REGULATORY GUIDE FOR THE PREPARATION OF APPLICATION OF RADIOACTIVE MATERIAL LICENSE FOR COMMERCIAL PROVIDERS OF NUCLEAR TECHNICAL SERVICES

(CPR PART 25)

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REGULATORY GUIDE FOR THE PREPARATION OF APPLICATION OF RADIOACTIVE MATERIAL LICENSE FOR COMMERCIAL PROVIDERS OF NUCLEAR TECHNICAL SERVICES

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE.

This regulatory guide is provided to assist the applicant in preparing an application for a license, as well as to provide PNRI with appropriate criteria for evaluating such applications. Technical service providers render commercial services to PNRI licensees in the management of licensed nuclear and radioactive materials. The Code of PNRI Regulations (CPR) Part 25 “Licenses for Commercial Providers of Nuclear Technical Services” describes service providers as entities providing the following types of commercial services:

(1) Installation, relocation, removal from services, disposal of radioactive waste, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed material, calibration, waste treatment and processing;
(2) Installation, relocation, removal from service, disposal of radioactive waste, radiation surveys, routine or preventive maintenance, adjustment, training of personnel or repair of large irradiators described in CPR Part 15;
(3) Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding or compromise the radiation safety of the device or safety systems;
(4) Calibration of survey instruments, alarm ratemeter and personnel dosimetry equipment;
(5) Leak testing of sealed sources, including analyzing the leak test smears;
(6) Environmental sample analysis;
(7) Training of personnel using sealed and unsealed sources;
(8) Calibration of medical dose calibrators;
(9) Nuclear laundry services;
(10) Waste management services including treatment and conditioning;
(11) Decontamination services;
(12) Personnel dosimetry service; and
(13) Repair, preventive maintenance and revalidation of radioactive exposure devices.

Compliance to this guide is not required. If the applicant cannot provide the methods and solutions as specifically suggested in this guide, he may submit an alternative procedure to comply with the regulatory requirements subject to approval of PNRI. Additional information may be required to ensure that the applicant complies with the requirements of CPR Part 25. An application for amendment or renewal of a license that would require significant modification of the contents and conditions of the license may use this guide to comply with corresponding licensing requirements.

The appendices to this guide provide additional information on certain subject areas, model procedures which the applicant may adopt in response to an item in the application form, or an outline that the applicant may use in developing a procedure for review by the PNRI staff.

1.2 MANAGEMENT RESPONSIBILITY.

PNRI recognizes that effective Radiation Safety Program management is vital to achieving safe and compliant operations. PNRI believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. The management needs to be committed to an effective radiation protection and safety policy, particularly at the senior level, and by demonstrable support for those individuals responsible for radiation protection.

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

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Conduct of annual review of the radiation safety program, including reviews of operating procedures, occupational dose records, regulatory inspections, etc.
- Knowledge about the contents of the license and application;
- Completeness and accuracy of the records and all information provided to PNRI;
- Compliance with applicable regulations from other government agencies and the licensee's operating and emergency procedures; and
- Commitment to provide adequate resources (including space, equipment, personnel, time, and if needed, contractors) for the implementation of the radiation safety program to ensure that public and workers are protected from radiation hazards.

1.3 APPLICABLE REGULATIONS.

- CPR Part 3, "Standards for Protection Against Radiation", published in the Official Gazette, 2004.
- CPR Part 4, "Safe Transport of Radioactive Material in the Philippines", published in the Official Gazette, 2004.
- CPR Part 22, "Fees and Charges for Licensing Radioactive Material and Other Related Regulatory Activities", published in the Official Gazette, 2003.
- CPR Part 25, "Licenses for Commercial Providers of Nuclear Technical Services", published in the Official Gazette, 2013.
- CPR Part 26, "Security of Radioactive Sources", published in the Official Gazette, 2007.

It is the responsibility of applicants/licensees to obtain copies of the regulations specified above and to read and abide by the provisions of these regulations that apply to commercial providers of nuclear technical services.

2. FILING AN APPLICATION

Complete **PNRI/NRD Form-025**, "Application for License for Commercial Providers of Nuclear Technical Services" 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 filing fee must be paid upon submission of documents and the appropriate license fee must be paid prior to the issuance of the license in accordance with CPR Part 22.

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-025**. For new license application, tick the box for sub-item A. For an amendment to an existing license, tick the box for sub-item B. For renewal of an existing license, tick the box for sub-item C. Write down the license number if you ticked sub-items B and C.

ITEM 1. NAME AND MAILING ADDRESS OF APPLICANT.

Write down the applicant's legal name, mailing address, telephone number, fax number, and email address. The applicant may be an individual, an institution, a firm, or a government agency. An individual may be accepted as the applicant if he or she is acting in a private capacity and the proposed activity is not connected with employment in a company or other legal entity. 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 materials 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 licensed material or activity is located. The telephone number, mobile phone number, facsimile number, and e-mail address of the applicant should be provided for easier and faster means of communication.

ITEM 2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Identify a contact person, usually the Radiation Safety Officer (RSO), 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. PNRI must be notified if the contact person, address, telephone number, fax number or e-mail address has been changed. 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 RSO.

ITEM 3. LOCATION(S) WHERE SERVICE WILL BE PROVIDED.

Specify the location(s) where licensed material will be used, stored or transported. Indicate the building number, street address, city/town, province, and telephone number to easily locate the facility. If the licensed activity is performed at more than one location, give the specific address of each location and list the specific activities to be conducted at each location.

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

ITEM 4. RADIOACTIVE MATERIALS AND PURPOSE(S) OF USE.

Regulation: Section 23 of CPR Part 25

Licensees will be authorized to possess and use only those radioactive sources and 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. For sealed sources/devices, identify the manufacturer or distributor, model and serial number, and the number of units/devices.

Applicants/Licensees must state that possession of these sources is incidental to performing services relative to installation, hazard evaluation, dosimetry, leak test sample analysis, equipment maintenance, environmental sample analysis, decommissioning, waste management, nuclear laundry services, etc.

ITEM 5. RADIATION MONITORING INSTRUMENTS.

Regulation: Sections 20 (c), 24, 25 of CPR Part 25

Individuals who are occupationally exposed are required to wear personnel 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.

Applicants/Licensees are also 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).

The specifications in **Appendix A** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities or job sites. PNRI regulations require that radiation monitoring devices be calibrated at least annually by organizations specifically authorized by PNRI.

Response from Applicant:

5.1 Personnel Monitoring Devices

- Specify the type of personnel monitoring device (e.g., 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.

5.2 Radiation Survey Instruments

- 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.
- Identify the organization that will perform the calibration of the survey instruments.

ITEM 6. PROPOSED RADIATION WORKERS.

6.1 Radiation Safety Officer (RSO)

Regulation: Sections 17, 18, 19, 22 of CPR Part 25

The person responsible for the day-to-day oversight of the radiation safety program and compliance with regulations for the use of radioactive material is the Radiation Safety Officer (RSO). In order to fulfill the duties and responsibilities, the RSO must be on site periodically to conduct meaningful interactions with other staff, commensurate with the scope of licensed activities. The duties and responsibilities of the RSO are enumerated in Section 17 (c) of CPR Part 25.

The individuals designated as RSO or ARSO must have successfully completed the applicable training and experience requirements as described in Section 19 of CPR Part 25. The proposed individual must show proof that he/she is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use. A sample Delegation of Authority of the RSO can be found in **Appendix B**.

Response from Applicant:

- Specify the names of the proposed RSO and assistant RSO, their telephone numbers and email addresses, and a brief description of their training and experience;
- Fill out **Attachment A** to the **PNRI/NRD Form-025** "TRAINING AND EXPERIENCE OF PROPOSED RADIATION SAFETY OFFICER (RSO) AND ASSISTANT RSO"; and
- Attach the following documents in the application:
  1. Delegation of Authority of the RSO and ARSO by the management with their acceptance;
  2. Certificates of relevant training and experience in radiation safety and/or other related training course/s; and
  3. Specific duties and responsibilities of the RSO as applicable to the licensed activity.

***Note**: It is important to notify PNRI and obtain a license amendment prior to making changes in the designation of the RSO and ARSO responsible for the radiation safety program. If the RSO leaves the organization before an amendment is approved by PNRI, the ARSO 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 and Ancillary Personnel

Regulation: Sections 20, 21, 22 of CPR Part 25

Any person who performs or supervises nuclear technical services must be identified in the license as the authorized personnel. He must have adequate training and experience

to use, possess, or provide services involving licensed materials. A description of the relevant training and experiences must be made available to show that the proposed individuals are qualified by training and experience for the type/s of services to be performed, in accordance with the requirements in Section 21 of CPR Part 25.

Ancillary personnel are individuals whose assigned duties involve exposure to radiation and/or radioactive materials, and individuals who in the course of their employment are likely to receive in a year an occupational dose greater than 1 mSv. These individuals, who may include clerical, housekeeping, security, any customer's personnel or staff member, should be informed about radiation hazards and the appropriate precautions they should take when working in the vicinity of radioactive materials. The applicant/licensee must assess each individual's involvement with licensed material and provide appropriate training.

Response from Applicant:

- List down the names of the proposed authorized and ancillary personnel, their telephone number/s and email address/es, and a brief description of their training and experience.
- Attach the following documents in the application:
  1. Resumè and/or employment record;
  2. Certificates of relevant training and experience relevant to the type of services to be performed; and
  3. Certificates of relevant training and experience in radiation safety.

ITEM 7. FACILITIES AND EQUIPMENT.

Regulation: Sections 8 (b), 28 of CPR Part 25

Applicants 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.

Licensed materials should be accessible only by authorized persons, and secured or locked when the authorized persons are not physically present.

Response from Applicant:

<u>For permanent facilities specifically identified on the license:</u>

Applicants requesting the use of sealed radioactive material in the following commercial applications:

- Leak Test Service Providers and Environmental Laboratories: No response required for facilities.
- Instrument Calibration: If only sealed sources are possessed in registered devices designed to emit a collimated beam for the purpose of instrument calibration, no response required.
- Services that involve handling of sealed sources in a shielded container: No response required.
- Services that involve handling of sealed sources outside a shielded container:
  1. Submit a drawing or sketch of the proposed permanent facility identifying areas where radioactive materials, including radioactive wastes, will be used or stored.
  2. Show in the drawings the relationship and distance between restricted areas and adjacent unrestricted areas.

3. Specify in the drawings shielding materials (concrete, lead, etc.) and means for securing radioactive materials from unauthorized removal.
4. Drawings, sketches, diagrams, etc. should indicate the scale, or include dimensions on each drawing or sketch.
5. Describe engineered safety systems e.g. area monitors, interlocks, alarms, etc.

Applicants requesting the use of unsealed radioactive material in the following applications:

- Leak Test Services and Environmental Laboratories: No response required for facilities.
- Other services that involve handling of unsealed radioactive material:
  1. Describe the permanent facilities and equipment to be made available at each location where unsealed radioactive material will be used or handled.
  2. Include a description of the area(s) assigned for the receipt, storage, security, preparation, handling, waste storage and measurement of radioactive materials.
  3. Submit a facility diagram showing the proximity of licensed materials to unrestricted areas.
  4. Drawings, sketches, diagrams, etc. should indicate the scale, or include dimensions on each drawing or sketch.
  5. Submit a diagram, sketch, or drawing, when applicable, that identifies areas where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and monitoring systems.
  6. Submit a diagram of radioactive waste handling equipment that includes incinerators, compactors, solidification equipment, hold-up tanks, sample collection points, etc.
  7. Describe proposed laundry facilities, if applicable, used for contaminated protective equipment and clothing. Specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.
  8. Describe protective clothing (such as rubber gloves, coveralls, respirators, and face shields), auxiliary shielding, absorbent materials, secondary containers for waste water storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available.
  9. Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems in the event that operation of a system could result in accidental exposure or release of material (e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks, etc.) or equipment.

<u>For temporary job sites:</u>

- No facility description is required.
  1. For applicants requesting the use of licensed sealed radioactive sources that do not require the use of specialized handling tools.
  2. For applicants requesting the use of licensed sealed radioactive material that requires the use of specialized handling tools.
- Applicants requesting the use of licensed sealed radioactive material that requires the use of specialized equipment or handling tools should provide a description, photograph, sketch, or drawing.

<u>For applicants requesting the use of unsealed radioactive material:</u>

- Describe protective clothing (such as rubber gloves, coveralls, respirators, and face shields), auxiliary shielding, absorbent materials, secondary containers for waste water storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available for use when handling unsealed or uncontained radioactive materials.

ITEM 8. TRAINING PROGRAM

Regulations: Sections 21 and 22 of CPR Part 25

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 - year intervals.

Topics of the training should depend on the purpose of the training, the participants, and the state of learning (background knowledge). 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 C** may be used to develop a training program. The program should consider all topics pertinent for each group of workers and also the method and frequency of training.

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.

ITEM 9. SCOPE OF SERVICES

Regulation: Section 30 of CPR Part 25

Applicants/Licensees are required to submit a program to be approved by PNRI for the services to be provided as specified in Section 30 (b) of CPR Part 25. The program must contain the following, as applicable:

- Organizational Structure
- Detailed procedures to describe how services will be performed
- Materials, equipment and other instrumentation needed to perform these activities
- Manufacturer's instructions and recommendations on the installation, repair, maintenance and other nuclear services for specific devices/equipment
- The names, functions and responsibilities of all authorized personnel involved in the performance of activities

Response from Applicant:

- Submit program or procedures of services to be provided as described above.

ITEM 10. QUALITY MANAGEMENT PROGRAM

Regulation: Section 16 of CPR Part 25

The applicant/licensee is required to establish and implement a quality management program governing its operation to ensure that the product, service or system satisfies specified requirements and meets the needs of the customer. The management system for service providers in radiation safety should be graded to the scope of their activities. The

management system should be documented, which may include policies, processes and procedures, and instructions, to the extent necessary to ensure the quality of the service provided. It should cover work carried out in permanent facilities, at sites away from permanent facilities, or in associated temporary or mobile facilities. An example of how to develop a management system for a service provider is presented in **Appendix D**.

Where a service provider is part of a larger organization, the organizational arrangements should be such that departments that may have conflicting interests, such as production, commercial marketing or financing departments, do not adversely influence the service providers' ability to comply with the requirements of their management system. If the service provider wishes to be recognized as a third party organization, it should be able to demonstrate that it is impartial and free from any undue commercial, financial or other pressures that might compromise their technical judgment. The third party organization should therefore not engage in any activities that may endanger trust in its independence of judgment and integrity in relation to its services.

The demonstration of an effective quality management system can be achieved through a third party audit or accreditation to internationally accepted management standards, such as the International Organization of Standardization (ISO). It is the responsibility of the service provider to carry out its activities in such a way as to satisfy the needs of its customers.

Response from Applicant:

- Submit an ISO certification or its equivalent, in accordance with the type of services rendered, within two (2) years after the initial issuance of the license.

ITEM 11. RADIATION SAFETY PROGRAM.

A radiation safety program must be established and submitted to PNRI as part of the application. The program must be commensurate with the scope and extent of activities for the use of licensed materials in service operations. Each applicant must develop, document, and implement a radiation safety program which addresses the individual components as described in the following subsections:

11.1 ALARA Program.

Regulation: Section 15 of CPR Part 25

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 as low as reasonably achievable (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 **A**s **L**ow **A**s **R**easonably **A**chievable 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 RSO of the entire radiation safety program including ALARA considerations.

A model ALARA program, which can be found in **Appendix E**, 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.

11.2 Personnel Monitoring Program.

Regulation: Section 24 of CPR Part 25

The applicant should submit a copy of the personnel monitoring program. 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 RSO) 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. 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 PNRI and should provide new employers with the data on former employee's radiation dose histories.

The main objective of monitoring the exposure of radiation workers is to ensure that exposures are kept ALARA and that the doses of individuals exposed to radiation is unlikely to exceed any relevant dose limits specified in CPR Part 3. **Appendix F** shows a model personnel monitoring program.

Response from Applicant:
- Submit a copy of the personnel exposure monitoring program.

11.3 Radiation Monitoring Program

Regulations: Sections 17(c)(16), 25, 33 of CPR Part 25

The applicant/licensee is required to perform radiation surveys before use, during use or operation, 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. The selection and proper

use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions.

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 mSv/hour. Records of radiation measurements should be retained until 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 G** 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.

11.4 Leak Testing of Radioactive Sources

Regulations: Sections 17(c)(22) of CPR Part 25

PNRI requires a leak testing for each radioactive source before its first use and annually thereafter, or as recommended by the manufacturer. Each radioactive source is supplied by a distributor with a certificate which indicates the results and date of the last leak test performed on the source. Without a certificate, the source may not be used until a leak test has been performed and the results of the test have been received showing that the source is not leaking or contaminated. If the applicant has a certificate from the supplier indicating that the radioactive source was leak tested within twelve (12) months before it was delivered to the applicant, the test before first use is not required. The source must be tested for leakage and contamination annually thereafter, or as recommended by the manufacturer.

The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Becquerel (0.005 microcurie) of radioactivity. Manufacturers, consultants, and other organizations may be authorized by PNRI to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Licensees may also be authorized to conduct the entire leak test sequence themselves. **Appendix H** describes a model procedure for leak testing of radioactive sources.

If you will be providing leak tests as a service to others, you may wish to distribute commercial leak test kits. Leak test kits should contain:

- Swabs, wipes, absorbent-tipped sticks, etc., that are to be used to make the wipes on the specified sources or devices;
- Envelopes, vials, etc., where wipe sample will be placed after sample has been taken;
- Step-by-step instructions for safe use of the particular kit (these instructions will be specific to the types of devices/sealed sources that the kit is designed);
- Procedures for returning the wipes to you for analysis;
- Label for the customer to fill out that identifies:
  (1) Customer's name;
  (2) License number;
  (3) Source or device (by manufacturer, model number, nuclide and activity) wiped; and
  (4) The name of the individual who made the wipes.

Response from Applicant:
- Submit a leak test program if you plan to conduct the leak test yourself. Otherwise, state the name of the organization licensed to perform the leak testing of your radioactive sources and its PNRI license number.

11.5 Operating and Emergency Plan

Regulations: Section 29 of CPR Part 25

A written emergency plan, designed to mitigate or control the consequence of an incident and to minimize radiation exposure of workers, the general public and the environment, should be developed and posted at convenient locations in the facility. The plan should include, but not limited to the following:
- Specify when they are to be implemented;
- Describe step-by-step actions that are to be taken and by whom;
- Identify immediate measures to assess the hazard;
- Describe protective actions to contain radioactive source and avoid unnecessary radiation doses to the operators and the public;
- Describe the emergency equipment and protective clothing to be used;
- Provide instructions posted in a visible area to the staff to avoid overexposure to radiation; and
- Specify the names and on-duty and off-duty telephone numbers of the responsible persons (i.e. RSO, ARSO and authorized operators)

Appendix I describes the proposed contents of a facility Radiological Emergency Plan including implementing procedures.

Response from Applicant:
- Submit the operating and emergency plan 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 PNRI during an emergency should also be posted.

11.6 Transport of Radioactive Material

Regulations: Section 26 of CPR Part 25

The applicant/licensee must not transport or cause the transport of any radioactive source outside of the confines of his/her facility or other authorized location, or deliver or cause the delivery of any radioactive source to a carrier, unless the applicant is authorized by PNRI and has complied with the requirements of CPR Part 4 and the rules and regulations of other

government agencies that govern transport modalities. 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 procedures for transporting radioactive sources to a temporary jobsite that will include the packaging, type and condition of storage containers in the vehicles, posting of vehicles, and control of the radioactive sources.

11.7 Security of Radioactive Sources

Regulations: Section 28 of CPR Part 25, CPR Parts 26 and 27

The applicant/licensee shall ensure that licensed radioactive sources are secured from unauthorized removal or access for malevolent use in accordance with applicable provisions of CPR Part 26.

Licensees must provide adequate security measures of sources and facilities on site and during transport of radioactive sources. Security measures of radioactive sources involve administrative and technical measures to avoid unauthorized removal of radioactive sources from authorized location. Security of radioactive sources must be accomplished by complying with the following methods at all times:

- 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 J describes the proposed contents of Security Measures for Security C and D.

Response from Applicant:

- Submit a copy of the security measures in accordance with the provisions in CPR Part 25, CPR Part 26 and CPR Part 27.

ITEM 12. RADIOACTIVE WASTE MANAGEMENT

Regulations: Section 34 of CPR Part 25, Section 30 of CPR Part 3

This section applies to service providers who generate radioactive waste as a result of services operations. It does not include licensees providing waste management services to customers. Service providers who perform these activities as a service to other licensees should refer to Item 11.5, “Operating and Emergency Procedures.”

Radioactive waste generated or handled when conducting licensed activities may include disused sealed sources and contaminated items such as absorbent paper, gloves, filters, tools, etc. Different types of radioactive waste must be segregated and treated separately to warrant differences in factors such as radionuclide content, half-life, concentration, volume and physical and chemical properties, taking into account the available options for waste disposal. During the period between storage and disposal

container integrity must be assured. All radioactive waste must be secured against access or removal by unauthorized persons.

A licensee who disposes the disused radioactive source to the original supplier must keep a special agreement for the return of the disused radioactive source to the original supplier or manufacturer of the source in the country of origin. A proof that the disused radioactive source was received by the supplier must be submitted to PNRI. Before transferring a radioactive source, a licensee must ensure and verify that the recipient is properly authorized to receive it.

Disused radioactive source(s) maybe disposed of at PNRI interim radioactive waste management facility if transfer to another recipient or return to the original supplier is not at all possible.

Appendix K provides general guidance for a Radioactive Waste Management Program.

Response from Applicant:

- Establish and submit radioactive waste disposal procedures. Indicate the isotope (element and mass number), activity, physical and chemical form, and the quantity to be disposed of in accordance with PNRI requirements.

- Upon disposal of disused radioactive sources, the licensee should:
  (1) Notify and secure the approval of PNRI before the transfer of radioactive sources to an authorized recipient.
  (2) Submit to 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 PNRI on the design and specifications of the container where the radioactive sources will be packed and shipped, as applicable
  (4) Submit to PNRI plans or other methods of disposition.

ITEM 13. APPLICATION AND LICENSE FEES

The applicant should refer to CPR Part 22, “Fees and Charges for Radioactive Material Licenses and Other Regulatory Fees”, to determine the application or license fee to be paid. The application fee must be paid upon submission of the application. For a new license, the license fee may be paid upon notification of approval of the license or upon issuance and release of the license. The application must indicate the amount of application fee or license fee paid, the official receipt numbers, and date of payment.

ITEM 14. CERTIFICATION

The application should be certified, signed and dated by an authorized representative of the institution, usually the Director, President, Chief Executive Officer or Vice President. Otherwise, a letter from such a person should be included affirming the signing authority of the representative who signed the application in his/her behalf. Unsigned applications will not be processed and will be returned to the applicant.

ITEM 15. ACKNOWLEDGEMENT

To attest to the correctness and veracity of statements and information contained in the application for a license, each application should be made under oath or affirmation.

4. AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: Sections 10, 11 and 12 of CPR Part 25

It is the applicant'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 10 of CPR Part 25, 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 thirty (30) days before the expiration date in accordance with Section 12 of CPR Part 25.

The corresponding license amendment and renewal fee prescribed in CPR Part 22 must be paid upon filing the application.

Response from Applicant:

- For license amendments,
  (1) Ensure that the most recent guidance is used in preparing for an amendment or renewal request;
  (2) Submit the Application Form PNRI/NRD-025 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 ACTIVITIES

Regulations: Section 13 of CPR Part 25.

The licensee must determine whether residual radioactivity is present at the facility and whether the levels of contamination make the facility or vicinity unsuitable for release according to PNRI requirements. A licensee's determination that a facility is not contaminated is subject to verification by PNRI inspection.

Before the termination of the license, the licensee must implement the following:

- Discontinuation of all activities involving licensed radioactive sources;
- Transfer or disposal of all licensed radioactive sources which are in the licensee's possession in accordance with the regulations;
- Assurance that no contamination levels in excess of the limits for supervised areas existing the facilities; and
- Assurance that the required records are complete and up-to date.

For guidance on the disposition of licensed material, refer to **ITEM 12**.

Response from Applicant:

- The licensee is not required to submit a response during the initial application. However, when the license expires or at the time the licensee ceases operations, then any necessary decommissioning activities must be undertaken, information relevant to decommissioning must be submitted to PNRI, and other actions must be taken as summarized in the decommissioning plan.

APPROVED:

(Sgd.) ALUMANDA M. DELA ROSA, Ph.D.
Director, PNRI

Date: April 29, 2015

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

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR COMMERCIAL PROVIDERS OF NUCLEAR TECHNICAL SERVICES

INSTRUCTIONS: To complete this application, refer to Part 25 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for a Radioactive Material License for Commercial Providers of Nuclear Technical Services. 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: (Tick appropriate box)

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

1. NAME AND COMPLETE ADDRESS OF APPLICANT.

Institution/Firm _____

Address _____

Director/Chairman of the Institution _____

Telephone Number _____

Fax Number _____

E-mail Address _____

2. PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____

Position/Title _____

Address _____

Telephone Number _____

Fax Number _____

E-mail Address _____

3. LOCATION(S) WHERE SERVICE WILL BE RENDERED.

Location (Address, Tel. Number)	Service(s) to be Provided

4. RADIOACTIVE MATERIALS AND PURPOSE(S) OF USE.

4.1 Unsealed Radioactive Materials

Radionuclide (Element/Mass Number)	Chemical/Physical Form	Max. Amount to be Possessed at any One Time (MBq)	Purpose of Use

4.2 Sealed Sources

Radionuclide (Element-Mass Number)	Manufacturer	Model/Serial Number	Number of Units (Quantity)	Max. Amount to be Possessed at any One Time (MBq)	Purpose of Use

5. RADIATION MONITORING INSTRUMENTS.

5.1 Personnel Monitoring Instruments

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 Safety Officer (RSO)			
Assistant RSO			
Authorized Personnel			
Ancillary Personnel			

Attached Remarks

7. FACILITIES AND EQUIPMENT.

7.1 Facility Layout

Layout of the Facility ☐ _____
Additional Safety Equipment ☐ _____
Shielding Design/Calculations ☐ _____

8. TRAINING PROGRAM. ☐ _____

9. SCOPE OF SERVICES. ☐ _____

10. QUALITY MANAGEMENT PROGRAM. ☐ _____

11. RADIATION SAFETY PROGRAM.

Item	Title	Model Procedure Attached	Equivalent Procedure Attached	N/A	Remarks
11.1	ALARA Program	☐	☐	☐	
11.2	Personnel Monitoring Program	☐	☐	☐	
11.3	Radiation Monitoring Program	☐	☐	☐	
11.4	Leak Testing of Radioactive Sources	☐	☐	☐	
11.5	Operating and Emergency Plan	☐	☐	☐	
11.6	Transport of Radioactive Material	☐	☐	☐	
11.7	Security of Sources	☐	☐	☐	

Attached Remarks

12. RADIOACTIVE WASTE MANAGEMENT. ☐ _____

13. APPLICATION FEE PhP_____ Official Receipt Number _____
Date _____

LICENSE FEE PhP_____ Official Receipt Number _____
Date _____

14. 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

15. 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 SAFETY OFFICER (RSO) AND ASSISTANT RSO

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

Radioactive Source/Device	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 RSO/ARSO

Date: _____

APPENDIX A

RADIATION MONITORING INSTRUMENTATION AND MODEL CALIBRATION OF SURVEY METER

Facilities and Equipment

(1) To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.

(2) Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

(1) Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.

(2) Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.

(3) Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

(4) Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

(5) The following table (except for items marked with an asterisk (*)), extracted from "The Health Physics & Radiological Health Handbook," Revised Edition, 1992, may be helpful in selecting instruments:

Table A-1: Typical Survey Instruments

Portable Instruments Used For Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	mR - R	Not applicable
Count Rate Meters			
Geiger-Mueller (GM)	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Gamma	C-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter	Alpha	All energies	High
	Beta	All energies	High
	Gamma	All energies	Moderate
Gamma Counter (NaI)	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Model Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ±5% accuracy by a Secondary Standards Dosimetry Laboratory (SSDL);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed or develop energy curves to compensate for differing energies;
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7 x 10-6 coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 GBqs (85 mCi) of cesium-137 or 7.8 x 102 MBqs (21 mCi) of cobalt-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

1) Linear readout instruments with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, the response of the instrument should be checked at approximately 20% and 80% of full scale. The instrument's readings should be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point.
2) Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument should be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration should be checked at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value of no more than 10% of the full decade value.
3) Meters with a digital display device shall be calibrated the same as meters with a linear scale.
4) Readings above 2.58 X 10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
5) The inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

1) A survey meter's efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure or develop energy curves to compensate for differing energies.
2) If each scale has a calibration potentiometer, the reading should be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at

approximately 20% of full scale should be observed. If only one calibration potentiometer is available, the reading should be adjusted at mid- scale on one of the scales, and readings on the other scales should be observed. Readings should be within 20% of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified to be within ± 5% accuracy by SSDL;
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

1) Calibration of survey instruments used in assessing dose or exposure rates must be conducted at 6 to 12 month intervals or after instrument servicing.
2) Calibration must produce readings within ± 20 per cent of the actual values over the range of the instrument.
3) Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

1) The owner or user of the instrument;
2) A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
3) A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
4) For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
5) For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
6) For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
7) For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
8) The exposure rate or count rate from a check source, if used;
9) The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

1) For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
2) The efficiency, of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
3) For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
4) The date of calibration and the next calibration due date;
5) The apparent exposure rate or count rate from the check source, if used.

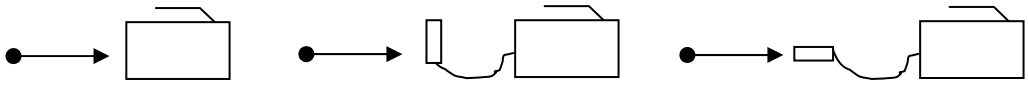
See **Exhibit 1** for a form you may want to use.

EXHIBIT 1

SURVEY METER CALIBRATION REPORT

OWNER: _____DEPARTMENT: _____
MANUFACTURER: _____ TYPE: ☐ Ion Chamber ☐ GM ☐ NaI(Tl) ☐ _____
Meter Model: _____ Meter S/N: _____ Probe Model: _____ Probe S/N: _____
Calibration Source: _____mCi of _____. _____mR/hr at _____ in, on _____,20___.
Instrument checks: Battery check:_____mR/hr or _____
Constancy check: ☐ integral check source indicates _____mR/hr.
☐ _____mCi of _____ indicates _____mR/hr.

Calibration Geometry:



Window: ☐ Open ☐ Closed ☐ Fixed

Dist (feet)	mR/hr today	Scale: Reading	CorFac	Scale: Reading	CorFac	Scale: Reading	CorFac	Scale: Reading	CorFac

Correction Factor: _____ _____ _____ _____

Name: _____
Date: _____

Calibration Sticker:

Cald ____-____-____ with _____
// ⊥, Window: _____
_____ _____ bat: "____mR/hr"
_____ _____ _____
_____ _____ chk: "____mR/hr"

APPENDIX B

SAMPLE DELEGATION OF AUTHORITY FOR THE RADIATION SAFETY OFFICER

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

You, __(*complete name of the RSO*)__, have been appointed Radiation Safety 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 and signature of Radiation Safety Officer — Date

cc: Affected department heads

APPENDIX C

CRITERIA FOR ACCEPTABLE 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.

Classroom Course Instructor Qualifications
The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program). Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective authorized users.

APPENDIX D

GENERAL GUIDANCE ON ESTABLISHING A QUALITY MANAGEMENT SYSTEM (QMS)

This appendix provides a method for establishing a management system in an organization in which there is no established management system.

INTRODUCTION

A management system consists of a set of interrelated or interacting elements. It is designed to establish the overall intentions and direction of an organization in relation to the ability of a product, system or service to fulfill the requirements of customers and other interested parties (see **Figure E.1**). A process approach is encouraged for developing the management system. In this context, any activity that receives inputs and converts them to outputs can be considered a process. For organizations to function effectively, they have to identify and manage numerous linked processes. Often the output from one process will be the direct input into the next process. The systematic identification and management of the processes applied within an organization and the interactions between such processes may be referred to as the process approach.

In a service provider organization it should be reflected in its quality management program that customers play a significant role in defining requirements for inputs. The satisfaction of customers should be monitored to evaluate and validate whether customers' requirements have been met.

REQUIREMENTS OF RELEVANT STANDARDS

A management system should enable an organization:

- To demonstrate its ability to deliver a product that consistently meets the customers' requirements and applicable regulatory requirements; and
- To achieve customer satisfaction through effective application of the system, including processes for continual improvement and for the prevention of non-conformances.

The steps that should be taken by an organization to implement a management system include:

(a) Identifying the processes necessary for the management system;
(b) Determining the sequence and interactions of these processes;
(c) Determining criteria and methods necessary to ensure the effective operation and control of these processes;
(d) Ensuring the availability of the information necessary to support the operation and monitoring of these processes;
(e) Measuring, monitoring and analyzing these processes and implementing the actions necessary to achieve the planned results and to bring about continual improvement.

IMPLEMENTATION PROCESS

The implementation of a management system in an operating organization starts with a decision by the senior management. There may be different external and internal factors that could convince the senior management of the need for such a system. Examples are:

- External factors such as demands by customers or regulatory bodies, or new information obtained at a peer meeting or conference;
- Internal factors such as demand by internal customers, cost-effectiveness analysis, or the need to restructure the organization owing to major changes in the focus of work or the workforce.

MANAGEMENT COMMITMENT

After arriving at the decision to implement a management system, the senior management should demonstrate its commitment to the project by:

(a) Appointing one of its members as the person responsible for the project;
(b) Providing adequate funds; and

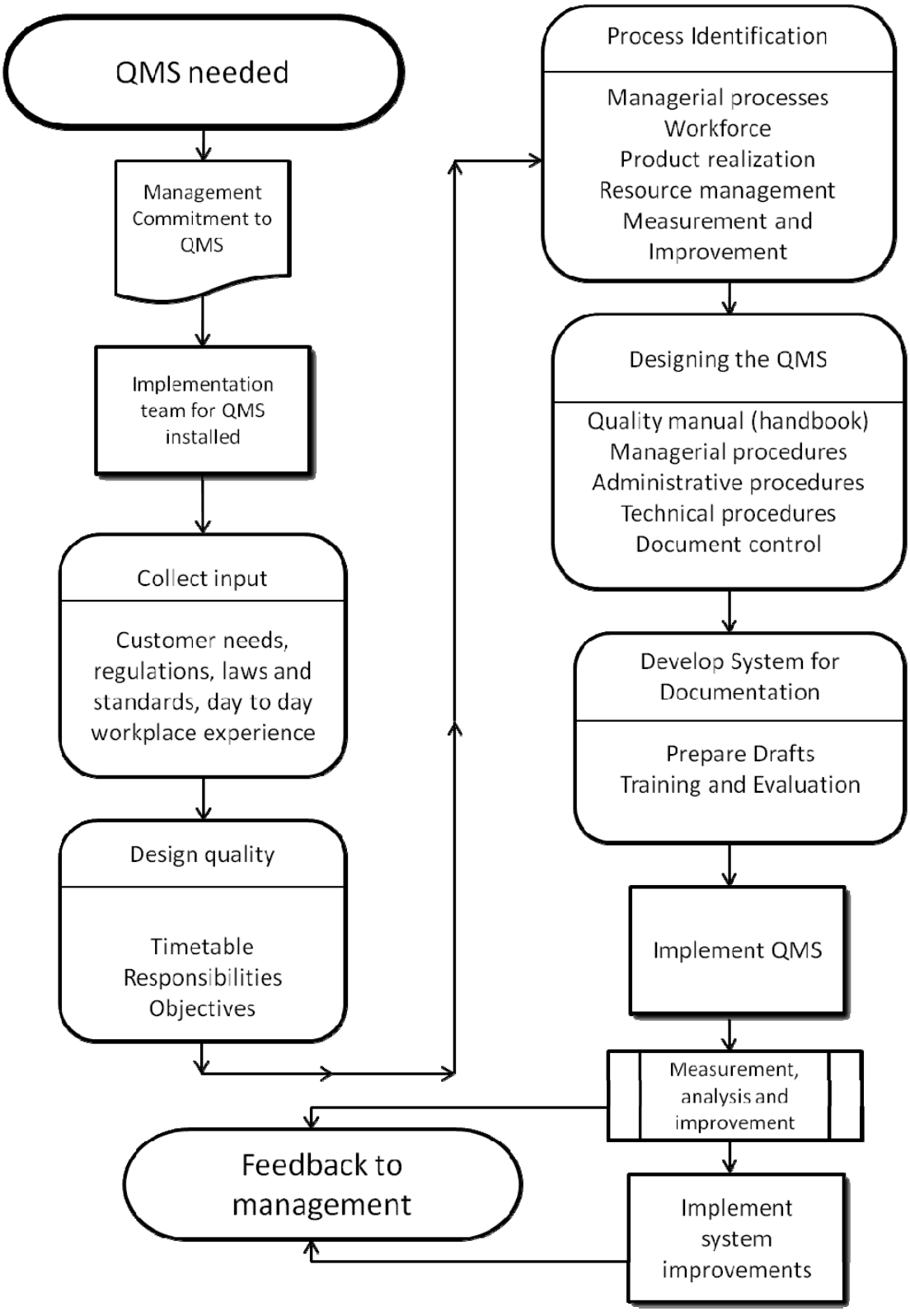


Figure E-1. Flowchart for establishing a quality management system (QMS).

(c) Establishing an information policy to ensure that the decisions on implementation of the project and the necessary actions are transparent to both the senior management and the staff.

This commitment should be communicated to the entire organization (by issuing a policy statement on quality and preliminary quality objectives and goals) and demonstrated throughout the entire process of implementing the management system (by active participation in review meetings).

APPOINTING AN IMPLEMENTATION TEAM

The next step is to appoint a task force (implementation team) under the supervision of the appointed member of the senior management. Here, the assistance of external experts might be requested, either as leaders of the task force or as advisory members.

Each member of the task force should have good knowledge and experience or should receive training, as appropriate, in at least one of the following fields:

(a) Structure and workload of the organization;
(b) Relevant standards, laws and regulations;
(c) Internal processes and procedures of the organization;
(d) Methods of communicating effectively within the company;
(e) Team organization and teamwork. The team should have an appointed leader who, in the course of the implementation of the management system, may become the quality manager of the organization.

PLANNING THE IMPLEMENTATION

The first task of the implementation team should be to evaluate the workload that will be necessary to reach the goal of an implemented management system. This information may already be available within the organization or it may be gathered by means of a newly organized initiative of the implementation team.

Means of gathering this information may include:

(a) Conducting a survey of laws, regulations and standards (in addition to the management system standards) applicable to the product portfolio of the organization;
(b) Collecting details of customer needs as expressed to representatives of the organization;
(c) Reviewing the day to day work schedule of the organization by means of direct contact with the staff;
(d) Conducting a survey and count of all processes already in operation in the organization.

Such a survey may be the first opportunity to motivate all the personnel of an organization to participate actively in the implementation of the QMS.

A preliminary timetable should be established for tracking progress in developing the management system. Depending on the size of the organization and the complexity of the task, this timetable could extend over a period ranging from several months to a year or more.

The implementation team should devise a quality plan for the implementation of the system, using the information gathered by means of the aforementioned or other methods. This plan should include:

(a) A representation of the workload, divided into work packages;
(b) A timetable for the completion of the different work packages;
(c) A person responsible for each of the different work packages;
(d) A reporting schedule for providing information to the responsible manager;
(e) A system of quality reviews to ensure the smooth performance of the plan.

IDENTIFYING EXISTING PROCESSES

To provide an overview, the existing processes should be grouped into four categories according to the action they are described:

(a) Management processes;
(b) Resource management processes;
(c) Product realization processes;
(d) Measurement, analysis and improvement processes.

In the identification of the processes, their interconnections should be identified in order to arrive at a process correlation diagram. This is a diagram that shows, in graphical form, how a change in one process may influence other processes and where there may be some gaps in the flow. These gaps will have to be filled by designing new processes.

The proper design of a management system requires knowledge of all existing processes and the development of a number of new ones. The best way to organize the management system depends on the organization of the laboratory providing the services.

DEFINING DOCUMENT STRUCTURE

The implementation team should define the structure of the ensuing documents to help the authors to develop their documentation. The quality manual, which contains the entire documentation of the QMS, may be organized in different ways. The quality manual may be one large manual containing all necessary statements, procedures and working instructions.

Another possibility is to create a centralized quality management document that contains the basic information about the organization and the principal commitment statements by senior management, and to supplement this with annexes containing the technical information necessary to perform the described tasks, which may be tailored to different branches of the organization.

WRITING PROCEDURES

A protocol or procedure should be written to define the process to be followed for writing, reviewing, approving and revising procedures and establishing their general format. With this protocol or procedure in place, the search for authors should be initiated. To ensure the acceptance of the QMS by all members of the staff, as many of the staff as possible should be included in the authoring process. The implementation team should devise the procedures in relation to such central themes as the QMS itself, document control and the assessment process. The assistance of, and authorship by, those people currently doing specific jobs should be solicited throughout the process of developing the management system, in particular for the technical procedures. Wherever necessary, the members of the implementation team should provide assistance in editing the process descriptions and procedures owing to their better training in the contents of standards and regulations.

All drafted procedures should be reviewed and compared by the implementation team; that is, checked against each other, against the management directives and against relevant international standards to ensure the conformance and integrity of the quality documentation. This process should include all necessary new procedures, changes to existing procedures, their authorization and their inclusion in the quality manual.

INITIAL TRAINING

In this way, the organization will arrive at a first version of the quality manual. This does not need to contain all the planned procedures, but may be used to train the personnel in the application of newly developed or revised procedures. Members of the implementation team, together with managers of the organization, should supervise this training in the application

of the management system to show the permanent commitment of management to the ideas of quality management.

IMPLEMENTATION, FIRST INTERNAL AUDIT AND MANAGEMENT REVIEW

After the training period, which in itself may reveal an additional need to revise the documentation, the QMS may be implemented for an initial testing period, typically a pilot project lasting three to six months. The first assessment of the management system and the first internal audit followed by the first management review should be scheduled at the end of this period.

The outcome of these two evaluation processes will show whether additional adaptation of the documentation is still necessary. When these changes have been made, the management system will be ready for final implementation and continual improvement. Senior management, with the assistance of the implementation team, should revise the quality policy and the quality objectives, which should be based on this policy and should be quantitative, at least at operational levels. These quality objectives may change over time, reflecting changes in the needs and priorities of the organization.

Finally, senior management should establish ways of assessing the performance of the organization by defining performance indicators (and the way these indicators should be derived on the basis of existing data) for quality related processes and the way of conducting the overall assessment of the management system through a management review.

APPENDIX E

MODEL ALARA PROGRAM

1. Management Commitment

a. We, the management of this ____ (*name of facility, institution, etc.*) ____, are committed to the program describe herein for keeping individual and collective doses as low as reasonably achievable (ALARA). In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if, necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing the.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this will involve exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Management Responsibilities

a. Delegation of Authority
(The judicious delegation of RSO authority is essential to the enforcement of an ALARA program).

1) The management will delegate authority to the RSO for enforcement of the ALARA concept.
2) The management will support the RSO when it is necessary for the RSO to assert authority. If the management has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

b. Review of ALARA Program

1) The management will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
2) The management will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RHSO, authorized users, and workers as well as those of management.

3. **Radiation Safety Officer (RSO)**

a. Annual and Quarterly Review
   1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
   2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA and will prepare a summary report for the RSC.
   3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were ALARA levels during the previous quarter and will prepare a summary report.

b. Educational Responsibilities for ALARA Program
   1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
   2) The RSO will ensure that authorized personnel and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that the management and the RSO are committed to implementing the ALARA concept.

c. Cooperative efforts for development of ALARA procedures

   Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
   1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
   2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing instances of deviation from good ALARA practices

   The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. **Signature of Certifying Official***

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____
Name and Signature

_____
Title

* The person who is authorized to make comments for the administration of the institution (e.g., hospital administrator)

APPENDIX F

PERSONNEL MONITORING PROGRAM

External Exposure Monitoring
The Annual Occupational Dose Limits for Adults are as follows:

	Dose Limit (mSv/yr)	
	Adult	Minor (<18 yrs)
Total Effective Dose Equivalent	20	6
Maximum effective dose in any single year	50	
Lens of the eye	20	50
Extremities/Skin	500	150

Required Dosimetry for Occupationally Exposed Personnel
Dosimeters (radiation badges) are required by regulation to be issued to those likely to receive ten percent of the above limits. By review of the results of monitoring, those persons who have exceeded ten percent of any limit or guidance in the table above will be identified and designated; monitored as required by regulation. For those monitored as required by regulation, all required records will be obtained and exposure reports provided as required by regulation. Records must be kept according to the requirements of Section 32 of CPR Part 25.

Internal Exposure Monitoring
Internal exposures are determined through bioassays.

Urine Bioassays
Urine bioassays will be run on personnel who use more than 296 MBq of volatile tritium on an annual basis. Prior bioassays of persons using stable tritium compounds did not yield any positive results.

Thyroid bioassays
Thyroid bioassays are required of personnel who perform iodinations with more than 37 MBq of free iodine or who administer liquid therapeutic doses of I-131.

Emergency Bioassay
Bioassays must also be done following spills that result in significant personnel contamination and/or airborne radioactive material.

Summation of Internal and External Dose
The total dose to the individual is a summation of external and internal exposure. The most likely route of internal exposure is the inhalation of volatile radionuclides. When airborne radionuclides are present, the Radiation Safety Officer will evaluate the protocol to determine if the use of a fume hood or a respirator is required. Radioactive material can also enter the body via oral ingestion, intake through wounds and absorption through the skin.

Review of Monitoring Program
Continuous evaluation of the results of personnel monitoring will identify any individual that achieves regulatory trigger levels, who will then be designated henceforth as monitored as required by regulation. All required records will be obtained and exposure reports provided as required by regulation.

Further Information Relating to Dosimeters

(a) Store dosimeters where they will not inadvertently be exposed to radiation, excessive heat or moisture. Badges should only be kept at work, never taken home.
(b) Wear only the dosimeter(s) assigned to you.
(c) Wear the whole body badge on the trunk of your body, at the point where it is most likely to receive maximum exposure. Be consistent in wearing the badges on the same area of the body.
(d) Wear ring badges under the glove on the hand that will receive the highest exposure, with the dosimeter name label side toward the palm.
(e) If wearing a lead apron, wear the badge on your collar, outside of the apron. If you have two dosimeters, then the whole body badge is worn under the lead apron and the second dosimeter (designated as a collar badge type) should be worn on your collar outside of the apron.
(f) If appropriate, declared pregnant workers will be issued a fetal dosimeter, along with their whole body dosimeter, for the duration of their pregnancy.
(g) Dosimeters are exchanged the first day of each calendar quarter (i.e. January 1, April 1, July 1 and October 1). Upon receipt of the new dosimeters, immediately turn in the previous dosimeters to your Approved Supervisor or the designated badge group leader.
(h) Do not wear your dosimeter when you undergo medical exams or therapies which involve radiation exposure. This includes medical and dental x-rays.
(i) If you suspect that you or your dosimeter may have been overexposed or contaminated, call Radiation Safety immediately.

Records

(a) For each individual who is likely to receive in a year an occupational dose requiring monitoring, the facility will determine the occupational radiation dose received during the current year and attempt to obtain the records of lifetime cumulative occupational radiation dose.

(b) We will prepare for employee requiring personnel monitoring a report of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body by the individual. This report will include data and results obtained as required by Section 32 of CPR Part 25.

(c) Upon the request of the employee, a written report of his/her exposure to radiation at this facility will be given after termination of employment. This report will be furnished to the former employee within 30 days of termination of the employee or within 30 days after the exposure of the individual has been determined by the facility, whichever is later. This report will cover each calendar quarter in which case the employee's working activities involved the exposure to sources of radiation and shall include dates and location of work under the license in which the worker participated. Records will be maintained for 3 years that indicate these reports were furnished to each employee.

APPENDIX G

MODEL RADIATION MONITORING PROGRAM

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys:

(1) Perform surveys of dose rates in locations where:
- Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
- An individual is working in an environment with a dose rate of 25 μSv/hour or more.

(2) Perform radiation level surveys with a survey meter sufficiently sensitive to detect 1 μSv/hour in the following areas, at the frequency specified:
- Survey at the end of each day of use all areas where radioactive materials are used.
- Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 7.4 MBq at a time).
- Survey weekly all radionuclide use, storage, and waste storage areas.
- Survey quarterly all sealed source and brachytherapy source storage areas.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted and unrestricted areas are presented in Table G-1.

Table G-1: Ambient Dose Rate Action Levels

Type of Survey	Area Surveyed	Action Level
Ambient Dose Rate	Unrestricted	1 μSv /hr
Ambient Dose Rate	Restricted	50 μSv/hr

Contamination Surveys

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

(1) Contamination surveys are performed in areas where unsealed forms of materials, including unsealed accelerator-produced radioactive materials or unsealed discrete sources of radium-226, are used:
- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;

- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

(2) Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables G-2 for restricted areas and G-3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:
   - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
   - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (< 7.4 MBq at a time).
   - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

(3) A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.

(4) The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

(5) If action levels are exceeded, follow internal procedures for responding and investigating what caused the action level to be tripped. Examples of action levels for restricted areas are presented in Table G-2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table G-2: Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

Area, clothing	Alpha emitters	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted Areas, protective clothing used only in restricted areas	200	2,000	20,000

Table G-3: Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)

Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
I-125, I-126, I-131, I-133, Sr-90	1,000	3,000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above	5,000	15,000	1,000
Ra-226	100	300	20

1 Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.
2 As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
3 Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
4 The maximum contamination level applies to an area of not more than 100 cm^2.
5 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
6 The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Contents of Survey Records

(1) A diagram of the area surveyed;
(2) A list of items and equipment surveyed;
(3) Specific locations on the survey diagram where wipe tests were taken;
(4) Ambient radiation levels in µSv/hr;
(5) Contamination levels Bq/cm^2 (dpm/100 cm^2);
(6) Make and model number of instruments used;
(7) Background levels;
(8) Actions taken in the case of excessive dose rates or contamination and follow-up survey information; and
(9) Name or initials of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX H

MODEL PROCEDURE FOR LEAK TESTING OF SEALED SOURCES

Facilities and Equipment

(1) To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
(2) Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
(3) Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting or alpha-emitting sources (e.g., Sr-90).
(4) Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 µCi) of radioactivity. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

Model Procedure for Performing Leak Testing

(1) For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
(2) Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
(3) Number each wipe to correlate identifying information for each source.
(4) Wear gloves.
(5) Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.

Model Procedure for Leak Test Analysis

(1) Sensitivity of Instrument
   a) Determine the minimum sample counting times needed to distinguish 0.005 microcurie from the background for each instrument.
   b) Measure the background count rate (R_b) in counts per minute (cpm) and record.
   c) Measure and record the correction factor (CF) using a known source whose activity is certified by the supplier. Assay a certified check source that has the same isotope as the sealed source being tested. If a certified check source is not available, it will be necessary to use one with a different isotope that has a similar energy spectrum.

$$CF = \frac{R_{std} - R_b}{A}$$

where: CF = Correction Factor
R_{std} = count rate of standard (cpm)
R_b= background count rate in counts per minute (cpm)
A = Activity of the source (µCi)

Calculate minimum sample counting time (t_{ms}) in minutes for the instrument.

Lower Limit of Detection (LLD)

$$LLD = \frac{4.66}{CF}\sqrt{\frac{R_b}{t_{ms}}} \qquad t_{ms} = \left[\frac{4.66}{CF(.005)}\right]^2 R_b$$

(2) Results:

a) Count each wipe at least t_{ms}.

b) Determine count rate for each sample $R_s = \frac{N_s}{t_s}(cpm)$

N_s = number of counts t_s = sample counting time

c) Determine activity as follows:

$$A(\mu Ci) = \frac{R_s - R_b}{CF}$$ Record in units of microcuries

d) Continue the same analysis procedure for all wipe samples.

e) If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or properly disposed. A report shall be filed within 5 days of the test with the PNRI.

For example:

Background is 150 counts in 5 minutes or 150/5= 30 cpm

10 µCi cesium standard measures 40,030 cpm

$$CF = \frac{40{,}030cpm - 30cpm}{10\mu Ci} = 4000cpm/\mu Ci$$

$$t_{ms} = \left[\frac{4.66}{4000(.005)}\right]^2 30 = 1.63\,\text{min}$$

Must count at least 1.63 minutes. Have chosen to count each sample 5 minutes.

Wipe #1: 159 counts in 5 minutes

$$R_1 = \frac{159}{5} = 31.8cpm$$

$$A_1 = \frac{31.8 - 30}{4000} = 0.00045\mu Ci$$

Wipe #2: 164 counts in 5 minutes

$$R_1 = \frac{164}{5} = 32.8cpm$$

$$A_1 = \frac{32.8 - 30}{4000} = 0.0007\mu Ci$$

Both are < 0.005 microcurie.

APPENDIX I

PROCEDURE FOR WRITING A FACILITY RADIOLOGICAL EMERGENCY PLAN

1. Aim and objectives of the plan

   The aim(s) and objectives of the plan should be clearly stated at the outset. Care needs to be taken that the body of the plan is consistent with this statement.

2. Introduction of the Plan

   2.1 Facility description

   Include a brief description of the facility and its operation

   - the location of the facility
   - a detailed map
   - an inventory of all radioactive materials on site and their location

   2.2 Definition of an emergency

   Define the situations that constitute an emergency for the facility. Other assumptions underpinning the plan should also be stated

3. Types and levels of emergency

   The types and levels of possible emergencies identified for the facility should be described.

   Emergencies can vary in scale. Different levels of emergency should be defined for the facility. Smaller facilities may only require one level of emergency, while medium to larger scale and more complex facilities could use one, two or more levels of emergency.

   Emergencies are also defined according to type on the basis of the radioactive material and the radioactivity involved. The type of emergency will determine the potential impact of the incident on people, property and the environment. Examples of types of emergencies are:

   - fire;
   - explosion;
   - spill;
   - natural event (including flood, earthquake, storms, etc.);
   - subversive activities (bomb threat, vandalism, sabotage, etc.); and
   - transport incident.

   These types of emergencies should be considered for:

   - an incident within the facility;
   - an incident occurring outside the facility where a radioactive material is the responsibility of the facility (e.g. during transport, etc.); and
   - secondary events or knock-on effects arising within or outside the facility (e.g., a flood or an explosion).

4. Emergency functions and organizational structure

   The functions nominated for the facility should be listed in the plan, together with the associated roles, responsibilities and duties of personnel assigned to these functions, and arrangements for appropriate backup. The functions should address the areas of responsibility required to manage the emergency. The specific manner of translating areas of responsibilities into functions will depend on the size and the resources of a facility. The following details should be provided.

- the contact details of, and the means of contacting, the persons at the facility;
- a list of 24-hour emergency contacts; and
- arrangements for assisting emergency services and nearby facilities with control actions taken in the surrounding area.

5. Emergency procedures

   The procedures should describe the steps to be undertaken, the precautions, the protective clothing and equipment to be used, any special conditions, and the responsibilities and duties of people undertaking these procedures. Emergency procedures should take into account the properties of the radioactive materials and the impacts on people, property and the environment.

6. Emergency resources

   The resources (equipment and amenities) provided to respond to emergencies should be identified and details provided. The emergency plan must include on-site emergency resources, including emergency equipment, personnel, and decontamination equipment; and off-site emergency resources, including arrangements for obtaining additional external resources (specific to the likely major incidents) to assist the control of major incidents and major incident hazards.

7. Emergencies with potential for environmental impact:

   The role, responsibilities and duties of the person nominated to notify the relevant agencies of an emergency with potential for environmental impact should be identified. The method of notification (e.g. telephone), the timing of notification (e.g. during or after the emergency) and the type of information required should be determined following consultation with these agencies.

8. Reporting of an emergency

   This refers to reporting to corporate personnel and government agencies or groups other than the Police, Fire and emergency services. The procedures for reporting emergencies and the role, responsibilities and duties of personnel reporting should be defined.

10. Termination of an emergency

    The plan should outline the procedures and responsibilities for terminating an emergency. These should be considered in terms of:

    - the return of control to the facility emergency manager by the emergency services; and
    - the declaration by the facility emergency manager that the emergency has been terminated.

11. Management of the plan

    The management of the plan and how it is to be achieved should be included in the plan.

APPENDIX J

SECURITY MEASURES FOR SECURITY GROUP C AND D

The security measures should satisfy the security provisions in CPR Part 26 for the source(s) under consideration. It should be reviewed at least annually to ensure that it is still current and applicable. System evaluations should be performed and documented as part of a quality assurance system.

1. Technical Measures
    - Deterrence provided by at least one (1) measure separating the source from unauthorized personnel;
    - Design features to evaluate the quality of the measures against the assumed threat deterrence provided by technical measures separating the source from unauthorized personnel, as may be applicable and practicable, such as fences, walls, cages, transport packaging, locks and interlocks for doors, locked and shield containers, and intrusion-resistant source-holding devices.
    - For sources in storage:
      The sources could be stored in a locked, fixed container and in a room with control on access. Whenever there are reasons to believe that any locks or settings may have been compromised, they should be changed.
    - For sources in use:
      The appropriate control for the source while in use could be to make sure that an authorized person uses the source only in an area that has controlled access, or that the source is in a secure containment in an area where there are personnel able to detect any interference with the source.

2. Administrative Measures

    2.1 Principal Party and Responsibilities
    Specify the name and designation of the principal party or the individual to represent the principal party. The principal party or his representative must be from the management of the licensed institution. The principal party should ensure that:
        - sources are managed in accordance with the license;
        - when sources are not in use, they are promptly stored in an approved manner;
        - storage should be in accordance with the requirements for the group to which the source belongs;
        - any transfer of sources to another person is documented and that person is authorized in accordance with the applicable regulatory requirements to receive the transferred source;
        - financial provisions in accordance with the regulatory requirements for the safe management of disused sources are in place; and
        - sources are shipped and received in accordance with regulatory requirements.

    2.2 Individual assigned for sources and his responsibilities
    Specify the name and designation of the responsible individual. The responsible individual should ensure that all personnel who use or have access to the sources are reliable, authorized, and have the proper training consistent with their duties in handling those sources.

2.3 Semi-annual accounting should be performed during:

- routine inventory;
- when recorded parameters change; and
- when sources are transferred.

The records should include the following particulars: location of the source; radionuclide; radioactivity on a specified date; serial number or unique identifier; physical form; source use history (e.g. logging all source handling operations); and receipt, transfer or disposal of the source.

2.4 Methods for access authorization should include the following:

- procedures of access control to source location allowing timely detection of unauthorized access, as may be applicable and practicable;
- access procedures; and
- key control procedures.

Requirements for Security Group D

There are no specific technical measures required for this group. Only routine measures to ensure safe use and to protect the source as an asset are required. Therefore, only subsections 2.1 to 2.3 of the Administrative Measures in Security Group C are applicable to Security Group D. Transport of source should be in accordance with CPR Part 4.

APPENDIX K

RADIOACTIVE WASTE MANAGEMENT PROGRAM

General Guidelines

1) All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2) Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
3) Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4) In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, inflammability), and costs.
5) Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
6) Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Model Procedure for Disposal by Decay-in-storage (DIS)

1) Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
2) Short-lived waste should be segregated from long-lived waste.
3) Waste should be stored in suitable well marked containers and the containers should provide adequate shielding.
4) Liquid and solid wastes must be stored separately.
5) When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
6) The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives that persons performing surveys should be aware of the potential for measurable radiation.
7) The contents of the container should be allowed to decay for at least ten half-lives of the longest lived radioisotope in the container.
8) Prior to disposal as ordinary trash, each container should be monitored as follows:
    a) Check the radiation detection survey meter for proper operation.
    b) Survey the contents of each container in a low background area.
    c) Remove any shielding from around the container.
    d) Monitor all surfaces of the container.
    e) Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e. surface readings are indistinguishable from background.
    f) If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

9) If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; and that the waste is incinerated, not placed in a landfill, and the waste disposal firm is cautioned not to open the container prior to incineration.

REFERENCES

- CPR Part 3, "Standards for Protection Against Radiation", Published in the Official Gazette, 2004
- CPR Part 4, "Safe Transport of Radioactive Materials in the Philippines", Published in the Official Gazette, 2004
- CPR Part 16, "Licenses for the Use of Radioactive Sources contained in Industrial Devices", Published in the Official Gazette, 2011
- CPR Part 22, "Fees and Charges for Licensing Radioactive Materials and Other Related Regulatory Activities", Published in the Official Gazette, 2003
- CPR Part 25, "Licenses for Commercial Providers of Nuclear Technical Services", Published in the Official Gazette, 2013
- CPR Part 26, "Security of Radioactive Sources", Published in the Official Gazette, 2007
- INTERNATIONAL ATOMIC ENERGY AGENCY*, The Management System for Technical Services in Radiation Safety, IAEA Safety Standards Series No. GS-G-3.2, IAEA,Vienna (2008).*
- CPR Part 27, "Security Requirements in the Transport of Radioactive Material", Published in the Official Gazette, 2013
- US NUCLEAR REGULATORY COMMISSION, *NUREG-1556 Vol.18, Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Service Provider Licenses, dated November 2000.*

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

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR COMMERCIAL PROVIDERS OF NUCLEAR TECHNICAL SERVICES

INSTRUCTIONS: To complete this application, refer to Part 25 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for a Radioactive Material License for Commercial Providers of Nuclear Technical Services. 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: (Tick appropriate box)

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

1. NAME AND COMPLETE ADDRESS OF APPLICANT.

Institution/Firm _____

Address _____

Director/Chairman of the Institution _____

Telephone Number _____

Fax Number _____

E-mail Address _____

2. PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____

Position/Title _____

Address _____

Telephone Number _____

Fax Number _____

E-mail Address _____

3. LOCATION(S) WHERE SERVICE WILL BE RENDERED.

Location (Address, Tel. Number)	Service(s) to be Provided

4. RADIOACTIVE MATERIALS AND PURPOSE(S) OF USE.

4.1 Unsealed Radioactive Materials

Radionuclide (Element/Mass Number)	Chemical/Physical Form	Max. Amount to be Possessed at any One Time (MBq)	Purpose of Use

4.2 Sealed Sources

Radionuclide (Element-Mass Number)	Manufacturer	Model/Serial Number	Number of Units (Quantity)	Max. Amount to be Possessed at any One Time (MBq)	Purpose of Use

5. RADIATION MONITORING INSTRUMENTS.

5.1 Personnel Monitoring Instruments

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)			
Assistant RPO			
Authorized Personnel			
Ancillary Personnel			

	Attached	Remarks
7. FACILITIES AND EQUIPMENT.		
7.1 Facility Layout		
Layout of the Facility	☐	_____
Additional Safety Equipment	☐	_____
Shielding Design/Calculations	☐	_____
8. TRAINING PROGRAM.	☐	_____
9. SCOPE OF SERVICES.	☐	_____

10. QUALITY MANAGEMENT PROGRAM. ☐ _____

11. RADIATION SAFETY PROGRAM.

Item	Title	Model Procedure Attached	Equivalent Procedure Attached	N/A	Remarks
11.1	ALARA Program	☐	☐	☐	
11.2	Personnel Monitoring Program	☐	☐	☐	
11.3	Radiation Monitoring Program	☐	☐	☐	
11.4	Leak Testing of Radioactive Sources	☐	☐	☐	
11.5	Operating and Emergency Plan	☐	☐	☐	
11.6	Transport of Radioactive Material	☐	☐	☐	
11.7	Security of Sources	☐	☐	☐	

Attached Remarks

12. RADIOACTIVE WASTE MANAGEMENT. ☐ _____

13. APPLICATION FEE PhP _____ Official Receipt Number _____
Date _____

LICENSE FEE PhP _____ Official Receipt Number _____
Date _____

14. 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

15. 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

Radioactive Source/Device	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: _____