(CAP. 15:15

Radiation Protection (Medical Practices) Regulations, 2014

ARRANGEMENT OF SECTIONS

Section

IT is hereby notified that the Office of the President and Cabinet has, in terms of section 22 of the Radiation Protection Act *iCnapter* 15:15] after consultation with the Board as required by subsection (1) of that section, made the following regulations:-

Title

1. These regulations may be cited as the Radiation Protection (Medical Practices) Regulations, 2014.

Interpretation

2. In these regulations-

"fee" means a fee prescribed in the First Schedule of the Radiation Protection (Fees) Regulations, 2012, published in Statutory Instrument 134 of 2012;

"licence" means an authorisation granted by the Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with;

"register oflicences " means a register oflicences maintained by the Authority in terms of section 17;

"users of radiation sources" means users of radiation sources in the practise of radiotherapy, radiology, nuclear medicine or research and development.

Utilisation oj radiation sources to be licensed

3. ·(1) No person shall utilise radiation sources- (a) for radiotherapy purposes;

(b) for radiology purposes; or

(c) in nuclear medicine; or

(d) for research and development in the medical sector;

except under the terms of a licence issued by the Authority.

Application for licence

4. (1) Any person who intends to utilise radiation sources for radiotherapy, radiology, purposes of nuclear medicine or research and development in the medical sector, must complete the appropriate form issued by the Authority in triplicate and shall submit two copies of it together with the prescribed fee to the Authority.

(2) Any person applying for a licence shall provide theAuthority with the information necessary to demonstrate the safety of the practice and adherence to the requirements of standards and norms issued by the Authority and the relevant information necessary to demonstrate the safety of the practice including a radiation protection programme.

(3) In considering an application submitted in terms of subsection (2), the Authority may require the applicant to submit such additional information and particulars as it deems fit.

(4) Upon receipt of an application in terms of subsection (2) and any additional information or particulars in terms of subsection (3), the Authori ty must review and assess the application, and for that purpose shall inspect any premises and equipment from which the service will be provided and ensure that the proposed service does not contravene the Act or any other enactment.

(5) The Authority shall consider the application and additional information submitted in terms of subsections (2) and (3) and the results of a review and assessment conducted in terms of subsection (4), within 90 days from the date indicated on the form as the date of application, and shall within that period, make a decision on the application, by remitting to the applicant a copy of the application whereon it shall be indicated whether the Authority-

(a) approves the application subject to specified conditions;
or

(b) rejects the application for specified reasons.

(6) Considering the complexity of medical practices, the risks involved and the fact that safety depends on human performance, demonstration of safety requires a detailed safety assessment and therefore authorisation shall take the form of multi-stage licences.

(7) The licensee shall comply with radiation safety requirements for the following stages of the medical practice-

(a) design and construction; and

(b) operation (acceptance, commissioning, clinical use, maintenance); and

(c) modifications; and

(d) decommissioning (partial or total) and return or disposal of sources.

(8) Any structural modification of the medical facilities, modification of the type and activity of radioactive substances and of procedures or cessation of the practice, shall require an amendment to the licence.

(9) Where an applicant has been licensed for the purposes of this section the licensee shall comply with such standards and norms which the Authority may issue from time to time.

(10) A licensee shall not assign, cede or otherwise transfer his or her licence without the prior written approval of the Authority.

(11) Failure to take corrective or preventive actions within a specified period of time shall be grounds for modifying, suspending or withdrawing any authorisation that had been granted the Authority.

Licensees to notifY changes

5. (1) If at any time after the issuance of a licence or renewal thereof there is any material change in the particulars furnished in connection with the application for the licence or renewal thereof, the licensee shall notify the Authority in writing within fourteen days from the date when the change occurs and the Authority may on the basis of such notification require the licensee to submit a new application for a licence in terms of section 4.

(2) The Authority may from time to time notify to the licensee what changes are to be considered material for the purposes of subsection (1).

Duration, surrender and renewal of licences

6. (1) A licence shall remain in force for a period of a year from the date of issue unless it is earlier surrendered to or revoked by the Authority.

(2) If any licensee wishes to surrender his or her licence, he or she shall give the Authority not less than thirty days written notice of his or her intention to do so.

(3) Upon expiry, of a licence, every licensee wishing to continue his or her licensed operation shall, on or before the 31st of December in each year, apply to the Authority in writing, together with the prescribed fee, for the renewal of the licence:

Provided that if the original licence is issued within a period of three months preceding the 31st of December, a certified operator shall only be required to apply for a renewal of the licence on the 31st of December of the following year.

(4) Sections 4(2), (3), (4), (5), (6), (7) and (8) shall apply to an application for renewal of certificate of approval in terms of this section.

(5) After considering an application for the renewal of a certificate of approval and any additional information requested and the results of a review and assessment by the Authority, the Authority may issue a certificate of renewal of approval in writing with conditions specified in the licence which conditions may relate to the matters specified in section 4(5).

Register of licences

7. (1) The Authority shall establish and maintain a register of licences of persons utilising radiation sources in the practises of radiotherapy, radiology, nuclear medicine or research and development in the medical sector in which the following shall be recorded-

(a) the name and address of every licensee and the addresses from which the use of radiation sources is conducted;
and

(b) the date of issue of every licence and of any renewal thereof; and

(c) any terms or conditions imposed on each licensee on the date of the issue of the certificate; and

(d) the particulars of any additional conditions imposed on or after the issuance of the original or renewed licence; and

(e) suspensions and revocations of licences; and

(f) amendments to licences.

(2) Any person may inspect either of the registers referred to in subsection (1) free of charge at all reasonable times at the premises of the Authority or at such other place as the Authority may direct.

(3)Where a licence is lost or destroyed, the licensee concerned may apply to the Authority in writing, together with the prescribed fee, for a replacement certificate.

Amendment of licences

8. (1) The Authority may at any time amend a licence or any terms or conditions of a licence-

(a) to correct any error in the licence; or

(b) if the licensee requests the amendment; or

(c) if the Authority considers the amendment necessary.

(2) Where licensee requests an amendment to his or her licensee, he or she shall make an application thereof, together with the prescribed fee, to the Authority.

Suspension or revocation of Licences

9. (1) Subject to subsection (2), the Authority may at any time suspend or revoke any licence if the Authority has reasonable grounds for believing that the-

(a) licence was issued in error or through fraud or misrepresentation or non-disclosure of a material fact by the licensee thereof; or

(b) licensee has contravened any provision of the Act or these regulations or any standards and norms that are applicable to him or her; or

(c) licensee misrepresents the service he or she offers; or

(d) licensee has ceased to utilise radiation sources as specified in the licence; or

(e) licensee has assigned, ceded or otherwise transferred the licence to another person without the prior written approval of the Authority; or

(f) licensee has failed to comply with any term or condition of the licence.

(2) Except where in the opinion of the Authority, radiation safety or the public interest is immediately at risk, the Authority shall notify the licensee in writing of its intention to suspend or revoke the licence concerned and the reasons for doing so, and shall call upon the licensee to show cause, within such reasonable period as may be specified in the notice, why the licence should not be suspended or revoked, as the case may be.

(3) If, at the expiry of the period specified in the notice given in terms of subsection (2), and after considering any representations made by the licensee, the Authority is satisfied for any reason specified in subsection (1) that the licence concerned should be suspended or revoked, the Authority may, by notice in writing to the licensee, suspend or revoke the licence or take such other action as it considers appropriate.

General obligations of licensed users of radiation sources

10.(1) A licensee shall on a continuous basis and to the satisfaction of the Authority -

(a) comply with the requirements of standards and norms issued by the Authority relating to the use of radiation sources in radiotherapy, radiology, nuclear medicine or research and development in the medical sector; and

(b) employ competent and qualified personnel to ensure the smooth and safe use of radiation sources;

(2) In the event of a breach of any licence condition, the licensee shall, as appropriate-

(a) investigate the breach and its causes, circumstances and consequences;

(b) take appropriateaction to remedy the circumstancesthat led to the breach and to preventa recurrenceof similarbreaches;

(c) communicate to the Authority, and to any relevant organisations when applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and

(d) take any other actions necessary as required by the Authority.

Personnel accreditation for radiation protection and safety

11. (1) All personnel on whom protection and safety depend, shall be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures.

(2) In all medical practices, the following individuals carry responsibility for protection and safety, by virtue of tasks involving decisions, operation or manipulation of sources or equipment used in radiotherapy-

(a) medical practitioners (...); 311d

(b) qualified experts (radiation consultants ...); and

(c) other health professionals operating equipment or handling radioactive sources (technologists); and

(d) Radiation Safety Officer; and

(e) staff for maintenance and quality control of radiation emitting medical equipment.

(3) These individuals shall provide evidence of educational qualifications and professional training relevant to their duties related to the use of radiation sources.

(4) For radiotherapists, radiation oncologists, medical physician, dosimetrists, radiotherapy technologists and radiation safety officers, typical documentary evidence indicated above, i.e., qualification credentials, shall as applicable, consist of-

(a) university degree or academic qualification relevant to the profession, issued by universities coUeges of health technology, polytechnics and colleges of technology and other accredited institutions; and

(b) accreditation to exercise the profession granted by the relevant competent authorities or other professional or academic bodies recognised by the Authority; and

(c) attendance at and passing of required examinations on a course on radiation protection for which the contents, the methodology and the teaching insti tution are accredited by the Authority. This course may be integrated in the cunicula of professional education under (a) and (b); and

(d) on-the-job training supervised by professionals with accreditation by the Authority or other appropriate competent authorities.

(5) The documentary evidence for the individual to perform maintenance of radiotherapy equipment of radiotherapy equipment shall consist of-

(a) certification by a manufacturer of his or her having completed a training programme on the type of authorised equipment (the certification should indicate the type of equipment that the engineer or technician has been trained to repair or adj ust, or the scope of the maintenance he/she is unable to perform); and

(b) a course on radiation protection for which contents methodology and teaching institution are approved by the Authority.

Authorisation of the activittes related to radiotherapy, radiology, nuclear medicine and research and development in the medical sector

12. Considering that according to the Act, the activities listed below also require authorisation, licensees shall contract any of the following services only to enterprises authorised by the Authority-

(a) import, distribution, sale or transfer or radioactive sources;

(b) installation, maintenance of equipment including source change and decommissioning;

(c) quality control, training and consultancy;

(d) waste management and disposal of radioactive sources.

Offences and penalties

13. (1) Any person who contravenes sections 4,5,6,7,8,9,10, 11 and 12 commits an offence.

(2) Any person or body corporate who, being a licensee under these regulations, who commits an offence shall be liable to prosecution in the court of law upon conviction be liable to pay a fine not exceeding Level 8 or to imprisonment not exceeding three years for an individual and a fine not exceeding Level 8 for the corporate body.

Appeals

14. (1)Any person who is aggrieved by a decision of the Authority to-

(a) reject an application for a licence in the circumstances specified in section 6(5); or

(b) grant an application subject to conditions in the circumstances specified in section 6(5); or

(c) cancel a licence in terms of section 9; or

(d) suspend a licence in terms of section 9; or

(e) amend a licence in terms of section 10(1) (c) or (d);

may appeal within 14 working days from the date he or she is notified of the decision.

(2) For the avoidance of doubt it is declared that where-

(a) an appellant whose application for a licence or permit has been rejected or whose licence or permit is granted conditionally or whose licence has been suspended or canceUed;and

(b) the appeal has not been determined timeously;

such appellant has a right under the Administrative Justice Act *[Chapter 10:28]* to apply to the High Court to compel the appellate authority to furnish reasons why the determination of his or her appeal has not been made timeously and for such other relief that the High Court may grant under that Act.

False entries and declarations informs

15. Any person who provides any information in or together with an application for any licence or permit under these regulations knowing that such information is false or not having reasonable grounds for believing that such information is true shall be guilty of an offence and liable to a fine not exceeding level 8 or to imprisonment not exceeding three years or to both such fine and such imprisonment.

Supplement to the Zimbabwean Government Gazette dated the 30th Ma): 2014.
Printed by the Government Printer. Harare.