8.6 Training Program.
8.7 Transport of Radioactive Material. Role of the applicant upon receipt of shipment from the Bureau of Customs (including safe transport of radioactive materials from the Bureau of Customs to the client).
8.8 Procedure for storage of radioactive material. If package will be stored in your facility please provide description of facility including control of access and personnel in-charge for the safekeeping and inventory
8.9 Procedure for conducting physical inventory of stored/undelivered radioactive materials.
8.10 Import and Export of Radioactive Material. Program for the disposal of expired/undelivered/spent radioactive materials.
8.11 Security and Control of Radioactive Sources.

9. RADIOACTIVE WASTE MANAGEMENT.

10. APPLICATION FEE PhP_____ Official Receipt Number _____
Date _____

LICENSE FEE PhP_____ Official Receipt Number _____
Date _____

11. CERTIFICATION.

The applicant understands that all statements and representations made in this application are binding upon us. Further, the applicant and any official executing this certification on behalf of the applicant certify that this application is prepared in conformity with the applicable requirements in the Code of PNRI Regulations and that all information contained herein is true and correct to the best of our knowledge and belief.

_____
Signature of Certifying Official

_____
Typed or Printed Name of
Certifying Official

_____
Title/Position of Certifying Official

_____
Date

12. ACKNOWLEDGEMENT.

{Republic of the Philippines}
{ }

Before me, a Notary Public for and in the above jurisdiction, personally appeared the following persons:

Name _____ CTC No. _____ Date/Place Issued _____
Name _____ CTC No. _____ Date/Place Issued _____

both known to me to be the same persons who executed the foregoing application and all attachments, and acknowledged to me the same to be their free and voluntary act and deed.

_____
Notary Public

Doc. No. _____
Page No. _____
Book No. _____
Series of _____

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

ATTACHMENT A

TRAINING AND EXPERIENCE OF PROPOSED RADIATION PROTECTION OFFICER (RPO) AND ASSISTANT RPO

NAME: _____
NAME OF COMPANY: _____
EDUCATIONAL DEGREE: _____

1" x 1" ID Photo

1. TRAINING IN RADIATION SAFETY

(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	Location of Training	Date of Training	Duration of Training (Hours)		
			Lecture	Laboratory	On-the-Job
a. Radiation Physics and Instrumentation					
b. Radiation Safety					
c. Mathematics Pertaining to the Use and Measurement of Radioactivity					
d. Security of Radioactive Sources					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE WITH RADIOACTIVE SOURCES AND ASSOCIATED EQUIPMENT/INSTRUMENTS/DEVICES

Radioactive Source/ Equipment/ Instruments/Devices	Maximum Amount of Radioactive Source Handled	Where Experience Was Gained	Duration of Experience	Type of Use

3. CERTIFICATES OF RELEVANT TRAININGS/EXPERIENCES (Submit certificates of relevant trainings & experience.)

Title of Training	Place of Training	Date of Training

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Proposed RPO/ARPO
Date: _____

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

ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED PERSONNEL

NAME: _____
NAME OF COMPANY: _____
EDUCATIONAL DEGREE: _____

1" x 1" ID Photo

1. TRAINING IN RADIATION SAFETY

(Enclose certificates of training and use additional sheets if necessary.)

Field of Training	Location of Training	Date of Training	Duration of Training (Hours)		
			Lecture	Laboratory	On-the-Job
a. Radiation Physics and Instrumentation					
b. Radiation Safety					
c. Mathematics Pertaining to the Use and Measurement of Radioactivity					
d. Security of Radioactive Sources					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE WITH RADIOACTIVE SOURCES AND ASSOCIATED EQUIPMENT/INSTRUMENTS/DEVICES

Radioactive Source/ Equipment/ Instruments/Devices	Maximum Amount of Radioactive Source Handled	Where Experience Was Gained	Duration of Experience	Type of Use

3. CERTIFICATES OF RELEVANT TRAININGS/EXPERIENCES (Submit certificates of relevant trainings & experience.)

Title of Training	Place of Training	Date of Training

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____
Signature of Proposed Authorized Personnel
Date: _____