UNITED REPUBLIC OF TANZANIA

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THE ATOMIC ENERGY (PROTECTION FROM IONIZING RADIATION) REGULATIONS, 2004

ARRANGEMENT OF REGULATIONS

PART I - PRELIMINARY

Short title

1. These Regulations may be cited *as* the Atomic Energy (Protection From Ionizing Radiation) Regulations, 2004.

Purpose

2. These Regulations are intended to revoke and replace the Protection from Radiation (Code of Practice) Regulations, 1990 and to specify the minimum requirements for protection of people against exposure to ionizing radiation and for the safety and security of radiation sources, hereinafter referred to radiation safety, protection and security.

Interpretation

3. In these Regulations, unless the context other wise requires:-

"A_1 and A_2" means quantities of radioactivity, which are used to determine such things as the type of packaging necessary for a particular radioactive material shipment. A_1 applies to special form and A_2 applies to other than special form radioactive material.

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

"Act" means the Atomic Energy Act, No.7 of 2003

"administer ionizing radiation" means an intentional act of subjecting ionizing radiation to persons for the purpose of medical treatment or diagnosis by a qualified expert whether it be internal or external ;

"**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 recognized by the Commission;

"**apparatus**" means equipment associated with the emission of radiation;
"article" means item or thing or equipment associated with emission of radiation;
"**atomic energy**" means ionizing radiation emitted as a result of electronic or nuclear transitions in an atom;
"authorization" means a permission granted in a document by the Commission to a legal person who has submitted an application to carry out a practice or any other action described in the general obligations for practices under this Act. The authorization can take the form of registration or a licence;
"authorized officer" means an officer appointed or authorized to perform any functions in relation to the enforcement of the provisions of these Regulations and includes a police officer;
"Board" means the Board of the Commission as provided for in the Schedule to the Act;
"Commission" means the Tanzania Atomic Energy Commission;
"Clearance" means removal of radioactive materials or radioactive objects within authorized practices from any further control by the Commission
"continuous exposure" means external exposure where the source of radiation subjects the body or any critical organ to prolonged exposure or internal exposure due to continuous intake;
" Critical Group" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathways and its typical of individuals receiving the highest effective dose (as applicable) by the given exposure pathway from the given source
"**Director General**" means the Director General of the Commission;
"disease" includes injury and bodily or mental deficiency or abnormality;
"**disposal**" means the emplacement of waste in an approved, specified facility (e.g. near surface or geological repository) without the intention of retrieval. Disposal may also include the approved direct discharge of effluents (e.g. liquid and gaseous wastes) into the environment with subsequent dispersion;
"dose" means a measure of the radiation received or "absorbed" by a target;
"dose constraint" means a prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source;
"dose equivalent" means a quantity used by the International Commission on Radiation Units and measurements (ICRU) in defining the operational quantities ambient dose equivalent, directional dose equivalent and personal dose equivalent.
"**dose limit**" means the value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.
"effective dose" means a summation of the tissue equivalent doses, each multiplied by the appropriate weighting factor;
"emergency plan" means a set of procedures to be implemented in the event of a radiation accident
"equivalent dose" means the quantity $H_{T,R}$ defined as $H_{T,R} = D_{T,R}.W_R$
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
"ethical review committee" means a Committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual
"exclusive use" means that a single consignor has sole use of the conveyance (or large freight container) such that all loading and unloading is carried out in accordance with the directions of the consignor or consignee.
"exposure" means the act or condition of being subjected to irradiation;

"external exposure" means the act or condition of being subjected to irradiation by a source outside the body;
"**facility"** means any assembly of devices, equipment, structures or natural features whether simple or complex which serves some purpose or performs some function, in the course of which radiation is, or is capable of being emitted;
"ionizing radiation" means the radiation of gamma rays and x-rays or corpuscular radiation, capable of producing ions directly or indirectly in its passage through matter;
"**internal exposure"** the act or condition of being subjected to irradiation by a source inside the body;
"licence" means an authorization granted by the Commission on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee;
"licensee" means a person holding a licence granted under the Act.
"Medical Practitioner" means an individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is a registrant or licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure;
"Minister" means the Minister for the time being responsible for matters relating to Atomic Energy and Nuclear technology;
"notification" means a document submitted to the commission by a legal person to notify requirements in such a manner as provided for in regulation 14 (1) and (2);
"nuclear safety' means the condition and ability of a nuclear Installation and its servicing Personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionizing radiation into the environment, and to reduce the consequences of accidents;
"nuclear installation" means a nuclear fuel fabrication plant, nuclear reactor (including critical and Sub critical assemblies), research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;
"physical protection" means a system of technical and organizational measures preventing unauthorized activities with nuclear Installations, nuclear materials and selected items;
"plant" means and includes any machinery, facility or installation, whether affixed to land or not, but does not include any thing comprised or to be comprised in any means of transport, whether by land, water or air;
"practice" means any human activity that introduces additional sources of exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;
"premises" means and includes any land, whether built up or not, including any place underground and any land covered by water;
"qualified expert" means an individual who by virtue of certification by appropriate boards or societies, professional licence or academic qualification and experience, is duly recognized by the Commission as having expertise in a relevant field of specialization e.g. medical physics, radiation protection, occupational health, quality assurance or any relevant engineering or safety specialty;
"**radiation"** means ionizing radiation ;
"**radiation device"** means an equipment capable of generating ionizing radiation when energized and it does not contain radioactive material;
"radiation accident" means any occurrence or succession of occurrences having the same origin, which results into the release of radioactive materials, or radiation doses, which exceeds the safety standards prescribed in Regulations;

"radiation protection" means a system of technical and organizational measures to reduce or limit exposure of people and the environment;
"Radiation Safety" means measures intended to minimize the likelihood of accidents with radiation sources and, should such an accident occur, to mitigate its consequences;
"Radiation Safety Officer" means an individual who is competent in radiation protection matters and relevant for a given type of practice who is designated the Licensee or Registrant as provided for under section 57(1) of the Act to oversee the implementation of the requirements of these Regulations and is recognized by the Commission;
"**Radiation Safety Inspector**" means any person appointed under section 9 (1) of the Act to perform radiation inspections and any other duties relating to inspections under the Act;
"**radioactive material**" means any matter or substance containing one or more radionuclides the activity or concentration of which is sufficiently intense to entail a significant risk or disability or disease to any person or organ on exposure;
"**radioactive waste"** means some material that contains or is contaminated with radionuclides at concentrations or activities greater than exemption levels as established by the Commission and for which no use is foreseen;
"safety culture" means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;
"**sealed source**" means a source consisting of radioactive material firmly incorporated in a solid of effectively inactive materials, or sealed in an inactive container of a strength sufficient to prevent, under normal conditions of use, any dispersion of radioactive material and any possibility of contamination;
"security" means measures to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of radioactive materials;
"**single exposure**" means external exposure where the source of radiation subjects the body or organ to exposure of short duration, or internal exposure following the intake of radionuclides over a short period;
"**source**" means an apparatus, device, material or anything capable of emitting radiation;
"Special form radioactive material" means is either an in dispersible solid radioactive material or a sealed capsule containing radioactive material. The material has a very high degree of physical integrity so that if the material were released from the package in an accident, while there might be a high radiation hazard, it is unlikely that there would be any contamination hazard.
"Transport Index (TI)" means a number that is assigned to transport package (or over pack, freight container or conveyance), which is used to provide control over groups of packages for the purposes of minimizing radiation risks.
"**undertaking**" means and includes any trade, practice, business or profession and in relation to a public or local authority, includes any of the powers or duties of that authority, and, in relation to any other body of persons, whether corporate or incorporate, includes any of the activities of that body;
Unsealed sources (open sources) means a source that does not meet the definition of a sealed source;
"user" means a person or body of persons or institution authorized under these Regulations or the Act;
"**using radiation**" means and includes possession, holding, storage, transporting importing, exporting, installing, purchasing, selling or applying radiation in any activity;
"Worker" means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection.

Application

4. (1) These Regulations shall apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage or disposal of a source within a practice unless exposure from the source is excluded or exempted in accordance with the provisions of these Regulations.

(2) The sources within any practice to which the requirements for practices of Regulations shall apply include:

(a) radioactive substances and devices that contain radioactive substances or produce ionizing radiation, including consumer products, sealed sources, unsealed sources, and ionizing radiation generators, including mobile radiography equipment;

(b) installations and facilities containing radioactive substances or devices which are used for industrial, medical, agricultural, research and education purposes; and

(c) any other source specified by the Commission.

Exposures

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

Exclusions

6. The following exposures are excluded from the requirements of these Regulations:

(1) (a). exposures from natural radioactivity in the body; and

(b). exposures from cosmic radiation and from unmodified concentrations of natural radionuclides in raw materials.

(2) any other sources that are essentially unamenable to control as may be determined by the Commission.

Responsible Parties and Responsibilities

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

(2) The parties having the main responsibilities for the application and compliance of these Regulations shall be:

(a) those authorized by registration or license; and

(b) employers

(3) The general responsibilities of the parties above 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 practice and interventions under their responsibility 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 regularly to verify that the radiation safety objectives are being achieved;

(ii) to identify and present, or promptly correct, any failures or shortcoming in the radiation safety measures;

(iii) to facilitate consultation and cooperation between all relevant parties with respect to radiation protection and safety; and

(iv) to keep appropriate records regarding the discharge of their responsibilities.

(4) Other parties that shall have subsidiary responsibilities for the application of these Regulations. These parties are: -

(a) suppliers and clearing and forwarding agents;
(b) workers;
(c) radiation safety officers;
(d) police, custom officials and harbors Authority
(e) medical practitioners;
(f) health professional;
(g) qualified experts;
(h) ethical review committees; and
(i) any other party to whom the party in 7 (3) has delegated specific tasks.

Right to enter And Inspect

8. A Radiation Safety Inspector or other authorized officer of the Commission in the course of his duties shall have the right and powers provided for under section 59 of the Act.

Incidents and Accidents

9. (1) In the event of an incident or accident, Registrants, Licensees and Employers shall as appropriate:

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

(2) The communication of an incident or accident to the Commission shall be within twenty-four hours after an emergency exposure situation has developed or is developing.

(3) Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be ground for modifying, suspending or withdrawing any authorization that has been granted by the Commission.

Applicability of Other Regulations and Requirements

10. (1) The requirements of these Regulations are in addition to, and not in place of, other applicable laws and regulations.

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

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

Additional Requirements

11. The Commission may impose requirements by regulation, order, or conditions of an authorization, in addition to those established in these Regulations, as it deems appropriate or necessary to protect health or to minimize risk from radiation hazards.

Enforcement

12.(1) The Commission may revoke, suspend or modify an authorization to use a source, or prohibit the possession of a source, upon finding an undue threat to health and safety or non-compliance with applicable requirements

(2) The Commission upon finding willful violations or attempted violations of these Regulations or requirements may recommend to the Director of Public Prosecution for prosecution.

(3) The Commission may as appropriate impose fines or direct closure or undertake an action for locking the premises for non-compliance with applicable Regulations and any other requirements commensurate with the nature of violation.

(4) Without prejudice to sub regulation (3) of regulation 12 above, other fines and or penalties under these Regulations shall be as specified in the Act.

PART II – ADMINISTRATIVE REQUIREMENTS

General Obligations

13. No person shall engage in activities, which involve practices or sources within practices as specified in regulation 4 of these Regulations unless the requirements of these Regulations, including the requirements for notification and authorization, are met.

Requirements for Notification

14. (1) All sources shall require notification.

(2) Except for License holders and/as provided for in regulation 16 any person who, on the effective date of these Regulations specified in regulation 1, is responsible for a practice or in possession of a radiation source referred in regulation 4, shall submit a notification to the Commission within 90 days of the effective date. The form for notification is specified in schedule 8 of these Regulations.

(3) Except as provided for in regulation 15, any person intending to initiate a practice or to possess a radiation source, shall submit a prior notification to the Commission of such an intention.

(4) After notification as specified in sub-regulation (1) or (2) above and for any practices or sources in sub regulation (3) above, such a person shall be required to apply for authorization.

Exemption of Practices and Sources

15. (1) Practices and sources within a practice may be exempted from the requirements of these Regulations provided that they comply with the exemption levels specified in schedule 1.

(2) Exemptions shall not be granted for practices deemed not to be justified as specified in sub-regulation (2) of regulation 21.

(3) The Commission is exempted from registration and licensing in terms of section 21 of the Act;

(4) Practices and sources within a practice are further exempted from the requirements of these Regulations including requirements for notification, registration or licensing as specified under section 4 and 21of the Act.

Requirements for Authorization by Registration or License

16.(1) Except as provided for in regulation 15 sub-regulation 4, and regulation 14 of these Regulations, any person intending to engage in a practice or possess a radiation source referred to in regulation 4 (2) shall apply to the Commission for an authorization, which shall take the form of either a registration or a license; and that in the case of existing practices or sources not yet registered

or licensed by the Commission, the above mentioned application shall be submitted within 90 days of the coming into operation of these Regulations.

(2). If the application refers to an industrial irradiation installation, an installation processing radioactive substances, a medical or industrial radiography facility, or for any use of source, which the Commission has not designated as appropriate for registration, the authorization shall take the form of a license.

(3) Any person applying for an authorization to use or possess ionizing radiation sources and radiation premises shall:

(a) submit to the Commission 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 source within the practice;

(ii) a safety assessment in cases where this is prescribed by the Commission, 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 relevant critical group.

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

(c) be required to fill the license application form for possession or use of radiation device as may be prescribed by the Commission;

(d) be required to fill the license application form for possession or use of radioactive material as specified in schedule 8;

(e) be required to fill the license application form for radiation premises as specified in schedule 8.

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

(5). Authorization to possess or use sources and radiation premises shall be granted for an interval of a fiscal year, in which case; the authorizations can be renewed after fulfillment of the safety requirements prescribed by the Commission. The licensee shall be required to submit the application for a renewal of license three months prior to the expiry date.

(6.) An application for possession or use of radiation source shall be made subject to payment of license fee prescribed in schedule 5.

(7). The form of authorization is as specified in schedule 8.

Authorization to import, export or transport

17. (1) Any person applying for an authorization to import, export or transport any apparatus, article, plant, installation or other material or substance which is a source or intended to be used for the purposes of an undertaking involving the emission of radiation shall:

(a) submit to the Commission relevant information necessary to support the application as detailed in the license application form specified in schedule 8;

(b) pay a license fee as prescribed in schedule *5;*

(2) Whenever an authorization to import, export or transport a radiation source is granted, its validity shall not exceed twelve months.

(3) The Commission may impose conditions or limitations, as it may deem fit or necessary in any particular case. In considering whether or not to grant an authorization to import, the Commission shall take into cognizance of section 17(4) of the Act.

Registration of qualified experts

18. (1) Every qualified expert intending to carry out a practice that involves the administering of ionizing radiation to any person for the purposes of diagnosing or treating a disease shall apply for an authorization and shall be required to:

(a) submit to the Commission relevant information necessary to support the application as detailed in the application form specified in schedule 8;

(b) pay a license application fee as prescribed in schedule *5*.

(2) Whenever an authorization to administer ionizing radiation to persons is granted, its validity shall not exceed five (5) years.

(3) Registration granted for administering ionizing radiation to persons may be suspended or revoked in case of violation of radiation protection and safety protocols or non-compliance with requirements prescribed by the Commission.

Responsibilities of Registrants or Licensees

19. (1) Licensees shall bear the responsibility for establishing and implementing the technical and organizational measures that are needed for ensuring protection and safety for the practices and sources for which they are authorized and for compliance with all applicable requirements of these Regulations. They may appoint and shall specifically identify other people to carry out actions and tasks related to these responsibilities, but they shall retain the responsibility for the actions and tasks themselves.

(2) Licensees shall notify the Commission of their intentions to introduce modifications to any practice or source and radiation premises for which they are licensed whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modifications unless specifically authorized by the Commission. The application form for modification of practices or sources and radiation premises shall be as prescribed by the Commission.

(3) Licensees shall ensure that only workers who are designated in the license application form by name and/or qualifications credentials 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 shall be permitted to fulfill such required assignments and tasks.

(4) A licensee shall be responsible for ensuring that no radiation emitted as a result of the carrying on of his undertaking on his premises, cause any harm or injury to any person or damage to any property, which is on the premises or elsewhere.

(5) A licensee shall be liable in respect of any harm to any person or any damage to any property caused by any radiation to which sub-regulation (4) applies.

(6) Licensees and registrants shall provide sufficient security measures against the misuse or theft of radiation sources under the authorized users' possession.

Clearance

20. Sources, including substances, materials and objects within authorized practices shall be cleared from further compliance with the requirements of these

Regulations provided that they comply with exemption levels set by the Commission.

PART III – RADIATION PROTECTION PERFORMANCE REQUIREMENTS

Justification of Practice

21(1) No practice shall be authorized unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors. The applicant for an authorization shall provide 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 substance 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 frivolous 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 Commission as unjustified.

Dose Limitation

22.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 authorized practices, exceeds any relevant dose limits specified in *schedule 2.* Dose limits shall not apply to medical exposures from authorized practices.

Optimization of Protection and Safety

23(1) In relation to exposures from any particular source within a practice, radiation safety shall be optimized in order that the magnitude of individual doses, except for therapeutic medical exposures, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the dose to individuals delivered by the source be subject to dose constraints.

(2) The process of optimization of protection and safety measures may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques, but shall be sufficient to take all relevant factors into account in a coherent way so as to contribute to achieving the following:

(a) to determine optimized protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and

(b) to establish criteria, on the basis of the results of the optimization, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.

Dose constraints

24.(1) Except for medical exposure, the optimization 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 no exceed dose constraints which are equal to the dose limits specified in schedule 2.

(2) A licensee shall, in case of any source that can release radioactive substances to the environment, establish the dose constraints so that the prospective annual doses to members of the public, including 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 schedule 2 or lower values established by the Commission.

PART IV – MANAGEMENT REQUIREMENTS

Safety Culture

25. Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:
    (a) policies and procedures be established that identify protection and safety as being of the highest priority;
    (b) problems affecting protection and safety be promptly identified and corrected in a manner commensurate with their importance;
    (c) the responsibilities of each individual, including those at senior management levels, for protection and safety be clearly identified and each individual be suitably trained and qualified;
    (d) clear lines of authority for decisions on protection and safety be defined; and
    (e) organizational arrangements and lines of communications be effected that result in an appropriate flow of information on protection and safety at and between the various levels in the organization of the registrant or licensee.

Quality Assurance

26. 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.

Human Factors

27. (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 or re-qualified as may be appropriate.
    (2) Licensees, in co-operation with suppliers as appropriate, shall follow sound ergonomic principles in possessing, obtaining and or designing equipment and preparing operating procedures, in order to facilitate the safe use of equipment and minimize 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 practicable, the possibility of human errors leading to unplanned exposure of any person;
    (b) provide means to detect and prevent human errors and correct or compensate for them; and
    (c) facilitate early intervention in the event of an accident.

Radiation Safety Officers

28. (1) Every user shall, after consultation with the Director General, appoint a qualified expert employed by him to be a Radiation Safety Officer in relation to his undertaking.

(2) For the purposes of this regulation, where an undertaking consists of practices carried on in two or more different premises, and the carrying on of the activities in such premises involves the use of ionizing radiation, there shall be appointed a Radiation Safety Officer in respect of each such premises.

(3) The qualifications of the Radiation Safety Officers shall include a level of academic knowledge and of professional experience compatible with the levels of risk associated with the authorized practices or sources within a practice.

(4) The Radiation Safety Officer shall be responsible to:

(a) advise the user appointing him in all matters pertaining to the protection of workers, patients, the public and the environment from ionizing radiation;

(b) advise the user regarding formulation, the observance and enforcement of local rules for the protection of workers, patients, the public and the environment from ionizing radiation;

(c) advise and liaise with the Commission regarding the implementation of radiation protection measures at his work place;

(d) assist the Commission in the enforcement of the provisions of this regulation in relation to the undertaking in respect of which he is appointed; and

(e) assist the licensee in keeping all records of the practice as prescribed in these Regulations.

PART V – VERIFICATION OF PROTECTION, SAFETY AND SECURITY

Safety and Security Assessment

29. Assessments related to protection, safety and security measures for sources within practices shall be made by registrants and licensees at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance, and decommissioning, as appropriate, in order to:

(a) 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) determine the expected magnitude of normal exposures;

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

(d) assess the quality and extent of the protection, and safety provisions; and

(e) assess the adequacy of the physical security measures to prevent loss or damage.

Monitoring and Verification of Compliance

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

(2) For the purposes of monitoring and verification of compliance, every licensee shall be required to: -

(a) make available an adequate number of survey instruments for area monitoring at radiation work place; and

(b) send the radiation survey instruments to an approved dosimetry laboratory at least once a year and every after its maintenance or repair for calibration.

Records

31. Records shall be maintained by licensees of the results of monitoring and verification of compliance, including:

(a) records of the tests and calibrations carried out in accordance with requirements of these Regulations;

(b) radiation dose records;
(c) cases of overexposure;
(d) medical records;
(e) cases of contamination of skin, hair and clothing;
(f) area monitoring;
(g) leakage tests of sealed radioactive sources;
(h) lists of all sealed radiation sources;
(i) list and radiation dose of persons undergoing treatment or diagnosis;
(j) stock of unsealed radioactive materials, with dates of receipt, issue and disposal; and supplier's or manufacture's certificate;
(k) investigation of emergencies, accident and disposal of radioactive wastes;
(l) any other relevant information as required by the Commission.

PART VI – OCCUPATIONAL EXPOSURE PROTECTION

General Responsibilities

32. (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 the said 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 schedule 2;
(b) radiation safety is optimized in accordance with regulations 23 and 24;
(c) policies, procedures and organizational 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 co-operation with workers, through their representatives where appropriate, about measures which are needed to achieve adequate radiation protection and 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 dosimetric and other appropriate information available to the employer for the purpose of demonstrating that the level of protection provided to such workers is compatible with the requirements of these Regulations.

(4) 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 and security of sources. In particular, licensees and employers shall ensure that workers:

(a) follow any applicable rules and procedures for protection and safety and security;

(b) properly use the monitoring devices and the protective equipment and clothing provided;

(c) abstain from any willful action that could put themselves or others in situations that contravene the requirements of these Regulations; and

(d) promptly report to the licensee and employer any circumstances that could adversely affect safety or security 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 and security conditions or compliance with the requirements of these Regulations, and shall take appropriate remedial actions.

Conditions of Services

33.(1) The conditions of service of workers shall be independent of the existence or the possibility of occupational exposure. 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. Once a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus is afforded the same broad level of protection, which is required for members of the public, as it is specified in Schedule 2. The notification of pregnancy shall not be considered a reason to exclude female workers from work.

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

(4) No person under the age of 16 years shall be subjected to occupational exposure and no person under the age of 18 years shall be allowed to work in a controlled area unless supervised and then only for the purpose of the training.

Classification of Areas

34. (1) There shall be controlled areas whereby:-

(a) Licensees shall designate such area in which specific protective measures or safety and security provisions are or could be required for:

(i) controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(ii) preventing or limiting the extent of potential exposures.

(b) Licensees shall:

(i) determine the boundaries of any controlled area on the basis of the magnitude and likelihood of expected exposures and the nature and extent of the required protection and safety provisions;

(ii) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;

(iii) where a source is brought into operation or energized only intermittently or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;

(iv) display a warning symbol, recommended by the International Organization for Standardization (ISO) and appropriate instructions at access points and other appropriate locations within controlled areas as described in schedule 6;

(v) establish occupational protection, safety and security measures, including local rules and procedures that are appropriate for controlled areas;

(vi) restrict access to controlled areas by means of administrative procedures, such as the use of work permits, and by physical barriers, which could include locks or interlocks; the degree of restriction being commensurate with the magnitude and likelihood of the expected exposures; and

(vii) provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.

(c) In normal working procedures with sources, the expected contamination shall not exceed the effective dose specified in schedule 2.

(2) There shall be supervised areas whereby:-

(a) licensees shall designate area as 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;

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

(3) 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.

Local Rules and Supervision

35. (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 and for the security of sources;

(b) include in the local rules and procedures the values of any relevant authorized level, investigation level or other reference level and the procedure to be followed in the event that such level is exceeded; and

(c) ensure that any work involving occupational exposure is adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions are observed.

(2) 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 fetus due to exposures 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.

Personal Protective Equipment

36. (1) The licensee or employer shall minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate well engineered controls and satisfactory working conditions.

(2) If necessary, ensure that workers are provided with suitable and adequate personal protective equipment, including as appropriate :

(a) protective clothing;

(b) protective respiratory equipment with information on its protection characteristics and instructions on its proper use; and

(c) protective aprons and gloves and organ shields.

(3) The licensee or employer shall arrange for regular testing and maintenance to be carried out on all personal protective equipment, including as required, special equipment for use in the event of accidents and interventions.

(4) The licensee or employer shall take into account the following factors when assigning personal protective equipment for a given task:-

(a) medical fitness to sustain possible extra physical effort while using the protective equipment; and

(b) additional work time or inconvenience or additional non radiological risks associated with the use of the protective equipment.

Exposure Assessment

37. (1) Licensees and employers shall arrange for the assessment of the occupational exposure of workers and shall ensure that adequate arrangements are made for the provision of such services by a dosimetry laboratory approved by the Commission.

(2) For any worker who is normally engaged in a controlled area, 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.

(3) For any worker who is normally engaged 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.

(4) 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.

(5) 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.

(6) Licensees and employers shall keep records of exposure which shall be made available to workers and the Commission when appropriate.

Monitoring of Workplace

38. (1) Licensees, in co-operation 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) evaluation of the radiological conditions in all workplaces;

(ii) assessment of the exposure of workers in controlled areas and supervised areas; and

(iii) review of the classification of controlled and supervised areas.

(b) depend on the levels of ambient dose equivalent and airborne and surface activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

(3) The programmes for monitoring of the workplace shall specify:

(a) the quantities to be measured;

(b) where and when the measurements are to be made and at what frequency;

(c) the most appropriate measurement methods and procedures; and

(d) reference levels and the actions to be taken if they are exceeded.

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

Health Surveillance

39. (1) Employers and licensees, in accordance with the rules that may be established or developed by the Commission, shall make arrangements for appropriate health surveillance based on the general principles of occupational health designed to assess the initial and continuing fitness of workers for their intended tasks.

(2) Employers and licensees shall take medical history or otherwise health surveillance of workers just before they take employment in a radiation related workplace.

Records of Worker Exposure

40. (1) Employers and licensees shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under regulation 39. Such worker exposure records shall include information on:

(a) the general nature of the work resulting in exposure, the doses and intakes at or above the relevant recording levels and the data upon which the dose assessments are based;

(b) the periods of employment with different employers, if any, and the corresponding doses and intakes in each period of employment; and

(c) the doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal conditions.

(2) Employers and licensees shall:

(a) provide for access by workers to information of their own exposure records and workplace monitoring where appropriate; and

(b) upon request by the Commission or other persons or organizations with a demonstrated need for such records, including relevant employers and supervisors of the health surveillance programme, provide access to worker exposure records with due care and attention to the maintenance of appropriate confidentiality.

(3) Exposure records for each worker shall be retained by the licensees and employers, or by the Commission or other designated organization in case the licensees and employers cease their activities. These records 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.

Investigation of Accidental occupational Exposures

41(1) Licensees shall promptly investigate any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a worker exposure significantly different from that intended.

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

(a) calculate or estimate the doses received and their distribution within the worker;

(b) indicate the corrective measures required to prevent recurrence of such an accident;

(c) implement all the corrective measures that are under their own responsibility;

(d) notify the Commission by telephone or electronic mail or any other efficient means of communication as soon as practicable, but not later than 24 hours after discovery, of any accident which has the potential for, or has resulted in, serious injury or death of a worker, or which involve more than one worker;

(e) submit to the Commission, within 30 days after discovery of the accident, a written report which states the cause of the accident and includes information on the doses, corrective measures and any other relevant information; and

(f) inform the worker and his or her doctor about the accident.

Special Circumstances

42. (1) If a practice which is justified and for which radiation safety is optimized presents special circumstances, which require a temporary change in some dose limitation requirements of these Regulations, the licensees shall not make any such temporary change without approval of the Commission.

(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 optimize radiation safety provisions in accordance with the requirements of these Regulations; and

(b) the relevant employers and workers, through their representatives where appropriate, have been consulted on the need for and the conditions of the temporary change in dose limitation requirements.

(3) 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 Schedule 2.

PART VII – MEDICAL EXPOSURE PROTECTION

General Responsibilities

43 .(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, and either are health professionals or have appropriate training adequately 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, brachytherapy and nuclear medicine), the calibration, dosimetry and quality assurance requirements of these Regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics;

(e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients be constrained as specified in Schedule 2*;* and

(f) personnel engaged in diagnostic or therapeutic uses of radiation are well trained and qualified.

(2) Licensees shall, to the extent practicable ensure that for diagnostic uses of ionizing radiation the imaging and quality assurance requirements of these Regulations are fulfilled with the advice of a qualified expert in radiodiagnostic physics, nuclear medicine physics and radiopharmacy in the compounding of radiopharmaceuticals, 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.

Justification of Medical Exposure

44. (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 examination or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

(3) Mass screening of population groups involving medical exposure is deemed to be not justified 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 deemed to be not justified unless it is:

(a) in accordance with the provisions of the Helsinki Declaration [1964] given in *schedule 7*; and

(b) subject to the advice of the *licensee's Ethical Review Committee* and to any other applicable laws and regulations.

Optimization of Protection for Medical Exposure

45. (1) In addition to satisfying the general requirements for optimization of radiation safety specified in other parts of these Regulations, licensees, in co-operation with suppliers where appropriate, shall satisfy the prescriptive design and operational requirements specified in schedule 3.

Calibration, Clinical Dosimetry and Quality Assurance for Medical Exposures

46. (1). Licensees shall ensure that:

(a) the calibration of sources used for medical exposure is traceable to a Standards dosimetry laboratory approved by the Commission;

(b) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;

(c) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered; and

(d) calibrations of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may affect the calibration, at least once in a year.

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

Dose Constraints

47. (1) The optimization 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 or other institutional body assigned a similar function.

(2) Licensees shall constrain any dose to individuals incurred while

voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radio nuclides or who are being treated with Brachytherapy sources, to a level not exceeding that specified in schedule 2.

Guidance Levels

48. (1) Licensees shall ensure that guidance levels for medical exposure, determined as specified in regulation 26, 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) review actions are considered if doses or activities exceed the guidance levels, as an input to ensuring optimized 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 26, 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 schedule 4.

(3) Guidance levels for medical exposure shall be used by medical practitioners in the conduct of diagnostic and therapeautic procedures involving exposure to radiation as well as in the optimization of protection of patients.

(4) The Commission in consultation with relevant professional bodies shall establish the guidance levels.

(5) The guidance levels shall be applied with flexibility to allow higher exposures if they are indicated by sound clinical judgement and shall be revised as required by technological and scientific developments.

Maximum Activity for Patients in Therapy on Discharge from Hospital

49. In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed and or unsealed radio nuclides 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 specified in schedule 4 unless otherwise justified and the justification is documented. Written instructions by licensee to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

Investigation of Accidental Medical Exposures

50. (1) Licensees shall promptly investigate any of the following accidents:-

(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 value prescribed by the medical practitioner;

(b) any diagnostic exposure substantially greater than 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 accident;

(c) implement all the corrective measures that are under their own responsibility;

(d) notify the Commission by telephone or electronic mail or any other efficient means of communication as soon as practicable, but not later than 24 hours after discovery, of any accident which has the potential for, or has resulted in, serious injury or death of a patient, or which involve more than one patient;

(e) submit to the Commission, within 30 days after discovery of the accident, a written report which states the cause of the accident and includes information on the doses, corrective measures and any other relevant information; and

(f) inform the patient and his or her doctor about the accident.

Medical dosimetry Records

51. Licensees shall keep and make available, as appropriate, 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 VIII – PUBLIC EXPOSURE PROTECTION

General Responsibilities

52. (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, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:

(a) radiation safety policies, procedures and organizational arrangements for control of public exposure;

(b) measures for ensuring:

(i) the optimization of the protection, subject to constraints as may be appropriate, of members of the public whose exposure is attributable to such sources; and

(ii) the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in schedule 2*;*

(c) measures for ensuring the safety and security of such sources, in order that the likelihood of public exposures is controlled in accordance with the requirements of these Regulations;

(d) suitable and adequate facilities, equipment and services for the protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the potential exposure;

(e) appropriate radiation safety training, and periodic retraining, to the personnel having functions relevant to the protection of the public;

(f) appropriate monitoring equipment and surveillance programmes to assess public exposure; and

(g) adequate records of the surveillance and monitoring programmes.

Control of Visitors

53. Licensees shall:

(a) ensure that visitors be 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.

Source of External Irradiation

54 . 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 utilizing such sources of external irradiation are subject to review and approval by the Commission;

(b) specific dose constraints for the operation of such a source are established to the satisfaction of the Commission; and

(c) shielding and other protective measures that are optimized in accordance with the requirements of these Regulations are provided as appropriate for restricting public exposure to the satisfaction of the Commission.

Radioactive Contamination in Enclosed Spaces

55. Licensees shall ensure that:

(a) for sources for which they are responsible, measures that are optimized 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 minimize the spread of contamination in areas accessible to the public.

Discharge of radioactive materials

56. Registrants and licensees shall ensure that radioactive materials from authorized practices and sources shall not be discharged to the environment unless the requirements set in the Radioactive Waste Management Regulations G N. No. 276 of 1999.

Monitoring of Public Exposure

57. Licensees shall, as appropriate:

(a) establish and carry out a monitoring programme, of 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 and or discharges of radioactive substances into the environment, as appropriate;

(b) keep appropriate records of the results of the monitoring programmes; and

(c) report a summary of the monitoring results to the Commission every year and promptly inform the Commission of any abnormal results which lead or could lead to an increase of public exposure.

Vacating of the Premises

58. Each specific licensee shall, in not less than thirty days before vacating or relinquishing possession or control of premises, which may have been contaminated with radioactive material as a result of these activities, notify the Commission in writing of intent to vacate. When deemed necessary by the Commission, the owner shall decontaminate the premises in such a manner as the Commission may specify.

Consumer Products

59(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 6; or

(b) such products meet the exemption requirements specified in regulation 15 or have otherwise been exempted by the Commission; or

(c) such products are authorized by the Commission for use by members of the public.

(2) Persons who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the Commission for authorization to

distribute, a copy of the license or authorization issued by the Regulatory Authority in the country of manufacture or origin which authorizes distribution to members of the public in that country.

(3) Persons who import consumer products for sale and distribution as exempt products shall ensure that:

(a) legible and prominently featuring radioactive labels are visibly and firmly affixed to each consumer product and its package, stating, in Kiswahili or English language, that:
  (i) the product contains radioactive materials; and
  (ii) the sale of the product to the public has been authorized by the Commission

(b) basic information and instructions on the precautions of use and disposal of the product, written or translated in the local language, are made available with the product.

PART IX – REQUIREMENTS FOR THE SAFETY AND SECURITY OF SOURCES

General Responsibilities

60. (1) Registrants or Licensees shall ensure the safety and security 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 (defense in depth) for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved is applied to the source under their responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purpose of:
  (a) preventing accidents that may cause unintended exposure;
  (b) mitigating the consequences of any such accident should it occur; and
  (c) restoring sources to safe conditions after any such accident.

(3) 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 and standards and technical and scientific developments;
  (b) is supported by reliable managerial and organizational features; and
  (c) includes adequate safety margins in the design, construction and operation of sources.

Storage of radiation sources

61. (1) Licensees shall ensure that the following requirements with regards to storage of radiation sources are met: -

(a) when not in use radiation sources shall be kept in a place of storage assigned for this purpose only, bearing the appropriate warning symbol;

(b) the place of storage shall be adequately shielded such that at the outside surface of its walls or containment the radiation dose shall not exceed 0.01 mSv per hour, and shall be chosen so as to minimize risks from fire or flood;

(c) the place of storage shall be inspected regularly and checked for possible contamination;

(d) the place of storage shall be sited and designed so as to ensure that both during storage and in the course of transfer of radiation sources to and from the store, the sources do not give excessive exposure to any person; and

(e) if the place of storage is to contain either sealed or unsealed radiation sources that are liable to release a radioactive gas or vapour the store shall be continuously vented to the open air, or provided with a mechanical venting system that can be operated from outside the store before the store is opened.

(2) All radiation sources shall be clearly labeled, giving information on their activity and nature (physical form).

(3) The containers for beta emitting radionuclides shall have adequate thickness to reduce the primary radiation to a safe level. Considerable bremsstrahlung radiation may arise from high intensity sources and additional shielding shall be provided if necessary.

(4) Gamma emitting and neutron sources shall be stored in such a way as to limit the radiation exposure from the other sources when any one source is being handled.

(5) Appropriate equipment shall be provided for storing unsealed radiation sources to prevent only external irradiation hazards but also internal contamination hazards.

(6) Records shall be kept of all stored radiation sources. These records shall give clear information on the type of source activity, times of removal and return, and the name of the person responsible for the source during its absence from the store.

(7) Inventories shall be updated periodically.

(8) Bottles containing radioactive materials in liquid forms shall be placed in non-fragile vessels large enough to hold the entire contents of the bottles in case of breakage.

Design and Procurement of sources

62. Licensees, in specific co-operation 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 Standards Organization (ISO) or equivalent standards as may be approved by the Commission. Except for IEC and ISO standards, other standards applied in the country of origin of such equipment and sources must have the specific approval of the Commission;

(b) ensure through an agreement that the supplier will take back the source when no longer in use;

(c) ensure that sources and equipment are tested to demonstrate compliance with the appropriate specifications;

(d) conduct a safety assessment, either generic or specific, for the sources for which they are responsible, according to the requirements of regulation 29;

(e) 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 Commission and in compliance with the relevant IEC and ISO standards with regard to 'accompanying documents', and that this information is translated into Kiswahili when appropriate; and

(f) 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 (e) above.

Supply and Procurement of Radioactive Sources

(1) Licensees who supply or distribute radioactive sources shall ensure that:

(a) those to whom the sources are being supplied are authorized to receive the sources;

(b) for Category 1, 2 and 3 sources, the activities, radionuclides and types of sources are consistent with the receiver's business and previous radioactive source purchases, where applicable;

Note: The intent of this Article is to try to validate orders to reduce the probability of sources being legally purchased for malicious purposes, without unduly hindering normal commerce.

(2) When purchasing radioactive sources, licensees shall make contractual arrangements for the return of the disused radioactive sources to the manufacturer or suppliers if appropriate. In particular, any legal person that proposes to import a radioactive source shall:

(a) require the manufacturer or supplier, as a condition of any contract for purchase or as acceptance of any gift, to receive the source back after its useful lifetime; and

(b) submit to the regulatory body 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) When contractual arrangements are not possible, the licensee shall, at the time of purchase, and prior to requesting the authorization from the regulatory body make the proper arrangements to manage and dispose of the source as radioactive waste at the end of its useful life.

Accountability and Security of Sources

63. (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 license and without immediate communication to the Commission of information regarding any decontrolled, lost, stolen or missing source;

(b) a source is not transferred unless the receiver possesses a valid authorization;
(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 license to confirm that they are in their assigned locations and are secure.

Feedback of Operating Experience

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

(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 X: REQUIREMENTS FOR EMERGENCY INTERVENTION

Responsibilities of licensees

65. (1) If an authorized 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 drilled.

(2) If an authorized 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 as set forth in the license application and emergency plans approved by the Commission, or as might otherwise be required by the Commission to protect against, mitigate or remedy a hazardous situation involving the licensed sources.

Licensee Emergency Response Planning Requirements

66. Each licensee responsible for sources shall ensure that the emergency plan defines on-site responsibilities and takes account of off-site responsibilities of other intervening organizations appropriate for implementation of the emergency plan. Such emergency plans shall, as appropriate:

(a) characterize the content, features and extent of the potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and 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 organization and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;
(h) provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals in conjunction with designated authorities; and
(i) provide for periodic review and updating of the plan.

Implementation of Intervention

67. (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 intervention shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) Licensees shall promptly notify the Commission when an accidental situation requiring intervention has arisen or is expected to arise and shall keep them informed of the:-
(a) current situation and its expected evolution;
(b) measures taken to terminate the accident and to protect workers and members of the public; and
(c) exposures that have been incurred and that are expected to be incurred.

Protection of Workers Undertaking an Intervention

68. (1) No worker undertaking an intervention shall be exposed in excess of the maximum single year dose limit for occupational exposure specified in schedule 2 except:-
(a) for the purpose of saving life or preventing serious injury; or
(b) if undertaking actions to prevent the development of catastrophic conditions.

(2) When undertaking intervention under these circumstances, all reasonable efforts shall be made to keep doses to workers below twice the maximum single year dose limit, except for life saving actions, in which every effort shall be made to keep doses below ten times the maximum single year dose limit in order to avoid deterministic effects on health. In addition, workers undertaking actions in which their doses may approach or exceed ten times the maximum single year dose limit shall do so only when the benefits to others clearly outweigh their own risk.

(3) Workers who undertake actions in which the dose may exceed the maximum single year dose limit shall be volunteers and shall be clearly and comprehensively informed in advance of the associated health risk, and shall, to the extent feasible, be trained in the action that may be required.

(4) 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.

(5) 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. When the intervention has ended, the doses

received and the consequent health risk shall be communicated to the workers involved.

(6) Workers shall not normally be precluded from incurring further occupational exposure because of doses received in an emergency exposure situation. However, qualified medical advice shall be obtained before any such further exposure if a worker who has undergone an emergency exposure receives a dose exceeding ten times the maximum single year dose limit, or at the worker's request.

PART XI: MANAGEMENT OF RADIOACTIVE WASTES

Protection of human health and environment

69. Radioactive wastes shall be managed in such a manner as to ensure the protection of human health and environment.

Classification of radioactive wastes

70. The steps for radioactive waste management shall consider classification of radioactive wastes according to physical form, composition, activity concentration, and halflife of radionuclides.

Compliance with GN No. 276 of 1999

71. Without prejudice to the foregoing provisions of this part, management of radioactive wastes shall comply with the requirements of Radioactive Waste Management Regulations, GN No. 276 of 1999.

PART XII TRANSPORT OF RADIOACTIVE MATERIALS

Transport within the establishment

72. Licensees shall ensure that the following requirements with regard to transport of radioactive materials are met: -

(a) The Radiation Safety Officer or any qualified expert identified at the establishment shall be responsible for the precautions to be taken in the movement of radioactive materials from one area to another within the establishment.

(b) Radioactive materials shall be transported within the licensed premises only in containers provided for the purpose and should properly be labeled. Such containers shall be designed to provide adequate protection for all persons during loading, transport and unloading and to prevent loss of radioactive material and minimize the risk of spilling unsealed radioactive sources.

(c) Radioactive materials may be moved within the establishment in packaging intended for transport outside the establishment.

Transport within and outside the country

73. (1) Transport may be by road, rail, air or sea, and as such, transportation shall be subject to a licence issued by the Commission for that purpose.

(2). Packaging of radiation sources shall be designed so as to provide the necessary shielding against ionizing radiations and to adequately prevent loss and spillage of radioactive materials during transport operation in case of transport accidents.

(3). According to radiation levels, packages containing radiation sources are placed in one of the following three categories:-

(a) **Category I - White.**

The radiation level originating from the package at any time during normal transport shall not exceed *5.0 micro Sievert* per hour at any location on the external surface of the package.

(b) **Category II - Yellow.**

The radiation level originating from the package at any time during transport shall not exceed 0.50 mSv per hour at any location on the surface of the package, and 0.10 mSv per hour measured at one metre from the external surface of the package.

(c) **Category III - Yellow.**

The radiation level originating from the package at any time during transport shall not exceed 2.0 mSv per hour at any location on the external surface of the package and 0.1 mSv per hour measured at one metre from the external surface of the package.

(4) Depending on the quantity of radioactive materials contained in it, the package may be of type: excepted, industrial, type A, type B (M), type B (U) and type C packages types as defined in scheduled 7

(5) The loose radioactive contamination on any external surface of the package shall be kept as low as practicable and shall not exceed the values given in the table below:

Table: Maximum Permissible Levels (MPL) of loose contamination on packages

CONTAMINANT	MPL (Bq/sq.cm)
U-nat, U-depleted and Th-nat	37.00
Beta and gamma emitters and low toxicity alpha emitters ++	3.70
All other alpha emitters	0.37

Note:

\+ Average over 300 sq. cm. of any part of the surface.

++ Low toxicity alpha emitters: U-235; U-238; Th-232; Th-228 and Th-230, when diluted to a specified activity of the same order as that of U-nat radionuclides with a half life of less than 10 days. U-nat and Th-nat (mean natural uranium and natural thorium), respectively.

(6) When transporting radiation sources, care shall be taken that persons involved are not exposed to ionizing radiation in excess of the limits given in schedule 2.

(7) All packages containing radiation sources shall be separated from undeveloped radiographic and photographic films.

(8) Packages of radioactive materials shall be stored in separate transit areas for as short a time as practicable and far from other hazardous materials.

SCHEDULE 1: EXEMPTION LEVELS
EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Nuclide	Activity Concentration Bq/g)	Activity (Bq)	Nuclide	Activity Concentration (Bq/g)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}	Fe-52	1×10^{1}	1×10^{6}
Be-7	1×10^{3}	1×10^{7}	Fe-55	1×10^{4}	1×10^{6}
C-14	1×10^{4}	1×10^{7}	Fe-59	1×10^{1}	1×10^{6}
O-15	1×10^{2}	1×10^{9}	Co-55	1×10^{1}	1×10^{6}
F-18	1×10^{1}	1×10^{6}	Co-56	1×10^{1}	1×10^{5}
Na-22	1×10^{1}	1×10^{6}	Co-57	1×10^{2}	1×10^{6}
Na-24	1×10^{1}	1×10^{5}	Co-58	1×10^{1}	1×10^{6}
Si-31	1×10^{3}	1×10^{6}	Co-58m	1×10^{4}	1×10^{7}
P-32	1×10^{3}	1×10^{5}	Co-60	1×10^{1}	1×10^{5}
P-33	1×10^{5}	1×10^{8}	Co-60m	1×10^{3}	1×10^{6}
S-35	1×10^{5}	1×10^{8}	Co-61	1×10^{2}	1×10^{6}
CI-36	1×10^{4}	1×10^{6}	Co-62	1×10^{1}	1×10^{5}
CI-38	1×10^{1}	1×10^{5}	Ni-59	1×10^{4}	1×10^{8}
Ar-37	1×10^{6}	1×10^{8}	Ni-63	1×10^{5}	1×10^{8}
Ar-41	1×10^{2}	1×10^{9}	Ni-65	1×10^{1}	1×10^{6}
K-40	1×10^{2}	1×10^{6}	Cu-64	1×10^{1}	1×10^{6}
K-42	1×10^{2}	1×10^{6}	Zn-65	1×10^{2}	1×10^{6}
K-43	1×10^{1}	1×10^{6}	Zn-69m	1×10^{1}	1×10^{6}
Ca-45	1×10^{4}	1×10^{7}	Zn-69	1×10^{4}	1×10^{6}
Ca-47	1×10^{1}	1×10^{6}	Ga-72	1×10^{2}	1×10^{5}
Sc-46	1×10^{1}	1×10^{6}	Ge-71	1×10^{1}	1×10^{8}
Sc-47	1×10^{2}	1×10^{6}	As-73	1×10^{4}	1×10^{7}
Sc-48	1×10^{1}	1×10^{5}	As-74	1×10^{3}	1×10^{6}
V-48	1×10^{1}	1×10^{5}	As-76	1×10^{1}	1×10^{6}
Cr-51	1×10^{3}	1×10^{7}	As-77	1×10^{2}	1×10^{6}
Mn-51	1×10^{1}	1×10^{5}	Se-75	1×10^{3}	1×10^{6}

Mn-52	1×10^{1}	1×10^{5}	Br-82	1×10^{2}	1×10^{5}
Mn-52m	1×10^{1}	1×10^{5}	Kr-74	1×10^{1}	1×10^{6}
Mn-53	1×10^{4}	1×10^{9}	Kr-76	1×10^{2}	1×10^{6}
Mn-54	1×10^{1}	1×10^{6}	Kr-77	1×10^{2}	1×10^{7}
Mn-56	1×10^{1}	1×10^{5}	Kr-79	1×10^{2}	1×10^{5}
Kr-81	1×10^{4}	1×10^{7}	Tc-97	1×10^{3}	1×10^{6}
Kr-83m	1×10^{5}	1×10^{12}	Tc-97m	1×10^{3}	1×10^{6}
Kr-85	1×10^{5}	1×10^{4}	Tc-99	1×10^{4}	1×10^{7}
Kr-85m	1×10^{3}	1×10^{10}	Tc-99m	1×10^{4}	1×10^{7}
Kr-87	1×10^{2}	1×10^{9}	Ru-97	1×10^{2}	1×10^{7}
Kr-88	1×10^{2}	1×10^{9}	Ru-103	1×10^{2}	1×10^{6}
Rb-86	1×10^{2}	1×10^{5}	Ru-105	1×10^{2}	1×10^{6}
Sr-85	1×10^{2}	1×10^{6}	Ru-106[a]	1×10^{1}	1×10^{5}
Sr-85m	1×10^{2}	1×10^{7}	Rh-103m	1×10^{2}	1×10^{8}
Sr-87m	1×10^{2}	1×10^{6}	Rh-105	1×10^{4}	1×10^{7}

SCHEDULE 1: (Cont)

Nuclide	Activity Concentration (Bq/g)	Activity (Bq)	Nuclide	Activity Concentration (Bq/g)	Activity (Bq)
Sr-89	1×10^{3}	1×10^{6}	Pd-103	1×10^{2}	1×10^{8}
Sr-90[a]	1×10^{2}	1×10^{4}	Pd-109	1×10^{3}	1×10^{6}
Sr-91	1×10^{1}	1×10^{5}	Ag-105	1×10^{3}	1×10^{6}
Sr-92	1×10^{1}	1×10^{6}	Ag-110m	1×10^{2}	1×10
Y-90	1×10^{3}	1×10^{5}	Ag-111	1×10^{1}	1×10^{6}
Y-91	1×10^{3}	1×10^{6}	Cd-109	1×10^{3}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}	Cd-115	1×10^{4}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}	Cd-115m	1×10^{2}	1×10^{6}
Y-93	1×10^{2}	1×10^{5}	In-111	1×10^{3}	1×10^{6}
Zr-93[a]	1×10^{3}	1×10^{7}	In-113m	1×10^{2}	1×10^{6}
Zr-95	1×10^{1}	1×10^{6}	In-114m	1×10^{2}	1×10^{6}
Zr-97[a]	1×10^{1}	1×10^{5}	In-115m	1×10^{2}	1×10^{7}
Nb-93m	1×10^{4}	1×10^{7}	Sn-113	1×10^{2}	1×10^{5}
Nb-94	1×10^{1}	1×10^{6}	Sn-125	1×10^{3}	1×10^{4}
Nb-95	1×10^{1}	1×10^{6}	Sb-122	1×10^{2}	1×10^{6}
Nb-97	1×10^{1}	1×10^{6}	Sb-124	1×10^{2}	1×10^{6}
Nb-98	1×10^{1}	1×10^{5}	Sb-125	1×10^{1}	1×10^{7}
Mo-90	1×10^{1}	1×10^{6}	Te-123m	1×10^{2}	1×10^{7}
Mo-93	1×10^{3}	1×10^{8}	Te-125m	1×10^{2}	1×10^{6}
Mo-99	1×10^{2}	1×10^{6}	Te-127	1×10^{3}	1×10^{7}
Mo-101	1×10^{1}	1×10^{6}	Te-127m	1×10^{3}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}	Te-129	1×10^{3}	1×10^{6}
Tc-96m	1×10^{3}	1×10^{7}	Te-129m	1×10^{2}	1×10^{6}
Te-131	1×10^{2}	1×10^{5}	Ce-143	1×10^{3}	1×10^{6}
Te-131m	1×10^{1}	1×10^{6}	Ce-144[a]	1×10^{2}	1×10^{5}
Te-132	1×10^{2}	1×10^{2}	Pr-142	1×10^{2}	1×10^{5}
Te-133m	1×10^{1}	1×10^{1}	Pr-143	1×10^{2}	1×10^{6}
Te-133	1×10^{1}	1×10^{1}	Nd-147	1×10^{4}	1×10^{6}
Te-134	1×10^{1}	1×10^{1}	Nd-149	1×10^{2}	1×10^{6}

I-123	1×10^{1}	1×10^{1}	Pm-147	1×10^{2}	1×10^{7}
I-125	1×10^{2}	1×10^{2}	Pm-149	1×10^{4}	1×10^{6}
I-126	1×10^{3}	1×10^{3}	Sm-151	1×10^{3}	1×10^{8}
I-129	1×10^{2}	1×10^{2}	Sm-153	1×10^{4}	1×10^{6}
I-130	1×10^{2}	1×10^{2}	Eu-152	1×10^{2}	1×10^{6}
I-131	1×10^{1}	1×10^{1}	Eu-152m	1×10^{1}	1×10^{6}
I-132	1×10^{2}	1×10^{2}	Eu-154	1×10^{2}	1×10^{6}
I-133	1×10^{1}	1×10^{1}	Eu-155	1×10^{1}	1×10^{7}
I-134	1×10^{1}	1×10^{1}	Gd-153	1×10^{2}	1×10^{7}
I-135	1×10^{1}	1×10^{1}	Gd-159	1×10^{2}	1×10^{6}
Xe-131m	1×10^{1}	1×10^{1}	Tb-160	1×10^{3}	1×10^{6}

SCHEDULE 1: (cont)

Nuclide	Activity Concentration (Bq/g)	Activity (Bq)	Nuclide	Activity Concentration (Bq/g)	Activity (Bq)
Xe-133	1×10^{4}	1×10^{4}	Dy-165	1×10^{1}	1×10^{6}
Xe-135	1×10^{3}	1×10^{3}	Dy-166	1×10^{3}	1×10^{6}
Cs-129	1×10^{3}	1×10^{3}	Ho-166	1×10^{3}	1×10^{5}
Cs-131	1×10^{2}	1×10^{2}	Er-169	1×10^{3}	1×10^{7}
Cs-132	1×10^{3}	1×10^{3}	Er-171	1×10^{4}	1×10^{6}
Cs-134m	1×10^{1}	1×10^{1}	Tm-170	1×10^{2}	1×10^{6}
Cs-134	1×10^{3}	1×10^{3}	Tm-171	1×10^{3}	1×10^{8}
Cs-135	1×10^{1}	1×10^{1}	Yb-175	1×10^{4}	1×10^{7}
Cs-136	1×10^{4}	1×10^{7}	Lu-177	1×10^{3}	1×10^{7}
Cs-137[a]	1×10^{1}	1×10^{5}	Hf-181	1×10^{3}	1×10^{6}
Cs-138	1×10^{1}	1×10^{4}	Ta-182	1×10^{1}	1×10^{4}
Ba-131	1×10^{1}	1×10^{4}	W-181	1×10^{1}	1×10^{7}
Ba-140[a]	1×10^{2}	1×10^{6}	W-185	1×10^{3}	1×10^{7}
La-140	1×10^{1}	1×10^{5}	W-187	1×10^{4}	1×10^{6}
Ce-139	1×10^{1}	1×10^{5}	Re-186	1×10^{2}	1×10^{6}
Ce-141	1×10^{2}	1×10^{6}	Re-188	1×10^{3}	1×10^{5}
Os-185	1×10^{2}	1×10^{7}	Rn-222[a]	1×10^{2}	1×10^{8}
Os-191	1×10^{1}	1×10^{6}	Ra-223[a]	1×10^{1}	1×10^{5}
Os-191m	1×10^{2}	1×10^{7}	Ra-224[a]	1×10^{2}	1×10^{5}
Os-193	1×10^{3}	1×10^{7}	Ra-225	1×10^{1}	1×10^{5}
Ir-190	1×10^{2}	1×10^{6}	Ra-226[a]	1×10^{2}	1×10^{4}
Ir-192	1×10^{1}	1×10^{6}	Ra-227	1×10^{1}	1×10^{6}
Ir-194	1×10^{1}	1×10^{4}	Ra-228[a]	1×10^{2}	1×10^{5}
Pt-191	1×10^{2}	1×10^{5}	Ac-228	1×10^{1}	1×10^{6}
Pt-193m	1×10^{2}	1×10^{6}	Th-226[a]	1×10^{1}	1×10^{7}
Pt-197	1×10^{3}	1×10^{7}	Th-227	1×10^{3}	1×10^{4}
Pt-197m	1×10^{3}	1×10^{6}	Th-228[a]	1×10^{0}	1×10^{4}
Au-198	1×10^{2}	1×10^{6}	Th-229[a]	1×10^{0}	1×10^{3}
Au-199	1×10^{2}	1×10^{6}	Th-230	1×10^{0}	1×10^{4}

Hg-197	1×10^{2}	1×10^{6}	Th-231	1×10^{3}	1×10^{7}
Hg-197m	1×10^{2}	1×10^{7}	Th-nat	1×10^{0}	1×10^{3}
Hg-203	1×10^{2}	1×10^{6}	(incl.Th-232)		
TI-200	1×10^{2}	1×10^{5}	Th-234	1×10^{3}	1×10^{5}
TI-201	1×10^{1}	1×10^{6}	Pa-230	1×10^{1}	1×10^{6}
TI-202	1×10^{2}	1×10^{6}	Pa-231	1×10^{0}	1×10^{5}
TI-204	1×10^{2}	1×10^{6}	Pa-233	1×10^{2}	1×10^{6}
Pb-203	1×10^{4}	1×10^{4}	U-230[a]	1×10^{1}	1×10^{3}
Pb-210[a]	1×10^{2}	1×10^{6}	U-231	1×10^{2}	1×10^{7}
Pb-212[a]	1×10^{1}	1×10^{4}	U-232[a]	1×10^{0}	1×10^{5}
Bi-206	1×10^{1}	1×10^{5}	U-233	1×10^{1}	1×10^{7}
Bi-207	1×10^{1}	1×10^{5}	U-234	1×10^{1}	1×10^{3}
Bi-210	1×10^{1}	1×10^{6}	U-235[a]	1×10^{1}	1×10^{4}

SCHEDULE 1: (cont)

Nuclide	Activity Concentration (Bq/g)	Activity (Bq)	Nuclide	Activity Concentration (Bq/g)	Activity (Bq)
Bi-212	1×10^{3}	1×10^{6}	U-236	1×10^{1}	1×10^{4}
Po-203	1×10^{1}	1×10^{5}	U-237	1×10^{2}	1×10^{4}
Po-205	1×10^{1}	1×10^{6}	U-238[a]	1×10^{1}	1×10^{4}
Po-207	1×10^{1}	1×10^{6}	U-nat	1×10^{0}	1×10^{6}
Po-210	1×10^{1}	1×10^{6}	U-239	1×10^{2}	1×10^{4}
At-211	1×10^{1}	1×10^{4}	U-240	1×10^{3}	1×10^{3}
Rn-220[a]	1×10^{3}	1×10^{7}	U-240[a]	1×10^{1}	1×10^{6}
Np-237[a]	1×10^{4}	1×10^{7}	Cm-244	1×10^{1}	1×10^{7}
Np-239	1×10^{0}	1×10^{3}	Cm-245	1×10^{0}	1×10^{6}
Np-240	1×10^{2}	1×10^{7}	Cm-246	1×10^{0}	1×10^{4}
Pu-234	1×10^{1}	1×10^{6}	Cm-247	1×10^{0}	1×10^{3}
Pu-235	1×10^{2}	1×10^{7}	Cm-248	1×10^{0}	1×10^{4}
Pu-236	1×10^{2}	1×10^{7}	Bk-249	1×10^{3}	1×10^{3}
Pu-237	1×10^{1}	1×10^{4}	Cf-246	1×10^{3}	1×10^{6}
Pu-238	1×10^{3}	1×10^{7}	Cf-248	1×10^{1}	1×10^{6}
Pu-239	1×10^{0}	1×10^{4}	Cf-249	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{4}	Cf-250	1×10^{1}	1×10^{3}
Pu-241	1×10^{0}	1×10^{3}	Cf-251	1×10^{0}	1×10^{4}
Pu-241	1×10^{2}	1×10^{5}	Cf-251	1×10^{1}	1×10^{3}
Pu-242	1×10^{0}	1×10^{4}	Cf-252	1×10^{2}	1×10^{4}
Pu-243	1×10^{3}	1×10^{7}	Cf-253	1×10^{0}	1×10^{5}
Pu-244	1×10^{0}	1×10^{4}	Cf-254	1×10^{2}	1×10^{3}
Am-241	1×10^{0}	1×10^{4}	Es-253	1×10^{1}	1×10^{5}
Am-242	1×10^{3}	1×10^{6}	Es-254	1×10^{2}	1×10^{4}
Am-242m[a]	1×10^{0}	1×10^{4}	Es-254m	1×10^{4}	1×10^{6}
Am-243[a]	1×10^{0}	1×10^{3}	Fm-254	1×10^{3}	1×10^{7}
Cm-242	1×10^{2}	1×10^{5}	Fm-255	1×10^{3}	1×10^{6}
Cm-243	1×10^{0}	1×10^{4}			

[a] Parent nuclides and their progeny include 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	TI-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, TI-208 (0.36), Po-212 (0.64)

SCHEDULE 1: (cont)

Rn-220	Po-216
Rn-222	Po-218, Pb-214,Po-214
Ra-223	Rn-219, Po-215, Pb-211, TI-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, TI-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Po-214, Pb-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, TI-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, TI-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, TI-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

SCHEDULE 2

DOSE LIMITS FOR EXPOSURES INCURRED FROM PRACTICES
OCCUPATIONAL DOSE LIMITS

The occupational exposure of any worker shall be so controlled that the following limits are not exceeded:

(a) an effective dose of 20 mSv per year averaged over five consecutive years; 1
(b) an effective dose of 50 mSv in any single year;
(c) an equivalent dose to the lens of the eye of 150 mSv in a year; and
(d) an equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

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:

- an effective dose of 6 mSv in a year;
- an equivalent dose to the lens of the eye of 50 mSv in a year; and
- an equivalent dose to the extremities or the skin of 150 mSv in a year.

SPECIAL CIRCUMSTANCES

When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to regulation 43:

(a) the dose averaging period mentioned in paragraph (a) above may exceptionally be up to 10 consecutive years as specified by the Regulatory Authority, and the effective dose for any worker 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 5 years.

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) the dose averaging period mentioned in paragraph (a) above may exceptionally be up to 10 consecutive years as specified by the Regulatory Authority, and the effective dose for any worker shall not exceed 20 mSv 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 5 years.

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 dose not exceed 1 mSv per year;

(c) an equivalent dose to the lens of the eye of 15 mSv in a year; and

(d) an equivalent dose to the skin of 50 mSv in a year.

INTERNAL EXPOSURE

Internal exposure caused by inhalation or ingestion of radioactive substances shall be estimated in accordance with the methodologies, parameters and value contained in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No.115 [1], Schedule II.

Note: Most radiation sources in the Member States to which this sample Regulations is addressed will not involve significant internal exposure. Therefore, it seems unnecessary and overly complicating to include all the tables, equations, etc. related to this subject in the sample Regulations.

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.

SCHEDULE 3

MEDICAL EXPOSURE – DESIGN AND OPERATIONAL REQUIREMENTS

Design of sources and equipment

1. The requirements for the safety of sources specified in Article 58 to 61 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:
    (a) failure of equipment or components can be promptly detected so that any unplanned exposure of patients can e avoided or minimized; and
    (b) the risk of delivering unplanned exposure to patients by human error is minimized.

2. Licensees, in co-operation with suppliers where relevant or appropriate, shall:
    (a) 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;
    (b) ensure that equipment containing sources for medical exposure is conform to applicable international *(e.g IEC, ISO)* and national standards;
    (c) 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;
    (d) 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;

(e) ensure that any radiation emitting equipment is provided with radiation beam control mechanisms, including safety interlocks and clear and fail-safe'on-off' indicators;
(f) 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;
(g) 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.

Operational aspects

1. 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 examination 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 paediatric 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 antiscatter grids;

(iv) proper collimation of the primary X-ray beam to minimize the volume of patient tissue being irradiated and to improved 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 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:

(h) the medial practitioners who prescribe or conduct diagnostic applications of radionuclides:

(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 radionuclides 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 radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling; 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.

(i) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:

(i) appropriate selection of the best available radiopharmaceutical and its activity, nothing 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 radiotherapeutic 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

SCHEDULE 4

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

GUIDANCE LEVELS FOR DIAGNOSTIC RADIOLOGY PROCEDURES

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

Examination		Entrance surface dose per radiograph[a] (mGy)
Lumbar spine	AP	10
	LAT	30
	LSJ	40
Abdomen, intravenous urography And cholecystography	AP	10
Pelvis	AP	10
Hip joint	AP	10

Chest	AP	0.4
	LAT	1.5
Thoracic spine	AP	7
Dental	Periapical	7
	AP	5
Skull	PA	5
	LAT	3

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

[a] Delived 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.

DOSE GUIDANCE LEVELS FOR MAMMOGRAPHY FOR A TYPICAL ADULT PATIENT

Average glandular dose per cranio-caudal projection[a]

1 mGy (without grid)
3 mGy (with grid)

[a] Determined 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.

DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT

Mode of operation	Entrance surface dose rate[a] (mGy/min)
Normal	25
High Level[b]	100

[a] In air with backscatter
[b] For 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

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

Test	Radionuclide	Chemical form	maximum usual Activity per test[b] (MBq)
Bone			
Bone imaging	$^{99}Tc^{m}$	Phosphate and Phosphate compounds	600
Bone imaging by single Photon emission computerized Tomography (SPECT)	$^{99}Tc^{m}$	Phosphate and Phosphate compounds	800
Bone marrow imaging	$^{99}Tc^{m}$	labeled colloid	400
Brain			
Brain imaging (static)	$^{99}Tc^{m}$	TcO_4	500
	$^{99}Tc^{m}$	DTPA, gluconate and glucoheptonate	500
Brain imaging (SPECT)	$^{99}Tc^{m}$	TcO4	800
	$^{99}Tc^{m}$	DTPA, gluconate and glucoheptonate	800
	$^{99}Tc^{m}$	Exametazime	500
Cerebral blood flow	^{133}Xe	In isotonic sodium Chloride solution	400
	$^{99}Tc^{m}$	Hexamethyl propylene amine oxime (HM-PAO)	500
Cisternography	^{111}In	DTPA	40

Lacrimal

Lacrimal drainage	$^{99}Tc^{m}$	TcO^{1}_{4}	4
	$^{99}Tc^{m}$	Labelled colloid	4

Thyroid

Thyroid imaging	$^{99}Tc^{m}$	TcO^{-}_{4}	200
	^{123}I	I^{-}	20
Thyroid metastases (after ablation)	^{131}I	I^{-}	400
Parathyroid imaging	^{201}TI	TI^{+}, chloride	80

Lung

Lung ventilation imaging	$^{81}Kr^{m}$	Gas	600
	$^{99}Tc^{m}$	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)	$^{99}Tc^{m}$	Macroaggregated Albumin (MAA)	200

Liver and spleen

Liver and spleen imaging	$^{99}Tc^{m}$	Labelled colloid	80
Functional biliary system imaging	$^{99}Tc^{m}$	Iminodiacetates And equivalent Agents	150
Spleen imaging	$^{99}Tc^{m}$	labeled denaturated Red blood cells	100

Liver imaging(SPECT)	$^{99}Tc^{m}$	Labelled colloid	200
Cardiovascular			
First pass blood flow	$^{99}Tc^{m}$	TcO^{-}_{4}	800
Studies	$^{99}Tc^{m}$	DTPA	800
	$^{99}Tc^{m}$	Macroaggregated 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
Myocardial imaging	$^{99}Tc^{m}$	Phosphonate and Phosphate Compounds	600
Myocardial imaging (SPECT)	$^{99}Tc^{m}$	Isonitriles	300
	^{201}TI	TI^{+} chloride	100
	$^{99}Tc^{m}$	Phosphonate and phosphate compounds	800
	$^{99}Tc^{m}$	Isonitriles	600
Stomach, Gastrointestinal tract			
Stomach/salivary gland Imaging	$^{99}Tc^{m}$	TcO^{-}_{4}	40
Meckel's diverticulum Imaging	$^{99}Tc^{m}$	TcO^{-}_{4}	400
Gastrointestinal bleeding	$^{99}Tc^{m}$	labeled colloid	400
	$^{99}Tc^{m}$	labeled normal red blood cells	400
Oesophageal transit and Reflux	$^{99}Tc^{m}$	labeled colloid	40
	$^{99}Tc^{m}$	non-absorbable compounds	40
Gastric emptying	$^{99}Tc^{m}$	non-absorbable Compounds	12
	^{111}In	non-absorbable compounds	12
	$^{113}In^{m}$	non-absorbable	12

		compounds	
Kidney, urinary system and adrenals			
Renal imaging	$^{99}Tc^{m}$	Dimercaptosuccinic Acid	160
Renal imaging/renography	$^{99}Tc^{m}$	DTPS, gluconate and Glucoheptonate	350
	$^{99}Tc^{m}$	Macroaggregated globulin 3	100
	^{123}I	O-iodohippuarate	20
Adrenal imaging	^{75}Se	Selenorcholesterol	8

Test	Radio-Nuclide	chemical form[a]	Maximum usual activity per test[b] (MBq)
Miscellaneous			
Tumour Or abscess	^{67}Ga	Citrate	300
Imaging	^{201}TI	Chloride	100
Tumour Imaging	$^{99}Tc^{m}$	Dimercaptosuccinic acid	400
Neuroectodermal Tumour imaging	^{123}I	Meta-iodo-benzyl guanidine	400
	^{131}I	Meta-iodo-benzyl guanidine	20
Lymph node Imaging	$^{99}Tc^{m}$	Labelled colloid	80

Abscess imaging	$^{99}Tc^{m}$	Exametazime labeled white cell	20
	^{111}In	labeled white cells	20
	^{111}In	labeled platelets	20

[a] In some countries some of the compounds are considered obsolete
[b] In some countries the typical values are lower than those indicated in the table.

GUIDANCE LEVEL OF ACTIVITY FOR DISCHARGE FROM HOSPITAL

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

Radionuclide	Activity (MBq)
Iodine-131	1100[a]

[a] In some countries a level of 400 MBq is used as an example of good practice

SCHEDULE 5: FEES AND CHARGES

(A)LICENSING/REGISTRATION FEES
(i) use and or possession fees.

No.	Type of practice(s)	Applicable fee
1.	Use or possession of diagnostic X-ray Equipment	Up to two units: 40,000/= with an increase of 25% for each additional unit.
2.	Use or possession of CT & MR I for each unit	80,000/=
3.	Use of possession of Therapeutic and Biological irradiation facilities including Nuclear Medicine	150,000/= for each practice
4.	Use of possession of Industrial Irradiation Facilities & Nuclear Reactors	To be determined by the Commission with the consent of the Minister.

5.	NDT and Industrial use	120,000/= per unit
6.	Use or possession of Teaching/Educational Radiation Sources	-
7.	Use or possession of Analytical techniques: XRF, XRD, NAA & others	60,000/= per each practice
8.	Administering Ionizing Radiation	10,000/=
9.	Registration of qualified experts	10,000/=

(ii) Fee for import/export of radiation sources/radioactive materials

Type of Source/Materials	Applicable Fee
1. Diagnostic X-ray Equipment	40,000/=
2. CT & MR I for each unit	50,000/=
3. Therapeutic and Biological irradiation facilities including Nuclear Medicine	150,000/=
4. Industrial Irradiation Facilities & Nuclear Reactors	To be determined by the Commission with the consent of the Minister
5. NDT and Industrial use	150,000/=
6. Teaching and Education Radiation Sources	20,000/=

(B) DOSIMETRY FEES

Service		Applicable fee
	(i) Personnel dosimetry service	40,000/= for up to two TLDs and 10,000/= for each additional TLD.
	(ii) Cost of lost TLD(s)	80,000/= per lost TLD

(C) CALIBRATION SERVICES

Service	Applicable fee
(a) Radiation Protection and environmental monitoring dosimeters (i) One (1) radiation survey meter/indicator	80,000/=

Each additional survey meter/indicator of the same type	40,000/=
(ii) Ten (10) TLDs or pocket (pen)	80,000/=
Each 10 dosimetry additional pieces of the same type	30,000/=
(b) Clinical dosimeters (i) one (1) instrument	120,000/=
(ii) Each additional of the same type	60,000/=
(c) Other types of radiation detecting instruments (i) One (1) instrument	60,000/=
(ii) Each additional of the same type	30,000/=

SCHEDULE 6: RADIATION SYMBOLS AND TRANSPORT PACKAGES

I-SYMBOLS TO INDICATE IONIZING RADIATION

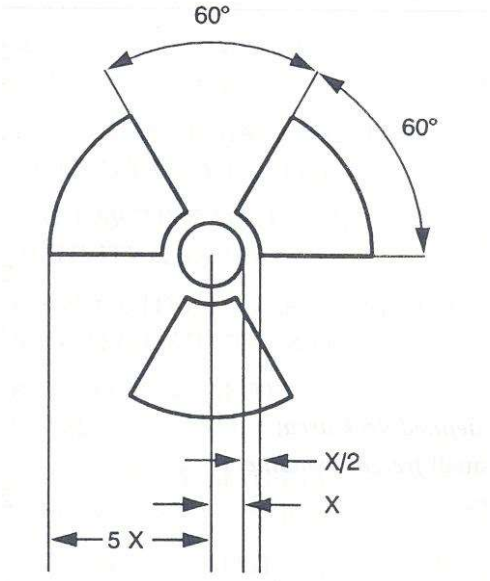

Figure 1. Basic trefoil symbol with proportions based on a central circle of radius X. The minimum allowable size of X shall be 4 millimeters.The symbol shall be in black colour and should be placed on yellow or white background.

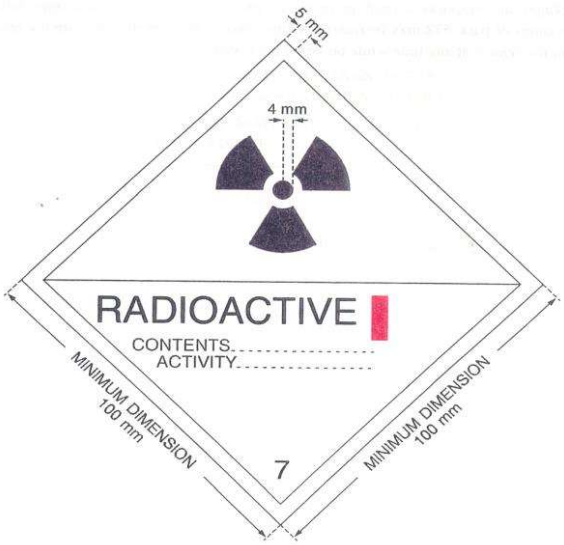

Figure 2 Category I-WHITE label.The background colour of the label shall be white, the colour of the trefoil and the printing shall be black, and the colour of the category bar shall be red.

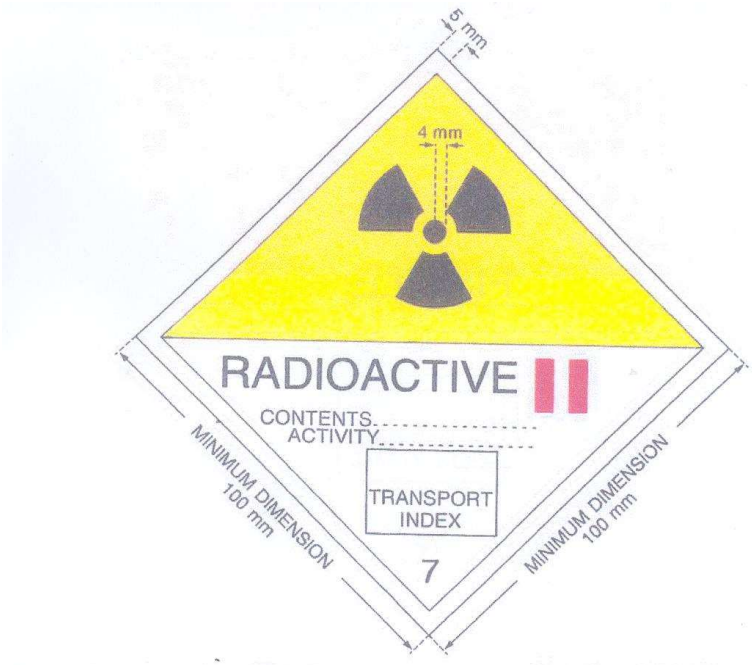

Figure 3. Category II-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

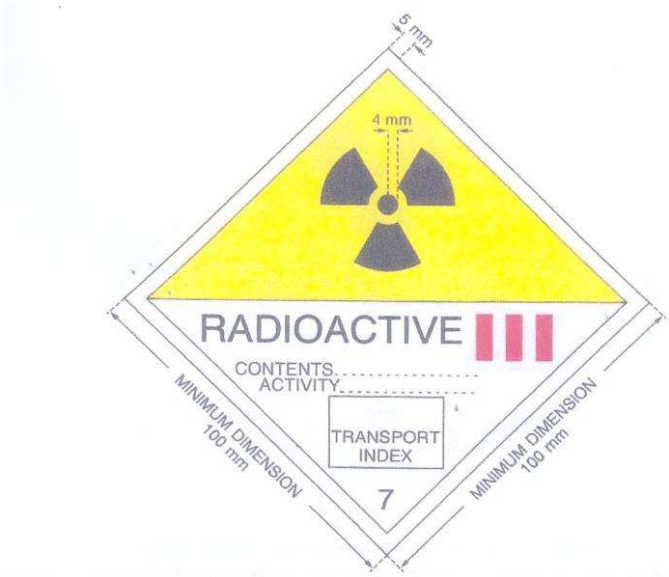

Figure 4. category III-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

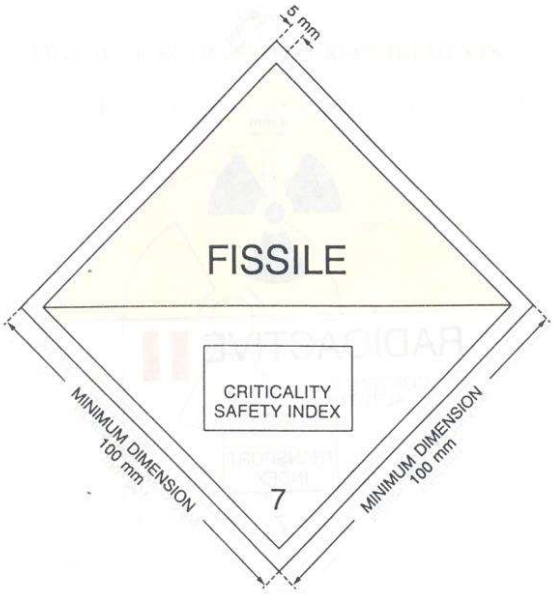

Figure 5. Criticality safety index label. The background colour of the label shall be white, the colour of the printing shall be black.

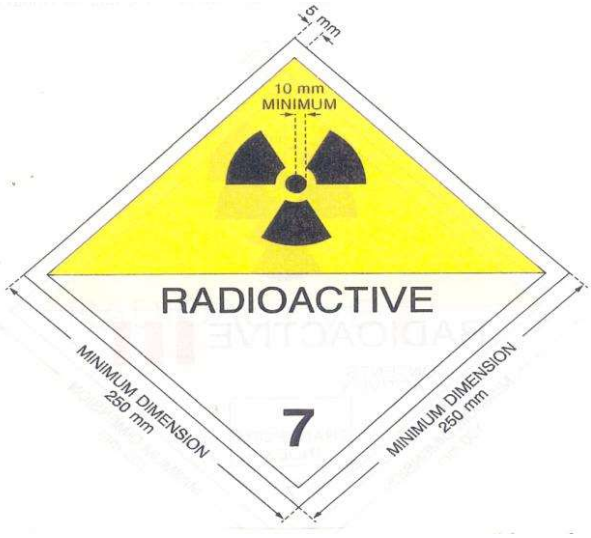

Figure 6. Pracard. Minimum dimensions shall be as shown; when different dimensions are used the relative proportions must be maintained. The number '7' shall not be less than 25 millimeters high. The background colour of the upper half of the pracard shall be yellow and of the lower half white, the colour of the trefoil and the printing shall be black. The use of the word "RADIOACTIVE" in bottom half is optional to allow the alternative use of this placard to display the appropriate united Nations for the consignment.

II-TYPES OF PACKAGES

Excepted packages

Excepted packages may only contain limited quantities of radioactive material, which are so small that the potential radiological hazards that might pertain during transport are very low. There are no test requirements for excepted packages and therefore it must be assumed that in any form of accident the package may fail completely and that the contents may be dispersed. The radiation level at any point on the surface of an excepted package cannot exceed 5 μSv/h to ensure that any radiation dose to members of the public would be insignificant and that any sensitive photographic material in close proximity would not be damaged.

Industrial packages

Industrial packages are used to transport low specific activity (LSA) and surface contaminate object (SCO) material. There are three types of industrial packages (Type IP-1, Type IP-2, and Type IP-3) that are used for LSA and SCO shipments. The requirements that packages have to meet to be classified as industrial packages are not demanding. Many normal packages used in industry, such as steel drums or bins, could meet the requirements.

Type A packages

Type A packages are intended to provide a safe and economical means of transporting a well defined, but significant, minor quantity of radioactive material. A total quantity of up to A1 special form radioactive material, or up to A2 if not special form, may be transported in a Type A package. They are required to maintain their integrity under the kind of abuse or mishandling which may be encountered in normal transport, for example: falling from vehicles, being dropped during manual handling, being exposed to the weather, being struck by a sharp object, or having other packages or cargo stacked on top. The specific tests required for Type A packages simulate such events.

Type B packages

The concept of a Type B package is that it should be capable of withstanding most accident conditions, without breach of its containment or an increase in radiation levels to a point that would endanger the general public and those involved in rescue or clean-up operations. In other words, the package could be safely recovered, but would not necessarily be capable of being reused.

While a Type B package is never required to withstand more than one accident, the design criteria imposed by the Regulations subjects the package to a series of mechanical and thermal tests with accumulative effects, each of which must cause the maximum damage. The requirements impose additional necessary design constraints over and above those imposed on packages that meet normal conditions of transport. The outcome

of these constraints is to dictate greater structural integrity, more careful consideration of containment features, and the ability to protect from elevated temperatures.

For most modes of transport, a Type B package may contain any quantity of any type of radioactive material up to that allowed by its approval certificate.

Type B packages may either be unilaterally approved (B(U), or multilaterally approved (B(M). Unilateral approval means that they are approved by the Competent Authority of the country of origin of the design only, while multilateral approval means that they are also approved by the Competent Authorities of the countries through, or into which, the consignment is to be transported.

Type C packages

In recognition of the fact that impact velocities from aircraft crashes can be significantly greater than those from surface modes of transport, the shipment of very large quantities of radioactive material by air requires the use of Type C packages. These are packages that must demonstrate the capability to withstand severe crush, puncture, and fire tests, as well as impact at the high speed of 90 metres/second. These features may all be encountered in a severe air accident.

SCHEDULE 7: HELSINKI DECLARATION

HELSINKI DECLARATION (1964/96)

World Medical Association Recommendations
Guiding Physicians in Biomedical Research Involving Human Subjects
(document 17.C)

Adopted by the
18th World Medical Assembly Helsinki, Finland, June 1964

and amended by the
29th World Medical Assembly, Tokyo, Japan, October 1975
35th World Medical Assembly, Venice, Italy, October 1983
41st World Medical Assembly, Hong Kong, September 1989 and the
48th General Assembly, Somerset West, Republic of South Africa, October 1996.

A. INTRODUCTION

1. It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

2. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The Health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

3. The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

4. In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

5. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

6. In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

7. Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

8. Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

B. BASIC PRINCIPLES

9. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

10. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

11. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of10. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed. a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

12. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

13. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

14. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

15. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

16. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

17. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the

discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

18. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

19. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

20. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

21. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

C. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

22. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

23. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

24. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

25. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

26. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2). In this version paragraph 10.

27. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

D. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS
(Non-Clinical Biomedical Research)

28. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
29. The subject should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.
30. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
31. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

SCHEDULE : 8 APPLICATION FORMS

UNITED REPUBLIC OF TANZANIA

Form TAEC 1

Tanzania Atomic Energy Commission
P. O. Box 743
ARUSHA

ATOMIC ENERGY ACT No. 7 OF 2003
PART III (read together with regulation 14)

FORM FOR NOTIFICATION OF A PRACTICE INVOLVING IONZING RADIATION

1. Name and address of applicant: ……
……..……..

Telephone No. ……. Title: ……

2. Name and address of the Centre where radioactive materials/radiation generating equipments will be used: …… …..

……
Telephone No. …… Fax No. ……

3.Location of facility: ……..

Name of Unit/Department: ……
Sub-Location/Town: …….
District: …….
Region: ……
Bulding …….. …….. Room No. …….

4. List names of individual users / operators:

NAME	TITLE

5. If the practice involves Radioactive Materials:
Give details of radioactive materials that you intend to import/use and attach supplier/manufactures sources certificate

Name of Source	Element Mass Numbers	Chemical or Physical state	Number of Sources	Activity (curies/Bq)	Model No. and Name of Manufacturer	Sale Price in US

6. If the practice involves Radiation Generating Equipment:
Give details of the equipment

Manufacture: …….

Model: ……...

Operating parameters: ……..

7. Purpose of Use:
Describe the purpose for which radioactive materials/radiation generating equipment will be used: …….
……
……

8. Declaration:

I, …… (name) certify that all the information given herein is true and correct to the best of my knowledge.

Date: …… Signature of Applicant: ……..

UNITED REPUBLIC OF TANZANIA

TAEC FORM 2

Tanzania Atomic Energy Commission
P. O. Box 743
ARUSHA

ATOMIC ENERGY ACT, No. 7 OF 2003
[PART I-III SECTION 18 AND 20]

APPLICATION FOR AUTHORIZATION TO POSSESS AND USE A MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

NB: To avoid delays in evaluation, respond to all questions

PART I: GENERAL INFORMATION

A. Name and Address of Organization (including head of organization):

1. Main address……..……..…..
   (GO/NGO) Tel.No……..……
   Fax No…….E-mail address……..…….
2. Mailing address ……..…….Tel.No……..……
   Fax No……..E-mail address……..……
3. Name of head of Organization …….…….
   (Prof/Dr/Mr/Sr/other)……..……
   Qualification…….…….

B. Name and information about qualified experts:

1. Name of Radiation Safety Officer……...……
   Qualification……...…….
   Certification…….experience……...……
   Tel.No……..e-mail address…….

2. Other qualified experts*
   2.1……..qualification……..…….
   2.2……..qualification……..…….……
   2.3……..qualification……..……..……...
   *(*continue on a separate sheet)*

PART II: TECHNICAL DETAILS OF EQUIPMENT*

1. Details of X-ray generator

Manufacturer/Address/ Workload	Number of tubes	Model number	Serial number	Maximum Voltage(kV)	Maximum Current (mA)
Name: …… Address: …… …… Max output: …….. Exposure time per week: …… Weekly workload: ……. ……					
Name: …… Address: ……. Max output:…… Exposure time per week: …… Weekly workload: …….					

2. Device Standards
   a. Is each device manufactured, prototype tested and subject to quality control provisions of any international standard setting organization (e.g. IEC, ISO etc)? Yes/No …….
   b. If the answer above is Yes, identify the standards and any classification numbers …… ……...

3. Is the type of installation of the x-ray machine fixed or mobile?
……..

4. Identify who is (or will be) authorized to perform the service and maintenance of the device (organization and address)
……..

……
….
5. Location of the device
   Provide the details of a location in which the device will be used:-
   a. Name of unit/department……..…..bldg No……Room no……
      floor……..….(if applicable)
   b. Place: Land reg. No./plot no/vehicle reg. No. ……..
   c. Location: Town/street/ward ……

d. District

…….

PART III: LAYOUT OF THE INSTALLATION*

1. Is the installation enclosed or open?

……

2. What are the construction materials

…….

3. Does the installation have on interlock system …… warning signals

…….

and radiation shields

…….

(mention them).

4. Describe the darkroom facilities in brief

…….

……

……

……

* *Attach a layout drawing of the installation showing adjacent surroundings. Controlled and supervised areas should be clearly identified in the drawing.*

PART IV: RADIATION PROTECTION AND SAFETY PROGRAMMES AND EMERGENCY PLANS*

1. Organizational Structure

(a) Describe your organizational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety.:

(i)staffing levels ……

(ii)equipment selection: ……

(iii) other assignments of the Radiation Safety Officer ……..

……

……

……

……

(iv) authority of the Radiation Safety Officer to stop unsafe operations

……

……

(v) personnel training ……

……

……

(vi) maintenance of records ……
……

……

(vii) how problems affecting safety are identified and corrected

……

……

(viii) other useful relevant information:

……

……

(b) Identify the authorized users, qualified experts, and Radiation Safety Officer by name and include their training, education, experience and qualifications. (Note: the authorized user and/or Radiation Safety Officer may be the same individual).

Name **Qualification** **Experience**

1.
……..

2.
……..

3.
……

4. ……

5.
……

2. Individual Monitoring

What are the personal dosimeters provided to workers?

(i) Thermo luminescent dosimeter (TLD) ……
(ii) Direct reading dosimeter (DRD) ……
(iii) Optically stimulated luminescence (OSL) ……...
(iv) Others: ……..

3.List the protective equipment (e.g. lead apron, gonad shield e.t.c.) available at the facility.

……
……..

4. Local rules and supervision

(a) Describe your training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety:

……
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……..

(b) Describe how you provide workers the information regarding health risks due to occupational exposure:

……
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……
……
……

(c) Describe your policies regarding female workers who become pregnant notification, adoption of working conditions to protect foetus/embryo and the instructions you will provide to them:

……
……
……
……
……
……
……
……
……

3. Emergency procedures

Provide your emergency procedures to address emergencies such as substantial accidental exposure of an individual or any other emergencies envisaged

……
……
……

……
……

** attach more sheets if necessary*

PART V: DECLARATION

I declare that to the best of my knowledge the information provided above are true and correct

Name
……

Address……

Signature
……

For Official Use Only

(i) Date at which application form was Received:……

(ii) Date at which the Application was evaluated:
……

(iii) Licence / Registration No.:…….

(iv) General Remarks and/or Comments:
……

……

UNITED REPUBLIC OF TANZANIA

Form TAEC 3

Tanzania Atomic Energy Commission
P.O. BOX 743,
ARUSHA.

ATOMIC ENERGY ACT (NO.7 OF 2003)
(PART III SECTION 18 AND 20)

INSTRUCTIONS : (i) Provide ALL the requested information
(ii) Information in item numbers 2 to 4 should be provided for each equipment/facility.Use page duplicates
(iii) Tick appropriate box, and use separate sheet where necessary

NOTE: The Commission may require additional information to fully consider this application prior to issuing a license

APPLICATION FOR AN AUTHORIZATION TO POSSES AND USE A RADIOTHERAPY SOURCE(S)

1. GENERAL INFORMATION

(a) Name of Applicant/Institution:……..……..……..
Address:
……..……...…….

……..

……..……..…
Telephone No:……..……Fax:…….……Email:……

(b) Classification of the Applicant: Government ☐ Non-government ☐

(c) Type of license application: : New ☐ Amendment…. ☐ renewal ☐ Year:……..

(d) Purpose of application: Construction ☐ use/begin operation .. ☐

(e) Name and Title of the head of Institution:…….……
……..……

(f) Person responsible for radiation safety:.
Name:…….……Title:……..…….……

Qualification:…….……..Certification:…….…….……
Experience:……..…….…….……..

(g) Radiation qualified experts (e.g. Radiation Oncologists, Radiologists, medical physicists, etc.)

Name	Title	Qualification	Certification	Experience	Registration No.
……	…….	……..	……	……	……..
……..	……	……..	…….	…….	……..
……	……	……..	…….	…….	…….
……..	……	……	…….	…….	…….
……..	……	……	…….	…….	…….
……...	……	……	……..	…….	…….
……..	……..	……	……..	……..	…….
……..	……..	……	……	……..	…….

(h) Other classified workers that will be responsible for the equipment (e.g. Technologists, Technicians, nurses, dieticians, social workers etc)

Name	Title	Qualification	Experience	Registration No

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(i) Proposed date of commissioning of facility /(*for new applications*)……
External beam therapy:…….
Brachytherapy:…….

2. SOURCES AND EQUIPMENT

Type: Accelerator ☐ Gamma ☐

(a) External beam therapy:-

Name of manufacturer: ……
Address: ……
……
……
Model No. and name: ……..
Country of manufacture: ……..
Year of manufacture: ……..
Type of gantry: Stationary ☐ rotary ☐
Output Gy/min: ……
Describe the movement of treatment table:……..
……..
……..

(i) For Gamma Units: Radionuclide:……Model No. of Source:……..……
Initial activity of the source:……
Maximum design activity:……
Total activity installed:…….
Type of source carrier or shutter (exposure mechanism):…
…….
Supplier of the source(s) and address……
…….
…….

(ii) For Accelerator: Type of radiation Maximum energy (MeV) Maximum Current (mA)

…… …..…….. ……..
……. …… ……..
…… …..…….. ……..
……. …… ……..
…… …..…….. ……..

(b) Brachytherapy:

(i) Equipment

Manufacturer	Model No	Radionuclide	Type of loading: Manual (M) Remote (R)	Dose rate: High (H) Low (L)	Number of channels (Remote)	Maximum Activity
			M R	H L		
			M R	H L		
			M R	H L		
			M R	H L		

(ii) Sources

Manufacturer	Model No.	Radionuclide	Physical type: Ribbon (R) Wire (W) Individual (I)	Physical dimensions and shape	Total activity (per cm for wires and ribbons)	Number of sources: (total activity for wire)

3. Standards:

Indicate to which IEC and ISO standards does the equipment and sources used for medical exposure conform:

Equipment:……
Are prototype test certificates available: Yes☐ No ☐ ; if yes attach copies

Sources:……
Are source certificates available: Yes/No; if yes attach original copies

4. Services and maintenance

Identify who will be authorized to perform the service and maintenance of the equipment:

Name:……Authorization reference No:……..
Organization:……..Address:…….
Telephone number:……

5. Location of equipment/Sources

Provide the details of the location of equipment/sources

(a) External beam therapy

(i)Name of Unit/Dept.……bldg No:……Room No:…….Floor (if applicable)……
(ii) Place: land reg.No./plot no……..
(iii) Location:;Town…….……; street:…….; ward:……
(iv) District:……..; Region:……

(b**) Brachytherapy**

(i)Name of Unit/Dept.……bldg No:……Room No:…….Floor (if applicable)……
(ii) Place: land reg.No./plot no……..
(iii) Location:;Town…….……; street:…….; ward:……
(iv) District:……..; Region:……

6. Layout of the installation

(a) Describe factors such as the lay out of the facility and its safety systems including (i)Building materials, (ii) Alarm, (iii) Shielding, (iv)Engineering controls (e.g. interlocks, warning safety devices, emergency stop button, prevention of unauthorized personnel entering area, means of escape or communication from within enclosure etc.)

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(b) Safety assessments:

(i) Taking into account of shielding, provide calculation of maximum dose rates in all adjacent areas outside the installation:……
……
……..
……..
……

(ii) Provide estimates of the magnitude of the expected doses to persons during normal operations:
……

(iii) Identify the probability and magnitude of potential exposures arising from accidents or
incidents:……
……
……..……
……..……..……

……..……..……
……

(*Attach a layout drawing of the installation showing adjacent surroundings with controlled and supervised areas clearly identified*).

7. Security and safety of radiation sources.

Describe measures to be undertaken to ensure the security and safety of radiation sources during:

Use……
……
transport ……
……
storage:……
……..……

8.Radioactive waste management:

How will the generated radioactive wastes be managed?

(a) Source(s) returned to the supplier: Yes ☐ No ☐ ; If yes attach a copy of the agreement; if no

(b) how will it be managed in the country?

……
……..……..……
……
……

9.Emergency procedures:

Is an emergency plan available? Yes ☐ No ☐ ; If yes, attach the summary of the plan and related information e.g. organization , implementation etc.

10. Other radiation protection and safety requirements:

(i) Occupational and public exposures control: Describe your program for monitoring your work place (e.g. dose rate measurements, leak tests etc.) including any dose constraints to be applied,

……...
……
……
……
……

(ii) Medical exposures control: Describe your program for ensuring the radiation protection of patients and/or comforters during treatment with reference to the patient flow in your department (e.g. diagnosis, prescription, simulation, physical dosimetry and treatment planning, patient set up, records keeping, patient follow up etc.):

……..……
……..
……..
……..
…….. …...
……..
…….

(iii) Indicate other ancillary equipment /facilities available to support radiotherapy activities (e.g. CT scanner, Simulator, Treatment planning system, MRI, Mammography unit, ultra sound, nuclear medicine etc)…….
……
……

11.**Declaration**:

I,……(*name*) certify that all the information given herein is true and correct to the best of my knowledge.

Signature :……..…….

Date:…… Official stamp:…….

For Official Use Only

(i) Date at which application form was Received:
……..

(ii) Date at which the Application was evaluated:
…….

(iii) Licence / Registration issued No:
……

(iv) General Remarks and/or Comments:

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……

UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission
P.O. Box 743
ARUSHA

TAEC 4
Regulations 17 & 18

ATOMIC ENERGY ACT, NO 7 2003
(PART III, SECTION 17)

APPLICATION FOR AUTHORIZATION TO POSSESS AND USE UNSEALED RADIOACTIVE MATERIALS IN NUCLEAR MEDICINE, ANALYTICAL AND RESEARCH LABORATORIES

1. Type of authorization and classification of the organization
(a) New / Renewal……..……
(b) Government/Non Government……..……..

2. Name and address of Applicant

(a) Name of organization
(b) Address ……..…….
(c)Telephone/Facsimile……..……
(d) E-mail……..…….……..
(e) Name and title of Head of Applying organizatgion:……..

3 (a) Name of Radiation Safety Officer…….……..
(b) Title…….……
(c) Telephone…….……..

4. Give name(s) and qualification of available qualified experts who will use the source (s)

	Name (s)	Qualification	Last training received relevant to the field and year of training
(a)			
(b)			
(c)			
(d)			
(e)			

(Use separate sheet where necessary)

5. State the practice for which the radioactive materials will be used for (i.e. nuclear medicine, analytical or research laboratories).....…….……..
…….

6. Give details of radioactive materials available

	Radionuclide(s)	Maximum activity (Bq)	Physical/chemical form	Use / Application
e.g	Tc 99^{m} generator	37 GBq	Sodium pertechnetale	Diagnostic imaging
(a)				
(b)				
(c)				
(d)				
(e)				

7. Attach a sketch of the laboratory layout and describe laboratory facilities and factors such as:
(a) Physical separation of the laboratory from personal offices, meeting space and eating areas …….
(b) Laboratory ventilation in order to allow air circulation
……..……
(c) Fume hood available in case of experiments involving the use of volatile radioactive sources (e.g. radio iodine, and sulphur-35 labelled amino acid compounds to avoid airborne radioactivity ……
(d) Working area for wet chemistry experiments or admission of radioisotopes to patients (in case of nuclear
medicine)……..……
……..
……
…….
(e) Laboratory emergency exit doors or windows with shutters, which open outwards
……..……
…….
8. Describe any arrangement or facilities made for working with radioactive sources in field (if applicable)
……
……

9. Describe procedures for monitoring and managing the generated wastes from patients who have been administered with radioactive materials in case of urination, vomiting etc
…….

10. Give details of the preparation made for which the radioactive material stock solution(s) will be kept secure both during use and storage including:-
(a) Materials used to construct shelving/cabinets for chemical storage (e.g. hardwood or metal etc)
……..……
(b) Physical barriers provided in store for safe storage of radioactive materials (e.g. locked doors/refrigerator/drawers/boxes)……..……
(c) Log books for recording receipts, usage, discharge or disposal of radioactive materials
…….…….
(d) Name of person responsible for constant surveillance of all radioactive stock materials in store and the control access to radioactive materials with unauthorized individuals……..
…….
11. Describe how arrangement is made to separate corrosive and flammable materials from radioactive stock solutions in store……..…..
……
……
12. Explain the availability of chemical resistant and readily cleaned bench surface used on bench tops (e.g. chemical grade formica
……..……..……...

13. Explain the availability of laboratory of washing sinks installed and labelled for radioactive materials:……
……
……

14. Describe the laboratory absorbent materials available to cover laboratory bench tops which can be changed periodically when contaminated……...

15. Describe the type of spill trays available to contain material in the event of spill
……..……..……..……...
…….
16. Mention the protective gears available for working with unsealed radioactive materials (e.g. laboratory coats, disposable gloves, shoe cover, safety glasses, pipettes (automatic/manual)……..…….…….……

17. Describe the type and model of survey meters or contamination monitors available……..……..…..
…….....
.....…….....
.

18. In the table below indicate the types of possible waste (s) that will be generated after the intended application of radioisotope :

Radionuclide(s)	Waste type	Maximum activity	Proposed disposal route

19. Give details on how foot operated dustbins with plastic liners inside are used to store the types of wastes indicated in table above ……..……..

20 Mention how radwastes with activity below clearance levels (e.g. boxes, gloves, liquid etc.) will be disposed (e.g. dumpsite,
incinerator)……..……...…….
……
21. Attach a written procedure for emergency plans in case of a radiological accident
……
……

22. Declaration: I……...hereby declare that the information provided above is true and correct; and that I have read and understood the Radioactive waste management for protection of Human health and environment regulations, 1999 which I am bound to comply with during my practice.

Date …….Signature of Applicant……

For Official Use Only

(i) Date at which application form was Received:……

(ii) Date at which the Application was evaluated: ……

(iii) Licence / Registration No.:…….

(iv) General Remarks and/or Comments:
……

……

……

……

UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission *TAEC FORM 5*
P. O. Box 743,
ARUSHA

ATOMIC ENERGY ACT (No. 7 of 2003)
(PART III SECTION 18 AND 20)

APPLICATION FOR AUTHORIZATION TO USE RADIATION DEVICES OR RADIOACTIVE MATERIALS (NON MEDICAL)

1(a) Name of Institution (Applicant) :
……..……..……
……

Address:
……..……..……

……..……
……

……..……
……..

Tel No: ……..……..… Fax No. ……..…….E-mail:
……..…….

(b) Name and Title of the Head of Institution ……..……..

2. Purpose of the Device or radioactive material will be used: (e.g. Well Logging, Portable Gauging, Detection and Analytical Devices Fixed/ Installed Gauging Detection and Other similar Devices)

……..……..…
……
……
…… ……..
……
……
……

3. Details of the radiation devices and radioactive materials to be used:

(a) Equipment with sealed sources incorporated :

(i) Manufacture:……

(ii) Model No. of Device : ……

(iii) Serial No. of Device : ……

(iv) Type of Radionuclide (Cs-137, Am/Be etc: ……

Total (maximum Activity of Radionuclide and Ref. Date ……
(attach copy Manufacture's certificate)

(i) Manufacture:
……

(ii) Model No. of Device :
……

(iii) Serial No. of Device:
……

(iv) Type of Radionuclide (Cs-137, Am/Be etc……..

(v) Total (maximum Activity of Radionuclide and Ref. Date ……..
(attach copy Manufacture's certificate)

(If more than one Device, please use additional sheet)

(b) Unsealed Radioactive Sources in Industry: (*Details of radionuclides involved in the work)*

Radionuclide	**Maximum Activity**	**Physical/Chemical Form**	**Application**
(eg Carbon-14)	(e.g. 20 kBq)	(e.g. solid/liquid/gas + chemical name)	(e.g. Tracer study of oil well)

(Attach copy of Manufacture's Certificate)

(c) Radiation devices (e.g. ……) ***[give at least two example]***

(i) Manufacture:_……

(ii) Model No. of Device : ……..

(iii) Serial No. of Device: ……

(If more than one Device, please use additional sheet)

3. Name and Information about qualified experts who will use the source(s)

Name: Qualification

i) ……..
ii) ……
iii) ……

use separate / additional sheet if necessary)

4(a) Location where the device is to be used or installed. If work will be carried out outside the institution/organization, provide the work programme indicating where /when the source is to be used.
……
……
……

.(b) Will the source be returned to Supplier/Manufacture after its useful time is over [Yes ☐ No ☐]
If not, provide details on how you would dispose of the source.
……
……
……

……
……

(c) If the source will still be in good condition after the work is completed, provide details on what you intend / plan to do with the source.

5. Describe your emergency plan and preparedness procedures and security measures

……
……
……..……

6. Declaration:

I hereby declare that the information provided in this form is correct and true to the best of my knowledge.

7. Responsible Representative of the Organization / Institution

Name: ……..

Signature:……. Date: ……..

For Official Use Only

(i) Date at which application form was Received:
…….

(ii) Date at which the Application was evaluated:
…….

(iii) Licence / Registration No.: …….

(iv) General Remarks and/or Comments:

UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission **TAEC Form 6**
P.O. Box 743
Arusha

ATOMIC ENERGY ACT (NO 7 OF 2003)
PART III SECTION 18

APPLICATION FOR authorization TO POSSESS OR USE IONIZING RADIATION EMITTING EQUIPMENT FOR NON-DESTRUCTIVE TESTING (NDT) PURPOSES

1 (a) Name of Applicant / Institution ……
Postal Address ……..
Tel: No. ……..Fax: ……..E-mail……..
(b) Name and Title of Head Of Institution……..
……..

2. Classification of the Applicant –

Government ☐ Non-government ☐

3. Name of the person responsible for Radiation Safety ……
Postal Address (If different from above) …….
Telephone: ……. Fax ……..…….. E-mail…….
Title ……. Qualification ……
Certification …….

4. List names and qualifications of personnel who will be operating the NDT equipment (Note that such personnel should be having the necessary qualifications for the NDT work).

4.1 Name …….. Qualifications…….…….
4.2 Name …….. Qualification ……..
4.3 Name: ……..Qualification …….
4.4 Name ……Qualification …….

NB: Use additional sheet of paper if need be**.**

5. Details of Equipment

(a) Equipment with Radioactive sources incorporated.
(i) Manufacturer ……
(ii) Model Number: ……
(iii) Serial No. of Equipment ……..
(iv) Radionuclide used ……

(b) Equipment not incorporating radioactive sources (eg x-ray machine)

(i) Manufacturer ……..……
(ii) Model number of generator and Tube ……..……..
(iii) Serial number of generator and tube ……..…….
(iv) Maximum kilovoltage peak (kvp) ……..
(v) Maximum Tube current ……..……
(vi) Maximum exposure Time: ……

(c) Purpose for which the equipment will be used for …….……
……..

6. Radioactive Waste:
(In the case of equipment with radioactive source incorporated) Describe in details the methods which will be used for disposing of the radioactive source when it becomes disused / spent. It is being encouraged to make contracts with suppliers to receive back the radioactive sources when they become spent or disused……..
……..……
……..……
……..……
…….

7. Equipment standards:
(a) Is the NDT ionizing radiation emitting equipment proto type tested and subject to quality control provisions of standards recognised by international standards setting organizations such as (ISO, IEC etc). Yes / No ……

(b) If the answer is yes please list and identify the standards and any applicable classification. ……..
…….

8. Give the name and address of the firm/person who will be responsible for the service/ maintenance of the equipment ……..
……..

9. Location of the equipment

(a) Name of installation ……..
building ……..

(b) Plot No. if applicable ……..

(c) Location: Town …… street……. ……..
Ward ……..

(d) District ……

10. lay out of the installation (for fixed equipment)

(a) Attach a sketch of the installation indicating location of the equipment adjacent occupancies, controlled and supervised areas.

(b) Name the construction materials and thickness of the walls. ……
…….

(c) Does the installation have any interlocks: Yes/ No ……
……

(d) In case of equipment incorporating radioactive source give details of storage of equipment when not in use ……..…….

11. Radiation Protection Safety Programme.

(a) Describe your organizational and management control systems,
including assignments of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the Radiation Safety Officer, authority of Radiation Safety Officer to stop unsafe operations, personnel training, maintenance of records and how problems affecting safety are identified and corrected.
……
……
……
……..…….

(b) If applicable give list of personal protective equipment used by
Workers (eg lead gloves)

---

12. Work place monitoring, area classification and individual monitoring.

(a) Describe your programme for monitoring the workplace, including:

the quantities to be measured, where and when the measurements are to be made, the reference levels and actions to be taken if they are…… exceeded.……
……
……
……

(b) Describe your policies and procedures for classification of controlled and supervised areas.

……
……
……

c) Which type of individual personnel monitoring do you use:-
(i) Thermo luminescent dosimeter (TLD) ……
(ii) Direct Reading Dosimeters (DRD) ……
(iii) Others (name them) ……

(d) Indicate (give address) of firm organization which will be providing you with the individual personnel monitoring services.

---

13. Local Rules and supervision:-

(a) Describe copies of your operating and safety procedures including source inventory and leak testing in the case of equipment incorporating radioactive sources.

……
……
……

(b) Describe your training programme to ensure that all appropriate personnel are adequately trained in the correct operating procedures.

……
……
……
……

(c) Describe your policies regarding female workers who become pregnant (notification, adoption of working conditions to protect foetus / embryo) and the instructions you will provide to them

……
……
……
……

(d) Describe the programme of health surveillance based on general principles of occupational health with regard to initial and continuing fitness of workers for their intended tasks.

……
……
……
……

14. Quality Assurance:

(a) Describe your quality Assurance programme for your equipment in particular performance of the equipment, safety interlocks, radiation meters e.t.c.

……..……
……
……
……...

(b) Describe your programme for optimizing occupational and public exposure as low as reasonably achievable……...……...

15. Emergency procedures
Describe your emergency procedures to address emergencies such as potential damage to the source, the safety control systems, loss of source shielding, stuck sources or substantial accidental exposure to an individual.
……..……
……..……
……..……..……..

16. Declaration: I ……hereby declare that the information provided above is true and correct to the best of my knowledge.

17. Date …… Signature of Applicant and official stamp.

For Official Use Only

(i) Date at which application form was Received……..

(ii) Date at which the Application was evaluated: ……

(iii) Licence / Registration No: ……..

(iv) General Remarks and/or Comments:

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……

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UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission **TAEC FORM 7**
P.O. Box 743,

ATOMIC ENERGY ACT, NO 7 2003
(PART III, SECTION 23)

APPLICATION FOR AUTHORISATION TO MAKE MODIFICATIONS OF RADIATION DEVICES, MATERIALS OR PREMISES

1. Name and address of Applicant:

(a) Head of Institution Applying for licence ……..
(b) Name of Institution Applying for licence ……
(c) P.O. Box ……
(d) Town / Country ……..
(e) Telephone ……..
(f) Fax ……
(g) E-mail ……

2. Licence No. of Device, Material or Premises for which licence for modification is being requested:……
……

3. Identify / Specify by giving the Technical or location details, as per the licence No. above of the device, materials or premises to be modified:
……
……

4. Describe the purpose, nature and extent of the modification requested, including relevant technical drawings:-

a. Purpose (*e.g. major repair, source change, protection etc*)……
……
b. Nature:- ……..……...
……
c. Extent:- ……...
……..……

5. Name and Address of company/organization authorized to make the modification: (give licence No. or authority reference)……
……
……

6. List the radiation protection measures to be taken to ensure that the modification does not alter or degrade the existing safety status, procedures and compliance with existing regulations:
……
……
……

7. Give details of the intended outcome of the modification if carried out:-……
……..
……
……

8. If a device (equipment) is to be modified, to what extent will the modification affect / impact on the work load and operational limits of the equipment in the facility;
……
……
……

(v) Declaration: I ……..do hereby certify that the information given above is correct and true.

10. Date ……..……Signature of Applicant…….……

For Official Use Only

(i) Date at which application form was Received:
…….

(ii) Date at which the Application was evaluated:
…….

(iii) Licence / Registration
No.:……

(iv) General Remarks and/or Comments:
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UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission **TAEC 8(a)**
P.O. Box 743,
ARUSHA

ATOMIC ENERGY ACT, NO 7 2003
PART III, SECTION 17

APPLICATION FOR AUTHORISATION TO IMPORT / EXPORT RADIATON DEVICE(S)

1. Name and address of Applicant:

(h) Head of Institution Applying for licence ……..…….
(i) Name of Institution Applying for licence ……..……
(j) P.O. Box ……
(k) Town / Country …….
(l) Telephone ……..
(m) Fax ……..……
(n) E-mail ……

2. Purpose for which the Radiation Device(s) will be used for (i.e Practice – Treatment, Diagnostic, NDT, Gauging, Biological irradiation etc.)
……
……

3. Valid licence of Applicant (*if not new Practice*)
……
……

4. Give a list and the corresponding Technical Details of the Radiation Device(s) to be imported or exported (a*ttach relevant parts of manuals if available);*

(a) Model Number
……..……

(b) Serial Number
……..……

(c) Maximum Voltage
……..……..

(d) Maximum Current
……..……..……..

(e) Radiation Type
……..……..……

(f) Year of Manufacture
……..……..……..

(g) Radiation device certificate, no (attach copy)
……..…..……...

(h) Type of Installation (Fixed / mobile)
……..……..

(i) Approximate cost of the radiation Device(s)……..

5. Compliance of radiation device(s) with recognized international standards: (i.e. *is the device prototype tested, and subject to quality control provisions of standards recognized by International standards setting organizations* (e.g. IEC or ISO). If so identify the standards *and any applicable classification numbers*.
……..…….
……
……..……
……..

(Please note that used /Old radiation devices are not encouraged and may be subjected to rigorous tests at a cost or demand of similar quality control test certificates).

6. Means of transport out / into country (*i.e. air, rood, rail, sea etc*.)
……
……

7. For importation

(a) Expected date of receipt
……..……

(b) For exportation expected date of shipment
……

8. Point of entry into /exit out the Country …….
……..……..……

9. Arrangements made for transport from establishment to exit point or entry point to establishment: (*You will be required to inform the Commission of arrival / transfer details for the monitoring of clearance and inland transport*).

……
……
……...

10. Preparations made for premises at which the radiation device will be used:
……
……
……..…….

11. Available qualified experts who will use the equipment (*names and qualifications*):
(i) ……
(ii)……
(iii)……..

12. Declaration: I ……..certify that I have read and understood the Atomic Energy (*Protection from Ionizing Radiation*) Regulations, 2004; and that the information given above is true and correct

13. Date ……Signature of Applicant
……..…….……

For Official Use Only

(i) Date at which application form was Received:
……

(ii) Date at which the Application was evaluated:
……

(iii) Licence / Registration No.:
……

(iv) General Remarks and/or Comments:

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UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission
P.O. Box 743,
ARUSHA

TAEC 8(b)
Regulation 17

ATOMIC ENERGY ACT, NO 7 2003
PART III, SECTION 17

APPLICATION FOR AUTHORISATION TO IMPORT / EXPORT RADIOACTIVE MATERIALS

1. (a)Name and address of Applicant:……..

(b)Head of Institution Applying for licence …….
©Name of Institution Applying for licence ……
(d)P.O. Box ……
(e)Town / Country …….
(f)Telephone ……..
(g)Fax ……
(h)E-mail ……

2 Purpose for which the Radioactive Materials will be used for (i.e. Practice: Treatment, Diagnostic, NDT, Gauging, Biological irradiation etc.)
……
……
……

3. Valid or previous Licence of Applicant (if not applying for first time):
……

4. Type of Radioactive Materials:
(a) Sealed radioactive materials (*equipment)*
……
……..……

(b) Unsealed radioactive materials (*Physical form*)
……...
……

5. For the equipment with sealed source(s) incorporated, give the following details:-

a. Is it a well logging, portable gauging, Detection or analytical etc? (*state which of above*). ……

b. State the technical details of the radioactive apparatus above:
(i) Manufacturer: ……..
(ii) Radiation type……..
(iii) Radionuclide ……
(iv) Maximum activity ……..

(v) Number of source(s) ……

(vi) Model No. of apparatus ……..……..

(vii) Name and address of supplier ……..

c. If it is a radiotherapy equipment; then give the details of the equipment as appropriate:-

(i) Name and address of manufacturer:
……..……..
……
……

(ii) Model No. and name
……
……..

(iii) Country of Manufacture ……..

(iv) Year of manufacture ……..……

(v) Radionuclides (s) ……..……

(vi) Model No. of the sources(s) ……..……

(vii) Initial activity of the sources(s) ……..……

(viii) Number of sources installed
……..

(ix) Maximum design activity ……..……..

(x) Total activity installed ……..……

(xi) Supplier of the sources
……

(xii) Cost of the equipment …….

6. For unsealed radioactive materials give the following details:-

(i) Radiopharmaceutical
……..……..……...

(ii) Maximum activity ……..……...

(iii) Physical form ……..……..

(iv) Chemical form
……..……..……

(v) Initial containment of the radionuclide(s):
……..……..……..
……
……..……..……

(vi) Use and method of application
……..……..……..
……..……..……

(vii) Radioactive waste management and method of disposal:
……
……
……

7. Give relevant details of any contract(s) with supplier particularly with regards to:-

a. Installation and Training of operators
……..……...
……..……

b. Repair and maintenance including warranty……
……..……..

c. Return or change of source after useful life:
……
……...……
.

8. Compliance of radioactive materials and equipment incorporating the sources with recognized international standards: (i.e. *Are the radioactive materials and equipment proto type tested, and subject to quality control provisions of standards recognized by the International Standards setting organizations: e.g. IEC or ISO).* If so identify the standards and any applicable classification numbers.

……
……

(*Please note that used/old radiation devices are not encouraged and may be subjected to vigorous control test certificates before being allowed into the country*).

9. Means of Transport out/into the country (*i.e. air, road, rail, sea etc.*)…….
……..……

10. For importation
    a. Expected date of receipt
    ……..……
    b. For exportation expected date of shipment
    ……..……

11 . Point of entry/exit into the country: …….
……
……

12. Arrangements made for transport from entry point to establishment or establishment to exit point.

(*You will be required to inform the Commission of the arrival / Transfer details prior to clearance of the radiation materials for monitoring during Transport*).
……
……

13. Give details of the preparations made for premises at which the radioactive materials will be stored prior to installation; and used or installed:
……
……

14. Give a list of available qualified experts who will use the equipment or radioactive materials:
(Names & Qualifications).

a. ……..
b. ……..
c. ……..

15 Declaration: I ……certify that I have read and understood the Atomic Energy (*Protection from Ionizing Radiation*) Regulations, 2004 and that the information given is true and correct.

16. Date: …… Signature of Applicant……..

For Official Use Only

(i) Date at which application form was Received:…….

(ii)Date at which the Application was evaluated: …….

(iii) Licence / Registration No.: …….

(iv) General Remarks and/or Comments: ……

……

……

UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission
P.O. Box 743,
ARUSHA

TAEC 8(c)
Regulations 17 & 73

ATOMIC ENERGY ACT, NO 7 2003
(PART III, SECTION 17)

APPLICATION FOR AUTHORISATION TO TRANSPORT RADIOACTIVE MATERIALS

1. Name and address of Applicant:

(o) Head of Institution Applying for licence ……..……..
(p) Name of Institution Applying for licence ……..……
(q) P.O. Box ……
(r) Town / Country ……..
(s) Telephone ……..
(t) Fax ……..……
(u) E-mail ……

2. State the practice for which the radioactive material(s) is used for (*e.g. Treatment, Diagnostic, NDT, Gauging, Logging, Biological Irradiation etc.)*

……
……

3. Valid licence or Registration No. for possession and use of radioactive materials by Applicant (if applicable) wishing to transport source in the Country. …….
……
……

4. Valid licence or Registration No. for Possession and use of radioactive materials by prospective recipient in Tanzania.
……
……

5. Type of Radioactive Materials to be transported:-
   a. Sealed radioactive Materials (Equipment): ……..…….
   ……..……..
   b. Radioactive Materials for use as Unsealed sources: …….……...
   ……..…….

6. Describe the purpose of the intended transport of the radioactive materials within or into country:- (*Sale, loan, normal operations in new area, Import/Export consignment, radiowaste to CRWMF etc*.)
……
……
……

7. Describe the packaging measures and methods made to comply with safety and transport requirements as per Regulations:- ……..……...
……..……
……..……

8. Describe the package details as established for compliance with Transport Regulations:……
……
……

9. Planned means of Transport within Country (*e.g. from exit / entry point to the establishment i.e. air, road, rail, sea etc).*
……
……
……

10. Give details of vehicle, company and personnel responsible for the conveyance of the radioactive material package(s) in …….……..……...
……
……
……

11. Give details of the preparations made with regards to safety for premises at end point or establishment (*if transport is within the country*) where the equipment or radioactive materials will be stored, managed or used:……..
……
……..……

12. Describe your emergency plan and preparedness procedures

……..…….
……
……..…….

13. Declaration: I …….declare that the information above is true and correct.

14. Date……..……Signature of Applicant……

For Official Use Only

(i) Date at which application form was Received:
……

(ii) Date at which the Application was evaluated:
……

(iii) Licence / Registration No:
…….

(iv) General Remarks and/or Comments:

……...

……

UNITED REPUBLIC OF TANZANIA

Tanzania Atomic Energy Commission
P.O. Box 743,
ARUSHA

TAEC 9
Regulation, 18

ATOMIC ENERGY ACT, NO 7 OF 2003
(PART III, SECTION 25

APPLICATION FOR A REGISTRATION TO ADMINISTER IONIZING RADIATION TO PERSONS / PATIENTS

1. Name and Address of Applicant:
   (a) Name ……..
   (b) Address ……..
   (c) Phone / Fax ……
   (d) E-mail …….

2. Highest qualification and specialization attained: (*attach certified copy of certificates and brief CV*)

……
……
……

3. Membership to Professional Bodies to which reference can be sought if needed:
……
……

4. Previous TAEC Registration No. (*if not new application*): ……
……

5. Give practice under which the administering of ionizing radiation is to be carried out:-
……
……

6. Personal details:-
   (a) Age:- ……
   (b) Gender ……..
   (c) Length of service and experience ……
   (d) Current employer and address (if different from that above)……
   ……..……..
   ……..……..
   ……
   (e) Institutions you work for as part time:-
   ……
   ……

7. Declaration: I …… hereby declare that the information provided above is true and correct; and that I have read and understood the Atomic Energy *(Protection from Ionizing Radiation*) Regulations, 2004 which I am bound to comply with during my practice.

Date: ……..……..…Signature of Applicant ……..……

For Official Use Only

(i) Date at which application form was received
……..……..

(ii) Date at which the Application was evaluated:
……

(iii) Licence / Registration No.:
……

(iv) General Remarks and/or Comments:
……
……
……
……