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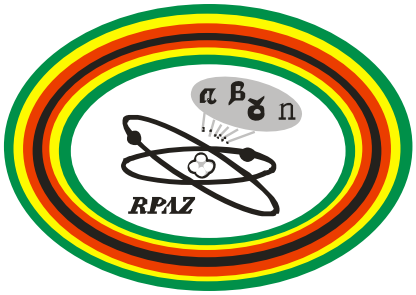

RADIATION PROTECTION AUTHORITY OF ZIMBABWE

RADIATION PROTECTION ACT [CHAPTER 15:15]

GUIDE FOR COMPLETING APPLICATION FORM: AUTHORISATION TO IMPORT/EXPORT RDIATION DEVICES

This guide provides guidance to assist prospective/current licensees on how to complete an application form for a Radiation Protection Authority of Zimbabwe (RPAZ) license to import or export radiation sources and equipment in accordance with the Radiation Protection Act (Act) and the regulations made under the Act.

Requirements for use or storage and possession of industrial radiation gauges should be applied in addition to the following regulations:

- Radiation Protection Act (Chapter 15:15) of 2004
- Statutory Instrument 62 of 2011, Radiation Protection (Safety and Security of Radiation Sources) Regulations;
- Statutory Instrument 106 of 2011, Radiation Protection (Safety and Security of Radiation Sources) (Amendment) Regulations;
- Statutory Instrument 134 of 2012 (Fee Schedule), Radiation Protection (Safety and Security of Radiation Sources) (Amendment) Regulations (No 2);
- Radiation Protection (Medical Practices) Regulations, 2014

Each application should demonstrate that the applicant is capable of and committed to complying with all requirements under the ACT and related regulations as above. The applicant must ensure that the information provided on the form and in the attached supporting documents is clear, precise, accurate, and complete. Supporting documentation should clearly reference the part of the application form to which the information pertains.

The Authority's staff can provide additional information upon request; applicants can contact Authority's Licensing Department on the following:

- Tel: +263 4 335627/ 335683/ 335792
- Email: licensing@rpaz.co.zw

In this part of the application, the Authority requires specific information on the entity to be licensed, including complete contact information and proof of legal status. The relevant sections as represented in the application for a license are detailed below;

1. GENERAL INFORMATION

a) Name of applicant/Institution

- In this section, provide the legal name of the person, institution or corporation who will be referred to as the "licensee" to whom the license should be issued.
- Indicate the name as it appears on the proof of legal status documentation, such as the proof of incorporation or sole proprietorship.
- An individual may be the Applicant only if they will be solely responsible for the licence and are not a corporation or institution.
- The Radiation Protection (Safety and Security of Radiation Sources) Regulations, 2011 require notification to the Authority in the event of a change in the applicant's name during the valid period of the licence.
- In order to ensure the necessary accountability and responsibility, the Applicant must be a 'person', which is a natural person (an individual), a government or public institution or a corporate person (a corporation). General or limited partnerships are not eligible to be an Applicant since the Authority cannot license a partnership under the Act.
- The applicant must indicate whether the application is from a natural person (individual/sole proprietorship), a public institution or a corporation (incorporated company).
- A sole proprietorship is where the business is owned and operated by one individual and where there is no legal distinction between the owner and the business. A public institution is any non-incorporated government department or agency, any non-incorporated public institution or any other site which is set up under enabling legislation.
- An incorporated company is any incorporated business, institution or company where incorporation is carried out under federal or provincial authorization. Append information that establishes the applicant as a "person" for the purpose of this application.
- Append the following documentation: Memorandum of Articles, Certificate of Registration, CR 14, CR 6, VAT Certificate and Tax clearance Certificate.

Address

- Provide the mailing address, if it is different than the head office address, including the complete street name and number, and rural route number if appropriate, city, province or territory, and postal code.
- If no address is provided here, a licence issued in response to the application will be mailed to the head office address. A post office box is acceptable as a mailing address. Licensees must notify the Authority within ten working days of any changes to this information.

b) Type of License

Mark the relevant section if application is to obtain:

- a new licence,
- Amendment, and
- renewal of an existing licence

For renewals, indicate the current licence number.

c) Purpose of License

In this section, identify the proposed activities and the locations which will be associated with the licensed activities of the radioactive material and radiation devices.

d) Name and Title of Head of Institution

Name of the person heading the company, institution or department such as the Chief Executive Officer, Managing Director or Head of department

e) Person Responsible for Radiation Safety (Radiation Safety Officer)

The designation of Radiation Safety Officer (RSO) is given to the person responsible for the management and control of the licensed activity and the radioactive materials and radiation devices. The RSO is the person the Authority will contact about radiation safety and compliance matters. The RSO must:

- have sufficient knowledge, experience and resources to effectively manage the radiation protection program,
- have sufficient time to respond to day-to-day situations that may arise as well as ongoing program oversight

- understand the nature of the licensed activity and be fully knowledgeable of applicable regulations
- understand the information requirements of the licence application and the reporting requirements for notifying the Authority of incidents and events

Authority requires the RSO be appropriately qualified and with sufficient knowledge and expertise with regards to the applicant's proposed activities. The RSO may be a consultant hired by the applicant to carry out this role, but must be clearly designated by the applicant authority to do so; this information must be communicated to the Authority as part of the licence application process. The role of RSO does not take off the responsibility for safety from the "licensee".

Applicants must provide the name, title, address, telephone number and email address of the RSO. The RSO must be at the site of the licensed activity or reasonably be able to attend to the site of licensed activity as required. Alternate RSOs may be utilized where a licensee has multiple locations of licensed activity.

Applicants must provide the signature of the Applicant Authority designating the RSO. Unless otherwise noted by the applicant authority, the RSO will be considered to have been designated the authority to act for the applicant and has signing authority for all matters encompassed by the Authority licence.

Licensees must notify the Authority within 10 working days of a change in RSO or in the RSO position.
(Also see notes on roles and responsibility of the RSO as explained in the Radiation Protection Act Section 16)

f) The Representative of the Legal Person

The Legal person is the Legal Institution that is applying for a license; representative of the Legal Person is therefore the Head or senior representative of that institution such as the Managing Director, the CEO Etc. In cases of non-compliance the representative of the Legal Person become accountable for the facility operational and legally. He/she has to ensure the facility complies with the requirements of the Act and put in place structures to ensure compliance thereof and provide the required resources thereof.

g) Radiation Qualified Experts

'Persons having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognised by the competent authorities. A qualified expert may be assigned the technical responsibility for the tasks of radiation protection of workers and members of the public'.

A radiation qualified expert can be a consultant, radiologist or medical physicist.

h) Other Classified Workers

Other classifies workers may be workers directly involved or working with the equipment such as technicians, nurses, and social workers.

2. EQUIPMENT

a) X-Ray Generators

- Manufacturer, model and serial numbers of the devices
- For X-ray generators also provide the Maximum Voltage (kV) and the Maximum Current (mA)
- Provide address where equipment shall be operational

Attach a layout plan of the x-ray facility showing the x-ray rooms, including the location of the control panel, shielded cubicle/mobile protective barrier, cassette pass box, doors, windows/ventilators, dark room, passages, patient changing room, patient waiting area, occupancies around the installation and materials and thickness of wall materials.

b) Standards and Classification

i. State if the radiation devices are manufactured, prototype tested and subject to quality control provisions of standards recognized by international standard setting organizations e.g. ISO or SAZ. The facility must also identify if the devices shall be subject to quality control and standards recognized by international standard setting organizations.

ii. State whether the devise is prototype tested and subject to quality control provisions of the standards recognised by international standard setting organisations. There is need to list and identify the standards and applicable classification numbers.

c) Installation type

State whether the equipment is fixed or is mobile

d) Storage Location for Mobile Devices

This section applies to mobile radiation sources and devices that need to be stored for some period at locations other than the one given in section I (a). List all details of the storage locations including their addresses.

e) Any other location

Provide details for other locations in which the equipment will be used apart from that in c). above.

f) Service and Maintenance

Provide a list of the entities and companies providing servicing and maintenance services for the equipment. Note that all service providers have to be accredited with the Radiation Protection Authority of Zimbabwe.

3. FACILITIES

a) Shielding and design of X-ray room and facilities

i. Licensee to describe factors such as the layout of the facility and its safety systems including, design, alarms, shielding and engineering controls. In case of medical X-Ray control panel, shielded cubicle/mobile protective barrier, cassette pass box, doors, windows/ventilators, dark room, passages, patient changing room, patient waiting area, occupancies around the installation and materials and thickness of wall materials.

b) Dose assessments

These sections should provide for safety assessments, including calculations for dose rates in areas adjacent and outside installation, provide estimates of the magnitude of the expected doses to persons during normal operations, and also identifying probability and magnitude of potential

exposures arising from accidents or incidents.

There is need to attach a layout drawing of the installation showing adjacent surroundings with the controlled and supervised areas clearly identified.

4. RADIATION PROTECTION AND SAFETY PROGRAM

This section shall be submitted as an attachment to the application form.

a) Organisational Structure

i. Describe your organization structure and management control systems including assignment of responsibilities related to radiation safety, include; staffing levels, equipment selection criteria, the duties and responsibilities of the radiation safety officer to stop unsafe operations, personnel training and maintenance of records.

The overall responsibility for radiation safety lies with the operating organization that is authorized to utilise nuclear gauges. Specific duties and the day to day responsibilities for safe operation of the equipment will, however, lie with a range of people, including senior management, the radiation protection officer, operators and their assistants, qualified experts and, for site work, the client responsible for the premises where the work is being carried out and any relevant subcontractors. All responsibilities and duties should be agreed to by all relevant parties and should be identified in writing.

ii. Provide information on planned on the job training including explanation of written procedures, use of equipment, quality assurance measuring warning lights and signs and radiation protection and safety program of the facility

b) Personnel monitoring and Classification and Monitoring of working areas

i. The operating organization should establish and describe a programme of monitoring of radiation levels in and around the workplace or onsite. The adequacy of the arrangements in place for protection in radiography work should be assessed in the programme, which should include measurements of radiation levels. The monitoring programme should describe the locations to

be monitored, the frequency of monitoring and the records to be kept. This information should be included in the local rules and should also be described in the radiation protection programme. Reference levels for each measurement location should be given, and the actions to be taken if these values are exceeded should be described. Records of the workplace monitoring programme should be made available to appropriate persons, including workers

ii. Classification of Areas;

The facility should be aware of any site specific hazards and develop policies and procedures to ensure onsite personnel are aware of the presence and type of radiation source that it is planning to use on the site and also that storage is available for any radioactive sources that are intended to be stored on the site overnight. Describe the appropriate classification of areas when working with gauges in the field, the boundary of the controlled area should be demarcated. When reasonably practicable, this should be done by physical means. Adequate warning signals should be given within the vicinity of the work area usually displayed as the radiation trefoil to warn of the potential hazard. Dose rates should be measured around the classified areas during exposures.

iii. Dosimeters

Indicate which dosimeters are being used

c) Local Rules and Supervision

i. Describe your local rules and procedures concerning investigation levels or authorized levels; protective measures and safety provisions, providing adequate supervision, provision of information to workers regarding health risks due to occupational exposure and emergency planning and response instructions.

ii. Describe your training program to ensure that all appropriate staff are adequately trained in the operating procedures

iii. Describe your policies regarding notification by female workers of pregnancy and the instruction you will provide to female workers

d) Quality Assurance

i. Describe your program to periodically review procedures maintain procedures, current and available, and your procedure modification process.

ii. Describe your program for optimizing occupational and public exposures to levels as low as reasonably achievable

iii. Describe your program of periodic maintenance.

5. EMERGENCY PROCEDURES

The primary objective of emergency preparedness and response should be to mitigate the consequences of emergencies. Operating organizations should submit their emergency plans and associated arrangements to the regulatory body, as required, when applying for an authorization. The plan should clearly give details of any response, and it should be ensured that the responders are fully aware of and accept their responsibilities; this plan should be integrated into the organisational or facility emergency plan.

6. SIGNATURE AND CERTIFICATION

This section must be filled in and signed by the representative of the Legal Person or any other senior representative of the applicant or institution and officially date stamped where appropriate.