

CHAPTER 24:03 - RADIATION PROTECTION: SUBSIDIARY LEGISLATION

INDEX TO SUBSIDIARY LEGISLATION

Radiation Protection Regulations

RADIATION PROTECTION REGULATIONS

(section 36)

(13th June, 2008)

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S.I. 47, 2008,
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PART I
Preliminary (regs 1-10)

1. Citation

These Regulations may be cited as the Radiation Protection Regulations.

2. Interpretation

In these Regulations, unless the context otherwise requires-

"approved medical practitioner" means a medical practitioner responsible for the medical surveillance of workers who are liable to receive a dose greater than three-tenths of the annual maximum permissible dose, whose capacity to act in this respect is recognised by authority;

"authorisation" means a permission granted in a document by the inspectorate to a legal person who has submitted an application to carry out a practice or any other action described in these Regulations;

"conditioning" means those operations that produce a waste package suitable for handling, transportation, storage or disposal and includes the conversion of the waste to a solid waste form, enclosure of the waste in containers and providing an overpack;

"consumer product" means a device that contains a small amount of radioactive substances;

"contamination" means the presence of a radioactive substance on a surface in quantities in excess of 0.4Bq/cm² for beta and gamma emitters and low toxicity alpha emitters, or 0.04Bq/cm² for all other alpha emitters;

"controlled area" means any area in which specific protection measures and safety

provisions are or may be required for-

- (a) controlling normal exposures or preventing the spread of contamination during normal working conditions, and
- (b) preventing or limiting the extent of potential exposures;

"**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 pathway and is typical of individuals receiving the highest effective dose or equivalent dose, as the case may be, by the given exposure pathway from the given source;

"**defence in depth**" means the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fails;

"**disposal**" means-

- (a) the emplacement of waste in an approved, specified facility without the intervention of retrieval; or
- (b) the approved direct discharge of airborne or liquid effluents into the environment with subsequent dispersion;

"**dose limit**" means the value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded;

"**employer**" means a legal person with recognised responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship;

"**effective dose**" means the radiation dose that the total body can receive uniformly and that can give the same cancer risk when exposing individual organs to different doses, expressed as quantity E , which is the summation (Σ) of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor-

$$E = \sum_T W_T H_T$$

where H_T is the equivalent dose in tissue T and W_T is the tissue weighting factor for tissue T .

"**equivalent dose**" means the quantity $H_{T,R}$, defined as:

$$H_{T,R} = D_{T,R} \cdot W_R$$

where $D_{T,R}$ 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 .

When the radiation field is composed of different radiation types with different values of W_R , the equivalent dose is-

$$H_T = \sum_R W_R D_{T,R}$$

The unit of equivalent dose is J.kg⁻¹ termed the Sievert (Sv).

"fixed contamination" means contamination other than non-fixed contamination;

"guidance level" means a level of a specified quantity above which appropriate actions should be considered;

"health professional" means a medical practitioner, a dentist or a pharmacist or an allied health professional registered under the Botswana Health Professions Act;

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

"intervening organisation" means an organisation designated or otherwise recognised by the Government of Botswana as being responsible for managing or implementing any aspect of an intervention;

"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;

"Inspectorate" means the Radiation Protection Inspectorate established under section 18 of the Radiation Protection Act;

"legal person" means any organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with any law, who or which has responsibility and authority for actions taken under these Regulations;

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

"licensee" means the holder of a current licence granted for a practice or source;

"limit" means the value of a quantity used in certain specified activities or circumstances that must not be exceeded;

"medical exposure" means exposure incurred-

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

"medical practitioner" means a person-

- (a) registered as a medical practitioner under the Botswana Health Professions Act;
- (b) who fulfils the national requirements on training and experience for prescribing

procedures involving medical exposure; and

- (c) is a licensee, or a worker who has been designated by a licensed employer for the purpose of prescribing procedures involving medical exposure;

"member of the public" means-

- (a) any individual in the population except, for the purposes of these Regulations, when subject to occupational or medical exposure; and
- (b) for the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group;

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

"non-fixed contamination" means contamination that can be removed from a surface during routine conditions of transport;

"normal exposure" means exposure which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control;

"notification" means a document submitted to the Inspectorate by a legal person to notify an intention to carry out a practice or any other action described in the general obligations for practices;

"occupational exposure" means exposure of workers incurred in the course of their work, with the exception of exposures excluded from these Regulations and exposures from practices or sources exempted by these Regulations;

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

"practice" means any human activity that introduces additional sources of exposure or 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;

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

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

"qualified expert" means an individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognised as having expertise in a relevant field of specialisation;

"quality assurance" means all those planned and systematic actions necessary to

provide adequate confidence that an item, process or service will satisfy given requirements for quality;

"Radiation Safety Officer" means an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee to oversee the application of the requirements of these Regulations;

"radioactive discharges" means radioactive substances arising from a source within a practice which are discharged as gases, aerosols, liquids or solids to the environment, generally with the purpose of dilution and dispersion;

"radioactive waste" means material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen, that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for exemption or clearance from regulatory requirements, and exposure to which is not excluded from these Regulations;

"reference level" means action level, intervention level, investigation level or recording level which may be established for any of the quantities determined in the practice of radiation protection;

"registration" means a form of authorisation for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the Inspectorate;

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

"safety culture" means the 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 radiation source consisting of a radioactive substance enclosed in enclosures or arranged in such a way that there is no risk of the substance being liberated or becoming accessible to direct contact during normal use;

"source" means anything that may cause radiation or releasing radioactive substances or materials;

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

"supervised area" means any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed;

"supplier" means any legal person to whom a licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source;

"treatment" means operations intended to benefit safety or the economy by changing the characteristics of the waste;

"unsealed source" means radioactive material that is-

- (a) not permanently sealed in a capsule;
- (b) not closely bounded and is not in a solid form;

"waste inventory" means a detailed, itemised record maintained by the operator or inspectorate in accordance with these Regulations, which may contain data on the physical quantity, the activity of the waste, the radionuclide content, and other characteristics;

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

"waste package" means the product of conditioning that includes the waste form and any container and internal barriers, as prepared in accordance with requirements for handling, transportation, storage and disposal;

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

3. Exemption of legal persons

These Regulations shall not apply to intervention by legal persons authorised to possess sources in the event of radiological emergencies involving such sources.

4. Exposures

The exposures to which the requirements of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any practice or source within the practice, including both normal exposures and potential exposures.

5. Exclusions

The following exposures are excluded from the requirements of these regulations-

- (a) exposures from natural radioactivity in the body;
- (b) exposures from cosmic radiation and from unmodified concentrations of natural radionuclides in raw materials; or
- (c) any other source that is essentially unamenable to control as may be determined by the Board.

6. Responsible parties

(1) The Inspectorate shall be responsible for the enforcement of these Regulations.

(2) The principal parties having the main responsibilities for the enforcement of these Regulations shall be-

- (a) those authorised by registration or licence; and
- (b) employers.

(3) The following parties shall have subsidiary responsibilities for the enforcement of these Regulations-

- (a) suppliers;
- (b) workers;
- (c) Radiation Safety Officers;
- (d) medical practitioners;
- (e) health professionals;
- (f) qualified experts; or
- (g) any other party to whom the principal party has delegated specific tasks.

(4) The general responsibilities of the principal parties include the following -

- (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 practices and interventions under their responsibility and sufficient to ensure compliance with the requirements of these Regulations, in particular, this programme shall include the following actions-
 - (i) to determine and keep continually under review the measures needed to achieve the radiation safety objectives, to ensure that the resources needed for their implementation are provided and regularly to verify that the radiation safety objectives are being achieved,
 - (ii) to identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures,
 - (iii) to facilitate consultation and cooperation between all relevant parties with respect to radiation safety, and
 - (iv) to keep appropriate records regarding the discharge of their responsibilities.

7. Access to premises and information

(1) Every legal person responsible for authorised practices or sources within practices shall permit a representative of the Inspectorate access to premises and facilities in which such practices are conducted or sources located in order to obtain information about the status of radiation safety and verify compliance with regulatory requirements.

(2) Every legal person authorised to engage in a practice covered by these regulations shall make available to the Inspectorate, upon reasonable notice, information and records regarding radiation safety.

8. Non-compliance

(1) In the event of a breach of any applicable requirement of these Regulations, the principal parties shall-

- (a) investigate the breach and its causes, circumstances and consequences of the breach;
- (b) take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;
- (c) communicate to the Inspectorate on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken; and
- (d) take whatever other actions that are necessary as required by these Regulations.

(2) The principal parties shall communicate the breach referred to in subsection (1) to the Inspectorate as soon as practicable after it has occurred and shall, whenever an emergency exposure situation has developed or is developing, immediately communicate it.

(3) Where the principal parties fail to take corrective or preventive actions within a reasonable time in accordance with these Regulations, the Inspectorate shall modify, suspend or withdraw any authorisation that it has granted.

9. Enforcement

The Board may-

- (a) revoke, suspend or modify an authorisation to use a radiation source, or prohibit the possession of a radiation source, upon finding an undue threat to health and safety or non-compliance with applicable regulatory requirements;
- (b) levy fines for non-compliance with applicable regulations and regulatory requirements commensurate with the nature of the breach; and
- (e) upon finding wilful violations or attempted violations of the regulations or requirements, make recommendations for prosecution.

10. Applicability of other regulations and requirements and resolution of conflicts

(1) The requirements of these Regulations are in addition to the requirements in other applicable laws.

(2) Nothing in these Regulations shall be construed as exempting employers from complying with applicable laws governing workplace hazards, including radiation hazards from natural sources which are unconnected with the work.

(3) Nothing in these Regulations shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

PART II ***Administrative Requirements (regs 11-16)***

11. General obligations

No person shall engage in activities which involve practices or sources within practices unless the requirements of these Regulations, including the requirements for notification and authorisation, are met.

12. Requirements for notification

(1) Except as provided for in regulation 14, any legal person who, on the date of commencement of these Regulations, is responsible for a practice or in possession of a radiation source, shall submit a notification to the Inspectorate in accordance with section 37 of the Act.

(2) Except as provided for in regulation 14, any legal person intending to initiate a practice or to possess a radiation source referred to in regulation 3, shall submit a prior notification to the Inspectorate of such an intention.

(3) A list of sources and practices requiring notification only shall be compiled by the Inspectorate and reviewed from time to time by the Board.

(4) After notification as specified in subregulation (1) or (2), and for any practices or sources not included in the list given in subregulation (3), every legal person who applies to the Board for an authorisation according to regulation 15 is permitted to continue existing activities specified in the notification, in compliance with the requirements of these regulations, until such time as the Board revokes such permission or grants an authorisation.

13. 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-

- (a) the exemption levels specified in the First Schedule; or
- (b) any exemption levels defined by the Board on the basis of the exemption levels specified in the First Schedule.

(2) Exemptions shall not be granted for practices deemed not to be justified as specified in regulation 18 (2).

(3) The following practices and sources within a practice are automatically exempted from the requirements of these Regulations, including the requirement for notification, registration or licensing-

- (a) radioactive substances for which the total activity of a given nuclide present on the premises at any one time or its activity concentration contained in a mass of 1000 kg or less of material does not exceed the exemption levels specified in the First Schedule;
- (b) apparatus containing radioactive substances exceeding the quantities or concentrations specified in paragraph (a):

Provided that:

- (i) it is of a type approved by the Board,

- (ii) it is constructed in the form of a sealed source, and
 - (iii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu\text{Sv/h}$ at a distance of 0.1 m from any accessible surface of the apparatus nor a dose to any member of the public exceeding 10 μSv in a year;
- (c) the operation of any electrical apparatus to which these Regulations apply, other than that referred to in paragraph (a):

Provided that:

- (i) it is of a type approved by the Board, and
 - (ii) it does not cause in normal operating conditions a dose rate exceeding 1 $\mu\text{Sv/h}$ at a distance of 0.1 m from any accessible surface of the apparatus; and
- (d) the operation of any cathode ray tube intended for the display of visual images or other electrical apparatus operating at a potential difference not exceeding 30 kV, provided that it does not cause in normal operating conditions a dose rate exceeding 1 $\mu\text{Sv/h}$ at a distance of 0.1 m from any accessible surface of the apparatus.

14. Requirements for authorisation by registration or licence

(1) Except as provided in regulation 12(4) and regulation 13 any legal person intending to engage in a practice or possess a radiation source shall apply to the Board for an authorisation which shall take the form of either a registration or a licence.

(2) If the application referred to in subregulation (1) refers to an industrial irradiation installation, an installation processing radioactive substances, a medical or industrial radiography facility, or for any use of a source which the Board has not designated as suitable for registration, the authorisation shall take the form of a licence.

(3) Any legal person applying for an authorisation shall-

- (a) submit to the Inspectorate relevant information necessary to support the application, including-
 - (i) an evaluation of the nature, magnitude and likelihood of the exposures attributed to the practice and sources within the practice,
 - (ii) a safety assessment in cases where this is prescribed by the inspectorate, to be submitted as part of the application, and
 - (iii) a determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group;
- (b) take all necessary steps for the protection and safety of workers, of members of the public and, when applicable, of patients.

(4) Any legal person responsible for a source to be used for medical exposure shall include in the application for a licence the qualifications in radiation protection of the medical practitioners who are to be so designated by name or by qualification credentials in the

licence as the only individuals permitted to prescribe medical exposure by means of the authorised source.

15. Responsibilities of licensees

Licensees shall-

- (a) bear the responsibility for establishing and implementing the technical and organisational measures that are needed for ensuring protection and safety for the practices and sources for which they are authorised and for compliance with all applicable requirements of these Regulations;
- (b) notify the Inspectorate of their intentions to introduce modifications to any practice or source for which they are licensed whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modification unless specifically authorised by the inspectorate; and
- (c) ensure that only workers who are designated in the application by name or qualification credentials and authorised by reference in the licence, as having key assignments related to protection and safety, and other workers assigned tasks involving operation or handling of radiation sources which could substantially affect protection and safety are permitted to fulfill such required assignments and tasks.

16. Clearance

Sources, including substances, materials and objects within authorised practices can be cleared from further compliance with the requirements of these regulations provided that they comply with exemption levels specified in the First Schedule or approved by the Board.

PART III

Radiation Protection Performance Requirements (regs 17-21)

17. Justification of practices

(1) No practice shall be authorised unless it-

- (a) 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; and
- (b) the applicant for an authorisation has provided to the Board sufficient information and evidence on the benefits and the harm to support the justification of the practice.

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

- (a) except for justified practices involving medical exposures, 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 the unjustified use of radiation or radioactive substances in

commodities or products such as toys and personal jewellery or adornments; and

- (c) any other practices determined by the Inspectorate as unjustified.

18. Dose limitation

(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 limit specified in the Second Schedule, except in the special circumstances considered in regulation 40.

- (2) Subregulation (1) does not apply to medical exposures from authorised practices.

19. Optimisation of protection and safety

(1) In relation to exposures from any particular source within a practice, radiation safety shall be optimised in order that the magnitude of individual doses, except-

- (a) for therapeutic medical exposures;
- (b) the number of people exposed;
- (c) and the likelihood of incurring exposures,

are kept as low as is reasonably practicable, taking into account, economic and social factors, within the restriction that the dose to individuals delivered by the source shall be subject to dose constraints, as provided for in regulation 20 (2).

(2) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation safety principles to achieve the objective intended in subregulation (1).

20. 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 the Second Schedule or any lower values established by the Board.

(2) In case of any source that can release radioactive substances to the environment, the dose constraints shall be established so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in the Fifth Schedule or any lower values established by the Board.

21. Guidance levels for medical exposure

(1) The 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.

(2) The guidance levels referred to in subregulation (1) shall be established by relevant professional bodies, in consultation with the Board, so as to provide an indication on what

doses are achievable with current good practice for average sized patients.

(3) The guidance levels referred to in subregulation (1) shall be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgments and shall be revised as required by technological and scientific developments.

PART IV

Management Requirements (regs 22-25)

22. Safety culture

Licensees shall establish a management system, commensurate with the size and nature of the authorised activity, which ensures that-

- (a) policies and procedures are established that identify protection and safety as being of 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 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 are established that result in an appropriate flow of information on protection and safety at and between the various levels in the entire organisation of the licensee.

23. Quality assurance

Licensees shall establish quality assurance programmes that provide, as appropriate-

- (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.

24. Human factors

(1) Licensees shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgment and according to defined procedures, and are periodically retrained.

(2) Licensees, in cooperation with suppliers, as appropriate, shall follow sound ergonomic principles in 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) Licensees shall provide appropriate equipment, safety systems and procedures which-

- (a) reduce, as far as is practicable, the possibility of human errors leading to unplanned

exposure of any person;

- (b) provide means to detect human errors and correct or compensate for them; and
- (c) facilitate intervention in the event of an accident.

25. Qualified radiation safety experts

(1) Licensees shall arrange for qualified radiation safety experts to be identified and made available for providing advice on the observance of these Regulations.

(2) The qualifications of the radiation safety experts shall include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the authorised practices or sources within a practice.

(3) Licensees shall keep the Inspectorate informed of the arrangements made with respect to subregulations (1) and (2).

PART V

Verification of Protection and Safety (regs 26-28)

26. Safety assessment

Safety assessments related to protection and safety measures for sources within practices shall be made by licensees at different stages, including location, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning, as appropriate, in order-

- (a) to identify the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;
- (b) to determine the expected magnitudes of normal exposures;
- (c) to estimate the probabilities and the magnitudes of potential exposures; and
- (d) to assess the quality and extent of the protection and safety provisions.

27. Monitoring and verification of compliance

(1) Monitoring and measurements of the parameters necessary for verification of compliance with the requirements of these Regulations and the licence shall be conducted by licensees.

(2) For the purposes of monitoring and verification of compliance in terms of subregulation (1), suitable equipment shall be provided and verification procedures introduced by licensees.

(3) The equipment referred to in subregulation (2) shall be properly maintained and tested and shall be calibrated at appropriate intervals with reference to standards traceable to national or international standards.

28. Records

Records shall be maintained by licensees of the results of monitoring and verification of

compliance, including records of the tests and calibrations carried out in accordance with the requirements of these Regulations.

PART VI
Occupational Exposure Protection (regs 29-30)

29. General responsibilities

(1) Licensees and employers of workers who are engaged in activities that involve or could involve occupational exposure shall be responsible for the protection of these workers against any occupational exposure which is not excluded from these Regulations.

(2) Licensees and employers shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that-

- (a) occupational exposures are limited as specified in the Fourth Schedule;
- (b) radiation safety is optimised in accordance with regulations 20 and 21;
- (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 needed to achieve adequate radiation safety by an effective implementation of these Regulations; and
- (g) necessary conditions are provided and arrangements are made to promote a safety culture in the work force and achieve adequate training of workers on radiation safety matters.

(3) If workers are to be engaged in work that involves or could involve a source which is not under the control of their employer, the licensee 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 such workers with protective measures and safety provisions which are at least as good as those provided for employees of the licensee; and
- (c) make dosimetry 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) Licensees 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) Licensees 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 of sources. In particular, licensees and employers shall ensure that workers-

- (a) follow any applicable rules and procedures for protection and safety;
- (b) properly use the monitoring devices and the protective equipment and clothing provided;
- (c) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of these Regulations; and
- (d) promptly report to the licensee and employer any circumstances that could adversely affect safety conditions or the requirements of these regulations.

(6) Licensees and employers shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of these Regulations, and shall take appropriate remedial actions.

30. Conditions of service

(1) 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 licensee or employer that it is desirable to notify the employer of pregnancy.

(3) After a female worker has, in terms of subregulation (2), notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection which is required for members of the public, as provided for in the Second Schedule.

(4) A notification of pregnancy in terms of subregulation (2) shall not be considered a reason to exclude a female worker 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 Inspectorate or in the framework of the health surveillance programme required by these Regulations, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

(6) No person under the age of 16 years shall be subjected to occupational exposure.

(7) No person under the age of 18 years shall be allowed to work in a controlled area unless such person is under supervision or training.

PART VII
Classification of Areas (regs 31-38)

31. Controlled areas and supervised areas

(1) Licensees shall designate as a controlled area any area in which specific protective measures or safety provisions are required, for-

- (a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
- (b) preventing or limiting the extent of potential exposures.

(2) Licensees shall-

- (a) 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;
- (b) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
- (c) 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;
- (d) display a warning symbol, recommended by the International Organization for Standardization (ISO), and appropriate instructions at access points and other appropriate locations within controlled areas;
- (e) establish occupational protection and safety measures, including local rules and procedures that are appropriate for controlled areas;
- (f) 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
- (g) provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.

(3) Licensees 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.

(4) Licensees shall delineate and identify the supervised areas by appropriate means, taking into account the nature and extent of radiation hazards in those areas.

(5) Licensees 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.

32. Local rules and supervision

(1) Licensees and employers shall, in consultation with workers, through their representatives, if appropriate-

- (a) establish, in writing, in a language comprehensible to the workers and others, such rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;
- (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 any such level is exceeded;
- (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; and
- (d) when required by the Inspectorate, designate a qualified radiation safety expert as Radiation Safety Officer.

(2) Employers and licensees 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.

33. Personal protective equipment

Licensees and employers shall-

- (a) 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;
- (b) if necessary, ensure that workers are provided with suitable and adequate personal

protective equipment, including as appropriate-

- (i) protective clothing,
 - (ii) protective respiratory equipment with information on its protection characteristics and instructions on its proper use, and
 - (iii) protective aprons and gloves and organ shields;
- (c) 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; and
- (d) take into account the following factors when assigning personal protective equipment for a given task-
- (i) medical fitness to sustain possible extra physical effort while using the protective equipment, and,
 - (ii) additional work time or inconvenience or additional non-radiological risks associated with the use of the protective equipment.

34. Exposure assessment

(1) Licensees and employers shall arrange for the assessment of the occupational exposure of workers and shall ensure that adequate arrangements are made with appropriate dosimetry services under an adequate quality assurance programme.

(2) For any worker who is normally employed in a controlled area, individual monitoring shall be undertaken where this is feasible.

(3) In cases where individual monitoring is not feasible, the occupational exposure of the workers shall be assessed on the basis of the results of monitoring of the workplace and of information on the locations and duration of exposure of the workers.

(4) For any worker who is normally employed in a supervised area or who enters a controlled area only occasionally, the occupational exposure of the worker shall be assessed, but the assessment may be on the basis of the results of monitoring of the workplace or of individual monitoring.

(5) The nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

(6) Licensees 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.

35. Monitoring of workplace

(1) Licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the

nature of and the risks associated with the source.

- (2) The nature and frequency of monitoring of workplaces shall-
 - (a) be sufficient to enable-
 - (i) the evaluation of the radiological conditions in all workplaces,
 - (ii) the assessment of the exposure of workers in controlled areas and supervised areas, and
 - (iii) the review of the classification of controlled and supervised areas; and
 - (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 actions to be taken if they are exceeded.

(4) Licensees shall keep appropriate records of the findings of the workplace monitoring programme, which shall be made available to workers, where appropriate through their representatives.

36. Health surveillance

Employers and licensees shall, in accordance with the rules established by the Inspectorate, make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks.

37. Records of worker exposure

- (1) Employers and licensees shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under regulation 34.
- (2) The records of exposure referred to in subregulation (1) 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) doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal conditions.

(3) Employers and licensees shall-

- (a) provide for access by workers to information in their own exposure records and workplace monitoring; and
- (b) upon request by the Inspectorate or other authorised 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.

(4) Exposure records for each worker shall be retained by the licensees and employers, or by the Inspectorate in case the licensees and employers cease their activities.

(5) The records referred to in subregulation (4) shall be preserved at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure.

38. 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, the licensee shall not make any such temporary change without approval of the Inspectorate.

(2) The application submitted by the licensee 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 the requirements of these regulations; and
- (b) 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) Any temporary change in a dose limitation requirement of these regulations shall be limited to specified work areas and shall be in accordance with the time and dose limitations for special circumstances specified in the Fourth Schedule.

PART VIII

Medical Exposure Protection (regs 39-47)

39. Responsibility of licensee

(1) Licensees 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 needed, as well as other

health professionals that have appropriate training and are adequately experienced to 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 and brachytherapy), 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 in the care, support or comfort of patients be constrained as specified in the Fourth Schedule; and
- (f) training of personnel is carried out according to criteria approved by the Inspectorate.

(2) Licensees shall to the extent practicable ensure that for diagnostic uses of radiation, that imaging and quality assurance requirements of these regulations are fulfilled with the advice of a qualified expert in radio diagnostic physics, nuclear medicine physics and radio-pharmacy in the compounding of radio-pharmaceuticals, as appropriate.

(3) Medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with these Regulations with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

40. 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 is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined 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 is prohibited 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 is prohibited unless it is-
 - (a) in accordance with the provisions of the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO); and
 - (b) subject to the advice of the licensee's Ethical Review Committee (ERC) and to any other applicable laws.

41. Optimisation of protection for medical exposures

In addition to satisfying the general requirements for optimisation of radiation safety

specified in other parts of these Regulations, licensees, in cooperation with suppliers where appropriate, shall satisfy the prescriptive design and operational requirements specified in the Third Schedule.

42. Calibration, clinical dosimetry and quality assurance for medical exposures

(1) Licensees shall ensure that-

- (a) the calibration of sources used for medical exposure is traceable to a standards dosimetry laboratory;
- (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, as well as at regular intervals established or approved by the Inspectorate.

(2) Licensees 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 possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

43. 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 subjected to individual dose constraints established on a case-by-case basis by the Ethical Review Committee of a practice or other institutional body assigned a similar function.

(2) Licensees shall constrain any dose to individuals incurred while voluntarily helping in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in the Fourth Schedule.

44. Guidance levels

(1) Licensees shall ensure that guidance levels for medical exposure, determined as specified in regulation 21, are revised as technology improves and are used as guidance by medical practitioners, in order that-

- (a) corrective actions are taken as necessary if 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; and
- (b) reviews are considered if doses or activities exceed the guidance levels, as an input to ensuring optimised protection of patients and maintaining appropriate levels of good practice.

(2) In the transition period while guidance levels for medical exposure are being determined as specified in regulation 21, licensees shall ensure that the performance of diagnostic radiology and nuclear medicine equipment is assessed on the basis of comparison with the guidance levels provided in the Fourth Schedule.

45. Maximum activity for patients in therapy on discharge from hospital

(1) In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level set out in the Fourth Schedule.

(2) Written instructions to the patient referred to in subregulation (1) and who has been discharged from hospital in accordance with that subregulation concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

46. Investigation of accidental medical exposures

(1) Licensees shall promptly investigate any of the following incidents-

- (a) any 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 values prescribed by the medical practitioner;
- (b) any diagnostic exposure substantially greater than that intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
- (c) any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

(2) Licensees shall, with respect to any investigation required above-

- (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 incident;
- (c) implement all the corrective measures that are under their own responsibility;
- (d) notify the Inspectorate by telephone or facsimile as soon as practicable, but not later than 12 hours after discovery of any incident which has the potential for, or has

resulted in, serious injury or death of a patient, or which involves more than one patient;

- (e) submit to the Inspectorate, within 30 days after discovery of the incident, a written report which states the cause of the incident and includes information on the doses, corrective measures and any other relevant information; and
- (f) inform the patient and his or her doctor about the incident.

47. Records to be kept

Licensees shall keep and make available, 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.

PART IX ***Public Exposure Protection (regs 48-53)***

48. Responsibility for practice or source

(1) Licensees 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 is exempted from the requirements of the regulations.

(2) Licensees shall be responsible, 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 the Second Schedule;
- (c) measures for ensuring the safety 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 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; and

- (g) up-to-date and accurate records of surveillance and monitoring.

49. Control of visitors

Licensees 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 so as 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 be maintained and that appropriate signs be posted in such areas.

50. Sources of external irradiation

Licensees 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 Inspectorate;
- (b) specific dose constraints for the operation of such a source are established to the satisfaction of the Inspectorate; and
- (c) shielding and other protective measures that are optimised in accordance with the requirements of these Regulations are provided as appropriate for restricting public exposure to the satisfaction of the Inspectorate.

51. Radioactive contamination in enclosed spaces

Licensees 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 spread of contamination in areas accessible to the public.

52. Monitoring public exposure

Licensees shall, as appropriate-

- (a) establish and carry out a monitoring programme, of a magnitude and complexity commensurate with the type of and risks associated with the sources under their responsibility, which is sufficient to ensure that the requirements of these Regulations are satisfied and to assess the exposure of members of the public from sources of external irradiation or 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 Inspectorate at approved intervals and promptly inform the Inspectorate of any abnormal results which lead or could lead to an increase of public exposure.

53. Consumer products

(1) Consumer products capable of causing exposure to radiation shall not be supplied to members of the public unless-

- (a) such exposure is excluded from these Regulations under regulation 5;
- (b) such products meet the exemption requirements specified in regulation 13 or have otherwise been exempted by the Board; or
- (c) such products are authorised by the Board for use by members of the public.

(2) Legal persons who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the Board for authorisation to distribute, a copy of the licence or authorisation issued by the country of manufacture or origin which authorises distribution to members of the public in that country.

(3) Legal persons who import consumer products for sale and distribution as exempt products shall ensure that-

- (a) legible labels are visibly and firmly affixed to each consumer product and its package, stating, in the local language, that-
 - (i) the product contains radioactive material; and
 - (ii) the sale of the product to the public has been authorised by the relevant Board; and
- (b) basic information and instructions on the precautions of use and disposal of the product, written in the local language, are made available with the product.

PART X

Requirements for the Safety of Sources (regs 54-57)

54. Ensuring safety of sources

(1) Licensees shall ensure the safety of the sources under their responsibility, from the moment of their acquisition throughout their entire operational life and up to their final disposal.

(2) For this purpose, licensees shall ensure that a multilayer system of provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved is applied to the sources under their responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of-

- (a) preventing accidents that may cause exposure;

- (b) mitigating the consequences of any such accident should it occur; and
- (c) restoring sources to safe conditions after any such accident.

(3) Licensees shall ensure that, as applicable and appropriate, the location, design, construction and assembly, commissioning, operation and maintenance, and decommissioning of sources are based on sound engineering practice which-

- (a) takes into account approved codes, standards as well as 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.

55. Design and procurement of sources

Licensees, in specific cooperation with suppliers whenever appropriate, shall-

- (a) ensure, on procurement of new equipment containing radiation generators or sources, that such equipment and sources conform to applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or equivalent standards as may be approved by the Inspectorate except for International Electrotechnical Commission and ISO standards, other standards applied in the country of origin of such equipment and sources must have the specific approval of the Inspectorate;
- (b) ensure that sources and equipment are tested to demonstrate compliance with 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 26.
- (d) ensure that performance specifications and operating and maintenance instructions, including protection and safety instructions, are provided in a major world language as approved by the Inspectorate and in compliance with the relevant International Electrotechnical Commission and ISO standards with regard to accompanying documents, and that this information is translated into the official local language when appropriate;
- (e) ensure that, where practicable, the operating terminology and operating values are displayed on operating consoles or other control systems in an appropriate language as specified in paragraph (d) above.

56. Accountability and security of sources

- (1) Licensees shall maintain an accountability system that includes records of-
 - (a) the location and description of each source for which they are responsible; and
 - (b) the activity and form of each radioactive substance for which they are responsible.
- (2) Licensees 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 Inspectorate of information regarding any de-controlled, 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.

57. Feedback of operating experience

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

(2) In addition, and where applicable, licensees shall make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer from licensees to suppliers of any information on the use, maintenance, disposal and malfunctioning that can be relevant for future improvements in the design and construction of the sources they have supplied.

PART XI

Radioactive Waste Management Requirements (regs 58-73)

58. Scope

These Regulations shall apply 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.

59. 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, as indicated in the Sixth Schedule.

60. Management of radioactive waste

Licensees 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 to this aim, 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 maintain records of such activities;
- (c) ensuring that disposal of radioactive waste is not unnecessarily delayed; and
- (d) reporting to the Inspectorate required information at intervals as may be specified in the licence.

61. Application of licence

No person or organisation shall generate, keep or manage radioactive waste except in accordance with a licence issued by the Board under the terms of Regulation 14.

62. Control of radioactive waste generation

Licensees 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 needed;
- (c) using short-lived radionuclides where possible;
- (d) minimising the amount of waste by preventing unnecessary contamination of materials; and
- (e) maintaining consistency with the management strategy and systems.

63. Segregation, collection and characterisation of radioactive waste

Licensees shall ensure that waste is segregated at the point of origin in accordance with the national waste management strategy as may be directed by the Inspectorate.

64. Treatment and conditioning of radioactive waste

Licensees shall ensure that the treatment and conditioning of radioactive waste is carried out in accordance with the national waste management strategy where appropriate, and, in particular, meet any waste acceptance criteria established by the Inspectorate.

65. Discharge or release of radioactive substances to the environment

(1) Licensees 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 Board as specified in regulation 13 of these Regulations.

(2) Licensees, 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 group of population;
- (c) report discharges to the Inspectorate at such intervals as may be specified in the licence; and
- (d) report promptly to the Inspectorate any discharges exceeding the authorised limits.

(3) Whether activity is released within the clearance levels established by the inspectorate or radioactive waste is discharged under licence, licensees shall consider the non-radiological hazards of the released waste and shall comply with the requirements of any other regulations concerning those hazards.

66. Disposal of radioactive waste

When 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 Inspectorate its proposals for disposal of the waste and ensure that the criteria set by the Inspectorate for acceptance of the waste at any repository or any national waste management organisation are met.

67. Transport of radioactive waste

Licensees 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).

68. Waste storage

Radioactive waste shall be stored in such a way as to protect human health and the environment, and, in particular, shall not be stored in the vicinity of corrosive, explosive or easily flammable materials.

69. Recycle and reuse of radioactive material

Licensees using radioactive material shall-

- (a) not dismantle any sealed source;
- (b) before declaring the radioactive material as waste, consider whether the licensee or any other organisation can make use of the material; and
- (c) if appropriate, transfer the material after confirming with the Inspectorate that the organisation to which it is transferred has the necessary authorisation to hold that material.

70. Return of sealed sources to the manufacturer

(1) When purchasing sealed sources, licensees shall make contractual arrangements for the return of the spent sealed sources to the manufacturer or supplier.

(2) Any person or organisation that intends to import a sealed source containing radioactive material which 10 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, provided that the recipient seeks to return the source to the supplier not later than 15 years after purchase; and
- (b) submit to the Inspectorate a copy of relevant parts of the contract or acceptance document and obtain its written agreement prior to entering the contract or accepting the source.

(3) Any person or organisation that intends to purchase, lease or rent generators of radionuclides, or if such generators are donated, must 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 storage.

71. Quality assurance programmes

(1) Licensees shall submit a Quality Assurance Programme to the Board for approval as part of the licence application covering all aspects of the radioactive waste management, especially those features important to safety such as facilities, activities and waste and 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) disposal facility or arrangements as outlined in regulation 70; and
- (i) detailed facility closure plan.

72. Physical protection

The licensee shall ensure that all necessary means are taken to prevent unauthorised

persons gaining access to the waste.

73. Records and reports

(1) Licensees shall report to the Inspectorate an up-to-date inventory record of radioactive waste in their possession.

(2) The inventory referred to in subregulation (1) shall be in such form and contain such details as the Inspectorate may require.

(3) Licensees shall send to the Inspectorate before 15th 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 Inspectorate may require.

(4) The Inspectorate has the right to inspect and review the records of a licensee at any time.

(5) If any radioactive waste has been lost, stolen or is missing, the licensee shall inform the Inspectorate not later than 24 hours of the occurrence or discovery.

(6) If radioactive material has been released to the environment above the clearance criteria established by the Board or if waste has been discharged above the limits of licence issued by the Board, the licensee shall inform the inspectorate not later than 24 hours of the occurrence or discovery.

(7) The reports made under subregulations (5) and (6) shall be followed by written reports submitted to the Inspectorate within 21 days concerning the matter and the actions which have been taken.

PART XII

Transport Requirements (regs 74-94)

74. Exemptions

The following materials are exempted from 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) natural 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 10 times the exempt values referred to in regulation 13.

75. Application of regulations

The provisions of these Regulations 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 defined in regulation 76 of these Regulations, unless specifically excluded from the scope of these Regulations in regulation 74.

76. 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 the Sixth Schedule 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 as follows-

$$x_m = \frac{1}{\sum_i \frac{f(i)}{X(i)}}$$

where-

- (a) $f(i)$ is the fraction of activity or activity concentration of radionuclide (i) in the mixture;
- (b) $X(i)$ is the appropriate value of the activity concentration for exempt material or the activity limit for an exempt consignment as appropriate for the radionuclide (i); and
- (c) X_m is the derived value of the activity concentration for exempt material or the activity limit for an exempt consignment in the case of a mixture.

(3) For unknown radionuclides or mixtures the more restrictive values of activity concentration for exempt material or activity limits for exempt consignments specified in the Sixth Schedule shall be used.

77. Material characterisation

(1) A1 and A2 values for individual radionuclides as provided 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 A1 or A2 value for the material shall be derived as follows-

$$A_m = \frac{1}{\sum_i \frac{g(i)}{A(i)}}$$

where,

- (a) $g(i)$ is the fraction of the activity of radionuclides in the mixture;
 - (b) $A(i)$ is the appropriate value of A_1 or A_2 for the radionuclide (i); and
 - (e) A_m is the derived value of A_1 or A_2 for the material containing a mixture of radionuclides.
- (3) For unknown radionuclides or mixtures the more restrictive A_1 or A_2 values as specified in the Sixth Schedule 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 the Seventh Schedule; 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 in these Regulations as LSA-I, LSA-II or LSA-III), surface contaminated objects, (referred to in these Regulations 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.

78. Unpackaged shipments

Some radioactive materials may be transported unpackaged 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 will be no escape of the radioactive contents from the conveyance nor will 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 10 times the levels specified in regulation 81;
- (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 81, measures shall be taken to ensure that radioactive material is not released into the conveyance.

79. Packaging

(1) Radioactive material or items which require packaging for transport shall 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 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 81(1)(b); and
- (d) any labels required for its previous use are no longer visible and all other requirements for excepted packages in these regulations are met.

80. Mixed contents

A package shall not contain any other items except documents that are necessary for the use of radioactive material.

81. Contamination

(1) 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 shall be kept as low as practicable and shall not exceed the following limits-

- (a) beta, gamma and low toxicity alpha emitters 4Bq/cm²; and

(b) all other alpha emitters 0.4Bq/cm².

(2) Fixed contamination levels are limited by radiation level limits for packages and conveyances, and by requirements for decontamination as specified in regulation 92.

82. Maximum radiation levels

(1) Radiation level limits apply to the following items and materials to be packaged for transport-

- (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 mSv/h;
- (b) the quantity of LSA material or SCO in a single industrial package (type IP-1, IP-2 or IP-3) shall be so restricted that the external radiation level at 3m from the unshielded material or object or objects does not exceed 10mSv/h;

(2) Radiation level limits apply to packages or overpacks as follows-

- (a) the radiation level limit for excepted packages is 5mSv/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 2mSv/h at any point on any external surface of the package or overpack and, in addition, shall not exceed 0.1 mSv/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 mSv/h and may only exceed 2mSv/h provided that specific vehicle and shipment conditions are met as specified in regulation 85;
- (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 in 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 specified in regulation 83.

83. Transport index

(1) To provide control over radiation exposure during transport, a transport index (TI), based on radiation levels, is assigned to a package, overpack or freight container or to unpackaged LSA-I or SCO-I as follows-

- (a) 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-1;

- (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) above 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) above shall be rounded up to the first decimal place (e.g. 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 10 shall be transported only under exclusive use.

(4) The TI limits for freight containers and conveyances not under exclusive use shall be as provided in the Sixth Schedule.

(5) There is no limit on the sum of transport indexes for consignments of LSA-I material.

84. Marking

(1) Where unpackaged LSA-I or SCO-I material is contained in receptacles or packing material and shipped under conditions specified in regulation 81, 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 an 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 from the Seventh Schedule table I preceded by the letters "UN" and for each package other than excepted packages the proper shipping name

as identified in the Seventh Schedule shall also be included with this 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 Inspectorate 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 shown in the Seventh Schedule.

85. Labelling requirements

(1) Labelling 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, I- YELLOW or HI- YELLOW in accordance with the conditions specified in the Seventh Schedule 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;
- (b) the transport index shall be determined following the procedures specified in regulation 83.

(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 labelling.

(5) All other packages, overpacks and freight containers shall bear labels which conform to the models in the Seventh Schedule.

(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 the Seventh Schedule, in which case no placarding shall be required.

86. 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 provided for in the Sixth Schedule,
 - (ii) for mixtures of radionuclides, the most restrictive nuclides must 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 necessary; the name of the radionuclide is not necessary,
- (b) the maximum activity of the radioactive contents during transport expressed in units of becquerels (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 subparagraphs (a) and (b), respectively, totalled 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.

87. Loading and segregation

- (1) The following conditions for loading and segregation apply to all consignments-
 - (a) 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 apply-
 - (a) the consignment shall not include any package or overpack having a transport index greater than 10;

- (b) the loading of freight containers and the accumulation of packages, overpacks and freight containers aboard a single conveyance shall be so limited 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 are controlled as follows-

For road and rail consignments under exclusive use the radiation level shall not exceed-

- (a) 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 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 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.

88. Placarding

- (1) Consignments consisting solely of excepted packages do not require placarding.
- (2) Where other packages are involved the following requirements for placarding apply-
 - (a) large freight containers carrying packages other than excepted packages, and tanks shall bear four placards which conform with the model given in the Seventh Schedule;
 - (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) any 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 the Seventh Schedule.
- (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 the Seventh Schedule, preceded by the letters "UN" and against the white background; or

(b) on the placard shown in the Seventh Schedule.

(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 the Seventh Schedule, or carrying consignments under exclusive use, shall display the placard shown in the Seventh schedule 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 rearwall 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 in the Seventh Schedule may be reduced to 100 mm.

(9) Any placards which do not relate to the contents shall be removed.

89. Transport documents

(1) Transport documentation, to accompany the consignment, shall include particulars of the consignment, a consignor's declaration and information for carriers.

(2) The consignor shall 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 the Seventh Schedule;

(b) the United Nations Class number "7";

(c) the United Nations number assigned to the material as specified in the Sixth

Schedule, 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 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.e. 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:

Provided that 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;
- (l) where a consignment is required to be shipped under exclusive use, the statement "EXCLUSIVE USE SHIPMENT"; and
- (m) for LSA-II, LSA-III, SCO-I and SCO-II, the total activity of the consignment as a multiple of A2.

(3) The consignor shall include in the transport documents a declaration in the following terms or in terms having an equivalent meaning-

"I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packed, marked and labelled, and are in all respects in proper condition for transport by (insert mode(s) of transport involved) according to the applicable international and national governmental regulations."

(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 regulation (7) shall be in the languages deemed necessary by the carrier or the authorities concerned, and shall include at least the following points-

- (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)(b) available to the carrier(s) before loading and unloading.

90. Storage and dispatch

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

- (a) segregation during storage in transit is required from other dangerous goods, and from persons and undeveloped photographic films and plates:

Provided that its average surface heat flux does not exceed 15W/m^2 and that the immediately surrounding cargo is not in sacks or bags, a package or overpack may be stored among packaged general cargo without any special stowage provisions except as may be specifically required by the Inspectorate in an applicable approval certificate; and

- (b) any provisions in the certificates and any relevant perusal and pre-shipment requirements shall be observed.

91. Carriage

(1) Category II-YELLOW or III-YELLOW packages or overpacks shall not be carried in compartments occupied by passengers, except those exclusively reserved for couriers specially authorised to accompany such packages or overpacks.

(2) For transport by road, 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.

92. Decontamination

(1) 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 previously stated contamination limits or which show a radiation level in excess of 5 $\mu\text{Sv/h}$ 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 previously stated contamination limits.

(4) The radiation level resulting from the fixed contamination on surfaces after decontamination shall be less than 5 $\mu\text{Sv/h}$.

93. Notification of Inspectorate

(1) Before the first shipment of any package requiring Inspectorate 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 Inspectorate, nor is the Inspectorate required to make such acknowledgement of receipt of the certificate.

(3) The following information shall be notified to an authority of each country through which the consignment is to be transported prior to the commencement of the shipment, and at least seven days in advance-

- (a) Type C packages containing radioactive material with an activity greater than 3000 A_1 or 3000 A_2 , as appropriate, or 1000 TBq, whichever is the lower;
- (b) Type B(U) packages containing radioactive material with an activity greater than 3000 A_1 or 3000 A_2 , 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 special form 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 is not required to send a separate notification if the required information

has been included in the application for shipment approval.

94. Other provisions

(1) For radioactive material having subsidiary risks and for transport of radioactive material with other dangerous goods, the relevant transport regulation for dangerous goods of each of the countries through or into which the material is to be transported shall apply in addition to these Regulations.

(2) Emergency response provisions, including provisions for damaged and leaking packages, shall be established.

(3) Quality and compliance assurance programmes, which are acceptable to the Inspectorate, based on international, national or other standards shall be established.

(4) Customs operations involving the inspection of the radioactive contents of a package should be carried out only in a place where adequate means of controlling radiation exposure are provided and in the presence of qualified persons.

(5) Any package opened on customs instructions shall, before being forwarded to the consignee, be restored to its original condition.

(6) Where a consignment is undeliverable, the consignment shall be placed in a safe location and the appropriate Inspectorate shall be informed as soon as possible and a request made for instructions on further action.

PART XIII

Requirements for Emergency Intervention (regs 95-98)

95. Responsibilities of licensees

(1) If an authorised practice or source within a practice has a potential for accidents which may provoke unplanned exposure of any person, the licensee shall ensure that an emergency plan appropriate for the source and its associated risks is prepared and is kept operational.

(2) If an authorised source is involved in an accident or incident, the licensee 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 set forth in the licence application and emergency plans approved by the Inspectorate, or as might otherwise be required by the inspectorate to protect against, mitigate or remediate a hazardous situation involving the licensed sources.

96. Licensee emergency response planning requirements

(1) Each licensee responsible for sources for which prompt intervention may be required shall ensure that there is an emergency plan which 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 referred to in subregulation (1) shall-

- (a) characterise the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from

operating experience and from 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 determining the need for protective actions;
- (f) allocate responsibilities for notifying the relevant authorities and for 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 personnel involved in implementing emergency plans to be rehearsed at suitable intervals in conjunction with designated authorities; and
- (i) provide for periodic review and updating of the plan.

97. Implementation of intervention

(1) The licensee 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 interventions shall be optimised so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) Licensees shall promptly notify the Inspectorate when an accidental situation requiring intervention has arisen or is expected to arise and shall keep them 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 that are expected to be incurred.

98. Intervention doses

(1) No worker undertaking an intervention shall be exposed in excess of the maximum single year dose limit for occupational exposure specified in the Second Schedule-

- (a) for the purpose of saving life or preventing serious injury; or
- (b) if undertaking actions to prevent the development of catastrophic conditions.

(2) 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 actions that may be required.

(3) 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 in these Regulations.

(4) 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 intervention.

(5) When the intervention has ended, the doses received and the consequent health risk shall be communicated to the workers involved.

(6) Workers shall not be precluded from incurring further occupational exposure because of doses received in an emergency exposure situation.

(7) Medical advice shall be obtained by the licensee before the exposure under subregulation (6) is incurred if a worker who has undergone an emergency exposure receives a dose exceeding 10 times the maximum single year dose limit, or at the worker's request.

PART XIV

Use of International Protection and Safety Guides (reg 99)

99. Adoption of prescriptive recommendations

(1) Applicants for authorisations may propose to adopt prescriptive recommendations regarding facilities and equipment, procedures, qualifications and training of personnel, maintenance and quality assurance contained in safety and good practice publications issued by the International Atomic Energy Agency, World Health Organization, Pan American Health Organization or other international bodies as methods by which performance requirements in these Regulations shall be met.

(2) In the instances referred to in subregulation (1), the applicant shall -

- (a) identify the document(s); and
- (b) identify both the particular recommendation or part of the document being adopted and the performance requirement in these Regulations it is intended to implement.

(3) The applicant for licence may adopt by reference any of the documents listed under references to the extent that they are relevant to the particular practice.

(4) Applicants may propose to use other relevant documents which are not listed under references provided that the documents are clearly identified and copies of the relevant parts of the documents are included with the application.

PART XV

General Provisions (regs 100-102)

100. Forms

The forms to be used in the issuance of licences, permits and certificates under section 23 of the Act shall be as set out in the Eighth Schedule.

101. Fees

The fees to be charged for the issuance of licences under section 23 of the Act, permits or certificates and charges for the services rendered by the inspectorate shall be as set out in the Ninth Schedule.

102. Penalties

(1) Any person who contravenes regulations 7, 15, 17, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 33, 34, 35, 36, 37, 57, 60, 63, 71, 74, 86, 91, 92, 97, or 98 or who fails to comply with any order, requirement or condition lawfully imposed on him or her by virtue of any such regulation, shall be guilty of an offence and liable to a fine not exceeding P25,000, or to imprisonment for a term not exceeding six months, or to both.

(2) Any person who contravenes regulations 38, 47, 48, 49, 50, 51, 52, 53, 54, 61, 71, 72, 73, 79, 93, 95 or 97 shall be guilty of an offence and liable to a fine not exceeding P100,000, or to imprisonment for a term not exceeding two years, or to both.

(3) Any person who contravenes regulations 39, 40, 41, 42, 43, 44, 45, 46, 65, 66, 67, 68, or 69 shall be guilty of an offence and liable to a fine not exceeding P500,000, or to imprisonment for a term not exceeding 10 years, or to both.

(4) Any person who deliberately exposes himself or herself or his or her monitoring equipment shall be guilty of an offence.

(5) Any person who is guilty of an offence under these Regulations for which no penalty is otherwise provided shall be liable to a fine not exceeding P25,000, or to imprisonment for a term not exceeding six months, or to both.

FIRST SCHEDULE EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

(regs 13 (1)(a) and (b), (3)(a) and 16)

<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>	<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>
H-3	1 x 10 ⁶	1 x 10 ⁹	Fe-52	1 x 10 ¹	1 x 10 ⁶
Be-7	1 x 10 ³	1 x 10 ⁷	Fe-55	1 x 10 ⁴	1 x 10 ⁶
C-14	1 x 10 ⁴	1 x 10 ⁷	Fe-59	1 x 10 ¹	1 x 10 ⁶
O-15	1 x 10 ²	1 x 10 ⁹	Co-55	1 x 10 ¹	1 x 10 ⁶
F-18	1 x 10 ¹	1 x 10 ⁶	Co-56	1 x 10 ¹	1 x 10 ⁵
Na-22	1 x 10 ¹	1 x 10 ⁶	Co-57	1 x 10 ²	1 x 10 ⁶
Na-24	1 x 10 ¹	1 x 10 ⁵	Co-58	1 x 10 ¹	1 x 10 ⁶
Si-31	1 x 10 ³	1 x 10 ⁶	Co-58m	1 x 10 ⁴	1 x 10 ⁷
P-32	1 x 10 ³	1 x 10 ⁵	Co-60	1 x 10 ¹	1 x 10 ⁵
P-33	1 x 10 ⁵	1 x 10 ⁸	Co-60m	1 x 10 ³	1 x 10 ⁶
S-35	1 x 10 ⁵	1 x 10 ⁸	Co-61	1 x 10 ²	1 x 10 ⁶
Cl-36	1 x 10 ¹	1 x 10 ⁶	Co-62m	1 x 10 ¹	1 x 10 ⁵
Cl-38	1 x 10 ¹	1 x 10 ⁵	Ni-59	1 x 10 ⁴	1 x 10 ⁸
Ar-37	1 x 10 ⁶	1 x 10 ⁸	Ni-63	1 x 10 ⁵	1 x 10 ⁸
Ar-41	1 x 10 ²	1 x 10 ⁹	Ni-65	1 x 10 ¹	1 x 10 ⁶
K-40	1 x 10 ²	1 x 10 ⁶	Cu-64	1 x 10 ²	1 x 10 ⁶
K-42	1 x 10 ²	1 x 10 ⁶	Zn-65	1 x 10 ¹	1 x 10 ⁶
K-43	1 x 10 ¹	1 x 10 ⁶	Zn-69	1 x 10 ⁴	1 x 10 ⁶
Ca-45	1 x 10 ⁴	1 x 10 ⁷	Zn-69m	1 x 10 ²	1 x 10 ⁶
Ca-47	1 x 10 ¹	1 x 10 ⁶	Ga-72	1 x 10 ¹	1 x 10 ⁵
Sc-46	1 x 10 ¹	1 x 10 ⁶	Ge-71	1 x 10 ⁴	1 x 10 ⁸
Sc-47	1 x 10 ²	1 x 10 ⁶	As-73	1 x 10 ³	1 x 10 ⁷
Sc-48	1 x 10 ¹	1 x 10 ⁵	As-74	1 x 10 ¹	1 x 10 ⁶
V-48	1 x 10 ¹	1 x 10 ⁵	As-76	1 x 10 ²	1 x 10 ⁵
Cr-51	1 x 10 ³	1 x 10 ⁷	As-77	1 x 10 ³	1 x 10 ⁶
Mn-51	1 x 10 ¹	1 x 10 ⁵	Se-75	1 x 10 ²	1 x 10 ⁶
Mn-52	1 x 10 ¹	1 x 10 ⁵	Br-82	1 x 10 ¹	1 x 10 ⁶
Mn-52m	1 x 10 ¹	1 x 10 ⁵	Kr-74	1 x 10 ²	1 x 10 ⁹
Mn-53	1 x 10 ⁴	1 x 10 ⁹	Kr-76	1 x 10 ²	1 x 10 ⁹
Mn-54	1 x 10 ¹	1 x 10 ⁶	Kr-77	1 x 10 ²	1 x 10 ⁹
Mn-56	1 x 10 ¹	1 x 10 ⁵	Kr-79	1 x 10 ³	1 x 10 ⁵
Kr-81	1 x 10 ⁴	1 x 10 ⁷	Tc-97	1 x 10 ³	1 x 10 ⁸
Kr-83m	1 x 10 ⁵	1 x 10 ²	Tc-97m	1 x 10 ³	1 x 10 ⁷
Kr-85	1 x 10 ⁵	1 x 10 ⁴	Tc-99	1 x 10 ⁴	1 x 10 ⁷
Kr-85m	1 x 10 ³	1 x 10 ¹⁰	Tc-99m	1 x 10 ²	1 x 10 ⁷
Kr-87	1 x 10 ²	1 x 10 ⁹	Ru-97	1 x 10 ²	1 x 10 ⁷
Kr-88	1 x 10 ²	1 x 10 ⁹	Ru-103	1 x 10 ²	1 x 10 ⁶
Rb-86	1 x 10 ²	1 x 10 ⁵	Ru-105	1 x 10 ¹	1 x 10 ⁶
Sr-85	1 x 10 ²	1 x 10 ⁶	Ru-106 ²	1 x 10 ²	1 x 10 ⁵
Sr-85m	1 x 10 ²	1 x 10 ⁷	Rh-103m	1 x 10 ⁴	1 x 10 ⁸

<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>	<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>
Sr-87m	1 x 10 ²	1 x 10 ⁶	Rh-105	1 x 10 ²	1 x 10 ⁷
Sr-89	1 x 10 ³	1 x 10 ⁶	Pd- 103	1 x 10 ³	1 x 10 ⁸
Sr-90 ²	1 x 10 ²	1 x 10 ⁴	Pd-109	1 x 10 ³	1 x 10 ⁶
Sr-91	1 x 10 ¹	1 x 10 ⁵	Ag-105	1 x 10 ²	1 x 10 ⁶
Sr-92	1 x 10 ¹	1 x 10 ⁶	Ag-110m	1 x 10 ¹	1 x 10 ⁶
Y-90	1 x 10 ³	1 x 10 ⁵	Ag-111	1 x 10 ³	1 x 10 ⁶
Y-91	1 x 10 ³	1 x 10 ⁶	Cd-109	1 x 10 ⁴	1 x 10 ⁶
Y-91m	1 x 10 ²	1 x 10 ⁶	Cd-115	1 x 10 ²	1 x 10 ⁶
Y-92	1 x 10 ²	1 x 10 ⁵	Cd-115m	1 x 10 ³	1 x 10 ⁶
Y-93	1 x 10 ²	1 x 10 ⁵	In-111	1 x 10 ²	1 x 10 ⁶
Zr-93 ^a	1 x 10 ³	1 x 10 ⁷	In-113m	1 x 10 ²	1 x 10 ⁶
Zr-95	1 x 10 ¹	1 x 10 ⁶	In-114m	1 x 10 ²	1 x 10 ⁶
Zr-97 ^a	1 x 10 ¹	1 x 10 ⁵	In-115m	1 x 10 ²	1 x 10 ⁶
Nb-93m	1 x 10 ⁴	1 x 10 ⁷	Sn-113	1 x 10 ³	1 x 10 ⁷
Nb-94	1 x 10 ¹	1 x 10 ⁶	Sn-125	1 x 10 ²	1 x 10 ⁵
Nb-95	1 x 10 ¹	1 x 10 ⁶	Sb-122	1 x 10 ²	1 x 10 ⁴
Nb-97	1 x 10 ¹	1 x 10 ⁶	Sb-124	1 x 10 ¹	1 x 10 ⁶
Nb-98	1 x 10 ¹	1 x 10 ⁵	Sb-125	1 x 10 ²	1 x 10 ⁶
Mo-90	1 x 10 ¹	1 x 10 ⁶	Te-123m	1 x 10 ²	1 x 10 ⁷
Mo-93	1 x 10 ³	1 x 10 ⁸	Te-125m	1 x 10 ³	1 x 10 ⁷
Mo-99	1 x 10 ²	1 x 10 ⁶	Te-127	1 x 10 ³	1 x 10 ⁶
Mo-101	1 x 10 ¹	1 x 10 ⁶	Te-127m	1 x 10 ³	1 x 10 ⁷
Tc-96	1 x 10 ¹	1 x 10 ⁶	Te-129	1 x 10 ²	1 x 10 ⁶
Tc-96m	1 x 10 ³	1 x 10 ⁷	Te-129m	1 x 10 ³	1 x 10 ⁶
Te- 131	1 x 10 ²	1 x 10 ⁵	Ce-143	1 x 10 ²	1 x 10 ⁶
Te-131m	1 x 10 ¹	1 x 10 ⁶	Ce-144 ^a	1 x 10 ²	1 x 10 ⁵
Te-132	1 x 10 ²	1 x 10 ⁷	Pr-142	1 x 10 ²	1 x 10 ⁵
Te-133	1 x 10 ¹	1 x 10 ⁵	Pr-143	1 x 10 ⁴	1 x 10 ⁶
Te-133m	1 x 10 ¹	1 x 10 ⁵	Nd-147	1 x 10 ²	1 x 10 ⁶
Te-134	1 x 10 ¹	1 x 10 ⁶	Nd-149	1 x 10 ²	1 x 10 ⁶
I-123	1 x 10 ²	1 x 10 ⁷	Pm-147	1 x 10 ⁴	1 x 10 ⁷
I-125	1 x 10 ³	1 x 10 ⁶	Pm-149	1 x 10 ³	1 x 10 ⁶
I-126	1 x 10 ²	1 x 10 ⁶	Sm-151	1 x 10 ⁴	1 x 10 ⁸
I-129	1 x 10 ²	1 x 10 ⁵	Sm-153	1 x 10 ²	1 x 10 ⁶
I-130	1 x 10 ¹	1 x 10 ⁶	Eu-152	1 x 10 ¹	1 x 10 ⁶
I-131	1 x 10 ²	1 x 10 ⁶	Eu-152m	1 x 10 ²	1 x 10 ⁶
I-132	1 x 10 ¹	1 x 10 ⁵	Eu-154	1 x 10 ¹	1 x 10 ⁶
I-133	1 x 10 ¹	1 x 10 ⁶	Eu-155	1 x 10 ²	1 x 10 ⁷
I-134	1 x 10 ¹	1 x 10 ⁵	Gd-153	1 x 10 ²	1 x 10 ⁷
I-135	1 x 10 ¹	1 x 10 ⁶	Gd-159	1 x 10 ³	1 x 10 ⁶
Xe-131m	1 x 10 ⁴	1 x 10 ⁴	Tb-160	1 x 10 ¹	1 x 10 ⁶
Xe-133	1 x 10 ³	1 x 10 ⁴	Dy-165	1 x 10 ³	1 x 10 ⁶
Xe-135	1 x 10 ³	1 x 10 ¹⁰	Dy-166	1 x 10 ³	1 x 10 ⁶
Cs-129	1 x 10 ²	1 x 10 ⁵	Ho-166	1 x 10 ³	1 x 10 ⁵

<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>	<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>
Cs-135	1 x 10 ⁴	1 x 10 ⁷	Yb-175	1 x 10 ³	1 x 10 ⁷
Cs-136	1 x 10 ¹	1 x 10 ⁵	Lu-177	1 x 10 ³	1 x 10 ⁷
Cs-137 ^a	1 x 10 ¹	1 x 10 ⁴	Hf-181	1 x 10 ¹	1 x 10 ⁶
Cs-138	1 x 10 ¹	1 x 10 ⁴	Ta-182	1 x 10 ¹	1 x 10 ⁴
Ba-131	1 x 10 ²	1 x 10 ⁶	W-181	1 x 10 ³	1 x 10 ⁷
Ba-140 ^o	1 x 10 ¹	1 x 10 ⁵	W-185	1 x 10 ⁴	1 x 10 ⁷
La-140	1 x 10 ¹	1 x 10 ⁵	W-187	1 x 10 ²	1 x 10 ⁶
Ce-139	1 x 10 ²	1 x 10 ⁶	Re-186	1 x 10 ³	1 x 10 ⁶
Ce-141	1 x 10 ²	1 x 10 ⁷	Re-188	1 x 10 ²	1 x 10 ⁵
Os-185	1 x 10 ¹	1 x 10 ⁶	Rn-222 ^a	1 x 10 ¹	1 x 10 ⁸
Os-191	1 x 10 ²	1 x 10 ⁷	Ra-223 ^a	1 x 10 ²	1 x 10 ⁵
Os-191m	1 x 10 ³	1 x 10 ⁷	Ra-224 ^a	1 x 10 ¹	1 x 10 ⁵
Os-193	1 x 10 ³	1 x 10 ⁶	Ra-225	1 x 10 ²	1 x 10 ⁵
Ir-190	1 x 10 ²	1 x 10 ⁶	Ra-226 ^a	1 x 10 ¹	1 x 10 ⁴
Ir-192	1 x 10 ¹	1 x 10 ⁴	Ra-227	1 x 10 ²	1 x 10 ⁶
Ir-194	1 x 10 ¹	1 x 10 ⁵	Ra-228 ^a	1 x 10 ¹	1 x 10 ⁵
Pt-191	1 x 10 ²	1 x 10 ⁶	Ac-228	1 x 10 ¹	1 x 10 ⁶
Pt-193m	1 x 10 ²	1 x 10 ⁷	Th-226 ^a	1 x 10 ³	1 x 10 ⁷
Pt-197	1 x 10 ³	1 x 10 ⁶	Th-227	1 x 10 ¹	1 x 10 ⁴
Pt-197m	1 x 10 ²	1 x 10 ⁶	Th-228 ^a	1 x 10 ⁰	1 x 10 ⁴
Au-198	1 x 10 ²	1 x 10 ⁶	Th-229 ^a	1 x 10 ⁰	1 x 10 ³
Au-199	1 x 10 ²	1 x 10 ⁶	Th-230	1 x 10 ⁰	1 x 10 ⁴
Hg-197	1 x 10 ²	1 x 10 ⁷	Th-231	1 x 10 ³	1 x 10 ⁷
Hg-197m	1 x 10 ²	1 x 10 ⁶	Th-nat	1 x 10 ⁰	1 x 10 ³
Hg-203	1 x 10 ²	1 x 10 ⁵	(incl.Th-232)		
Tl-200	1 x 10 ¹	1 x 10 ⁶	Th-234 ^a	1 x 10 ³	1 x 10 ⁵
Tl-201	1 x 10 ²	1 x 10 ⁶	Pa-230	1 x 10 ¹	1 x 10 ⁶
Tl-202	1 x 10 ²	1 x 10 ⁶	Pa-231	1 x 10 ⁰	1 x 10 ³
Tl-204	1 x 10 ⁴	1 x 10 ⁴	Pa-233	1 x 10 ²	1 x 10 ⁷
Pb-203	1 x 10 ²	1 x 10 ⁶	U-230 ^a	1 x 10 ¹	1 x 10 ⁴
Pb-210 ^a	1 x 10 ¹	1 x 10 ⁴	U-231	1 x 10 ²	1 x 10 ⁷
Pb-212 ^a	1 x 10 ¹	1 x 10 ⁵	U-232 ^a	1 x 10 ⁰	1 x 10 ³
Bi-206	1 x 10 ¹	1 x 10 ⁵	U-233	1 x 10 ¹	1 x 10 ⁴
Bi-207	1 x 10 ¹	1 x 10 ⁶	U-234	1 x 10 ¹	1 x 10 ⁴
Bi-210	1 x 10 ³	1 x 10 ⁶	U-235 ^a	1 x 10 ¹	1 x 10 ⁴
Bi-212 ^a	1 x 10 ¹	1 x 10 ⁵	U-236	1 x 10 ¹	1 x 10 ⁴
Po-203	1 x 10 ¹	1 x 10 ⁶	U-237	1 x 10 ²	1 x 10 ⁶
Po-205	1 x 10 ¹	1 x 10 ⁶	U-238 ^a	1 x 10 ¹	1 x 10 ⁴
Po-207	1 x 10 ¹	1 x 10 ⁶	U-nat	1 x 10 ⁰	1 x 10 ³
Po-210	1 x 10 ¹	1 x 10 ⁴	U-239	1 x 10 ²	1 x 10 ⁶
At-211	1 x 10 ³	1 x 10 ⁷	U-240	1 x 10 ³	1 x 10 ⁷
Rn-220 ^a	1 x 10 ⁴	1 x 10 ⁷	U-240 ^a	1 x 10 ¹	1 x 10 ⁶
Np-237 ^a	1 x 10 ¹	1 x 10 ⁶	Cm-244	1 x 10 ¹	1 x 10 ⁸
Np-239	1 x 10 ²	1 x 10 ⁷	Cm-245	1 x 10 ²	1 x 10 ⁵
Np-240	1 x 10 ³	1 x 10 ⁷	Cm-246	1 x 10 ¹	1 x 10 ⁵
Pu-234	1 x 10 ³	1 x 10 ⁶	Cm-247	1 x 10 ²	1 x 10 ⁵
Pu-235	1 x 10 ²	1 x 10 ⁶	Cm-248	1 x 10 ¹	1 x 10 ⁴
Pu-236	1 x 10 ¹	1 x 10 ⁴	Bk-249	1 x 10 ²	1 x 10 ⁶

<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>	<i>Nuclide</i>	<i>Activity Concentration (Bq/g)</i>	<i>Activity (Bq)</i>
Pu-237	1 x 10 ¹	1 x 10 ⁵	Cf-246	1 x 10 ¹	1 x 10 ⁵
Pu-238	1 x 10 ²	1 x 10 ⁶	Cf-248	1 x 10 ¹	1 x 10 ⁶
Pu-239	1 x 10 ²	1 x 10 ⁷	Cf-249	1 x 10 ³	1 x 10 ⁷
Pu-240	1 x 10 ³	1 x 10 ⁶	Cf-250	1 x 10 ¹	1 x 10 ⁴
Pu-241	1 x 10 ²	1 x 10 ⁶	Cf-251	1 x 10 ⁰	1 x 10 ⁴
Pu-242	1 x 10 ²	1 x 10 ⁶	Cf-252	1 x 10 ⁰	1 x 10 ³
Pu-243	1 x 10 ²	1 x 10 ⁶	Cf-253	1 x 10 ⁰	1 x 10 ⁴
Pu-244	1 x 10 ²	1 x 10 ⁷	Cf-254	1 x 10 ³	1 x 10 ⁷
Am-241	1 x 10 ²	1 x 10 ⁶	Es-253	1 x 10 ⁰	1 x 10 ³
Am-242	1 x 10 ²	1 x 10 ⁵	Es-254		
Am-242m ^a	1 x 10 ¹	1 x 10 ⁶	Es-254m	1 x 10 ³	1 x 10 ³
Am-243 ^a	1 x 10 ²	1 x 10 ⁶	Fm-254	1 x 10 ¹	1 x 10 ⁶
Cm-242	1 x 10 ²	1 x 10 ⁶	Fm-255	1 x 10 ⁰	1 x 10 ³
Cm-243	1 x 10 ⁴	1 x 10 ⁴			

^aParent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

SECOND SCHEDULE DOSE LIMITS FOR EXPOSURES INCURRED FROM PRACTICES

(regs 18(1), 20(1))

1. OCCUPATIONAL DOSE LIMITS

(a) The occupational exposure of any worker shall be so controlled that the following limits are

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not exceeded-

- (i) an effective dose of 20 mSv per year averaged over five consecutive years;
 - (ii) an effective dose of 50 mSv in any single year;
 - (iii) an equivalent dose to the lens of the eye 150 mSv in a year; and
 - (iv) an equivalent dose to the extremities (hands and feet) or the skin of 50mSv in a year.
- (b) For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded-
- (i) an effective dose of 6 mSv in a year;
 - (ii) an equivalent dose to the lens of the eye 50 mSv in a year; and
 - (iii) an equivalent dose to the extremities or the skin of 150 mSv in a year.

2. SPECIAL CIRCUMSTANCES

When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to regulation 40-

- (a) the dose averaging period mentioned in subparagraph (a) of paragraph (1) may exceptionally be up to 10 consecutive years as specified by the Radiation Protection Inspectorate, and the effective dose for any worker shall not exceed 20mSv per year averaged over this period and shall not exceed 50 mSv in any single year, and the circumstances shall be reviewed when the dose accumulated by any worker since the start of the extended averaging period reaches 100 mSv; or
- (b) the temporary change in dose limitation shall be as specified by the Regulatory Authority, but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed five years.

3. DOSE LIMITS FOR THE PUBLIC

The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed the following limits-

- (a) an effective dose of 1 mSv in a year;
- (b) in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year;
- (c) an equivalent dose to the lens of the eye 15 mSv in a year; and
- (d) an equivalent dose to the skin of 50 mSv in a year.

¹ The start of the averaging period shall be coincident with the first day of the relevant annual period starting from the date of entry into force of the regulations, with no retroactive averaging.

INTERNAL EXPOSURE

Internal exposure caused by inhalation or ingestion of radioactive substances shall be estimated in accordance with the methodologies, parameters and values contained in the International Basic

Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No.15 [1], Schedule II.

DOSE LIMITATION FOR COMFORTERS AND VISITORS OF PATIENTS

The dose limits set out in this part shall not apply to comforters or visitors of patients. However the dose of any such comforter or visitor shall be constrained so that it is unlikely that the dose will exceed 5 mSv during the period of the diagnostic examination or treatment. The dose to children visiting patients who have ingested or have been injected radioactive materials shall be similarly constrained to less than 1 mSv.

THIRD SCHEDULE MEDICAL EXPOSURE DESIGN AND OPERATIONAL REQUIREMENTS

(reg 41)

1. Design of sources and equipment

- (a) The requirements for the safety of sources specified in regulations 56 to 59 of these regulations shall apply to sources used in medical exposure where relevant and, in particular, equipment used in medical exposure shall be so designed that-
 - (i) failure of equipment or components can be promptly detected so that any unplanned exposure of patients can be avoided or minimised; and
 - (ii) the risk of delivering unplanned exposure to patients by human error is minimised.
- (b) Licensees, in cooperation with suppliers where relevant or appropriate, shall-
 - (i) ensure that radiation generators, sources and accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information or therapeutic results;
 - (ii) ensure that equipment containing sources for medical exposure conforms to applicable international and national standards;
 - (iii) ensure that performance specifications and operating and maintenance instructions, including radiation safety aspects, are provided in a major world language understandable to the users as well as in the local language;
 - (iv) identify and take all reasonable measures to prevent failures and human errors that could result in unplanned medical exposures, including the establishment of adequate procedures for calibration, quality assurance and operation of diagnostic and therapeutic equipment as well as the selection, training and periodic retraining of suitably qualified personnel;
 - (v) ensure that any radiation emitting equipment is provided with radiation beam control mechanisms, including safety interlocks and clear and fail-safe "on-off " indicators;
 - (vi) ensure that devices are provided to limit the exposure to the area being examined or treated and keep exposure rates outside this area, due to radiation leakage or scattering, as low as reasonably achievable;
 - (vii) ensure that, when appropriate, monitoring equipment is installed or is available to give warning of an unusual situation or trend in the use of radiation emitting equipment for diagnostic or therapeutic applications.

2. Operational aspects

Diagnostic exposure

Licensees shall make sure that-

- (a) the medical practitioners who prescribe or conduct radiological diagnostic examinations-
 - (i) ensure that the appropriate equipment is used,
 - (ii) ensure that the exposure of patients is the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure,
 - (iii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations,
 - (iv) avoid radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical reasons for such examinations,
 - (v) plan any diagnostic examination of the abdomen or pelvis of women of reproductive capacity so as to deliver the minimum dose to any embryo or foetus that might be present,
 - (vi) ensure that portable and mobile radiological equipment is used only for examinations where it is impractical or not medically acceptable to transfer patients to a stationary radiological installation and only after proper attention has been given to the radiation protection measures required in its use; and
 - (vii) ensure that, whenever feasible, shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid is provided as appropriate;
- (b) the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for pediatrics radiology and interventional radiology-
 - (i) the area to be examined, the number and size of views per examination (e.g. number of films or computed tomography slices) or the time per examination (e.g. fluoroscopic time),
 - (ii) the type of image receptor (e.g. high versus low speed screens),
 - (iii) the use of anti-scatter grids,
 - (iv) proper collimation of the primary X-ray beam to minimise the volume of patient tissue being irradiated and to improve image quality,
 - (v) appropriate values of operational parameters (e.g. tube generating potential, current and time or their product),
 - (vi) appropriate image storage techniques in dynamic imaging (e.g. number of images per second); and
 - (vii) adequate image processing factors (e.g. developer temperature and image reconstruction algorithms).

2. Nuclear medicine

Licensees shall make sure that-

- (a) the medical practitioners who prescribe or conduct diagnostic applications of radio nuclides-
 - (i) ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective taking into account relevant guidance levels for medical exposure,
 - (ii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations,
 - (iii) avoid administration of radio nuclides for diagnostic procedures to women pregnant or likely to be pregnant unless there are strong clinical indications,
 - (iv) for mothers in lactation, recommend discontinuation of nursing until the radio pharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursing, and
 - (v) ensure that administration of radionuclides to children for diagnostic procedures is carried out only if there is a strong clinical indication, and the activity of the radionuclides administered is reduced according to body weight, body surface area or other appropriate criteria;
- (b) the medical practitioner, the technologist or other imaging staff, as appropriate, shall endeavor to achieve the minimum patient exposure consistent with acceptable image quality by-
 - (i) appropriate selection of the best available radio pharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function,
 - (ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable, and
 - (iii) appropriate image acquisition and processing.

3. Therapeutic exposure

Licensees shall make sure that the medical practitioners who prescribe or conduct radiotherapy procedures with radiation sources or with radionuclides-

- (a) ensure that the prescribed absorbed dose is delivered to the planning target volume or organ;
- (b) ensure that exposure of normal tissue during radiotherapy is kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding is used when feasible and appropriate;
- (c) avoid radio therapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical indications;
- (d) avoid administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing, unless there are strong clinical indications;
- (e) plan any therapeutic procedure for pregnant women so as to deliver the minimum dose to any embryo or foetus; and

- (f) inform the patient of possible risks.

FOURTH SCHEDULE
GUIDANCE LEVELS OF DOSE, DOSE RATE AND ACTIVITY FOR MEDICAL EXPOSURE

(regs 29(2)(a), 30(3), 38(3), 39(e), 43(2), 44(2), and 45(1))

GUIDANCE LEVELS FOR
DIAGNOSTIC RADIOLOGICAL PROCEDURES

TABLE 4.1 GUIDANCE LEVELS OF DOSE FOR DIAGNOSTIC RADIOGRAPHY FOR
A TYPICAL ADULT PATIENT

Examination		Entrance surface dose * Per radiograph (mGy)
Lumbar spine	AP	10
	LAT	30
	LSJ	40
Abdomen, intravenous urography and cholecystography	AP	10
Pelvis	AP	10
Hip joint	AP	10
Chest	PA	0.4
	LAT	1.5
Thoracic spine	AP	7
	LAT	20
Dental	Periapical	7
	AP	5
Skull	PA	5
	LAT	3

Notes: PA: posterior-anterior projection; LAT: lateral projection; LSJ: lumbo-sacral-joint projection; AP: anterior-posterior projection.

*In air with backscatter. These values are for conventional film-screen combination in the relative speed of 200. For high speed film-screen combinations (400-600), the values should be reduced by a factor of 2 to 3.

TABLE 4.2 DOSE GUIDANCE LEVELS FOR COMPUTED TOMOGRAPHY FOR A TYPICAL ADULT PATIENT

Examination	Multiple scan average dose ^a (mGy)
Head	50
Lumbar spine	35
Abdomen	25

^aDerived from measurements on the axis of rotation in water equivalent phantoms, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and abdomen) in diameter.

TABLE 4.3 DOSE GUIDANCE LEVELS FOR MAMMOGRAPHY FOR A TYPICAL ADULT PATIENT

Average glandular dose per cranio-caudal projection
1 mGy (without grid)
3 mGy (with grid)

^aDetermined in a 4.5 cm compressed breast consisting of 50% glandular and 50% adipose tissue, for film-screen systems and dedicated Mo-target Mo-filter mammography units.

TABLE 4.4. DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT

Mode of operation	Entrance surface dose rate (mGy/min)
Normal	25
High level ^b	100

^a In air with backscatter.

^bFor fluoroscopes that have an optional "high level" operational mode, such as those frequently used in interventional radiology.

GUIDANCE LEVELS FOR
DIAGNOSTIC PROCEDURES IN NUCLEAR MEDICINE

TABLE 4.5. GUIDANCE LEVELS OF ACTIVITY FOR PROCEDURES IN NUCLEAR MEDICINE FOR A TYPICAL ADULT PATIENT

Test	Radio-Nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Bone			
Bone imaging	^{99m} Tc	Phosphonate and Phosphate compounds	600
Bone imaging by single photon emission computerised tomography (SPECT)	^{99m} Tc	Phosphonate and Phosphate compounds	800
Bone marrow imaging	^{99m} Tc	Labelled colloid	400
Brain			
Brain imaging (static)	^{99m} Tc	TcO ₄ ⁻	500
	^{99m} Tc	Diethylenetriaminepenta-acetic acid (DTPA), gluconate and lucoheptonate	500
Brain imaging (SPECT)	^{99m} Tc	TcO ₄ ⁻	800
	^{99m} Tc	DTPA, gluconate and glucoheptonate	800
Cerebral blood flow	^{99m} Tc	Exametazime	500
	¹³³ Xe	In isotonic sodium chloride solution	400
	^{99m} Tc	Hexamethyl propylene amine oxime (HM-PAO)	500
Cisternography	¹¹¹ In	DTPA	40
Lacrima			
Lacrimal drainage	^{99m} Tc	TcO ₄ ⁻	4
	^{99m} Tc	Labelled colloid	4
Thyroid			
Thyroid imaging	^{99m} Tc	TcO ₄ ⁻	200
Thyroid metastases (after ablation)	¹²³ I	I ⁻	20
	¹²³ I	I ⁻	400
Parathyroid imaging	²⁰¹ Tl	Tl ⁺ , chloride	80

TABLE 4.5. (Cont.)

Test	Radio-Nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Lung</i>			
Lung ventilation imaging	⁸¹ Kr ^m	Gas	6000
	⁹⁹ Tc ^m	DTPA-aerosol	80
Lung ventilation study	¹³³ Xe	Gas	400
	¹²⁷ Xe	Gas	200
Lung perfusion imaging	⁸¹ Kr ^m	Aqueous solution	6000
	⁹⁹ Tc ^m	Human albumin (macroaggregates or microspheres)	100
Lung perfusion imaging (with venography)	⁹⁹ Tc ^m	Human albumin (macroaggregates or microspheres)	160
Lung perfusion studies	¹³³ Xe	Isotonic solution	200
	¹²⁷ Xe	Isotonic chloride solution	200
Lung imaging (SPECT)	⁹⁹ Tc	Macroaggregates albumin MAA	200
<i>Liver and spleen</i>			
Liver and spleen imaging	⁹⁹ Tc ^m	Labelled colloid	80
Functional biliary system imaging	⁹⁹ Tc ^m	Iminodiacetates and equivalent agents	150
Spleen imaging	⁹⁹ Tc ^m	Labelled denaturated red blood cells	100
Liver imaging (SPECT)	⁹⁹ Tc ^m	Labelled colloid	200
<i>Cardiovascular</i>			
First pass blood flow studies	⁹⁹ Tc ^m	Tc04-	800
	⁹⁹ Tc ^m	DTPA	800
	⁹⁹ Tc ^m	Macroaggregates Globulin	400
Blood pool imaging	⁹⁹ Tc ^m	Human albumin complex	40
Cardiac and vascular imaging/probe studies	⁹⁹ Tc ^m	Human albumin complex	800
Myocardial imaging/probe studies	⁹⁹ Tc ^m	Labelled normal red blood cells	800

TABLE 4.5. (Cont.)

Test	Radio-Nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Myocardial imaging	^{99m} Tc	Phosphonate and phosphate compounds	600
Myocardial imaging	^{99m} Tc	Isonitriles	300
(SPECT)	²⁰¹ Tl	Tl ⁺ chloride	100
	^{99m} Tc	Phosphonate and Phosphate compounds	800
	^{99m} Tc	Isonitriles	600
Stomach, gastrointestinal tract			
Stomach / salivary gland imaging	^{99m} Tc	TcO ₄	40
Meckel diverticulum imaging	^{99m} Tc	TcO ₄	400
Gastrointestinal bleeding	^{99m} Tc	Labelled colloid	400
		Labelled normal red blood	400
Oesophageal transit and reflux	^{99m} Tc	cells	
	^{99m} Tc	Labelled colloid	40
Gastric emptying	^{99m} Tc	Non-absorbable compounds	40
	^{99m} Tc	Non-absorbable compounds	12
	^{99m} Tc	Non-absorbable compounds	12
	^{99m} Tc	Non-absorbable compounds	12
Kidney, urinary system and adrenals			
Renal imaging	^{99m} Tc		160
Renal imaging/renography	^{99m} Tc	Dimercaptosuccinic acide DPTA, gluconate and glucoheptonate	350
		Macroaggregated globulin 3	100
		O-iodohippurate	20
		Selenorcholesterol	8

TABLE 4.5. (Cont.)

Test	Radio-Nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Miscellaneous			
Tumour or abscess imaging	⁶⁷ Ga	Citrate	300
	²⁰¹ Tl	Chloride	100
Tumour imaging	⁹⁹ Tc ^m	Dimercaptosuccinic acid	400
Neuroectodermal tumour imaging	¹²³ I	Meta- iodo-benzyl Guanidine	400
	¹²³ I	Meta-iodo-benzyl guanidine	20
Lymph node imaging	⁹⁹ Tc ^m	Labelled colloid	80
Abscess imaging	⁹⁹ Tc ^m	Exametazime labelled white cells	400
	¹¹¹ In	Labelled white cells	20
Thrombus imaging	¹¹¹ In	Labelled platelets	20

^aIn some countries some of the compounds are considered obsolete.

^bIn some countries the typical values are lower than those indicated in the table.

GUIDANCE LEVEL OF
ACTIVITY FOR DISCHARGE FROM HOSPITAL

TABLE 4.6. GUIDANCE LEVEL FOR MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

Radionuclide	Activity (MBq)
Iodine- 131	1100 ^a

^aIn some countries a level of 400 MBq is used as an example of good practice.

FIFTH SCHEDULE
DOSE LEVELS ATWHICH INTERVENTION IS EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES

(reg 20(2))

TABLE 5.1. ACTION LEVEL OF DOSE FOR ACUTE EXPOSURE

Organ or tissue	Projected absorbed dose to be organ of tissue in less than 2 days (Gy)
Whole body (bone marrow)	1
Lung	6
Skin	3
Thyroid	5
Lens of the eye	2
Gonads	3

Note: The possibility of deterministic effects for doses greater than about 0.1 Gy (delivered over less than two days) to be foetus should be taken into account in considering the justification and optimisation of actual action levels for immediate protection.

TABLE 5.2. ACTION LEVEL OF DOSE RATE FOR CHRONIC EXPOSURE

Organ or tissue	Equivalent dose rate (Sv-a ⁻¹)
Gonads	0.2
Lens of the eye	0.1
Bone marrow	0.4

SIXTH SCHEDULE RADIOACTIVE WASTE CLASSIFICATION

(regs 59, 76(1) and (3), 77(3), 83(4), 86(a)(i) and 89(2)(c))

Class	Description
Cleared material/waste	Materials containing levels of radionuclides at concentrations less than the clearance levels established by the Radiation Protection Inspectorate
Low level (short-lived)/ Decay waste	Low level radioactive waste containing short-lived radionuclides only (<i>e.g. with half-lives less than 10 days</i>) that will decay to clearance levels within three years after the time of its generation
Low and intermediate level short-lived waste (LILW-SL)	Waste which will not decay to clearance levels within <i>three years</i> and contains beta/gamma emitting radionuclides with half-lives less than <i>30 years</i> and/or alpha emitting radionuclides with an activity less than <i>400Bq/g</i> and a total activity less than <i>4000 Bq</i> in each waste package

Low and intermediate level long-lived waste (LILW-LL)

Radioactive waste containing radionuclides with concentrations above those for LBLW-SL, but which does not generate heat at above 2 kW/m^3 of waste.

**SEVENTH SCHEDULE
REQUIREMENTS AND CONTROLS FOR TRANSPORTATION OF RADIOACTIVE
MATERIAL**

**INCLUDING
LIST OF UNITED NATIONS NUMBERS, PROPER SHIPPING NAMES AND
DESCRIPTION AND SUBSIDIARY RISKS**

(regs 84(4), (8), 85(6), 88(2)(a) and (d), 3(a), (b), (5) and (8))

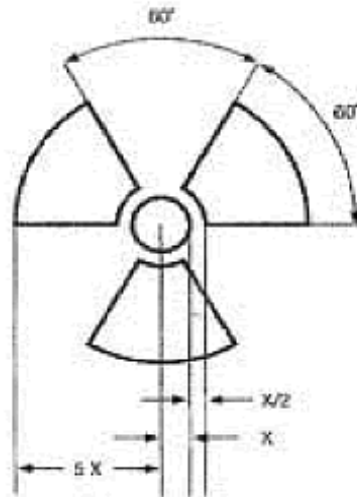


FIG. 1. Basic trefoil symbol with proportions based on a central circle of radius X .
The minimum allowable size of X shall be 4 mm.

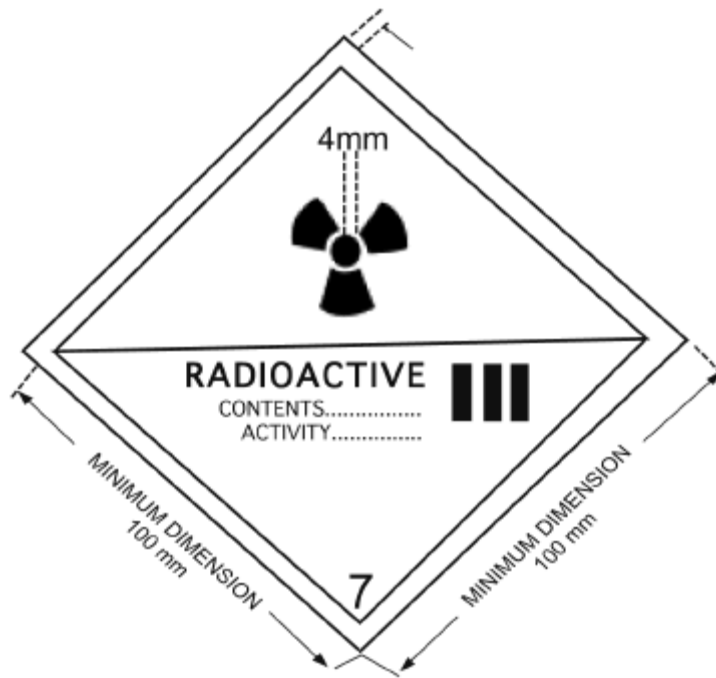


FIG. 2. Category I-WHITE label: The background colour of the label shall be white, the colour of the trefoil and the printing shall be black, and the colour of the category bar shall be red.

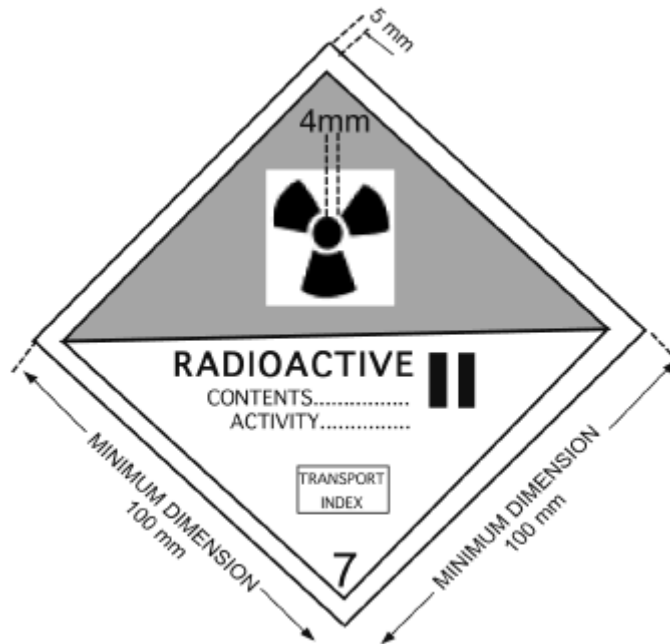


FIG. 3. Category II-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

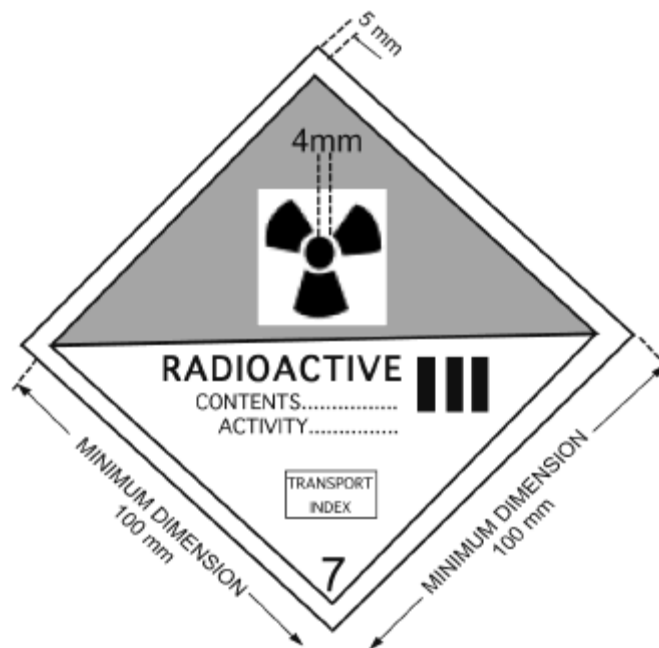


FIG. 4. Category III-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of category bars shall be red.

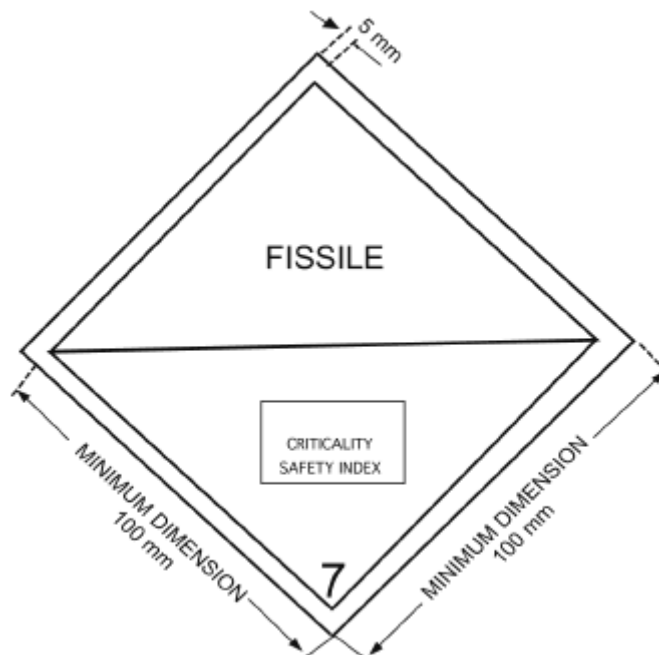


FIG. 5. Critically safety index label. The background colours of the label shall be white, the colours of the printing shall be black.

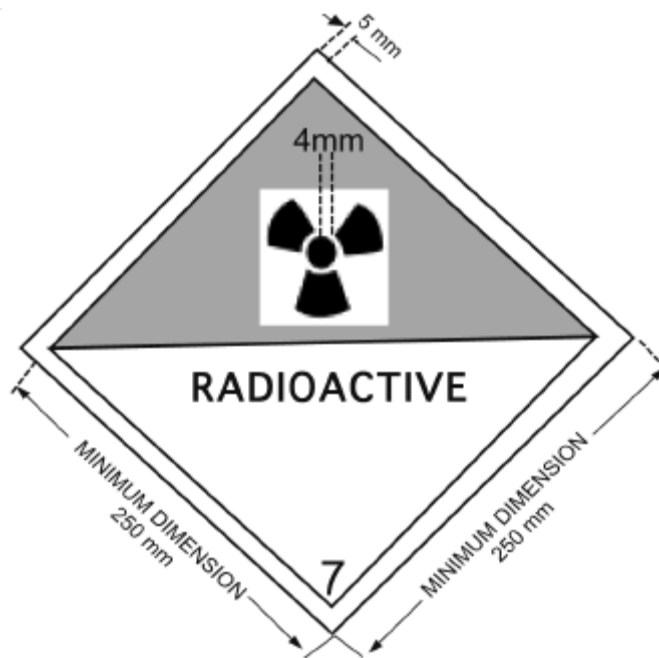


FIG. 6. Placard except as permitted by para. 571 minimum dimensions shall be as shown when different dimensions are used the relative proportions must be maintained. The number "7" shall not be less than 25 mm high. The background colour of the upper half of the placard shall be yellow and of the lower half white, the colour of the trefoil and the printing shall be black. The use of the word "RADIOACTIVE" in the bottom is optional to allow the alternative use of this placard to display the appropriate United Nations number for the consignment.

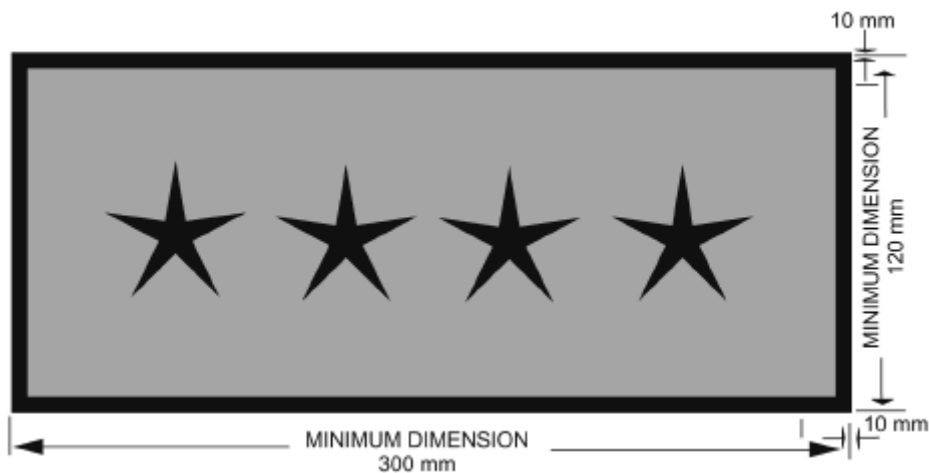


FIG. 7. Placard for separate display of United Nations number. The background colour of the placard shall be orange and the border and United Nations number shall be black. The symbol denotes the space in which the appropriate United Nations number for radioactive material, as specified in Table 8, shall be displayed.

UN No.	PROPER SHIPPING NAME ^a and description	Subsidiary risks
2910	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE-LIMITED QUANTITY OF MATERIAL	
2911	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE-INSTRUMENTS or ARTICLES	
2909	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE-ARTICLES MANUFACTURED FROM NATURAL URANIUM or DEPLETED URANIUM or NATURAL THORIUM	
2908	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - EMPTY PACKAGING	
2912	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-I) non-fissile or fissile-excepted	
3321	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY(LSA-II) non-fissile or fissile-excepted ^b	
3322	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-III) non-fissile or fissile-excepted ^b	
2913	RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II) non fissile or fissile-excepted ^b	
2915	RADIOACTIVE MATERIAL, TYPE A PACKAGE, non-special form, non-fissile or fissile-excepted ^b	
3332	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM non-fissile or fissile excepted ^b	
2916	RADIOACTIVE MATERIAL TYPE B(U) PACKAGE, non-fissile or fissile-excepted ^b	
2917	RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, non-fissile or fissile-excepted ^b	
3323	RADIOACTIVE MATERIAL, TYPE C PACKAGE, non-fissile or fissile-excepted ^b	
2919	RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, non-fissile or fissile-excepted ^b	

UN No.	PROPER SHIPPING NAME AND DESCRIPTION	Subsidiary Risks
2978	RADIOACTIVE MATERIAL, URANIUM HEXA-FLUORIDE non-fissile or fissile-excepted ^{b c}	Corrosive (UN Class 8)
3324	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II), FISSILE ^b	
3325	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA- 111), FISSILE	
3326	RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-1 or SCO-11), FISSILE	
3327	RADIOACTIVE MATERIAL, TYPE A PACKAGE, FISSILE non-special form	
3333	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, FISSILE	
3328	RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, FISSILE	
3329	RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, FISSILE	
3330	RADIOACTIVE MATERIAL, TYPE C PACKAGE, FISSILE	
3331	RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, FISSILE	
2977	RADIOACTIVE MATERIAL, URANIUM HEXA-FLUORIDE, FISSILE ^c	Corrosive (LTN Class 8)

^a The “PROPER SHIPPING NAME” is found in the column “PROPER SHIPPING NAME and description” and is restricted to that part shown in CAPITAL LETTERS. In the case of UN 2909, UN2911, UN 2913 and UN 3326 where alternative proper shipping names are separated by the word “or”, only the relevant proper shipping name shall be used.

^b “Fissile-excepted” applies only to those packages complying with para. 672.

“In the case of non-fissile or fissile-excepted uranium hexafluoride, LTN 2978 and the proper shipping name and description, “RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE, non-fissile and fissile excepted”, takes precedence over other UN numbers applicable to non-fissile and fissile-excepted. In the case of uranium hexafluoride that is fissile material, UN 2977 and the proper shipping name,

“RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE, FISSILE”, takes precedence over other LTN numbers applicable to fissile material.

EIGHTH SCHEDULE FORMS

(reg 100)

Form 01 RADIATION PROTECTION User Registration

1. Applicant (Institution, Company, Organisation etc.)

Postal address (for correspondence):	Premises (Physical) address:
Telephone No:	
Facsimile No:	

2(a). Details of Licensee

Name:		Occupation:	
Qualifications:	Designation	ID No.	
I am aware of and accept my duties as Licensee:		Signature:	Date:

2(b). Radiation Safety Officer (Must be appointed if not already appointed)

Name:		Occupation:	
Qualifications:	Designation:	ID No.	
Experience/training in handling radioactive material:		Address:	
I am aware of and accept my duties as Radiation Safety Officer:		Signature	Date:

2(c). Deputy Radiation Safety Officer

Name:		Occupation:	
Qualifications:	Designation:	ID No.	
Experience/training in handling radioactive material:		Address:	
I am aware of and accept my duties as deputy Radiation Safety Officer:		Signature:	Date:

3(a). Appointed medical physicist (where more than 370 MBq is administered to patients)

Name:	Address:
Qualifications:	
Telephone No.	
Cell/Mobile :	

3(b). Appointed deputy medical physicist

Name:	Address:
Qualifications:	
Telephone No.	
Cell/Mobile:	

4. Details of radiation monitoring equipment (e.g. rate meter and/or contamination monitor):

Name of Manufacturer	Model	Type	Calibration date

Calibration certificate issued by:

5. Proposed dosimetry service provider:

Name
Address:

6. Declaration by licensee

This is to certify that I, (Print) :.....hereby declare that the information supplied is to the best of my knowledge true and correct.	
Signature:	Date:
Designation:	

No fee

Form 02
RADIATION PROTECTION
**Application for licence/permit to import/export/transport/
possess and use of radioactive sources/generators/equipment**

Complete this application and the supplementary form. Return both signed forms with the fee. Where space is insufficient for any item, attach additional signed sheets.

Purpose of this application. (Please place "X" opposite the purpose as appropriate.

POSSESS & USE..... SELL IMPORT EXPORT TRANSPORT.....

1. Name of Applicant (*Renewal notices will be sent to this address*)

Address

..... Tel: Fax:.....
E-mail

2. Location of the Premises where the Radioactive Equipment/Sources/Generators will be used, stored, manufactured, etc.

3. Nature of business

4. Purpose(s) for which the radiation generator(s)/radioactive source(s) are to be used
.....
.....

5. Name and Registration number of the Radiation Safety Officer
.....

6. Particulars of the Qualified Experts to advise the applicant (eg name, qualifications, experience).....
.....

7. Particulars of the radioactive sources used, stored, manufactured or otherwise dealt with on the premises
.....
.....

8. Name of Supplier/Manufacturer.

Registration No.

AddressTown/CityCountry.....

Tel:Fax: e-mail

9. Vehicle Registration No: : Make & Model:

Owned by:.....

Address of owner:.....: Transport. Permit

No.....

Date issued:.....Name of Radiation Protection

Inspector:

Official Use

Date received:by:.....Signature.....

(Inspector -Radiation Protection)

Form 02 (con't)

(a) RADIOACTIVE SOURCES INTENDED FOR POSSESSION AND USE

Nuclide eg ⁶⁰ Co	Form eg Liquid, Gas or solid	Activity	Use	Location on premises	IF SOURCE IS ENCLOSED IN A DEVICE		
					Manufact- urer	Model	Serial No.

(b) RADIATION GENERATORS INTENDED FOR USE

RAIS No.	Manufa-turer	Model No.	Serial No.	Max kVp	Maxm	Use	Location on Premises

NOTES:

- a) The application must be accompanied by a Radiation Protection Programme that addresses all relevant radiation safety issues including -

for radioactive sources obtained regularly, the quantity in each shipment and the frequency of supply; radiation monitoring instruments available on the premises and their calibration; arrangements for personnel radiation monitoring; the proposed method for disposing of radioactive waste or of sealed sources which are no longer required; the security of sources; source storage conditions; the protective equipment that is required and handling techniques for the radioactive sources; the qualifications required of persons who use radiation sources; regular radiation safety training programmes for workers; where the sources are used for human diagnosis or therapy, the name and qualifications of the responsible medical practitioner, how patient exposures are justified and optimized and the dose guidelines adopted by the practice; details of emergency procedures, etc.

- b) A Scale Plan of the premises must be provided with the application showing the location where the radioactive sources are normally used, manufactured, stored or otherwise dealt with. The plan must show the purpose of all adjacent areas and the nature of the construction materials. For unsealed substances, additional information on waste lines, laboratory facilities, surface finishes and ventilation is also required. A report from a Qualified Expert must also be provided certifying that the premises and facilities are so constructed, and work practices instituted, that compliance with the prescribed dose and discharge limits will be achieved.

Return the completed and signed form with the fee to: The Director, Radiation Protection Inspectorate, Private Bag BO1, Gaborone Republic of Botswana.

FORM 02(a)
LICENCE TO POSSESS AND USE RADIOACTIVE SOURCES

(section 23)

(Not transferable)

LICENCE No.../.....

Authority is hereby granted to:

Name of Licensee:.....Address.....

Physical Address of Premises

Name of Responsible Person

to possess and use radioactive sources as listed below:

RADIOACTIVE SOURCES APPROVED FOR POSSESSION AND USE

RAIS No.	Nuclide	Form	Use	Location on premises	IF SOURCE IS ENCLOSED IN A DEVICE		
					Manufacturer	Model	Serial No.

in accordance with the requirements of the Radiation Protection Regulations.

Date of Issue Place of Issue

Date of Expiry

.....
Director - Radiation Protection

Official Stamp

THIS LICENCE MUST BE DISPLAYED IN A CONSPICUOUS PLACE AT THE PREMISES

**FORM 02(b)
LICENCE TO POSSESS AND USE IONIZING RADIATION GENERATOR**

(section 23)

(Not transferable)

LICENCE No...../.....

Authority is hereby granted to:

Name of Licensee:Address.....

Physical Address of Premises

Name of Responsible Person

to possess and use ionizing radiation generator(s) as listed below :

IONIZING RADIATION EQUIPMENT APPROVED FOR USE

Manufacturer	Model	Ser. No.	Max kVp	Max mA	Use	Location Premises	Date Installed

in accordance with the requirements of the Radiation Protection Regulations.

Date of Issue..... Place of Issue.....

Date of Expiry

.....
Director – Radiation Protection

Official Stamp

THIS LICENCE MUST BE DISPLAYED IN A CONSPICUOUS PLACE AT THE PREMISES

**FORM 02
PERMIT TO TRANSPORT RADIOACTIVE SOURCES**

(section 23)

(Not transferable)

LICENCE No..../.....

Permission is hereby granted for:

Vehicle registration No. :..... Make & Model.....

Owned by.....Address.....

Name of Responsible Person

to transport radioactive sources as listed below :

RADIOACTIVE SOURCE(S) APPROVED FOR TRANSPORT

Nuclide	Activity	Category eg II- Yellow	Package Type	Radiation Level at 10cm	SOURCE IS ENCLOSED IN A DEVICE		
					Manufacturer	Model	Serial No.

Date of issue

Place of issue.....

Date of Expiry

.....
Inspector - Radiation Protection

Official Stamp

This permit will become null and void if the carrier is modified, involved in an accident or its roadworthi certificate issued by appropriate government authority is withdrawn or expires.

**FORM 02(IE)
PERMIT TO IMPORT/EXPORT IONIZING RADIATION SOURCE(S)/GENERATOR**

(section 23)

(Not transferable)

PERMIT No...../.....

Authority is hereby granted to:

Name of Licensee:..... Address.....

Physical Address of Premises

Name of Responsible Person

to import/export ionizing radiation generator(s) as listed below:

RADIATION GENERATOR(S) / EQUIPMENT

Manufacturer	Model	Ser. No.	Max kVp	Max mA	Use	Location on Premises	Date Installed

RADIOACTIVE SOURCE(S)

Nuclide	Activity	Category eg II- Yellow	Package Type	Radiation Level at 10cm	IF SOURCE IS ENCLOSED IN A DEVICE		
					Manufacturer	Model	Serial No.

Date of Issue.....

Place of Issue.....

Date of Expiry

.....
Director – Radition Protection

Official Stamp

FORM 02 (S)
LICENCE TO SELL IONIZING RADIATION SOURCE(S)/GENERATOR

(section 23)

(Not transferable)

PERMIT No...../.....

Authority is hereby granted to:

Name of Licensee:.....Address.....

Physical Address of Premises

Name of Responsible Person

to sell radioactive sources/generators as listed below:

RADIOACTIVE SOURCE(S)

No.	Nuclide	Activity	Use	IF SOURCE IS ENCLOSED IN A DEVICE		
				Manufacturer	Model	Serial No.

RADIATION GENERATOR(S)/EQUIPMENT

Manufacturer	Model	Ser. No.	Max kVp	Max mA	Use	Facility	Date Installed

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Date of Issue..... Place of Issue.....

Date of Expiry

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Director – Radiation Protection

Official Stamp

**NINTH SCHEDULE
Fees**

(reg 101)

ITEM	TYPE OF SERVICE	CHARGE
10.1	Personal Dosimetry	P30 per person per month
10.2	Replacement of Lost Card	P550
10.3	Food Radionuclide Contamination Test	P325 per sample
10.4	Safety Assessment For Authorisation	P250
10.5	Authorisation Certificate - Low Risk Practices	P400
10.6	Authorisation Certificate - Medium Risk Practices	P825
10.7	Authorisation Certificate - High Risk Practices	P1,625
10.8	Notification	P50
10.9	Calibration of Dosimeters	P825
10.10	Permit to Import/Export Radiation Sources - Low Risk Practices	P400
10.11	Permit to Import/Export Radiation Sources - Medium Risk Practices	P825
10.12	Permit to Import/Export Radiation Sources - High Risk Practices	P1,625
10.13	Consultancy	P2,250
10.14	Permit to Transport and Store	P1,625
10.15	Licence to Possess and Use or Sell Radiation Sources	P2,500

Notes:

1. Cardiac pacer implants inside a living subject are exempted from all charges.
2. Fees exclude operational costs where applicable.
3. The fees are revised annually.