GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE OF A PARTICLE ACCELERATOR FACILITY FOR THE PRODUCTION OF RADIONUCLIDE

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APPENDICES

REPUBLIC OF THE PHILIPPINES
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
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GUIDE FOR THE PREPARATION OF AN APPLICATION FOR A LICENSE OF PARTICLE ACCELERATOR FACILITY FOR THE PRODUCTION OF RADIONUCLIDE

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE

This regulatory guide is intended to assist applicants who are preparing an application for a license to construct and operate a particle accelerator facility for the production of radionuclide pursuant to CPR Part 21, "Licensing and Safety Requirements of Particle Accelerator Facilities for the Production of Radionuclide". It contains information and model procedures on how applicants/licensees may choose to develop their programs in order to meet PNRI regulatory requirements. The applicant may adopt or adapt the guidance and model procedures as specifically suggested in this regulatory guide or he may submit an alternative procedure to comply with the regulatory requirements subject to PNRI approval. Additional information may be required to ensure that the applicant complies with the requirements of CPR Part 21. 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 specific licensing requirements.

1.2 MANAGEMENT RESPONSIBILITY.

PNRI believes that an effective radiation safety program management is vital to safe operations that comply with PNRI regulatory requirements. To ensure adequate management involvement, a management representative must sign the submitted application acknowledging the management's commitment to and responsibility for the establishment of an effective radiation safety program to keep individual and collective doses as low as reasonably achievable (ALARA); and the provision of adequate resources (including space, equipment, personnel, time, and if needed, contractors) for the implementation of the radiation safety program to ensure that the general public, environment and radiation workers are protected from radiation hazards.

Management and organization structure that relates to radiation protection matters must include the names and position titles of the persons who are to be responsible for the management and control of radioactive substances or radiation devices during the conduct of the activity to be licensed.

1.3 APPLICABLE REGULATIONS.

- CPR Part 21, "Licensing and Safety Requirements of Particle Accelerator Facilities for the Production of Radionuclide", published in the Official Gazette on May 30, 2016.

- CPR Part 3, “Standards for Protection Against Radiation”, published in the Official Gazette, 2004.
- CPR Part 4, “Safe Transport of Radioactive Materials in the Philippines”, published in the Official Gazette, 2004.
- CPR Part 13, “Licenses for Medical Use of Unsealed Radioactive Material” published in the Official Gazette, 2014.
- CPR Part 17, “Licenses for Commercial Sale and Distribution of Radioactive Materials and its Associated Devices published in the Official Gazette, 2010.
- CPR Part 22, “Fees and Charges for Licensing Radioactive Materials and Other Related Regulatory Activities” rev. 2, published in the Official Gazette, 2016.
- CPR Part 26, “Security of Radioactive Sources; Rev. 1”, Official Gazette, 2014
- CPR Part 27, “Security Requirements in the Transport of Radioactive Material”, Official Gazette, 2013
- Other related PNRI regulations, as necessary and appropriate.

It is the responsibility of applicants to obtain copies of the regulations specified above and to read and abide by the provisions of these regulations that apply to particle accelerator for the production of radionuclide.

2. FILING AN APPLICATION

Complete **PNRI/NRD Form-021**, "Application for Radioactive Material License of a Particle Accelerator Facility for the Production of Radionuclide”. The application must include all information necessary to support its intended purpose. Completeness of submitted information will be determined by the PNRI reviewer before the application is docketed. All applications for a new license must be affirmed or notarized.

For new license applications, submit a copy of the registration from the Securities and Exchange Commission (SEC) or the Department of Trade and Industry (DTI) together with the application form. For public institutions, specify the enabling legislation (Act), as appropriate. The filing fee shall be paid upon submission of the application documents and the appropriate license fee shall be paid prior to the issuance of the license in accordance with CPR Part 22.

3. CONTENTS OF APPLICATION

This portion of the regulatory guide explains, item by item, the information requested in the **PNRI/NRD Form-021**. For new license, tick sub-item I.A. For an amendment to an existing license, tick sub-item I.B. For renewal of an existing license, tick sub-item I.C. The license number shall be provided for sub-items B and C.
As for the Type of License requested, tick sub-item II.A for Provisional Permit, Sub-item II.B for License to Construct and Sub-title II.C for License to Operate.

ITEM 1.0 NAME AND MAILING ADDRESS OF APPLICANT.

List the applicant’s legal name, mailing address, telephone number, fax number, and email address. The applicant may be an institution or a government agency. If the applicant is a firm, institution or government agency, the name and signature of the individual who has the authority and responsibility over the operation of a particle accelerator for the production of

radionuclide shall appear in the application, indicating his title or position in the institution. Provide the mailing address where correspondence should be sent.

ITEM 2.0 PERSON TO BE CONTACTED ABOUT THE APPLICATION.

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

ITEM 3.0 TYPES OF AUTHORIZATION AND GENERAL REQUIREMENTS

Regulation: Section 7 of CPR Part 21

3.1 Provisional Permit

The applicant formally informs PNRI in writing its intention to construct and operate an accelerator facility by filing an application in the appropriate form. A **Preliminary Safety Analysis Report (PSAR)** which includes the proposed civil works plans, construction plan and schedule of activities, technical specification of the proposed facility, proposed contractors and organizational set-up, and other relevant technical information are submitted to PNRI for review in anticipation of a formal application for the authority to commence the planned construction activity.

The applicant is advised to maintain close communication with PNRI to avoid delays and any future problem.

3.2 License to Construct

PNRI requires that the construction of the facility conforms with a *License to Construct* that is issued pursuant to the application to construct that is submitted by the applicant.

A License to Construct is issued to cover all the phases of construction covering civil works, electrical and mechanical installations, and environmental assessment, with reference to the ***Preliminary Safety Analysis Report***. Normally, the issuance would include a *provisional license to construct* that is converted to a *full license to construct* as the activities progress in accordance with an approved construction milestone schedule and visibility chart. A *Quality Assurance Program – Construction Phase* must be submitted and will address the criteria that are associated to a safe construction activity. PNRI will be guided by this program in the conduct of regulatory inspections to determine that safety in all construction activities is observed and that activities are completed and achieved as planned.

3.3 License to Operate

The license to construct will be converted to a *License to Operate* when the applicant has satisfied the requirements for construction and the other requirements relative to the operation of the facility.

This phase involves the performance of system tests, calibration, and other operation of the facility after construction is completed but will not involve the production of radiation. The *license to construct* would be converted to a *license to operate* if PNRI is satisfied that the construction is completed as planned and the ***Final Safety Analysis Report*** has been submitted. The licensee should submit a construction report and a commissioning plan in support of the conversion of the license to construct to an operating license. The licensee should also establish a *Quality Assurance Program- Operation Phase.*

ITEM 4.0 LOCATION AND TECHNICAL SPECIFICATION OF THE PARTICLE ACCELERATOR FACILITY.

4.1 LOCATION OF FACILITY

The applicant must provide a detailed description of the facility and its site including the site address. Specify the location of the particle accelerator facility by the building, room number, department, street address, city/town, and province, telephone number, fax number to easily locate the facility.

Attached the layout of the particle accelerator facility and the laboratory facility. Include the description of the shielding design and the ventilation system.

A description of the purpose of the facility and specific information relevant to the type of authorization applied must be provided.

Building _____ Room _____

Street _____

City _____ Province _____

Telephone and Fax Number _____

Attachment 1:

Particle Accelerator Facility Layout

		Attached	Remarks
4.1.1	Layout of the facility	☐	_____
4.1.2	Rooms/areas	☐	_____
4.1.3	Description of shielding design	☐	_____
4.1.4	Description of ventilation system	☐	_____

Laboratory Facility Layout

Attachment 2:

		Attached	Remarks
4.1.5	Layout of the facility	☐	_____
4.1.6	Rooms/areas	☐	_____

4.1.7 Description of shielding design ☐ _____
4.1.8 Description of ventilation system ☐ _____

4.2 Technical Specifications of the Particle Accelerator.

Manufacturer _____ Installation Date _____

Model Name _____ Serial Number _____

Types of Beam _____

Maximum Energy and Current _____

Maximum Particle Velocity/Acceleration _____

Accelerator Targets – for each accelerator target provide the following information:

Target Chamber				Maximum Beam Current (uA)	Bombardment Time (Min.)	Maximum EOB activity (GBq)
Part No.	Nuclear Reaction	Product	Material			

Attachment 3:
Information regarding the equipment (e.g., brochure) ☐ Attached ☐ NA Remarks_____

This item should include technical details about the accelerator system and beam transport. Technical drawings with sufficient detail should be provided.

The applicant must provide information of the technical specifications of the particle accelerator that includes the manufacture, model and serial number, beam energy, beam current, number of targets/target material, number of hot cells.

4.2.1 Particles Accelerated

This section should identify the particles accelerated and the method for creation of the charged particles. (e.g. electron gun, ion source). This should include output and expected average life-time of the particle source.

4.2.2 Acceleration System

This section should describe the acceleration mechanisms. This should include the design range and physical limitations of the primary beam; particle energies, beam intensity, time function output (pulse shape and frequency) and output dimensions. If applicable, the R.F. system should also be described.

4.2.3 Beam Transport System

This section should describe all beam transportation and containment devices and all possible geometrical configurations of the beam.

Beam transportation system means all devices that interact with the accelerated beam before it reaches its target. This may include steering devices, focusing devices, guide tubes and vacuum windows. Beam containment is a radiation safety concern in an accelerator facility because the high power beam may pass through lightly shielded areas.

4.2.4 Target- Irradiation Course

This section should specify the target materials, physical form, and the interaction expected.

4.3 Facility and Equipment Description.

This item should contain information, with reference to drawings, about the engineering design of the facility. This should include the auxiliary systems such as ventilation and cooling systems, fire protection system, and power supply.

Any system to be used for radioactive material transport and handling should also be described. For radioisotope production accelerators, a flow chart that describes liquid and gaseous effluent circuits upstream and downstream from the target(s) should be provided. In addition, all research or radionuclide processing facilities associated with the accelerator should be described in appropriate details.

This item also contains a detailed description of all equipment available in the facility. It should include the name of the manufacturer, model number, serial number, date of calibration.

ITEM 5.0 PROOF OF LEGAL STATUS

Under Section 9. Citizenship Requirement of RA 5205, An Act Providing for the Licensing and Regulation of Atomic Energy Facilities and Materials, Establishing The Rules On Liability for Nuclear Damage, and for Other Purposes, governs that no license issued pursuant to the CPR will be granted to an alien, or any corporation or other entity that is owned or controlled by an alien, a foreign corporation, or a foreign government, unless otherwise exempted by law.

Under Section 6, Application for New License, the applicant must submit a certified true copy of the registration from the Security and Exchange Commission (SEC). The applicant must also submit current business permit issued by responsible local government agency.

ITEM 6.0 RADIONUCLIDE(S) PRODUCED AND PURPOSE(S) OF USE.

Regulation: Section 5; Section 8 (a) of CPR Part 21.

The licensee must provide the list of radionuclide to be produced, the chemical/physical form, the maximum activity to be produced per run and the maximum activity to be dispensed. For all types of radionuclide produced, the applicant should define the purpose of use.

The proposed activity is authorized by the PNRI and the facility will only be used for the purposes for which they were designed and according to the manufacturer's/distributor's recommendations. The applicant/licensee should be authorized to produce, possess, transport and transfer radioactive material and to construct or operate a particle accelerator for the purpose of producing radionuclides for medical use in accordance with a license issued by PNRI pursuant to CPR Part 21.

An applicant will be issued a license for activities authorized under this Part if:

- The proposed activities are consistent with the policies declared under the Act;
- The applicant is technically and financially qualified to engage in the proposed activities in accordance with the requirements of this Part and applicable Parts of the Code;
- The proposed activities will not pose undue risk to the health and safety of the workers, the general public and the environment; and
- The applicant has financial capability to fulfill the obligations for decommissioning and liability for damage to life or property arising from the operation of the facility.

Response from Applicant:

- Submit a list of all radionuclides produced in the particle accelerator and specify the use of each. Specify the maximum amount of radionuclide produced at one time and the max. total activity in one year. Submit safety analysis report and procedures, if needed to support the purpose.
- Specify also the list of radioactive sealed sources that is being possessed to be use such as check sources. The applicant/licensee must provide the manufacturer's and distributor's names, number of quantity, model and serial number for each radioactive source and the maximum amount of activity to be possessed at one time.

ITEM 7.0 RADIATION WORKERS AND THEIR TRAINING AND EXPERIENCE

7.1 Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO).

Regulation: Section 19; 36 of CPR Part 21

The person responsible for the day-to-day oversight of the radiation safety program is the Radiation Safety Officer (RSO). The RSO should ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the course of daily operation. A Delegation of Authority, as in Appendix D must be signed by the designated RSO. In order to fulfill the duties and responsibilities (found in Appendix E), the RSO must be present at all time to oversee licensed activities. PNRI recommends that the

RSO is a full-time employee of the particle accelerator facility. The Assistant RSO will perform the duties and responsibilities of the RSO in his absence. The designated RSO and ARSO must be endorsed and approved by the Radiation Safety Committee.

The individuals designated as RSO and ARSO must have successfully completed at least one (1) year of relevant, fulltime experience in the administrative and operational control of radiation within the facility. A description of the relevant training and experiences of the RSO and ARSO must be made available to show that the proposed individuals are qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use.

The RSO and ARSO must have completed 200 hours of PNRI-approved classroom and laboratory training in basic radionuclide handling techniques of radioactive material, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material, radiation biology, and nuclear regulations and licensing

This sub-section should describe the duties and qualifications of the facility's Radiation Safety Officer (RSO). The designated RSO should have the following functions:

- Advise top management on all matters concerning radiation and radiation safety.
- Define, with the concurrence of management, the radiation safety requirements and assure compliance with PNRI regulations and the license conditions.
- Monitor, and report to top management, the effectiveness of the radiation safety program.
- Have authority to stop activities which appear to have imminent hazard or which violate the facility's safety policies.

The qualifications of the RSO will depend upon the operations of the institution but should include a thorough understanding of both technical operations and radiation protection. The required areas of knowledge are as follows:

- Physics – Knowledge of the physics of the interactions for the appropriate particle types and energy is essential.
- Radiation Physics - Calculations of shielding and activation are needed in order to predict both prompt and residual radiation levels.
- Operational Health Physics – There should be a good understanding of radiation and protection methods, dosimetry, and regulatory requirements.
- Familiarity is also needed with electronics, accelerator design and operation, beam transport and experimental techniques.

Response from Applicant:

- Specify the names of the proposed RSO and ARSO, their telephone/mobile numbers and email addresses, and a brief description of their training and experience;
- Fill out the attachment to the **PNRI/NRD Form-021** as "**Attachment A - RSO and ARSO TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION**"; and
- Attach proofs of compliance with Sec. 36 of CPR Part 21, i.e. copies of diploma, PRC license (as applicable), certificate/s of training, and proof of one (1) year relevant fulltime experience.

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

7.2 Authorized Operator.

Regulation: Section 37 of CPR Part 21

The applicant must only authorize an individual to operate a particle accelerator upon the endorsement and approval of the Radiation Safety Committee if he has met the training and experience requirements prescribed in the regulation.

The applicant will specifically name each individual authorized to operate a particle accelerator that produces radionuclide. The individuals named in the application must be qualified to perform its duties, including for instance, liaising with a production radiochemist to schedule [18F] fluoride production (beam current, duration, dual or single irradiation); performing a preliminary particle accelerator check to prepare it for operation; tuning and operating the particle accelerator; and the performance of radiation surveys. The operator must have completed 40 hours of PNRI- approved classroom and laboratory training in basic radionuclide handling techniques of radioactive material, including radiation physics and radiation detection instrumentation, radiation protection, radiation biology, and nuclear regulations and licensing before he/she can be authorized in the license. The operator should have experience in target preparation, maintenance and troubleshooting. Practical knowledge of radiation protection related to particle accelerator operation and radioactivity is also required.

In a facility producing several batches of radionuclide per day, a particle accelerator operator is likely to be required full time.

Response from Applicant:

- Specify the names of authorized operators;
- Describe the relevant trainings and experiences of the Authorized Operators by accomplishing **Attachment B** of the **PNRI/NRD Form-021;** and
- Submit certificates of these trainings and experiences.

7.3 Authorized Technical Staff.

Regulation: Section 38 of CPR Part 21

The applicant must only authorize an individual to be an authorized technical staff who is a health professional, with specialist education and training in manufacturing and dispensing of radioisotope according to the prescribed standard operating procedures and assessing radioisotope quality parameters prior to release for medical use upon the endorsement and approval of the Radiation Safety Committee if he has met the training and experience requirements prescribed in the regulation. The authorized technical staff can be a radiochemist, who is responsible for the dispensing of radionuclides, and a radiopharmacist, who prepares radiopharmaceuticals to ensure safety and efficacy of radioisotopes.

This section should describe the training which will be received by the technical staff before they are authorized to work without direct supervision. The training, including classroom instructions and on-the-job training, should include the following elements, as may be appropriate:

- Fundamentals of Radiation Protection
- Instrumentation
- Residual Radioactivity/Contamination
- Radiation/Radiological Emergencies
- Transport of Radioactive Materials

- Storage of Radioactive Material
- Radioactive Waste
- Radioactive Sources
- Personnel Dosimetry
- Accelerator Operation
- Beam Transport
- Interlock Systems
- Shielding Calculations
- Review of Operations/Experiments for Radiation Safety
- Regulatory Requirements
- Environmental Protection

Response from Applicant:
- Specify the names of authorized technical staff;
- Describe the relevant trainings and experiences of the Authorized Technical Staff by accomplishing **Attachment C** of the **PNRI/NRD Form-021;** and
- Submit certificates of these trainings and experiences.

ITEM 8.0 SAFETY ANALYSIS REPORT.

Regulation: Section 20 of CPR Part 21

For each step of the licensing process the applicant must apply for a formal authorization from PNRI. The application must be supported by technical documents that verify compliance with requirements for the specific authorization requested, and subsequently for the succeeding authorization. Pertinent parts of the ***Safety Analysis Report*** must be addressed and supplied with the application. The applicant must make arrangements with PNRI for timeliness of submissions of applications to facilitate a smooth transition between authorizations.

PNRI requires that the applicant submit a ***Safety Analysis Report*** that specifies the conditions under which the facility will be constructed and operated. The ***Safety Analysis Report*** represents the principal technical and administrative link between the applicant and PNRI. It should therefore contain precise and correct information on the facility and its operating conditions.

The main purpose of the ***Safety Analysis Report*** is to provide information, such as design criteria, the site and facility characteristics, the limits and conditions of operation and the accident analysis, in such a manner that PNRI may be able to correctly evaluate the safety of the facility. The report should be written concisely and precisely such that the contents can be easily understood and analyzed. If possible, it should present thorough and sufficient information on the facility so that, for the purpose of safety analysis, no other document would normally be required. Nevertheless, supplementary information may be required to be made available.

It may be emphasized that the writing of a ***Safety Analysis Report*** is continuous process. It should be considered a method to enhance the safety of the facility and its operating conditions. In the preliminary stages of writing the report, some chapters are not required, e.g., detailed decommissioning information. Some information, likewise, cannot be available in certain stages while some are required in each licensing step.

In order for an application to be accepted and the corresponding authorizations to be issued by PNRI, the applicant must comply with PNRI regulations, orders and rules applicable to the licensed activity.

Each licensing step requires the applicant to submit an accomplishment report to be reviewed and approved by PNRI, and the corresponding portions of the ***Safety Analysis Report.*** The report specifies the safety documentation and conditions under which the facility was constructed or operated. These documents are the basis of the PNRI review and will be part of the license issued for each specific authorization. The Licensee must adhere to the technical specifications specified in an approved ***Safety Analysis Report*** and any deviation from these specifications would require prior approval by PNRI. Depending upon the degree of importance and significance of the deviation, this approval may require an amendment to the license.

When the licensee has received the *license to operate,* the facility according to a routine schedule the licensee will be required to submit an *Annual Compliance Report,* at the end of each year of operation, that summarizes the significant operational events or changes during the past year.

For the production of radionuclide, the radionuclide processing and dispensing laboratories and subsequent medical administration of the radioactive materials must be authorized under appropriate licenses issued pursuant to corresponding Parts of the Code of PNRI Regulations.

Response from Applicant:

- The applicant must submit a Safety Analysis Report at each step in the licensing process. You may choose to adopt the model for the typical contents of a Safety Analysis Report found in **Appendix B** of this Regulatory Guide or you may develop an equivalent SAR for review by the PNRI staff

ITEM 9.0 RADIATION SAFETY PROGRAM.

Regulation: Section 17 of CPR Part 21

Applicants must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation safety program during the licensing process. The appendices in this guide may be helpful in determining what information should be provided in the Radiation Safety Program.

The table below presents all programs and procedures that are required to be included in your Radiation Safety Program. You may choose to adopt the model procedures or programs found in **Appendices C** to **S** of this Regulatory Guide or you may develop an equivalent procedure or program for review by the PNRI staff. Each procedure or program of the Radiation Safety Program must be customized to reflect the current practices or information of the facility.

Item	Section in the CPR	Title	Appendix
1.	Section 18	Organization, Duties and Responsibilities of the Radiation Safety Committee	C
2.	Section 19	Designation of a Qualified Radiation Safety Officer (RSO) and Assistant RSO	D
3.	Section 19	Duties and Responsibilities of the RSO	E

4.	Section 7	MODEL ALARA Program	F
5.	Section 26	Personnel Monitoring Program	G
6.	Sections 36-39	Training/Refresher Program	H
7.	Section 40	Procedure for Keeping Records of Radionuclide Produced	I
8.	Section 32	Quality Assurance Program	J
9.	Section 27	Procedure for Radiation Surveys (dose rate and contamination monitoring)	K
10.	Section 21	Model Procedure for Performance Testing of Fumehood	L
11.	Section 27	Calibration of Survey Instruments and Other Devices	M
12.	Section 34	Radioactive Waste Management	N
13.	Section 24	Operating Procedure	O
14.	Section 25	Emergency Plan including Conduct of Drill	P
15.	Section 30	Transport of Radioactive Materials	Q
16.	Section 35	Decommissioning Plan	R
17.	Section 40	Recordkeeping	S

Response from Applicant:
Submit a copy of each procedure/program required in Section 17 of CPR Part 21. If you submit a copy of the model procedure or program, edit the content to identify key individuals, equipment by name or model, room numbers, or other specific information. Complete the application by marking the appropriate box for each procedure.

ITEM 10.0 SECURITY OF PARTICLE ACCELERATOR FACILITY.

Regulations: Section 31 CPR Part 21; CPR Part 26; CPR Part 27.

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:

This section should demonstrate how the operation of the accelerator and access to any radioactive material is restricted to authorized personnel only. This should include a description of physical (e.g., use of key or passwords) and administrative means.

Licensees must provide adequate physical protection of sources and facilities on site and during transportation of radioactive sources. Physical protection of radioactive sources involves 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.

Response from Applicant:

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

This section should demonstrate how the operation of the accelerator and access to any radioactive material is restricted to authorized personnel only. This should include a description of physical (e.g., use of key or passwords) and administrative means.

ITEM 11.0 APPLICATION AND LICENSE FEES.

The applicant shall refer to CPR Part 22, "Fees and Charges for Radioactive Material Licenses and Other Regulatory Fees", to determine the amount of application or license fee to be paid. The application fee must be paid upon submission of the application. For a new license, the license fee may be paid upon notification of approval of the license or upon issuance and release of the license. For amendment to a license, the applicant shall not implement any amendment until he/she has received a written approval from PNRI and after payment of the amendment fee. For a license renewal, the required license fee must likewise accompany an application for renewal of a license. The application must indicate the amount of application fee or license fee paid, the official receipt numbers and date the fees were paid.

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

Duration of License and License Fee:

The duration of the license for the routine operation of the accelerator facility from first use of the facility and the frequency of license renewal, and the corresponding license fees will be determined by PNRI.

ITEM 12.0 CERTIFICATION.

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

ITEM 13.0 ACKNOWLEDGEMENT.

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

4. AMENDMENTS AND RENEWALS OF LICENSE

Regulations: Sections 10; 12 of CPR Part 21

It is the applicant's obligation to keep the license current. If any of the information in the original application is to be modified or changed, the licensee must submit an application for a license amendment 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 sixty (60) days before the expiration date in accordance with Section 12(a) of CPR Part 21.

An amendment to the operating license must be issued by PNRI if the licensee plans to modify the facility or its operating conditions in a manner that will create a hazard that is not analyzed in the ***Safety Analysis Report.*** This application for an amendment of the license should be supported by a revision of any affected parts of the ***Safety Analysis Report****.*

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

In general, the operating license should always be amended upon a major change in the construction of the facility (e.g. adding shielding, upgrading the safety systems), major modification of the radiation safety programme, and of the operating conditions (increase in the workload, using different targets).

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 for an amendment or renewal request.
- Submit the Application Form PNRI/NRD-021 or a letter requesting amendment.
- Provide the license number.
- For renewals, provide complete and up-to-date documentation 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 LICENSE

Regulations: Section 13 of CPR Part 21.

Prior to informing PNRI, a licensee who decides to terminate a license must 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. The termination of a license maybe initiated at any time at the request of the licensee. A licensee's determination that a facility is not contaminated is subject to verification by PNRI. The PNRI

will formally terminate the license to operate when the procedures and activities described in the approved decommissioning plan were satisfactorily met.

For guidance on the disposition of licensed material, refer to Section 13 of CPR Part 21 and for decommissioning requirements, refer to Section 35 of CPR Part 21.

Response from Applicant:

The licensee is not required to submit a response to the PNRI during the initial application. However, when the licensee decides to cease operations, any necessary decommissioning activities must be undertaken and information relevant to decommissioning must be submitted to PNRI at least **six (6) months** before the start of decommissioning activities. The licensee should submit a report on the completion of decommissioning activities, safe disposal of radioactive sources and personnel doses received during the decommissioning operations.

APPROVED:

CARLOS PRIMO C. DAVID, Ph.D.
OIC, Director

Date: March 30, 2017

APPENDIX A

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

APPLICATION FOR A LICENSE OF PARTICLE ACCELERATOR FACILITY FOR THE PRODUCTION OF RADIONUCLIDE

INSTRUCTIONS: To complete this application, refer to Part 21 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for a License of a Particle Accelerator Facilities for the Production of Radionuclide. Submit duplicate copies of the completed application form, with the specified application/license fee, and all required attachments, to the Nuclear Regulatory Division, Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City.

I. This is an application for: (Check appropriate box)

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

II. Type of License:

☐ A. PROVISIONAL PERMIT
☐ B. LICENSE TO CONSTRUCT
☐ C. LICENSE TO OPERATE

I. GENERAL INFORMATION

1.0 NAME AND MAILING ADDRESS OF APPLICANT.

Institution/Firm _____

Address _____

Director/Chairman of the Institution _____

Telephone & Fax Nos. _____

E-mail Address _____

2.0 PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____

Position/Title _____

Address _____

Tel/Fax Number/E-mail Address _____

3.0 TYPES OF AUTHORIZATION AND GENERAL REQUIREMENTS

4.0 LOCATION AND TECHNICAL SPECIFICATION OF THE PARTICLE ACCELEARTOR FACILITY.

4.1 Location of Facility

Building _____ Room _____

Street _____

City _____ Province _____

Telephone and Fax Number _____

Attachment 1:

Particle Accelerator Facility Layout

		Attached	Remarks
4.1.1	Layout of the facility	☐	_____
4.1.2	Rooms/areas	☐	_____
4.1.3	Description of shielding design	☐	_____
4.1.4	Description of ventilation system	☐	_____

Attachment 2:

Laboratory Facility Layout

		Attached	Remarks
4.1.5	Layout of the facility	☐	_____
4.1.6	Rooms/areas	☐	_____
4.1.7	Description of shielding design	☐	_____
4.1.8	Description of ventilation system	☐	_____

4.2 Technical Specifications of the Particle Accelerator.

Manufacturer _____ Installation Date _____

Model Name _____ Serial Number _____

Types of Beam _____

Maximum Energy and Current _____

Maximum Particle Velocity/Acceleration _____

Accelerator Targets – for each accelerator target provide the following information:

Target Chamber				Maximum Beam Current (uA)	Bombardment Time (Min.)	Maximum EOB activity (GBq)
Part No.	**Nuclear Reaction**	**Product**	**Material**			

Attachment 3:
Information regarding the equipment (e.g., brochure) ☐ Attached ☐ NA Remarks_____

4.3. Facility and Equipment Description.

4.3.1 QA/QC Instrumentation

Type of Equipment	Manufacturer	Model	Serial Number	Supplier/ Distributor

4.3.2 Dose Calibrator and/or Other Equipment Used to Measure Dosages of Radionuclides

Type of Equipment	Manufacturer	Model	Serial Number	Supplier/ Distributor	Date of Last Calibration	Organization to Perform Calibration

4.3.3 Personnel Monitoring Instruments

a. Personnel Monitoring Badge

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

b. Direct Reading Dosimeters

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

4.3.4 Radiation Instruments

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

Attachment 4:
Calibration Certificates of Radiation Survey Instruments ☐ Attached ☐ NA Remarks_____

5.0 PROOF OF LEGAL STATUS.

SEC Registration Number _____

Business Permit Number _____

Attachment 5:
Proof of applicant's incorporation, registration or charter (SEC registration or equivalent) ☐ Attached ☐ NA Remarks_____

For public institutions, specify the enabling legislation (Act):

_____

6.0 RADIONUCLIDE(S) PRODUCED AND PURPOSE(S) OF USE.

6.1 Radionuclide produced using the particle accelerator

Radionuclide (Element/Mass Number)	Max. Amount at Any One Time	Max. Total Activity in One Year

6.2 Radioactive Sources (e.g., Check Sources)

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

Attachment 6:

Calibration Certificates of Radioactive Sources ☐ Attached ☐ NA Remarks_____

7.0 RADIATION WORKERS AND THEIR TRAINING AND EXPERIENCES

Pls. refer to Attachment A to C

Worker	Name	Trainings	Experiences
Radiation Safety Officer (RSO)			
Assistant RSO			
Authorized Operator			
Authorized Technical Staff			

8.0 SAFETY ANALYSIS REPORT (SAR)

Attachment 7:

1. INTRODUCTION

1.1 General Description ☐ Attached ☐ NA Remarks_____
1.2 Identification of Owner, Agents and Contractors ☐ Attached ☐ NA Remarks_____
1.3 Use of the Facility ☐ Attached ☐ NA Remarks_____

2. SITE SUITABILITY

2.1 Description of the Location of the Facility ☐ Attached ☐ NA Remarks_____
2.2 Description of Surroundings and Access Roads ☐ Attached ☐ NA Remarks_____

3. TECHNICAL SPECIFICATIONS OF THE ACCELERATOR

3.1 Particles Accelerated ☐ Attached ☐ NA Remarks_____
3.2 Acceleration System ☐ Attached ☐ NA Remarks_____
3.3 Beam Transport System ☐ Attached ☐ NA Remarks_____
3.4 Target-Irradiation Course ☐ Attached ☐ NA Remarks_____

4. FACILITY DESIGN

4.1	Facility Plans and Drawing	☐ Attached	☐ NA	Remarks_____
4.2	Classification of Adjacent Areas	☐ Attached	☐ NA	Remarks_____
4.3	Fire Protection System	☐ Attached	☐ NA	Remarks_____
4.4	Ventilation and Cooling Systems	☐ Attached	☐ NA	Remarks_____

5. ANALYSES OF RADIATION HAZARDS AND SAFETY FEATURES

5.1	Radiation	☐ Attached	☐ NA	Remarks_____
5.2	Radioactivity	☐ Attached	☐ NA	Remarks_____
5.3	Designation of Controlled Areas	☐ Attached	☐ NA	Remarks_____
5.4	Shielding Design and Calculations	☐ Attached	☐ NA	Remarks_____
5.5	Radiation Warning System	☐ Attached	☐ NA	Remarks_____
5.6	Radiation Damage to Components	☐ Attached	☐ NA	Remarks_____
5.7	Handling and Confinement of Radioactive Materials	☐ Attached	☐ NA	Remarks_____
5.8	Environmental Releases	☐ Attached	☐ NA	Remarks_____

6. NON-RADIATION HAZARDS

6.1	Description of any hazard associated with the operation of the accelerator other than radiation hazards	☐ Attached	☐ NA	Remarks_____

7. CONSTRUCTION REPORT

7.1	Construction Report	☐ Attached	☐ NA	Remarks_____

8. COMMISSIONING

8.1	Commissioning Plan	☐ Attached	☐ NA	Remarks_____
8.2	Commissioning Report	☐ Attached	☐ NA	Remarks_____

9.0 RADIATION SAFETY PROGRAM

9.1	Organization, Duties and Responsibilities of the Radiation Safety Committee	☐ Attached	☐ NA	Remarks_____
9.2	Designation of a Qualified Radiation Safety Officer (RSO) and Assistant RSO	☐ Attached	☐ NA	Remarks_____
9.3	Duties and Responsibilities of the RSO	☐ Attached	☐ NA	Remarks_____
9.4	Model ALARA Program	☐ Attached	☐ NA	Remarks_____
9.5	Personnel Monitoring Program	☐ Attached	☐ NA	Remarks_____
9.6	Training/Refresher Program	☐ Attached	☐ NA	Remarks_____
9.7	Procedure for Keeping Records of Radionuclide Produced	☐ Attached	☐ NA	Remarks_____

9.8 Quality Assurance Program ☐ Attached ☐ NA Remarks_____
9.9 Procedure for Radiation Surveys (dose rate and contamination monitoring) ☐ Attached ☐ NA Remarks_____
9.10. Model Procedure for Performing Testing of Fumehood ☐ Attached ☐ NA Remarks_____
9.11 Calibration of Survey Instruments and Other Devices ☐ Attached ☐ NA Remarks_____
9.12 Radioactive Waste Management ☐ Attached ☐ NA Remarks_____
9.13 Operating Procedure ☐ Attached ☐ NA Remarks_____
9.14 Emergency Plan including Conduct of Drill ☐ Attached ☐ NA Remarks_____
9.15 Transport of Radioactive Materials
9.16 Decommissioning Plan
9.17 Recordkeeping ☐ Attached ☐ NA Remarks_____

10.0 SECURITY OF PARTICLE ACCELERATOR FACILITY

10.1 Security Plan ☐ Attached ☐ NA Remarks_____

11.0 APPLICATION AND LICENSE FEES

APPLICATION FEE PhP_____
Official Receipt Number _____
Date _____

LICENSE FEE PhP_____
Official Receipt Number _____
Date _____

12.0 CERTIFICATION:

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

_____
Signature of Certifying Official

_____
Typed or Printed Name of Certifying Official

_____
Title/Position of Certifying Official

_____
Date

13. ACKNOWLEDGEMENT

{Republic of the Philippines}
{ }

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

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

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

_____
Notary Public

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

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

ATTACHMENT A

TRAINING AND EXPERIENCE OF PROPOSED RADIATION SAFETY OFFICER (RSO) AND ASSISTANT RSO

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

1" x 1" ID Photo

1. TRAINING IN RADIATION SAFETY
(Enclose certificates of training and use additional sheets if necessary.)

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

2. EXPERIENCE WITH OPERATION AND USE OF PARTICLE ACCELERATOR

Specification (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**Where Experience Was Gained**	**Duration of Experience**	**Type of Use**

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

Title of Training	Place of Training	Date of Training

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

_____
Signature of Proposed RSO/ARSO

Date: _____

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

ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED OPERATORS

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					
b. Radiation Safety					
c. Radiation Detection instrumentation					
d. Radiation Protection					
e. Security of Radioactive Sources/Facility					
f. Nuclear Regulations and Licensing					

2. EXPERIENCE IN THE OPERATION AND USE OF PARTICLE ACCELERATOR

Specifications (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**Max. Activity Produced** (Bq)	**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 Authorized Operator

Date: _____

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

ATTACHMENT C

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED TECHNICAL STAFF

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. Radiation Detection & Measurement					
d. Security of Radioactive Sources/Facility					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE IN QUALIY CONTROL, MANUFACTURE AND DISPENSE OF RADIOISOTOPE (List laboratory facilities and equipment)

Specifications (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**Max. Activity Produced** (Bq)	**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 Authorized Operator

Date: _____

APPENDIX B

TYPICAL CONTENTS OF A SAFETY ANALYSIS REPORT

I. INTRODUCTION

The first chapter of the ***Safety Analysis Report*** should present an introduction to the report and a general description of the facility.

1.0 General Description

This section should briefly present the principal aspects and components of the entire facility and other systems that interface with the facility, a historical background, the type of accelerator, and the general arrangement of the facility and its equipment.

2.0 Identification of Owner, Agents and Contractors

This section should identify the owner of the facility and the prime agents, consultants or contractors for procurement, design, construction and maintenance services.

3.0 Use of the Facility

The main purpose of the facility should be described. It should include the expected output and other systems that benefit from the operation of the accelerator facility.

4.0 Reference Materials

This section should provide a listing of references to all topical reports **incorporated** by reference as part of the report. This usually includes, among others, the manufacturer's documentation and technical drawings.

II. SITE SUITABILITY AND FACILITY DESIGN INFORMATION

This chapter should include the location and address of the facility, its layout and boundaries. It should show with sufficient detail the surroundings of the facility and access roads and gateways.

III. ANALYSES OF RADIATION HAZARDS AND SAFETY FEATURES

This chapter should analyze the radiation hazards for the workers and the public due to the normal operation of the accelerator facility and in emergency situations. In addition, it should state the protective measures used to limit the radiation exposures and to reduce the chance of accidental exposures.

1.0 Source of Radiation Hazards

a) Radiation

This section should summarize the sources of prompt radiation during accelerator operation, and the locations, nature, and range of high radiation levels at different points in the system. In addition, information on the nature

and magnitude of the radiation expected due to activation of components should be provided.

All other expected radiation fields, such as those created by “dark currents” or x-rays from radio-frequency systems, should be described.

b) Radioactivity

This section should provide information on the expected quantities and nature of the radioactive materials that will be produced by bombarding the target with projectiles (production of radionuclide) and those that will be produced in the components and shielding (induced activity).

2.0 Designation of Controlled Areas

This section should specify the areas where no person shall be present during operation (exclusion areas), the areas where the radiation field may be high during certain operating conditions (high radiation areas) and all other occupied areas where occupants may receive non-negligible doses due to the operation of the facility. Distinction should be made between the controlled and uncontrolled areas. Information on the type, limitation and duration of occupation of these areas should be provided.

3.0 Shielding Design and Calculations

This section should provide estimates for the doses that may be received by the persons who occupy the areas surrounding the radiation sources due to the routine operation of the facility. All assumptions that have to be used for these estimates should be stated. This should include the workload (weekly or yearly) and the average beam-on time. When different modes of operation are used, an estimate of the percentage of each mode should be provided. Operational modes (or beam configurations) should be described in terms of beam current, particles, energies, orientations and targets. Simplified assumptions may be used taking into account the worst bean configuration.

It should be noted that the workload assumed in the calculations, as any other information in the Safety Report, would become a condition in the license. The licensee may not go beyond this limit without a prior modification of the license. Therefore, it is advisable to assume a conservative value for the maximum workload, thereby providing a margin for eventual increase of workload in the future.

In order for PNRI to evaluate the shielding specifications, information and drawings should be provided that describe the radiation shielding material, densities, thickness, and locations with regard to the radiation source. The calculations should be provided for a sufficient number of points to represent the most critical locations around the radiation sources.

4.0 Radiation Warning Systems

This section should provide information on the radiation warning systems installed in the accelerator facility. The radiation warning systems, preferably, include two groups of systems: access control systems and alarm systems.

Access control systems are intended to prevent unauthorized or accidental entry into the radiation areas. Elements of this system include physical barriers, signs, closed circuit TV, flashing lights, audible warning devices, interlock systems and administrative procedures that define conditions where the entry is safe.

A radiation alarm system is a system that alerts individuals to a potential or actual change in the safe working environment. A visual or audible alarm may result from an increase in the radiation exposure rate or an increase in the amount of ambient airborne radioactive material. The radiation field is measured either directly by an appropriate detector or indirectly by monitoring a non-radiological parameter, such as high voltage or beam current.

This section should also include:

(a) The search procedure of a radiation area before start-up. This includes the responsibility for persons effecting the search and secure, the search path, and whether "search start", "search complete" or time delay switches are mounted. Their locations should be specified.

(b) The control logic of the interlock system, whether it is a relay logic, solid state or computer dependent.

(c) A description of the alarm system including the type and specifications of sensors, the preset alarm level, and the alarm action.

(d) Wiring diagrams for the interlock circuit and the radiation monitoring circuits should be provided.

(e) In the case of computer-based interlock system, the following information should be provided:
    (i) The functional specification
    (ii) Design documentation including:
        - Software specification and outline
        - Listing
        - Hardware specification and description
        - Schematics (interfacing)
    (iii) Test specifications and results

The radiation warning systems should meet the following requirements:

(1) The interlock components and materials should be of high grade for dependability and long life. Materials that resist radiation should be selected.

(2) Fail-safe circuits and components should be used whenever practicable.

(3) Duplicate (parallel) circuits or redundant components should always be used in critical applications. Whenever possible, at least two different methods should be in place to remove the beam or radiation source. Whether or not interlock redundancy is required, it must, therefore, be evaluated and decided by risk analysis process.

(4) Continuous radiation monitoring devices should be operating in or adjacent to all high radiation areas, and in all other areas where radiation intensity may increase with the operational level of the accelerator. Such monitoring devices should provide an audible warning to personnel in the vicinity when preset maximum levels are exceeded.

(5) Emergency stop buttons must be located in all high radiation areas accessible to humans. They should be clearly visible, labelled, and readily accessible. Their locations and type should be indicated.

(6) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and finally at the main control console.

(7) "Run-safe" switches or keys should be installed to prevent start-up of an accelerator or radiation source when a radiation area is occupied.

(8) Warning lights should be located outside entrance to accelerator enclosures and high radiation areas.

(9) An audible warning should be sounded inside accelerator enclosure before the accelerator is turned on.

5.0 Radiation Damage to Components

High radiation levels inside the accelerator shielding can damage the facility's components including electronic devices, cables, wiring, water hoses, motors, loudspeakers, and alarms. The damaging radiation for proton accelerators will be mostly neutrons and charged particles, and for electron accelerators the main causes will be bremmsstrahlung, secondary electrons, synchrotron radiation and perhaps neutron. This is important since the devices that fail may be critical to radiation safety and also, failures will require work in areas that often have the highest residual radiation levels, thus increasing the total doses to workers.

This section should provide estimates of the radiation damage for sensitive components. Also it should provide information on the design solutions to limit or minimize the damage such as positioning sensitive devices in areas with lower radiation levels, choosing material of best radiation resistance, or installing shielding at critical points.

6.0 Handling and Confinement of Radioactive Materials

This section should describe the radiation exposure hazard as a result of handling irradiated targets during normal operation and activated components during maintenance. Protective measures including engineered features and administrative controls should be described.

When a radioactive effluent transport system is used, an analysis of the reliability of this system during any accident that involves a loss of confinement of radioactive materials should be provided. Also, an estimate of the dose of radiation that may be received by any person from such an accident should be provided. Any emergency system that provides an action

such as re-routing, ventilation, or blocking the flow of radioactive effluent, or any other action should be described.

7.0 Environmental Releases

This section should evaluate the releases of radioactive effluents outside the boundary of the facility in order to demonstrate that these releases do not exceed acceptable limits. Depending on the magnitude of the release from the facility, pathway analyses may be required. A pathway analysis should identify all significant pathways from the facility that may lead to human exposure. Then, the derived emission limits or the limits governing the releases should be calculated and tabulated. Also, the expected level of irradiated gaseous and liquid releases should be stated. In addition, the maximum release from a radiological accident should be estimated.

In case of electron accelerators, an analysis of the ventilation system should be provided to ensure that the hazard on-site and off-site from the produced radioactivity in air (N-13 and O-15) as well as ozone and other noxious gases, must not exceed acceptable limits. This should include estimates of the quantities produced, the ventilation flow rate, the location of intakes and discharge points and the ventilation type (once-through or re-circulated).

IV. NON-RADIATION HAZARDS

This chapter should describe any hazards associated with the operation of the accelerator facility other than the radiation hazards. This may include the following:

- Use of hazardous materials such as toxic, inflammable, compressed gas, etc.;
- Mechanical hazards;
- Fire and explosion hazards;
- Electrical hazards; and
- Microwave hazards.

The PNRI review of this information is limited to the impact of an accident initiated by a non-radiation source, on radiation safety. The applicant must address the regulations imposed by concerned government

V. CONSTRUCTION REPORT

This chapter should be provided at the completion of the construction and installation of the accelerator facility. This chapter of the ***Safety Analysis Report*** should include any modifications of the dimensions or layout of the facility or its surroundings which were introduced after the application for construction approval. Drawings should be updated, if applicable, and confirmation that construction has been performed as planned, should be supported by information on the quality of shielding materials, especially the density of concrete shields.

VI. COMMISSIONING REPORT

Commissioning, for the purpose of this guide, means all radiation and non-radiation tests that are performed on the facility to ensure that it is ready for routine operation.

The licensee, as authorized in the license to construct, may perform any tests to systems or components prior to issuance of the Operating License, provided that there is no production of any radiation.

This chapter should provide the plan for commissioning and the commissioning results.

1.0 Commissioning Plan

This section should include information on the tests to be performed, an analysis of the hazards involved and the precautions to be taken during these tests to ensure safety of the personnel and the public.

a) A general program of the radiation test including an estimate of the duration of time and the maximum radiation parameters to be applied.

b) Brief information on the non-radiation tests to be performed on the accelerator or its systems and components.

c) Detailed information on the tests to be performed on the safety feature e.g., door interlock, emergency stop buttons, beam warning light, etc.

2.0 Personnel

This sub-section should list the personnel involved in the commissioning activity and describe their responsibilities, training and experience.

It should be specified whether these individuals are a part of the facility staff who will be involved in future operation, or whether they are from an outside consultant or manufacturer.

3.0 Precautions During Commissioning

This sub-section should analyze the hazards involved during testing. It should specify any non-routine conditions (e.g., overriding an interlock, etc.). It should also describe the precautions during commissioning. This may include administrative and physical controls to restrict occupancy of certain areas during commissioning. An estimate of the radiation dose to personnel and to the public due to the commissioning should be provided.

4.0 Commissioning Report

This section should be provided upon completion of commissioning. It should summarize the results of commissioning, particularly the following:

a) A statement that the commissioning has been performed according to the plan or identification of any modification to the plan.

b) Any unusual event or incident that occurred during commissioning which is of interest for radiation safety should be described and analyzed.

c) Confirmations that the safety features are operable.

d) Radiation survey results:

This sub-section should show the results of the radiation survey performed during commissioning, report the results in a table format and include the calculated values for comparison. Any discrepancy between the measured and calculated values should be interpreted.

In addition to the dose rate measurements the annual doses to different categories of persons should be estimated based on occupancy and workload assumptions.

Response from Applicant:

- Upon completion of the construction, the licensee must request the license to commission the facility, i.e. to produce radiation.

- The purpose of the commissioning is to verify the operating and technical characteristics of the machine, the adequacy of the shielding and other engineering controls and to test the safety systems.

- Upon successful commissioning and the acceptance of the commissioning report by PNRI, the licensee may commence routine operation.

VII. CONDUCT OF OPERATION

Specific elements of an application to operate:

1.0 For the purposes of commissioning the facility

a) The physical and administrative controls used to restrict access to the cyclotron area during the tests.

b) The description of the precautions taken to ensure safety during the tests.

c) Detailed description of the tests intended to ensure that the safety devices will operate as intended. Tests must be performed on the following safety devices:

i. Door interlock
ii. Beam on/ beam off indicator lights
iii. Emergency off push buttons
iv. Last Person Out interlock

d) The name and title of the person who will be responsible for planning and supervising the tests. If this person is different from the RSO, describe this person's training and experience and include his/her position and responsibilities in the facility's organization**.**

e) The operation time that will be required during commissioning and the dose rates at the locations adjacent to the exclusion area during commissioning.

f) A list of safety related tests that intended to verify the performance of the cyclotron.

g) A plan that you will follow for the safe verification of the adequacy of shielding including a measurement of the dose and the dose rate at

accessible points where calculations were made and a walk-through survey.

i. A list and descriptions of the radiation detection instruments that you will use for the survey.

ii. The ventilation must be shown by measurements to provide the number of air changes per hour submitted in the application for a license to construct.

iii. A confirmation statement that is signed by both the signing authority of the applicant and the contractor **after the completion of the construction** stating that the **as-built** shielding density, composition and thickness are according to the specifications submitted by the applicant.

iv. A list of anticipated non-radiation hazards in the facility with the precautions taken against them.

APPENDIX C

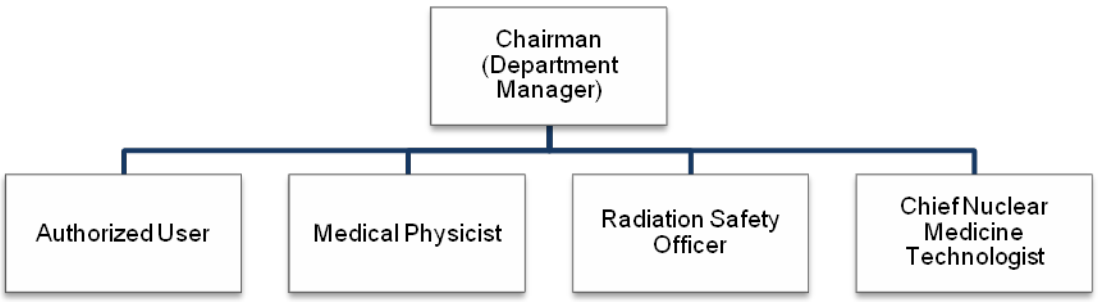
ORGANIZATION, DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY COMMITTEE

A Radiation Safety Committee (RSC) should be formed. If the institution has already established a Medical Isotopes Committee (MIC), with reference to other facilities licensed by PNRI, the RSC may be integrated into the MIC or may constitute as an Ad-Hoc group of the MIC. The functions of the RSC, with respect to the accelerator facility, should include:

- Advising management on radiation safety policy and procedures,
- Monitoring radiation safety performance,
- Reviewing unusual procedures or operations and requests for variance from established policies, and
- Providing guidance to the RHSO.

This sub-section should provide information on the composition of the RSC, the frequency of meeting and its responsibilities.

Organizational Structure:



Mandate. The Committee shall:

(1) Ensure that the operation of a particle accelerator facility for the production of radionuclide for medical use is in accordance with the regulations.
(2) Ensure that the radionuclide produced will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;
(3) Ensures that radioactive material is used in compliance with PNRI regulations and the radioactive material license;
(4) Ensure that the operation of the particle accelerator is consistent with the ALARA philosophy and program;
(5) Establish a table of investigational levels for individual occupational radiation exposures; and
(6) Identify program problems and solutions.
(7) Have the authority to terminate all operations in a particle accelerator facility if such action is deemed necessary to minimize danger to the workers, public health and safety or property.

Duties and Responsibilities. The Committee shall:

(1) Be familiar with all pertinent PNRI regulations, the license application, the license, and amendments;
(2) Review the training and experience of the proposed authorized operator, the authorized technical staff, Radiation Safety Officer (RSO), Assistant RSO and other workers to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
(3) Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all request for authorization to operate a particle accelerator facility, such as the production of radionuclide, processing, dispensing and transport;
(4) Prescribe special conditions that will be required during the operation of the facility such as requirements for bioassays, physical examinations of users and workers, and special monitoring procedures;
(5) Review semi-annually the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
(6) Establish a program to ensure that all persons whose duties may require them to work in or frequent high risk areas are appropriately instructed.
(7) Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with PNRI regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of PNRI inspections, written safety procedures, and the adequacy of the management control system;
(8) Recommend remedial action to correct any deficiencies identified in the radiation safety program;
(9) Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and
(10) Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

(1) The Committee shall meet as often as necessary to conduct its business but not less than twice in each calendar year.

(2) Membership must include at least one authorized operator, the RSO, authorized technical staff, service providers for the repair and maintenance of the facility and a representative of management who is neither an authorized operator nor a RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct member representatives from security, physical plant, housekeeping and other departments. (Adjunct members should abstain from voting on radiation safety technical questions such as Items 2 through 5 in the "Duties and Responsibilities" section above).

(3) To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

APPENDIX D

DESIGNATION OF A QUALITIED RADIATION SAFETY OFFICER (RSO) AND ASSISTANT RSO

SAMPLE DELEGATION OF AUTHORITY FOR THE RADIATION SAFETY OFFICER AND ASSISTANT RSO

Memo To: _____, Radiation Safety Officer

From: _____, Department Manager

Subject: **RSO Delegation of Authority**

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

_____ _____

Signature of Department Manager Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX E

DUTIES AND RESPONSIBILITIES OF THE RSO

This sub-section should describe the duties and responsibilities of the facility's Radiation Safety Officer (RSO). The designated RSO should have the following functions:

- Advise top management on all matters concerning radiation and radiation safety.

- Define, with the concurrence of management, the radiation safety requirements and assure compliance with PNRI regulations and the license conditions.

- Monitor, and report to top management, the effectiveness of the radiation safety program.

- Have authority to stop activities which appear to have imminent hazard or which violate the facility's safety policies.

- Investigate, document and report to PNRI overexposures, accidents, spills, losses, and thefts; unauthorized orders, receipts, uses, transfers, and disposals; and other deviations from the approved radiation safety practice and implement corrective actions, as necessary.

- Establish and implement written policy and procedures for:
  a) Authorizing the production of radionuclide;
  b) Storing radionuclide;
  c) QA/QC results of the radionuclide for every production
  d) Ensuring that all radiation workers are properly trained;
  e) Taking emergency action in the event of an accident involving radioactive material;
  f) Ensuring the use of personnel monitoring devices as required;
  g) Performing periodic radiation surveys;
  h) Performing operational checks of survey instruments and other safety equipment;
  i) Inventory of radionuclide produce;
  j) Disposing of radioactive waste;
  k) Transport of radioactive material or radioactive waste;
  l) Training personnel;
  m) Decommissioning of the facility; and
  n) Keeping a copy of all records and reports required by the regulations, a copy of these regulations, a copy of each licensing request, license and license amendments, and the written policy and procedures required by the regulations.

- Interface with regulatory inspectors and provide access to required records for inspection,

- Conduct briefings to management once each year on the production of radionuclide.

- Establish investigational levels for personnel exposure, that, when exceeded, will initiate an investigation by the RSO of the cause of the exposure.

- Establish higher personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RSO of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

- Conduct review of radiation safety program and ensure that the results of audits, identification of deficiencies and recommendations for change are documented, maintained and provided to management for review. He shall ensure that prompt action is taken to correct deficiencies; and

- Assist the Radiation Safety Committee (RSC) in the performance of its duties.

APPENDIX F

MODEL ALARA PROGRAM

1. Management Commitment

a. We, the management of this (Particle Accelerator Facility), are committed to the program describe herein for keeping individual and collective doses as low as is 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. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

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

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

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

2. Radiation Safety Committee (RSC)

a. Review of Proposed Radiation Workers and Types of Use
   1) The RSC will thoroughly review the qualifications of each applicant with respect to duties, responsibilities and assignment for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
   2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA.
   3) The RSC will ensure that the users and workers justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority
   (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program).
   1) The RSC will delegate authority to the RSO to enforce the ALARA concept.
   2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the meeting.

c. Review of ALARA Program
   1) The RSC will encourage RSO, authorized operator, authorized technical staff and other workers to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
   2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the Investigational Level I Table F-1 is exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when trigger levels are exceeded (see Item 6 below for the discussion of trigger levels)*
   3) The RSC will evaluate the institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized operator, authorized technical staff, and other workers as well as those of management.

3. Radiation Safety officer (RSO)

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

b. Educational Responsibilities for ALARA Program
   1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

   2) The RSO will ensure that authorized operators, authorized technical staff and other workers who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures
   Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

   1) The RSO will be in close contact with the authorized operator, authorized technical staff and other workers in order to develop ALARA procedures for working with radioactive materials.
   2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

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

4. Authorized Operator

a. New Methods of Use Involving Potential Radiation Doses
   1) The Authorized Operator will consult with the RSO and/or RSC during the planning stage before operating the particle accelerator to produce radionuclide.
   2) The Authorized Operator will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized Operator's Responsibility to Supervised Individuals
   1) The Authorized Operator will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
   2) The Authorized Operator will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions
b. Workers will be instructed in resources available if they feel ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses)*

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or RSO. The investigational levels that we have adopted are listed in **Table F-1**. These levels apply to the exposure of individual workers. The RSO will review and record results of personnel monitoring at least every six (6) months.

In cases where a worker's or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

Table F-1. Investigational Levels

	Investigational Levels* (mSv)
1. Total Effective Dose Equivalent	1
2. Lens of the Eye	1
3. Extremities (hands and feet) or to the skin	25

*The investigational levels in this program are not new dose limits but, serve as a check points above which the results are considered sufficiently important to justify investigations. It is based on the recommended monitoring dose equivalent to 3/10 of the annual dose limit for the exposed worker.

7. **Signature of Certifying Official** *

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

_____
Signature

_____
Name

_____
Title

* The person who is authorized to make comments for the administration of the institution

APPENDIX G

PERSONNEL MONITORING PROGRAM

This section should describe the personnel monitoring program. This program must comply with regulatory requirements for personnel dosimetry. This section should include:

- The type(s) of personal dosimeters used (e.g., OSL, TLD, pocket dosimeter, DRD, neutron dosimeter, extremity dosimeter, etc.).

- If more than one type is used, the category of workers and the type of activity associated to each type of personal dosimetry should be specified.

- The number of monitored workers.

- Depending on the nature of the radiation fields, especially the neutron contribution to personal doses, neutron dosimetry may be required. Also, in case of handling activated parts, extremity dosimeters may be required. The licensee should demonstrate that the choice of dosimeters is appropriate.

- The application of a non-personal monitoring technique, if any, should be justified.

PROGRAM

(1) The Radiation Safety Officer (RSO) will review, sign and date all exposure reports at least every six months to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a thermoluminescent dosimeter (TLD), or optically stimulated luminescent dosimeter (OSL).

(2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a TLD or OSL whole body monitor that will be processed by a PNRI service provider or a PNRI licensee who is qualified to perform dosimetry processor.

(3) All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a TLD or OSL extremity monitor that will be processed by a contract service on a bi-monthly basis.

(4) All individuals who are occupationally exposed to radiation in excess of 5 mSv in a year, such as those who are entering a high or very high radiation area will be issued a whole body monitor.

(5) Individuals who are exposed to radiation on an occasional basis are not normally issued exposure monitors. Examples of these individuals are: security personnel who receive or deliver packages; secretarial personnel who work in the administrative section of the facility and transport workers.

(6) All personal dosimeters will be processed and evaluated by a dosimetry provider holding a PNRI license.

RECORDS

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

(2) We will prepare for employee requiring personnel monitoring a report of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body by the individual. This report will include data and results obtained as required by Section 40 of CPR Part 21.

(3) Upon the request of the employee, a written report of his/her exposure to radiation at this facility will be given after termination of employment. This report will be furnished to the former employee within 30 days of termination of the employee or within 30 days after the exposure of the individual has been determined by the facility, whichever is later. This report will cover every two months in which case the employee's working activities involved the exposure to sources of radiation and shall include dates and location of work under the license in which the worker participated. Records will be maintained for 2 years that indicate these reports were furnished to each employee.

Table G.1 Personnel Monitoring Devices

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

APPENDIX H

TRAINING/REFRESHER PROGRAM

Regulations: Section 36, 37, 38, 39 of CPR Part 21

Training and Experiences

One of the most important aspects of operating an particle accelerator facility is personnel training. GMP guidelines clearly state training requirements and the need to maintain records of such training. Basic training in GMP and quality assurance must be provided for all personnel at the time of initial hiring, and special training should be provided according to assigned duties. Furthermore, for all new employees hired, equipment specific and site specific training should be and can be provided by an experienced person or through the services of an external consultant. A system must be in place to ensure that all training remains current. Moreover, retraining should be a process of continuing education to ensure that staff performance continues to be at the highest level to guarantee the highest quality product and best safety standards in radionuclide production. This is particularly true when a new process or piece of equipment is to be brought into daily use. Each individual's training record should include the specifics of training provided. Some important training topics include:

1. Radiation Safety Officer (200 hours of PNRI-approved classroom and laboratory training):

The qualifications of the RSO will depend upon the operations of the institution but should include a thorough understanding of both technical operations and radiation protection. The required areas of knowledge are as follows:

- Basic radionuclide handling techniques of radioactive material including:
  - Radiation physics and instrumentation - calculations of shielding and activation are needed in order to predict both prompt and residual radiation levels;
  - Radiation protection;
  - Mathematics pertaining to the use and measurement of radioactivity;
  - Chemistry of radioactive material;
  - Radiation biology
  - Nuclear regulations and licensing
- Quality control (analytical applications);
- Quality assurance;
- Equipment specific (production and QC) training;
- New processes and procedures;
- Aseptic operations.
- Familiarity is also needed with electronics, accelerator design and operation, beam transport, and experimental techniques.

2. Authorized Operator and Authorized Technical Staff (40 hours of PNRI-approved classroom and laboratory training):

- Basic radionuclide handling techniques of radioactive material including:
  - Radiation physics and radiation detection instrumentation;
  - Radiation protection;
  - Radiation biology; and
  - Nuclear regulations and licensing
- GMP (concept and application);
- Quality control (analytical applications);
- Quality assurance;
- Radiation protection;
- Equipment specific (production and QC) training;
- New processes and procedures;
- Aseptic operations.

Experiences

1. The RSO and ARSO must have at least one (1) year of relevant, fulltime experience in the administrative and operational control of radiation within the facility
2. The authorized operator must have at least six (6) months of supervised training in the technical aspects and safe operation of the particle accelerator.
3. The authorized technical staff must have at least six (6) months of relevant, fulltime work experience in laboratory operations in the particle accelerator

Refresher Course

Employees (RSO, ARSO, Authorized Technical Staff and Authorized Operator) should be retrained on a regular basis. This time period varies based on the type of training required and local or national regulations, but a reasonable time is once every five (5) years, since training tends to decline after that period of time. Complacency also becomes a possibility over a period of time and should be guarded against

.

Employees should periodically reread the radiation safety program and other procedural documents to ensure that practices have not drifted from those specified. The Radiation Safety Program should be reviewed on at least an annual basis to ensure that they stay up to date. Concurrently, good radiation protection practice and a strong safety culture are also essential components of an FDG production facility.

Management should convey in unambiguous terms the expected operations practices and quality policies of their facility.

APPENDIX I

PROCEDURE FOR KEEPING RECORDS OF RADIONUCLIDE PRODUCED

Regulations: Section 32(d); Section 40 of CPR Part 21

Table I.1 MODEL FORM FOR DOCUMENT PREPARATION

		Page 1 of 1
DP No. 01-01-001	**Revision No.**	**Effective Date**
Procedure for documentation (Preparation, review, approval, distribution and control)	**Prepared by:**	**Date:**
	Reviewed by:	**Date:**
	Approved by:	**Date:**

Purpose:
To establish a procedure for documentation preparation and control, including drafting, reviewing, approval, distribution and documentation change policy.

Responsibility:
Quality assurance staff or assigned staff

Note:

- This procedure describes the method for document preparation and handling, including: drafting, review, approvals, disposition and change control;
- All documents shall be authorized by the appointed person(s); unauthorized documents shall not be used;
- All documents have a unique and controlled identification number;
- Copying and distribution of documents shall be controlled;
- Only current documents shall be in use;
- RSP shall be reviewed at regular intervals.

Procedure:

1. New Radiation Safety Program (RSP) or revisions of existing RSP including shall be initiated and prepared by staff members familiar with the process.
(A process being written into a RSP should be tried, tested, verified and ultimately validated for applicability and durability).
2. A draft RSP must be reviewed by another person (or persons) familiar with the process.
3. The drafting procedure and validation data are reviewed by QA staff or an appointed person with authority and responsibility.
4. A new RSP is subsequently approved for use in routine practice if its performance is found to be satisfactory.
5. A unique ID number is assigned to new RSP. A revised RSP, on the other hand, should continue to have the previously assigned RSP number, but with a new revision number.
6. For a revised RSP, the older version is marked as ‘expired’ or ‘replaced’ or another distinct notation meaning ‘not in use anymore’. Copies of all previous RSP versions should be removed from their point of use and from wherever they are stored.
7. The original document must be securely filed and safe-guarded from inadvertent or deliberate modification.
8. Copies of the approved SOPs should be issued and controlled by the QA group or an assigned authorized person. Copies should be numbered and their distribution controlled and recorded.

Table I.2. EXAMPLE OF A QC RECORD

Quality Control Section: Finished Product QC Record **Form No.: QC-XX-YY**			
Product: [^{18}F]Fluorodeoxyglucose (FDG) Injection Item Code: _____ Lot No.: _____	Rev. No. _____	Effective Date:	Page 1 of 3
	Prepared by:		Date:
	Reviewed by:		Date:
	Approved by:		Date:

Except for a sterility test, each lot must meet all specifications prior to release.

Manufacturing Date: _____

Calibration Date/Time: _____

Expiration Date/Time _____

Test	Specification	Result: Pass/Fail	Analyst
1. Sterility	Must be sterile.	_____ _____ To be recorded later	
2. Psrogenicity	Must be apyrogenic.		
	20 minutes test	_____ _____	
	1 hour test	_____ _____	
3. pH	4.5–7.5	_____ _____	
4. Radionuclide Identification	A. The gamma ray spectrum must reveal the presence of photo peak energy of 511 KeV, possibly up to 1022 keV.	_____ _____	
	B. Half-life must be between 105 and 115 minutes.	_____ _____	
5. Radionuclide purity	No gamma emission other than at 511 and 1022 keV.	_____ _____	

Quality Control Section: Finished Product QC Record **Form No.: QC-XX-YY**			
Product: [^{18}F]Fluorodeoxyglucose (FDG) Injection	Rev. No. _____	Effective Date:	Page 2 of 3
Item Code: _____	Prepared by:		Date:
	Reviewed by:		Date:
Lot No.: _____	Approved by:		Date:

Except for sterility test, each lot must meet all specifications prior to release.

Manufacturing Date:_____

Calibration Date/Time: _____

Expiration Date/Time: _____

Test	Specification	Result: Pass/Fail	Analyst
6. Specific concentration at calibration time/date	Report reading	_____ mCi/mL	
Total activity	Report reading	_____ mCi	
Volume	Report reading	_____ mL	
7. Radiochemical purity	Not less than 90%	_____ %_____	
8. Kryptofix	Not more than 50 µg/mL	_____ _____ µg/mL	
8. Osmolality	250–350 mOsm/kg	_____mOsm/kg	
9. Acetonitrile	Not more than 0.04% v/v	_____ % _____	
10. Ethanol	Not more than 0.50% v/v	_____ % _____	
12. Visual inspection	Must be clear, Colourless and free from visible particles.	_____ _____	

Quality Control Section: Finished Product QC Record Form No.: QC-XX-YY			
Product: [^{18}F]Fluorodeoxyglucose (FDG) injection	Rev. No. _____	Effective Date:	Page 3 of 3
Item Code: _____	Prepared by:		Date:
	Reviewed by:		Date:
Lot No.:	Approved by:		Date:

Except for sterility test, each lot must meet all specifications prior to release.

Manufacturing Date: _____

Calibration Date/Time: _____

Expiration Date/Time: _____

Test	Specification	Result: Pass/Fail	Analyst
13. Final package inspection	Conforms to packaging prescribed	_____ _____	
14. Reserve sample	Received, logged and stored	_____ _____	

Q.C. Status: Pass _____ Fail_____

By:_____Date: _____

For Q.A. use only:

Production record review: _____ Reviewed by: _____
Quality control record review: _____ Reviewed by: _____

Product Disposition: Released _____ Rejected _____

By: _____ Date: _____

Table I.3 EXAMPLE OF A PRODUCT RELEASE CERTIFICATE

Product Release Certificate

Manufacturer: ……

Product name: [^{18}F]Fluorodeoxyglucose (FDG) injection

BATCH NUMBER: …… Date of production: ……

Pressure differential in class D cleanroom (production laboratory, >15 kPa)	Pass___or Fail_____
Current operator aseptic training	Yes_____or No_____
Product specifications meet the requirements	Pass___or Fail_____
Deviations from product process/QC/specification	Yes_____or No_____ If yes, action taken:
Product released for human use	Yes_____or No_____
Maximum injection volume	(10 mL by default)
Product calibration time	…… (Date and time zone)
Product expiry time	…… (Date and time zone)
Production chemist	Sign and date:
QC chemist	Sign and date:
Post-release review by head of QC or QA	Sign and date:
Qualified person authorization for release	Sign and date:

Table I.4. EXAMPLE OF A PRODUCTION BATCH RECORD

<table>
<tr><td rowspan="4">PRODUCT:[^{18}F]Fluorodeoxyglucose (FDG) injection

Item Code: _____

Lot No. : _____</td><td>Rev. No. _____</td><td>Effective Date:</td><td>Page 1 of 5</td></tr>
<tr><td colspan="2">Prepared by:</td><td>Date:</td></tr>
<tr><td colspan="2">Reviewed by:</td><td>Date:</td></tr>
<tr><td colspan="2">Approved by:</td><td>Date:</td></tr>
<tr><td colspan="4">Batch record approved for use: _____ _____
Q.A. Signature Date</td></tr>
<tr><td colspan="4">Date of Manufacture:_____ __ _____Calibration. Time/Date:_ _____

Expiration Date/Time:_____ (8 hours post calibration)

Operator: _____ Checker: _____</td></tr>
</table>

PRODUCT: [^{18}F]Fluorodeoxyglucose (FDG) injection Item Code: _____ Lot No. : _____	Rev. No. _____	Effective Date:	Page 2 of 5
	Approved by:		Date:

A: Materials:

Operator	No.	Description	Qty.	Item Code	Lot No.
	1	Enriched (^{18}O) water for irradiation	2 mL		
	2	Kit mounted on the module Expiration date:	One set		
	3	Eluent mixture (Kryptofix 222/K_2CO_3 in 1:1 water/acetonitrile) 600 µL in 1.2 mL vial	1 vial		
	4	Citrate/HCl buffer, 6 mL in 10 mL vial Expiration date:___	1 vial		
	5	Acetonitirile HPLC grade, 7 mL in 10 mL vial Expiration date:_____	1 vial		
	6	Mannose triflate, 25 mg in 5 mL vial Expiration date:__	1 vial		
	7	Ethanol, 5 mL in 10 mL vial Expiration date:_____	1 vial		
	8	Sep-Pak light Accell plus QMA cartridge Expiration date_	1 Piece		
	9	Sterile water for Inj. in bag (250 mL) Expiration date: _	1 Bag		
	10	30 cc syringes	2		
	11	Filter Millex-GS, 0.22 µm Expiration date:	1		
	12	Filter Millex-GS, 0.22 µm (vented) Expiration date:	1		
	13	FDG collection vial (30 cc) Expiration date:	1		
	14	Inlet reservoir, 10 mL	1		
	15	Depyrogenated serum vials, 5 mL Expiration			
	16	Sterile toppers, 20 mm, Expiration date: _____			
	17	Aluminum seals, 20mm			

Note: Operator to check mark or initial in column 1

B. Procedure:
Note: Operator is required to check mark each step upon execution.

1. Execute appropriate file to load the fluorine target with ^{18}O water.
   Request cyclotron beam current:_____µA
   BOT on @_____; EOB@ _____
2. Open the nitrogen gas tank valve and turn on the power to synthesizer.
3. Double click the FDG icon on the desk top screen.
4. FDG synthesizer programme will open up in standby mode.
5. Click on the box 'Start the Procedure for FDG Synthesis'. If it is the second run of the day, click on the 'Start New Synthesis' box.
6. Remove the old kit from the synthesizer and empty the waste bottle.
7. Click 'Start Tests' on the FDG programme screen.

An automated system test without the kit begins. If all conditions are fulfilled, the window closes automatically after 15 seconds. If a non-critical condition failed, the user is requested to acknowledge the error before continuing normal operation. If a critical condition fails, it must be resolved before proceeding further.

8. A dialogue box appears requiring operator name, kit reference and batch identification. Fill the information in the box.
9. Install a new kit, and ensure that the enriched water recovery vial is attached (Kit is prepared in Class A LFH as per SOP XXX).
10. Clamp the kit. Click 'Begin Test' with this new kit in the dialogue box.
11. This test is a leakage test based upon the vacuum upholding in the kit tubing, with various valves open and closed. If a leak is detected, a message asks the operator to correct the problem. The test can be restarted. If it says kit test passed click 'Next'.

12. When all reagents are in place click 'Start Synthesis' (this takes a few minutes). The preliminary steps of synthesis such as reagent transfers, syringe hookups, etc. will commence. The module is now ready to receive the fluoride activity.

DO NOT CLICK SYNTHESIS UNTIL FLUORIDE IS COLLECTED.

Procedure (Cont.):

Note: Operator is required to check mark each step upon execution.

13. Record E.O.B. time:_____Total integrator current:_____µA. Hrs
14. Collect fluoride-18 activity from the irradiated target onto the ion exchange column in the synthesis unit. Wait for a constant reading on the radiation detector for fluoride.
15. When the fluoride activity is considered to be fully recovered, click on the small FDG synthesis window on the screen to continue the hot synthesis process and write the measured F^{18} in the logbook.
16. At end of synthesis, collect the FDG.
17. Wash the target and fluoride line and make sure no wash is left in the line. Dry the line with clean air or nitrogen gas for at least 20 minutes, after closing the programme.
18. Return the unit to standby mode after closing the programme. Turn off the computer.
19. Close the gas cylinder valves.

C. **Calculations:**

1. EOB time:_____EOS time or FDG measuring time: _____
2. At the end of synthesis, measure FDG in a dose calibrator.
   Measured DG_____mCi at_____,
   Elapsed time since EOB_____mins.
   D.F.:_____, FDG corrected to EOB:_____mCi.

   FDG EOB. Yield =_____mCi /_____µAh.
   =_____mCi/ µAh.
3. Weight of the empty collection vial: =_____g. Weight of the collection vial with FDG: =_____g.
4. Aseptically remove 1.5 mL in a syringe. Dispense 0.5 mL each into two pyrogen burned vials, one for sterility testing and the other for a reserve sample; send the remaining FDG in the syringe for QC analysis.
5. Total volume of FDG =_____mL (Before sampling);

   Measured activity:_____mCi/mL Decay time until noon:_____min.

   Decay factor for noon calibration : _____

   Activity at noon = Activity at time measured_____x D.F._____

   =_____mCi.

   Concentration at noon = Activity at noon_____/Total volume _____

   =_____mCi/mL

Procedure (Cont.):

Note: Operator is required to check mark each step upon execution.

6. Using concentrations from #5 above, complete the following table.

Vial No.	**Reading (mCi)**	**Activity at Calibration Time (mCi)**	**Approximate Volume and Distribution**
1			0.5 mL QC
2			0.5 mL reserve
3			_____mL PET center
4			0.5 mL for sterility test

7. Filter integrity test (SOP-XXX); Result: _____
8. Submit required samples for QC tests and reserve.
9. Labels control:

			U S E D				
	Issued	Reject	Record	Batch	Customer	Returned	Total
Vials							
Shields							

Note: If a corrective action is required, refer to SOP-XXX and fill out the form.

Operator: _____ Date: _____ Initial: _____

Checker: _____ Date: _____Initial: _____

Supervisor: _____ Date: _____ Initial: _____

QA: _____ Date: _____ Initial: _____

Batch record complete and accurate. Returned labels disposed. QA: _____

APPENDIX J

REPAIR AND MAINTENANCE PROGRAM

Regulation: Section 32 of CPR Part 21

Only qualified persons specifically authorized or licensed by the PNRI in accordance with CPR Part 25 must install and conduct maintenance or repair a particle accelerator.

The applicant must implement and maintain procedures for installation and routine maintenance according to the manufacturer's recommendations and instructions.

The maintenance program must include the following activities:

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

Maintenance in accelerator facilities is a radiation safety concern for two reasons:

- Errors in performing the maintenance activity may lead to a malfunction or failure which has radiological consequences;
- Maintenance work in certain areas may expose workers to high radiation fields or radioactive contamination.

This section should provide information on preventive and corrective maintenance that may include the following:

- The program of scheduled maintenance;
- The organization that will be responsible for maintenance. This should specify whether or not an outside contractor will do the work;
- An analysis of radiation hazards involved in performing maintenance activities; and
- Precautions to be taken during maintenance. This may include monitoring instruments, personal dosimetry, protective clothing, or special ventilation.

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

The applicant must submit installation, repair and maintenance program including procedures according to manufacturer's recommendations and instructions. All information and data resulting from the program must be recorded and maintained. The records of regular quality control tests must be retained for two (2) years and the annual performance evaluation for five (5) years.

APPENDIX K

QUALITY ASSURANCE (QA) PROGRAM

Regulation: Section 32 of CPR Part 21

Maintenance in accelerator facilities is a radiation safety concern for two reasons:

- Errors in performing the maintenance activity may lead to a malfunction or failure which has radiological consequences;
- Maintenance work in certain areas may expose workers to high radiation fields or radioactive contamination.

This section should provide information on preventive and corrective maintenance that will include the following:

- The program of scheduled maintenance;
- The organization that will be responsible for maintenance. This should specify whether or not an outside contractor will do the work;
- An analysis of radiation hazards involved in performing maintenance activities; and
- Precautions to be taken during maintenance. This may include monitoring instruments, personal dosimetry, protective clothing, or special ventilation.

APPENDIX L

PROCEDURE FOR RADIATION SURVEYS (DOSE RATE AND CONTAMINATION MONITORING)

Regulation: Section 27 of CPR Part 21

The purpose of the radiation survey is to confirm the radiation calculations and radiation dose estimates made during design stages. This section should provide information on the radiation measurements to be performed in the facility. This should include the following:

- Drawings showing the location of measurement points. These points should match as much as possible the calculation points.
- The accelerator radiation parameters applied during the radiation survey.
- For new installations, pre-commissioning measurements of the natural radiation background are recommended.
- Selection of instruments to be used for measurements and the reasons for this selection.
- Record of dates and results of the most recent calibration of the survey instruments.

Applicants are required to possess radiation detection and measuring instruments used to detect and measure radiation levels, and radioactive contamination, as applicable. These instruments must be calibrated for the type of radiation to be measured and should be available for use at all times in the facility during the conduct of licensed activities.

As a minimum requirement, the applicant should possess survey instruments for area monitoring sufficiently sensitive to measure from 1 uSv/h through 10 mSv/h and a contamination meter capable of measuring nanocurie or Becquerel amounts of activity per unit area (Bq/cm^2).

The following may be considered in selecting the proper instrument to be used in the facility:

- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with an asterisk (*)), extracted from “The Health Physics & Radiological Health Handbook,” Revised Edition, 1992, may be helpful in selecting instruments:

Each radiation survey instrument shall be calibrated before its first use, annually and following repair. Calibrations must be performed by a secondary standard dosimetry laboratory (SSDL),

including PNRI-licensed service providers who are qualified to perform calibration under CPR Part 25.

Table 1: Typical Survey Instruments

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

Response from Applicant:

- Specify the type and quantity of each instrument, manufacturer, model, serial number, operating range (e.g. µSv/h, mSv/h, counts per minute, or counts per second, etc.) of the instrument, the date of last calibration, the name of the supplier/distributor, and the name and PNRI license number of the service provider that will perform calibration including the measures to ensure the traceability of calibration.
- The quality control procedures for all radiation detection instruments used for radiation protection must be provided.

CONTROL OF RADIOACTIVE CONTAMINATION

Regulation: Section 20 of CPR Part 21

This section should describe the routine sampling and monitoring program to ensure that both on-site and off-site releases of radioactivity do not exceed acceptable limits. This should include information on the instruments to be used and the monitoring or sampling location.

The potential for contamination or activation at an accelerator facility can vary widely. Factors such as beam type (proton, electrons, or heavy ions), energy, intensity, pulse repetition rate, target and shielding materials can affect the extent to which radio-activation and contamination become important concerns. The presence of intrinsically radioactive materials such as sources, target (e.g. tritium), or detector components such as depleted uranium, all creates potential problems.

Most radioactive contamination from accelerators is created when the beam activates dispersible materials. Thus, if liquids, small particles, dust, gas, or grease are present, and beam losses are large enough, contamination will be a potential problem. The magnitude of the problem is strongly affected by the composition and amount of the material, as well as by how easily it is dispersed. Reducing the amount of material has obvious benefits. Simple things like good housekeeping to reduce dust and debris within accelerator enclosures, can significantly control contamination.

Special attention should be considered where air activation is a concern. It may be necessary to delay entry after beam shut-off for a time appropriate to the half-lives and airborne concentrations. The ventilation flow rate should be checked periodically and real-time, continuous monitoring of gaseous effluent from some enclosures may be needed to ensure that releases to the environment remain acceptable.

APPENDIX M

MODEL PROCEDURE FOR PERFORMANCE TESTING OF FUMEHOOD

GENERAL TEST CONDITIONS

The following must be observed:

(1) Any room ventilating systems shall be in operation during these tests.
(2) Any standard procedures for the laboratory shall be observed during these tests (e.g. limitations on the number of hoods in operation at one time, etc.)
(3) The sash or sashes shall be located in the design position or positions.
(4) If the hood has an auxiliary supply, the supply shall be in operation during the tests. If the supply is capable of convenient adjustment by laboratory personnel, the adjustments shall be as specified.
(5) General activity in the laboratory shall be maintained in as normal a state as possible.
(6) The tests shall be conducted with normal hood apparatus in place and in operation.

FLOW VISUALIZATION TEST

Purpose:

The purpose of the flow visualization test is to visualize the hood's ability to contain vapors and render an observation of hood performance as it is typically used. The test includes both a small local challenge and a gross challenge to the hood.

Equipment:

(1) Controllable source of visible smoke (e.g. titanium tetrachloride or another source of persistent, neutral buoyancy aerosols that can be discharged under the control of the person conducting the test).
(2) Watch or other timer.
(3) Notebook for recording observations.

Procedure:

A. Local Visualization Challenge

In the following tests, it is expected that all smoke shall be carried to the back of the hood and exhausted. Any movement of smoke towards the face of the hood is defined as negative airflow, and any lack of movement is defined as dead air space.

Note: *If there is visible smoke flow out of the front of the hood during any of these tests, the hood fails the test and shall be taken out of service.*

Perform the following challenges. In all cases, airflow patterns and time for hood clearance should be recorded.

a) Bottom Air Bypass Air Foil - run smoke under the air foil. Smoke should be exhausted smoothly and not be entrained in the vortex at the top of the hood.
b) Walls and Floor - discharge a stream of smoke along both walls and the floor of the hood in a line parallel to the hood face and 15 cm behind the face of the hood and along the top of the face opening.
c) Back of Hood - discharge smoke in a 20 cm diameter circle on the back of the hood.
d) Top of Hood - discharge smoke at top of hood and observe airflow patterns and time for hood clearance.
e) Equipment in Hood - discharge smoke around any equipment in hood.

B. Large Volume Visualization Challenge

In the following test, a release of smoke from the hood that is steady and visible is an indication of failure and the hood shall be taken out of service.

a) A large volume of smoke shall be released inside the hood and observations of containment shall be made from the side of the hood face, as well as time for hood clearance.
b) The smoke shall be released from the center of the sash opening on the work surface, 15 cm inside the rear edge of the sash.
c) The smoke should not have an unacceptably high directional component to it that would affect hood performance (e.g. a jet of high velocity smoke), nor should the smoke source be designed/used in a manner that disrupts hood performance.

FACE VELOCITY MEASUREMENTS

Purpose: The purpose of this test is to quantitatively measure air velocity at the hood face.

Equipment:

1) Anemometer or velometer, either mechanical or electrical, that has been recently calibrated. It shall be capable of measuring in the range of 0.25 m/s to 2.0 m/s (50 to 400 fpm) with an accuracy of 5% of the reading.
2) Notebook for recording observations.

Procedure:

The minimum acceptable velocity for each hood face cell shall be 0.5 m/s (100 fpm). If any cell fails to meet this requirement, the hood fails the test and shall be taken out of service.

a) Divide the hood opening into a grid of equally spaced imaginary cells (about 30 cm x 30 cm).
b) Air velocity measurements shall be taken with a properly calibrated anemometer fixed at the center of each cell, with the anemometer held in the plane of, and parallel to, the hood sash (if the airflow is not perpendicular to the plane of the sash opening, the anemometer should be held perpendicular to the airflow, even if this causes it to not be parallel with the sash opening). Care should be taken to stand to the side during measurement so as to affect the airflow as little as possible.
c) Velocity measurements shall be integrated over a period of at least five (5) seconds. If the anemometer takes only instantaneous readings, at least four (4) readings shall be taken at each point.
d) Calculate the average of the velocity measurements, noting the minimum and maximum measurements as well.
e) Compare measured face velocities with manufacturer specifications.

Performance testing of fume hood adapted from the ANSI/ASHRAE "Method of Testing Performance of Laboratory Fume Hoods" standard (ANSI/ASHRAE 110-1995).

EXHIBIT 1.0

FUME HOOD PERFORMANCE TESTING REPORT

Name and Location of Facility: _____ Date: _____
_____
_____

Radioactive Material and Activity: _____

DATA AND RESULTS

a. Description of Fume Hood:

1. Fume Hood Dimensions

Item	Dimension per submitted documents	Actual Measurements
Length (L)		
Width (W)		
Height (H)		
Volume (V)		

2. Room Dimensions

Item	Dimension per submitted documents	Actual Measurements
Length (L)		
Width (W)		
Height (H)		
Volume (V)		

3. Blower/Motor Specifications

Item		

4. Face Velocity

Item	1	2	3	4	Ave
Fully-opened (m/s)					
Area (sq. m)					
Half-opened (m/s)					
Area (sq. m)					

b. Observations and Analysis of Flow Visualization Test

1. Local Visualization Challenge

2. Large Volume Visualization Challenge

c. Radiation Monitoring Results (include drawings and locations of where monitoring is conducted)

1. Before Opening the Vials
   - 1.1 Door
   - 1.2 One meter from the fume hood
   - 1.3 Filter box

	Closed (blower off)	Closed (blower on)
Prefilter		
Hepa		
Charcoal		

   - 1.4 Filter box

	Open (blower off)	Open (blower on)
Prefilter		
Hepa		
Charcoal		

2. After Opening the Vials
   - 2.1 Door
   - 2.2 Fume hood
   - 2.3 Filter box

	Vial closed (blower off)	Vial open (blower on)
Prefilter		
Hepa		
Charcoal		

d. Contamination Monitoring Results (include drawings and locations where monitoring is conducted)

e. Air Sampling Results
1. Air sampling 1 _____
2. Air sampling 2 _____
3. Air sampling 3 _____
4. Air sampling 4 _____

f. Calculations for Room Air Changes
Ave. face velocity = _____
Area of sash opening = _____
Volume of Room = _____
Room Air Change (h^{-1}) = _____

g. Evaluation
h. Recommendation

Performed by:

_____
_____
_____

Date: _____

Approved by:

_____

Date:_____

APPENDIX N

CALIBRATION OF SURVEY INSTRUMENTS AND OTHER DEVICES

Calibration of Radiation Survey Meters

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered “servicing”).

(1) The source must be approximately a point source.

(2) Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

(3) A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

(4) The source should be of sufficient strength to give an exposure rate of about 0.3 mSv/hr (30mR/hr) at 100 cm. Minimum activities of typical sources are 3.145 GBq (85 mCi) of Cs-137 or 0.78 GBq (21 mCi) of Co-60.

(5) The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

(6) A record must be made of each survey meter calibration.

(7) A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

(8) Three kinds of scales are frequently used on survey meters:
   a) Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
   b) Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on each one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.
   c) Meters that have automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

(9) Readings above 10mSv/hr (1000 mR/hr) need not be calibrated. However, such sales should be checked for operation and approximately correct response.

(10) At the time of calibration, the apparent exposure rate from a built-in or owner-supplier check source must be determined and recorded.

(11) The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
   a) The owner or user of the instrument;
   b) A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

c) The description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
d) For each calibration point, the calculated exposure rate, the indicated exposure rate, the deducted correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
e) The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
f) The angle between the radio flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons travel either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specific surface of the instrument);
g) For detectors with removable shielding, an indicator of whether the shielding was in place or removed during the calibration procedure;
h) The apparent exposure rate from the check source; and
i) The name of the person who performed the calibration and the date on which the calibration was performed.

(12) The following information will be attached to the instrument as a calibration sticker or tag:

a) The source that was used to calibrate the instrument;
b) The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
c) For each scale or decade, one of the following as appropriate;
   - The average correction factor,
   - A graph of graphs from which the correction factor for each scale or decade may be deducted, or
   - An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
d) The angle between the radiation flux and the detector during the calibration; and
e) The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report May be used on the calibration sticker.

Calibration of Dose Calibrator

(1) Test for the following at the indicated frequency. Repair, replace, or correct mathematically if the dose calibrator falls outside the stated tolerances.
- Constancy at least once each day prior to assay of patient dosages, during an assigned shift for facilities operating continuously, or after re-location of the dose calibrator. Repair or replace if outside ± 10 percent.
- Accuracy at installation and at least every 12 months thereafter. Repair or replace if outside ± 10 percent.
- Linearity at installation and at least every three months thereafter. Repair, replace or correct mathematically if outside ± 10 percent.
- Geometry dependence at installation. Repair, replace or correct mathematically if outside ± 10 percent.

(2) After repair or adjustment of the dose calibrator, repeat the above tests as appropriate.

(3) Any of the above dose calibrator tests other than daily constancy tests may be performed by an individual licensed by the PNRI. Nationally recognized standards or the manufacturer's instructions may be used to calibrate instrumentation. The standards or instructions used must be available for inspection by the department.

a) Constancy Test Procedures:

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, or Co-57 using a reproducible geometry each day before using the calibrator. Use the following procedure:

i. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs- 137 setting to assay Cs-137).
ii. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
iii. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
iv. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
v. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of a suspected malfunction of the calibrator. These action levels will be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

b) Accuracy Test Procedures

Accuracy means that, for a given calibrated reference source, the indicated activity (in mCi or Bq) value is equal to the activity value determined by the Secondary Standards Dosimetry laboratory (SSDL) or by the supplier who has compared that source to a source that was calibrated by the SSDL. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) will be used. One source will have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it will be at least 10 µCi (3.7×10^5 Bq); other sources will be at least 50 µCi (1.85×10^6 Bq). Use at least one reference source with an activity in the range of activities normally assayed.

i. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
ii. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.
iii. Repeat the procedure for other calibrated reference sources.
iv. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

c) Linearity Test Procedures

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of that calibrator. This test will be done using a vial or syringe of Tc-99m or F-18 whose initial activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy dose, whichever is largest. The test shall continue

until the activity contained in the vial or syringe is smaller than the smallest activity assayed, but greater than 10 µCi (3.7 x10^5 Bq).

Decay Method

1. Assay the Tc-99m or F-18, syringe or vial in the dose calibrator, and subtract background to obtain the net activity in mCi (or in Bq). Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.
2. If starting at 8:00 a.m., repeat the assay at 2:00 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity normally assayed. For dose calibrators with a range switch, select the range normally used for the measurement.
3. Convert the time and date information recorded for each assay to hours elapsed since the first assay.
4. On a sheet of semi-log graph paper, label the logarithmic vertical axis in mCi (or in Bq) and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
5. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A(observed) - A(line)}{A(line)} = deviation$$

6. If the worst deviation is more than ± 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
7. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Shield Methods

For initial calibration or reinstallation of the dose calibrator the decay method will be used to determine linearity and to establish calibration factors for shield methods.

☐ A nationally recognized standard or the manufacturer's linearity test kit and instructions will be used for doing linearity tests of the dose calibrator. These standards or instructions must be available for review by the department for inspection. Submission of standards or manufacturer's instructions to the PNRI is not required.

☐ We will use a set of "sleeves" of various thicknesses' to test for linearity other than the manufacturer's test kit. The sleeves will be calibrated using the following procedure:

Calibration of the sleeves:

(1) Begin the linearity test as described in the above decay method. After making the first assay, the sleeves will be calibrated as follows. Steps (b) – (d) below must be completed within six minutes.
(2) Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.
(3) Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.
(4) Continue for all sleeves.
(5) Complete the decay method linearity test steps (b) – (g) above.

(6) From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve one in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step (b).
(7) Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step (c).
(8) Continue for all sleeves.
(9) The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

Calibration of the dose calibrator:

(1) Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the new activity in mCi (or in Bq). Record the net activity.
(2) Steps (c) – (e) below must be completed within six minutes.
(3) Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
(4) Remove sleeve one and put it in sleeve two. Record the sleeve number and indicated activity.
(5) Continue for all sleeves.
(6) On a sheet of semi-log graph paper, label the logarithmic vertical axis in mCi (or in Bq), and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
(7) Plot the data using the equivalent decay time associated with each sleeve.
(8) Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A(observed) - A(line)}{A(line)} = deviation$$

(9) If the worst deviation is more than ± 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow a conversion from activity indicated by the dose calibrator to "true activity."
(10) Place a sticker on the dose calibrator or record in log book when next linearity test is due.

d) Geometry Test Procedures

Geometry dependence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. When using generators and radiopharmaceutical kits, you will also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cm^3 plastic syringes and that radiopharmaceutical kits are made in 30-cm^3glass vials. If volumes of syringes and vials differ from above, then the procedures will be changed so that syringes and vials are tested throughout the range of volumes commonly used.

(1) In a small beaker or vial, mix 2 cm^3 of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline or tap water.
(2) Draw 0.5 cm^3 of the Tc-99m solution into the syringe and assay it. Document the volume, mCi and record instrument setting.

(3) Remove the syringe from the calibrator, draw an additional 0.5 cm^3 of non-radioactive saline or tap water, and assay again. Record the volume and mCi indicated.
(4) Repeat the process until a 2.0-cm^3 volume has been assayed.
(5) Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. The data will be graphed with horizontal 10 percent error lines drawn above and below the chosen "standard volume."
(6) If any correction factors are greater than 1.10 or less than 0.90, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
(7) To test the geometry dependence for a 30-cm^3 glass vial, draw 1.0 cm^3 of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and mCi indicated.
(8) Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cm^3 of nonradioactive saline or tap water, and assay again. Record the volume and mCi indicated.
(9) Repeat the process until a 19.0-cm^3 volume has been assayed. The entire process must be completed within 10 minutes.
(10) Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed and draw horizontal 10 percent error lines above and below the chosen "standard volume."
(11) If any correction factors are greater than 1.10 or less than 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Calibration Records

1. Constancy check records shall include:
   (a) The model and serial number of the dose calibrator;
   (b) The identity and decay corrected activity of the radionuclide contained in the check
   (c) source;
   (d) The date of the check;
   (e) The activity measured;
   (f) The percent error;
   (g) The instrument settings; and
   (h) The initials of the individual who performed the check.
2. Accuracy test records shall include:
   (a) The model and serial number of the dose calibrator;
   (b) The model and serial number of each source used and the identity of the radionuclide
   (c) contained in the source and its activity;
   (d) The date of the test;
   (e) The results of the test;
   (f) The instrument settings; and
   (g) The name of the individual performing this test.

3. Linearity test records shall include:
    b. The model and serial number of the dose calibrator;
    c. The calculated activities;
    d. The measured activities;
    e. The date of the test; and
    f. The name of the individual performing this test.
4. Geometry dependence test records shall include:
    (a) The model and serial number of the dose calibrator;
    (b) The configuration of source measured;
    (c) The activity measured and the instrument setting for each volume measured;
    (d) The date of the test; and
    (e) The name of the individual performing this test.

Note: See **Exhibits 2.0 – 4.0** for some forms on calibration of dose calibrator.

EXHIBIT 2.0

DOSE CALIBRATOR ACCURACY WORKSHEET

Facility Name:_____ Test Date: _____/_____/_____

Instrument Name: _____ Model Number:_____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Source	Calculated Current Activity	Measured Activity #1	Measured Activity #2	Measured Activity #3	Background
Co-57	Bq	Bq	Bq	Bq	Bq
Ba-133	Bq	Bq	Bq	Bq	Bq
Cs-137	Bq	Bq	Bq	Bq	Bq

Accuracy Performed by: _____

EXHIBIT 3.0

DOSE CALIBRATOR LINEARITY WORKSHEET

Facility Name:_____ Test Date: ____/___/____@_____

Instrument Name: _____ Model Number: _____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Delay	Measurement Date	Actual Time	Measured Activity	Background
0.0 Hours	____/____/_____	:	Bq	Bq
6.0 Hours	____/____/_____	:	Bq	Bq
24.0 Hours	____/____/_____	:	Bq	Bq
30.0 Hours	____/____/_____	:	Bq	Bq
48.0 Hours	____/____/_____	:	Bq	Bq
54.0 Hours	____/____/_____	:	Bq	Bq
72.0 Hours	____/____/_____	:	Bq	Bq
78.0 Hours	____/____/_____	:	Bq	Bq

Note: Reading should be taken at the lowest possible range setting and converted to Bq units.

Linearity Performed by: _____

EXHIBIT 4.0

DOSE CALIBRATOR GEOMETRY WORKSHEET

Facility Name:_____ Test Date: _____/_____/_____

Instrument Information

Instrument Name: _____ Model Number: _____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Volume	Actual Time	Activity
1 ml	:	Bq
2 ml	:	Bq
3 ml	:	Bq
5 ml	:	Bq
10 ml	:	Bq
20 ml	:	Bq

Dose calibrator geometry must be performed at installation and after repair / relocation of the calibrator according to facility license conditions.

Geometry Performed by: _____

APPENDIX O

RADIOACTIVE WASTE MANAGEMENT

Regulation: Section 34 of CPR Part 21

This section should provide information and describe the methods to be applied for handling and disposal of radioactive wastes. This should include:

- The isotopes that are likely to be produced in waste, their origins, nature and quantities;
- The designated locations for storing radioactive materials; and
- Disposal procedures.

The radioactive waste from an accelerator facility tends to be mostly machine components (e.g., targets, septa, etc.) or experimental equipment used in or near the particle beam. Other items contributing to the radioactive waste are pump (vacuum or radioactive effluent circulation) oils, shielding blocks, ion exchange resins and protective clothing.

- Possible releases and wastes:
  - During irradiation: evaporation of target material, activation of air and structural elements of the cyclotron & target assembly
  - During processing: radioactive solutions and vapours, contaminated recipients and materials
  - Not only limited to radionuclide of interest (several reaction channels, different target isotopes, activation products of backstopper, structural elements and air)

- Management:
  - correct collection and segregation of solid and liquid wastes, according to physicochemical properties and half-life;
  - Forced ventilation of irradiation rooms and hot cells with radiation monitoring inside chimney for gaseous effluents.

- There should be a provision space for the storage of unused radioisotopes produced for decay. The unused isotopes are decayed for one (1) year or 10 half-life before disposal.

APPENDIX P

OPERATING PROCEDURE

Regulation: Section 24 of CPR Part 21

This section should describe the operating procedures during normal and abnormal situations.

This section should describe and give reference to the facility's operating procedures. The term *"written procedure"* means a document that describes the operation in detail by writing each specific step of the procedure.

Written procedures serve, among others, three especially significant functions. First, they provide personnel in management operations, and safety with statements about important aspects of the facility or operation. Second, the procedure that is properly drafted and followed can significantly reduce potential for serious incidents. Third, a written procedure serves as a valuable training aid for the health physics staff, facility operations personnel, and the experimenters.

Specific areas where written procedures are recommended to be include:

- Searches of secured high radiation areas;
- Bringing new beam lines or experimental caves into operation;
- Interlock checks;
- Calibration of area radiation monitors;
- Monitoring equipment or materials for release to public domain;
- Intra-site transfers of radioactive or contaminated materials;
- Off-site packaging and shipment of radioactive or other hazardous materials;
- Handling and disposal of radioactive wastes;
- Decontamination of facilities or equipment.

Of particular importance are the procedures that specify administrative controls. Administrative controls are implemented during situations where physical barriers do not exist, are inappropriate, or are temporarily deactivated. Administrative controls leave more room for human error than safe design and safety warning devices.

The written procedures should have provisions for review, approval, and, if appropriate, periodic re-certification. In addition, they should be readily available at locations appropriate to the operation.

<u>Model Operating Procedures for Cyclotron:</u>

- Who may enter and perform maintenance on the cyclotron and the safety systems of the facility.
- Who may operate particle accelerator. Only authorized and trained personnel should operate or have access to controls and radiation areas.
- The modes and conditions of routine operation of the facility.
- The policy for intentional bypass of safety interlocks to include that the bypass is recorded in a permanent log. Include a notice to be posted at the control console to warn personnel of the bypass.
- The program for regular testing of the safety devices to ensure proper operation, the frequency of the testing and who will perform the testing. A log of these records must be maintained.

- The emergency instructions that will be followed to avoid or minimize radiation exposure to persons in the vicinity of the cyclotron. The instructions must include the name of contact persons who will direct remedial actions.
- The proposed methods, procedures and equipment for conducting radiation surveys, including the frequency of the surveys and the location of radiation survey points.
- The Quality assurance program for the operation of the facility.

APPENDIX Q

EMERGENCY PLAN INCLUDING CONDUCT OF DRILL

Regulation: Section 25 of CPR Part 21

This sub-section should provide written procedures to be applied in case of abnormal operating conditions. The emergency procedures should identify the emergency situations and the actions to be taken by the personnel to limit or minimize consequence. This sub-section should also confirm that emergency procedures would be included in initial and annual instructions given to the staff, and that this instruction will include annual exercises of emergency procedures.

Methods, procedures and equipment that will be used during and following an accident involving the facility including instructions for dealing with fires, spills, and transportation accidents in which radioactive substances or radiation devices may be involved, or accidents involving over-exposures to radiation must be provided.

Examples of emergencies are as follows:

- Device malfunction
- Falls/collisions/crushing of cyclotron
- Fires
- Spills of product from PET cyclotrons or spills of other radioactive materials
- Unauthorized access to the facility

The applicant must identify a ***muster point*** where everyone is ordered to go when there is an emergency.

APPENDIX R

TRANSPORT OF RADIOACTIVE MATERIALS

Regulation: Section 30 of CPR Part 21; CPR Part 4

During transport of radionuclide the licensee should comply with CPR Part 4, Regulations for the Safe Transport of Radioactive Material in the Philippines depending on activity of content: exempted or type A packages. Shielding should be so that dose rate at package remains below 2 mSv/h (usually much lower).

Radioactive material must be packaged to ensure that radiation levels at the package surface do not exceed the levels set by CPR Part 4. This ensures that carriers, the public and the environment are not exposed to radiation levels that exceed recognized safe limits. Different packages for use in shipping are required for various types, forms, quantities and levels of radioactivity.

These are:
1. Excepted packages;
2. Industrial packages;
3. Type A packages: typically constructed of steel, wood or fibreboard, and have an inner containment vessel made of glass, plastic or metal surrounded with packing material made of polyethylene, rubber or vermiculite.;
4. Type B packages.

In case of transport of radionuclide: special attention should be given to sterility.

Transport of PET tracers only on-site:
- Inter-national transport regulations usually not applicable
- No approved type of containers needed
- Placarding of radioactive content needed

If transported off-site: usually much higher activities needed because of short half live
- Important shielding requirements

The applicant is required to submit transport safety plan; prepare a Consignor's Declaration for each package to be transported and must submit to PNRI on a quarterly basis a report of all radioactive materials transported. If a PNRI license holder not specifically authorized in the radioactive material license to transport radioactive material must secure a Permit to Transport from PNRI.

APPENDIX S

DECOMMISSIONING PLAN

APPENDIX T

RECORDKEEPING

Regulation: Section 40 of CPR Part 21

The applicant shall meet the recordkeeping requirements in the operation of a particle accelerator to produced radionuclide in accordance with Section 40 of CPR Part 21.

The applicant must generate and maintain certain records including among others:

a) Radiation Safety Program;
b) Preliminary Safety Analysis Report;
c) Final Safety Analysis Report;
d) Records of the calibrations of radiation survey instruments;
e) Records of quarterly inventory of radioactive sources;
f) Records of training and certification of RSO, ARSO, authorized operator and authorized technical staff;
g) Records of current operating and emergency procedures;
h) Records of exposure of each individual employee;
i) Quality assurance;
j) Document control, revision, and distribution;
k) SOP preparation, review and approvals;
l) Change control;
m) Production batch and record review;
n) Product and raw materials release, rejection, disposition;
o) Customer complaints;
p) Product recall;
q) Product rejections and rework;
r) Inspection/internal audits;
s) Employee records;
t) Adverse event reports;
u) Investigations.

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Commonwealth Avenue, Diliman, Quezon City

APPLICATION FOR A LICENSE OF PARTICLE ACCELERATOR FACILITY FOR THE PRODUCTION OF RADIONUCLIDE

INSTRUCTIONS: To complete this application, refer to Part 21 of the Code of PNRI Regulations and the corresponding Regulatory Guide for the Preparation of Application for a License of a Particle Accelerator Facilities for the Production of Radionuclide. Submit duplicate copies of the completed application form, with the specified application/license fee, and all required attachments, to the Nuclear Regulatory Division, Philippine Nuclear Research Institute, Commonwealth Avenue, Diliman, Quezon City.

I. This is an application for: (Check appropriate box)

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

II. Type of License:

- ☐ A. PROVISIONAL PERMIT
- ☐ B. LICENSE TO CONSTRUCT
- ☐ C. LICENSE TO OPERATE

I. GENERAL INFORMATION

1.0 NAME AND MAILING ADDRESS OF APPLICANT.

Institution/Firm _____

Address _____

Director/Chairman of the Institution _____

Telephone & Fax Nos. _____

E-mail Address _____

2.0 PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____

Position/Title _____

Address _____

Tel/Fax Number/E-mail Address _____

3.0 TYPES OF AUTHORIZATION AND GENERAL REQUIREMENTS

4.0 LOCATION AND TECHNICAL SPECIFICATION OF THE PARTICLE ACCELEARTOR FACILITY.

4.1 Location of Facility

Building _____ Room _

Street _____

City _____ Province ___

Telephone and Fax Number _____

Attachment 1:

Particle Accelerator Facility Layout

		Attached	Remarks
4.1.1	Layout of the facility	☐	_____
4.1.2	Rooms/areas	☐	_____
4.1.3	Description of shielding design	☐	_____
4.1.4	Description of ventilation system	☐	_____

Attachment 2:

Laboratory Facility Layout

		Attached	Remarks
4.1.5	Layout of the facility	☐	_____
4.1.6	Rooms/areas	☐	_____
4.1.7	Description of shielding design	☐	_____
4.1.8	Description of ventilation system	☐	_____

4.2 Technical Specifications of the Particle Accelerator.

Manufacturer _____ Installation Date _____

Model Name Serial Number

Types of Beam _____

Maximum Energy and Current _____

Maximum Particle Velocity/Acceleration _____

Accelerator Targets – for each accelerator target provide the following information:

Target Chamber				Maximum Beam Current (uA)	Bombardment Time (Min.)	Maximum EOB activity (GBq)
Part No.	Nuclear Reaction	Product	Material			

Attachment 3:
Information regarding the equipment (e.g., brochure) ☐ Attached ☐ NA Remarks_____

4.3. Facility and Equipment Description.

4.3.1 QA/QC Instrumentation

Type of Equipment	Manufacturer	Model	Serial Number	Supplier/ Distributor

4.3.2 Dose Calibrator and/or Other Equipment Used to Measure Dosages of Radionuclides

Type of Equipment	Manufacturer	Model	Serial Number	Supplier/ Distributor	Date of Last Calibration	Organization to Perform Calibration

4.3.3 Personnel Monitoring Instruments

a. Personnel Monitoring Badge

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

b. Direct Reading Dosimeters

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

4.3.4 Radiation Instruments

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

Attachment 4:
Calibration Certificates of Radiation Survey Instruments ☐ Attached ☐ NA Remarks_____

5.0 PROOF OF LEGAL STATUS.

SEC Registration Number _____

Business Permit Number _____

Attachment 5:
Proof of applicant's incorporation, registration or charter (SEC registration or equivalent) ☐ Attached ☐ NA Remarks_____

For public institutions, specify the enabling legislation (Act):

_____

6.0 RADIONUCLIDE(S) PRODUCED AND PURPOSE(S) OF USE.

6.1 Radionuclide produced using the particle accelerator

Radionuclide (Element/Mass Number)	Max. Amount at Any One Time	Max. Total Activity in One Year

6.2 Radioactive Sources (e.g., Check Sources)

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

Attachment 6:

Calibration Certificates of Radioactive Sources ☐ Attached ☐ NA Remarks_____

7.0 RADIATION WORKERS AND THEIR TRAINING AND EXPERIENCES

PIs. refer to Attachment A to C

Worker	Name	Trainings	Experiences
Radiation Protection Officer (RPO)			
Assistant RPO			
Authorized Operator			
Authorized Technical Staff			

8.0 SAFETY ANALYSIS REPORT (SAR)

Attachment 7:

1. INTRODUCTION

1.1 General Description ☐ Attached ☐ NA Remarks_____
1.2 Identification of Owner, Agents and Contractors ☐ Attached ☐ NA Remarks_____
1.3 Use of the Facility ☐ Attached ☐ NA Remarks_____

2. SITE SUITABILITY

2.1 Description of the Location of the Facility ☐ Attached ☐ NA Remarks_____
2.2 Description of Surroundings and Access Roads ☐ Attached ☐ NA Remarks_____

3. TECHNICAL SPECIFICATIONS OF THE ACCELERATOR

3.1 Particles Accelerated ☐ Attached ☐ NA Remarks_____
3.2 Acceleration System ☐ Attached ☐ NA Remarks_____
3.3 Beam Transport System ☐ Attached ☐ NA Remarks_____
3.4 Target-Irradiation Course ☐ Attached ☐ NA Remarks_____

4. FACILITY DESIGN

4.1	Facility Plans and Drawing	☐ Attached	☐ NA	Remarks	_____
4.2	Classification of Adjacent Areas	☐ Attached	☐ NA	Remarks	_____
4.3	Fire Protection System	☐ Attached	☐ NA	Remarks	_____
4.4	Ventilation and Cooling Systems	☐ Attached	☐ NA	Remarks	_____

5. ANALYSES OF RADIATION HAZARDS AND SAFETY FEATURES

5.1	Radiation	☐ Attached	☐ NA	Remarks	_____
5.2	Radioactivity	☐ Attached	☐ NA	Remarks	_____
5.3	Designation of Controlled Areas	☐ Attached	☐ NA	Remarks	_____
5.4	Shielding Design and Calculations	☐ Attached	☐ NA	Remarks	_____
5.5	Radiation Warning System	☐ Attached	☐ NA	Remarks	_____
5.6	Radiation Damage to Components	☐ Attached	☐ NA	Remarks	_____
5.7	Handling and Confinement of Radioactive Materials	☐ Attached	☐ NA	Remarks	_____
5.8	Environmental Releases	☐ Attached	☐ NA	Remarks	_____

6. NON-RADIATION HAZARDS

6.1	Description of any hazard associated with the operation of the accelerator other than radiation hazards	☐ Attached	☐ NA	Remarks	_____

7. CONSTRUCTION REPORT

7.1	Construction Report	☐ Attached	☐ NA	Remarks	_____

8. COMMISSIONING

8.1	Commissioning Plan	☐ Attached	☐ NA	Remarks	_____
8.2	Commissioning Report	☐ Attached	☐ NA	Remarks	_____

9.0 RADIATION SAFETY PROGRAM

9.1 Organization, Duties and Responsibilities of the Radiation Safety Committee	☐ Attached	☐ NA	Remarks	_____
9.2 Designation of a Qualified Radiation Protection Officer (RPO) and Assistant RPO	☐ Attached	☐ NA	Remarks	_____
9.3 Duties and Responsibilities of the RPO	☐ Attached	☐ NA	Remarks	_____
9.4 Model ALARA Program	☐ Attached	☐ NA	Remarks	_____
9.5 Personnel Monitoring Program	☐ Attached	☐ NA	Remarks	_____
9.6 Training/Refresher Program	☐ Attached	☐ NA	Remarks	_____
9.7 Procedure for Keeping Records of Radionuclide Produced	☐ Attached	☐ NA	Remarks	_____

9.8 Quality Assurance Program	☐ Attached	☐ NA	Remarks_____
9.9 Procedure for Radiation Surveys (dose rate and contamination monitoring)	☐ Attached	☐ NA	Remarks_____
9.10. Model Procedure for Performing Testing of Fumehood	☐ Attached	☐ NA	Remarks_____
9.11 Calibration of Survey Instruments and Other Devices	☐ Attached	☐ NA	Remarks_____
9.12 Radioactive Waste Management	☐ Attached	☐ NA	Remarks_____
9.13 Operating Procedure	☐ Attached	☐ NA	Remarks_____
9.14 Emergency Plan including Conduct of Drill	☐ Attached	☐ NA	Remarks_____
9.15 Transport of Radioactive Materials			
9.16 Decommissioning Plan			
9.17 Recordkeeping	☐ Attached	☐ NA	Remarks_____

10.0 SECURITY OF PARTICLE ACCELERATOR FACILITY

10.1 Security Plan ☐ Attached ☐ NA Remarks_____

11.0 APPLICATION AND LICENSE FEES

APPLICATION FEE

PhP_____
Official Receipt Number _____
Date _____

LICENSE FEE

PhP_____
Official Receipt Number _____
Date _____

12.0 CERTIFICATION:

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

_____
Signature of Certifying Official

_____
Typed or Printed Name of Certifying Official

_____
Title/Position of Certifying Official

_____
Date

13. 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 _____

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Department of Science and Technology
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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/Facility					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE WITH OPERATION AND USE OF PARTICLE ACCELERATOR

Specification (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**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: _____

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ATTACHMENT B

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED OPERATORS

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					
b. Radiation Safety					
c. Radiation Detection instrumentation					
d. Radiation Protection					
e. Security of Radioactive Sources/Facility					
f. Nuclear Regulations and Licensing					

2. EXPERIENCE IN THE OPERATION AND USE OF PARTICLE ACCELERATOR

Specifications (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**Max. Activity Produced** (Bq)	**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 Authorized Operator

Date: _____

Republic of the Philippines
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Commonwealth Avenue, Diliman, Quezon City

ATTACHMENT C

TRAINING AND EXPERIENCE OF PROPOSED AUTHORIZED TECHNICAL STAFF

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. Radiation Detection & Measurement					
d. Security of Radioactive Sources/Facility					
e. Nuclear Regulations and Licensing					

2. EXPERIENCE IN QUALIY CONTROL, MANUFACTURE AND DISPENSE OF RADIOISOTOPE (List laboratory facilities and equipment)

Specifications (Brand Name, Model/Serial Numbers)	**Radioisotopes Produced** (Element & Mass No.)	**Max. Activity Produced** (Bq)	**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 Authorized Operator

Date: _____