AUTHORISATION GUIDELINES FOR MEDICAL IMAGING 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 medical X-Ray imaging facilities (CT, Fluoroscopy, c-arm, radiography, etc). 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 with the Radiation Protection Agency Act 2018, any individual or organization who intends to set up or operate a medical X-Ray imaging 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 medical X-Ray imaging facility or device 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

In the application, clearly provide the following 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. 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 attachments to the application for authorization should cover the following:

INTEGRATED MANAGEMENT SYSTEM

(1) **Management structure and responsibilities.** Describe overall organizational structure and integrated management system ensuring that protection, safety and security are effectively incorporated into the overall management system of the applicant. Describe and clearly define responsibilities for radiation safety 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 such as a quality control programme and plans for regular reviews.

(3) **Submission of the following documentation, procedures and programmes to the regulatory body**:

(a) Radiation source inventory, supply of sources, prior assessment of radiation generators, and inventory of disused devices;

(b) Education, training and competence of the staff and their training, 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) Control of import and export of radiation sources;

(h) Control of visitors;

(i) Programme for the improvement of the integrated management system.

TECHNICAL INFORMATION

(1) Information on radiation sources.

(a) ***Information on imaging devices using radiation sources:***

(i) Type of the device (e.g. radiography, mammography, computed tomography or interventional radiology)

(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) Description of the facility.

(a) X ray imaging room and adjacent areas:

(i) **Layout of the X - ray imaging room and adjacent areas.** Demonstrate that design of the X-ray imaging room 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 X-ray imaging room and adjacent areas, e.g. control room, patient waiting areas and other areas accessed by members of the public (supervised areas). Include details related to other adjacent offices and areas. Specify all construction materials, e.g. material type, thickness and density. Specify which existing sources and equipment will be used in which room. Give the position(s) of source(s) and equipment.

(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 the radiation fields produced by the sources during their use. Provide dose and dose rate calculations, as appropriate, related to the exposure of workers and members of the public. Specify the maximum operating condition of equipment, e.g. workload. 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 positions of all technical safety features and warning systems, such as the emergency button of a device, use of key control, 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 facility. Demonstrate that good engineering practices are taken into account.

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

(3) Technical information of radiation monitoring equipment.

(a) ***Portable survey meters***. Provide technical information related to portable survey meters to be used, as appropriate. Demonstrate the suitability and calibration of portable survey meters and specify their number.

(b) ***Personnel monitoring devices***. Demonstrate that personnel monitoring devices have been provided to all workers (OSL or TLD). Specify all technical information and dosimetry services to be used.

SAFETY ASSESSMENT

The safety assessment has to address 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 occupationally exposed workers. Specify names, educational qualification, training and retraining of workers (including assistants and trainees). Specify whether the Radiation Protection Officer (RPO) 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), education and experience of the qualified expert.

(2) Personal dosimetry. Specify the authorized dosimetry service (RPA) and the arrangements related to the monitoring of personal 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.

(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 or 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 radiation 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 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 PATIENTS

(1) **Responsibilities.**

Specify how radiological medical practitioners ensure that protection and safety is justified and optimized for each medical exposure and who is responsible for that, e.g. the chief radiologist. Specify who is the responsible medical physicist where applicable e.g. the chief physicist.

(2) **Justification**.

(a) Specify who can prescribe an X-ray imaging procedure, e.g. a physician.

(b) Specify how the patient is verified not to be pregnant.

(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 X-ray imaging procedures. Describe briefly the most common imaging procedures and **how optimization has been ensured** (exposure to ionizing radiation should be the last option). Describe the implementation of diagnostic reference levels.

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

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

(4) **Quality assurance.**

(a) ***Technical quality control:***

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.

(i) *Quality control programme*. Measurements of the physical parameters of medical radiological equipment 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. 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.

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

(b) ***Other quality assurance:***

(i) *Records of imaging procedures*. Describe how records of relevant procedures and results are maintained.

(ii) *Reporting and learning systems*. Describe how the results of the investigation of an unintended exposure 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 X - ray imaging.

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