AUTHORISATION GUIDELINES FOR NUCLEAR MEDICINE FACILITIES

Facilities and activities using radioactive material need to be authorized by the Radiation Protection Agency (RPA) in accordance with the provisions of the Radiation Protection Agency Act, 2018. Section18(1) of the Radiation Protection Agency Act states that a person shall not carry out an activity or practice involving ionizing radiation, import or export a radiation source, radioactive material unless he is issued a license or authorization by the Radiation Protection Agency or unless the activity is removed from the regulatory control.

AUTHORISATION GUIDELINES

These guidelines apply to nuclear medicine facilities. They have been developed to provide a detailed description of the information and documentation that must be submitted to RPA during the authorization process for review and assessment of compliance with the regulatory requirements. In order to ensure compliance of the Radiation Protection Agency Act 2018, any individual/organisation who intends to set up or operate a nuclear medicine facility should satisfy the requirements of the authorisation process.

For authorisation, an applicant shall submit documents as per these guidelines as attachments to the application form.

Step 1. Notification

Notification is required for a new nuclear medicine facility where the legal person is to demonstrate justification of the practice. The legal person or facility should obtain and complete the notification form from the RPA offices or at www.rpa.org.ls prior to full application.

Step 2. Application for authorisation

GENERAL INFORMATION

General information should be completed as per the application form.

ADMINISTRATIVE INFORMATION

1. Legal person. Specify the formal name of the applicant (*A legal person can be any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, person/individual having an authority over a facility/activity*).
2. Address of head office. Specify the address of the headquarters of the legal person.

3. Name and title of the representative of the legal person (Head of the Institution). Specify the name and title of the representative of the legal person.
4. Location(s) of the practice. Specify the address(es) of the practice.
    a. Telephone number;
    b. Email address.
5. Contact details of the radiation protection officer(s). Specify the details of the radiation protection officer(s) to be contacted with respect to the authorization:
   (a) Telephone number;
   (b) Email address.
6. Contact details of the qualified expert(s).
7. Endorsement of application (the application must be signed by the representative of the legal person):
   (a) Name;
   (b) Signature;
   (c) Date;
   (d) Official stamp/seal.

The supporting documents that must be submitted as attachment to the application for authorization should cover the following:

INTEGRATED MANAGEMENT SYSTEM

1) **Management structure and responsibilities**. Describe the overall organisational structure and integrated management system ensuring that protection and safety and security are effectively incorporated into the overall management system of the applicant. Describe and clearly define responsibilities for radiation safety and security for the following parties as appropriate:
   - Management of the Facility
   - Radiation protection officer(s)
   - Person(s) responsible for security
   - Occupationally exposed workers, itinerant workers
   - Radiation safety committee
   - Responsibilities for cooperation and consultation

2) **Verification of compliance**. Describe the regular assessment of protection and safety, and security, such as a quality control programme and plans for regular reviews.

3) **Submission of the following documentation including procedures and programmes to the RPA as applicable**:

(a) Radiation source inventory, supply of sources, prior assessment of radioactive sources and radiation generators, and inventory of disused sources;
(b) Education, training and competence of the staff and their retraining and informing (attach education and training certificates); ;
(c) Testing, routine and periodic examination and maintenance, and quality assurance programme;
(d) Investigation of incidents and accidents;
(e) Emergency preparedness and response measures;
(f) Control of modification(s) of facilities, equipment and activity;
(g) Management of disused sources and depleted uranium, if applicable

(h) Safe transport of radioactive material
(i) Controlled import and export of radioactive sources
(j) Control of visitors;
(k) Release of patients after radionuclide therapy
(l) Programme for the improvement of the integrated management system

TECHNICAL INFORMATION

(1) Information on radiation sources

(a) Information on unsealed sources (information on each radionuclide to be provided separately):
(i) Radionuclide (chemical form);
(ii) Maximum activity at a specific time;
(iii) Physical form (e.g. liquid or encapsulated);
(iv) Main purposes of use (e.g. diagnostic imaging, therapy or marker) and location;
(v) Manufacturer of the source;
(vi) Supplier of the source.

(b) Information on sealed sources:
(i) Radionuclide.
(ii) Model.
(iii) Source serial number.
(iv) Source activity and reference date.
(v) Manufacturer of the source.
(vi) Supplier of the source.
(vii) Special form certificate. Attach special form certificate for the radioactive source.
(viii) Design, manufacturing and testing of the source. Demonstrate that the design, manufacturing and testing of the source were conducted in accordance with ISO 2919:2012 or another appropriate standard.
(ix) Leak test. Demonstrate that the leak test was conducted in accordance with ISO 9978:2020 or another appropriate standard.
(x) Working life of the source. Specify the recommended working life given by the manufacturer.
(xi) Certificate for the sealed radioactive source, according to ISO 2919:2012 or equivalent standard, specifying source classification, model designation, serial number, content activity, leak test results according to ISO 9978:2020, radiation output, special form approval certificate number and recommended working life.
(xii) Purpose of use and location.

(c) Information on imaging devices using radiation sources:
(i) Type of the device (e.g. computed tomography);
(ii) Manufacturer of the device;
(iii) Model of the device;
(iv) Serial number(s) of the device (generator);
(v) Supplier of the device;
(vi) Maximum voltage (kV) and current (mA or mA · s).

(2) Information on measuring instruments for quality control.
Activity calibrator.
*(*a) Manufacturer of the device;
(b) Model of the device;
(c) Serial number of the device;
(d) Supplier of the device.

(3) Description of the facility.
(a) Nuclear medicine laboratory and adjacent areas:

(i) Layout of the nuclear medicine laboratory. Demonstrate that the design of the laboratory enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the characteristics of the laboratory and adjacent areas, e.g. laboratory for preparation of the nuclear medicine dose and dosage; injection room; patient waiting areas; imaging rooms; patient toilets; offices and other working areas and areas for the staff; corridors; storages; and radionuclide therapy patient rooms. Include details of the patient flow and estimated stay in different rooms. Specify all construction materials, e.g. material type, thickness, density, and features to prevent contamination and to facilitate decontamination. Provide air pressure differentials and directions of air flow. Mark release points for liquid and gaseous waste discharges. Specify which existing sources and equipment will be used in which room and provide a process flow diagram. Give the position(s) of source(s) and equipment. Specify all adjacent equipment, such as imaging devices and their control rooms.

(ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. use factor and occupancy factor), took into account radiation fields produced by sources, including patients (assuming maximum activity of each radionuclide in the patient). Provide dose and dose rate calculations related to exposure for workers and members of the public. Specify the maximum operating condition of the equipment, e.g. workload. Provide a plan of the surrounding areas. Demonstrate that doses are below the dose limits and dose constraints for workers and members of the public. Demonstrate that a qualified expert was involved in the calculations.

(iii) Safety features. Specify the position of all technical safety features and warning systems, such as the emergency button of a device, radiation monitor(s) in case of a discharge, use of key control, and warning signs and notices. Describe the design of the facility for safety. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the nuclear medicine facility. Specify how fire protection manages hazards related to the existing radioactive sources. Demonstrate that good engineering practices are taken into account.

(iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.

(*b) Radioactive source and temporary radioactive waste storage:*
(i**) Layout of the radioactive source storage and the temporary radioactive waste storage**. Demonstrate that the design of the storages enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the storage characteristics, e.g. entrances, doors, roof, floors, penetrations and

adjacent offices or buildings. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be stored in the storage area. Specify the maximum capacity of the storage.

(ii) Shielding calculation and assumptions used. Demonstrate that the design and shielding, as well as the assumptions used (e.g. workload and occupancy factor), took into account radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, that dose constraints for workers and members of the public are established, and that doses are optimized to be as low as possible. Demonstrate that a qualified expert was involved in the calculations.

(iii) Safety features. Specify the positions of all technical safety systems, e.g. monitors, sensors, access control measures and barriers. Describe the design and function of safety and warning systems. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the radioactive source storage and temporal radioactive waste storage.
(iv) Boundaries of controlled and supervised areas. Demonstrate that controlled and supervised areas are designated.

(4) Technical information of radiation monitoring equipment.
(a) Radiation monitors installed in laboratories in 'hot cells' and for discharges as appropriate. Provide technical information related to permanently installed radiation monitors. Demonstrate suitability and calibration of the monitors.
(b) Portable survey meters. Provide technical information related to portable survey meters for monitoring external exposure, air contamination and surface contamination. Demonstrate suitability and calibration of portable survey meters and contamination monitors. Specify their use and number.
(c) Personnel monitoring devices. Demonstrate that personnel monitoring devices have been provided to all workers (OSL or TLD). Demonstrate that personal dosimetry devices with direct reading and alarm functions are available, if required. Specify all technical information and dosimetry services to be used.

(5) **Safe and secure management and control of radioactive waste and radiation sources** once it has been decided to take them out of use, including financial provisions. Demonstrate that radioactive waste and disused sources are managed in line with safety requirements, e.g. demonstrate that storage for radioactive waste and disused sources is designed and controlled using optimization and dose limitations and that management of the storages includes all safety and security precautions. Specify financial provisions for safe and secure management of all disused sources and radioactive waste as applicable.

SAFETY ASSESSMENT

A safety assessment that addresses the following aspects:

(1) Expected doses (occupational, public and from medical exposure) arising from normal operation of the practice.
(2) Estimation of the potential doses (occupational, public and from medical exposure) from anticipated operational occurrences and accident conditions (failures or internal or external events that challenge the safety of the facility or activity).

(3) Identification of postulated accident initiating events, commensurate with the particular features of the practice.
(4) Description of the severity of the potential consequences for workers, members of the public and patients associated with each of the accident initiating events. Provide an evaluation of the consequences for workers, members of the public and patients based on the potential effect that each accident initiating event could have without taking into account the safety measures or barriers envisaged.
(5) Description, for each accident initiating event, of existing safety barriers aimed at preventing or mitigating accidents.
(6) Risks associated with each accident initiating event. Risk needs to be expressed as a function of the frequency with which the initiating event occurs, the robustness of the safety barriers and the severity of the potential consequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.
(7) Conclusions. Include a programme of safety measures to be carried out for higher risk initiating events to ensure optimization of protection to the highest reasonably achievable safety level.
(8) Independent verification. Attach the results of an independent verification of the safety assessment.
(9) Review of safety assessment. Demonstrate that regular and documented reviewing of the safety assessment is in place.

PROTECTION OF WORKERS

(1) Education and training of workers. Specify names, qualification, education, training and retraining of workers. Describe how staff (including assistants and trainees) are trained and qualified. Specify whether the radiation protection officer complies with the criteria established by the regulatory body, e.g. education, training and experience (attach the appointment letter giving the RPO the authority to stop any unsafe operations).. If the applicant uses a qualified expert, provide information on the certification (formal recognition by RPA), education and experience of the qualified expert.
(2) Personal dosimetry. Specify the authorized or approved dosimetry service and the arrangements related to the monitoring of personal doses. Provide the results of the reviews of past occupational doses. Provide the records of past occupational exposure of workers (including itinerant), if not already recorded in the registry of occupational doses.

(3) Workers' health surveillance. Specify programmes for health surveillance.
(4) Itinerant workers. Describe the allocation and documentation of the responsibilities of the employer and the applicant for the safety and protection of itinerant workers, if any.
(5) Arrangements for the radiation protection programme. Demonstrate that all of the following elements of the radiation protection programme are in place:
(a) Assignment of responsibilities for the radiation protection programme.
(b) Designation of controlled or supervised areas. Specify the designation of controlled and supervised areas using a safety assessment and measured dose rates in working rooms/areas and storages. Demonstrate the appropriate management of labels, marks and notices.
(c) Practice specific local rules. Demonstrate that local rules applicable for workers are prepared for all processes and that an adequate number of workers is involved in the practice. In particular, specify the roles and responsibilities of workers and demonstrate that processes are supervised. Demonstrate that rules, labels and notices are written in a language understood

by those for whom they are intended. Provide a workplace and area monitoring programme. Demonstrate that the necessary radiation monitoring equipment is available. Provide the technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment. Demonstrate that the monitoring programme takes into account all processes of the applicant, e.g. use and maintenance of radiation equipment, accepting packages with new radioactive sources and preparing packages for transport.

(d) Personal protective equipment. Demonstrate that the need to rely on administrative control and personal protective equipment for protection and safety is minimized, giving priority to engineering controls. Demonstrate that appropriate personal protective equipment i.e thyroid shields, lead aprons, safety googles is provided and arrangements are made for its proper use, testing and maintenance.

(e) Recording and reporting of information. Describe the system for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety, as well as individual radiation monitoring.

(f) Audit and review of the radiation protection programme and the security programme. Specify methods for periodic auditing and review of the implementation of the radiation protection and security programmes.

PROTECTION OF THE PUBLIC

System of protection and safety for members of the public:

(1) Describe a system of protection and safety for members of the public. Demonstrate that optimization of radiation protection of the public is in place.

(2) Demonstrate that assessment, control and surveillance of the external exposure of the public are implemented, i.e. use of dose constraints for members of the public. Provide the assumptions used to assess the external exposure of the public.

(3) Describe the training of personnel having functions relevant to the protection and safety of members of the public. Demonstrate that a monitoring programme and management of records are in place.

(4) Describe the use of signs, labels, marks and notices addressing members of the public. Confirm that these are in a language understood by members of the public.

PROTECTION OF NUCLEAR MEDICINE PATIENTS

(1) Responsibilities.

Specify how radiological medical practitioners ensure that protection and safety are justified and optimized for each medical exposure and who is responsible for that, e.g. chief nuclear medicine physician. Specify who is the responsible medical physicist e.g. the chief physicist.

(2) Justification

(a) Specify who can prescribe a nuclear medicine procedure, e.g. a physician or oncologist.

(b) Specify how the patient is verified not to be pregnant or breastfeeding. Describe a procedure to justify medical exposure for a pregnant or breastfeeding patient. Describe procedures to inform the patient on precautions to protect the infant after receiving radionuclides.

(c) Procedure for patient identification. Describe how each individual is identified before a justified and optimized medical exposure.

(3) Optimization

(a) Procedures for most common nuclear medicine procedures and treatments**.** Describe briefly the most common imaging and treatment procedures and how optimization has been ensured. Describe the implementation of diagnostic reference levels.

(b) Patient records (information of medical exposure). Describe how patient records are kept and what kind of medical exposure information is recorded.

(c) Follow-up of procedures. Describe how radiological reviews of diagnostic imaging and treatments are carried out, including an investigation and critical review of the current practical application of radiation protection principles for the justification and optimization of procedures performed in the medical radiation facility.

(4) Quality assurance

(a) Technical quality control:

(i) *At the time of acceptance and commissioning of the equipment, prior to its clinical use on patients*: measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist. Describe the tests, responsibilities for performing the tests and approving the results, criteria for the tests and used standards, e.g. a reference to a standard procedure of acceptance testing.

(ii) Quality control programme. Measurements of the physical parameters of medical radiological equipment and activity calibrator made by, or under the supervision of, a medical physicist periodically, after any major maintenance procedure that could affect the protection and safety of patients, and after any installation of new software or modification of existing software that could affect the protection and safety of patients. Perform tests to verify the quality of radiopharmaceuticals. Describe the tests, responsibilities for performing the tests and approving the results, established tolerance limits, and implementation of corrective actions if the measured values of the physical parameters are outside established tolerance limits.

(iii) Maintenance. Describe how adequate maintenance of the imaging equipment has been arranged.

(**b) Other quality assurance:**

(i) Imaging and treatment procedures:

- Treatment planning. Describe the qualifications and training of planners and the instructions for planning, e.g. used guidelines or ‘cook books’.
- Responsibilities. Describe the responsibilities for dose planning, verification and approval. Describe the procedure for approval, e.g. assignment of the treatment plan.
- Records. Describe how records of relevant procedures and results are maintained.

(ii) Reporting and learning systems. Describe how the results of the investigation of unintended exposures are used to improve safety and patient protection.
(iii) Regular and independent audits. Describe how regular and independent audits are performed for the quality assurance programme for nuclear medicine.

(iv) Procedures for carers and comforters. Describe the optimization of protection for carers and comforters and the established dose constraints.

SECURITY OF RADIOACTIVE SOURCES

Assignment of radioactive material to a category and a security level. Identify and explain the basis for the categorization of each radioactive material and its associated security level.

(2) Site description. Describe the physical features of the site where the practice is conducted and its surrounding environment, including diagrams and scale floor and building drawings and photographs. This information must include:
(a) The location and layout of the site, particularly indicating areas accessible to the public, roads and parking areas; nearest public thoroughfares, the central security office, building and site perimeter, access points and physical barriers.
(b) The site's surrounding environment, such as industrial, commercial, residential or other areas; distances to nearest police stations and other response services; proximity to other buildings and roads; and other features of security or operational interest, such as other facilities with hazardous materials.

(3) Operational description. Describe site operations in relation to the practice, including working and non-working hours; the number and type of staff involved in the site's operations; and the typical number, type and frequency of other people (such as visitors, public, patients, customers, service personnel or contractors) who may be at the site during scheduled operations or at any other time.

(4) Security roles and responsibilities. Document the assignment of all roles and responsibilities with respect to the security of radioactive material, including the roles and responsibilities of the following:(a) Site leadership, management and supervisors.
(b) Positions directly responsible for the security of radioactive material.
(c) Positions with responsibility for regulatory matters, including any positions prescribed by the regulatory authority, such as the licensee, radiation safety officer, security personnel, advisers, guards and other security related positions specifically required by regulation. Provide an organization chart showing the staffing structure with lines of authority and supervision to demonstrate how the security organization and responsibilities fit within the overall site organization.

(5) Security training and qualification. Provide the following information:
(a) Requirements for qualification of staff with security responsibilities.
(b) Training to be provided to each individual, including the required initial, specialized, advanced or refresher training for each position with security responsibilities; security awareness training for all staff; and other relevant, specific, on the job training, such as procedures and work instructions.

(c) Provider(s) of the identified training and how frequently each part of the training must be conducted.
(d) How training records that document satisfactory completion of all security related training are established and maintained.

(6) Access authorization. Describe the process used for authorizing personnel who need unescorted access to radioactive source locations, secured areas and/or security sensitive information in order to perform their duties (which may or may not be directly related to security), including how the following functions are performed:
(a) Identification of the positions requiring unescorted access;
(b) Verification that individuals holding the identified positions are trustworthy;
(c) Verification that individuals holding the identified positions have the necessary training;
(d) Timely withdrawal of access for individuals who no longer require it;
(e) Periodic review and re-evaluation for particular circumstances, such as withdrawing access authorization when personnel or positions no longer need unescorted access, transfer of job responsibilities or termination of employment;
(f) Maintain up to date records of personnel authorized for unescorted access.

(**7) Trustworthiness evaluation**. Describe the process for evaluating the trustworthiness and reliability of personnel to determine whether they may be granted unescorted access to radioactive material, secured areas and/or security sensitive information, including the following:(a) Basis for identifying individuals whose trustworthiness must be evaluated for access authorization;
(b) Requirements regarding trustworthiness in applicable regulations or elsewhere, including any requirements that vary depending on security level or other factors;
(c) Method by which each individual is evaluated;
(d) Requirements for periodic review and any re-evaluation for particular circumstances;
(e) Maintenance of records to document trustworthiness evaluations.

(8) Information protection. Describe the measures for protecting information the unauthorized disclosure of which could compromise the security of radioactive material, including the following:
(a) The information that needs protection;
(b) How the protected information is identified, such as the use of markings or other designators that will ensure that all users of this information recognize it as requiring protection;
(c) The forms of protected information, such as paper documents, electronic media or video recordings;
(d) Where the protected information is stored and who has custody of it;
(e) Who has access to sensitive information and how that access is determined (e.g. required to perform job, appropriate level of trustworthiness);
(f) The protection measures in place to prevent unauthorized access when the information is being used or stored (e.g. physical protection, encryption);
(g) The requirements in place for preventing unauthorized access when protected information is being reproduced or transmitted inside or outside of the site;
(h) How protected information is destroyed when no longer needed to prevent recovery, including who is authorized to destroy it and by what means the various forms will be destroyed.

(9) Maintenance programme. Describe the programme for maintaining security equipment to ensure continuous and reliable operation.

(10) Budget and resource planning. Describe how financial resources are allocated to the security of radioactive material.

(11) Evaluation for compliance and effectiveness. Describe the process used by the site to independently verify that the site is in compliance with all applicable security requirements, and for assessing the effectiveness of the security system in identifying any weaknesses that need to be corrected and any opportunities for continuous improvement, including arrangements for performance testing.

(12) Threat information. Describe the types of threat information provided, and how it is provided.

(13) Security assessment methodology. Describe the process or methodology used to design the security system and assess its vulnerabilities, taking into account the threat information provided.

(14) Security system design. Describe how the security system has been designed to provide the level of protection required, taking into account the graded approach and principles of defence in depth and balanced protection. Indicate how each secured area and associated radioactive material are protected by detection, delay and response measures in an integrated and balanced way. Identify the types of equipment and systems installed and their location.

(15) Access control. Describe the physical measures for controlling access, including the following:(a) How personnel are physically controlled at each control point to limit access only to authorized persons according to the access authorization procedure and to prevent unauthorized access;
(b) Specific media used to authenticate the identity of authorized persons, such as key card, personal identification number, biometric device or a combination;
(c) Procedures to be followed by authorized persons to access a secured area, including application of the two-person rule, where relevant.

(16) Detection, assessment, and delay measures. For each controlled or secured area, describe the following:(a) Means of detection, including intrusion detection systems and observation by site personnel;
(b) Method of assessment, including people and equipment supporting the assessment;
(c) Delay measures used to increase adversary task time relative to response time.

(17) Procedures for routine, off-shift and emergency operations. Describe how assigned personnel, such as staff and contractors, operate security systems and discharge their other security related responsibilities during the following periods:
(a) Business hours;
(b) Non-business hours (off-shift or after hours, when staff are not ordinarily present, generally at nights, on weekends and during holidays);
(c) Emergency operations.

(18) Procedures for opening and closing secured areas. Describe the procedures for opening and closing each secured area within the site, particularly activities such as unlocking and locking doors and other barriers, as well as communication with the alarm monitoring station to deactivate and activate detection systems. Identify who in the organization is responsible for

opening and closing these areas, and include actions to validate that other delay mechanisms (e.g. cages) have been appropriately secured.

(19) Procedures for key and lock control. Describe the procedures used for the control of all keys, locks, combinations, passwords and related measures used to control access to secured areas and security systems. Identify who is responsible for changing access control measures and the specific conditions that require them to be changed, such as the compromise of a combination or password, loss of a security key or termination of a staff member's access.

(20) Procedures for accounting and inventory. Describe how the site performs periodic accounting for radioactive material, including the following:
(a) Verification method used, such as a physical check, remote video monitoring, examination of seals or other tamper indicating devices, or radiation measurements.
(b) Records indicating the results of each verification, as well as when, by whom and by what method the verification was conducted.
(c) Requirements for corrective actions and reporting whether the presence of radioactive material cannot be verified. In addition, describe how the site establishes and maintains an inventory of its radioactive material.

(21) Procedures for receipt and transfer of radioactive material. Describe the procedures for ensuring that security and control of a radioactive source are maintained when it is being received from outside the site and when it is transferred to another authorized person.

(22) Response to a nuclear security event. Describe the arrangements with local law enforcement or other designated response authority for responding to a security event, including attempted or actual theft or sabotage of a radioactive source or device.

(23) Communications. Describe the communication methods used to summon a response.

(24) Security event reporting. Describe how security events are reported to the operator's security organization. Describe how events are documented, who is responsible to document the event, and subsequent external reporting requirements.

(25) Security during emergencies and contingencies. Summarize arrangements and actions to be taken during non-security emergencies or other contingency situations to ensure that the protection of the radioactive material is maintained.

(26) Increased threat level. Describe how notifications of an increased threat level are addressed.