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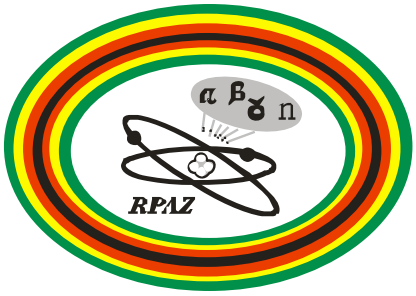

RPA-AUTH/FRM-02/GD/10

RADIATION PROTECTION AUTHORITY OF ZIMBABWE

RADIATION PROTECTION ACT [CHAPTER 15:15]

GUIDE FOR COMPLETING APPLICATION FORM: AUTHORISATION FOR (FIXED/MOBILE) GAUGING, DETECTION AND OTHER 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 for nuclear gauging facilities in accordance with the Radiation Protection Act (Act) and the regulations made under the Act. The following practices shall apply;

- Nuclear Gauging
- Industrial Radiography
- Detection Equipment: Baggage Scanners, Whole body scanners, Truck scanners
- Industrial X-ray Generators

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);

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, expert in the field. In other cases a qualified expert maybe engineers responsible for installation, maintenance and repair of the equipment. A facility may engage such persons as consultants. In addition persons responsible for equipment such technicians may be included.

h) Other Classified Workers

Other classifies workers may be workers directly involved or working with the equipment such as operators, technicians, radiographers etc

2. EQUIPMENT

a) Type of radiation material and radiation emitting devices

State whether the equipment is fixed or mobile.

i. Sealed sources

For equipment with sealed sources incorporated provide the following;

- Manufacturer, model and serial numbers of the devices,
- name or symbol and mass number of each sealed nuclear substance or radionuclide in possession as a sealed source; for example, Co-57 and Cs-137. Maximum activity contained in any single sealed source, and
- Sealed Radioactive materials are licensed according to the maximum individual activity rather than sums of total activity.

ii. Neutron Generators- Accelerator

Provide the following;

- Manufacturer, model and serial numbers of the devices, neutron energy and target nuclide

iii. 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)

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) 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.

3. FACILITIES

a) Location of Facility

Indicate the main address for the applicant's storage and/or use of nuclear substances and radiation devices. The address should be a physical address as a post office box is not acceptable as a principal storage location. For other storage locations especially for mobile and movable devices provide a complete list of the sites.

b) Layout of the installation

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.

ii, iii, iv, 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. SECURITY AND SAFETY OF RADIATION SOURCES

a) Describe measure to be undertaken to ensure safety and security o radiation sources during;

i. Use

This should include the operating procedures during the use of the equipment, classification of areas (controlled, supervised areas), access controls, qualifications of the operators and supervision. Also to be included is the programme of monitoring of radiation levels in and around the workplace as well as personnel dose monitoring including maintenance and calibration and leak testing of equipment.

ii. Transport

Include procedures for safe transport of radioactive sources and equipment, personal responsibility for transport, appropriate transport packages, roles and responsibility of personnel as well as ensuring that there is a system of accountability to be put in place to ensure that the location of the sources is known throughout.

iii. Storage

Arrangements for effective storage of the radiation sources, appropriate building of facility with adequate shielding, procedures for access to the storage facility or room as well as the periodic

inventory verification and accountancy of the stored radiation sources.

b) Radioactive Waste Management

i. Indicate is radioactive waste will be returned to country of origin or suppler or not. Government policy states that all radioactive sources shall be returned to supplier at the end of their useful life, in such a case an agreement should be submitted in which the supplier commits to receiving back the sources at the end of their useful life.

In case of X-Ray generating equipment the policy on return to suppler may not necessarily apply.

In case the response in b (i) is "No" state and describes how the waste will be managed in the country if it's not returned back to supplier. This applies to short lived radiation sources as well as X-Ray generating equipment that can either be stored before disposal or decommissioned or dismantled.

c) 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.

d) Other Radiation Protection and Safety Requirements

This should include the procedures for personnel monitoring and workplace monitoring, this must include leak tests, dose rate measurements for the workplace.

e) Transfer or Disposal of Radioactive Sources

Transfer of sources to other users is applicable, however, the transfer should be carried out in a controlled manner and involves taking on responsibilities for safety and accountability that are equivalent to those of the original source manufacturer.

f) System of Records

Provide details on how the applicant manages records in the areas highlighted. The records should be kept by the RSO for each relevant sections.

5. DECLARATION

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.