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Radiation Protection (Safety and Security of Radiation Sources) Regulations, 2011

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IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 22 of the Radiation Protection Act [*Chapter 15:15*], made the following regulations—

PART I

PRELIMINARY

Title

1. These regulations may be cited as the Radiation Protection (Safety and Security of Radiation Sources) Regulations, 2010.

Scope of application

2. Without prejudice to the provisions of section 14 of the Act, these regulations shall apply to practices and sources above the exemption or clearance levels, places and interventions prescribed below—

(a) the production of radioactive sources and the use of radiation or radioactive substances for medical, Industrial, veterinary or agricultural purposes, or for education, training or research, including any other activities related to that use which involve or could involve exposure to radiation;

(b) sealed or unsealed radioactive materials, substances or devices that contain radioactive materials, consumer products, fixed and mobile radiography equipments;

(c) facilities which contain radioactive materials or substances or devices which produce radiation, irradiation installations, and radioactive waste facilities;

(d) any occupational exposure, medical or public exposure due to any relevant practices or sources within the practice, including both normal and potential exposure;

(e) emergency exposure situations requiring protective action to reduce or avert temporary or chronic exposure;

(f) any other exposure situation identified by the Authority as warranting intervention or remedial action.

Interpretation

3. In these regulations—

"accident" means any unintended harmful or potentially harmful event, including operation errors, equipment failures , the consequences or potential consequences of which are not negligible from the view point of protection or safety;

"Act" means the Radiation Protection Act [*Chapter 15:15*] No. 5/2004;

"activity" means—

(a) the design, manufacture, construction, import, export, distribution, sale, loan, commissioning, use, operation, maintenance, repair, transfer, decommissioning or possession of radiation sources for industrial, education, research, agriculture and medical purposes;

(b) the transport of radioactive material;

(c) the mining and processing of radioactive ores;

(d) the closing down of associated facilities;

(e) the cleanup of sites affected by residues from past activities; and

(f) radioactive waste management activities such as the discharge of effluents;

"authority" means the Radiation Protection Authority of Zimbabwe;

"authorisation" means permission in a document by the Authority to a legal person who submitted an application to carry out practice, such authorisation can take the form of a registration or licence;

"Civil Protection Organisation" means the Civil Protection Organisation as defined in the Civil Protection Act [*Chapter 10:06*];

"clearance" means the removal of radioactive materials or radioactive substances within authorized practices from any further control by the Authority;

"clearance levels" means values determined by the Authority and expressed in terms of activity concentrations and/or total activity , at or below which sources of radiation are released from regulatory control;

"critical group" shall mean a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure path way and is typical of individuals receiving the highest effective dose or equivalent dose (as applicable) by the given exposure pathway from the given source;

"decommissioning plan" means a document containing detailed information on the proposed decommissioning of a facility;

"decommissioning" means administrative and technical actions taken to allow the removal of all of the regulatory controls from the facility (except for a repository which is closed and not decommissioned);

"exemption" means a determination by the Authority that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects;

"exposure" means the act or condition of being subject to irradiation;

"facility" means irradiation installations, mining and milling facilities, waste management facilities and any other place where radioactive materials are produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required;

"guidance level" shall mean a level of specified dose limit quantity, above which appropriate actions should be considered;

"health surveillance" means medical supervision to ensure the initial and continuous fitness of workers for their intended task;

"intervention" means any action intended to reduce or avert exposure or the likelyhood of exposure to sources which are part of controlled practices;

"legal person" means any organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these regulations. This includes natural persons;

"licensee" means the holder of a licence granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection and safety;

"medical exposure" means exposure received by patients as part of their own medical or dental diagnosis or treatment by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

"medical practitioner" means a medical doctor, dentist, radiologist, or other health personnel who is licensed to examine and diagnose the disease of humans and treat them by radiation;

"monitoring" means the measurement of dose or contamination for the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results;

"normal exposure" means any exposure, which is expected to be received under normal operating conditions of an practice or a source, including possible minor occurrences that can be kept under control.

"notification" means a document submitted to the Authority by a licensee or registrant to notify an intention to carry out an activity or practice;

"occupational exposure" means any exposure of workers incurred in the course of their work;

"potential exposure" means exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;

"protection action" means any intervention intended to avoid or reduce radiation doses to members of the public in chronic or emergency exposure situations;

"public exposure" means exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorised sources and practices and from intervention situations;

"Public Protector" has the same meaning as in the Public Protector's Act [*Chapter 10:18*];

"quality assurance" means all those planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality;

"radiation protection officer" means a person technically competent in radiation protection matters and who has been granted a certificate of authorisation and is an employee of the Authority;

"radiation safety officer" means a person technically competent in radiation protection and safety matters for a given type of practice designated by a registrant or licensee to oversee the application of the requirements of these regulations;

"radioactive discharges" means radioactive substances arising from a source within a practice discharged as gases,

aerosols, liquids or solid to the environment, generally with the purpose of dilution and dispersion;

"radioactive material" means any substance consisting of, or containing any radioactive nuclide, whether natural or artificial, including but not limited to, radioactive waste;

"radioactive waste disposal" means disposal of waste in an approved and specified facility without the intention of retrieving and including the approved direct discharge or airborne or liquid effluents into the environment for subsequent dispersion;

"radioactive waste management" means all activities, administrative and operational, including decommissioning activities involved in the handling, pre-treatment, conditioning, storage and disposal of waste from facility;

"radioactive waste" means material—

(a) remaining from practices or interventions and for which no further use is foreseen;

(b) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements;

(c) that is radioactive exists in any physical form and is not exempted from regulatory requirements in these regulations;

"registrant" means an applicant who is granted registration of a practice or source and has recognized rights and duties of such a practice or source, particularly to protection and safety;

"registration" means a form of authorisation for practices of low or moderate risk whereby the person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the Authority, such practice or use is authorised with conditions or limitations as appropriate. The requirements for safety assessment and the conditions

or limitations applied to the practice should be less severe than those for licensing;

"safety assessment" shall mean a review of the aspects of design and operation of a source relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations;

"safety culture" means the totality of characteristics and attitudes in organisations and individuals, which establishes that, as an overriding priority, protection and safety issues receive due attention warranted by their significance;

"security" means measures to prevent unauthorised access or damage to, loss, theft or unauthorised transfer of, radioactive sources.

PART II

ADMINISTRATIVE REQUIREMENTS

General obligations

4. No person shall engage in activities which involve practices or sources specified in section 2 unless requirements in the Act and these regulations, including the requirements for notification and authorisation, are met.

Notification requirements

5. (1) Except for sources and practices exempted from regulatory control referred to in section 6, any person—

(a) who, on the effective date of these regulations, is responsible for a practice or is in possession of a radiation source referred to in section 2, shall submit a notification of such to the Authority.

(b) intending to initiate a practice or to possess a radiation source referred to in section 2, shall submit a prior notification to the Authority of such an intention.

(3) Sources and practices requiring notification only shall be prescribed in the directive issued there under by the Authority.

Exemption of practices and sources

6. (1) Practices and sources within practices may be exempted from the requirements of these regulations, including those for notification, registration or licensing, if the Authority is satisfied that the sources meet the exemption criteria or the exemption levels specified in Schedule I or other exemption levels specified by the Authority on the basis of the exemption criteria. Exemption should not be granted to permit practices that would otherwise not be justified.

(2) The general principles for exemption are that the—

(a) radiation risks to individuals caused by the exempted practice or source be sufficiently low as to be of no regulatory concern;

(b) collective radiological impact of the exempted practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and

(c) exempted practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

(3) A practice or a source within a practice may be exempted without further consideration provided that the following criteria are met in all feasible situations—

(a) the effective dose expected to be received by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year, and

(b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimisation of protection shows that exemption is the optimum option.

(4) Under the criteria in subsection (1), (2) and (3), the sources provided in the Second Schedule within practices are automatically exempted without further consideration from the

requirements of these regulations, including those for notification, registration or licensing.

Requirements for authorisation

7. (1) Except for sources and practices exempted from regulatory requirements in terms of section 6 or requiring only notification in terms of section 5, any legal person intending to engage in a practice or possess a radioactive source referred to in section 2 shall apply to the Authority for authorisation.

(2) The Authority ensuring the fulfilment of the requirements shall provide authorisation, as per the type of the source or practice applied for, either by registration or licence.

(3) The importation of radioactive materials and substances shall be in conformity with standards recognised by the Authority, therefore any person who applied to import radioactive sources shall submit from the foreign supplier, seller or manufacturer—

(a) evidence regarding the conformity of sources with the quality standards; and

(b) necessary assurance as to how reshipment will be undertake in cases where they are found to be not in conformity with the quality standards after inspection.

(4) Any person who applied for authorisation to import sealed sources shall, depending on the radioactivity of the source, make an agreement with the producer or supplier that enables him to return the sources back when discarded and furnish the Authority with a copy of the agreement.

(5) Any person applying for authorisation shall—

(a) submit to the Authority relevant information necessary to support the application, including—

(i) an evaluation of the nature, magnitude and likelihood of the exposure attributed to the practice and source within the practice; and

(ii) a safety assessment in case where this is prescribed by the Authority, to be submitted as part of the application; and

(iii) a determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group.

(b) take all necessary steps for the protection and safety of workers, members of the public and when applicable, patients.

(5) Any person responsible for a source to be used for medical exposure shall include in the application for a licence, the qualifications in radiation protection of the medical practitioners who are to be so designated by name or by qualification credentials in the licence as the only individuals permitted to prescribe medical exposure by means of the authorised source.

Responsibilities of licensees

8. (1) Licensees shall—

(a) bear the primary responsibility for —

(i) establishing and implementing the technical and administrative measures that are needed for ensuring protection and safety of the practices and sources for which they are authorised; and

(ii) compliance with all applicable requirements of these regulations.

(b) notify the Authority of their intentions to introduce modifications to any practice or source for which they are licensed—

(i) whenever the modifications could have significant implications for protection and safety; and

(ii) shall not carry out any such modification unless a written authorisation is given by the Authority.

(3) Licensees shall ensure that medical practitioners referred to in section 7(5), are the ones having key assignments related to protection and safety, and radiation sources are operated only by them.

Clearance

9. Radiation sources, including substances, materials and objects within authorised practices can be removed from further compliance with the requirements of these regulations: Provided that they comply with the clearance levels defined by the Authority.

PART III

RADIATION PROTECTION REQUIREMENTS

Justification of practices

10. (1) No practice or source within a practice should be authorised unless the practice is justified in that it produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors.

(2) Except for justified practices involving medical exposures, the following practices are deemed to be not justified whenever they would result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products—

(a) practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being; and

(b) practices involving the use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments.

Dose limitation

11. (1) Dose limits shall not apply to medical exposures for patients from authorised practices.

(2) The conditions concerning internal body exposure that may be caused by inhaling or ingesting of radioactive material shall be determined by directives issued by the Authority.

(3) The dose limits set out in subsection (2) and (4) shall not apply to comforters or visitors of patients as the relevant details on the

dose constraints of any such comforter or visitor shall be determined by the Authority.

(4) When under special circumstances a temporary change in dose limitation is required, the Authority may issue revised dose limits for specified periods of time.

(5) Without prejudice to sub-section (1), (3), and (4) exposures from any particular source in a practice shall be optimised for protection and safety in order that the individual dose be kept as low as reasonably achievable.

(6) The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorised practices, exceeds any relevant dose limit specified in the Second Schedule.

Optimisation of protection

12. In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimised in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as is reasonably achievable, economic and social factors being taken into account within the restriction that the doses to individuals delivered by the source be subject to the dose constraints.

Safety culture

13. (1) A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency, which shall ensure that—

(a) policies and procedures are established that identify protection and safety as being of the highest priority; and

(b) problems affecting protection and safety be promptly identified and corrected in a manner commensurate with their importance; and

(c) the responsibilities of each individual, including those at senior management levels, for protection and safety are clearly identified; and

(d) each individual is suitably trained and qualified; and

(e) clear lines of authority for decisions on protection and safety are defined; and

(f) organisational arrangements and lines of communications be effected that result in an appropriate flow of information on protection and safety at and between the various levels in the organisation of the registrant or licensee.

Quality assurance

14. (1) Registrants and licensees shall observe quality assurance standards prescribed in the Act, these regulations and directives issued by the Authority to ensure that—

(a) the specified requirements as required by the Authority, relating to protection and safety are satisfied; and

(b) all personnel assigned with the responsibility of protection and safety be appropriately trained and qualified to understand their responsibilities and perform their duties with appropriate judgment and according to defined procedures; and

(c) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures are in place; and

(d) radiation sources used for measuring are timely and periodically calibrated.

(2) Licensees shall—

(a) keep the results of monitoring and verification of compliance, records of the tests and calibration carried out, records of maintenance, training of personnel and all records related to implementation of the radiation protection programme; and

(b) maintain exposure records for each radiation worker for whom assessment of occupational exposure is required and such exposure records shall include information on doses, exposures and intakes at or above the relevant recording levels and the data upon which the dose assessments are based.

(4) Licensees rendering medical services using radiation sources shall keep—

(a) in diagnostic radiology, records of necessary information that allow retrospective dose assessment, including the number of exposures and the duration of fluoroscopic examination;

(b) in nuclear medicine, records of the type and activity of radiopharmaceuticals administered and their activities;

(c) in radiation therapy, records of description of the planning target volume, the dose to the centre of the planning target volume, the doses to other relevant organs, the dose fraction and the overall treatment time;

(d) records of the exposures of volunteers in medical research;

(e) records of the result of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments.

(5) The time limit to maintain the records prescribed in this section shall be forty years from the date of last record entry.

Qualified radiation safety experts

15. Licensees shall—

(a) commensurate with the scope of the work, designate qualified radiation safety experts to be identified and made available to act as radiation safety experts.

(b) shall ensure the level of academic knowledge and of professional experience of the radiation safety expert is compatible with the level of risk associated with the authorised practices or sources within a practice.

(c) shall keep the Authority informed of the arrangements made with respect to paragraph (a) and (b).

Human factors

16. Licensees shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgment and according to defined procedures, and are periodically retrained or re-qualified as may be appropriate.

Security of sources

17. Sources shall be kept secure so as to prevent theft or damage, by ensuring that—

(a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence, and without immediate communication to the Authority.

(b) a source is not to be transferred unless the receiver possesses valid authorisation; and

(c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure.

PART IV

VERIFICATION OF RADIATION PROTECTION AND SAFETY

Safety assessments

18. (1) Licensees shall as a minimum, make safety assessments related to protection and safety measures for sources within practices at different stages, including location, design, manufacture, construction, assembly, commissioning, operation, maintenance, decommissioning in order—

(a) to identify the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the source as

well as events directly involving the sources and their associated equipment; and

(b) to determine the expected magnitude of normal exposures; and

(c) to estimate the probabilities and the magnitudes of potential exposures; and

(d) to assess the quality and extent of the protection and safety provision.

Monitoring and verification of compliance

19. (1) Monitoring and measurements shall be conducted by licensees on the parameters necessary for verification of compliance with the requirements of these regulations and the licence or registration.

(2) For the purpose of monitoring and verification of compliance—

(a) suitable equipment shall be provided and verification procedures introduced by licensees;

(b) the equipment shall be properly maintained and tested and shall be calibrated at appropriate intervals with reference to standards traceable to national and international standards.

Liability for and custody of radiation sources

20. (1) Licensees shall—

(a) ensure the safety and security of sources under their responsibility from the moment of their acquisition throughout their entire operational life and up to their final disposal; and

(b) maintain an accountability system that includes records of the location and description of each source, the activity and form of each radioactive substances for which they are responsible; and

(c) inform the Authority while transferring radioactive material or substances under their control and shall ensure that the person to whom they transfer the sources has notified or applied for authorisation; and

(d) make periodic inventory of sources, and shall maintain records of receipt, transfer and disposal of sources the time interval for inventory of sources shall be specified in the directive issued by the Authority.

(2) Any person who is authorised to import sealed sources shall submit to the Authority, every three months, a written report regarding sources and machines under his or her custody or transferred to another person with valid authorisation.

(3) The responsibility of registrants and licensees for the loss, theft or missing of authorised sources shall not relinquish unless the Administrative Court decides otherwise.

PART V

OCCUPATIONAL EXPOSURE CONTROL

Conditions of service of radiation workers

21. (1) Without prejudice to the provisions of other relevant laws licensees shall—

(a) not use special compensatory arrangements, such as, preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits and other arrangements as a substitute for the provision of adequate protection and safety measures;

(b) make any reasonable effort to provide radiation workers with an alternative work place in circumstances where the Authority determines or when the relevant physician decides that the radiation worker, for medical reasons, may no longer continue in employment involving occupational exposure;

(c) advise female workers that it is desirable to notify the employer of pregnancy;

(d) once a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo is afforded the same broad of protection which is required for members of the public;

(e) not consider the notification of pregnancy as a reason to exclude a female worker from work;

(f) not allow any person between the ages of sixteen to eighteen years to work in controlled areas unless for training and educational purposes under supervision.

Classification of areas

22. Licensees shall designate—

(a) areas in which there is a potential to receive more than tenths of the annual occupational dose limits specified in section 11 as controlled areas; and

(b) areas in which the annual dose limits specified in section 11 as supervised areas.

Personal protective equipment

23. Registrants and licensees shall—

(a) ensure that the application of administrative measures and uses of personal protection equipment for protection and safety are implemented and the details about personal protective equipment shall be provided in the directives issued by the Authority; and

(b) ensure that radiation workers be provided with suitable and adequate personal protective equipment; and

(c) ensure that regular testing and maintenance be carried out on all protective equipment including, as required, special equipment for use in the event of accidents and interventions; and

(d) assign personal protective equipment for a certain task taking into account the physical and medical fitness and the capacity of the assignee to cope with the inconveniencies and other non radiological risks with the use of protective equipment.

Monitoring of the work place

24. (1) Registrants and Licensees shall establish, maintain and keep under review a program for the monitoring of the work place

commensurate with the nature of the risks associated with the sources or the radiation generating equipment.

(2) The details on monitoring of the work place shall be determined in the directive issued by the Authority.

Organisational rules and supervision

25. Licensees shall—

(a) establish in writing comprehensive rules and procedures in English and Shona or Ndebele to ensure adequate levels of protection and safety for workers and other persons; and

(b) provide to all workers adequate information on the health risks due to their occupational exposure, whether normal or potential exposure; and

(c) adequate instruction and training on protection and safety including information on general and organisational rules and procedures and on available protection and safety provisions, as well as adequate information on the significance of protection and safety of their action.

(d) provide to female workers who enter into controlled areas or supervised areas appropriate information on—

(i) the risk to the embryo due to exposure of a pregnant woman; and

(ii) the importance for a female worker to notify her employer as soon as she confirms that she is pregnant; and

(iii) the risk to an infant ingesting radioactive substances by breast feeding.

(e) provide to those workers who could be affected, an emergency plan, appropriate information, instructions and training.

Individual monitoring and exposure assessment of radiation workers

26. (1) Registrants and licensees and shall be responsible for arranging the assessment of occupational exposure of the radiation

workers working in controlled areas and provide for individual monitoring at frequency determined by the Authority.

(2) Registrants and licensees and shall ensure that radiation workers using protective respiratory equipment, be identified and shall arrange for appropriate monitoring to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses.

PART VI

MEDICAL EXPOSURE CONTROL

Medical exposure

27. (1) Unless administered by a medical practitioner, the delivery of diagnostic or therapeutic services and machines is prohibited.

(2) The medical exposure of a person shall not in general exceed the guidance levels provided under the relevant directives issued by the Authority under special circumstances, however it can be exceeded by applying sound clinical judgment.

(3) A medical practitioner administrating diagnostic or therapeutic services shall ensure the safety and protection of patients in the prescription of and during the delivery of medical exposure.

(4) The undertaking of any activity involving medical exposure shall only be conducted by or under the supervision of a medical practitioner.

(5) The medical exposure to individuals voluntarily engaged in helping patients shall be kept within the limit specified under the directives issued by the Authority.

(6) Notwithstanding the responsibility of registrants and licensees, medical practitioners shall promptly inform the registrants and licenses about any deficiencies or needs regarding compliance with these regulations with respect to protection and safety of patients

Justification of medical exposure

28. (1) Medical exposure shall be deemed to be justified only where there is no alternative to medical exposure and diagnostic or therapeutic benefits outweighs the potentially adverse effects.