

STATUTORY INSTRUMENTS

SUPPLEMENT No. 4

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2012 No. 4.

THE ATOMIC ENERGY REGULATIONS, 2012

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STATUTORY INSTRUMENTS

2012 No. 4. The Atomic Energy Regulations, 2012.

(Under section 73 of the Atomic Energy Act, 2008, Act No. 24 of 2008).

In exercise of the powers conferred upon the Atomic Energy Council by section 73 of the Atomic Energy Act, 2008, these Regulations are made this 24th day of November, 2011.

Part I—Preliminary.

1. Title.

These Regulations may be cited as the Atomic Energy Regulations, 2012.

2. Purpose.

The purpose of these Regulations is—

- a. to specify the minimum requirements for the protection of individuals, society and environment from the dangers resulting from ionising radiation;
- b. to provide for the safety and security of radiation sources, hereinafter referred to as radiation safety, protection and security; and
- c. to revoke and replace the Atomic Energy (Ionising Radiation Protection) Standards Regulations (S.I. 143 - 1).

3. Application.

1. These Regulations apply to—

- a. the introduction, conduct, discontinuance, or cessation of a practice;
 - b. to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, production, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport of all situations involving exposure or the potential for exposure to ionising radiation, storage; and
 - c. disposal of a source within a practice unless exposure from the source is excluded or exempted in accordance with these Regulations.
2. The sources within any practice to which the requirements for practice of these Regulations apply include—
- a. radioactive substances and devices that contain radioactive substances or produce ionising radiation, including consumer products, sealed sources, unsealed sources, and ionising radiation generators, including mobile radiography equipment;
 - b. installations and facilities containing radioactive substances or devices which are used for industrial, medical, agricultural, research, power generation and education purposes; and
 - c. any other source specified by the Council.
4. Interpretation.

In these Regulations, unless the context otherwise requires—

“accident” means any unintended event including an operating error, equipment failures or other mishap, the consequences or potential consequences of which is not negligible from the point of view of protection or safety;

“Act” means the Atomic Energy Act, 2008;

“administer ionising radiation” means the intentional act of subjecting ionising radiation whether internal or external to a person for the purpose of medical treatment or diagnosis by a qualified expert;

“article” means an item or thing or equipment associated with the emission of radiation;

“atomic energy” means ionising radiation emitted or energy released as a result of electronic or nuclear transitions in an atom;

“authorisation” means permission granted in writing by the council to a person who has submitted an application to carry out a practice or any other action described in the general obligations for practices under the Act and includes a certificate of registration, licence or permit granted by the Council under section 37 of the Act;

“authorised officer” means an officer appointed or authorised to perform any functions in relation to the enforcement of these Regulations and includes a police officer;

“authorised person” means a person issued an authorisation under section 37 of the Act;

“certificate of registration” means a certificate issued under section 51 of the Act;

“chairperson” means the chairperson of the council;

“clearance” means the removal of radioactive materials or radioactive objects within authorised practices from any further control by the council;

“continuous exposure” means external exposure where the source of radiation subjects the body or any critical organ to prolonged exposure or internal exposure due to continuous intake;

“Council” means the Atomic Energy Council established by section 4 of the Act;

“critical group” means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathways and its typical of individuals receiving the highest effective dose (as applicable) by the given exposure pathway from the given source;

“currency point” means the value assigned to a currency point in Schedule 14;

“decommissioning” means administrative and technical action taken to allow removal of some or all of the regulatory controls from a nuclear facility except for a repository, which is closed and not decommissioned; and it includes decontamination, dismantling and removal of radioactive materials, waste, components and structures;

“disease” includes injury and bodily or mental deficiency or abnormality;

“disposal” in relation to waste, includes its removal, deposit or destruction, its discharge, whether into water or into air or into a sewer or drain or otherwise, its burial whether underground or otherwise and “dispose of” shall be construed accordingly;

“dose” means a measure of the radiation received or absorbed by a target;

“dose constraint” means a prospective and source related restriction on the individual dose delivered by the source which serves as a bound or limit in the optimisation of protection and safety of the source;

“dose equivalent” means a quantity used by the International Commission on Radiation Units and measurements (ICRU) in defining the operational quantities ambient dose equivalent, directional dose equivalent and personal dose equivalent;

“dose limit” means the value of the effective dose or the equivalent dose to an individual that is not to be exceeded in activities of controlled practices;

“effective dose” means a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor;

“emergency plan” means a set of procedures to be implemented in the event of a radiation accident;

“equivalent dose” means the measure of the radiation dose to the tissue where an attempt has been made to allow for the different relative biological effects of different types of ionising radiation; (The quantity H_{TR} defined as $H_{TR} = D_{TR} \cdot W_R$ where D_{TR} is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and W_R is the radiation weighting factor for radiation type R);

“ethical review committee” means a committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual;

“exclude” means the exclusion from regulation of any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the standards;

“exclusive use” means that a single consignor has sole use of the conveyance or large freight container such that all loading and unloading is carried out in accordance with the directions of the consignor or consignee;

“exempt” means the determination by the Council that a source or practice need not to be subject to some or all aspects of regulatory control on the basis that the exposure, including potential exposure due to source or practice is too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of dose or risks;

“exposure” means the act or condition of being subjected to irradiation;

“external exposure” means the act or condition of being subjected to irradiation by a source outside the body;

“facility” means any assembly of devices, equipment, structures or natural features whether simple or complex which serves some purpose or performs some function, in the course of which radiation is, or is capable of being emitted;

“IAEA” means the International Atomic Energy Agency;

“incident” means any unintended event which under slightly different circumstances, could have resulted in harm to people, damage to property, or loss of process;

“internal exposure” means the act or condition of being subjected to irradiation by a source inside the body;

“intervention” means any action intended to reduce or avert exposure, or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident;

“investigation level” means the value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation should be conducted;

“ionising radiation” means electromagnetic or corpuscular radiation, consisting of photons or particles capable of producing ions, directly or indirectly, in its passage through matter;

“licence” means an authorisation granted by the Council on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by an authorised person;

“medical practitioner” means an individual who—

- a. has been accredited through appropriate national procedures as a health professional;
- b. fulfils the national requirements for training and experience of prescribing procedures involving medical exposure; and
- c. is a registrant or an authorised person, or a worker who has been designated by a registered or licenced employer for the purpose of prescribing procedures involving medical exposure;

“Minister” means the minister responsible for atomic energy and radiation protection;

“notification” means a document submitted to the Council by a person to notify requirements in such a manner as provided for in regulation 13(1) and 13(2);

“nuclear installation” means a nuclear fuel fabrication plant, a nuclear reactor, including critical and sub critical assemblies, research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;

“nuclear safety” means the condition and ability of a nuclear installation and its servicing personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionising radiation into the environment, and to reduce the consequences of accidents;

“physical protection” means methods or ways of preventing unauthorised access or activities to a facility through a system of mechanical, technical and organisational measures;

“plant” means any machinery, facility or installation, whether affixed to land or not, but does not include anything comprised or to be comprised in any means of transport, whether by land, water or air;

“practice” means any human activity that introduces additional sources of exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;

“premises” means any land, whether developed or not, including any place underground and any land covered by water;

“qualified expert” means an individual who by virtue of certification by appropriate boards or societies, professional licence or academic qualification and experience, is duly recognised by the Council as having expertise in a relevant field of specialisation e.g. medical physics, radiation protection, occupational health, quality assurance or any relevant engineering or safety specialty;

“radiation” means ionising radiation;

“radiation device” means equipment capable of generating ionising radiation when energized;

“radiation protection” means a system of technical and organisational measures to reduce or limit exposure of people and the environment from ionising radiation;

“Radiation Protection Officer” means any person appointed under section 19 of the Act;

“radiation safety” means measures intended to minimise the likelihood of accidents with radiation sources and, should such an accident occur, to mitigate its consequences;

“Radiation Safety Officer” means an individual who is competent in radiation protection matters as provided for by section 36 of the Act, to oversee the implementation of the requirements of these Regulations and is recognised by the Council;

“radioactive material” means any matter or substance containing one or more radionuclides, the activity or concentration of which is sufficiently intense to entail a significant risk or

disability or disease to any person or organ on exposure, whether external or internal, and whether continuous or total;

“radioactive waste” means material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen—

- a. that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements; and
- b. exposure to which is not excluded from the Standards;

“recording level” means a level of dose, exposure or intake specified by the Council at or above which values of dose exposure or intake received by workers are to be entered in their individual exposure record;

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

“sealed source” means a source consisting of radioactive material firmly incorporated in a solid of effectively inactive materials, or sealed in an inactive container of a strength sufficient to prevent, under normal conditions of use, any dispersion of radioactive material and any possibility of contamination;

“security” means measures to prevent unauthorised access or damage to, and loss, theft or unauthorised transfer of radioactive materials;

“source” means an apparatus, device, material or anything capable of emitting radiation;

“special form radioactive material” means either an indispersible solid radioactive material or a sealed capsule containing radioactive material that has a very high degree of physical integrity so that if the material were released from the package in an accident, while there might be a high radiation hazard, it is unlikely that there would be any contamination hazard;

“Standards” means the International Basic Safety Standards for Protection against ionising radiation and for the safety of radiation sources issued by the IAEA;

“Transport Index (TI)” means a number that is assigned to transport package, over pack, freight container or conveyance, which is used to provide control over groups of packages for the purposes of minimising radiation risks;

“unsealed sources or open sources” means a source that does not meet the definition of a sealed source;

“user” means a person or body of persons or institution authorised to use ionising radiation under these Regulations or the Act;

“worker” means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection.

5. Exposures.

The exposures to which these Regulations apply include—

- a. any occupational exposure;
- b. medical exposure; or
- c. public exposure,

due to any relevant practice or source within a practice, including both normal exposures and potential exposures.

6. Exclusions.

1. The following exposures are excluded from the requirements of these Regulations—
 - a. exposures from natural radioactivity in the body; and
 - b. exposures from cosmic radiation and unmodified concentrations of natural radionuclides in raw materials.
2. Any other sources that are essentially unamenable to control as may be determined by the Council.

7. Persons responsible for application of Regulations.

1. The Council shall be responsible for the enforcement of these Regulations.
2. The persons that have principle responsibility for the application and compliance with these Regulations include—
 - a. authorised persons; and
 - b. employers.
3. The general responsibilities of the parties referred to in subregulation (2) include—
 - a. to establish radiation safety objectives in conformity with the relevant requirements of these Regulations; and
 - b. to develop, implement and document a radiation safety programme commensurate with the nature and extent of the risks associated with the practice and interventions under

their responsibility sufficient to ensure compliance with the requirements of these Regulations.

4. The radiation safety programme shall include the following actions—
 - a. to determine and keep continually under review the measures needed to achieve the radiation safety objectives;
 - b. to ensure that the resources needed for their implementation are provided regularly;
 - c. to verify that the radiation safety objectives are being achieved;
 - d. to identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures;
 - e. to facilitate consultation and cooperation between all relevant parties with respect to radiation protection, safety and security; and
 - f. to keep appropriate records regarding the discharge of their responsibilities.
5. Persons that have subsidiary responsibility for the application of these Regulations include—
 - (a) suppliers, clearing and forwarding agents;
 - (b) workers;
 - (c) radiation safety officers;
 - (d) the army, police and customs officials;
 - (e) medical practitioners;
 - (f) health professionals;
 - (g) qualified experts;
 - (h) ethical review committees; and
 - (i) any other party specially delegated by a party referred to in regulation 7(2).

8. Right to enter and inspect.

A Radiation Protection Officer or other authorised officer in the course of his or her duties shall have the rights and powers provided for by section 21 of the Act.

9. Incidents and accidents.

1. In the event of an incident or accident, an authorised person or an employer shall—
 - a. investigate the incident or accident and its causes, circumstances and consequences;

- b. take appropriate action to remedy the circumstance and prevent a recurrence of a similar situation;
 - c. communicate to the Council the incident or accident, its causes, its circumstances, consequences, any loss of life and serious personal injury caused by the accident or incident, and recommend the corrective or preventive actions taken or to be taken; and
 - d. take any other action necessary under these Regulations.
2. The communication of an incident or accident to the Council shall be made as soon as possible, but in any case within forty eight hours after an emergency exposure situation has developed or is developing.
 3. Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be ground for modifying, suspending or withdrawing any authorisation.
 4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

10. Applicability of other regulations and requirements.

1. Nothing in these Regulations shall be construed as relieving employers from complying with applicable laws and regulations governing workplace hazards, including radiation hazards from natural sources, which are unconnected with the work.
2. Nothing in these Regulations shall be construed as restricting any action that may otherwise be necessary for protection and safety.

11. Enforcement.

1. The Council may revoke, suspend or modify an authorisation to use a source, or prohibit the possession of a source, upon finding an undue threat to health, safety and security or non-compliance with applicable requirements.
2. The Council may, upon finding willful violations or attempted violations of these Regulations or requirements, institute legal proceedings.
3. The Council may as appropriate impose fines or direct closure or undertake an action for locking the premises for non-compliance with these Regulations and any other requirements commensurate with the nature of violation.

Part II—Administrative Requirements.

12. General obligations.

1. A person shall not engage in activities, which involve practices or sources within practices as specified in regulation 3 unless he or she has complied with the requirements of these Regulations.

2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

13. Requirements for notification.

1. All practices and sources shall require notification as specified in Form 1A or 1B, Schedule 1.
2. Subject to regulation 15, any person intending to initiate a practice or to possess a radiation source, shall submit a prior notification to the Council, and notices of his or her intention shall be handled in accordance with section 34 of the Act.
3. A person shall after giving notification as specified in subregulation (1) and (2), apply to the Council for authorisation as specified in regulation 15.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

14. Exemption of practices and sources.

1. Practices and sources within a practice may be exempted from the requirements of these Regulations provided that they comply with the exemption levels specified in Schedule 2.
2. Exemptions shall not be granted for practices not regarded as justified by regulation 23.
3. Practices and sources within a practice are further exempted from the requirements of these Regulations, including requirements for authorisation specified in section 33 of the Act.

15. Application for authorisation.

1. Except as provided for by regulation 14(3) and regulation 13, a person who intends to engage in a practice or possess a radiation source referred to in regulation 3 shall apply to the Council for an authorisation specified in Form 2A, 2B, 3, 4, 5, 6 and 7, Schedule 1.
2. An application for an authorisation shall be submitted to the Council and shall contain—
 - a. the legal status and technical competence of the applicant;
 - b. a technical description of the practice to be carried out;
 - c. the planned time of commencement and completion of the construction of installations relating to the practice;
 - d. the name and qualifications of at least one person designated as a radiation safety officer for purposes of the practice;
 - e. an evaluation of the nature, magnitude and likelihood of the exposures attributed to the practice and source within the practice;
 - f. reports and studies undertaken, including an environmental impact assessment and a safety assessment of the proposed practice;
 - g. a determination of the characteristics and activities of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the relevant critical group;

- h. in case of a source meant for medical exposure the qualifications in radiation protection of the medical practitioners who are to be designated by name or by qualification credentials in the authorisation as the only individuals permitted to administer medical exposure by means of the authorised source;
- i. necessary steps to be taken for the protection and safety of workers, members of the public and where applicable, patients;

- (j) the impact of the proposed practice on public and private interests, including the interests of affected landowners and holders of other rights and possible mitigation measures;

(k) an emergency response plan for the proposed practice;

- consents and permits required under any other law;

(m) the fees as specified in Schedule 6; and

(n) any further information that the Council may require.

3. The Council shall, within thirty days after receipt of an application for an authorisation, confirm in writing to the applicant, that the application is complete in all aspects; and where the application is not complete, shall request the applicant to re-submit the application.
4. The Council shall process every application for an authorisation expeditiously and in any case, not later than ninety days after receipt of the application.
5. Where an application refers to an industrial irradiation installation, nuclear installation, an installation processing radioactive substances, a medical or industrial radiography facility, or for any use of source, which the Council has not designated as appropriate for registration, the authorisation shall take the form of a licence.
6. An authorisation to possess or use sources and radiation premises specified in Form 3, Schedule 1 shall be granted for the duration specified in Table 2, Schedule 10 and may be renewed by the Council after fulfillment of the safety requirements.

(9) A person shall submit his or her application for a renewal of an authorisation three months prior to the expiry date.

16. Modifications.

1. All modifications, change of ownership, transfer, sell, lease or loan of any apparatus, article, plant, installation or other material or substance shall require authorisation.
2. A person applying for an authorisation to modify any apparatus, article, plant, installation or other material or substance shall—

- a. submit to the Council relevant information necessary to support the application as specified in Form 6, Schedule 1;
 - b. pay a license fee as specified in Schedule 6.
3. Any person applying for an authorisation to transfer, sell, lease or loan of any apparatus, article, plant, installation or other material or substance shall—
- a. submit to the Council relevant information necessary to support the application as specified in Form 7, Schedule 1;
 - b. state how the specific security measures required by these Regulations will be met;
 - c. state a final disposal solution for generated radioactive waste and disused sealed sources; and
 - d. pay a license fee as specified in Schedule 6.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

17. Grounds for grant and rejection of application.

1. The Council shall, in granting or rejecting an application for an authorisation, take into consideration, as far as is adequate for the practice applied for—
 - a. the legal status of the applicant;
 - b. the impact of the practice on the social, cultural and recreational life of the community;
 - c. the need to protect the environment and to conserve natural resources;
 - d. the land use and siting of the practice;
 - e. the ability of the applicant to operate in a manner designed to protect the health and safety of users, workers, beneficiaries and other members of the public who would be affected by the practice; and ensure the security of radiation sources and installations; and
 - f. public and private interests affected by the practice.
2. The Council may, grant an authorisation subject to the conditions set out under subregulation (1).
3. The Council shall, where it refuses to grant an authorisation, give the applicant a statement of its reasons for the refusal within thirty days after the decision.
4. A person aggrieved by the decision of the Council under subregulation (3) may appeal to the High Court.
5. Nothing under these Regulations shall prevent the holder of an authorisation who has fulfilled all the obligations under that authorisation from applying for and obtaining any other authorisation under these Regulations.

18. Cessation or suspension of an authorised activity or operation

of an authorised facility.

1. A person who holds an authorisation shall not, without prior written approval or instruction of the Council—
 - a. cease or suspend the authorised activity or the operation of an authorised facility; or
 - b. decommission or abandon an installation or waste management system.
2. An authorised person shall decontaminate his or her premises to the justification of the Council before vacating the premises.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

19. Authorisation to import, export or transport.

1. A person who applies for an authorisation to import, export or transport any apparatus, article, plant, installation or other material or substance which is a source or intended to be used for the purposes of emission of radiation, shall—
 - a. submit to the Council information necessary to support his or her application as specified in Form 4 and Form 8, Schedule 1;
 - b. pay a licence fee as specified in Schedule 6.
2. An authorisation to import, export or transport a radiation source is valid six months from the date of grant of the authorisation.
3. The Council shall, in granting or rejecting an application for an authorisation under subregulation (1), take into consideration the matters specified in regulation 17.

20. Registration of experts.

1. An expert who intends to carry out a practice that involves the administering of ionising radiation on any person for the purposes of diagnosing or treating a disease shall apply for an authorisation specified in Form 2B, Schedule 1.
2. The expert shall in addition—
 - a. submit to the Council relevant information necessary to support his or her application as specified in Form 5, Schedule 1;
 - b. pay the authorisation application fee as specified in Schedule 6.
3. An authorisation to administer ionising radiation to person shall be valid for five years from the date of the grant of the licence.

4. An authorisation for administering ionising radiation to persons may be suspended or revoked in case of violation of radiation protection and safety protocols or non-compliance with the requirements prescribed by the Council.

21. Responsibilities of authorised persons.

1. An authorised person shall establish and implement the technical and organisational measures required for ensuring protection and safety for the practices and sources for which the authorisation is made and for compliance with all applicable requirements of these Regulations.
2. An authorised person may appoint and identify other persons to carry out actions and tasks related to the responsibilities under subregulation (1), but shall retain the responsibility for the actions and tasks themselves.
3. An authorised person shall notify the Council of his or her intention to introduce modifications to any practice or source and radiation premises for which they are authorised whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modifications unless specifically authorised by the Council.
4. An authorised person shall ensure that only workers designated in the authorised application form by name or qualification credentials are given key assignments related to protection and safety, or are assigned tasks involving operation or handling of radiation sources which could substantially affect protection and safety.
5. An authorised person shall ensure that no radiation emitted as a result of the carrying on of his or her undertaking on his or her premises, causes any harm or injury to any person or damage to any property, which is on the premises or elsewhere.
6. An authorised person is liable for any harm to any person or any damage to any property caused by radiation to which sub-regulation (5) applies.
7. An authorised person shall provide sufficient security measures against the misuse or theft of radiation sources under their possession.
8. An authorised person shall ensure that, as applicable and appropriate, the location, design, construction and assembly, commissioning, operation and maintenance, and decommissioning of sources as well as devices and facilities are based on sound engineering practices that—
 - a. take into account approved codes of practice, standards, technical and scientific developments;
 - b. are supported by reliable managerial and organisational features; and
 - c. include adequate margins in the design, construction and operation of sources.
9. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

22. Clearance.

Sources, including substances, materials and objects within authorised practices shall be cleared from further compliance with the requirements of these Regulations, provided that they comply with the exemption levels as specified in Schedule 2, approved by the Council.

Part III—Radiation Protection Performance Requirements.

23. Justification of practice.

1. A practice shall not be authorised unless 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. An applicant for an authorisation shall provide sufficient information and evidence on the benefits to support the justification of the practice.
3. The following practices shall not be regarded as justified—
 - 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;
 - b. practices involving use of radiation or radioactive substances in commodities or products such as toys, personal jewellery or adornments; and
 - c. any other practice determined by the Council.

24. Dose limits.

1. 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 limits specified in Schedule 3 except in special circumstances considered under regulation 45.
2. A person who contravenes subregulation (1) commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

25. Optimisation of protection and safety.

1. In case of exposures from any particular source within a practice, radiation safety shall be optimised in order to ensure that the magnitude of individual doses are kept as low as reasonably achievable, taking into account economic and social factors, being within the restriction that the dose to individuals delivered by the source is subject to dose constraints,

specified in regulation 26, except in the following situations—

- a. therapeutic medical exposures;
- b. the number of people exposed; and
- c. likelihood of incurring exposures.

2. The process of optimisation of protection and safety measures shall range from intuitive qualitative analysis to quantitative analysis using decision aiding techniques, but shall be sufficient to take all relevant factors into account in a coherent way in order to contribute to achieving the following—
 - a. to determine optimised protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and
 - b. to establish criteria, on the basis of the results of the optimisation, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.

26. Dose constraints.

1. Except for medical exposure, the optimisation of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses to the individuals of the critical group do not exceed dose constraints which are equal to the dose limits specified in Schedule 3.
2. An authorised person shall, in case of any source that can release radioactive substances to the environment, establish the dose constraints, so that the prospective annual doses to members of the public, including persons distant from the source and those of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in Schedule 3 or lower values established by the Council.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points

27. Safety culture.

1. An authorised person shall establish a management system, commensurate with the size and nature of the authorised activity.
2. The management system shall ensure that—
 - a. policies and procedures are established to identify protection and safety as being the highest priority;
 - b. problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;
 - c. the responsibilities of each individual, including those at senior management levels, for protection and safety are clearly identified and each individual is suitably trained and qualified;
 - d. clear lines of authority for decisions on protection and safety are defined; and

- e. organisational arrangements and lines of communications that result in an appropriate flow of information on protection and safety are effected at and between the various levels in the organisation of a person.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

28. Quality assurance.

1. An authorised person shall establish quality assurance programmes that provide—
- a. adequate assurance that the specified requirements relating to protection and safety are satisfied; and
 - b. quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

29. Human factor.

1. An authorised person shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified, in order that they understand their responsibilities and perform their duties with appropriate judgment according to defined procedures, and are periodically retrained.
2. An authorised person, in co-operation with suppliers, shall follow sound ergonomic principles in possessing, obtaining and or designing equipment and preparing operating procedures, in order to facilitate the safe use of equipment and minimise the contribution of human errors to accidents or incidents.
3. An authorised person shall provide appropriate equipment, safety systems and procedures which shall—
- a. reduce, as far as practicable, the possibility of human errors leading to unplanned exposure of any person;
 - b. provide means to detect and prevent human errors and correct or compensate for them; and
 - c. facilitate early intervention in the event of an accident.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

30. Radiation Safety Officer.

1. An authorised person shall, after consultation with the Council, appoint a qualified person employed by him or her to be a Radiation

Safety Officer in relation to his undertaking.

2. For the purposes of this regulation, where an undertaking consists of practices carried on in two or more premises and involves the use of ionising radiation, a Radiation Safety Officer shall be appointed in respect of each.
3. The qualifications of the Radiation Safety Officer shall include a level of academic knowledge and professional experience compatible with the levels of risk associated with the authorised practices or sources within a practice.
4. The Radiation Safety officer shall—
 - a. advise his or her employer in all matters pertaining to the protection of workers, patients, the public and the environment from ionising radiation, and the security of radiation sources;
 - b. advise the user regarding formulation, the observance and enforcement of local rules for the protection of workers, patients, the public and the environment from ionising radiation;
 - c. advise and liaise with the Council regarding the implementation of radiation protection measures at his or her work place;
 - d. monitor the purchase and stock levels, the safe use, handling, transport and storage of radioactive materials;
 - e. inspect and monitor the facility for radiation safety;
 - f. assist in the training of all relevant aspects of radiation protection;
 - g. ensure that all workers are monitored regularly with personal dosimetry badges and a record system kept of the doses received;
 - h. ensure that all reports of the work under the officer are made

available to the council;
- i. assist the Council in the enforcement of these regulations in relation to the undertakings for which he or she is appointed and assist the authorised person in keeping all records of the council.
5. A person who contravenes subregulation (1) commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

31. Radiation Safety Committee.

1. An authorised person shall, after consultation with the Council, constitute a Radiation Safety Committee for each premise, comprising of—

- a. a representative of management;
 - b. a qualified expert;
 - c. a representative of workers; and
 - d. the Radiation Safety Officer.
2. The Radiation Safety Committee shall—
- a. review local rules, radiation protection and safety programmes;
 - b. organise drills and exercises on emergency response for workers;
 - c. advise authorised persons on how to achieve safety and security of sources.
3. A person who contravenes subregulation (1) commits an offence and is liable on conviction to a fine not exceeding 50 currency

32. Safety and security assessments.

1. An authorised person shall make assessments related to protection, safety and security measures for sources within practices at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning, as appropriate, in order to—
 - a. identify the ways through which normal exposures and potential exposures can be incurred, taking into consideration the effect of events external to the sources as well as events directly involving the sources and their associated equipment;
 - b. determine the expected magnitude of normal exposures;
 - c. estimate the probabilities and magnitude of potential exposures;
 - d. assess the quality and extent of the protection, and safety provisions; and
 - e. assess the adequacy of the physical security measures to prevent loss or damage.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

33. Monitoring and verification of compliance.

1. An authorised person shall monitor and measure the parameters necessary for verification of compliance with the requirements of these Regulations.
2. For the purposes of monitoring and verification of compliance, an authorised person using sources in categories 1, 2 and 3 specified in Table 1, Schedule 10, shall be required to—
 - a. make available an adequate number of survey instruments for

area monitoring at the radiation work place; and

b. maintain, test and calibrate the survey instruments at appropriate intervals with reference to national or international standards.

3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

34. Records.

1. An authorised person shall keep records of the results of monitoring and verification of compliance, which shall include—

- a. records of the tests and calibrations carried out in accordance with these Regulations;
- b. radiation dose records;
- c. cases of overexposure;
- d. medical records;
- e. cases of contamination of skin, hair and clothing;
- f. area monitoring;
- g. leakage tests of sealed radioactive sources;
- h. lists of all sealed radiation sources and their details including—
 - i. location of each source;

ii. radionuclide;

iii. radio activity on a specified date;

iv. serial number or unique identifier;

v. chemical or physical form;

vi. each source use history, including recording all movements into and out of the storage location;

(vii) receipt, transfer or disposal of each source.

i. list and radiation dose of persons undergoing treatment or diagnosis;

(j) stocks of unsealed radioactive materials, with dates of receipt, issue and disposal; and supplier's or manufacture's certificate;

(k) investigation of emergencies, accident and disposal of radioactive wastes;

1. maintenance records of apparatus; and

(m) any other relevant information as required by the Council.

2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

Part VI—Occupational Exposure Protection.

35. General responsibilities of authorised persons and employers.

1. An authorised person and every employer engaged in activities that involve or could involve occupational exposure shall protect the workers against any occupational exposure which is not excluded from these Regulations.
2. An authorised person and an employer shall ensure that for all workers engaged in activities that involve or could involve occupational exposure—
 - a. occupational exposures are limited as specified in Schedule 3;
 - b. radiation safety is optimised in accordance with regulations 25 and 26;
 - c. policies, procedures and organisational arrangements for occupational protection and safety are established to implement the relevant requirements of these Regulations, and the resulting decisions on measures to be adopted for this purpose are recorded and made available to relevant parties, including workers, through their representatives where appropriate;
 - d. suitable and adequate facilities for radiation safety are provided, including personal protective devices and monitoring equipment, and arrangements are made for their proper use;
 - e. radiation safety and health surveillance services are provided through qualified experts;
 - f. arrangements are made to facilitate consultation and cooperation with workers, through their representatives where appropriate, about measures which are required to achieve adequate radiation protection and safety by effective implementation of these Regulations; and
 - g. necessary conditions are provided and arrangements made to promote a safety culture in the work force and achieve adequate training of workers on radiation safety matters.
3. Where workers are engaged in work that involves or could involve a source which is not under the control of their employer, the authorised person responsible for the source shall—
 - a. obtain from the employer, as a pre-condition for engagement of such workers, information on their previous occupational exposure history and other information as may be necessary to provide protection and safety in compliance with these Regulations;
 - b. provide the workers with protective measures and safety provisions which are at least as good as those provided for employees of the authorised person; and
 - c. make dosimetric and other appropriate information available to the employer for the purpose of demonstrating that the level of protection provided to such workers is compatible with the requirements of these Regulations.

4. Authorised persons and employers shall ensure that workers under their responsibility who are exposed to radiation from sources, other than natural sources, that are not directly related to or required by

their work, receive the same level of protection as if they were members of the public.

5. Authorised persons and employers shall ensure that workers are informed of their obligations and responsibilities for their own protection and the protection of others against radiation and for the safety and security of sources.
6. Authorised persons and employers shall ensure that workers—
 - a. follow applicable rules and procedures for protection, safety and security;
 - b. properly use the monitoring devices, the protective equipment and clothing provided;
 - c. abstain from any willful action that could put themselves or others in situations that contravene the requirements of these Regulations; and
 - d. promptly report to the authorised person and employer any circumstances that could adversely affect safety or security conditions or the requirements of these Regulations.
7. Authorised persons and employers shall record any report received from a worker that identifies any circumstances that could affect safety and security conditions or non compliance with the requirements of these Regulations, and shall take appropriate remedial actions.
8. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

36. Conditions of service.

1. The employers shall ensure that the conditions of service of workers shall be independent of the existence or the possibility of occupational exposure and special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of these Regulations.
2. Female workers shall be advised by the authorised person or employer that it is desirable to notify the employer of pregnancy.
3. Where a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational exposure to ensure that the embryo or fetus is accorded the same broad level of protection, which is required for members of the public, as specified in Schedule 3.
4. The notification of pregnancy shall not be considered a reason to exclude female workers from work.
5. Employers shall make every reasonable effort to provide workers with suitable alternative workplace or employment in circumstances where it has been determined,

either by the Council or in the framework of the health surveillance programme required by these Regulations, that the workers, for health reasons, may no longer continue in employment involving occupational exposure.

6. A person under the age of 16 years shall not be subjected to occupational exposure and a person under the age of 18 years shall not be allowed to work in a controlled area unless supervised, for the purpose of the training.
7. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

37. Classification of areas.

(1) There shall be controlled areas where—

- a. an authorised person shall designate an area in which specific protective measures or safety and security provisions are or can be required to—
 - i. control normal exposures or prevent the spread of contamination during normal working conditions; and
 - ii. prevent or limit the extent of potential exposures.
- b. an authorised person shall—
 - i. determine the boundaries of any controlled area on the basis of the magnitude and likelihood of expected exposures and the nature and extent of the required protection and safety provisions;
 - ii. delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
 - iii. where a source is brought into operation or energised only intermittently or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;
 - iv. display a warning symbol, recommended by the International Organisation for Standardisation (ISO) and appropriate instructions at access points and other appropriate locations within controlled areas as prescribed in Fig.1 Schedule 7;
 - v. establish occupational protection, safety and security measures, including local rules and procedures that are appropriate for controlled areas;
 - vi. restrict access to controlled areas by means of administrative procedures, such as the use of work permits, and by physical barriers, which could include locks or interlocks; the degree of restriction being commensurate with the magnitude and likelihood of the expected exposures; and
 - vii. provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.
- c. under normal working procedures with sources, the expected contamination shall not exceed the effective dose specified in Schedule 3.

2. An authorised person shall designate, as a supervised area, any area not already designated as a controlled area, but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.
3. An authorised person shall delineate and identify the supervised areas by appropriate means, taking into account the nature and extent of radiation hazards in those areas.
4. An authorised person shall periodically review conditions to determine the possible need to revise the protection measures or safety provisions, including the boundaries of controlled and supervised areas.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

38. Local rules and supervision.

1. An authorised person and employers shall, in consultation with workers, through their representatives where appropriate—
 - a. establish in writing, in a language comprehensible to the workers and others, such local rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons and for the security of sources;
 - b. include in the local rules and procedures, the values of any relevant authorised level, investigation level or other reference level and the procedure to be followed in the event that such level is exceeded; and
 - c. ensure that any work involving occupational exposure is adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions are observed.
2. An authorised person and employers shall—
 - a. provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety, including information on general and local rules and procedures and on available protection and safety provisions, as well as adequate information on the significance for protection and safety of their actions;
 - b. provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on—
 - i. the risk to the embryo or foetus due to exposure of a pregnant woman;
 - ii. the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant; and
 - iii. the risk to an infant ingesting radioactive substances by breast feeding;

- c. provide to those workers who could be affected by an emergency plan, appropriate information, instruction and training; and
 - d. keep records of the training provided to individual workers.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

39. Protection of employees.

- 1. An authorised person or employer shall minimise the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate well engineered controls and satisfactory working conditions.
- 2. The authorised person or employer shall ensure that workers and employees are provided with suitable and adequate personal protective equipment, including as appropriate—
 - a. protective clothing;
 - b. protective respiratory equipment with information on its protection characteristics and instructions on its proper use; and
 - c. protective aprons and gloves and organ shields.
- 3. The authorised person or employer shall arrange for regular testing and maintenance to be carried out on all personal protective equipment, including as required, special equipment for use in the event of accidents and interventions.
- 4. The authorised person or employer shall take into account the following factors when assigning personal protective equipment for a given task—
 - a. medical fitness to sustain possible extra physical effort while using the protective equipment; and
 - b. additional work time or inconvenience or additional non radiological risks associated with the use of the protective equipment.
- 5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

40. Exposure assessment.

- 1. Authorised persons and employers shall arrange for the assessment of the occupational exposure of workers and shall ensure that adequate arrangements are made for the provision of such services by a dosimetry laboratory approved by the Council.
- 2. A worker who is normally engaged in a controlled area, where individual monitoring is not feasible shall be assessed on occupational exposure, on the basis of the results of

monitoring of the workplace and on information on the location and duration of exposure of the worker.

3. A worker who is normally engaged in a supervised area or who enters a controlled area only occasionally, shall be assessed on occupational exposure, on the basis of the results of monitoring of the workplace or individual monitoring.
4. The nature, frequency and precision of individual monitoring shall be determined by consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.
5. Authorised persons and employers shall ensure that workers who may be exposed to radioactive contamination, including workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses, as appropriate.
6. Authorised persons and employers shall keep records of exposure which shall be made available to workers and the Council when required.
7. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

41. Monitoring of workplace.

1. Authorised persons, in co-operation with employers where appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of the source and the risks associated with the source.
2. The nature and frequency of monitoring of a workplace shall—
 - a. be sufficient to enable—
 - i. evaluation of the radiological conditions in all workplaces;
 - ii. assessment of the exposure of workers in controlled areas and supervised areas; and
 - iii. review of the classification of controlled and supervised areas.
 - b. depend on the levels of ambient dose equivalent and airborne and surface activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.
3. The programmes for monitoring of the workplace shall specify—
 - a. the quantities to be measured;
 - b. where and when the measurements are to be made and at what frequency;
 - c. the most appropriate measurement methods and procedures; and
 - d. reference levels and the action to be taken where they are exceeded.

4. An authorised person shall keep appropriate records of the findings of the work place monitoring programme, which shall be made available to workers, through their representatives where appropriate.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

42. Health surveillance.

1. Authorised persons and employers, in accordance with rules

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established by the Council, shall make arrangements for appropriate health surveillance based on the general principles of occupational health designed to assess the initial and continuing fitness of workers for their intended tasks.

2. Authorised persons and employers shall take the medical history or otherwise health surveillance of workers before they take employment in a radiation related workplace.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

43. Records of worker exposure.

1. Authorised persons and employers shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under regulation 42 and the worker exposure records shall include information on—
 - a. the general nature of the work resulting in exposure, the doses and intakes at or above the relevant recording levels and the data upon which the dose assessments are based;
 - b. the periods of employment with different employers, if any, and the corresponding doses and intakes in each period of employment; and
 - c. the doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal conditions.
2. Authorised persons and employers shall—
 - a. provide for access by workers to information of their own exposure records and workplace monitoring where appropriate; and
 - b. upon request by the Council or other persons or organisations with a demonstrated need for such records, including relevant

employers and supervisors of the health surveillance programme, provide access to worker exposure records with due care and attention to the maintenance of appropriate confidentiality.

3. Exposure records for each worker shall be kept by the authorised persons and employers, or by the Council or other designated organisation where the authorised persons or employers cease their activities.
4. Records kept under subregulation (3) shall be preserved at least until the worker attains or would have attained the age of seventy five years, and for not less than thirty years after the termination of the work involving occupational exposure.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

44. Investigation of accidental occupational exposures.

1. An authorised person shall promptly investigate any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a worker exposure significantly different from that intended.
2. An authorised person shall, with respect to any investigation required—
 - a. estimate the doses received and their distribution within the worker;
 - b. indicate the corrective measures required to prevent recurrence of such an accident;
 - c. implement all the corrective measures that are under the authorised person's responsibility;
 - d. notify the Council and other relevant agencies by telephone or electronic mail or any other efficient means of

communication as soon as practicable, but not later than twenty four hours after discovery of the accident which has the potential for, or has resulted in, serious injury or death of a worker, or which involve more than one worker;

- e. for minor injuries, notify the Council by telephone or electronic mail or any other efficient means of communication as soon as possible;
 - f. submit to the Council, within fifteen days after discovery of the accident, a written report which states the cause of the accident and includes information on the doses, corrective measures and any other relevant information; and
 - g. inform the worker and his or her doctor about the accident.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

45. Special circumstances.

1. If a practice which is justified and for which radiation safety is optimised, presents special circumstances which require a temporary change in some dose limitation requirements of these Regulations, an authorised person shall not make any temporary change without the approval of the Council.
2. The application submitted by the authorised person to obtain this approval shall include evidence to demonstrate that—
 - a. all reasonable efforts have been made to reduce exposures and optimise radiation safety provisions in accordance with these Regulations; and
 - b. the relevant employers and workers, through their representatives where appropriate, have been consulted on the need for and the conditions of the temporary change in dose limitation requirements.
3. A temporary change in the dose limitation requirement shall be limited to specified work areas and shall be in accordance with the time and dose limitations for special circumstances specified in Schedule 3.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

Part VII—Medical Exposure Protection.

46. General responsibilities under medical exposure.

1. An authorised person shall ensure that—
 - a. no patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;
 - b. medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
 - c. medical and paramedical personnel are available as required, and are either health professionals or have appropriate training to adequately discharge assigned tasks in the conduct of the diagnostic or therapeutic procedures that the medical practitioner prescribes;
 - d. for therapeutic uses of radiation including teletherapy, brachytherapy and nuclear medicine, the calibration, dosimetry and quality assurance requirements of these Regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics;
 - e. the exposure of individuals incurred knowingly while voluntarily helping, other than in their occupation in the care, support or comfort of patients be constrained as specified in Schedule 3; and

- f. personnel engaged in diagnostic or therapeutic uses of radiation are well trained and qualified according to the criteria approved by the Council.
2. An authorised person shall, as far as practicable, ensure that for diagnostic uses of ionising radiation, the imaging and quality assurance requirements of these Regulations are complied with, on the advice of a qualified expert in radiodiagnostic physics, nuclear medicine physics and radiopharmacy in the compounding of radiopharmaceuticals, as appropriately required.
3. Medical practitioners shall promptly inform the authorised person of any deficiencies or needs regarding compliance with these Regulations with respect to protection and safety of patients and shall take action as may be appropriate to ensure the protection and safety of the patients.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

47. Justification of medical exposure.

1. Medical practitioners shall consider the justification of medical exposures that they prescribe by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.
2. Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications shall be deemed unjustified unless it is expected to provide useful information on the health of the individual examination or unless the specific type of examination is justified by those requesting it in

consultation with relevant professional bodies.

3. Mass screening of population groups involving medical exposure shall be deemed unjustified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.
4. The exposure of humans for medical research shall be deemed to be unjustified unless it is—
 - a. in accordance with the Helsinki Declaration [1964] specified in Schedule 8 and follows the guidelines for its application prepared by the Council for International Organization for Medical Science (CIOMS) and the World Health Organization (WHO); and
 - b. subject to the advice of the Ethical Review Committee and to any other applicable laws and regulations.

5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

48. Optimisation of protection for medical exposure.

1. In addition to satisfying the general requirements for optimisation of radiation safety specified in these Regulations, an authorised person, in co-operation with suppliers where appropriate, shall satisfy the prescriptive design and operational requirements specified in Schedule 4.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

49. Calibration, clinical dosimetry and quality assurance for

medical exposures.

1. Authorised persons shall ensure that—
 - a. the calibration of sources used for medical exposure is traceable to a Standards Dosimetry Laboratory approved by the Council;
 - b. each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;
 - c. unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered; and
 - d. calibrations of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may affect the calibration, at least once in a year as well as at regular intervals approved by the Council, taking into consideration the manufacturer's recommendation and risk associated with the practice.
2. Authorised persons shall ensure that representative values of clinical dosimetry parameters are determined and documented.
3. Quality assurance programmes for medical exposures shall include—
 - a. measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
 - b. verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
 - c. written records of relevant procedures and results;
 - d. verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
 - e. as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

4. A person who contravenes subregulation (1) and (2) commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

50. Dose constraints.

1. The optimisation of protection of persons exposed for medical research purposes, if such medical exposure does not produce direct benefit to the exposed individuals, shall be subject to individual dose constraints established on a case-by-case basis by the Ethical Review Committee or other institutional body assigned a similar function.
2. Authorised persons shall constrain any dose to individuals incurred while voluntarily helping, other than in their occupation, in the care, support or comfort of patients undergoing medical exposure, and to visitors of patients who have received therapeutic amounts of radio nuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Schedule 3.
3. A person who contravenes subregulation (2) commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

51. Guidance levels.

1. Authorised persons shall ensure that guidance levels for medical exposure, as specified in Schedule 5, are revised as technology improves and are used as guidance by medical practitioners, in order to ensure that—
 - a. corrective actions are taken as necessary where doses or activities fall substantially below the guidance levels, resulting in a decrease of medical benefit to patients by ineffective diagnostic information or insufficient therapeutic dosage;
 - b. review actions are considered where doses or activities exceed the guidance levels, as an input to ensuring optimised protection of patients and maintaining appropriate levels of good practice; and
 - c. during the transition period, the performance of diagnostic radiology and nuclear medicine equipment is assessed.
2. Guidance levels for medical exposure shall be used by medical practitioners in the conduct of diagnostic and therapeutic procedures involving exposure to radiation as well as in the optimisation of protection of patients and the guidance level of activity for discharge of a patient from a hospital.
3. The guidance levels shall be established by relevant professional bodies or well known specialists in consultation with the Council, in order to provide an indication on what doses are achievable with current good practice for average sized patients.
4. The guidance levels shall be applied with flexibility to allow higher exposures, where they are indicated by sound clinical judgment and shall be revised as required by technological and scientific developments.

5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

52. Maximum activity for patients in therapy on discharge from

hospital.

1. The authorised person shall not discharge a patient from hospital before the activity of radioactive substances in the body falls below the level specified in Table 6, Schedule 5 unless otherwise justified and the justification is documented in order to restrict the exposure of any members of the household from a patient who has undergone a therapeutic procedure with sealed and or unsealed radio nuclides and of members of the public.
2. Written instructions by an authorised person to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided where necessary.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

53. Investigation of accidental medical exposures.

1. An authorised person shall promptly investigate any of the following accidents—
 - a. a therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the value prescribed by the medical practitioner;
 - b. a diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
 - c. a repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.
2. An authorised person shall, with respect to any investigation required under subregulation (1)—
 - a. calculate or estimate the doses received and their distribution within the patient;
 - b. indicate the corrective measures required to prevent recurrence of such an accident;
 - c. implement all the corrective measures that are under their own responsibility;
 - d. notify the Council by telephone or electronic mail or any other efficient means of communication as soon as practicable, but not later than twenty four hours after discovery, of any accident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient;
 - e. notify the Council about any minor injuries by telephone or electronic mail or any other efficient means of communication as soon as practicable, but not later than forty eight hours after discovery;

- f. submit to the Council, within fifteen days after discovery of the accident, a written report which states the cause of the accident and includes information on the doses, corrective measures and any other relevant information; and
 - g. inform the patient and his or her doctor about the accident.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

54. Medical dosimetry records.

- 1. An authorised person shall keep and make available, as required, records of equipment calibration, clinical dosimetry and quality assurance, as well as any other necessary information to allow retrospective assessments of the doses received by patients.
- 2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

Part VIII—Public Exposure Protection.

55. General responsibilities for authorised person for public exposure.

- 1. Authorised persons shall apply the requirements of these Regulations to any public exposure delivered by a practice or source for which they are responsible, unless the exposure is excluded from the regulations or the practice or source delivering the exposure.
- 2. Authorised persons shall be responsible, with respect to the sources under their charge for the establishment, implementation and maintenance of—
 - a. radiation safety policies, procedures and organisational arrangements for control of public exposure;
 - b. measures for ensuring—
 - i. the optimisation of the protection, subject to constraints as may be appropriate, of members of the public whose exposure is attributable to such sources; and
 - ii. the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in Schedule 3;
 - c. measures for ensuring the safety and security of such sources, in order that the likelihood of public exposures is controlled in accordance with the requirements of these Regulations;
 - d. suitable and adequate facilities, equipment and services for the protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the potential exposure;

- e. appropriate radiation safety training, and periodic retraining to the personnel having functions relevant to the protection of the public;
- f. appropriate monitoring equipment and surveillance programmes to assess public exposure;
- g. adequate records of the surveillance and monitoring programmes; and
- h. informing the public and particularly critical groups about radiation safety measures to be taken in case of an accident or

incident.

- 3. Authorised persons shall be responsible for informing the public and particularly critical groups, about radiation safety measures to be taken in case of an accident or incident.
- 4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

56. Control of visitors.

- 1. Authorised persons shall—
 - a. ensure that visitors are accompanied in any controlled area by a person knowledgeable about the radiation safety measures for that area;
 - b. provide adequate information and instruction to visitors before they enter a controlled area, to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions; and
 - c. ensure that adequate control over entry of visitors to a supervised area is maintained and that appropriate signs are posted in such areas.
- 2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

57. Source of external irradiation.

- 1. Authorised persons shall ensure that, if a source of external irradiation can cause exposure to the public—
 - a. prior to commissioning, the floor plans and equipment, arrangement for all new installations, and all significant modifications to existing installations utilising such sources of external irradiation are subject to review and approval by the

Council;

- b. specific dose constraints for the operation of such a source are established to the satisfaction of the Council; and
 - c. shielding and other protective measures that are optimised in accordance with the requirements of these Regulations and measures are provided as appropriate for restricting public exposure to the satisfaction of the Council.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

58. Radioactive contamination in enclosed spaces.

1. Authorised persons shall ensure that—
- a. for sources for which they are responsible, measures that are optimised in accordance with the requirements of these Regulations are taken as appropriate for restricting public exposure in areas accessible to the public; and
 - b. specific containment provisions are established for the construction and operation of those sources in order to avoid or minimise the spread of contamination in areas accessible to the public.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

59. Discharge of radioactive materials.

1. Subject to regulation 78, authorised persons shall ensure that radioactive materials from practices and sources are not discharged to the environment.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

60. Monitoring of public exposure.

1. Authorised persons shall, as appropriate—
- a. establish and carry out a monitoring programme of a magnitude and complexity commensurate with the type of risks associated with the sources under their responsibility, which is sufficient to ensure that the requirements of these Regulations are complied with and the monitoring programme shall assess the exposure of members of the public from sources of external irradiation and discharges of radioactive substances into the environment;
 - b. keep appropriate records of the results of the monitoring programmes; and

- c. report a summary of the monitoring results to the Council every year and promptly inform the Council of any abnormal results which lead or may lead to an increase of public exposure.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

61. Consumer products.

1. Consumer products capable of causing exposure to radiation shall not be supplied to members of the public unless—
 - a. the exposure is excluded as specified in regulation 6; or
 - b. such products meet the exemption requirements specified in regulation 14 or have otherwise been exempted by the Council; or
 - c. such products are authorised by the Council for use by members of the public.
2. Persons who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the

Council for authorisation to distribute, a copy of the licence or authorisation issued by the Regulatory Authority in the country of manufacture or origin.

3. Persons who import consumer products for sale and distribution as exempt products shall ensure that—
 - a. legible and prominently featuring radioactive labels are visibly and firmly affixed to each consumer product and its package, stating, in the English language, that—
 - i. the product contains radioactive materials; and
 - ii. the sale of the product to the public has been authorised by the Council.
 - b. basic information and instructions on the precautions of use and disposal of the product, written or translated in the local language, are made available with the product.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

Part IX—Requirements for the Safety and Security of Sources.

62. General responsibilities of authorised person for safety and security of sources.

1. Authorised persons shall ensure the safety and security of the sources under their responsibility, from the moment of their acquisition throughout their entire operational life, up to their final disposal.
2. Authorised persons shall ensure that a multilayer system of provisions defence in depth for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved is applied to the source under their responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purpose of—
 - a. preventing accidents that may cause unintended exposure;
 - b. mitigating the consequences of any such accident should it occur; and
 - c. restoring sources to safe conditions after any such accident.
3. Authorised persons shall ensure that, as far as appropriate, the location, design, construction and assembly, commissioning, operation and maintenance, and decommissioning of sources is based on sound engineering practice which—
 - a. takes into account approved codes, standards, technical and scientific developments;
 - b. is supported by reliable managerial and organisational features; and
 - c. includes adequate safety margins in the design, construction and operation of sources.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

63. Storage of radiation sources.

1. Authorised persons shall ensure that the following requirements with regard to storage of radiation sources are complied with—
 - a. when not in use, radiation sources shall be kept in a place of storage assigned for this purpose only, bearing the appropriate warning symbol while they are not in use;
 - b. the place of storage shall be adequately shielded such that at the outside surface of its walls or containment, the radiation dose shall not exceed 0.01 mSv per hour, and shall be chosen in order to minimise risks from fire or flood;
 - c. the place of storage shall be inspected regularly and checked for possible contamination at such a frequency as approved by
 - d. the place of storage shall be sited and designed so as to ensure that both during storage and in the course of transfer of radiation sources to and from the store, the sources do not give excessive exposure to any person; and

- e. if the place of storage is to contain either sealed or unsealed radiation sources that are liable to release a radioactive gas or vapour the store shall be continuously vented to the open air, or provided with a mechanical venting system that can be operated from outside the store before the store is opened.
2. All radiation sources shall be clearly labeled, giving information on their activity, nature and physical form.
3. The containers for beta emitting radionuclides shall have adequate thickness to reduce the primary radiation to a safe level and considerable bremsstrahlung radiation may arise from high intensity sources and additional shielding shall be provided.
4. Gamma emitting and neutron sources shall be stored in such a way as to limit the radiation exposure from the other sources when any one source is being handled.
5. Appropriate equipment shall be provided for storing unsealed radiation sources to prevent both external irradiation, hazards and internal contamination hazards.
6. Records shall be kept of all stored radiation sources and the records shall give clear information on the type of source activity, times of removal and return, and the name of the person responsible for the source during its absence from the store.
7. An authorised person shall ensure that inventories are updated periodically.
8. Bottles containing radioactive materials in liquid forms shall be placed in non-fragile vessels large enough to hold the entire contents of the bottles in case of breakage.
9. A person who contravenes this provision commits an offence

and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

64. Design and procurement of sources.

1. Authorised persons, in co-operation with suppliers, shall—
 - a. ensure, on procurement of new equipment containing radiation generators or sources, that the equipment and sources conform to applicable standards of the International Electrotechnical Commission (IEC) and the International Standards Organisation (ISO) or equivalent standards as may be approved by the Council;
 - b. ensure that sources and equipment are tested to demonstrate compliance with the appropriate specifications;

- c. conduct a safety assessment, either generic or specific, for the sources for which they are responsible, according to the requirements of regulation 32;
 - d. ensure that performance specifications, operating and maintenance instructions, including protection and safety instructions, are provided in English and in compliance with the relevant IEC and ISO standards with regard to ‘accompanying documents’; and
 - e. ensure that, the operating terminology and operating values are displayed on operating consoles or other control systems in the English and in the language of the supplier; and
 - f. where appropriate, ensure through an agreement concluded between the authorised person and the supplier that the supplier will take back the source when it is no longer in use.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

65. Accountability and security of sources.

1. Authorised persons shall maintain an accountability system as provided for in section 55 of the Act, that includes records of—
 - a. the location and description of each source for which an authorised person is responsible; and
 - b. the activity and form of each radioactive substance for which they are responsible.
2. An authorised person shall make arrangements for the sources under their responsibility to be kept secure, by ensuring that—
 - a. control of a source is not relinquished without compliance with all relevant requirements specified in the licence and without immediate communication to the Council of information regarding any decontrolled, lost, stolen or missing source;
 - b. a source is not transferred unless the receiver possesses a valid authorisation;
 - c. records are maintained of source inventory, including records of receipt, transfer and disposal of sources; and
 - d. a periodic inventory of sources is conducted at intervals specified in the licence to confirm that they are in their assigned locations and are secure.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

66. Feedback of operating experience.

1. Authorised persons shall ensure that information on both normal operation performance and abnormal conditions and events significant to radiation safety and security is disseminated or made available, as appropriate, to the Council and other relevant parties, including other users, as specified by the Council.

2. Authorised persons shall, where applicable, make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer from authorised persons to suppliers of any information on use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and construction of the sources they have supplied.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

Part X—Requirements for Emergency Intervention.

67. Responsibility of authorised persons in an emergency.

1. Where an authorised practice or source within a practice has a potential for accidents which may provoke unplanned exposure of any person, the authorised person shall ensure that an emergency plan appropriate for the source and its associated risks is prepared and drilled.
2. Where an authorised source is involved in an accident or incident, the authorised person is responsible for taking such protective actions as may be required for protection of occupationally exposed workers undertaking intervention and for protection of the public from exposure as prescribed in the application for authorisation and emergency plans approved by the Council, or as might otherwise be required by the Council to protect against, mitigate or remedy a hazardous situation involving the licensed sources.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

68. Authorised person emergency response planning requirements.

1. An authorised person responsible for a source shall ensure that the emergency plan referred to in regulation 67 defines on-site responsibilities and takes account of off-site responsibilities of other intervening organisations appropriate for implementation of the emergency plan.
2. The emergency plan shall, as appropriate—
 - a. characterise the content, features and extent of the potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and accidents that have occurred with sources of a similar type;
 - b. identify the various operating and other conditions of the source which could lead to the need for intervention;
 - c. describe the methods and instruments for assessing the accident and its consequences on and off the site;
 - d. provide for protection and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;
 - e. provide for rapid and continuous assessment of the accident as it proceeds and determine the need for protective actions;

- f. allocate responsibilities for notifying the relevant authorities and initiating intervention;
 - g. provide procedures, including communication arrangements, for contacting any relevant intervening organisation and for obtaining assistance from fire-fighting, medical, police and other relevant organisations;
 - h. provide for training of personnel involved in implementing emergency plans and be rehearsed at suitable intervals in conjunction with designated authorities; and
 - i. provide for periodic review and updating of the plan.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

69. Implementation of intervention.

1. An authorised person shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.
2. The form, scale and duration of any justified intervention shall be optimised so as to produce the maximum net benefit under the prevailing social and economic circumstances.
3. An authorised person shall promptly notify the Council when an accidental situation that requires intervention has arisen or is expected to arise and shall keep the Council informed of—
 - a. the current situation and its expected evolution;
 - b. the measures taken to terminate the accident and to protect workers and members of the public; and
 - c. the exposures that have been incurred and are expected to be incurred.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

70. Protection of workers undertaking an intervention.

1. A worker undertaking an intervention shall not be exposed in excess of the maximum single year dose limit for occupational exposure specified in Schedule 3 except—
 - a. for the purpose of saving life or preventing serious injury; or
 - b. when undertaking actions to prevent the development of catastrophic conditions.
2. Where a worker is undertaking an intervention under the circumstances in subregulation (1), all reasonable efforts shall be made to keep doses to workers below twice the maximum single year dose limit, except for life saving actions, in which every effort shall be made to keep doses below ten times the maximum single year dose limit, in order to avoid deterministic effects on health.

3. Workers undertaking actions in which their doses may approach or exceed ten times the maximum single year dose limit, shall do so only when the benefits to others clearly outweigh their own risk.
4. Workers who undertake actions in which the dose may exceed the maximum single year dose limit shall be volunteers and shall be clearly and comprehensively informed in advance of the associated health risk, and shall, to the extent feasible, be trained in the action that may be required.
5. Once the emergency phase of an intervention has ended, workers undertaking recovery operations, such as repairs to equipment and buildings, waste disposal or decontamination shall be subject to the full system of detailed requirements for occupational exposure specified under Part VI of these Regulations.
6. All reasonable steps shall be taken to provide appropriate protection during the emergency intervention and to assess and record the doses received by workers involved in emergency interventions and when the intervention has ended, the doses received and the consequent health risk shall be communicated to the workers involved.
7. Workers shall not normally be excluded from incurring further occupational exposure because of doses received in an emergency exposure situation and qualified medical advice shall be obtained before any such further exposure of a worker who has undergone an emergency exposure receives a dose exceeding ten times the maximum single year dose limit, or at the worker's request.
8. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

Part XI—Management of Radioactive Waste.

71. Application of radioactive waste management requirements.

For the avoidance of doubt, this part applies to all aspects of radioactive waste management including collection, segregation, characterisation, classification, treatment, conditioning, storage and disposal where the waste arises from medical, agricultural, industrial, research and educational applications.

72. Radioactive waste classification.

Radioactive waste shall be classified in accordance with the nationally agreed strategy options and according to the activity concentration and half-lives of the radionuclides, specified in Schedule 9.

73. Management of radioactive waste.

1. The owner of a radioactive waste or of a facility shall be responsible for its safe management, decommissioning and disposal.
2. In cases where the owner cannot be identified or does not exist anymore, the Council shall determine the method to use in order to safely manage and dispose of the material in question.
3. If any radioactive waste or any radioactive waste management facility is present at the time of entry into force of these Regulations, the Council shall—
 - a. ensure that a detailed inventory of that material is established;
 - b. determine what risk such waste or facility represents for individuals, society or the environment;
 - c. determine what measures, if any, need to be taken to upgrade the existing level of safety.
4. Authorised persons shall be responsible for the safe management of the radioactive waste generated by the practices or sources for which they are authorised and shall take all necessary steps including—
 - a. keeping the generation of both the activity and volume of radioactive waste to the minimum practicable by suitable

design, operation and decommissioning of its facilities;

- b. ensuring that radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and maintaining records of such activities;
 - c. ensuring that disposal of radioactive waste is not unnecessarily delayed; and
 - d. reporting to the Council required information at intervals as may be specified in the authorisation.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

74. Authorisation to manage radioactive waste.

1. An authorised person or organisation shall not generate, keep or manage radioactive waste except in accordance with an authorisation issued by the Council under the terms of regulation 15.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

75. Control of radioactive waste generation.

1. Authorised persons shall ensure that steps are taken to keep generation of radioactive waste and its environmental impact and cost to the minimum practicable by—
 - a. avoiding the use of unnecessarily hazardous or toxic materials;
 - b. minimising the activity of waste by using the minimum quantity of radioactive material required;
 - c. using short-lived radionuclides where possible;
 - d. minimising the amount of waste by preventing unnecessary contamination of materials;
 - e. maintaining consistency with the management strategy and systems; and
 - f. applying careful planning to the design, construction, administration, operation and decommissioning of facilities so that the generation of radioactive waste is kept to the minimum practicable.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

76. Segregation, collection and characterisation of radioactive waste.

1. Authorised persons shall ensure that waste is collected, segregated, and characterised, at the point of origin in accordance with the waste classification specified in Schedule 9, using the following criteria—
 - a. non-radioactive and radioactive;
 - b. short-lived suitable for decay storage;
 - c. activity and radionuclide content;
 - d. physical and chemical form of—
 - i. liquid, both aqueous and organic;
 - ii. non-homogeneous;
 - iii. solids, combustible or non-combustible and compactable or non-compactable, where applicable;
 - e. spent sealed source;
 - f. non-radiological hazardous waste like toxic, pathogenic, infectious, genotoxic, biological; and
 - g. mixed waste including radioactive and hazardous waste.
2. After segregation, each waste stream shall be kept, in separate containers.
3. Authorised persons shall ensure that the waste containers—
 - a. are clearly identified;

- (b) bear a radiation trefoil when in use for radioactive waste;
- (c) are robust;
- (d) are compatible with the waste contents; and
- (e) are able to be filled and emptied safely.

(4) All waste containers shall have a record of the following information—

- (a) identification number;
- (b) radionuclides;
- (c) activity if measured or estimated and the date of measurement;
- (d) origin such as the room, laboratory, individual, where applicable;
- (e) potential or actual hazards, chemical and infectious hazards;
- (f) surface dose rate and date of measurement;
- (g) quantity in weight or volume; and
- (h) the responsible person.

5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

77. Treatment and conditioning of radioactive waste.

1. The waste packages selected by the authorised person shall be compatible with planned storage or disposal options and shall also meet waste acceptance criteria for storage and disposal as approved by the Council.
2. In selecting a conditioning process, the authorised person shall consider whether safety would be improved from the use of a matrix material and shall ensure compatibility of the radioactive waste with the selected materials and processes.
3. Waste packages shall be designed and produced so that radionuclides are confined under both normal conditions and under the accident conditions that may occur during handling, storage, and disposal.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

78. Discharge or release of radioactive substances to the environment.

1. Authorised persons shall ensure that radioactive substances from their practices and sources are not discharged to the environment unless—
 - a. such discharge is within the limits specified in the licence and is carried out in a controlled fashion using authorised methods; or
 - b. the activity discharged is confirmed to be below clearance levels established by the Council and exemption levels specified in Schedule 2.
2. A person, shall, during the operational stages of sources under their responsibility—
 - a. keep all radioactive discharges as far below the authorised limits as is reasonably achievable;
 - b. monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorised discharge limits and to permit estimation of the exposure of critical groups of the population;
 - c. report discharges to the Council at such intervals as may be specified in the licence;
 - d. report promptly to the Council, any discharges exceeding the authorised limits and take corrective action; and
 - e. set up an adequate programme for environmental monitoring and accounting of the radioactive substances which have been released.
3. Where an activity released is within the clearance levels established by the Council or radioactive waste is discharged under an authorisation, authorised persons shall consider the non-radiological hazards of the released waste and shall comply with the requirements of any other regulations concerning those hazards.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

79. Disposal of radioactive waste.

1. Where the radioactive waste is not suitable for discharge or release to the environment or for clearance within a reasonable time, the holder of the waste shall submit to the Council its proposals for disposal of the waste and ensure that the criteria set by the Council for acceptance of the waste at any repository or any national waste management organisation are complied with.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

80. Transport of radioactive waste.

1. Authorised persons shall ensure that radioactive waste is prepared for transport to a storage or disposal site, and is regarded as a radioactive source for transport in

accordance with these Regulations as well as the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material (TS-R-1).

2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

81. Radioactive waste storage facilities.

1. Authorised persons shall ensure that radioactive waste is stored in such a way that human health and the environment are protected, and, in particular, it shall not be stored in the vicinity of corrosive, explosive or easily flammable materials.
2. An applicant for an authorisation to operate a radioactive waste facility shall—
 - a. meet safety requirements for the protection of human health and the environment by appropriate planning for the design, construction, operation and maintenance of the respective facility, including provisions for eventual retrieval of the waste;
 - b. design the facility—
 - i. on the basis of assumed conditions for its normal operation and assumed incidents or accidents;
 - ii. for the likely period of storage, with the potential for degradation being taken into account;
 - iii. in such a way that the waste can be retrieved whenever required;
 - iv. so that it is adequately ventilated to exhaust any gas generated in normal conditions or under anticipated accident conditions;
 - v. so that measures to prevent, detect and control fires are incorporated as required; and
 - vi. so that radiological monitoring and visual inspection is readily possible.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

82. Recycle and reuse of radioactive material.

1. Authorised persons using radioactive material shall—
 - a. not dismantle any sealed source unless specifically allowed in the authorisation;
 - b. before declaring the radioactive material as waste, consider whether the authorised person or any other organisation can make use of the material; and
 - c. where appropriate, transfer the material after confirming with the Council that the organisation to which it is transferred has the necessary authorisation to hold that material.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

83. Return of sealed sources to manufacturer.

1. Authorised persons shall, upon purchasing sealed sources, make contractual arrangements for the return of the spent sealed sources to the manufacturer or supplier.
2. A person or organisation that intends to import a sealed source containing radioactive material which within ten years after receipt will have an activity greater than 100 MBq shall—
 - a. require the supplier, as a condition of any contract for purchase or as acceptance of any gift, to receive the source back after its useful lifetime within one year of the recipient requesting such return, except that the recipient seeks to return the source to the supplier not later than fifteen years after purchase; and
 - b. submit to the Council a copy of relevant parts of the contract or acceptance document and obtain the written agreement of the Council before the entering into contract or accepting the source.
3. A person or organisation that intends to purchase, lease or rent generators of radionuclides, or if such generators are donated, shall make arrangements with the supplier or donor, to return the waste resulting from the use of radionuclides, if such waste cannot be cleared after decay or storage.
4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

84. Quality assurance programmes.

1. An authorised person shall submit a quality assurance programme to the Council for approval as part of the authorisation application for covering all aspects of the radioactive waste management, especially those features important to safety such as facilities, activities and waste which shall be commensurate with the scale of operations.
2. The effectiveness of the quality assurance programme shall be verified by independent audits to ensure that radioactive waste management activities are carried out to meet the requirement to protect human health and the environment.
3. Quality assurance documentation shall include—
 - a. an inventory of radioactive waste, including origin, location, physical and chemical characteristics, and, as appropriate, a record of radioactive waste removed or discharged from the facility;
 - b. site plans, engineering drawings, specifications and process descriptions;
 - c. data resulting from quality assurance and quality control procedures and from operating activities;
 - d. safety and environmental assessment methods and computer codes;
 - e. results of safety and environmental assessments;
 - f. effluent and environmental impact monitoring results;
 - g. radioactive waste package identification;

- h. waste management or arrangements as specified in regulation 79; and
- i. a detailed facility closure plan.

4. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

85. Physical protection.

- 1. An authorised person shall ensure that all necessary means are taken to prevent unauthorised persons gaining access to the waste.
- 2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

86. Records and reports.

- 1. An authorised person shall submit to the Council, an up-to-date inventory record of radioactive waste in his or her possession.
- 2. The inventory referred to in subregulation (1) shall be in such form and contain such details as the Council may require.
- 3. An authorised person shall send to the Council, before the fifteenth day of January, every year a copy of their waste inventory and a report for the previous year giving types, quantities and destinations of—
 - a. cleared materials released to the environment;
 - b. waste discharged to the environment;
 - c. spent radiation sources returned to suppliers; and
 - d. such other details as the Council may require.
- 4. The Council may inspect and review the records of an authorised person at any time.
- 5. Where any radioactive waste has been lost, stolen or is missing, the authorised person shall inform the Council not later than forty eight hours of the occurrence or discovery.
- 6. Where radioactive material has been released to the environment above the clearance criteria established by the Council or if waste has been discharged above the authorised limits issued by the Council, the authorised person shall inform the Council not later than forty eight hours of the occurrence or discovery.
- 7. The reports made under subregulations (5) and (6) shall be followed by written reports submitted to the Council within thirty days, concerning the matter and the actions which have been taken.

8. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

Part XII—Transport of Radioactive Materials.

87. Exemptions.

The following materials are exempted from the requirements of these Regulations—

- a. radioactive material that is an integral part of the means of transport;
- b. radioactive material moved within an establishment which is subject to appropriate safety regulations in force in the establishment and where the movement does not involve public roads or railways;
- c. radioactive material implanted or incorporated into a person or live animal for diagnosis or treatment;
- d. radioactive material in consumer products which have received regulatory approval, following their sale to the end user; and
- e. naturally occurring radioactive materials (NORMS) and ores containing naturally occurring radionuclides which are not intended to be processed for use of these radionuclides provided the activity concentration of the material does not exceed ten times the exempt values specified under Schedule 2.

88. Application of regulations.

For the avoidance of doubt, this part shall govern the domestic and international transport of radioactive material, which for the purpose of these Regulations means any material containing radionuclides where both the activity concentration and the total activity exceed the limits for exempt consignments, as specified in regulation 89, unless specifically excluded as specified in regulation 87.

89. Exempt consignments.

1. Consignments where either the activity concentration of the material or the total activity of the consignment is below the exempt limits specified in Schedule 2 for individual radionuclides that are exempt from the requirements of these Regulations.
2. For material containing mixtures of radionuclides, the activity concentration for exempt material and the activity limit for an exempt consignment shall be derived in the formula 1 specified in Schedule 13.
3. For unknown radionuclides or mixtures the more restrictive values of activity concentration for exempt material or activity limits for exempt consignments specified in Table 1, Schedule 11.

90. Material characterisation.

1. A_1 and A_2 values for individual radionuclides provided for in the International Atomic Energy Agency Safety Standards Series No. TS-R-1 are basic activity values which shall be used for characterising material to be transported and for specifying activity limits in these Regulations.
2. For material containing mixtures of known radionuclides the A_j or A_2 value for the material shall be derived in formula 2 specified in

Schedule 13.

3. For unknown radionuclides or mixtures, the more restrictive A_j or A_2 values as specified in the Table 2, Schedule 11 shall be used.
4. Radioactive material or items to be transported shall be classified, using A_1 or A_2 values, as follows—
 - a. material or instruments not exceeding the limits for an excepted package (activity limits are specified in Table 3, Schedule 11; in addition, the radiation level at 10 cm from any point on the external surface of any unpackaged instrument shall not be greater than 0.1 mSv/h, low specific activity material referred to as LSA-I, LSA-II or LSA-III), surface contaminated objects, referred to as SCO-I or SCO-II);
 - b. type A package quantity provided the activity of the material does not exceed the A_1 or A_2 values in the International Atomic Energy Agency Safety Standards Series No. TS-R-1 or the A_1 or A_2 values as derived for material containing a mixture of known radionuclides; or
 - c. type B package quantity when the activity of the material exceeds the limits for a type A package but not any limit specified in the certificate for the type B(U) or type B(M) package in which it is to be transported.

91. Unpackaged shipments.

1. An authorised person shall ensure that unpacked radioactive materials are transported under the following conditions—
 - a. LSA-I and SCO-I may be transported unpackaged under exclusive use provided that all unpackaged material other than ores containing only naturally occurring radionuclides shall be transported in such a manner that under routine conditions of transport, there shall be no escape of the radioactive contents from the conveyance nor shall there be any loss of shielding;
 - b. exclusive use is not required for SCO-I shipments where contamination on the accessible and the inaccessible surfaces is not greater than ten times the levels specified in regulation 94;
 - c. for SCO-I shipments where it is suspected that non-fixed contamination exists on inaccessible surfaces in excess of ten times the levels specified in regulation 94, measures shall be taken to ensure that radioactive material is not released into the conveyance.

2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

92. Packaging.

1. Radioactive material or items which require packaging for transport shall only be packaged only in any of the following packages in order of increased protection—
 - (a) excepted package;
 - (b) industrial package (Type IP-1, IP-2 or IP-3);
 - (c) Type A package;
 - (d) Type B(M) package;
 - (e) Type B(U) package; and
 - (f) Type C package.
2. Industrial packages, (IP-1, IP-2 or IP-3) may be used for the transport of low specific activity material or surface contaminated objects provided that the external radiation level at 3m from the unshielded material or object or objects does not exceed 10mSv/h.
3. Radioactive material or items may be transported in packages which provide more protection than required for the material.
4. Empty packages, which previously contained radioactive material, may be shipped as excepted packages as specified in Table 3, Schedule 11, provided that—
 - a. they are in a well maintained condition and securely closed;
 - b. the outer surface of any uranium or thorium in its structure is covered with an inactive sheath made of metal or some other substantial material;
 - c. the level of internal non-fixed contamination does not exceed 100 times the levels specified in regulation 94(1)(b); and
 - d. any labels required for its previous use are no longer visible and all other requirements for excepted packages under these Regulations are complied with.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

93. Mixed content.

1. An authorised person shall ensure that a package shall not contain any other items except documents that are necessary for the use of radioactive material.

2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

94. Contamination.

1. An authorised person shall ensure that non-fixed contamination on the external surfaces of packages, and on the internal and external surfaces of overpacks, freight containers, tanks and intermediate bulk containers are kept as low as practicable and shall not exceed the following limits—
 - a. beta, gamma and low toxicity alpha emitters $4\text{Bq}/\text{cm}^2$; and
 - b. all other alpha emitters $0.4\text{Bq}/\text{cm}^2$.
2. Fixed contamination levels are limited by radiation level limits for packages and conveyances and by requirements for decontamination specified in regulation 108.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

95. Maximum radiation levels.

1. Radiation level limits shall apply to materials to be packaged for transport and to the following items—
 - a. the radiation level at 10 cm from any point on the external surface of any unpackaged instrument which has activity levels below the limits for excepted packages, shall not be greater than $0.1\text{ mSv}/\text{h}$;
 - b. the quantity of LSA material or SCO in a single industrial package (type IP-1, IP-2 or IP-3) shall be restricted so that the external radiation level at 3m from the unshielded material or object or objects does not exceed $10\text{mSv}/\text{h}$.
2. Radiation level limits shall apply to packages or overpacks as follows—
 - a. the radiation level limit for excepted packages is $5\text{ Sv}/\text{h}$ at the surface of an excepted package;
 - b. the radiation levels for all other packages and overpacks, except for consignments under exclusive use, shall not exceed $2\text{mSv}/\text{h}$ at any point on any external surface of the package or overpack and, in addition, shall not exceed $0.1\text{ mSv}/\text{h}$ at 1 m from the external surfaces of the package or overpack;
 - c. for consignments to be transported by road or rail under exclusive use, the radiation levels on the external surface of any package or overpack shall not exceed $10\text{ mSv}/\text{h}$ and may only exceed $2\text{mSv}/\text{h}$ provided that—
 - i. the vehicle is equipped with an enclosure which, during

routine conditions of transport, prevents the access of unauthorised persons to the interior of the enclosure;

- ii. provisions are made to secure the package or overpack so that its position within the vehicle enclosure remains fixed during routine conditions of transport; and
- iii. there is no loading or unloading during the shipment.
- d. for exclusive use, shipments by air or by vessel, the radiation levels on the external surface of any package or overpack greater than 2mSv/h may be allowed only under special arrangement conditions which are not covered under these Regulations.

3. Radiation levels for conveyances are limited as follows—

- a. loading of freight containers and the accumulation of packages, overpacks and freight containers aboard a single conveyance shall be such that the radiation level under routine conditions of transport shall not exceed 2mSv/h at any point on, and 0.1 mSv/h at 2m from, the external surface of the conveyance;
- b. further control over radiation exposure during transport is provided with limits on the transport index as provided for under regulation 96.

96. Transport index.

- 1. In order to provide control over radiation exposure during transport, a transport index (TI), based on radiation levels shall be assigned to a package, overpack or freight container or to unpackaged LSA-I or SCO-I as follows—
 - a. to determine the maximum radiation level in units of millisieverts per hour (mSv/h) at a distance of 1m from the external surfaces of the package, overpack, freight container, or unpackaged LSA-I and SCO-I;
 - b. the value determined in paragraph (a) shall be multiplied by 100 and the resulting number is the transport index;
 - c. for uranium and thorium ores and their concentrates, the maximum radiation level at any point 1m from the external surface of the load may be taken as—
 - i. 0.4mSv/h for ores and physical concentrates of uranium and thorium,
 - ii. 0.3mSv/h for chemical concentrates of thorium, or
 - iii. 0.02mSv/h for chemical concentrates of uranium, other than uranium hexafluoride,
 - d. for tanks, freight containers and unpackaged LSA-I and SCO- I, the value determined in paragraph (a) shall be multiplied by the appropriate factor from appropriate tables provided in International Atomic Energy Agency Safety Standards Series No. TS-R-1;
 - e. the value obtained in paragraphs (b) and (d) shall be rounded up to the first decimal place for example 1.13 becomes 1.2, except that a value of 0.05 or less may be considered as zero.

2. The transport index for each overpack, freight container or conveyance shall be determined as either the sum of the TIs of all the packages contained, or by direct measurement of the radiation level, except in the case of non-rigid overpacks for which the transport index shall be determined only as the sum of the TIs of all the packages.
3. Any package or overpack having a TI greater than ten shall be transported only under exclusive use.
4. The total number of packages, overpacks and freight containers aboard a single conveyance not under exclusive use, shall be limited so that the sum of the Transport Indices (TIs) aboard the conveyance does not exceed the values specified in Table 5, Schedule 11.
5. There shall be no limit on the sum of transport indexes for

consignments of LSA-I material.

97. Marking.

1. Where unpackaged LSA-I or SCO-I material is contained in receptacles or packing material and shipped under conditions specified in regulation 91, the outer surface of these receptacles or wrapping materials shall bear the marking "RADIOACTIVE LSA-I" or "RADIOACTIVE SCO-I" as appropriate.
2. All packages shall be legibly and durably marked on the outside of the packaging with the identification of either the consignor or consignee, or both.
3. Each package of gross mass exceeding 50 kg shall have its permissible gross mass legibly and durably marked on the outside of the packaging.
4. All packages shall be legibly and durably marked on the outside of the packaging with the appropriate United Nations number specified in Table 4, Schedule 11 preceded by the letters "UN" and for each package, other than excepted packages, the proper shipping name as specified in Table 4, Schedule 11 shall also be included with the marking.
5. Industrial packages shall be legibly and durably marked on the outside of the packaging with the words "TYPE IP- 1", "TYPE IP-2" or "TYPE ip-3".
6. Type A packages shall be legibly and durably marked on the outside of the packaging with the words "TYPE A".
7. Each package which conforms to an approved Type B(U), Type B(M) or Type C package design shall be legibly and durably marked on the outside of the packaging with—
 - a. the identification mark allocated by the Council to the design of that package;
 - b. a serial number to uniquely identify each packaging which conforms to that design; and
 - c. in the case of a Type B(U) or Type B(M) package design, with "TYPE B(U)" or "TYPE B(M)".
8. In the case of a Type C package design, with the words "TYPE C" in addition, each package which conforms to a Type B(U), Type B(M) or Type C package design shall have the outside of the outermost receptacle which is resistant to the effects of fire and

water plainly marked by embossing, stamping or other means resistant to the effects of fire and water with the trefoil symbol for radioactive material specified in Figure 1, Schedule 7.

98. Labeling requirements.

1. Labeling shall be done in accordance with the assigned category for packages and overpacks.
2. Packages and overpacks shall be assigned to either category I- WHITE, II-YELLOW or III-YELLOW in accordance with the conditions specified in Figure 2, 3, 4 and 5, Schedule 7 and with the following requirements—
 - a. for a package or overpack, both the transport index and the surface radiation level conditions shall be taken into account in determining which is the appropriate category;
 - b. where the transport index satisfies the condition for one category but the surface radiation level satisfies the condition for a different category, the package or overpack shall be assigned to the higher category and category I-WHITE shall be regarded as the lowest category;
 - c. the transport index shall be determined following the procedures specified in regulation 96.
3. For all packages any labels which do not relate to the contents shall be removed or covered.
4. Excepted packages shall not require any labeling.
5. All other packages, overpacks and freight containers shall bear labels which conform to the models specified in Schedule 7.
6. The labels referred to in this regulation shall be affixed to two opposite sides of the outside of a package or overpack or on the outside of all four sides of a freight container or tank.
7. On large freight containers and tanks, enlarged labels may be used, in accordance with dimensions specified in Schedule 7, in which case no placarding shall be required.

99. Information required on labels.

Labels shall be completed with the following information—

- a. contents—
 - i. except for LSA-I material, the name(s) of the radionuclide(s) shall be as specified in Table 1, Schedule 11;
 - ii. for mixtures of radionuclides, the most restrictive nuclides shall be listed to the extent the space on the line permits;

- iii. the group of LSA or SCO shall be shown following the name(s) of the radionuclide(s) and the terms “LSA-II”, “LSA-III”, “SCO-I” and “SCO-II” shall be used for this purpose; or
 - iv. for LSA-I material, the term “LSA-I” is all that is required; the name of the radionuclide is not required;
- b. the maximum activity of the radioactive contents during transport expressed in units of Becquerel (Bq) with the appropriate SI prefix;
 - c. for overpacks and freight containers the “contents” and “activity” entries on the label shall bear the information

required in subregulations (a) and (b), respectively, totaled together for the entire contents of the overpack or freight container except that on labels for overpacks or freight containers containing mixed loads of packages containing different radionuclides, such entries may read “See Transport Documents”;

- d. no transport index entry is required for category I-WHITE.

100. Loading and segregation.

- 1. The following conditions for loading and segregation shall apply to all consignments—
 - a. radioactive consignments shall be segregated from other dangerous goods during transport; and
 - b. radioactive material shall be segregated from undeveloped photographic film so that the radiation exposure of film due to the transport of radioactive material is limited to 0.1mSv per consignment of such film.
- 2. Where a consignment is to be transported, not under exclusive use, the following conditions shall apply—
 - a. the consignment shall not include any package or overpack having a transport index greater than ten;
 - b. the loading of freight containers and the accumulation of packages, overpacks and freight containers aboard a single conveyance shall be limited so that the total sum of the transport indexes aboard the conveyance does not exceed the values shown in the IAEA Safety Standards Series no. TS-R-1; and
 - c. the loading of freight containers and the accumulation of packages, overpacks and freight containers aboard a single conveyance shall be such that the radiation level under routine conditions of transport shall not exceed 2mSv/h at any point on, and 0.1 mSv/h at 2m from, the external surface of the conveyance.
- 3. Where a consignment is to be transported under exclusive use there is no limit on the sum of transport indexes, but radiation levels shall be controlled as follows—

- a. for road and rail consignments under exclusive use the radiation level shall not exceed 10mSv/h at any point on the external surface of any package or overpack, and may only exceed 2mSv/h provided that—
 - i. the vehicle is equipped with an enclosure which, during routine conditions of transport, prevents the access of unauthorized persons to the interior of the enclosure,
 - ii. provisions are made to secure the package or overpack, so that its position within the vehicle remains fixed during routine conditions of transport, and
 - iii. there is no loading or unloading during the shipment;
- b. 2mSv/h at any point on the outer surfaces of the vehicle, including the upper and lower surfaces, or, in the case of an open vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load, and on the lower external surface of the vehicle; or
- c. 0.1 mSv/h at any point 2m from the vertical planes represented by the outer lateral surfaces of the vehicle, or, if the load is transported in an open vehicle, at any point, 2m from the vertical planes projected from the outer edges of the vehicle.

101. Placarding.

- 1. Consignments consisting solely of excepted packages do not require placarding.
- 2. Where other packages are involved, the following requirements for placarding shall apply—
 - a. large freight containers carrying packages other than excepted packages, and tanks shall bear four placards which conform

with the model specified in Figure 6 and 7, Schedule 7;

- b. the placards shall be affixed in a vertical orientation to each side wall and each end wall of the large freight container or tank;
 - c. placards which do not relate to the contents shall be removed;
 - d. instead of using both labels and placards, enlarged labels shall be used as specified in Figure 6, Schedule 7.
- 3. Where the consignment in the freight container or tank or vehicle is unpackaged LSA-I or SCO-I or where an exclusive use consignment in a freight container is packaged radioactive material with a single United Nations number, the appropriate United Nations number for the consignment shall also be displayed, in black digits not less than 65mm high, either—
 - a. in the lower half of the placard shown in Figure 6, Schedule 7, preceded by the letters “UN” and against the white background; or

- b. on the placard shown in Figure 7, Schedule 7.
4. When the alternative given in subsection 3(b) is used—
 - a. in the case of a freight container or tank, the subsidiary placard shall be affixed immediately adjacent to the main placard, on all four sides of the freight container or tank; or
 - b. in the case of a vehicle, the subsidiary placard shall be affixed immediately adjacent to the main placard, either on the two external lateral walls in the case of a rail vehicle or the two external lateral walls and the external rear wall in the case of a road vehicle.
5. Rail and road vehicles carrying packages, overpacks or freight containers labelled with any of the labels shown in Figure 2, 3 and 4, Schedule 7, or carrying consignments under exclusive use, shall display the placard shown in Figure 6, Schedule 7 on each of—
 - a. the two external lateral walls in the case of a rail vehicle; and
 - b. the two external lateral walls and the external rear wall in the case of a road vehicle.
6. In the case of a vehicle without sides, the placards may be affixed directly on the cargo-carrying unit provided that they are readily visible.
7. In the case of physically large tanks or freight containers, the placards on the tanks or freight containers shall suffice.
8. In the case of vehicles which have insufficient area to allow the fixing of larger placards, the dimensions of the placard as described in Figure 6, Schedule 7 may be reduced to 100 mm.
9. Any placards which do not relate to the contents shall be removed.

102. Transport documents.

1. A consignor shall include in the transport documentation to accompany the consignment the particulars of the consignment, a consignor's declaration and information for the carriers.
2. The consignor shall also include in the transport documents with each consignment, the following information, as applicable in the order given—
 - a. the proper shipping name, as specified in Table 4, Schedule 11;
 - b. the United Nations Class number “7”;
 - c. the United Nations number assigned to the material as specified in Table 4, Schedule 11, preceded by the letters

“UN”;

- d. the name or symbol of each radionuclide or, for mixtures of radionuclides, an appropriate general description or a list of the most restrictive nuclides;
 - e. a description of the physical and chemical form of the material, or a notation that the material is special form of radioactive material;
 - f. the maximum activity of the radioactive contents during transport expressed in units of becquerels (Bq) with an appropriate SI prefix;
 - g. the category of the package - I-WHITE, II-YELLOW, III- YELLOW;
 - h. the transport index categories - II-YELLOW and III- YELLOW only;
 - i. for consignments including fissile material other than excepted fissile material, the criticality safety index;
 - (j) the identification mark for each competent authority approval certificate (special form radioactive material, package design, or shipment) applicable to the consignment;
 - (k) for consignments of packages in an overpack or freight container, a detailed statement of the contents of each package within the overpack or freight container and, where appropriate, of each overpack or freight container in the consignment;
 - where packages are to be removed from the overpack or freight container at a point of intermediate unloading, appropriate transport documents shall be made available;
 - (m) where a consignment is required to be shipped under exclusive use, the statement “EXCLUSIVE USE SHIPMENT”; and
 - (n) for LSA-II, LSA-III, SCO-I and SCO-II, the total activity of the consignment as a multiple of A_2 .
3. The consignor shall include in the transport documents a declaration in the terms specified in Schedule 12.
 4. The declaration in subregulation (3) shall be signed and dated by the consignor.
 5. Facsimile signatures shall be acceptable where applicable laws and regulations recognise the legal validity of facsimile signatures.
 6. The declaration shall be made on the same transport document which contains the particulars of consignment listed in subregulation (2).
 7. The consignor shall provide in the transport documents, a statement regarding actions, if any that are required to be taken by the carrier.

8. The statement referred to in subregulation (7) shall be in the languages deemed necessary by the carrier or the authorities concerned, and shall include the following—
 - a. supplementary requirements for loading, stowage, carriage, handling and unloading of the package, overpack or freight container including any special stowage provisions for the safe dissipation of heat or a statement that no such requirements are necessary;
 - b. restrictions on the mode of transport or conveyance and any necessary routing instructions;
 - c. emergency arrangements appropriate to the consignment;
 - d. the applicable certificates need not necessarily accompany the consignment.
9. The consignor shall make certificates under subregulation (8)(d) available to the carrier before loading and unloading.

103. Storage and dispatch.

Consignments of radioactive material shall be stored and dispatched as follows—

- a. segregation shall be required while in transit of dangerous goods from persons and undeveloped photographic films and plates;
- b. a package or overpack may be stored among packaged general cargo without any special storage provisions except as may be

specifically required by the council provided the average

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surface heat flux does not exceed 15W/m and that the immediate surrounding cargo is not in sacks or bags; and

- c. any provisions in the certificates and any relevant perusal and preshipment requirements shall be observed.

104. Carriage.

1. Category II-YELLOW or III-YELLOW packages or overpacks shall not be carried in compartments occupied by passengers, except those packages exclusively reserved for couriers specially authorised to accompany such packages or overpacks.
2. In the case of road transport, no persons other than the driver and assistants shall be permitted in vehicles carrying packages, overpacks or freight containers bearing category II-YELLOW or III- YELLOW labels.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

105. Sender to receive acknowledgement receipt of materials.

The person who sends the radioactive materials shall ensure that an acknowledgement receipt of the dispatched radioactive materials is received by him or her within thirty days from the date of dispatch.

106. Monitoring arrival of shipment.

The person who sends the radioactive materials shall monitor the arrival of any shipment or part of a shipment to its destination where acknowledgement is received in accordance with regulation 105 and shall carry out an investigation regarding the status of the shipment or part shipment.

107. Investigation of shipment and report to the Council.

1. A person who sends radioactive material in a shipment shall monitor the shipment, and after investigation of the status of the shipment or part shipment he or she shall prepare a report which shall be submitted to the Council within one week of completing the investigation.
2. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 50 currency points or imprisonment for a term not exceeding 2 years or both.

Part XIII—Miscellaneous

108. Decontamination.

1. An authorised person shall ensure that conveyances and equipment used regularly for the transport of radioactive material shall be periodically checked to determine the level of contamination.
2. The frequency of such checks shall be related to the likelihood of contamination and the extent to which radioactive material is transported.
3. Conveyances and equipment which have, in the course of transport of radioactive material, become contaminated above the contamination limits specified in regulation 94(1)(a) and (b) or which show a radiation level in excess of 5 μ Sv/h at the surface, shall be decontaminated as soon as possible by a qualified person and shall not be reused unless the non-fixed contamination does not exceed the contamination limits specified in regulation 94(1)(a) and (b).
4. The radiation level resulting from the fixed contamination on surfaces after decontamination shall be less than 5 μ Sv/h.
5. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

109. Decommissioning and disposal of radioactive waste.

1. An authorised person shall establish and maintain a decommissioning plan commensurate with the type and status of the facility.
2. The authorised person shall be responsible for the safety of a facility during the decommissioning operations.
3. During all phases of decommissioning, the authorised person shall ensure that the workers, the public and the environment are properly protected from hazards, including radiological hazards resulting from decommissioning activities.
4. The applicant for an authorisation shall ensure that the initial design and any subsequent modifications of a facility include consideration of future decommissioning requirements.
5. The authorised person shall submit an application for authorisation to decommission a facility to the Council specified in Form 9, Schedule 1.
6. The application provided for in subregulation (5) shall contain the final decommissioning plan and a justification of the proposed decommissioning option.
7. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

110. Radioactive waste from mining and mining operations.

1. An authorised person shall ensure that the same established safety requirements that apply to the disposal of radioactive waste also apply, in the same way, to the waste from mining and milling operations.
2. The authorised person shall propose to the Council which option is followed for the siting, design, construction, operation, closure

and post-closure activity for a mining and milling waste disposal facility.

3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

111. Notification of Council.

1. Before the first shipment of any package requiring Council approval, the consignor shall ensure that copies of each applicable certificate applying to that package design have been submitted to the authority of each country through or into which the consignment is to be transported.
2. The consignor is not required to await an acknowledgement from the Council, nor is the Council required to make an acknowledgement of receipt of the certificate.
3. The authority of each country through which the consignment is to be transported shall be notified at least seven days in advance and the notification shall include the following information—
 - a. Type C packages containing radioactive material with an activity greater than 3000 A₁ or 3000 A₂, as appropriate, or 1000 TBq, whichever is the lower;

- b. Type B(U) packages containing radioactive material with an activity greater than 3000 A₁ or 3000 A₂, as appropriate, or 1000 TBq, whichever is the lower;
 - c. Type B(M) packages; or
 - d. shipment under special arrangement.
4. The consignment notification shall include—
 - a. sufficient information to enable the identification of the package or packages including all applicable certificate numbers and identification marks;
 - b. information on the date of shipment, the expected date of arrival and proposed routing;
 - c. the names of the radioactive materials or nuclides;
 - d. descriptions of the physical and chemical forms of the radioactive material, or whether it is a special form of radioactive material or low dispersible radioactive material;
 - e. the maximum activity of the radioactive contents during transport expressed in units of a Becquerel (Bq) with an appropriate SI prefix; and
 - f. for fissile material, the mass of fissile material in units of grams (g), or multiples thereof may be used in place of activity.
 5. The consignor shall not be required to send a separate notification where the required information has been included in the application for shipment approval.
 6. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 150 currency points or imprisonment for a term not exceeding 4 years or both.

112. Security of package.

1. An authorised person in charge of transportation shall be responsible for the security of the packages from the port of entry to the final user institution.
2. The authorised person in charge of transportation shall put in place measures to ensure security of the source in accordance with the conditions in the transport permit.
3. A person who contravenes this provision commits an offence and is liable on conviction to a fine not exceeding 200 currency points or imprisonment for a term not exceeding 4 years or both.

113. General penalty.

Any person who commits an offence under these Regulations for which