ARRANGEMENT OF SECTIONS

Section

IT is hereby notified that the Office of the President and Cabinet in consultation with the Board has, in terms of section 22 of the Radiation Protection Act [*Chapter 15:15*], made the following regulations—

Title

1. These regulations may be cited as the Radiation Protection (Naturally Occurring Radioactive Material) Regulations, 2013.

Application

2. These regulations shall apply to—

(a) any person who generates, possesses, uses, transfers, or disposes of Naturally Occuring Radioactive Material (NORM); and

(b) the manufacture and distribution of products containing Naturally Occuring Radioactive Material (NORM) in which the Naturally Occuring Radioactive Material (NORM) or its emitted radiation is considered to be a beneficial attribute.

Interpretation

3. In these regulations—

"beneficial attribute" or "beneficial to the product" means radioactivity of the product is necessary for the use of the product;

"consumer products" means appliance or device produced, made, manufactured, refined, or beneficiated in which a small amount of radioactive substance has been deliberately incorporated or induced, and which can be supplied to members of the public;

"containment" means methods or physical structures that prevent the dispersion of radionuclides;

"contamination" means the presence of radioactive substances in or on a material or in the human body or other place where they are undesirable or could be harmful;

"decontaminate" includes maintenance which incidentally results in removal of contamination;

"effective dose" means the quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor—

$$E = \sum_T W_T H_T$$

where HT is the equivalent dose in tissue T and WT is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that—

$$E = \sum_T W_T \cdot \sum_R W_R \cdot D_{T,R}$$

where WR is the radiation weighting factor for radiation R and DT,R the average absorbed dose in the organ or tissue T. The unit of effective dose is J. kg-1, termed the Sievert (Sv);

"exempt waste" means any waste that is released from nuclear regulatory control in accordance with clearance levels because the associated radiological hazard is negligible. The designation should be in terms of activity concentration and/or total activity and may include a specification of the type, chemical/physical form, mass or volume of waste, and its potential use;

"external radiation" means, in relation to a person, ionizing radiation coming from outside the body of a person;

"effluent" means gaseous or liquid radioactive materials which are discharged into the environment;

"exposure" means irradiation of people or materials this can either be external exposure from sources outside the body or internal exposure from sources inside the body;

"decontamination" means the removal or reduction of radioactive contamination by a physical or chemical process;

"disposal" means the emplacement of waste in an approved, specified facility without the intention of retrieval;

"general environment" means the total terrestrial, atmospheric, and aquatic environments outside the site boundary

within which any activity, operation, or process authorized by a general or specific license issued is performed;

"institutional control" means control of a waste site by the authority or an institution designated to do so under regulations;

"licence" means a licence issued in terms of sections 5, 6 and 7;

"monitoring" means the measurement of radiation or radionuclides for reasons related to the assessment or control of exposure and the interpretation of such measurements;

"Naturally Occurring Radioactive Material" or "NORM" means naturally occurring materials whose radionuclide concentrations have been increased by or as a result of human practices. NORM does not include the natural radioactivity of rocks or soils, or background radiation, but instead refers to materials whose radioactivity is enhanced by controllable practices (or by past human practices);

"notification" a written notification submitted to the Authority by a legal person to notify an intention to carry out a practice or any other action described in the general obligations for practices of the standards;

"probabilistic analysis" means a statistical method for studying the expected behaviour of a system defined by parameters, events and features whose values are represented by a statistical distribution;

"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, for example, those specified in the licence;

"quality control" means action which provides means to control and measure the characteristics of an item, process, facility or person in accordance with quality assurance requirements;

"safety analysis" means the evaluation of the potential hazards associated with the implementation of a proposed activity;

"safety criteria" means safety conditions on which a decision or judgment can be based as set out by the Authority;

"shielding" means a material interposed between a source of radiation and persons, or equipment or other objects, in order to absorb radiation and thereby reduce radiation exposure;

"storage" means the placement of waste in a facility where isolation, environmental protection and human control are provided with the intent that the waste will be retrieved for exemption, processing or disposal at a later time;

"transport" means, in relation to NORM, carriage of substance on a road within the meaning of, or through another public place, whether on a conveyance or not, or by rail, inland waterway, sea or air and, in the case of transport on a conveyance NORM shall be deemed as being transported from the time that it is loaded onto the conveyance for the purpose of transporting it until it is unloaded from that conveyance, but NORM shall not be considered as being transported if—

(a) it is transported by means of a pipeline or similar means; or

(b) it forms an integral part of a conveyance and is used in connection with the operation of that conveyance;

"treatment" means the operations intended to benefit safety and economy by changing the characteristics of waste with the following objectives—

(a) volume reduction;

(b) removal of radionuclides from the waste;

(c) change of composition;

after treatment, the waste may or may not be immobilised to achieve an appropriate waste form;

"unrestricted use" means a designation, by the Authority that enables the use of equipment, materials, buildings or the site without radiological restriction;

Exemptions

4. (1) Any person who generates, receives, owns, possesses, uses, processes, transfers, distributes, and disposes of NORM is exempted from the requirements of these regulations if the materials contain or are contaminated at concentrations less than 1 Bq/g of uranium or thorium series radionuclides.

(2) Any person who receives products or materials containing NORM distributed in accordance with a specific licence issued by the Authority pursuant to these regulations is exempted from the requirements of these regulations with regard to those products or materials.

(3) Any person who purposefully dilutes to render NORM exempt in terms of subsection (1) shall be guilty of an offence and liable to a fine not exceeding level three or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

General licence

5. (1) No person shall generate, possess, own, use, transfer and dispose of NORM except under the terms of a general licence issued by the Authority.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level three or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

(3) A general licence shall not authorise the manufacturing or distribution of products containing NORM in concentrations greater than those specified in section 4 nor the receipt and disposal of wastes from other persons.

(4) Decontamination other than that incidental to routine maintenance by a licensee of its own equipment or facilities shall be conducted pursuant to a specific licence.

(5) Any person wishing to generate, possess, own, use, transfer and dispose of NORM must apply to the Authority in writing and submit two copies of it, together with the prescribed application fee (which is non-refundable), to the Authority.

(6) Any application made in terms of subsection (4) must include the following information—

(a) name and address of the applicant; and

(b) location and description of the facility or operation; and

(c) description of the NORM including estimates of the amount and extent of NORM.

(7) Upon receipt of an application for a general licence, the Authority shall consider the application within 30 days from the date indicated on the application as the date of application, and shall within that period, make a decision on the application by remitting to the licensing authority a copy of the application whereon it shall be indicated whether the Authority—

(a) approves the application unconditionally; or

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

(c) rejects the application for specified reasons.

(8) As soon as possible after a decision on an application is made, the Authority shall notify the applicant of the granting or rejection of the application for a general licence by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

Provided that where an application is rejected or granted with conditions the Authority shall inform the applicant of his or her right of appeal under section 22.

(9) The Authority may, by written notice, require any licensee under a general licence to apply for a specific licence stating the reason or reasons for the requirement.

Specific licence

6. (1) No person shall—

(a) manufacture and distribute any material or product containing NORM unless otherwise exempted under the provisions of section 4;

(b) except as provided in section 9(3), decontaminate equipment or land not otherwise exempted under the provisions of section 4 or facilities contaminated with NORM in excess of the levels set forth in section 7, as applicable;

(c) receive NORM from other persons for disposal;

unless under the terms of a special licence.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level three or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

Requirements for the issuance of a specific licence

7. (1) In applying for a specific licence, an applicant must provide information that assists the Authority to determine that the—

(a) applicant is qualified by reason of radiation training and experience to use the NORM in question for the purpose requested and, in such a manner as to protect public health, safety and property;

(b) applicant's proposed equipment, facilities and procedures are adequate to protect public health, safety and property; and

(c) issuance of the licence will not be inimical to the health and safety of the public; and

(d) applicant has satisfied any applicable special requirement in these regulations; and

(e) applicant has met any financial requirements; and

(f) applicant has adequately addressed the following items in the application—

(i) procedure and equipment for monitoring and protecting workers; and

(ii) an evaluation of the radiation levels and concentrations of contamination expected during normal operations; and

(iii) operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

(iv) a method for managing the radioactive material removed from contaminated equipment and facilities.

(2) An application for a specific licence to decontaminate equipment, land, or facilities contaminated with NORM in excess of the levels set forth in the First Schedule applicable and the disposal of the resulting waste may be approved if the—

(a) applicant satisfies the general requirements specified in this section; and

(b) applicant has adequately addressed the following items in the application—

(i) procedures and equipment for monitoring and protection of workers; and

(ii) an evaluation of the radiation levels and concentrations of contamination expected during normal operations; and

(iii) operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

(iv) the method of disposing the NORM removed from contaminated equipment, facilities or land.

(3) An application for a specific licence to manufacture or initially transfer products or materials containing NORM to persons exempted pursuant to section 4(2) may be approved if the—

(a) applicant satisfies the general requirements specified in section 7(1)(a); and

(b) NORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

(c) applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking and conditions of handling, storage, usage and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in section 20 including—

(i) a description of the material or product and its intended use or uses; and

(ii) the type, quantity, and concentration of NORM in each material or product; and

(iii) the chemical and physical form of the NORM in the material or product and changes in chemical and physical form that may occur during the useful life of the material or product; and

(iv) an analysis of the solubility in water and body fluids of the NORM in the material or product; and

(v) the details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product; and

(vi) the degree of access of human beings to the material or product during normal handling, use, and disposal; and

(vii) the total quantity of NORM expected to be distributed annually in the material or product; and

(viii) the expected useful life expectancy of the material or product; and

(ix) the proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclides and quantity of NORM in the material or product; and

(x) the procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal; and

(xi) the results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the

NORM may be released to the environment, any change in radiation levels, and any other changes in safety features; and

(xii) the estimated external radiation doses and dose commitments relevant to the safety criteria in section 20 and the basis for such estimates; and

(xiii) a determination that the probabilities with respect to doses referred to in section 20 meet the safety criteria; and

(xiv) the quality control procedures to be followed in the production of lots of the material or product, and the quality control standards the material or product will be required to meet; and

(xv) any additional information, including experimental studies and tests, required by the Authority to facilitate a determination of the radiation safety of the material or product.

(4) An application for a specific licence to dispose of NORM received from others may be approved if—

(a) the applicant demonstrates that operation of the facility will comply with the standards of sections 15 and 18; and

(b) the applicant demonstrates that adequate institutional controls have been implemented.

(5) Notwithstanding the provisions of section 20, the Authority may deny an application for a specific licence if the end users of the product are frivolous or cannot be reasonably foreseen.

Application for a specific licence

8. (1) Any person wishing to apply for a specific licence shall make such application to the Authority and submit two copies of such application together with the prescribed fee.

(2) Upon receipt of an application for a specific licence, the Authority shall consider the application within 30 days from the date indicated on the application as the date of application, and shall within that period, make a decision on the application by remitting

to the licensing authority a copy of the application whereon it shall be indicated whether the Authority—

(a) approves the application unconditionally; or

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

(c) rejects the application for specified reasons.

(3) As soon as possible after a decision on an application is made, the Authority shall notify the applicant of the granting or rejection of the application for a specific licence by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

Provided that where an application is rejected or granted with conditions the Authority shall inform the applicant of his or her right of appeal under section 22.

(4) The Authority may at any time after the submission of the original application and before the expiration of the licence, require further statements in order to enable the Authority to determine whether the application shall be granted or denied or whether a licence shall be amended or revoked.

(5) An application may be signed by the applicant or a person duly authorised to act for and on the applicant's behalf.

(6) An application for a licence may include a request for a licence authorising one or more activities.

(7) The applicant may incorporate by reference information contained in previous applications, statements or reports provided to the Authority in the application, provided such references are clear and specific.

Licensees to notify changes

9. (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 a 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 5 or 7, whichever is applicable.

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

Issuance, duration, surrender and renewal of licences

10. (1) Every licence shall be valid for a period of a year or part of a year ending on 31st December of the year in which the applicant received the licence, unless it is earlier surrendered to or cancelled by the Authority.

(2) If an application for a licence is successful (whether approved with or without conditions) the Authority shall—

(a) inform the applicant accordingly in accordance with sections 5 and 8; and

(b) issue to the applicant a licence, upon payment by the applicant of the prescribed issuance fee; and

(c) make an appropriate entry in the licence register.

(3) If a licensee ceases to operate as such, he or she shall, within thirty (30) days of ceasing to operate, surrender his or her licence to the Authority.

(4) Any person who contravenes subsection (4) shall be guilty of an offence and liable to a fine not exceeding level three or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

(5) The Authority may incorporate in a licence at the time of issuance or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of NORM subject to this regulations as it deems appropriate or necessary in order to—

(a) protect public health, safety and property; and

(b) provide for such inspections of activities under the licence as may be appropriate, require report of the inspections and keep the record of same; and

(c) prevent loss or theft of NORM.

(6) Upon expiry of a licence, every licensee wishing to continue his or her operations 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 was issued within a period of three months preceding the 31st of December, a licensee shall only be required to apply for a renewal of the licence on the 31st of December of the following year.

(7) Sections 5 and 7 shall apply for an application for renewal of a licence in terms of this section.

(8) After considering an application for the renewal of a licence and any additional information requested and the results of an investigation by the Authority, the Authority may, on payment of a prescribed fee, issue a licence, in writing, with or without conditions specified in the licence which conditions may relate to any of the matters specified in section 6(5).

(9) Where a licensee does not submit an application for licence renewal under Article 18 of these Regulations, the licensee shall on or before the expiration date specified in the licence—

(a) terminate use of NORM; and

(b) remove NORM contamination consistent with the requirements of section 17; and

(c) properly dispose of NORM; and

(d) submit a report of disposal of NORM and radiation surveys to confirm the absence of NORM or to establish the levels of residual NORM contamination. The licensee shall, as appropriate—

(i) report levels of radiation in units of microsieverts per hour of beta and gamma radiation at one centimeter and gamma radiation at one metre from surfaces and report levels of radioactivity in units of Becquerels per 100 square centimetres removable and fixed on surfaces, Becquerel per millilitre in water, and Becquerels per gram in contaminated solids such as soils or concrete; and

(ii) specify the instruments used and certify that each instrument is properly calibrated and tested.

Conditions attaching to licences

11. (1) Any licence issued and any right to possess or to utilise NORM granted by any licence issued shall not be transferred, assigned or disposed of in any manner either voluntarily or involuntarily, directly or indirectly, through transfer of control of any licence to any person unless the Authority after securing full information, finds that the transfer is in accordance with the provisions of these regulations and shall give its consent in writing.

(2) A person licensed by the Authority shall confine the use and possession of the NORM licensed to the locations and purposes authorised in the licence.

(3) A licensee shall—

(a) carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Authority; and

(b) label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the NORM in the product can be identified.

(4) Each licensee shall notify the Authority in writing and request termination of the licence when the licensee decides to terminate all activities involving NORM authorised under the licence. This notification and request for termination of the licence must include the reports and information specified in subsection (5).

(5) If no radioactivity attributable to activities conducted under the licence is detected, the licensee shall submit a certification that no detectable NORM contamination was found. If the Authority determines that this certification and the information submitted under section10 (6)(d) is adequate and surveys confirm the findings, the Authority will notify the licensee, in writing, that the licence is terminated.

(6) If levels of residual NORM are not in conformance with criteria established in section 17, the licensee continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Authority notifies the licensee, in writing, that the licence is terminated. During this time, the licensee is subject

to the provisions of subsection (7). In addition to the information submitted under section 10(6)(d), the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.

(7) A licensee who possesses residual NORM in terms of subsection (6), following the expiration date specified in the licence, shall—

(a) be limited to actions involving NORM related to preparing the locations for release for unrestricted use; and

(b) continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the Authority notifies the licensee in writing that the license is terminated.

Register of licences

12. (1) The Authority shall establish and maintain a register of licences in which the following shall be recorded—

(a) the name and address of every licensee and the addresses from which the operations are taking place; 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 licence; and

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

(e) any suspensions and revocations of licences; and

(f) any amendments of licences.

(2) Any person may inspect the register 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.

(4) Any person who wishes to make an authenticated copy of any entry in the register referred to in subsection (1) shall pay a prescribed fee therefor.

Amendment of licences

13. (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 to reflect the true nature of the operations which the licensee is undertaking; or

(d) if for any other reason the Authority considers the amendment necessary or desirable in the interests of public health and safety or in the public interest.

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

Suspension or revocation of licences

14. (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—

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

(b) the licensee has contravened the Act or these regulations that is applicable to him or her by virtue of these regulations; or

(c) the licencee misrepresents the operations he or she is undertaking; or

(d) the licensee has ceased to undertake the activities specified in the licence; or

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

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

(2) Except where in the opinion of the Authority, public health and 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 certificate 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.

Standards for radiation protection for NORM

15. (1) A licensee shall not conduct operations, use or transfer NORM in a manner such that a member of the public will receive an annual effective dose in excess of 1 mSv/yr from all licensed sources including NORM.

(2) A licensee shall comply with radiation protection standards set out in the Radiation Protection (Safety and Security of Sources) Regulations, 2011 published under Statutory Instrument 162 of 2011.

(3) Doses from indoor radon and its progeny shall not be included in Effective Dose calculations.

(4) The use, transfer or disposal of NORM shall be done in such a way as to prevent accumulation of radon in residential structures and other public buildings in concentrations exceeding 0.2 Bq/l and 1.0 Bq/l respectively.

(5) No person shall dispose or release NORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual Effective Dose in excess of 0.25 mSv/yr, excluding natural background.

Protection of workers during operations

16. A licensee shall conduct operations in compliance with the standards for radiation protection set out in the Radiation Protection

(Safety and Security of Sources) Regulations, 2011, published under Statutory Instrument 162 of 2011, except for the release of radioactivity in effluents, which shall be governed by the other relevant regulations dealing with disposal.

Release for unrestricted use

17. Each licensee shall—

(a) ensure that facilities and equipment contaminated with NORM in excess of the levels set forth in the First Schedule—

(i) shall not be transferred or released for unrestricted use; or

(ii) shall be evaluated prior to release for unrestricted use to ensure that the levels in the First Schedule are not exceeded;

(b) not transfer land for unrestricted use where the concentration of uranium or thorium series radionuclides in soil averaged over any 100 square metres exceeds the background level by more than 1 Bq/g, averaged over top 15 cm layer of soil.

Management and transfer of waste for disposal

18. (1) A licensee shall manage and dispose of wastes containing NORM in accordance with Radiation Protection (Safety and Security of Radiation Sources) Regulations, published under Statutory Instrument 162 of 2011—

(a) by transfer of the wastes for disposal to a disposal facility licensed by the Authority; or

(b) in accordance with alternate methods authorised by the Authority upon application or upon the Authority's initiative, and consistent with section 15.

(2) Equipment contaminated with NORM in excess of levels specified in the First Schedule, which is to be disposed of as waste shall be disposed of—

(a) to prevent any reintroduction into commercial or unrestricted use; and

(b) within disposal areas specifically designed to meet the criteria of section 18 of these regulations.

(3) Transfers of waste containing NORM for disposal shall be made only to a person specifically authorised by the Authority to receive such waste.

(4) Records of disposal, including manifests, shall be maintained pursuant to the provisions of these regulations.

(5) Disposal practices and sites shall be subject to institutional control as appropriate and determined by the Authority.

Transfer of NORM contaminated facilities

19. (1) The transfer of NORM not exempted from these Regulations from one general licensee to another general licensee shall be authorised by the Authority if—

(a) the equipment and facilities contaminated with NORM are to be used by the recipient for the same purpose; or

(b) the transfer of control or ownership of land contaminated with NORM includes an annotation of the deed records to indicate the presence of NORM.

(2) The Authority may approve transfers which do not meet the criteria of subsection (1).

(3) Transfers made under subsection (1) do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of NORM contamination or material present, evaluating the hazards of the NORM, informing the general licensee receiving the NORM of these assessments and evaluations, and maintaining records required by these regulations.

(4) A general licensee intending to transfer NORM contaminated facilities for unrestricted use shall document compliance with the requirements of section 17 and records of such compliance shall be kept.

Safety criteria for products

20. An applicant for a license under section 8 shall demonstrate that the product is designed in such a way that, when manufactured—

(a) the use and disposal of a single exempt item and the handling and storage of the quantities of exempt items likely to accumulate in one location during—

(i) marketing;

(ii) distribution;

(iii) installation; and

(iv) servicing of product;

is unlikely that the external radiation dose in any one year or the dose commitment resulting from the intake of radioactive material in any one year by individuals who are most exposed to radiation or radioactive materials from the product; and

(b) in use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the Table in the Second Schedule and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the Table in the Second Schedule; and

(c) it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

Offences and penalties

21. Any person who—

(a) being certified, assigns, cedes or otherwise transfers his or her certificate without the prior written approval of the Authority in terms of section 11(1); or

(b) being certified, fails to notify the Authority of any material change in the particulars furnished in connection with the application for the licence or renewal of a licence in terms of section 9; or

(c) being certified, fails to notify the Authority of his or her intention to surrender his or her licence in terms of section 10(4) and 10(6);

commits an offence and shall be liable, on conviction, to a fine not exceeding level five, or to period of imprisonment not exceeding six months or both such fine and imprisonment.

Appeals

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

(a) reject an application for a licence; or

(b) grant an application for a licence subject to conditions; or

(c) cancel or revoke a licence; or

(d) suspend a licence; or

(e) amend a licence;

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

(2) Subject to subsection (3), the period between the lodging of the appeal in terms of subsection (1) and its determination shall not exceed thirty days, and if the appeal has not been determined after that period it shall be deemed (except in the case of an appeal against the rejection of an application for a licence or conditional granting or suspension or cancellation of a licence) to have been determined in favour of the appellant.

(3) An appellate authority may before deciding an appeal request the appellant to make such further written submissions or supply such further information as he or she considers will be of assistance in determining the appeal, in which event the thirty day period referred to in subsection (3) shall be extended by a further period so that the appeal may be determined on a date no later than sixty days from the date when the appeal was lodged.

(4) On an appeal under this section, the appellate authority may confirm, vary or set aside the decision or action appealed against.

(5) Upon making his or her determination, the appellate authority shall notify the determination to the appellant and the Authority in writing stating his or her reasons for the determination.

(6) If the determination is favourable to the appellant the Authorityshall within seven working days from the date of such notification, grant to the appellant the licence in question.

(7) For the avoidance of doubt it is declared that where—

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

(b) the appeal has not been determined timeously in accordance with subsection (2);

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 in forms

23. Any person who provides any information in or together with an application for any licence 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 five or to imprisonment not exceeding six months or to both such fine or such imprisonment.

FIRST SCHEDULE (*section 7(2), 17, 18(2)*

ACCEPTABLE SURFACE CONTAMINATION[1] LEVELS FOR NORM

	AVERAGE[2,3,6]	MAXIMUM[2,4,6]	REMOVABLE[2,3,5,6]
Alpha	80 Bq/100 cm²	250 Bq /100 cm²	16 Bq /100 cm²
Beta Gamma	80 Bq/100 cm²	250 Bq /100 cm²	16 Bq /100 cm²

[1] Where surface contamination by both alpha and beta-gamma emitting nuclides exist, the more restrictive limit applies.

[2] As used in this table, Bequerel (Bq) means the rate of emission by radioactive material as determined by correcting the counts per second observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contamination level should not be averaged over more than one square metre. For objects of less surface area, the average should be derived for each object.

[4] The maximum contamination level applies to an area of not more than 100 cm².

[5] The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 2 μGy/hr at 1cm and 10 μGy/hr at 1 cm, respectively, measured through not more than 7 milligrams per square centimetre of total absorber.

SECOND SCHEDULE (*Section 20*)

TABLE OF ORGAN DOSES

Part of Body	Column I* Dose Limits/h	Column II* Dose Limits/yr	Column III* Dose Limits/5yrs
Whole body; head and truck; active blood-forming organs; gonads; or lens of eye	0.05 mSv	5 mSv	150 mSv
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimetre	0.75 mSv	75 mSv	1000 mSv
Other organs	0.15mSv	15 mSv	500 mSv
*Dose limit is the dose above background from the product.			

Supplement to the Zimbabwean Government Gazette dated the 5th July, 2013.
Printed by the Government Printer, Harare.