REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR THE USE OF RADIOACTIVE SOURCES CONTAINED IN INDUSTRIAL DEVICES

TABLE OF CONTENTS

REGULATORY GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE FOR THE USE OF RADIOACTIVE SOURCES CONTAINED IN INDUSTRIAL DEVICES

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE.

The purpose of this regulatory guide is to assist applicants in the preparation of an application for a license for the use of radioactive sources contained in industrial devices, in accordance with CPR Part 16, "Licenses for the use of Radioactive Sources contained in Industrial Devices ".

This regulatory guide provides the information needed to understand the specific safety and security requirements and licensing policies that apply to the use of radioactive sources contained in industrial devices. License application must correctly and adequately address the required radiation safety and security measures and procedures to provide the needed radiation protection of radiation workers and members of the public and the security of sources.

This guidance addresses various radiation safety issues associated with portable and fixed gauges of different designs based, in part, on their intended use (e.g. to measure moisture, density, thickness, level, etc.). Note that because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, the radioactive sources may be oriented in different locations within the device, resulting in different radiation safety problems. Within this document, the terms or phrases, “industrial devices”, “industrial gauges”, “portable and fixed gauges” are used interchangeably.

1.2 MANAGEMENT RESPONSIBILITY.

The PNRI believes that an effective radiation safety program and security management is vital to achieving safe and compliant operations. Moreover, consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely and securely.

The PNRI finds that ineffective management is the underlying cause of safety, security and compliance problems. Management refers to a senior-level manager who has responsibility for overseeing licensed activities. To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management’s commitment and responsibility for the following:

a) Radiation safety and security of radioactive sources and compliance with regulations;

b) Completeness and accuracy of the records and all information provided to the PNRI;

c) Knowledge about the contents of the license and application;

d) Commitment to provide adequate resources (including space, equipment, personnel, time, and if needed, contractors) to the radiation safety program to ensure that public and workers are protected from radiation hazards;

e) Selection and assignment of qualified individuals to serve as the Radiation Safety Officer, Assistant Radiation Protection Officer and authorized operators for licensed activities;

f) Obtaining PNRI's prior written consent before transferring control of radioactive source;

g) Notifying the PNRI in writing, immediately following filing of petition for voluntary or involuntary bankruptcy;

h) Development and maintenance of a radiological emergency plan;

i) Selection of management representative(s) with authority to stop unsafe operation; and

j) Commitment to provide information regarding employee's protection.

1.3 APPLICABLE REGULATIONS.

- CPR Part 3, "Standards for Protection Against Radiation", published in the Official Gazette, 2021
- CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines", published in the Official Gazette, 2017
- CPR Part 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 Radioactive Material License and Other Related Regulatory Services", published in the Official Gazette, 2016
- 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, 2014

It is the responsibility of applicants and licensees to obtain copies of the regulations specified above and to read and abide by the provisions of these regulations that apply to industrial devices.

2. FILING AN APPLICATION FOR A LICENSE

An application for a license must be filed by completing ***PNRI/NRD Form-016, "Application for Licenses for the use of Radioactive Sources contained in Industrial Devices"*** in duplicate copies. The application must include all the information necessary to support its intended purpose. Completeness of submitted information will be determined by the PNRI reviewer before the application is docketed. All applications for a new license must be affirmed or notarized.

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. The filing fee must be paid upon submission of the application documents and the appropriate license fee must be paid prior to the issuance of the license in accordance with CPR Part 22.

3. CONTENTS OF APPLICATION

ITEM 1. NAME AND MAILING ADDRESS OF APPLICANT.

Enter 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 source and the proposed use shall appear in the application.

A section, division or department within a firm, institution, or government agency cannot be the applicant. The address specified in the application should be the mailing address where correspondence will be sent. This may or may not be the same as the address at which the radioactive source is located or will be used.

ITEM 2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Identify a contact person, usually the Radiation Protection Officer (RPO), who can answer questions about the application. The position or title, address, telephone number, fax number and e-mail address of the contact person must be listed. The PNRI must be notified if the contact person, address, telephone number, fax number or e-mail address changes. This is for information purposes only and will not entail any fee.

ITEM 3. RADIOACTIVE SOURCE(S)

Regulation: Section 5 of CPR Part 16

Criteria:

The applicant/licensee must provide the manufacturer's and distributor's names, model and serial number for each radioactive source and industrial device and must ensure that the radioactive source is compatible with the industrial device.

Discussion:

A radioactive source contained in an industrial device is physically small in size, typically a few cm long by a few cm in diameter, and may be located either completely within the device or at the end of a rod/handle assembly. Depending upon the specific application, industrial gauges may contain relatively small quantities of radioactive sources or may contain sources with activities approaching 1 TBq.

Response from Applicant:

- Submit a list of all radioactive sources to be used in each industrial device, together with the information on the manufacturer and distributor (foreign and local), model/serial number of each radioactive source, number of units, chemical and/or physical form, and the maximum activity per device. Specify radionuclide activities in becquerels.
- Attach a Certificate of Design Approval for Special Form radioactive source (if applicable) and the Initial Leak Test Certificate.

ITEM 4. PURPOSE(S) OF USE.

Regulation: Section 7 (a); Section 8 (e) of CPR Part 16.

Criteria:

The proposed activity is authorized by the PNRI and the device will only be used for the purposes for which they were designed and according to the manufacturer's/distributor's recommendations.

Discussion:

Portable gauges are used to measure physical properties of materials while fixed gauges include process control methods such as measuring thickness of paper, bulk density and weight of coal on the belt scale, level of material in vessel and tanks, etc.

If the gauge(s) will be used for other purposes, submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the radioactive source or source shielding, or other radiation safety-critical components of the device. The PNRI will evaluate the radiation safety program for each type and use of the gauge requested.

Response from Applicant:

Specify the purposes for which the industrial device will be used and submit safety analysis and procedures, if needed to support the purpose.

ITEM 5. LOCATION(S) OF USE.

Regulation: Section 7(b); Section 8(e) and Sec. 28(a & c) of CPR Part 16.

Criteria:

Applicants must specifically identify and describe the facilities where the industrial device containing radioactive sources will be used. For portable gauges, applicants must provide specific address(es) for a prospective temporary jobsite(s).

Discussion:

5.1 Permanent Facility

The location(s) where industrial gauges are permanently installed should be secured to prevent unauthorized removal or access. Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. For portable gauges, the permanent facility is the location used for storage when the gauges are not in use. A location map or building plan should be included. A post office box address is not acceptable.

5.2 Temporary Jobsites

A temporary jobsite is a location where industrial devices containing radioactive sources are temporarily used and where the devices may be stored other than those location(s) of use described in **5.1**.

Authorized operators are required to maintain continuous direct surveillance of operations to prevent unauthorized entry to the radiation area during operation. Operating procedures should specify steps for responding to an unauthorized entry to the restricted area.

Response from Applicant:

- Describe the location where industrial device is permanently installed. Specify the name of the department, room number or line number, building, street address or other descriptive address, if different from **Item 1** of the Application Form. Attach a location map or building plan for easy reference of PNRI staff to locate the facility.

- Describe the location where industrial device is temporarily used or stored. The location should be precisely specified (e.g. the name of department, building, street address, or other descriptive address and telephone number). Provide a sketch or layout of the facility where the industrial device will be used or temporarily stored when not in use.

Note:

License amendment is required before locating an industrial device at an address other than those listed on the license, whether the device is an additional unit or a relocation of an existing unit.

ITEM 6. FACILITIES AND RADIATION MONITORING INSTRUMENTS.

6.1 Industrial Device(s) and Associated Equipment

Regulation: Section 7 (c), Section 28(c), Section 30 of CPR Part 16; Section 30 of CPR Part 3.

Criteria:

Applicants/licensees must specifically identify and describe the facilities where the industrial device and radiation monitoring instruments will be used. The facilities and equipment must be adequate to protect health and to minimize danger to life or property.

Discussion:

A licensee will only be authorized to possess and use only those industrial devices included in the license. The licensee must ensure that safety evaluation of each industrial device was performed by submitting a copy of the registration certificate issued by the regulatory authority of the country of origin. Applicants may not make modifications to the industrial device and associated equipment that would compromise the safety features of the system. All areas where the industrial device is used or stored requires posting with signs bearing the radiation symbol and the words: "CAUTION OR DANGER RADIATION AREA" at the point where radiation levels have been measured or estimated to reach 0.02 mSv in any one hour.

Response from Applicant:

- Identify the industrial device(s) and other equipment by indicating the type of equipment/device (e.g. level gauge, density gauge, etc.), the manufacturer's and distributor's names, the model/serial number, number of units of equipment/device and Device Registry Number.
- Submit a copy of the registration certificate issued by a competent authority.

6.2 Radiation Survey Instruments.

Regulation: Section 23 of CPR Part 16

Criteria:

The applicant must possess an appropriate radiation survey instrument required for the proposed licensed activity. The survey instrument must be calibrated and operable. It should:

a) be capable of accurately measuring the radiation fields produced by the radioactive source currently in use;
b) be visually checked for damage and for proper operation with a check source before use each day; and
c) be calibrated before its first use, annually and following repair and maintenance as may be determined by the PNRI.

Discussion:

An applicant should keep an adequate number of appropriate radiation survey instruments that are calibrated and operable at each location where a radioactive source is present to make the required radiation surveys. The instruments shall be capable of measuring from 10 uSv/hour

through 10 mSv/hour. Written procedures are required for inspection and routine maintenance of the survey instruments to ensure proper functioning.

Each radiation survey instrument shall be calibrated before its first use, annually and following repair. Calibration of survey instruments must only be performed by persons who are qualified and duly licensed by the PNRI to perform such activity. If the applicant avails the services of another person or firm for the calibration of his/her instrument, the applicant, prior to accepting the services, must verify that the service provider was licensed by the PNRI.

Response from Applicant:

- Describe the radiation survey instruments by indicating the type of instrument (e.g. GM counter, density gauge, 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.

6.3 Personnel Monitoring Devices.

Regulation: Section 22 (a) of CPR Part 16

Criteria:

The licensee must make available the use of personnel monitoring devices.

Discussion:

The applicant/licensee should provide workers working near portable or fixed gauges with suitable and appropriate personnel monitoring devices (e.g., pocket dosimeters, Optically Stimulated Luminescence Dosimeter [OSL], thermoluminescent dosimeters [TLDs], or film badges). Pocket dosimeters should be operational, calibrated, and tested for drift at intervals not to exceed one (1) year. Records of pocket dosimeter calibration must be maintained for two (2) years. Personnel monitoring devices should be worn so that the part of the body likely to receive the greatest dose will be monitored.

Response from Applicant:

- Specify the type of personnel monitoring device that will be provided to the workers including the names and addresses of the suppliers;
- Indicate the frequency of change of film badge or TLD or OSL; and
- Specify the date of calibration and the range of pocket dosimeters to be used.

ITEM 7. PROPOSED RADIATION WORKERS.

7.1 Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO).

Regulation: Section 7(e & f); Section 9(b)(2), Section 17, Section 18, Section 20 of CPR Part 16

Criteria:

The applicant has designated a qualified Radiation Protection Officer (RPO) and Assistant RPO, who shall both consent and agree in writing, and shall ensure the effective implementation of the radiation safety and security programs in accordance with approved procedures and regulatory requirements. The applicant's designated RPOs and ARPOs must have adequate training and experience.

Discussion:

The persons responsible for the radiation safety program are the RPO and ARPO. The RPO and ARPO must confirm in writing his/her acceptance of the appointment. The RPO and ARPO are responsible for overseeing and ensuring proper implementation of the licensee's

radiation safety and security program. The RPO needs independent authority to stop any licensed activity that he considers unsafe. He must have sufficient time and commitment from the management to fulfill certain duties and responsibilities to ensure that radioactive sources are used in a safe and secure manner. The RPO should ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the course of daily operation. The assistant RPO will perform the duties and responsibilities of the RPO in his absence.

Response from Applicant:

- Specify the names of the proposed RPO and assistant RPO who will be responsible for the radiation safety program;
- Describe the relevant trainings and experiences of the RPO and ARPO by accomplishing the **PNRI/NRD Form-016** and submit certificates of these trainings and experiences; and
- Attach the Official appointment of RPO and ARPO with their acceptance.

Appendix A describes the duties and responsibilities of a RPO.

Note:

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

7.2 Authorized Operator.

Regulation: Section 7(d), Section 19, Section 20 of CPR Part 16

Criteria:

The applicant must only authorize an individual to operate an industrial device if he has met the training and experience requirements prescribed in the regulation.

Discussion:

The applicant will specifically name each individual authorized to operate an industrial device that contains a radioactive source. The individuals named in the application must be qualified to operate an industrial device, including the manipulation of equipment and the performance of radiation surveys. The operator must have completed the following before he/she can be authorized in the license:

a) Manufacturer's training program on the technical and safe operation of the industrial device; and
b) Adequate training conducted by the PNRI or its equivalent.

Response from Applicant:

- Specify the names of authorized operators;
- Describe the relevant trainings and experiences of the Authorized Operators by accomplishing the **PNRI/NRD Form-016**; and
- Submit certificates of these trainings and experiences.

ITEM 8. RADIATION SAFETY PROGRAM.

8.1 Description of the Organization.

Regulation: Section 16 of CPR Part 16

Criteria:

The applicant should have established an organization responsible for implementing the radiation safety program, including specific delegation of authorities and responsibilities to individuals involved in the operation of the program.

Discussion:

Individuals who will be involved in the active control over the radiation safety program must be listed in the organizational structure of the applicant. Each individual in the line of authority should be identified by name and title. If persons of lesser authority will assume some of the duties and responsibilities normally reserved for the management, the application should identify those persons and specify how the management will ensure that their duties are properly performed.

Response from Applicant:

- Submit a description of the overall organizational structure pertaining to the radiation safety program, including personnel assignments, and delegations of specific authority and responsibility for the program;
- Provide the name, training and experience of the individual who will exercise management control over the radiation safety program.

8.2 ALARA Program.

Regulation: Section 7(g), Section 16, Sec. 36 of CPR Part 16.

Criteria:

The applicant must have an adequate radiation safety program that includes provisions for keeping doses ALARA in accordance with Section 14 of CPR Part 3. The content and implementation of which must be reviewed annually to ensure the following:

a) Compliance with the Code of PNRI Regulations, and the terms and conditions of the license;
b) Occupational doses and doses to members of the public are ALARA; and
c) Records of audits and other reviews of program content are maintained for three (3) years.

Discussion:

The applicant must develop and implement a written radiation safety program that includes:

- a description of the organization and a notice to workers of the program's existence;
- definition of functions and responsibilities to help keep doses ALARA;
- radiation safety procedures and safety measures;
- results of audits and other reviews of program content and implementation; and
- continuing education and training program for the RPO, ARPO and all authorized operators.

Response from Applicant:

Submit a program that ensures doses to workers and the public are kept ALARA.

Appendix B shows a proposed ALARA program.

8.3 Inventories.

Regulations: Section 8(h and I) of CPR Part 16.

Criteria:

Each applicant must conduct an inventory at least on a semi-annual basis of all radioactive sources and devices received and possessed. Records of such inventory must be retained for three (3) years and be made available for inspection by the PNRI.

Discussion:

The PNRI recognizes the importance of conducting inventory of all radioactive sources to prevent it from being lost or misused. In addition to safety issues, this is also related to security issues to ensure that radioactive sources will not be used for malevolence or acts of terrorism.

Response from Applicant:

- Maintain records of receipt, transfer, and disposal of gauges; and
- Conduct a semi-annual inventory of radioactive sources received and possessed.

8.4 Leak Testing Program

Regulation: Section 25 of CPR Part 16

Criteria:

The PNRI requires a leak testing for each radioactive source contained in an industrial device before its first use and annually thereafter, or as recommended by the manufacturer. 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.

Discussion:

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. The source must be tested for leakage and contamination annually thereafter, or as recommended by the manufacturer.

If the applicant performs the entire leak-test procedure himself/herself, the applicant must describe and submit the procedure for taking the test sample and the instrumentation that will be used for measurement for approval by the PNRI. Sources that are stored and not being used need not be leak tested. Should the testing reveal the presence of 185 Bq or more of removable contamination, the industrial device must be removed from use.

Records of leak tests must be retained for the duration of use of the source. The records must contain the identity of the source, its estimated activity, the manufacturer, model number and serial number, activity of test sample, description of the method used to measure each test sample, the date of the test and the license number of the service provider, if appropriate.

Response from Applicant:

Submit a leak test program. If the source had been leak-tested within twelve (12) months before it was delivered to the licensee, submit the Initial Leak Test Certificate or Certificate for Sealed Radioactive Source, if already available.

Appendix C describes a model procedure for leak testing of radioactive sources.

8.5 Operating Procedures.

Regulations: Section 27 (b) (1-4) of CPR Part 16

Criteria:

Written operating procedures must be established and submitted to the PNRI as part of the application. Topics such as the use of personnel monitoring device, step-by-step procedures for the use of industrial device, storage of portable gauge when not in use, and transport procedure of portable gauge to and from temporary job site must be addressed and discussed in the operating procedures.

Discussion:

Operating procedures should be developed, maintained, and implemented to ensure that gauges are used only in accordance with their design. Copies of the operating procedures shall be posted at convenient, visible locations in the licensed facility. A sequential set of procedures and instructions from the beginning to the end of the workday is an acceptable format.

Response from Applicant:

Submit a written operating procedure that conforms to the above requirements.

Appendix D presents a proposed Operating Procedures.

8.6. Radiation Monitoring.

Regulation: Section 39 of CPR Part 16

Criteria:

The applicant shall 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.

Discussion:

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. In general, a survey should be performed each time the device is manipulated or moved. Surveys that need to be performed should include:

a) Determination of the boundary of the controlled area.
b) Determination of radiation levels at external surfaces of industrial devices in storage facilities.
c) Determination of radiation levels in and around vehicles used for transporting or storing sources and industrial devices.
d) Determination that containers prepared for shipment comply with the requirements in CPR Part 4. (For example, 0.1 mSv/hour at 1 meter from any surface and 2 mSv/hour at the surface of the container).
e) Determination of radiation levels for radioactive sources contained in fixed gauges for open and close shutter.
f) Determination of radiation levels during and after use of portable gauge in temporary jobsites.

The acceptable radiation levels for surveys should be expressed in mSv/hour. Records of radiation measurements should be retained until the PNRI authorizes their disposition. It must include the date of the surveys, a plan of each area that was surveyed, the background dose rate level, the measured dose rate (mSv/hr) at several points in each area, the survey instrument used including its last calibration period, the name and signature of the individuals who made the survey. For fixed gauges, radiation survey should be conducted at contact and at 1 meter away from the radioactive source.

Response from Applicant:

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

Appendix E shows a proposed radiation monitoring program.

8.7 Installation, Maintenance and Repair.

Regulation: Section 24 of CPR Part 16

Criteria:

Only persons specifically authorized or licensed by the PNRI in accordance with CPR Part 25 must install, remove or relocate, conduct maintenance or repair on an industrial device that contains radioactive source.

Discussion:

The applicant must implement and maintain procedures for installation and routine maintenance (cleaning and lubrication) of industrial device according to the manufacturer's recommendations and instructions. For the portable gauge, the device must be sent to the manufacturer for non-routine maintenance or repair operations that require removal of the radioactive source or source rod from the gauge.

The maintenance program must include the following activities:

a) Preventive maintenance, such as periodic cleaning and lubrication of equipment. The applicant must follow the maintenance program recommended by the manufacturer, as adequate.
b) Removal from service of any equipment found to be defective in the course of the inspection program until all defects are corrected.

The applicant must record all the necessary data involving installation and maintenance carried out with the device.

Response from Applicant:

Submit installation, repair and maintenance program including procedures according to manufacturer's recommendations and instructions. All information and data resulting from the program must be recorded and maintained until such time that PNRI authorizes its disposal.

8.8 Personnel Monitoring.

Regulation: Section 22 (b – d) of CPR Part 16

Criteria:

For fixed gauges that are remotely located, personnel monitoring device should be worn during repair and maintenance of the gauge or of nearby equipment. For portable and fixed gauges located near the authorized operators, personnel monitoring devices should be worn during the use of the gauge. Licensees who intend to maintain and service their own industrial gauges should require their personnel who will perform the procedures to use and wear personnel monitoring devices.

Discussion:

Authorized Operators of the industrial device containing radioactive sources are required to wear personnel monitoring devices as specified in **Item 6.3**. Procedures must be provided for the appropriate use of these devices. An instruction concerning steps that must be taken immediately by the operator in the event a dosimeter is found to be off-scale should be included in the procedures. This instruction should include the requirement that an individual's film badge, OSL or TLD be processed immediately if his pocket dosimeter is discharged beyond its range. Additionally, instructions about how and where dosimetry devices are to be stored when not in

use should be addressed. The storage place should be dry, radiation free, and cool so that the devices will not be affected by adverse environmental conditions.

Response from Applicant:

Submit procedures for personnel monitoring, including instructions for proper use of personnel monitoring device.

8.9 Transport of Radioactive Sources

Regulation: Section 7(i), Section 8(f), Section 26, Section 28 (b); Section 29, Section 30 of CPR Part 16

Criteria:

Licensees must develop, implement, and maintain procedures for transporting radioactive source, industrial device, and storage containers to ensure compliance with CPR Part 4. This regulation covers, among other things, packaging and securing of the industrial device and storage container in the vehicle and posting of radiation warning signs on the vehicle during transport.

Discussion:

The applicant must not transport or cause the transport of any radioactive source contained in an industrial device outside of the confines of his/her facility or other authorized location, or deliver or cause the delivery of any radioactive source contained in an industrial device to a carrier, unless the applicant is authorized by the PNRI and has complied with the requirements of CPR Part 4 and the rules and regulations of other government agencies that govern transport modalities.

All areas used for storage including vehicles, i.e., when the portable gauge is not being transported, and where the posting requirements in CPR Part 3 are applicable, should be posted with a sign bearing the words **"CAUTION RADIOACTIVE MATERIAL"**.

Operating organizations, who are often the consignors (shippers) of portable gauge to and from temporary jobsites, should ensure that all packages are properly prepared for transport and safety locks are secured before transport. All conditions of any applicable authorization for the package must be met.

Response from Applicant:

Submit procedures for transporting industrial devices that contain radioactive sources to a temporary jobsite that will include the packaging of industrial device, type and condition of storage containers in the vehicles, posting of vehicles, and control of the radioactive sources.

8.10 Emergency Plan and Procedure.

Regulation: Section 27 and Section 44 of CPR Part 16

Criteria:

The applicant should develop an emergency plan which includes procedures designed to mitigate or control the consequence of an incident and to minimize radiation exposure of workers and the general public.

Discussion:

A written emergency procedure that addresses radiological incidents should be developed and posted at convenient locations in the facility. The procedure should include, but not limited to the following:

a) Specify when they are to be implemented;
b) Describe step-by-step actions that are to be taken and by whom;
c) Identify immediate measures to assess the hazard;

d) Describe protective actions to contain radioactive source and avoid unnecessary radiation doses to the operators and the public;
e) Describe the emergency equipment and protective clothing to be used;
f) Provide instructions posted in a visible area to the staff to avoid overexposure to radiation; and
g) Specify the names and on-duty and off-duty telephone numbers of the responsible persons (i.e. RPO, ARPO and authorized operators)

Response from Applicant:

Submit an emergency plan. Copies of PNRI-approved written emergency procedures will be posted at convenient visible locations in the licensed facility. The names and telephone numbers of the persons to be notified within the organization and the responsible person who shall notify the PNRI during an emergency should also be posted.

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

8.11 Recordkeeping.

Regulation: Sections 36, 37, 38, 39, 40 and 42 of CPR Part 16

Criteria:

The applicant must meet the records and documentation required to be maintained at permanent and temporary jobsites.

Discussion:

The applicant is required to maintain and make systematic recordkeeping procedures to ensure that all activities are properly documented in order to retrieve pertinent data as specified in the requirements of CPR Part 16. These records will be the basis for audits during regular inspection conducted by the PNRI. It must be authentic and properly written with full responsibility by the applicant.

Response from Applicant:

Maintain records of the use/storage and transport of radioactive source contained in industrial device that include:

a) Radiation safety program;
b) Exposure for each worker;
c) Results of tests after maintenance and repair of industrial device including the date of performance of the tests and the names of the individuals performing the tests;
d) Results of surveys conducted on the use of the radioactive source;
e) Disposal/transfer of radioactive source; and
f) Utilization logs for portable gauge showing the following:
    - Description (or make and model number) of the portable gauge or transport container;
    - Description of the radioactive source contained in the portable gauge, including activity and reference date;
    - Identity of the authorized operator to whom the device is assigned; and
    - Facility or temporary jobsite where the device is used and dates of use including date returned to storage after use.

ITEM 9. TRAINING PROGRAM.

Regulations: Section 18 (a & b)**,** Section 19(b), Section 20 of CPR Part 16

Criteria:

The applicant must develop a program for training and re-training of radiation workers. Training and experience requirements for RPO, ARPO and authorized operators must be in accordance with Sections 18 and 19 of CPR Part 16, as appropriate.

The applicant must also ensure that workers undertake a refresher course on radiation safety, upon the approval of the PNRI, every three (3) years.

Discussion:

A training program that provides necessary instructions must be written and implemented. All training activities must be tailored to meet the needs of the individual in attendance. Topics of the training should depend on the purpose of the training, the participants, and the state of learning.

The applicant must provide manufacturer's training program on the technical and safe operation of the industrial device that includes appropriate references to any instructions given by the outside service agencies. The name, training and experience of each person who will provide substantial input for the instruction, examination or qualification of operators should be given in sufficient detail to establish his qualifications to perform these services. Appropriate experience in the operation and safety in the use of the industrial device that contains radioactive source must be considered in qualifying an individual as an RPO, ARPO and authorized operator.

The applicant must keep records of the trainings of each individual and shall maintain the record for three (3) years from the date the training was completed.

Response from Applicant:

- Submit an outline of the training program to be given to RPO, ARPO and prospective operators of industrial device;
- Submit procedures for determining the knowledge and competency for experienced operators who have worked for another licensee.
- Describe the refresher training program, names/qualifications of trainors including topics to be covered and how the training will be conducted.

Appendix G shows the criteria for a training program.

ITEM 10. SECURITY AND CONTROL OF RADIOACTIVE SOURCES

Regulations: Section 7(h) and Section 31 of CPR Part 16.

Criteria:

Physical security measures for fixed and portable gauges must be established and implemented in accordance with the requirements of CPR Part 26.

Discussion:

The 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 instrumentation systems, administrative procedures and structures installed to avoid unauthorized removal of radioactive sources from authorized location. Security of radioactive sources must be accomplished by at least one of 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.

Response from Applicant:

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

Appendix H describes the proposed contents of Security Measures.

ITEM 11. RADIOACTIVE WASTE MANAGEMENT

Regulation: Section 33, 34, and 35 of CPR Part 16

Criteria:

Licensed radioactive source must be disposed of in accordance with PNRI requirements. Disposal of disused radioactive sources can be accomplished by transferring the source to an authorized recipient, returning the source to the original supplier or manufacturer in the country of origin, or storing the source at the PNRI interim radioactive waste facility.

Discussion:

The applicant must establish a waste management program for the disposal of disused radioactive sources approved by the PNRI. The applicant may transfer disused radioactive sources contained in industrial devices to another licensee authorized by the PNRI to receive the source for the same or another purpose upon written consent by the PNRI.

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 the PNRI.

Before transferring a radioactive source, a licensee must ensure and verify that the recipient is properly authorized to receive it. In addition, all radioactive sources must be packed and shipped in accordance with CPR Part 4. Records of transfer must be maintained.

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

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 the PNRI requirements.

The licensee should:

- Notify and secure the approval of the PNRI before the transfer of radioactive sources to an authorized recipient.
- Submit to the PNRI information that includes the name, address and license number of the licensee; 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.
- Secure the approval of the PNRI on the design and specifications of the container where the radioactive sources will be packed and shipped.
- Submit to the PNRI plans or other methods of disposition.

Appendix I provides general guidance for disposal of disused radioactive sources.

ITEM 12. APPLICATION AND LICENSE FEES

The applicant should refer to CPR Part 22 to determine the amount of 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. For amendment to a license, the licensee shall not implement any amendment until he/she has received a written approval from the PNRI and after payment of the amendment fee. For license renewal, the required license fee must likewise accompany an application for renewal of a license. The application must indicate the amount of application fee or license fee paid, the official receipt numbers and date.

In addition, licensees are required to pay other applicable regulatory service fees (e.g., storage license fee, surcharge fee, release certificate fee, etc.,), as applicable.

ITEM 13. CERTIFICATION

The application should be certified, signed and dated by an authorized representative of the institution, usually the Director, Chief Executive Officer, President 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 14. 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 9 and 11 of CPR Part 16

Criteria:

The applicant must amend its license before:

1) It receives and uses an industrial device that contained a radioactive source or device other than what is indicated in the license;
2) It replaces the RPO and ARPO designated in the license;
3) It orders and receives radioactive source in excess of the activity authorized in the license;
4) It changes or modifies the areas or locations of use or storage of licensed radioactive source within the premises of the facility identified in the license;
5) It relocates the portable gauge to a temporary jobsite or storage facility;
6) It implements any major change in the approved radiation safety program; and
7) Any substantial change in any conditions of the license takes effect.

The applicant must renew its license at least thirty (30) days before the expiration date and comply with the other requirements for license renewal in accordance with Section 11 of CPR Part 16**.**

Discussion:

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 9 of CPR Part 16, 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 11 of CPR Part 16.

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

Response from Applicant:

- Submit the Application Form PNRI/NRD-016A or a letter requesting amendment.
- Provide the license number.
- For renewals, 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. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

5. TERMINATION OF ACTIVITIES

Regulations: Section 12 of CPR Part 16.

Criteria:

Termination of licensed activities will be effected after the following procedures have been implemented and approved by the PNRI:

- a certified statement that the licensee no longer has in his possession any radioactive source that requires a license;
- a listing of the radioactive source(s) transferred or disposed of and the person(s) to whom the source was transferred or the method of disposal for each item;
- a certified statement that the facilities are not contaminated; and
- a statement that the licensee agrees that records and facilities will be available for inspection by the PNRI at a mutually agreeable date within three (3) months after the rumination of the license.

Discussion:

Before the termination of the license, the licensee must implement decommissioning according to its decommissioning plan and shall perform the following:

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

For guidance on the disposition of licensed material, refer to Section 33 of CPR Part 16 and for decommissioning requirements, refer to Section 13 of CPR Part 16.

Response from Applicant:

At the time the licensee ceases operations, any necessary decommissioning activities must be undertaken, information relevant to decommissioning must be submitted to the PNRI, and other actions must be taken as summarized in the decommissioning plan.

APPROVED:

(SGD) CORAZON C. BERNIDO, Ph.D.
Officer-in-Charge, PNRI
Date: May 31, 2013

APPENDIX A

DUTIES AND RESPONSIBILITIES OF A RADIATION PROTECTION OFFICER (RPO)

The individual assigned with the duties of maintaining active management control of the radiation safety program should be qualified with training in the use of the equipment proposed in the application and should bear the title of Radiation Protection Officer (RPO). Thorough knowledge of management policies, company administrative and operating procedures, and safety procedures related to protection against radiation exposures should be prerequisites for the position.

A list of the duties that must be performed by the licensee's designated RPO and ARPO is presented below. It is not intended to be all-inclusive nor should it be interpreted as a requirement that any one person assume all of the listed duties. Some duties may be delegated to persons of lesser authority.

a. Serve as the licensee's liaison officer with the Philippine Nuclear Research Institute on matters affecting the safety and security of radioactive sources and of licensed activities.
b. Maintain control of possession and disposal of radioactive source(s).
c. Develop and maintain up-to-date operating and emergency procedures.
d. Establish and maintain personnel monitoring program.
e. Procure and maintain radiation survey instruments.
f. Establish and maintain the training program for authorized operators.
g. Establish and maintain storage facilities.
h. Maintain industrial devices and associated equipment.
i. Establish and maintain a leak-testing program.
j. Conduct semi-annual inventories and maintain utilization logs.
k. Establish a survey instrument calibration program.
l. Establish and maintain the licensee's record-keeping system.
m. Establish emergency response plan and assume control in emergency situations.
n. Investigate the cause of incidents, determine and institute necessary corrective action.
o. Advise licensee's management and authorized operators on radiation protection matters.
p. Establish a procedure for evaluating and reporting defects and noncompliance pursuant to PNRI regulations.

APPENDIX B

ALARA PROGRAM

A. Management Commitment

1. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as reasonably achievable (ALARA). In accord 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.
2. 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.
3. 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 unjustified. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing the changes.
4. In addition to maintaining doses to individuals as far below the limits as reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

B. Radiation Protection Officer (RPO) Commitment

1. Annual and Quarterly Review:
   a. Annual review of the radiation safety program. The RPO 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.
   b. Quarterly review of occupational exposures. The RPO will review at least quarterly the external radiation doses of radiation workers to determine that their doses are ALARA.
2. Education Responsibilities for ALARA Program:
   a. The RPO will schedule briefing and educational sessions to ensure radiation workers and personnel who may be exposed to radiation will be instructed in the ALARA philosophy.
   b. The RPO will inform radiation workers that management and the RPO are committed to implementing the ALARA concept.
3. Cooperative Efforts for Development of ALARA Procedures:
   a. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
   b. The RPO will be in close contact with all workers in order to develop ALARA procedures for working with radioactive source.
   c. The RPO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of these programs.
4. Reviewing Instances of Deviation from Good ALARA Practices:

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

APPENDIX C

PROCEDURE FOR LEAK TESTING OF RADIOACTIVE SOURCES

1. Prepare the materials needed for leak/wipe testing of radioactive sources, i.e. pair of tongs, gloves, filter paper/cotton swab or tissue pad, plastic bags, ethyl alcohol. (Note: It is recommended that the diameter of the filter paper should be about 2.4 cm.)

2. Prepare separate plastic bags labeled with the serial/model number of each radioactive source.

3. With gloved hands, moisten/wet the filter paper/cotton swab or tissue pad with ethyl alcohol.

4. With a pair of tongs, wipe the surface of the radioactive source (shutter) with the moistened filter paper/cotton swab or tissue pad. Take three swipe/smear samples.

5. Each sample must be placed in its designated plastic bag with the proper labeling. Avoid placing the samples in once plastic bag to prevent cross-contamination.

6. Repeat step 4, this time taking the samples at the body of the gauge. Each sample must be placed in its designated plastic bag.

6. Repeat steps 4, 5 & 6 for each radioactive source.

7. Check the wipe samples for gross contamination using a dose rate meter or a contamination monitor. The meter should be set to its most sensitive range and check in an area away from the industrial device to minimize the background radiation. Move the swab in its plastic bag to the meter, not the meter to the swab.

8. If the indication is no more than twice the background radiation, send/mail the samples to PNRI, c/o Radiation Protection Section (RPS), Nuclear Services and Training Division (NSTD), for more sensitive assessment.

9. If the wipe samples show twice the background or more, do not send the sample thru mail. Contact the PNRI for specific instructions.

10. Keep/file records of the results.

Note: It is required that the illustration of the industrial device indicating the areas where the wipe samples were taken be sent together with the samples to the PNRI.

APPENDIX D

OPERATING PROCEDURES

1. If personnel monitoring device is provided:

    a. Always wear your assigned TLD, OSL or film badge when using the gauge.
    b. Never wear another person's monitoring device.
    c. Never store your monitoring device near the gauge.

2. Use the gauge according to the manufacturer's or distributor's instructions and recommendations. Perform routine cleaning and maintenance according to the manufacturer's or distributor's instructions and recommendations.

3. Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the Manufacturer's Sealed Source Device certificate.

4. Do not touch the unshielded source with your fingers, hands, or any part of your body.

5. Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded source.

6. Post radiation warning signs at each entryway to an area where it is possible to be exposed to the beam.

7. Prevent unauthorized access, removal, or use of the gauge.

8. Reevaluate compliance with dose limits after making changes affecting the gauge such as, but not limited to, changing the location of gauges, removing the shielding, adding gauges, and changing the occupancy of adjacent areas.

9. Conduct physical inventory every 6 months to account for all sealed sources and devices.

APPENDIX E

RADIATION MONITORING PROGRAM

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

2. Measurements to be performed should include the following:
   a. Radiation level at the source housing with the source in the shielded position.
   b. Radiation levels at external surfaces of portable gauge.
   c. Radiation levels in storage room for portable gauge and disused radioactive sources.
   d. Radiation levels of containers for shipment of disused radioactive sources showing compliance with CPR Part 4, “Regulations for the Safe Transport of Radioactive Materials in the Philippines”.
   e. Radiation levels in uncontrolled areas.

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

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

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

6. If the results of the surveys indicate any dose rate values that are likely to exceed 0.03 mSv/hr at 10 cm from the surface of the industrial device that contained radioactive source, secure the area and cordon the surrounding area. Do not operate the device until corrective measures have been undertaken such as the reduction of the measurements to the acceptable dose rate, and the approval of the resumption of the operation by the RPO.

APPENDIX F

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 G

CRITERIA FOR ACCEPTABLE TRAINING PROGRAM FOR AUTHORIZED OPERATORS AND RADIATION PROTECTION OFFICERS

The following training program will be adopted and provided to individuals who frequent areas where a radioactive source is used or stored in order to avoid radiological health problems. Training will be in lecture format with a written outline of the presented scope provided to the individuals. Supporting handouts, audio/video tape may also be utilized. Training will be provided initially before assigning duties involving radioactive source and following changes in duties or procedures or potential radiation hazards. **Refresher courses** which cover all of the topics below will be provided every three (3) years.

Training for RPO, ARPO and Authorized Operator(s) may contain the following topics, commensurate with their duties:

Radiation Safety:

1. Radiation vs. contamination
2. Internal vs. external exposure
3. Biological effects of radiation
4. Types and relative hazards of radioactive material
5. ALARA concept
6. Use of time, distance, and shielding to minimize exposure
7. Location of sealed source within the gauge
8. Control and surveillance of gauges

Regulatory Requirements:

1. Applicable regulations
2. License conditions, amendments, renewals
3. Locations of use and storage of radioactive materials
4. Material control and accountability
5. Annual audit of radiation safety program
6. Transfer and disposal of radioactive materials
7. Recordkeeping
8. Handling incidents involving industrial gauges
9. Recognizing and ensuring that radiation warning signs are visible and legible
10. Licensing and inspection by the PNRI
11. Need for complete and accurate information
12. Employee protection
13. Deliberate misconduct

Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:

1. Operating and emergency procedures
2. Routine vs. non-routine maintenance
3. Lock-out procedures

In addition to the training requirements above, the following basic concepts of radiation and radioactivity should also be covered:

1. Atomic structure
2. Radiation and Radioactive decay
3. Radiation Quantities and Units
4. Interaction of Radiation with Matter

APPENDIX H

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 I

GENERAL GUIDANCE FOR DISPOSAL OF DISUSED RADIOACTIVE SOURCES

a) Prior to the import of a radioactive source:
   1) require the supplier, as a condition of any contract for purchase, to receive the source back after its useful lifetime within one year from the time the recipient requested such return, provided that the recipient seeks to return the source to the supplier not later than 15 years after purchase; and
   2) submit to the PNRI a copy of relevant parts of the contract or acceptance document and obtain its written agreement prior to entering the contract or accepting the source.

c) Do not dismantle any radioactive source.

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

e) Disused radioactive sources should be shipped back to the manufacturer in the original transport container or in a properly labeled and shielded transport container whose design is acceptable to PNRI.

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

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

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE
(Radioactive Sources Contained in Industrial Devices)

INSTRUCTIONS: To complete this application, refer to Part 16 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of an Application for a License for the Use of Radioactive Sources Contained in Industrial Devices. Submit one copy of the completed application, with the specified application/license fee and all required attachments, to the Nuclear Regulatory Division of the Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City.

This is an application for: (Check appropriate box)

☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

1. NAME AND MAILING ADDRESS OF APPLICANT.

Company: _____
Address: _____
Head of the Company: _____
Telephone/Mobile Phone Number: _____
Fax Number: _____
E-Mail Address: _____

2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Name: _____
Position/Title: _____
Address: _____
Telephone/Mobile Phone Number: _____
Fax Number: _____
E-Mail Address: _____

3. RADIOACTIVE SOURCE(S)

3.1 Radioactive Source(s) Contained in Industrial Devices

Radioactive Source (Element/ Mass Number)	Model Number	Serial Number	Manufacturer	Maximum Activity in each Radioactive Source (Bq)*(Indicate reference date for each source)*

4. PURPOSE(S) OF USE.

_____
_____
_____

5. LOCATION(S) OF USE.

5.1 Permanent Facility

Address: _____
Telephone Number: _____ _____
Fax Number: _____
E-Mail Address: _____ _____

5.2 Temporary Jobsites

Address: _____
Telephone Number: _____
Fax Number: _____ ___
E-Mail Address: _____

6. FACILITIES AND EQUIPMENT (Attach supplementary sheets, if necessary).

6.1 Industrial Device(s)

Device	Model Number	Serial Number	Manufacturer	For Use In	
				Permanent Facility	Temporary Jobsite
Industrial Devices					
Associated Equipment					

6.2 Radiation Survey Instruments

Type of Instrument	Model No.	Serial No.	Manufacturer	Sensitivity Range (mSv/h)	Date of Last Calibration	Organization to Perform Calibration

6.3 Personnel Monitoring Devices

Passive Devices	No. of Units	Name and Address of Supplier(s)	Frequency of Change	
Film Badge				
TLD				
OSL				
Active Devices	No. of Units	Name and Address of Supplier(s)	Date of Last Calibration	Range
Pocket Dosimeter				
Alarm Ratemeters				
Others				

7. PROPOSED RADIATION WORKERS.
(Accomplish Attachments A and B for the training and experience of each person named below and submit certificates of relevant trainings and experiences.)

Worker	Name	Description of Training/Experience
Radiation Protection Officer		
Assistant RPO		
Authorized Operators		

8. RADIATION SAFETY PROGRAM. (Check appropriate space and attach the required Information. Additional specific procedures may be required as may be deemed necessary.)

Description	**Attached**	**Remarks**
8.1 Organization		
8.2 ALARA Program		
8.3 Inventories		
8.4 Leak Testing of Radioactive Sources		
8.5 Operating Procedures		
8.6 Radiation Monitoring		
8.7 Installation, Repair and Maintenance		
8.8 Personnel Monitoring		
8.9 Transport of Radioactive Sources		
8.10 Emergency Plan and Procedure		
8.11 Recordkeeping		

9. TRAINING PROGRAM

10. SECURITY AND CONTROL OF RADIOACTIVE SOURCES.

11. RADIOACTIVE WASTE MANAGEMENT PROGRAM.

12. APPLICATION FEE _____ Official Receipt No. _____
Date: _____
LICENSE FEE _____ Official Receipt No. _____
Date: _____

13. CERTIFICATION.

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

_____
Signature over Printed Name

_____
Title/Position

_____
Date

14. 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

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

Title of Training	Place of Training	Date of Training

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

_____
Signature of Proposed RPO/ARPO

Date: _____

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

ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED OPERATORS OF INDUSTRIAL DEVICE

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

1" x 1" ID PHOTO

1. TRAINING IN RADIATION SAFETY

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

2. EXPERIENCE IN THE OPERATION OF AN INDUSTRIAL DEVICE

Equipment (Brand Name, Model/Serial Numbers)	Radioactive Source (Element & Mass No.)	Activity of the Source (Becquerels)	Where Experience was Gained	Duration of Experience (Months)

3. CERTIFICATES OF RELEVANT TRAININGS/EXPERIENCES

Title of Training	Place of Training	Date of Training

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

_____
Signature of Proposed Authorized Operator
Date: _____