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

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

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 and radiographic exposure devices for performing industrial radiography, in accordance with CPR Part 11, "Licenses for Industrial Radiography and Requirements for Radiographic Operations".

This regulatory guide is also intended to provide the information needed to understand the specific safety and security requirements and licensing policies that apply to gamma industrial radiography. A new application must correctly and adequately address the required radiation safety and security measures and procedures to provide the needed protection of radiation workers and members of the public and security of sources.

The applicant, however, may submit alternative safety and security measures and procedures which the PNRI will review to determine acceptability.

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.

1.2 APPLICABLE REGULATIONS

- CPR Part 3, "Standards for Protection Against Radiation", Official Gazette, 2004
- CPR Part 4, "Safe Transport of Radioactive Materials in the Philippines", Official Gazette, 2004
- CPR Part 11, "Licenses for Industrial Radiography and Requirements for Radiographic Operations", Official Gazette, 2010
- CPR Part 22, "Fees and Charges for Licensing Radioactive Materials and Other Related Regulatory Activities", Official Gazette, 2003
- CPR Part 26, "Security of Radioactive Sources", Official Gazette, 2007

It is the responsibility of license 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 radiography.

2. FILING AN APPLICATION FOR A LICENSE

An application for a new license must be filed by completing PNRI/NRLSD Form – 011, "Application for a License for the Use of Radioactive Sources and Devices in Industrial Radiography" in duplicate copies. The application must include all the information that are 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 license must be affirmed or notarized.

A copy of the applicant's registration with the Securities and Exchange Commission must be submitted with the application. The filing fee must be paid upon submission of the application and the appropriate license fee must be paid prior to the issuance of the license in accordance

with CPR Part 22, “Fees and Charges for Licensing Radioactive Materials and Other Related Regulatory Activities”.

3. CONTENTS OF APPLICATION

ITEM 1. NAME AND MAILING ADDRESS OF APPLICANT

The applicant may be an individual, an institution, a firm, or 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 an applicant. The address specified in the application should be the mailing address for correspondence. This may or may not be the same as the address at which the radioactive source is located and will be used. The telephone number, mobile phone number, facsimile number, and/or e-mail address of the applicant should be provided for easy and fast means of communication. The applicant should demonstrate or provide evidence of authenticity of business name issued by the Securities and Exchange Commission and a copy of business permit issued by the responsible government agency.

ITEM 2. PERSON TO BE CONTACTED ABOUT THE APPLICATION

The applicant must designate a contact person who can answer questions about the application. The contact person is typically the proposed RSO or a knowledgeable person who officially represents the management. The position or title, address, telephone number, fax number and/or e-mail address (if applicable) of the contact person must be specified. The PNRI must be notified if the contact person, address, telephone number, fax number or e-mail address changes. This is for information only and does not require any fee.

ITEM 3. RADIOACTIVE SOURCE(S)

3.1 Radioactive Sources Used in Radiography

Regulation: Section 7(p) and Section 28 of CPR Part 11

Criteria: The applicant shall ensure that the radioactive source is compatible with the radiographic exposure device and tested for leakage at intervals not to exceed six months.

Discussion:

The applicant/licensee must provide description of the radioactive source by indicating the radionuclide, model number, serial number, manufacturer or distributor of the source, and the maximum activity per source in Becquerels (Bq).

When carrying out gamma radiography, licensees should use only radioactive sources that meet international or equivalent national standards described below. These standards set out the normal operating conditions that a sealed radioactive source must withstand. Only radioactive sources that meet the following criteria should be used for industrial radiography. Sources should be:

- Certified as meeting the requirements of 'special form' radioactive material specified in the CPR Part 4;
- Designed, manufactured and tested to meet the requirements of the appropriate ISO standard or equivalent national standard;
- Leak-tested in accordance with the appropriate ISO standard and have a valid leak-test certificate that is traceable to each individual source.

Radioactive sources used for industrial radiography are normally part of a source assembly (often called a 'pig-tail') that is connected to the drive cable in source projection type systems. Source assemblies should be:

- Designed, manufactured and tested to ensure they meet the requirements of the appropriate ISO Standard or an equivalent national standard;
- Compatible with the exposure container, ancillary equipment (such as guide tubes) and any source changer with which they are used.
- Marked in accordance with CPR Part 4 or as a minimum, marked with the radiation trefoil sign and a legend "RADIOACTIVE". They should also be durably marked with the manufacturer's serial number.

The source assembly must be compatible with the specific exposure device it is intended to be used in and have proven testing in 50,000 cycle endurance test. Some manufacturers provide a recommended working life (RWL) for a sealed radioactive source. The RWL is based on a number of factors, including the half-life of the source and the construction of the sources capsule, and is an indication of the period of time over which the source is expected to retain its integrity.

3.2 Other Radioactive Sources

Identify by radionuclide, model number, and manufacturer or distributor (foreign or local) of any other radioactive sources (i.e., any source that will be used for calibration of survey instrument and will not be used for performing radiography). Indicate the total activity in becquerel (Bq) of each source and the purpose of use.

ITEM 4. LOCATION(S) OF USE

Regulation: Sections 8 (d) of CPR Part 11

Criteria:

Applicants must provide a specific address for each location where radioactive sources will be used or stored.

Discussion:

A description of the permanent radiographic installations must be submitted to PNRI. The locations should be precisely specified (e.g. the name of department, building, street address, or other descriptive address and telephone number) to allow the PNRI staff to easily locate the facility. A location map or building plan should be included. A post office box address is not acceptable.

Response from Applicant:

- If an exposure device will be used in a permanent radiographic installation, give the specific address of the location.
- If radiography equipment will be stored temporarily at field station, give specific address of each field station and describe the mode of storage of the exposure devices.

ITEM 5. FACILITIES AND EQUIPMENT

Regulation: Sections 7 (c) and (e), Section 30, and Section 35 of CPR Part 11; Section 13.6 of CPR Part 3.

Criteria:

Applicants/licensee must specifically identify and describe the facilities and equipment, in permanent radiographic installations and field stations, where industrial radiographic operations will be conducted.

5.1 Permanent Radiographic Installations

Discussion:

A permanent radiographic installation is an enclosed shielded area in which radiography may be performed. A facility is considered “permanent” if it is intended to be used for radiography. All radiographic operations conducted at locations of use authorized in the license must be conducted in a permanent radiographic installation. If licensees need to perform radiography at their place of business outside of a permanent facility due to unique circumstances (the item to be radiographed is too large for the facility), authorization from the PNRI for this method of use must be obtained

Requirements for a permanent radiographic installation:

1) Audible – visible signals:

Each access point is equipped with a visible-audible signal system. The signals are activated by radiation whenever the source is exposed or if anyone tries to enter the installation while the source is exposed. The requirement for the visible-audible signal system is in addition to other measures that may be taken to prevent access to the installation, such as locked doors.

2) Diagram depicting the shielding, layout, and audible-visual alarms:

A diagram of the installation is helpful in evaluating the shielding and determining compliance with regulations regarding restricted and unrestricted areas, location of access points and locations of audible-visible signals.

3) Calculations or survey results of radiation levels:

For a determination of installation adequacy, provide information showing that the radiation level in all directions around the installation, including the roof, will not exceed a dose of 0.02 mSv/h. Take into account the highest quantity of radioactive material that will be used in the installation and any limitations on source positioning in the installation. If no limitations are specified, then PNRI will assume that the source will be next to each of the walls. Radiation levels in all directions around the installation that are below 0.02 mSv/h are considered acceptable. If the radiation levels will exceed 0.02 mSv/hour, then steps should be taken (use lower-activity source, collimator) to reduce the radiation level to the acceptable level.

A radiation level on the roof that exceeds 1.0 mSv/hour is considered a “high radiation area” and requires special precautions to control access to the area. Licensees should make efforts to lower a radiation level exceeding 1.0 mSv/hour by using additional shielding, collimators, or other engineering controls. The roof of a fixed radiography cell is a potentially occupied area, and applicants must demonstrate that no individual member of the public could receive effective doses in excess of 0.02 mSv/h or 1 mSv/y.

Response from Applicant: Provide the following information for each installation:

Describe the permanent radiographic exposure facility. If possible, provide photographs of the facility. The description should include the following:

- Drawing or sketches of the facility and its surroundings.
- The scale to which the sketch or drawings are made. The recommended scale is 1 cm. = 0.48 m.
- The location of the source within the radiographic room.
- The type, thickness, and density of the shielding materials used on all sides of the room, including the floor and roof.
- Identification of entranceways and other points of access to the facility.
- The locations of doors, windows, conduits, and other penetrations and voids in the shielding materials.
- The nature of and distances to all areas adjacent to the radiographic room (including above and below).
- The type of use of all areas adjoining the radiographic room.

Variances will be considered if construction requirements preclude shielding the roof in order to meet the requirement not to exceed 0.02 mSv/h. Provide the following information to obtain approval for a variance:

- Means of preventing access to the roof.
- Procedures for ensuring that no individual is on the roof or could gain access to the roof during radiography.
- Posting the roof with "Caution (or Danger) Radiation Area" signs.
- Steps taken to minimize radiation on the roof.
- Limitations (if needed) on positioning of sources or amount of radioactive material that may be used in the installation to ensure that areas adjacent to, above, and below the installation will be unrestricted areas during the performance of radiography.

If the calculations or measurements show that radiation levels on the roof might exceed 1 mSv/hour, the applicant should consider the use of collimating devices or additional shielding in the roof or ceiling and posting the roof with "Caution (or Danger) High Radiation Area" signs.

A properly shielded facility will permit the performance of radiography within the facility with the areas outside the facility considered as unrestricted areas. A radiation level of not more than 0.02 mSv/h at a distance of 45 cm from any external surface of the facility will be considered acceptable for considering the area as unrestricted area.

If radiation levels on the radiographic installation roof exceed 1.0 mSv (100 mrem) in any one hour, then provide the following information in addition to the items above to apply for this variance:

- A commitment that the roof will be posted with "Caution (or Danger) High Radiation Area" signs.
- Evidence of constant surveillance of the roof by closed-circuit TV.
- Fluctuation of the dose rate.
- A description of a control device that would automatically reduce the radiation level to 1 mSv (100 mrem) in any one hour at 30 cm from the radiation source if someone enters the roof.
- A description of a control device that activates a visible-audible signal so that both an individual entering the roof and the radiographer on duty are made aware of the entry.

5.2 Field Stations

Discussion:

A field station is a facility where licensed material may be stored and/or used and from which equipment is dispatched. Radiographic personnel are required to maintain continuous direct surveillance of operations to protect against unauthorized entry to the high radiation area during

radiographic operations. Radioagraphic personnel should be instructed to keep the perimeter of the restricted area under continuous surveillance to prevent unnecessary exposure of individuals. Operating procedures should specify the steps for responding to an unauthorized entry to the restricted area. For example, personnel should be instructed to terminate the radiographic exposure immediately, before confronting the person who entered the restricted area.

All areas where radiographic operations are conducted require posting of the radiation areas and the high radiation areas. Personnel should be instructed to post “Caution Radiation Area” signs at the point where radiation levels have been calculated to reach 0.02 mSv in any one hour. A confirming survey during the first exposure of the source should be conducted to confirm the location of the boundary and any necessary adjustments should be made.

The perimeter of the high radiation area must be posted with “Caution (or Danger) High Radiation Area” signs at the point where radiation levels have been calculated to reach 1 mSv in any one hour. A confirming survey of the high radiation area perimeter should not be conducted, since such a survey could lead to unnecessary exposure of the personnel.

Response from Applicant:

Provide the following:

- Describe the storage location(s) at the address (es) listed in the application and submit a diagram showing where the radiography camera will be stored at the field stations.
- Provide the telephone number, fax number and e-mail address in each facility, as applicable.
- Indicate whether or not radiography will be performed at the place of business outside of a permanent radiographic installation. If radiography will be performed at a site outside of a permanent radiographic installation, provide a diagram of the location where radiography may be performed and its surroundings, including a description of adjacent property.

Note: ***Certain records described in the regulations which pertain to radiation safety may need to be on file at these field stations and each temporary jobsite.***

5.3 Radiation Survey Instruments

Regulation: Section 7(j) and Section 36 of CPR Part 11

Criteria:

A radiation survey meter intended for industrial radiography that utilizes sealed radioactive sources should:

a) Be capable of accurately measuring the radiation fields produced by the sealed radiography source currently in use;
b) Be visually checked for damage and for proper operation with a check source before use on each day; and
c) Be calibrated at intervals not to exceed 6 months and after each servicing (except for battery changes).

Discussion:

Licensee shall keep an adequate number of appropriate radiation survey instruments that are calibrated and operable, at each location where radioactive material is present to make the required radiation surveys. Written procedures are required for inspection and routine maintenance of the survey meters to ensure proper functioning.

The instruments shall be capable of measuring from 0.02 mSv/h through 10 mSv/h. Each radiation survey instrument shall be calibrated at intervals not to exceed 6 months and after each instrument servicing, except for battery changes.

Records of survey instrument calibrations shall be kept and retained for 2 years.

Appendix A shows a model procedure for calibrating radiation survey instruments.

Response from Applicant:

Provide the following:

a) A statement that: "We will possess and use adequate number of appropriate calibrated and operable radiation survey meters";

and

b) If instrument calibration will be performed by another organization, the application should include the name, address and license number of the organization **(PNRI license number if based in the Philippines).**

or

c) If an applicant intends to calibrate survey instruments in-house, the following information should be submitted:
   - The type (radioisotope, model number, serial number and manufacturer) and exposure rate of the source to be used for calibration.
   - The accuracy of the source that will be used.
   - Description of the calibration program for the survey instrument.
   - The specific procedures to be used for calibration, including radiation safety procedures to be followed.
   - The name and pertinent experience of the individual who will perform instrument calibration may be omitted if the applicant has an adequate program for the training of radiographers that includes instrument calibration procedures. If radiographers will perform instrument calibration, specific instructions and procedures should be written for use by radiographers and should be included in the operating and emergency procedures.

d) Survey instruments should be identified by type (i.e., ionization chamber, G.M., scintillation) and exposure range.

5.4 Personnel Monitoring Devices

Regulation: Section 7(k) and Section 38 of CPR Part 11

Criteria:

The RSO, ARSO, radiographers, and radiographer's assistants should at all times during radiographic operations wear a personnel monitoring device.

Discussion:

The licensee should provide occupational workers working in controlled areas with suitable and adequate personnel monitoring devices (e.g., pocket dosimeters, thermoluminescent dosimeters (TLDs), film badges). The pocket dosimeters should be operable, calibrated, and tested for drift at intervals not to exceed 1 year. Records of calibration must be maintained for two years. Film badges should be worn so that the part of the body likely to receive the greatest dose will be monitored. These badges and the TLDs should be sent to PNRI for processing.

Alarm ratemeters should be checked to ensure proper functioning prior to use at the start of each shift. Calibration should be done at periods not to exceed one (1) year. Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.

Response from Applicant:

- Specify the type of personnel monitoring device (for example, film badge or TLD, pocket dosimeter, alarm ratemeter) that will be used, number of units of each device, the names and addresses of the suppliers, and the date of last calibration, as applicable.
- Specify the frequency of change of film badge or TLD.
- Specify the range of pocket dosimeters to be used (0-200 mR).
- Describe the procedure for checking pocket dosimeter linearity and energy response.

ITEM 6. PROPOSED RADIATION WORKERS

6.1 RADIATION SAFETY OFFICER (RSO) AND ASSISTANT RSO

Regulation: Section 7(d) and Section 17 of CPR Part 11

Criteria:

RSOs and ARSOs must have adequate training and experience.

Discussion:

The person responsible for the radiation safety program is called the RSO. The RSO shall be responsible for overseeing and ensuring safe operation of the licensee's radiography program. The RSO needs independent authority to stop any licensed activity that he considers unsafe. He must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive material are used in a safe manner. The RSO should ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the course of the daily operation. The assistant RSO will perform the duties and responsibilities of the RSO in his absence.

Appendix B describes the duties and responsibilities of the RSO.

Response from Applicant:

Provide the following:

- The name of the proposed RSO and assistant RSO who will be responsible for the radiation protection program.
- The specific training and experience of the RSO and ARSO.
- Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position, demonstrating day-to-day oversight of the radiation safety activities.

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

6.2 RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS

Regulation: Section 7(i), Section 19, Section 20 of CPR Part 11

Criteria:

The licensee shall only authorize an individual to act as radiographer or radiographer's assistant if he has met the training and experience requirements prescribed in the regulation.

Discussion:

The licensee should have a complete training program which includes appropriate references to any instructions given by outside service agencies. The name, training and experience with radiation of each person who will provide substantial input for the instruction, examination or qualification of trainees should be given in sufficient detail to establish his qualifications to perform these services. If an individual will teach only certain parts of the course, this should be specified.

In certain cases where a radiography program is limited to a few individuals and personnel turnover is not anticipated, a complete training program may not be necessary provided each individual has had adequate training and experience. In such a situation, the applicant should request that specific individuals be named on the license in lieu of submitting details of a complete training program.

When the applicant has not established a complete program for training radiographers and radiographer's assistants, the limitations imposed in licenses should be clearly understood. The applicant will specifically name each individual authorized to act as a radiographer or radiographer's assistant. The individuals named in the application must be qualified to perform all radiographic operations conducted under the license, including the manipulation of equipment and the performance of radiation surveys. No individual may act as radiographer's assistant unless the license has been amended to provide for an individual to act in that capacity. An individual should not enter into on-the-job training until the license has been amended to permit that training.

The qualification of each individual designated as radiographer or radiographer's assistant should include the following information:

- The individual's name and the capacity in which that individual will function (radiographer or radiographer's assistant).
- A detailed description of each individual's training and experience in the principles of radiation and radiation safety. The information provided should specify when (dates) and where training was received. The name of the individuals who provided the training should include names of previous employers, dates employed, type of equipment used, and the length of time the equipment was used for each previous employer.
- The specific experience of each individual in the use and handling of the type of equipment specified in the application. The information should include names of previous employers, dates employed, type of equipment used and length of time the equipment was used for each previous employer.
- A description of the instruction that each prospective radiographer and radiographer's assistant has received on the applicant's operating and emergency procedures.
- A description of the means used to determine competence of individuals to act as radiographers and radiographer's assistants and by whom such determination is made. Copies of examinations given to determine their knowledge and understanding of the topics in **CPR Part 11**, applicant's operating and emergency procedures, PNRI regulations and use of equipment should be submitted.

Appendix C describes the elements of a training program that is acceptable to PNRI.

Response from Applicant:

- Submit an outline of the training to be given to prospective radiographers and radiographer’s assistants. Submit your procedure for determining the knowledge and competency for experienced radiographers who have worked for another licensee.
- Specify the qualifications of your instructors in radiation safety principles and describe their experience with radiography. If training will be conducted by someone outside the applicant’s organization, identify the course by title and provide the name and address of the company providing the training.

- Describe the annual refresher training program, including topics to be covered and how the training will be conducted.
- Submit your procedures for verifying and documenting the certification status of radiographers and radiographer's assistants and for verifying that their certification remains valid.
- Submit the complete list of radiographers and radiographer's assistants. Include their complete addresses.
- Attach the updated resume of the relevant training and experience of each individual including certificate of training.

ITEM 7. RADIATION SAFETY PROGRAM.

7.1 ORGANIZATION

Regulation: Section 7 (b) of CPR Part 11

Criteria:

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

Discussion:

Management personnel occupying positions of authority must exercise active control over the radiography program. 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 management, the application should identify those persons and specify how management will ensure that their duties are properly performed.

Response from Applicant:

The applicant should:

- Submit a description of the overall organizational structure pertaining to the radiography program, including personnel assignments, and delegations of specific authority and responsibility for the program.
- Describe how active control over the radiography program will be exercised by management personnel.
- Provide the name, training and experience of the individual who will exercise management control over the radiography program and radiographic operations.

7.2 INTERNAL INSPECTION PROGRAM

Regulation: Section 7(g) and Section 32 of CPR Part 11

Criteria:

The applicant should have an adequate internal inspection program to ensure that its radiographers and radiographer's assistants comply with the regulatory requirements in accordance with Section 32 of CPR Part 11.

Discussion:

The licensee should have an internal inspection system for controlling the receipt, possession, use and disposition of radioactive material. The system should ensure that license conditions, PNRI regulations and operating and emergency procedures are followed by radiographers and radiographer's assistants.

Internal inspections, including evaluation of radiographers and radiographer's assistants, should be made by a person of authority in management. This person should have a thorough knowledge on equipment, procedures, regulations and level of compliance and competence at or above that expected of the radiographer.

Other management controls may include a description of:

- The type of internal inspection to be made and their frequency;
- The qualification of each person responsible for maintaining such control;
- The responsibilities of each person in the program;
- The procedure for recording and reporting deficiencies to appropriate management personnel; and
- The education and follow-up program to be utilized in correcting deficiencies noted during inspections.

The type and extent of the radiography program to be conducted will usually determine the nature of the internal inspection system and inspection frequency. **An internal inspection should be performed at intervals not exceeding three (3) months and the records of each inspection be retained for three (3) years**.

Appendix D describes the criteria for establishing the Inspection & Maintenance Program for Radiographic Equipment.

Response from Applicant:

- Provide a description of the internal inspection system for controlling the receipt, possession, use and disposition of radioactive material.
- Describe how management makes a continuing review of quarterly inventories, utilization logs and records of receipt and disposal of licensed material, personnel monitoring results and surveys, maintenance of equipment, and survey instrument calibration.
- Specify other management controls.

7.3 ALARA PROGRAM.

Regulation: Section 16 of CPR Part 11.

Criteria:

Each licensee must have an adequate radiation safety program, the content and implementation of which must be reviewed at least **every 12 months** to ensure the following:

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

Discussion:

Each licensee must develop and implement a written radiation safety program that includes:

- a description of functions and program of the organization;
- notice to workers of the program's existence;
- functions and responsibilities to help keep equivalent dose ALARA;
- a review of summaries of occupational doses;
- changes in radiation safety procedures and safety measures; and
- continuing education and training for all personnel who work with, or in the vicinity of radioactive sources.

The radionuclide and the activity of the radiographic source are selected such that the dose for all workers is kept ALARA, consistent with obtaining adequate diagnostic information. It is

possible to do most radiographic work by using iridium-192 with an activity of up to 1850 GBq (50 Ci). Advanced techniques are available, such as image intensifying screens or fast film and screen combinations, to keep doses ALARA.

Appendix E shows a model ALARA program.

Response from Applicant:

The applicant should submit its ALARA program in accordance with Section 16 of CPR Part 11.

7.4 MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: Section 44 (c) and (f) of CPR Part 11.

Criteria:

Licensees must do the following:

- Maintain records of receipt, transfer, and disposal of sources/devices and
- Conduct physical inventories at quarterly intervals (not to exceed 3 months) to account for all radioactive sources containing byproduct material and devices containing depleted uranium.

Discussion:

Licensed materials must be tracked from "cradle to grave" in order to ensure accountability; identify when sources/devices may be lost, stolen, or misplaced; and ensure that the possession limit stated on the license is not exceeded.

Conduct physical inventories (i.e., locate, verify the presence of the material, and account for it in material transfer records) at quarterly intervals (not to exceed 3 months) to account for all radioactive sources and devices containing depleted uranium.

Maintain inventory records that contain the following types of information:

- Radionuclide and amount (in units of Bq) of byproduct material in each radioactive source
- Manufacturer's name, model number, and serial number of each radioactive source containing byproduct material.
- Manufacturer's name, model number, and serial number of each device containing depleted uranium or byproduct material.
- Location of each radioactive source and device.
- Date of the inventory.
- Name of individual performing inventory.

Response from Applicant:

Provide the following:

A statement that: "Physical inventories will be conducted and documented at quarterly intervals (not to exceed 3 months) to account for all radioactive sources containing byproduct material and devices containing depleted uranium received and possessed under the license."

7.5 LEAK TESTING OF RADIOACTIVE SOURCES

Regulation: Section 28 of CPR Part 11

Criteria:

PNRI requires testing to determine whether there is any radioactive material leakage from the source or from devices containing depleted uranium shielding. PNRI finds leak testing to be

acceptable if it is conducted by organizations authorized by PNRI or conducted in accordance with procedures approved by PNRI.

Discussion:

PNRI may authorize qualified organizations to 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 device manufacturer's and 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 subject to certain requirements. Measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity. Sealed sources containing radioactive material must be leak tested at intervals not to exceed 6 months.

Each radiographic exposure device using depleted uranium (DU) shielding and an “S-tube” configuration shall be tested for DU contamination at intervals not to exceed twelve (12) months. Should the testing reveal the presence of 185 Bq or more of removable DU contamination, the exposure device must be removed from use until evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again.

Appendix F describes the program for leak testing of radioactive sources.

Response from Applicant:

Do either of the following:

- "Leak tests will be performed by an organization authorized by PNRI to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by PNRI to provide leak test and/or services to other licensees and according to the instructions provided in the leak test kit".

or

- "Leak tests will be done by applicant. Provide the information to perform leak testing and sample analysis and either state that you will follow the model procedures in **Appendix E** or describe alternative procedures".

7.6 OPERATING AND EMERGENCY PROCEDURES

Regulations: Section 7 (f) and (l) and Section 22 of CPR Part 11

Criteria:

Operating and emergency procedures must be established and submitted to PNRI as part of the application. Operations such as source change, leak-testing, and quarterly inspection and maintenance of equipment, appropriate procedures and instructions for these operations should be included in the operating and emergency procedures.

Discussion:

The purpose of operating and emergency procedures is to provide radiography personnel with specific guidance for all operations they will perform. These topics should be included in the operating and emergency procedures and need not be presented in order of importance. A sequential set of procedures and instructions from the beginning to the end of the workday is an acceptable format. Instructions for non-routine operations, for example, quarterly inspection and maintenance or instrument calibration may be included.

Response from Applicant:

Each licensee must develop, implement, and maintain operating and emergency procedures that include, at least, the instructions in 7.6.1 to 7.6.11 below. Such procedures must be submitted to PNRI for review.

7.6.1 Handling and Use of Licensed Radioactive Sources, Radiographic Exposure Devices, Source Changers, and Instrument Calibration Equipment.

Regulation: Section 22 (a)(1) of CPR Part 11

Criteria:

The licensee's operating and emergency procedures should include instructions on appropriate handling and use of radioactive sources, radiographic exposure devices, source changers, and storage containers such that no person is likely to be exposed to radiation doses in excess of the limits established in CPR Part 3.

Discussion:

Specific procedures should be required for performing source changes, including those in the field and in permanent radiographic installation. The procedures should contain warnings of areas of concern during source changes. Recent incidents of sources becoming dislodged from the shielded position indicate the importance of training personnel in the appropriate techniques. Procedures should require the use of survey instruments during and after movement of sources.

- Step-by-step instructions of the "cookbook" type for the use and handling of radiographic exposure devices and related equipment should be provided. When appropriate, the procedures should include instructions for use of radiation collimating cones or other auxiliary shielding material.
- If source change will be performed by radiography personnel, step-by-step instructions for source change, including surveys to be performed during the source change and acceptable radiation levels for these surveys, should be in the procedures. Such instructions should also state the steps to be taken if the survey levels exceed acceptable limits.
- If radiography personnel will perform survey instrument calibration, step-by-step instructions should be in the procedures.
- If radiography personnel will perform leak testing of radioactive sources, specific instructions for performing the leak test should be in the procedures. If the applicant will use commercially available leak-test kits, the instructions and procedures provided by the kit suppliers should fit the applicant's program.

Response from Applicant:

- Provide step-by-step instructions for using each type of radiographic exposure device.
- Include instructions for performing source changes.

7.6.2 Conducting Radiation Surveys.

Regulation: Section 22 (a)(2) and Section 37 of CPR Part 11

Criteria:

Perform radiation surveys during use, movement, and storage of licensed material to ensure its safe use and storage and comply 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 a source is manipulated or moved. Surveys that need to be performed should include:

- Determination after each exposure that the source has returned to the safe storage position. The entire circumference of the radiographic device must be surveyed, including the guide tube.
- Determination of the boundary of the restricted area.
- Determination of radiation levels at external surfaces of exposure devices in storage facilities.
- Determination of radiation levels in and around vehicles used for transporting or storing sources and exposure devices.
- Determination that the source is in the safe storage position prior to securing a radiographic exposure device or source changer.
- Determination that containers prepared for shipment comply with the requirements in CPR Part 4, "Safe Transport of Radioactive Material in the Philippines". (For example, 0.1 mSv/h at 1 meter from any surface and 2 mSv/hour at the surface of the container).

The acceptable radiation levels for surveys should be expressed in mSv/hour. Section 37(c) of CPR Part 11 requires that the records of specific surveys be maintained.

Response from Applicant:

Operating and emergency procedures must include each of the surveys enumerated above, where applicable.

7.6.3 Controlling Access to Radiographic Areas.

Regulation: Section 22(a)(3), Section 31 of CPR Part 11

Criteria:

Licensees must control access to areas where licensed material is used or stored to prevent the unnecessary exposure of members of the public. This can be achieved through the use of posting, locking devices in areas where licensed materials are stored, and by maintaining constant control and continuous surveillance of areas where radiographic operations are conducted. Operating and emergency procedures should include steps for radiographic personnel to ensure that access to licensed materials is controlled.

Discussion:

Field/Temporary Jobsites

Instructions for controlling access to radiographic areas should be specifically stated in the procedures.

The boundaries of radiation areas and high radiation areas are required to be posted. **"Caution Radiation Area"** signs should be posted at the boundary of the restricted area at the point where radiation levels have been calculated to reach 0.02 mSv in any one hour. **"Caution High Radiation Area"** signs should be posted at the boundary of the high radiation area at the point where radiation levels have been calculated to reach 1 mSv in any one hour.

Signs, by themselves, do not provide adequate means of access control. For radiographic operations performed outside a permanent radiographic installation, instructions requiring surveillance of the area are necessary. The instructions for control of access to permanent radiographic installations should be separate and distinct from the instructions for temporary job-site operations.

A physical survey with a survey meter should be performed to confirm the 0.02 mSv/hour radiation level for the restricted area boundary after the source has been exposed. It is neither necessary nor desirable for a physical survey to be made to confirm the radiation level at the boundary of the high radiation area since such a survey may lead to unnecessary exposure of personnel.

Permanent Radiographic Installations

Instruct personnel about posting each entrance to the facility with a "Caution (or Danger) High Radiation Area" sign(s), and provide procedures to ensure that the visible-audible signal system is operable. The operability of the visible-audible system must be checked daily. The following procedures may be used:

- Expose a radiation source in the permanent installation with all entrances closed.
- Determine that each visible signal in and outside the installation is functional.
- Open the door to each entrance into the installation to activate the audible alarm.
- Close the entrance and confirm that the alarm stops. If the installation has more than one entrance, only one entrance should be tested at a time.
- Record results of test.

Specific instructions concerning use of interlocking devices and systems, locking of the facility, security of keys, use of warning lights and alarms, etc., should be included in the procedures.

Storage Areas

Radiographic equipment containing licensed materials stored in controlled areas must be secured from unauthorized removal or access. Operating procedures should specify how stored licensed materials should be secured and who has authorized access to licensed material.

A vehicle used to transport licensed material can also be used for temporary storage at locations such as temporary job sites or overnight lodging. If the applicant plans to use vehicles for storage, there should be procedures and instructions to personnel about proper posting of the vehicle. Vehicles should be posted with a "Caution – Radioactive Material" sign on the entrance to the area of the vehicle where licensed material is stored. A physical survey should be performed to confirm that the area around the storage facility is an unrestricted area. Radiation levels may not exceed 0.02 mSv/hour from any external surface of the vehicle and the vehicle should be locked when it is used for storage.

Radiographic equipment stored at temporary job sites must be secured at a location that prevents access by unauthorized personnel. This usually requires that the equipment be locked in a cabinet or other secure area where key access is controlled by site management and radiographic personnel. It is not acceptable for a device to be chained to a post and left unattended at the place of use during lunch, breaks, or after hours. Storage of exposure devices at a private residence is unacceptable unless it has been identified and approved in the license.

Response from Applicant:

Submit procedures to control access to radiographic operations and storage areas.

a) Submit a description of the storage vault/pit including photographs and a drawing with dimensions and shielding details. Survey information, if available, should be supplied.

b) Submit a description of the security measures provided to prevent unauthorized removal of devices containing radioactive material.

c) Submit a description of the building in which the storage vault/pit is located, its relationship to other buildings in the area (especially to occupied office areas) and a description of the security provided by the building to prevent any unauthorized entry into the storage vault/pit.

d) Submit a detailed description of the precautions that will be taken for storage of radioactive material. This should include the following:

- Detail of storage vault/pit or container that is provided in transporting vehicles, including dimensions and shielding information.
- Posting of radiation and warning signs.
- Precautions that will be taken to prevent unauthorized removal of radioactive material.

7.6.4 Locking and Securing Radiographic Exposure Devices, Storage Containers, and Radioactive Sources.

Regulation: Section 27 and Section 22 (a)(4) of CPR Part 11

Criteria:

PNRI regulations require locking and securing radiographic equipment to protect the public and radiographers from inadvertent exposures to radiation.

Discussion:

All radiographic devices, i.e., gamma cameras, radioactive source storage containers, and source changers are required to have a lock or outer-locked container to maintain the radioactive source in its shielded position. During radiographic operations the source must automatically be secured in the shielded position each time the source is returned. Radiographers must not attempt to circumvent the automatic securing features or tamper with the safety features of radiographic devices. Radiographers must never leave the exposure device at the temporary job site without securing it properly from unauthorized removal or tampering. Except at permanent radiographic installations, radiographers and radiographer's assistants must ensure that the exposure device and source changers are maintained locked.

Response from Applicant:

Submit operating and emergency procedures that include procedures for locking and securing radiographic equipment.

7.6.5 Personnel Monitoring and Use of Personnel Monitoring Equipment.

Regulation: Section 22 (a)(5) and Section 38 of CPR Part 11

Criteria:

The licensee's operating and emergency procedures should include instructions on the conduct of personnel monitoring and the appropriate use of personnel monitoring equipment.

Discussion:

Radiography personnel are required to wear their personnel monitoring devices, e.g., direct-reading dosimeters and either film badges or TLDs, or alarm ratemeters when they are engaged in radiographic operations.

Film badges or TLDs must be assigned to and worn by only one individual. To ensure full-scale reading capability, direct reading such as pencil (pocket) dosimeters or electronic personal dosimeters must be recharged or reset at the start of each shift so that the dosimeters will be capable of reading the full scale. Personnel should be instructed that direct reading dosimeters must be read and recorded at the beginning and end of each shift. Proper operation of alarm ratemeters must be checked each day before use.

An instruction concerning steps that must be taken immediately by radiography personnel 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 or TLD be processed immediately if his pocket dosimeter is discharged beyond its range.

Include instructions about how and where dosimetry devices are to be stored when not in use. The storage place should be dry, radiation free, and cool so that the devices will not be affected by adverse environmental conditions.

All radiographers or radiographer's assistants are required to wear alarm ratemeters except at permanent radiographic facilities where other appropriate alarm or warning devices (e.g., visible and audible alarms) are in routine use and are operable.

Response from Applicant:

The operating procedures must include instructions for personnel monitoring and proper use of personnel monitoring equipment.

7.6.6 Transporting Radioactive Sources to Field Locations, Packaging of Radiographic Exposure Devices and Storage Containers in the Vehicles, Posting of Vehicles, and Control of the Radioactive Sources.

Regulation: Section 7(n), Section 22 (a)(6) of CPR Part 11

Criteria:

Licensees must develop, implement, and maintain procedures for transporting radioactive material, radiographic exposure devices, and storage containers to ensure compliance with **CPR Part 4, "Safe Transport of Radioactive Materials in the Philippines"**. These regulations cover, among other things, packaging and securing of radiographic exposure devices and storage containers in the vehicles and posting of the vehicle during transportation.

Discussion:

Industrial radiographic exposure containers should satisfy the requirements of Type A or Type B packages for transport. The following items should be covered in instructions to personnel:

- Labeling containers appropriately (i.e., when to use labels Radioactive White I, Radioactive Yellow II, or Radioactive Yellow III).
- Securing the exposure device or storage container within the transporting vehicle. The instructions should specify how to prevent the package from moving during transport.
- Preparation of shipping papers. The instructions should specify that the papers must be completed before transporting the licensed material and must be accessible in the driver's compartment at all times.
- Placarding both sides, the front, and the back of the vehicle with "RADIOACTIVE" placards if the package being transported requires a Radioactive Yellow III label. If the vehicle requires placarding, exterior surfaces and passenger compartment of the vehicle must be surveyed to ensure that the radiation levels do not exceed 0.02 mSv/h at 45 cm (18 inches) from any exterior surface and 0.02 mSv/h in the passenger compartment. Include instructions to personnel on the measures to take if the radiation level exceeds 0.02 mSv/h in the passenger compartment (e.g., adding more shielding or repositioning the device within the vehicle.
- If an exposure device is transported in an overpack, the procedures should include instructions that the overpack must be properly marked with the shipping name and identification number, labeled (Radioactive White I, Radioactive Yellow II), and marked when required with a statement that indicates the inner package complies with prescribed specifications.

When a vehicle is used for storage, i.e., when the sources are not being transported, the posting requirements in **CPR Part 3, "Standards for Protection Against Radiation"** are applicable, and the vehicle should therefore be posted with **"CAUTION-RADIOACTIVE MATERIAL"** signs.

Operating organizations, who are often the consignors (shippers) of exposure devices to and from temporary work sites, should ensure that all packages are properly prepared for transport, including the securing of all required plugs, caps and locks before transport. All conditions of any applicable authorization for the package must be met.

Gamma exposure devices are frequently transported by road by the operating organizations. Drivers and vehicles must comply with the applicable requirements of national and international roads. These requirements prescribe the necessary safety equipment on vehicles, placarding, transport documentation and training of drivers.

Response from Applicant:

Submit operating and emergency procedures for transporting radioactive sources, exposure devices, and source changers.

7.6.7 Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, Associated Equipment, Source Changers and Survey Instruments.

Regulation: Section 22 (a)(7), Section 29 of CPR Part 11

Criteria:

The licensee shall perform visual and operability checks on survey instruments and radiography equipment before use on each day of use.

Discussion:

Visual and operability checks must be performed on radiographic exposure devices and associated equipment, and storage containers before use each day the equipment is used. These checks are intended to ensure that the equipment is in good working condition.

Inspection records shall contain information about equipment problems found in daily checks and quarterly maintenance inspections. Records shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

Inspections are to be made before the equipment is used each day. While not a requirement, good practice would be that if the equipment is used on more than one shift in the day, the equipment should be inspected before the start of each shift.

The procedures should specify the items that are to be checked and the steps that are to be taken if any defects are found. If problems are found, the equipment must be removed from service until it is repaired.

A list of items that should be checked in the daily inspection of radiography equipment should be provided.

Permanent radiographic installation visible and audible alarms must be checked for operability daily before use, and faulty radiographic equipment must be repaired within 7 days, with compensatory measures taken in the interim. Compensatory measures taken include:

- Immediately label faulty equipment as defective.
- Continuous surveillance requirements are implemented until repairs are completed.
- Alarm ratemeters shall be worn and checked for alarm function at the beginning of each shift.

- Records must be maintained of faulty equipment.

Direct reading dosimetry devices must be read and the exposures recorded at the beginning and end of each shift. Alarm ratemeters shall be checked for alarm function at the beginning of each shift. Records are to be maintained.

Inspection and preventive maintenance of equipment prior to the first use and at intervals not exceeding three (3) months thereafter are also required by **Section 29 of CPR Part 11**. The procedures should contain clear and specific instructions for inspection and maintenance. As part of the inspection and preventive maintenance program, all connectors, drive cables, source guide tubes, on-off indicator mechanisms, and moving parts should be checked for defects. Cables should be cleaned and lubricated, and all defective and excessively worn components repaired or replaced. If components essential to the safe operation of the device are found to be defective or in poor operating condition, the device should be immediately removed from service and an instruction to be followed in this event should be written. Records of quarterly inspections and maintenance must be kept for two (2) years.

Response from Applicant:

Submit procedures for daily inspection and maintenance of radiographic equipment.

7.6.8 Ratemeter Alarms or Off-Scale Pocket Dosimeter Readings.

Regulation: Section 22 (a)(8), Section 38(c) of CPR Part 11

Criteria:

Licensees must instruct personnel in:

- The licensee's license and operating and emergency procedures.
- Actions to be taken if a dosimeter shows off-scale reading or an alarm ratemeter alarms unexpectedly.
- Procedures for notifying the proper persons in the event of an accident.

Discussion:

The RSO must be notified immediately if an individual's self-reading pocket dosimeter is found to be off-scale, an individual's electronic personal dosimeter reads above 2mSv, or an alarm ratemeter alarms (sounds, etc.) unexpectedly. If radiation exposure cannot be ruled out by the RSO or designee as the root cause, the individual's film badge or TLD must be sent to PNRI for processing within 24 hours. The effected individual may not resume work with licensed radioactive material until the RSO or designee has determined the individual's radiation exposure.

If any of the events described above should occur, personnel should be instructed to do the following at a minimum:

- Stop work immediately, place the source in the safe storage position in the exposure device, and vacate the radiation area.
- Initiate emergency procedures if the source is exposed and cannot be retracted; otherwise, retract the source safely.
- Notify the Radiation Safety Officer immediately. In this regard, the name of the RSO and manner in which this individual can be reached should be included in the emergency procedures.
- If the alarm ratemeter sounds, evaluate pocket dosimeter reading.
- If pocket dosimeter is off-scale, do not resume operations until authorized by the RSO.

Response from Applicant:

Submit operating and emergency procedures to address ratemeter alarms or off-scale dosimeters.

7.6.9 Identifying and Reporting Equipment Malfunctions and Defects.

Regulation: Section 22 (a)(l5) of CPR Part 11.

Criteria:

Licensees must notify PNRI if defects are found in the radiography equipment.

Discussion:

Equipment deficiencies or failures that could create a substantial safety hazard must be reported to PNRI. If the radiographer discovers any malfunction or defect in the equipment, the radiographer should notify the RSO. Procedures to be followed in such event should tell the radiographer what to report, when to report the problem, and the individual to whom it should be reported.

Response from Applicant:

Submit operating and emergency procedures for notifying management of equipment malfunction or defect.

7.6.10 Recordkeeping.

Regulation: Section 22 (a)(12) and (b), Section 44 of CPR Part 11

Criteria:

The licensee shall meet the recordkeeping requirements at permanent and temporary jobsites in accordance with Section 44 of CPR Part 11.

Discussion:

Personnel must generate and maintain certain records when performing radiography, including:

a) Utilization logs showing the following:
   - Description, including the make, model, and serial number of the exposure device used.
   - Identification and signature of the radiographer.
   - Where the device is used and dates of use, dates and times device is removed and returned to storage.

b) Records of daily inspection of equipment
c) Pocket dosimeter readings recorded at the beginning and end of a work shift.
d) Results of the physical survey following each day's final exposure.
e) Records of the calibrations of radiation survey instruments.
f) Records of leak test results for radioactive sources and for devices containing depleted uranium.
g) Records of shipment of packages.
h) Records of quarterly inventory of radioactive sources.
i) Records of training and certification of radiographers and radiographer's assistants.
j) Records of current operating and emergency procedures.
k) Records of exposure of each individual employee

Radiographers performing radiographic duties should be given specific instructions for recordkeeping. These should not include instructions about records that are the responsibility of management and supervisors.

Response from Applicant:

Submit operating and emergency procedures which ensure proper maintenance of records.

7.6.11 Emergency Planning and Response.

Regulation: Section 7(l) of CPR Part 11

Criteria:

An emergency plan must be established in accordance with the requirement of Section 7(l) of CPR Part 11.

Discussion:

Accidents have occurred in industrial radiography resulting in workers and members of the public being exposed to radiation and other health and safety hazards. Typical situations which have led to a radiological hazard include loss of control of the source or exposure device, damage to the source or exposure device, and direct contact with the source.

An emergency plan in case of an accident that could involve radiation sources must include, in accordance with Section 17 of CPR Part 3:

a) a description of the licensed facility and areas in the vicinity of the facility;
b) an identification of each type of accident involving radioactive materials for which protective actions may be needed;
c) a system for classifying accidents as alerts or site area emergencies;
d) means and methods for detecting each type of accident in a timely manner;
e) a description of the means and equipment for mitigating the consequences of each type of accident;
f) a description of the methods and equipment to assess releases of radioactive materials;
g) a description of the responsibilities of emergency response personnel;
h) provisions for training of emergency response groups and for conducting emergency drills and exercises;
i) a description of measures to restore the facility to safe normal condition after an accident; and
j) provision for a periodic review or update of the emergency plan.

In the event of a transport accident, the vehicle driver, local emergency services or any other person discovering the accident will contact the package consignor and/or the consignee who are identified on the transport documentation. Both organizations are to be fully aware of the emergency plans and provide or call for practical advice and assistance.

Appendix G provides Specific Emergency Procedures.

Response from Applicant:

Applicant must submit an emergency plan and provide training to personnel who will be involved in emergency response.

7.6.11.1 Minimizing Exposure of Persons in the Event of an Accident.

Regulation: Section 22 (a)(9) of CPR Part 11

Criteria:

Exposure of persons to radiation must be maintained as low as possible in the event of an accident.

Discussion:

An emergency situation is considered to exist whenever an abnormal event occurs and/or the source has failed to return to the safe position. Since it is not possible to specify all possible situations that would constitute an emergency, a general instruction is acceptable. The general instruction should describe licensee actions to maintain the dose at a minimal level after an abnormal event is identified.

Instructions to personnel should include procedures for minimizing the exposure of persons in the event of an accident or other unusual occurrence. Possible malfunctions of equipment should be considered, and steps to follow in each case of malfunction should be specified.

The procedures should contain clear and specific instructions on the steps to be taken by radiography personnel, such as (1) surveying the area, (2) establishing a restricted area, (3) notifying appropriate persons, and (4) maintaining direct surveillance and control over the area until the situation is corrected. Limitations on the action that may be taken by radiography personnel should be clearly specified, e.g., recovery of a source that has become detached from an exposure device, an operation that may result in exposure to high levels of radiation should not be attempted by radiography personnel, unless specifically trained and experienced in source retrieval.

Response from Applicant:

Submit operating and emergency procedures that include instructions for minimizing exposure of persons in the event of an accident.

7.6.11.2 Notifying Proper Persons in the Event of an Accident.

Regulation: Section 22 (a)(10), Sections 42 and 43 of CPR Part 11.

Criteria:

Operating and emergency procedures must ensure that appropriate notifications are made during and after an emergency.

Discussion:

The emergency procedures should clearly identify the names and telephone numbers of the RSO or other persons who can provide assistance in an emergency or accident. Such persons may also include the exposure device manufacturer and local agents. The emergency procedures should always be available to radiography personnel during radiography and must be as up-to-date as possible.

PNRI regulations also require immediate notification upon the discovery of certain events. Notify PNRI when radiographic devices are lost or stolen or if there is indication of overexposures of personnel or the public.

Response from Applicant:

Submit operating and emergency procedures that include appropriate instructions for notifying the RSO or other proper persons and/or PNRI in the event of an emergency.

ITEM 8. SECURITY AND CONTROL OF RADIOACTIVE SOURCES

Regulations: Section 7(m) and Section 33 of CPR Part 11, CPR Part 26.

Criteria:

A Physical Protection and Source Security Plan must be established and implemented.

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

Discussion:

Licensees must provide adequate physical protection of sources and facilities on site and during transportation of radioactive sources. Physical protection of radioactive sources involve instrumentation systems, administrative procedures and structures installed to provide adequate monitoring, surveillance and control measures to ensure unauthorized removal of radioactive sources from its authorized location. A periodic inventory of movable sources must be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure. Sources should be removed from a source store or moved to another location only by authorized persons who accurately log their name and the date, time and new location of the source(s). These records should be audited by the RSO at least once per month to ensure that all radioactive sources are where they are supposed to be. Containers that incorporate depleted uranium shielding should be included in the accountancy procedures. 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 unoccupied;
- Place source in locked storage, such as a cabinet;
- Store source in a locked and fixed container or device.

Appendix H describes Security Measures for Gamma Radiography Sources.

Response from Applicant:

The applicant must submit to PNRI a Source Security Plan in accordance with the provisions in CPR Part 26.

ITEM 9. RADIOACTIVE WASTE MANAGEMENT PROGRAM

Regulation: Section 39 and Section 40 of CPR Part 11

Criteria:

Disused radioactive sources must be disposed of in accordance with Section 39 of CPR Part 11 by transfer to an authorized recipient; by disposal as radioactive waste in accordance with an approved radioactive waste management program; or by return to the original supplier or manufacturer in the country of origin.

Discussion:

Licensees who dispose of disused radiography sealed sources or radiography devices containing depleted uranium, must transfer them to authorized recipients. The supplier or manufacturer of the radioactive source is the most logical recipient of these disused sources.

Before transferring radioactive material, a licensee must ensure and verify that the recipient is properly authorized to receive it. Disused radioactive sources must be returned to the original supplier or manufacturer in accordance with **Appendix B** of CPR Part 11, "Requirements on the Import and Export of Radioactive Sources". In addition, all radioactive sources must be packed and shipped in accordance with CPR Part 4, "Safe Transport of Radioactive Material in the Philippines". Records of transfer must be maintained.

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

Response from Applicant:

The applicant should establish waste disposal procedures that indicate the isotope (element and mass number), physical and chemical form, and the quantity to be disposed.

The licensee should:

- Notify and secure the approval of PNRI before he transfers radioactive sources to an authorized recipient. He should submit to PNRI information that includes his name, address and license number; type, form 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 PNRI on the design and specifications of the container where the radioactive sources will be packed and shipped.
- Submit to PNRI plans or other methods of disposition.

ITEM 10. APPLICATION AND LICENSE FEES

An application fee normally accompanies the application for a new license. The required license fee should be paid only when the initial application is approved and the new license is ready to be issued. A required license fee must also accompany an application for renewal of a license. Regulatory and licensing fees are provided in the **PNRI "Schedule of Fees for Licensing and Related Regulatory Activities".**

ITEM 11. CERTIFICATION

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

ITEM 12. ACKNOWLEDGEMENT

All license applications must be notarized.

4. AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: Sections 9 and 11 of CPR Part 11

Criteria:

a) The licensee must amend its license before:
   1) It permits anyone to work as RSO, ARSO, radiographer, or radiographer's assistant other than those previously authorized in the license;
   2) It replaces RSO,ARSO, radiographers or radiographers' assistants;
   3) It possesses at any one time radioactive sources in excess of the activity authorized in the license;
   4) It receives and uses radioactive sources or radiographic exposure device other than what is indicated in the license;
   5) It relocates or modifies the storage area in the field station;]
   6) It modifies its permanent radiographic installation; or
   7) It implements any major change in the approved radiation safety program.

b) The licensee must renew its license at least 30 days before the expiration date in accordance with Section 11 of CPR Part 11.

Discussion:

It is the licensee's obligation to keep the license current. If any of the information in the original application is to be modified or changed, the licensee must submit an application for a license amendment, in accordance with **Section 9 of CPR Part 11**, before the change takes

place. To continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date.

Response from Applicant:

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests, applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit duplicate copies of the Application Form NRLSD-011 or a letter requesting amendment or renewal.
- Provide the license number.
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, the licensee's organization, or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

5. TERMINATION OF ACTIVITIES

Regulations: Section 13 of CPR Part 11.

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

a) Notify PNRI, in writing, within 30 days of:
   1) the expiration of its license;
   2) a decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
   3) a decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to PNRI requirements;
   4) no principal activities having been conducted at the entire site under the license for a period of 24 months; and
   5) no principal activities having not been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to PNRI requirements.

b) Submit decommissioning plan;

c) Conduct decommissioning, as required by **Section 13 of CPR Part 11**;

d) Submit to PNRI information and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey)

e) Before a license is terminated, send the records important to decommissioning to PNRI.

Discussion:

A licensee who decides to cease licensed activities must, before informing PNRI, determine whether residual radioactivity is present at the facility and whether the levels make the building or outdoor area unsuitable for release according to PNRI requirements. A licensee's determination that a facility is not contaminated is subject to verification by PNRI inspection.

For guidance on the disposition of licensed material, refer to Section 39 of CPR Part 11 and for decommissioning requirements, refer to Section 13 of CPR Part 11.

Response from Applicant:

The licensee is not required to submit a response to the PNRI 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 Criteria.

APPENDIX A

MODEL PROCEDURE FOR CALIBRATING RADIATION SURVEY INSTRUMENTS

a) Calibrate survey meters with radionuclide sources that approximate point sources at intervals not exceeding 3 months, and after servicing.

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- The standard source exposure rates should be traceable to within 5% accuracy.
- Each scale in the range from two milliroentgens per hour through one roentgen per hour is required to be calibrated. Other scales should also be checked for operability.
- The highest and lowest points used to calibrate each scale of the instrument should be separated by at least 50% of the scale.
- The exposure rate measured by the instrument should be within $\pm$ 20% of the exposure rate specified for the standard source.
- The calibration factor, the date of last calibration and due date of next calibration should be affixed to the survey meter.

b) Record survey meter calibration data and maintain written records for each instrument being used. Survey meter calibration reports should indicate the procedure used and the data obtained.
Maintain records of the calibrations for two (2) years. Records should contain the following information:

- Owner or user identification, including name, address, and person to be contacted.
- Instrument description that includes manufacturer, model number, serial number, and type of detector.
- Calibration source description that includes radioisotope, indicated exposure rate at a specified distance on a specified date.
- Each calibration point identifying the calculated exposure rate, the indicated exposure rate, the deduced correction factor, and the scale on the instrument.
- Exposure reading indicated with the check source.

c) The inverse square law and radioactive decay law may be used in the calibration. A calibrated source will have a calibration certificate giving its output (dose rate) at a given distance measured on a specified date by the manufacturer. The inverse square law may be used to calculate exposure rates at other distances. The radioactive decay law may be used to calculate the output at any time after the specified date.

- **Inverse Square Law**

a If $\mathbf{R_1}$ is the exposure rate at a distance $\mathbf{D_1}$ from a point source and $\mathbf{R_2}$ is the exposure rate at distance $\mathbf{D_2}$ from the same point source, then

$$\mathbf{R_1(D_1)^2 = R_2(D_2)^2}$$

Note: $\mathbf{R_1}$ and $\mathbf{R_2}$ must be in the same units of exposure rate (e.g., mR/hr, R/hr, etc.) and $\mathbf{D_1}$ and $\mathbf{D_2}$ must be in the same units of distance (e.g., centimeters, meters, etc.).

If $\mathbf{R_1}$, $\mathbf{D_1}$ and $\mathbf{D_2}$ are known, $\mathbf{R_2}$ can be calculated from

$$\mathbf{R_2 = R_1(D_1/D_2)^2}$$

- **Radioactive Decay Law**

The exposure rate of a standard source at a time, **t**, after a specified calibration date is given by

$$R_1 = R_o e^{-0.693t/T_{1/2}}$$

where,

R_0 is the exposure rate at a time t after the source calibration date

R_1 is the exposure rate on the day of calibration

t is the time elapsed since the calibration date

$T_{1/2}$ is the radionuclide half-life

Note: R_o and R_1 must be in the same units of exposure rate (e.g., mR/hr, R/hr, etc.) and **t** and $T_{1/2}$ must be in the same units of time (e.g., seconds, hours, days, years, etc.).

d) Attach the following information to the instrument as a calibration sticker or tag:

- Source that was used to calibrate the instrument.
- Date of calibration.
- Date survey instrument is due for calibration.
- Name or initials of individual calibrating the instrument.
- Orientation of detector with source.
- Dose rate with check source.

Note:

1) The survey meter must be calibrated with the same radionuclide for which the instrument will be used.
2) The use of a small check source is not acceptable for calibration purposes.

APPENDIX B

DUTIES AND RESPONSIBILITIES OF A RADIATION SAFETY OFFICER

The individual assigned the duties of maintaining active management control of the radiation safety program should be a qualified radiographer with training in the use of the types of equipment proposed in the application and should bear the title of **Radiation Safety Officer (RSO)**. 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. Alternates meeting the same qualifications as the RSO should be designated to assume these functions when necessary.

A list of the duties that must be performed by the licensee's management personnel 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 of licensed activities.
b) Maintain control of procurement and disposal of licensed material.
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 radiographers and radiographer's assistants.
g) Examine and determine competency of radiographic personnel.
h) Establish and maintain storage facilities.
i) Maintain radiography facilities, exposure devices, and associated equipment.
j) Establish and maintain a leak-testing program.
k) Establish and maintain an internal inspection program.
l) Perform source replacement operations.
m) Conduct quarterly inventories and maintain utilization logs.
n) Establish a survey instrument calibration program.
o) Establish and maintain the licensee's record-keeping system.
p) Establish emergency response plan and assume control in emergency situations.
q) Investigate the cause of incidents, determine and institute necessary corrective action.
r) Advise licensee's management and radiography personnel on radiation protection matters.
s) Establish a procedure for evaluating and reporting defects and noncompliance pursuant to PNRI regulations.
t) Establish and implement security measures

APPENDIX C

TRAINING PROGRAM

An applicant for a radiography license is required to have an adequate program for the training of radiographers and radiographer's assistants. The description of the complete training program should include the sequence of events in the training of a person to become a radiographer or radiographer's assistant from the time of hiring through the time the job begins. Since **CPR Part 11** has different requirements for radiographers and radiographer's assistants, separate narratives pertaining to the training of individuals for each category should be submitted. The narratives should include appropriate references to the more detailed description of each of the various parts of the training program described in accordance with the items identified below.

a) Initial Training

- **Radiographers**

Classroom Training

The course content should include a detailed outline of the topics in **Section 19 (c) of CPR Part 11** and the approximate time to be spent on each major area of instruction should be specified.

On-the-Job Training

The period of on-the-job training under the supervision of experienced personnel should be specified. However, no individual should be permitted to enter into on-the-job training until completion of the requirements for a radiographer's assistant. The content of on-the-job training and the minimum time that will be spent in it will be dictated by the applicant's scope of operation, the variety of the work, and the aptitude of the trainee and should be specified in the application. A minimum of three months of full-time equivalent work as a radiographer's assistant should be provided.

Examinations

A comprehensive examination covering all items in **Section 19(c) of CPR Part 11** would be considered to be an adequate examination to qualify individuals as radiographers. In addition, practical or field examination should be administered to determine the competency of radiographers to perform surveys, posting, equipment operation, etc. Additional information is provided in Item 3, **"Testing Procedures".** Successful candidates should be given additional instructions in those areas where the examination indicates weakness.

- **Radiographer's Assistants**

Classroom Training

A description of the training program for radiographer's assistant should be given. **Section 19(b) of CPR Part 11** specifies training requirements and the subjects in which radiographer's assistants must demonstrate understanding and competence. The description should contain a detailed outline of those items covered in the operating and emergency procedures and the use of radiographic equipment and should specify the approximate time to be spent on each major item listed in the outline.

Examinations

A comprehensive examination covering the applicant's operating and emergency procedures and the use of radiographic equipment would be considered to be an adequate examination to qualify individuals as radiographer's assistants. Additional information is provided in Item 3, **"Testing Procedures"**. Successful candidates should be given additional instruction in those areas where the examination indicates weakness.

b) Periodic Training

Periodic training should include a description of the content and scheduling of training sessions given for the purpose of ensuring (1) the knowledge and proficiency of radiographers and radiographer's assistants with respect to new regulations, procedures, policies, and equipment and (2) continuing proficiency with present equipment and procedures. Periodic training should be conducted at least annually.

c) Testing Procedures

A description of each test to be given should be submitted. **Radiographers must successfully complete the written test and field examination**. Radiographer's assistants must successfully complete a written or oral test and a field examination of the subjects covered in training. A description of an oral or written test may be given by submitting a sample test with answer for each question.

A description of an oral examination should be given in the same form as a written examination. A list of subject areas for the field examination should be given and should include, as a minimum, performance of radiation surveys, posting, operation of equipment, emergency procedures, and other items of radiation safety that may be encountered in the discharge of duties.

A description of the testing procedure is not complete without a clear and specific description of the criteria and procedure to be followed in evaluating test results and determining whether an individual is qualified to act as a radiographer or radiographer's assistant. The relative importance assigned to each question or area performance, the minimum acceptable number of correct answers or proper responses, and re-testing procedures should all be given.

The points within the training program at which each test will be given should be clearly indicated. For example, some training programs include a written or oral exam following the initial training phase, followed by an oral and practical exam at the close of the on-the-job training phase.

The testing procedures must ensure compliance with **Section 19 of CPR Part 11**. If a trainee is to be utilized as a radiographer's assistant during the training period, the trainee should be tested and qualified as a radiographer's assistant before assuming those duties.

- **Instructor's Qualifications**

The person who makes the final determination of the adequacy of a trainee's knowledge and competency should preferably be a qualified radiographer with a strong background of training and experience with radiation. On-the-job training must be given by someone who is, as a minimum, a qualified radiographer.

- **Records**

A copy of the test given to each trainee, records showing trainee performance in each examination (including oral and practical examinations), and the examiner's overall evaluation of the trainee who qualified to act as a radiographer or radiographer's assistant must be maintained for a period of three years.

APPENDIX D

INSPECTION AND MAINTENANCE PROGRAM FOR RADIOGRAPHIC EQUIPMENT

Section 29 of CPR Part 11 requires that the license applicant establishes a program for inspection and maintenance of his survey instruments, radiographic exposure devices, transport and storage containers, associated equipment and source changers. The program should include written procedures in the form of specific instructions from management to radiography personnel and are to be part of your operating and emergency procedures. Record keeping procedures for all inspection and maintenance operations, including daily checks by the radiographer, should be included.

Although the type and extent of the radiography program and the types of radiographic equipment being used will determine the detail of the inspection and maintenance program, the program should include:

a) **Inspection Program**

Your inspection program should include the following activities:

- Each day radiography is to be performed, the following daily inspection of exposure devices, including auxiliary devices, shall be accomplished, before taking the devices from the storage facility except that: (i) if space in the storage facility is not sufficient to allow proper inspection, the exposure devices may be inspected at a nearby area; and (ii) if the storage facility is composed of only a vehicle, the exposure devices may be inspected outside the vehicle. Discovering a discrepancy before leaving a storage building is preferable to discovering it later at a field location.
    1) Survey shield assembly for excessive or abnormal radiation levels.
    2) Inspect shield assembly for damage to fittings, lock, and labels. Ensure that the safety plug is in place.
    3) Inspect crank assembly for damage and loose hardware.
    4) Check crank assembly operation for freedom of movement.
    5) Inspect all guide tubes for cuts, kinks, crushed sections, and broken or defective fittings, including excessively worn threads.
    6) Connect control cable to dummy source-pigtail assembly. Inspect connectors for excessive wear, damage, distortion, improper fit, and the possibility of accidental disconnection.

- In addition to activities listed under item a) above, the following inspection of exposure devices, including auxiliary equipment, shall be accomplished, as applicable, at field locations.
    1) Check for smooth operation of the crank assembly during movement of the source from the shield assembly to the end of the guide tube.
    2) Inspect for proper operation of all indicator lights.
    3) Inspect for proper operation of source position indicator.

- In addition to the daily inspections listed above, the following inspection of exposure devices, including auxiliary equipment, shall be accomplished, as applicable, at intervals not to exceed three months.
    1) For panoramic devices (devices in which the source is physically removed from the shield assembly during exposure)
        i) On the shield assembly
            - Check for excessive or abnormal radiation levels anywhere near the surface of the shield assembly.
            - Inspect safety plug for proper condition.

- Check locking mechanism for proper operation and for firm attachment to the shield assembly.
- Inspect for proper alignment of "S" tube with entrance and exit ports.

ii) On the source-pigtail assembly
- Inspect connector for proper condition. The connector should meet the specifications of the manufacturer.

iii) On the guide tubes (all tubes for containment of source-pigtail assembly and/or cable)
- Inspect for rust, dirt, or sludge buildup inside the tubes.
- Inspect tube connectors for proper condition.
- Inspect for kinks, crushed sections, or other damage that could prevent proper operation.

iv) On the crank assembly
- Check for operating characteristics.
- Inspect for excessive wear or damage to components.
- Check for proper operation of source position indicator.

v) On the cable
- Inspect connector for proper condition. The connector should meet the specifications of the manufacturer.
- Remove and inspect entire cable for flexibility, wear, rust, and broken wires.

vi) To assure mechanical compatibility of components.
- Check connectors on source-pigtail assembly and cable for proper fit and the possibility of accidental disconnection.
- Check connectors on shield assembly and tubes for a proper fit.

2) For directional beam devices.

i) Surveys for excessive or abnormal radiation levels anywhere near the shield surface.

ii) Check for changes in operating characteristics of the device. (Other operators may be able to provide useful information on this matter).

iii) Check for proper operation of shutter mechanism. There should be no chafing or binding of the shutter mechanism.

iv) Inspect for damage to the device which may impair its operation.

v) Check for proper operation of locking mechanism.

vi) Check for compatibility of shield assembly and drive mechanism.

- The following inspections for shielded room facilities shall be accomplished at intervals not to exceed six months.

Check all area safeguards for proper operation, including the following equipment:

i) Door interlocks.

ii) Equipment interlocks.

iii) Audible and visible warning devices.

iv) Access door-locking devices.

b) **Maintenance Program**

Your maintenance program must include the following activities:

1) Preventive maintenance, such as periodic cleaning and lubrication of equipment. We will normally accept the maintenance program recommended by the manufacturer as adequate.

2) Removal from service of any equipment found to be defective in the course of the inspection program until all defects are corrected.

c) **Records Required**

You must maintain records, available for inspection, of each inspection of equipment and each maintenance operation which require disassembly of equipment.

1) Maintenance of such records is facilitated by a checklist form for each inspection and maintenance operation to be recorded. We suggest that you have a form for each of the following operations:
   i) Daily inspection
   ii) Quarterly inspection
   iii) Semi-annual inspection
   iv) Periodic preventive maintenance

2) Each form should include the following items, as applicable:
   i) Device manufacturer
   ii) Device model number
   iii) Device serial number
   iv) Date and time
   v) Location
   vi) Radiographer's signature

Radiography equipment manufacturers usually provide a manual which includes step-by-step procedures for periodic inspection, maintenance, and repair of the equipment. These procedures may be adapted into your procedures.

Note: Since some inspection procedures could lead to exposure of the radioactive source, the applicant should consider possible exposure hazards when developing his inspection and maintenance procedures. The replacement (exchange) of sources provides an opportunity for a thorough inspection of exposure devices following source removal and prior to source replacement.

APPENDIX E

MODEL 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 as 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 Safety Officer (RSO) Commitment

1. Annual and Quarterly Review:
   a. 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.
   b. Quarterly review of occupational exposures. The RSO 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 RSO 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 RSO will inform radiation workers that management and the RSO 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 RSO will be in close contact with all workers in order to develop ALARA procedures for working with radioactive materials.
   c. 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 these programs.
4. 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.

APPENDIX F

LEAK TESTING OF RADIOACTIVE SOURCES

a) Distributors of radioactive sources usually supply a certificate with each source giving the results and date of the last leak test performed on the source. If such certificate is not received, the source is not to be used until a leak test has been performed and the results of the test show that the source is not leaking or contaminated. Thereafter, the source must be tested for leakage at intervals not to exceed six months. Records of the testing of each source, identifying the source tested, date of the test, and results of the test in units of Becquerels must be maintained for inspection.

b) The applicant should submit a description of the leak-testing program for radioactive sources as follows:

- If the applicant wishes to use a commercially available leak-test kit, the application should identify each kit to be used by identifying the kit supplier and the kit model number. Only leak-test kits that are identified will be authorized. The application should also identify the individuals who will perform the swipe-test (using kits).
- If the applicant wishes to avail itself of the services of a consultant or commercial organization licensed by PNRI to take the necessary test samples (smears), evaluate the samples and report the results to the customers, name, address and license number of the consultant or commercial organization should be specified.
- If the applicant wishes to be licensed by PNRI to perform leak-tests, including evaluating the smears, the applicant is required to describe the procedures to be used. The following information should be included:

    1) A description of the instrumentation to be used in evaluating the smears, including its sensitivity and accuracy;

    2) A description of calibrating and standardizing procedures with sample calculation showing conversion of results to the required Becquerels. Survey instruments are not designed for such measurements and unacceptable for this use;

    3) A description of the material to be used in taking the smears, the points on the equipment that will be smeared (smears are not normally taken directly from the surface of the source);

    4) The radiation safety procedures to be followed during the smearing process, the method for handling and disposing of the smears; and

    5) A description of the pertinent training and experience of each person who will take or evaluate the smears.

APPENDIX G

SPECIFIC EMERGENCY PROCEDURES

A. FAILURE OF RADIOGRAPHIC SOURCE TO RETURN TO THE SHIELDED POSITION

Most gamma radiography incidents involve a failure of the radiographic source to return to the shielded position. In dealing with these incidents, special equipment is necessary, and the first priority is protection of persons. In what follows, practical guidance is provided for remedial actions. The application of each procedure will depend on the specific details of each case. Although the steps are listed in the general sequence in which they are to be performed, it is possible that the sequence may need
to be adapted at the time of the response.

NOTE: The operating organization authorizes and trains different workers to implement different remedial actions within the emergency plan. Individual workers are only to implement parts of the emergency plan for which they have been authorized and trained and for which they have the appropriate equipment. For guidance, the steps are classified according to designated officers' responsibilities, i.e. radiographer, RSO or Emergency Manager.

Radiographer (Response Initiator)

(a) Recognize that an abnormal situation has occurred which might constitute an emergency;
(b) Move away from the exposed source and remain calm;
(c) Measure the radiation dose rates;
(d) Establish controlled area barriers based on dose rate limit requirements;
(e) Prevent access to the new controlled area;
(f) Do not leave the controlled area unattended;
(g) Inform the RSO of the operating organization and the client and seek assistance.

Radiation Safety Officer (RSO)

(a) Plan a course of action based on previously established emergency procedures, taking into account the doses that may be received by this course of action and keeping it ALARA. Rehearse the planned course of action before entering the controlled area.
(b) Implement the planned course of action to the extent that training, equipment and authorizations allow; under no circumstances should the source be allowed to come into contact with the hands or other parts of the body.
(c) If the planned course of action is unsuccessful, leave the controlled area and consider the next course of action while continuing surveillance of the controlled area.
(d) Call technical assistance, if needed, from qualified experts or manufacturers.
(e) Notify the Regulatory Authority as required.
(f) When the emergency is resolved, reconstruct the accident, assess the doses received and prepare a report.
(g) Send out personal dosimeters for exposure assessment.
(h) Send the damaged or malfunctioning equipment to the manufacturer or qualified expert for a detailed inspection before reuse.

B. MISSING OR STOLEN SOURCES OR EXPOSURE DEVICES

A missing or stolen exposure device containing the radiographic source(s) can be a significant hazard if members of the public who are not aware of the danger of radiation find it. The first priority in this type of accident will be to identify the location of the source as well as all the people who may have unknowingly handled it. Information on the type of source, its activity and other physical and chemical characteristics will be essential in assessing its potential hazard for

the public. Efforts to track the source would normally start at the last known location. Investigative work is conducted to retrace the sequence of events. Reports from the medical community on possible contaminated or overexposed victims, surveys by RSO and investigation by the police are all possible sources of information on the source's whereabouts. Searching for a lost source with radiation monitoring equipment is effective for a high activity unshielded, high energy gamma source, such as industrial radiography sources. Instruments with large sodium iodide detectors are able to detect such unshielded sources at distances of up to a few hundred meters. If a source is missing, the following items give practical guidance for remedial actions. The steps are classified according to designated officers, i.e. radiographer, RSO or Emergency Manager.

Radiographer (Response Initiator)

(a) Initiate a search immediately, using a radiation monitoring instrument. If the source has been lost in transit, retrace the planned route taken by the device and source and search visually and with the aid of radiation monitoring instruments.
(b) If it is concluded that the source is lost or stolen, notify the RSO and/or the Regulatory Authority immediately.

Radiation Safety Officer (RSO)

(a) Initiate emergency plan;
(b) When the source is found, inspect it for evidence of tampering and monitor it for shielding damage;
(c) Perform a wipe test for leakage of radioactive material;
(d) If the test results are satisfactory, the source is returned to the manufacturer or qualified expert for detailed testing;
(e) If test results are not satisfactory, initiate emergency plan.

Emergency Manager

Communicate with hospitals, the media and the public, when necessary, to help locate the missing source and, if necessary, warn of potential health effects.

APPENDIX H

SECURITY MEASURES FOR GAMMA RADIOGRAPHY SOURCES

SECURITY PLAN

The security plan should describe how the security provisions in CPR Part 26 are met for Security Group B sources.

The plan 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.

SECURITY PLAN CONTENT

1. Description of the source and its use

2. Description of the environment, building and/or facility where the source is used or stored

3. Location of the building or facility relative to areas accessible to the public

4. Objectives of the security plan for the specific application:
   - specific concern to be addressed: theft, destruction, or malevolent use
   - kind of control needed to prevent undesired consequences including the auxiliary equipment that might be needed
   - equipment or premises that will be secured

5. Technical measures:
   - deterrence provided by at least one (1) measure separating the source from unauthorized personnel, as may be applicable and practicable: fences, walls, cages, transport packagings, locks and interlocks for doors, locked, shield containers, and intrusion-resistant source-holding devices.
   - design features to evaluate the quality of the measures against the assumed threat.

6. Administrative measures
   - responsibilities of principal party

     The principal party should ensure that:
     - *sources are managed in accordance with the authorization;*
     - *sources, when not in use, are promptly stored in an approved manner;*
     - *storage is in accordance with the requirements for Group B sources;*
     - *any transfer of sources to another person is documented and that person is authorized 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.*

   - responsibilities of individuals assigned for sources

     The responsible individual should ensure that all personnel who use or have access to the sources:
     - *are reliable;*
     - *are authorized; and*

- *have the proper training consistent with their duties in handling those sources.*

- routine and non-routine operations
- maintenance (procedures)
- determination of the trustworthiness of personnel

  The principal party should ensure that persons engaged in the management of the sources are trustworthy. Background checks should be made prior to the granting of the authorization. Others with access to the sources do not necessarily need background checks as long as they are appropriately escorted or kept under visual surveillance by persons who have undergone background checks.

- weekly accounting:
  - routine inventory
  - when recorded parameters change
  - when sources are transferred

  The records should include the following particulars: l
  - *location of the source;*
  - *radionuclide;*
  - *radioactivity on a specified date;*
  - *serial number or unique identifier;*
  - *physical form;*
  - *source use history; and*
  - *receipt, transfer or disposal of the source*

- application of information security

  The following information or documents should be controlled and distributed on a need to know basis taking into account the State's regulations on classified documents:
  - *specific locations of sources;*
  - *the facility's security plan and security system associated with the sources;*
  - *temporary or permanent weaknesses in the security system;*
  - *source utilization plans and records;*
  - *proposed date and time of source(s) shipment or transfer; and emergency response plans and systems.*

- methods for access authorization, i.e., procedures

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

- deterrence provided by at least one (1) measure separating the source from unauthorized personnel.
- timely detection provided by remotely monitored intruder alarm
- emergency plans:
  - responsibilities of responders, etc.
  - procedures
  - notifications/status and event reporting

  Provide emergency response procedures in case of false and true alarms. Highlight responsibilities of security guards and other responders.

As a minimum, include notification in the event of a loss of the source; press release procedures; and initial measures to recover lost or stolen source.

Events to be reported to PNRI could include:

- *loss of control over a radioactive source;*
- *unauthorized access to, or unauthorized use of, a source;*
- *malicious acts threatening authorized activities;*
- *failures of equipment containing sources which may have security implications; and*
- *discovery of any unaccounted source.*

- response plan to an increased threat

Planning for response to an increased threat of malevolent use should take place in close cooperation with the PNRI and the competent emergency agencies.

There should be pre-arranged procedures with law enforcement regarding intelligence information and use of secure communications as well as the reactions to an increased threat.

If there is a specific threat targeting a source or source storage location, security should be increased in accordance with the threat.

The increased security measures should be continued until such time as it is determined that the specific threat is no longer present.

The following measures should be considered:

- *if the source is in use, return the source to its secure storage location;*
- *provide a 24-hour guard, or use video observation, or an intrusion alarm;*
- *ensure that the law enforcement and regulatory authorities are made aware of the suspected threat;*
- *review the security procedures, facility layout, and radiation safety practices with the law enforcement and emergency response personnel; and*
- *ensure that local medical facilities are available where there are personnel trained and equipped to handle radiological emergencies.*

APPENDIX I

GENERAL GUIDANCE FOR DISPOSAL OF DISUSED RADIOACTIVE SOURCES

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

b) Prior to the import of a radioactive source which, 10 years after receipt, will have an activity greater than 100 MBq:
   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 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 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. Export of the disused radioactive sources should be done in accordance with **Appendix B of CPR Part 11**.

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”.

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

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE (INDUSTRIAL RADIOGRAPHY)

INSTRUCTIONS: To complete this application, refer to Part 11 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for a License for the Use of Sealed Sources and Devices in Industrial Radiography. Submit an original and 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.

(Attach copy of SEC registration and business permit issued by the responsible government agency.)

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) Used in Radiography

Radioactive Source (Element/ Mass Number)	Model Number	Serial Number	Manufacturer	Maximum Activity in each Radioactive Source (Bq)

3.2 Other Radioactive Sources (e.g. calibration sources)

Radioactive Source	Model Number	Manufacturer (or Distributor)	Total Activity (Bq)	Purpose of Use

4. FACILITIES AND LOCATION(S) OF USE.

4.1 Permanent Radiographic Installation (Describe the permanent radiographic facility, to include photographs, drawings or sketches of rooms where radioactive material will be used and/or stored).

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

4.2 Field Stations or Temporary Jobsites (Describe the temporary facility and submit a diagram showing where the radiography camera will be stored and the location where radiography may be performed).

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

5. RADIOGRAPHIC EQUIPMENT/INSTRUMENTS/DEVICES (Attach supplementary sheets, if necessary).

5.1 Radiographic Equipment (To be used with sources listed in Item No. 3.1).

Device	Model Number	Serial Number	Manufacturer	For Use at/in	
				Permanent Radiographic Installation	Temporary Jobsite
Radiographic Exposure Device					
Source Changer					
Associated Equipment					

5.2 Radiation Survey Instruments

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

5.3 Personnel Monitoring Devices

Monitoring Device	No. of Units	Name and Address of Supplier(s)	Date of Last Calibration
Film Badge			
TLD			
Pocket Dosimeter			
Alarm Ratemeters			
Others			

6. 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 (RPO)		
Assistant RPO		
Radiographers		
Radiographer's Assistants		

7. 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
7.1 Organization		
7.2 Internal Inspection Program		
7.3 ALARA Program		
7.4 Material Receipt & Accountability		
7.5 Leak Testing of Radioactive Sources		
7.6 Operating & Emergency Procedures		
7.6.1 Handling and Use of Licensed Radioactive Sources, Radiographic Exposure Devices, Source Changers, and Instrument Calibration Equipment.		
7.6.2 Conducting Radiation Surveys.		
7.6.3 Controlling Access to Radiographic Areas.		
7.6.4 Locking and Securing Radiographic Exposure Devices, Storage Containers, and Radioactive Sources.		
7.6.5 Personnel Monitoring and the Use of Personnel Monitoring Equipment.		
7.6.6 Transporting Radioactive Sources to Field Stations or temporary jobsites, Packaging of Radiographic Exposure Devices and Storage Containers in the Vehicles, Posting of Vehicles, and Control of the Radioactive Sealed Sources.		
7.6.7 Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, and Source Changers.		
7.6.8 Ratemeter Alarms or Off-Scale Pocket Dosimeter Readings.		
7.6.9 Identifying and Reporting Equipment Malfunctions and Defects.		
.6.10 Recordkeeping.		
.6.11 Emergency Planning and Response.		
7.6.11.1 Minimizing Exposure of Persons in the Event of an Accident		
7.6.11.2 Notifying Proper Persons in the Event of an Accident		

8. SECURITY AND CONTROL OF RADIOACTIVE SOURCES. (Submit procedures on how to ensure the control and security of radioactive sources during use and storage)

9. RADIOACTIVE WASTE MANAGEMENT PROGRAM. (Submit a detailed description of methods which will be used for disposal of disused radioactive sources. If disused radioactive sources are to be returned to original supplier or manufacturer, submit copy of agreement with original supplier or manufacturer).

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

11. 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

12. ACKNOWLEDGEMENT.

{Republic of the Philippines}
{ }

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

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

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

_____
Notary Public

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

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

ATTACHMENT A

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

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

1" x 1" ID Photo

1. TRAINING IN RADIATION SAFETY

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

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

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

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

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

Title of Training	Place of Training	Date of Training

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

_____
Signature of Proposed RPO/ARPO

Date: _____

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

ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS

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 IN THE OPERATION OF A RADIOGRAPHIC EQUIPMENT/ INSTRUMENTS / DEVICES

Equipment/Instruments/ Devices (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 (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 Radiographer/Radiographer's Assistant

Date: _____