GOVERNMENT NOTICE NO. 840 published on 17/11/2023

THE ATOMIC ENERGY ACT,
(CAP. 188)

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REGULATIONS

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(Made under section 70)

THE ATOMIC ENERGY (PROTECTION FROM IONIZING AND NON-IONIZING RADIATION) REGULATIONS, 2023

ARRANGEMENT OF REGULATIONS

Regulations *Title*

GN NO. 480 (Contd)

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(c) Public Exposure

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THE ATOMIC ENERGY ACT,
(CAP. 188)

REGULATIONS

(Made under section 70)

THE ATOMIC ENERGY (PROTECTION FROM IONIZING AND NON-IONIZING RADIATION) REGULATIONS, 2023

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Atomic Energy (Protection from Ionizing and Non-Ionizing Radiation) Regulations, 2023.

Application

2. These Regulations shall apply to-

(a) activities involving the adoption, introduction, conduct, discontinuance or cessation of a practice, mining, extraction, processing, design, manufacture, sitting, construction or assembly, acquisition, import or export, distribution, locating, commissioning, possession, use and operation, maintenance or repair, selling, loaning, lending, letting, hiring or transfer of radiation sources;

(b) decommissioning, disassembly, transport, storage or disposal of radioactive materials, radiation generators or devices within a practice;

(c) non-ionizing radiation in the frequency range from 0 to 300 GHz;

(d) all aspects of radioactive waste, spent nuclear fuel, disused sealed radiation sources arising from medical, industrial and research applications; and

(e) any other radiation practice which may be specified by the Commission.

Interpretation

3. In these Regulations, unless the context otherwise requires-

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"laser product" means any manufactured product or assemblage of components, which constitutes, incorporates, or is intended to incorporate a laser or laser system, which emit electromagnetic radiations; and a laser or laser system that is intended for use as a component of an electronic product shall itself be considered as laser product;

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

"unsealed source" means a radioactive source in which the radioactive material is neither permanently sealed in a capsule nor closely bonded and in a solid form;

"sealed source" means a radioactive material that is permanently sealed in a capsule, or closely bonded and in a solid form;

"container" means the vessel into which the waste is placed for handling, transport, storage or eventual disposal; also the outer barrier protecting the waste form from external intrusion;

"referring medical practitioner" means health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure;

"radiological medical practitioner" means a health professional with specialist education and training in the medical uses of radiation, who is competent to perform independently or to oversee procedures involving medical exposure in a given specialty;

"dose" means a measure of radiation received or absorbed by a target;

"dose constraint" means a prospective and source related value of individual dose that is used in planned exposure situations as a parameter for the optimisation of protection and safety for the source, and that serves as a boundary in defining the range of options in optimisation;

"phantom" means a physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement;

"existing exposure situation" means a situation that already exists when a decision on control has to be taken, including natural background radiation and residues from past practices that were operated outside the regulatory requirements;

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"technical services" includes personnel dosimetry services, individual and work place monitoring services, standard calibration services, environmental monitoring services, radio analytical measurements, repair and maintenance of nuclear equipment and any other related services as determined by the Commission;

"device" means a manufactured product that produces radiation;

"equipment" means manufactured products that produce radiation;

"radioactive waste management facility" means facility specifically designed to handle, treat, condition, store or permanently dispose of radioactive waste;

"reference level" means radiation exposure level provided for practical exposure assessment purposes to determine whether the basic restrictions are likely to be exceeded;

"radiation generator" means a device capable of generating both ionising and non-ionising radiation including ultrasound equipment, magnetic resonance imaging (MRI), class 4 laser products, radio transmitters, radar stations, communication base stations, X-Ray equipment, and any other devices of similar nature that may be used for scientific, industrial, communication, or medical purposes;

"containment" means the methods or physical structure designed to prevent the dispersion of radioactive substances;

"conditioning" means preparation of disused radioactive sources or radioactive waste packages with the aim of placing them in a protective and safe structure for handling, transportation, storage or disposal;

"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;

"spent nuclear fuel" means nuclear fuel removed from a reactor following irradiation, which is no longer usable in its present form because of depletion of fissile material, buildup of poison or radiation damage;

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

"radiation" includes both ionising and non-ionising radiation;

"laser radiation" means all electromagnetic radiation emitted by a laser product or laser sourcewithin the spectral range

that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance;

"occupational exposure" means an exposure to radiation experienced by a worker in the course of performing his work;

"safety case" means a collection of arguments and evidence in support of the safety of a facility or activity;

Cap. 188 "Act" means the Atomic Energy Act;

"Commission" means the Tanzania Atomic Energy Commission established under section 5;

"treatment" means a process and method of changing the characteristics of the radioactive waste through volume reduction, removal of radionuclides from the radioactive waste or change of composition with the intention to benefit safety and economy;

"quality assurance" means all those planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example those specified in license;

"surveillance" means monitoring of human exposure to radiation or monitoring of a radiation emitting source;

"storage" means the holding of spent nuclear fuel or radioactive waste in a facility approved by the Commission that provides for its containment, with the intention of retrieval;

"exposure limit" means an upper limit placed on human exposure to radiation to protect against adverse physiological responses that are causally related to radiation field, and such limits are not intended to provide protection against other effects arising from fear of such exposures;

"security" means the prevention of, detection of, and response to, criminal or intentional unauthorised acts involving or directed at nuclear material, other radioactive material, associated facilities or activities;

"public" means the entire population excluding workers, members of the military or a patient under medical care, and includes individuals of all ages, and of varying health status, and articularly vulnerable groups or individuals such as the frail, elderly, pregnant workers, babies and young children;

"discharge" means the direct release of effluents into the environment with subsequent dispersion;

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"waste management" means all the activities, administrative and operational, that are involved in the handling, pretreatment, treatment, conditioning, transportation, storage and disposal of radioactive waste;

"installation" means a mounting or erection or assemblage that incorporates a source of radiation;

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

"clearance" means removal of radioactive materials or radioactive objects within authorised practices from any further control by the Commission;

"waste package" means the product of conditioning that includes the waste form, any containers and internal barriers such as absorbing materials and liners, prepared in accordance with the requirements for handling, transport, storage or disposal; and

"clearance levels" means the values established by the Commission and expressed in terms of activity concentration or total activity concentration, at or below the level which the source of radiation may be released from the control of the Commission.

PART II
ADMINISTRATIVE REQUIREMENTS

General obligations

4. A person shall not engage in activities, which involve practices, radiation generators, radioactive waste, unless the requirements of these Regulations are complied.

Responsibilities for protection, safety and security

5.-(1) A licensee and registrant responsible for a facility or activity that gives rise to radiation risks shall have the prime responsibility for protection, safety and security.

(2) Parties responsible for protection, safety and security are-

(a) licensees or registrants, the person or organisation responsible for facilities and activities;

(b) employers, in relation to occupational exposure;

(c) radiological medical practitioners, in relation to medical exposure;

(d) persons or organisations designated to deal with

emergency exposure situations or existing exposure situations.

(3) Other parties that have specified responsibilities in relation to protection, safety and security including:

(a) suppliers of sources, providers of equipment and software, and providers of consumer products;

(b) radiation protection officers;

(c) referring medical practitioners;

(d) medical physicists;

(e) medical radiation technologists;

(f) qualified personnel or any other party to whom a principal party has assigned specific responsibilities;

(g) workers other than workers listed in regulation; and

(h) law enforcers and other relevant regulatory authorities.

(4) A licensee and registrant shall apply measures for protection and safety that are commensurate with the radiation risks associated with the exposure situation.

(5) A licensee and registrant shall ensure that, in the implementation of the protection, safety and security program include the following:

(a) measures and resources that are necessary for achieving the objectives for protection and safety have been determined and are duly provided;

(b) periodic review to assess its effectiveness and its continued fitness for purpose;

(c) identified failures or shortcomings are corrected, and steps are taken to prevent their recurrence;

(d) arrangements made to consult with interested parties;

(e) record keeping and maintenance.

(6) A licensee and registrant shall ensure that all personnel engaged in activities relevant to protection, safety and security have appropriate education, training and qualification.

Responsibilities of Commission

6. The Commission shall-

(a) review the monitoring programs of registrants and licensees;

(b) review of periodic reports on occupational and public exposure including results of monitoring programs and dose assessments submitted by registrant and licensee;

(c) provide maintaining exposure records and results of the assessment of doses from occupational

exposure;

(d) approve documents addressing the optimisation of protection and safety;

(e) establish program for managing, controlling and recording the doses received in an emergency by emergency worker, which shall be implemented by response organisations and employers;

(f) establish reference levels for exposure due to radionuclides in commodities;

(g) enforce compliance with the dose limits and reference levels specified in Second and Eighth Schedules of these Regulations for public exposure;

(h) approve dose constraints on dose and on risk, in consultation with professional bodies as appropriate, or establish or approve a process for establishing such constraints, to be used in the optimisation of protection and safety;

(i) provide information on levels of indoors radon exposure and the associated health risks;

(j) implementation of an action plan for controlling public exposure due to radon indoors;

(k) evaluate the efficiency of the actions planned and implemented;

(l) review and approve monitoring programs of registrant and licensee;

(m) make provision for an independent monitoring programs;

(n) make provision for maintaining records of discharges of radioactive materials, results of dose monitoring programs and results of assessments of public exposure;

(o) verify the compliance of an authorised practice with the requirements for control of public exposure;

(p) maintain record of results from source monitoring, environmental monitoring programs and assessments of doses from public exposure;

(q) establish and provide information on levels of indoors radon and the associated health risks;

(r) specify general principles for protection strategies to reduce exposure when remedial actions and protective actions have been determined;

(s) arrange for evaluation of the available remedial actions and protective actions for achieving the

objectives;

(t) to assign responsibilities for the establishment and implementation of protection strategies to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions;

(u) specify the exposure situations that are included in the scope of existing exposure situations;

(v) establish protection strategies for existing exposure situation which include the objectives to be achieved by means of the protection and appropriate reference levels;

(w) provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies;

(x) review periodically, the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances;

(y) ensure that the protection strategies for the management of existing exposure situations are established and commensurate with the radiation risks associated with the existing exposure situation; and

(z) ensure that a strategy for radioactive waste management is put in place to deal with any waste arising from the remedial actions and that provision for such a strategy is made in the framework for protection and safety.

Exemption of practices and sources

7.-(1) Practices and sources within a practice may be exempted from the specific safety requirements as provided in these Regulations provided that they comply with criteria for exemption prescribed in the First Schedule of these Regulations.

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

(3) The following practices and sources within a practice are exempted from the specific safety requirements, including the requirements for notification, registration or licensing as provided in these Regulations.

(a) radioactive materials in a moderate amount for which the total activity of a given radionuclide present on the premises at any one time or its activity concentration does not exceed the applicable

exemption levels prescribed in First Schedule of these Regulations;

(b) radioactive material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in the First Schedule to these Regulations;

(c) Magnetic Resonance Imaging (MRI) equipment other than for patients in the health sector;

(d) non-ionising radiations practices which include Devices emitting electromagnetic radiation in the Ultra Violet (UV), laser sources in these spectral regions, infra red (IR) radiation, radio frequencies (RF) radiation in spectra range 1mm -1000km shall be exempted from these regulations as prescribed in the Ninth Schedule to these Regulations.

PART III
NOTIFICATION AND AUTHORISATION

Requirements for notification

8.-(1) A person who intends to carry out any of the actions specified in these Regulations shall submit a notification to the Commission in a manner prescribed by the Commission.

(2) After receipt of notification as specified in subregulation (1) the Commission shall inform the person if the actions require authorisation.

Requirements for authorisation

9.-(1) A person who intends to carry out any activities specified in these Regulations shall apply to the Commission for authorisation through registration or licensing.

(2) A person who applies for authorisation shall-

(a) submit an application form as prescribed by the Commission with documents necessary to support the application as required in the form;

(b) assess the nature, likelihood and magnitude of the expected exposures due to the source and take measures for protection, safety and security;

(c) submit a radiation safety and security plans;

(d) submit appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity;

(e) provide qualifications in radiation protection of the

persons dealing with the radiation sources;

(f) submit report of the information and consultation with public and other interested parties that will be affected by activity or facility; and

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(g) pay license fee as prescribed in the Atomic Energy (Fees and Charges) Regulations, 2022.

(3) Notwithstanding the provision of subregulation (2) an application for authorisation of a radioactive waste management or interim storage facility shall specify the following:

(a) the quantity, type and characteristic of radioactive waste, spent nuclear fuel or disused sealed radiation sources to be managed;

(b) the suggested operation of the proposed facility or activity and equipment to manage the radioactive waste, spent nuclear fuel or disused sealed radiation sources (DSRS);

(c) a safety case;

(d) a proposed destination for the disposal of the radioactive waste, spent nuclear fuel or disused sealed radiation sources (DSRS);

(e) a proposed system for record keeping;

(f) contingency plans in the event of emergency;

(g) proposal for discharge and environmental monitoring; and

(h) any other details the Commission may consider necessary for the purpose.

(4) Applications for authorisations involving Category 1 to 5 radioactive sources shall describe arrangements for the safe management of the sources, including declaration of financial soundness and provisions for return of the source to the Country of origin once they have become disused.

(5) A licensee or registrant shall apply for authorisation to transport Category 1 to 5 radioactive material, minerals containing radioactive materials, nuclear materials, and Naturally Occurring Radioactive Materials (NORMs) within or on transit through Tanzania and pay fees in accordance with the Atomic Energy (Fees and Charges) Regulations, 2022.

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(6) The Commission may impose conditions or limitations, as it may deem fit or necessary in any particular case.

Requirements for authorisation of technical

10.-(1) A person who intends to carry out any technical services specified in these Regulations shall apply to the Commission for authorisation in terms of registration or licensing.

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services

(2) A person who applies for authorisation for technical services shall-

(a) submit an application form and supporting documents as prescribed by the Commission to be appropriate;

(b) assess the nature, likelihood and magnitude of the expected exposures due to the source and take measures for protection, safety and security;

(c) submit a plan for safety, radiation protection, waste management or security depending on the nature of activity;

(d) provide a certificate in radiation protection from a recognised institution of the persons who will be providing technical services; and

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(e) pay license fee as prescribed in the Atomic Energy (Fees and Charges) Regulations, 2022.

Authorisation and prescriptions of all forms by Commission

11.-(1) Where the Commission is satisfied that the applicant has complied with the conditions specified under regulation 9, the Commission shall grant the authorisation as follows:

(a) in case of authorisation to import, export and transport of radiation sources, its validity shall not exceed twelve months;

(b) incase of authorisation to use or possess radiation source and radiation premise, the validity for authorisation shall be for the interval of a fiscal year;

(c) in case of authorisation to use, possess, generate, transport, import, export, dispose, produce, manufacture of products, distribute products, store, transfer, extract any material containing naturally occurring radioactive material and any other related activities as may be specified by the Commission and provider of technical services, the validity for authorisation shall be three years;

(d) in case of authorisation to prospect radioactive minerals, sitting and construction of a mining or processing facilities, mining or processing of radioactive minerals, transport of concentrate radioactive minerals, decommissioning of a mining or processing facilities the ores, the validity for authorisation shall be as prescribed in the mining license issued by the Ministry responsible for

mining.

(2) For the purposes of implementing the provisions of these Regulations, the Commission may prescribe all forms relating to applications, notifications and authorisations issued under these Regulations.

Renewal of authorisation

12. A licensee or registrant may apply for renewal of the authorisations of the license three months prior to the expiry date of License.

Modification, suspension and revocation of authorisation

13.-(1) The Commission may modify, suspend or revoke an authorisation where the Commission-

(a) find an undue threat to health, safety or non-compliance with applicable requirements;

(b) receives an application for modification from licensee or registrant.

(2) The licensee or registrant may apply for authorisation for modification as prescribed in regulation 8.

Registration of qualified personnel performing radiation exposures

14.-(1) Every qualified personnel or expert intending to-

(a) administer radiation to person for the purposes of diagnosis or treating a disease; or

(b) install, operate, handle, maintain, repair radiation sources or devices,

shall be registered or licensed by the Commission.

(2) Subject to the provisions of subregulation (1) the qualified personnel or expert shall-

(a) submit to the Commission an application form as prescribed by the Commission;

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(b) pay a license application fee as prescribed in the Atomic Energy (Fees and Charges) Regulations, 2022;

(c) submit a certificate of radiation protection course from a recognised institution.

(3) The authorisation for qualified personnel or expert shall be valid for period of five years.

(4) A person justifying medical exposures to patients for diagnosis or therapy shall be a medical practitioner or dentists.

Transfer of radiation sources, disused radioactive sources,

15.-(1) In the event the licensees or registrant decides to transfer the radiation sources, disused sealed radioactive source, spent nuclear fuel and nuclear materials to any other person, the licensees or registrant shall obtain an authorisation from the

spent nuclear fuel and nuclear materials

Commission prior to the transfer.

(2) The licensees or registrant shall ensure that the person to whom the radiation sources, disused sealed radioactive source, spent nuclear fuel and nuclear materials is to be transferred has a valid license or registration.

Incidents and accidents

16. In the event of an incident or accident, licensees and registrants shall-

(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) take whatever other actions necessary as required by these Regulations.

Reporting in case of incident or accident

17.-(1) A licensee or registrant shall-

(a) notify the Commission by appropriate and fastest means such as telephone, facsimile, e-mail immediately of any event in which a dose limit or reference level is exceeded;

(b) notify the Commission by telephone, facsimile, e-mail within twenty four hours of the discovery of any significant unintended or accidental medical exposures;

(c) submit to the Commission, within thirty days after discovery of any significant unintended or accidental exposures, a written report which states:

(i) the cause of any significant unintended or accidental exposures and includes information on the doses, corrective measures, preventive actions taken or to be taken and any other relevant information;

(ii) summary of the public exposure monitoring results at approved intervals;

(iii) discharges of radioactive waste to the environment at intervals as may be specified in the license and promptly report any discharges exceeding the authorised limits; and

(iv) any releases of radioactive material to the environment above the clearance criteria established in these Regulations;

(d) promptly inform the Commission of any abnormal results which lead or could lead to an increase of

public exposure.

(2) In addition to the radiation safety report, licensee and registrant shall report to the Commission and the police station within twenty four hours on-

(a) loss of control over a radioactive source;

(b) unauthorised access to, or unauthorised use of, a source;

(c) discovery of any orphan sources; and

(d) actual or attempted theft of sources.

Reporting

18. A licensee or registrant shall report to the Commission on-

(a) radioactive source inventory data and subsequent changes to those data, except for routine movements of the source allowed in the authorisation;

(b) any intentions to introduce modifications to any practice with a radioactive source whenever the modifications could have significant implications for safety;

(c) measures addressing the optimisation of protection and safety;

(d) a copy of relevant parts of any contract or acceptance document relating to the return to the supplier of radioactive sources intending to be imported.

Investigations and feedback of operating experience

19.-(1) The licensee or registrant shall investigate on-

(a) quantity or operating parameters relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions; or

(b) any equipment failure, accident, error, mishap or other unusual event or condition that may occur has the potential for causing a quantity to exceed any relevant limit or operating restrictions.

(2) The licensee or registrant shall prepare and submit to the Commission and other relevant parties, a written report on normal operation performance as well as abnormal conditions and events significant to radiation safety, its causes or suspected causes, including determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.

Research

20. A person or organisation intending to carry out

approval

research work related to peaceful application of nuclear technology shall apply to the Commission for approval by-

(a) submitting an application form with relevant information to support the application including the research proposal;

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(b) paying for fees as prescribed in the Atomic Energy (Fees and Charges) Regulations, 2022.

Clearance of radiation sources

21.-(1) Radiation sources, including substances, materials, radioactive waste and objects within notified or authorised practices can be released from further compliance with the radiation protection and safety requirements provided that they comply with criteria for clearance in First Schedule to these Regulations or clearance levels established by the Commission.

(2) A person shall not clear materials from licensed facilities and activities or from unlicensed contaminated land or facilities unless it is approved by the Commission.

PART IV
REQUIREMENTS FOR RADIATION PROTECTION

Justification of practices

22.-(1) No practice shall be authorised unless it is likely to produce sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors.

(2) The applicant for an authorisation shall provide sufficient information and evidence on the benefits and the harm to support the justification of the practice or source.

(3) The following practices shall be deemed to be not justified:

(a) practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, fertilizer, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;

(b) practices involving the frivolous use of radiation or radioactive substances in commodities or in products such as toys and personal jewelry or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;

(c) human imaging using radiation that is performed as a form of art or for publicity purposes;

(d) human imaging using radiation for theft detection purposes;

(e) human imaging using radiation for the detection of concealed objects for anti-smuggling purposes; and

(f) human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication.

(4) Where, in exceptional circumstances, the Commission decides that the justification of such human imaging for specific practices is to be considered, such practice shall comply with regulation 33.

(5) Human imaging using radiation for the detection of concealed objects that can be used for criminal acts or to pose a national security threat shall be justified only by the Government.

Optimisation of protection and safety

23.-(1) A licensee or registrant shall ensure that protection and safety is optimised for occupational and public exposure.

(2) A licensee and registrant shall ensure that all relevant factors are taken into account in a coherent way in the optimisation of protection and safety to achieving the following objectives:

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

(b) to establish criteria, on the basis of the results of the optimisation, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that may occur;

(c) for occupational and public exposure, licensee and registrant shall ensure that relevant constraints are used in the optimisation of protection and safety for any particular source within a practice.

Dose constraints

24.-(1) For occupational and public exposure, licensee and registrant shall ensure relevant constraints are used in the optimisation of protection and safety for any particular source

within a practice.

(2) In case of any source that can release radioactive material to the environment, the dose constraints shall be established by licensee or registrant, so that the prospective annual doses to workers summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in the Second Schedule to these Regulations.

Dose limits and reference level

25.-(1) A licensee or registrant shall ensure that the exposures of individuals due to the authorised practices are restricted so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit or reference levels specified in Second, Fourth and Eighth Schedules to these Regulations.

(2) The dose limits or reference levels shall not apply to medical exposures from authorised practices.

(3) A licensee and registrant shall ensure that exposure limits are in conformity with those of the Commission and International Commission on Non-Ionizing Radiation Protection (ICNIRP) which are recommended by World Health Organisation (WHO), to protect workers and general public against excessive exposure to non ionising radiations.

Management for protection and safety

26.-(1) The licensee and registrant shall ensure that protection and safety is effectively integrated into the overall management system of the organisations for which they are responsible.

(2) The licensee and registrant shall establish a management system, commensurate with the size and nature of the authorised activity, which ensures that-

(a) policies and procedures are established that identify safety as being of the highest priority;

(b) problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;

(c) the responsibilities of each individual for safety are clearly identified and each individual is suitably trained and qualified;

(d) clear lines of authority for decisions on safety are defined;

(e) Organisational arrangements and lines of communications are established that result in an appropriate flow of information.

(3) The registrants and licensees shall ensure that the management system is designed and implemented to enhance protection, safety and security by-

(a) applying the requirements for protection and safety coherently with other requirements including requirements for operational performance, and coherently with guidelines for security;

(b) describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;

(c) ensuring that radiation protection is not compromised by other requirements;

(d) providing for the regular assessment of performance for protection and safety and the application of lessons learned from experience;

(e) promoting safety culture; and

(f) ensuring confidentiality of information that it receives from another party is protected.

(4) The licensee and registrant shall ensure that the protection, safety and security elements of the management system are commensurate with the complexity of and the radiation risks associated with the activity.

Safety culture

27. The licensee and registrant shall promote and maintain a safety culture by-

(a) promoting individual and collective commitment to protection and safety at all levels of the organisation;

(b) ensuring a common understanding of the key aspects of safety culture within the organisation;

(c) providing the means by which the organisation supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organisation;

(d) encouraging the participation of workers, their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;

(e) ensuring accountability of the organisation and of individuals at all levels for protection and safety;

(f) encouraging open communication with regard to protection and safety within the organisation and with relevant parties, as appropriate;

(g) encouraging a questioning and learning attitude and

discouraging complacency with regard to protection and safety; and

(h) providing means by which the organisation continually seeks to develop and strengthen its safety culture.

Human factors

28.-(1) The licensee and registrant 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 re-trained or re-qualified as may be appropriate.

(2) The licensee and registrant shall follow sound ergonomic principles in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment, to minimise the possibility that operator errors will lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions will be misinterpreted.

(3) The licensee and registrant shall provide appropriate equipment, safety systems and operational procedural which-

(a) reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other incidents leading to the exposure of any person;

(b) provide means for detecting human errors and for correcting or compensating them;

(c) facilitate protective and corrective actions in the event of failures of existing safety systems or failures of existing measures for protection and safety.

PART V
VERIFICATION OF SAFETY

Safety assessment

29.-(1) The licensee and registrant shall submit a safety assessment which shall be reviewed by the Commission.

(2) The licensee and registrant shall conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible.

(3) Safety assessments shall be conducted at different stages including the stages of site design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning or closure of facilities or parts thereof, as appropriate, for the purpose of-

(a) identifying the ways in which exposures could be incurred, account being taken of the effects of external events as well as of events directly involving the sources and associated equipment;

(b) determining the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, to make an assessment of potential exposures;

(c) assessing the adequacy of the provisions for protection and safety.

(4) The safety assessment shall include, as appropriate, a systematic critical review of-

(a) operational limits and conditions for the operation of the facility;

(b) ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;

(c) determining the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, to make an assessment of potential exposures;

(d) assessing the adequacy of the provisions for protection, safety and security;

(e) ways in which external factors could affect protection and safety;

(f) ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;

(g) implications for protection and safety of any modifications;

(h) any uncertainties or assumptions and their implications for protection and safety.

(5) The registrant or licensee shall take into account in the safety assessment-

(a) factors that could give rise to a substantial release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;

(b) factors that could give rise to a smaller but

continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;

(c) factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or to control such occurrences;

(d) the extent to which the use of redundant and diverse safety features that are independent of each other, so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposures.

Monitoring and verification of compliance

30.-(1) The licensee and registrant shall conduct monitoring to verify compliance with the requirements for protection and safety.

(2) The licensee and registrant shall submit to the Commission for review and authorisation its monitoring and measurement programs.

(3) The licensee and registrant shall ensure that-

(a) monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and license conditions;

(b) suitable equipment is provided and procedures for verification are implemented;

(c) equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;

(d) records of the results of monitoring and verification of compliance that include records of the tests and calibrations carried out are maintained;

(e) the results of monitoring and verification of compliance are shared with the Commission as required;

(f) routine compliance inspections are conducted at least once in every year for high risk radiation facilities, once in two years for medium risk radiation facilities, and once in three to five years for low risk radiation facilities.

Inventory and records

31.-(1) The licensee and registrant shall maintain records and make available to the Commission whenever they are

required.

(2) The records in subregulation (1) shall include information relating to-

(a) inventory of sealed sources, unsealed sources and radiation generators;

(b) records of doses from occupational exposures;

(c) records relating to facilities and activities;

(d) inventory of radioactive waste;

(e) records of events, including non-routine release of radioactive material to the environment;

(f) records that might be necessary for decommissioning or closure of facilities;

(g) transfer of radioactive sources;

(h) testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of these Regulations.

(3) Individual sealed source records shall include the-

(a) location of the source;

(b) radionuclide;

(c) radioactivity on a specified date;

(d) serial number or unique identifier;

(e) chemical and physical form;

(f) source use history, including recording all movements into and out of the storage location;

(g) receipt, transfer or disposal of the source;

(h) other information, as appropriate, to enable the source to be identifiable and traceable; and

(i) chemical and physical form.

(4) The licensee and registrant shall keep a system for recording information on the generation, characteristics; processing, conditioning, storage, transportation and disposal of the waste, spent nuclear fuel and disused sealed radiation sources.

PART VI
HUMAN IMAGING FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS, MEDICAL TREATMENT OR BIOMEDICAL RESEARCH

Justification of practices of any type of human

32. The justification process applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or as part of a program of biomedical research shall

imaging using radiation

include the consideration of-

(a) the benefits and detriments of implementing and not implementing the type of human imaging procedure;

(b) any legal or ethical issues associated with the introduction of the type of human imaging procedure;

(c) the effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;

(d) the availability of sufficient resources to conduct the human imaging procedure safely throughout the intended period of the practice.

Optimisation of protection and safety

33. For the purpose of optimising protection and safety, the licensee and registrant shall-

(a) for human imaging using medical radiological equipment which exposes human to radiation without reference to clinical indications, comply with the appropriate optimisation requirements for medical exposure with dose constraints used instead of diagnostic reference levels;

(b) ensure that, subject to any dose constraints for public exposure, procedures with inspection imaging devices in which radiation is used to expose persons-

(i) for the purpose of the detection of concealed weapons, contraband or other objects on or within the body are considered to give rise to public exposure and shall apply the requirements specified under these Regulations;

(ii) person who undergo procedures with such inspections devices are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionising radiation;

(iii) for the detection of concealed objects on or within the body conforms to applicable laws as well guidelines issued by the Commission.

PART VII
PLANNED EXPOSURE SITUATIONS

GN NO. 480 (Contd)

Requirement for planned exposure situation

34.-(1) The Commission shall establish requirements for planned exposure situations which include the following practices:

(a) production, supply, provision and transport of radiation sources and devices that contain radioactive materials and of consumer products;

(b) production and supply of devices that generate radiation;

(c) generation of nuclear power, including any activities within the nuclear fuel cycle that involve exposure to radiation;

(d) use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes, including the use of associated equipment, software or devices where such use could affect exposure to radiation;

(e) use of radiation sources for education, training or research, including any activities relating to such use that involve exposure to radiation;

(f) mining and processing of raw materials that involve exposure due to radiation; and

(g) any other practice as specified by the Commission.

(2) The requirements for planned exposure situations apply to exposure due to sources within practices, as follows:

(a) radiation facilities that contain radiation sources that involve exposure to radiation;

(b) individual radiation sources within the facility.

(3) The relevant requirements for planned exposure situations apply to-

(a) exposure due to material in a practice specified in these Regulations where the activity concentration in the material of any radionuclide in the uranium decay chain or the thorium decay chain is greater than 1 Becquerel per gram (Bq/g) or the activity concentration of Potassium (^{40}K) is greater than 10 Bq/g;

(b) public exposure due to discharges or due to the management of radioactive waste arising from a practice involving material as specified in these regulation;

(c) exposure due to Radon (^{222}Rn) and its progeny in workplaces in which occupational exposure due to other radionuclides in the uranium decay chain or the thorium decay chain is controlled as a planned

exposure situation;

(d) exposure due to Radon and its progeny where the annual average activity concentration of Radon in air in workplaces remains above the reference level established in these Regulations.

Emergence exposure

35. The Commission shall establish requirements for emergency exposure situation to activities undertaken in preparedness for and in response to a nuclear or radiological emergency.

Existing exposure

36. The Commission shall establish requirements for existing exposure situations applying to-

(a) exposure due to contamination of areas by residual radioactive material deriving from-

(i) past activities that were never subject to regulatory control or that were subject to regulatory control but not in accordance with the requirements of these Regulations;

(ii) a nuclear or radiological emergency, after an emergency has been declared to be ended;

(b) exposure due to commodities and construction materials, that incorporate radionuclides deriving from residual radioactive material;

(c) exposure due to natural sources, including-

(i) radon gas and its progeny in workplaces other than those workplaces for which exposure due to other radionuclides in the uranium decay chain or the thorium decay chain is controlled as a planned exposure situation, in dwellings and in other buildings with high occupancy factors for members of the public;

(ii) radionuclides of natural origin, regardless of activity concentration, in commodities, soil amendments, construction materials and residual radioactive material in the environment;

(iii) materials, other than those stated in these Regulation in which the activity concentration of radionuclide in either the uranium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity concentration of Potassium-40 (40K) does

not exceed 10 Bq/g.

Exclusion from requirements of these Regulations

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

(a) exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level;

(b) exposure of members of the public or workers other than air or space crew to cosmic radiation in flight or in space, lightning and earth magnetic field;

(c) above ground exposure to radionuclides present in the undisturbed earth's crust;

(d) exposures from natural non ionising radiation in the body; and

(e) the Commission may determine any other radiation sources that are essentially unamenable to control.

(a) Occupational Exposure

General responsibilities

38.-(1) The licensee and registrant shall ensure that protection and safety is optimised and that the dose limits or reference levels for occupational exposure are not exceeded.

(2) The licensee and registrant shall ensure, for workers who are engaged in activities in which they are or could be subject to occupational exposure, that-

(a) relevant dose limits or reference levels for occupational exposure specified in Second and Eighth Schedules to these Regulations are not exceeded;

(b) protection and safety is optimised in accordance with these Regulations;

(c) decisions with regard to measures for protection and safety are recorded and made available to relevant parties, through their representatives where appropriate;

(d) policies, procedures and organisational arrangements for occupational protection and safety are established with priority given to design and technical measures for controlling occupational exposure;

(e) suitable and adequate facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of the

occupational exposure;

(f) necessary workers', health surveillance and health services for workers are provided;

(g) appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for their proper use, calibration, testing and maintenance;

(h) adequate records are maintained in accordance with the requirements of these Regulations; and

(i) necessary conditions for promoting a safety culture are provided.

(3) A licensee and registrant shall-

(a) involve workers, through their representatives where appropriate, in optimisation of protection and safety;

(b) establish and use, as appropriate, dose constraints as part of optimisation of protection and safety;

(c) ensure that workers are informed that protection and safety is an integral part of a general occupational health and safety program in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources;

(d) record any report received from a worker that identifies any circumstances that could affect safety and security conditions and take appropriate remedial actions.

Classification of areas

39.-(1) A licensee and registrant shall designate as a controlled area any area in which specific measures for protection and safety are required for-

(a) controlling exposures or preventing the spread of contamination in normal operations;

(b) preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

(2) A registrant and licensee shall-

(a) determine the boundaries of controlled area on the basis of the likelihood, magnitude of expected exposures, the type and extent of the procedures required for protection and safety;

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

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

(d) display appropriate radiation warning symbol as prescribed in Fifth Schedule to these Regulation, and display signs and instructions at access points to and at appropriate locations within controlled areas;

(e) establish measures for occupational protection and safety, including, as appropriate, physical measures to control the spread of contamination and institutional local rules and procedures for controlled areas;

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

(g) provide, as appropriate, at entrances to controlled areas-

(i) personal protective equipment;

(ii) equipment for individual monitoring and workplace monitoring;

(iii) suitable storage for personal clothing;

(h) provide, as appropriate, at exits from controlled areas:

(i) equipment for monitoring for contamination of skin and clothing;

(ii) equipment for monitoring for contamination of any objects or material being removed from the controlled area;

(iii) washing or showering facilities and other personal decontamination facilities;

(iv) suitable storage for contaminated personal protective equipment;

(i) periodically review conditions to assess whether there is any need to modify the measures for protection and safety or the boundaries of controlled areas;

(j) provide appropriate information, instructions and training for persons working in controlled areas;

(k) designate as a supervised area any area which is not

designated as controlled area, where occupational exposure conditions need to be kept under surveillance even though specific protection measures and safety provisions are not normally needed.

(3) A licensee and registrant taking into account the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall-

(a) delineate the supervised areas, by appropriate means;

(b) display approved signs, as appropriate, at access points to supervised areas;

(c) periodically review conditions to assess whether there is any need for further measures for protection and safety or any need for changes to the boundaries of supervised areas.

(4) A licensee and registrant shall designate such area in which specific protective measures or safety and security provisions could be required for preventing or limiting unauthorised person to gain access to energised antenna or facing it.

(5) A registrant and licensee of telecommunication infrastructure shall ensure that the installed antennas are located and positioned such that no habitable structures are within a zone of 50 meters directly facing the antennas.

Occupational exposure assessment and records

40.-(1) A licensee and registrant shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual dose monitoring where appropriate, and shall ensure that arrangements are made with appropriate or approved dosimetry service providers that operate under a quality management system.

(2) For a worker who works in a controlled and supervised area, individual monitoring shall be undertaken.

(3) A registrant or licensee shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment.

(4) A licensee and registrant shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the annual effective doses.

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

(6) A registrant and licensee shall keep records of exposure, which shall be made available to workers and the Commission.

(7) The records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.

(8) The records of occupationally exposed workers that are recorded in a server and the server itself shall be available on site within the United Republic of Tanzania.

(9) A licensee and registrant shall maintain confidentiality of the records.

Institutional rules, procedures and personal protective equipment

41.-(1) The licensee and registrant shall minimise the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered design controls and satisfactory working conditions, in accordance with the following hierarchy:

(a) engineered controls;

(b) administrative controls;

(c) personal protective equipment.

(2) The licensee and registrant shall, in consultation with workers, through their representatives, in a language appropriate to the audience addressed-

(a) establish in writing institutional rules and procedures that are necessary for protection and safety for workers and other persons;

(b) include in the institutional rules and procedures any relevant investigation level or authorised level, and the procedures to be followed in the event that any such level is exceeded;

(c) make the institutional rules and procedures and the measures for protection and safety known to those workers to whom they apply and to other persons who may be affected by them;

(d) ensure that any work in which workers are or could be subject to occupational exposure is adequately supervised and take all reasonable steps to ensure that the rules, procedures, measures for protection and safety provisions are observed.

(3) A registrant and licensee shall provide to female workers who are liable to enter controlled areas or supervised

areas appropriate information on-

(a) the risk to the embryo or fetus due to exposure of a pregnant woman;

(b) the importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant or if she is breast-feeding;

(c) the risk of health effects for a breast-fed infant due to ingestion of radioactive substances.

(4) A registrant and licensee shall ensure that-

(a) workers are provided with suitable and adequate personal protective equipment that meets relevant standards or specifications, including as appropriate:

(i) protective clothing;

(ii) respiratory protective equipment;

(iii) protective aprons, gloves, goggles, and organ shields;

(b) where appropriate, workers receive adequate instruction in the proper use of protective equipment, including testing for good fit;

(c) tasks requiring the use of certain personal protective equipment are assigned only to workers who on the medical advice shall be given personal protective equipment;

(d) all personal protective equipment are maintained in proper condition and, if appropriate, are tested at regular intervals;

(e) if the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time taken or the inconvenience, and of any non-radiological risks that might be associated with using personal protective equipment while performing the task.

Radiation monitoring of workplace

42.-(1) The licensee and registrant shall establish, maintain and keep under review a program for the monitoring at the workplace under the supervision of a radiation safety officer commensurate with the graded approach.

(2) The program for monitoring shall specify-

(a) type, place and frequency of monitoring of workplaces;

(b) evaluation of the radiological conditions in all workplaces;

(c) assessment of the exposure of workers in controlled

and supervised areas;

(d) review of the classification of controlled and supervised areas;

(e) the quantities to be measured including energy absorption rate dose rate, activity concentration in air and surface contamination, expected fluctuations, likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions;

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

(g) investigation levels and the actions to be taken if they are exceeded.

(3) The licensee and registrant shall maintain records of the findings of the workplace monitoring program and make available to workers.

Workers ' health surveillance

43. A licensee and registrant shall make arrangements for appropriate health surveillance based on the general principles of occupational health to assess the initial fitness and continuing fitness of workers for their intended tasks.

Information

44. A licensee and registrant shall provide all workers with adequate information on health risks due to exposure in normal operation, anticipated operational occurrences and accident conditions.

Conditions of service

45.-(1) The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure.

(2) For the purpose of subregulation (1), special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall not be granted or used as substitutes for measures for protection and safety in accordance with the requirements of these Regulations.

(3) A licensee and registrant shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances where it has been determined, that workers, for health reasons, may no longer continue in employment in which they are or could be subject to occupational exposure.

(4) A person under the age of 16 years shall not be subjected to occupational exposure and person under the age of 18 years shall not be allowed to work in a controlled area unless

supervised and then only for the purpose of the training.

(b) Medical Exposure

General responsibilities

46.-(1) A licensee and registrant shall ensure that a patient undergoes a medical exposure where-

(a) it is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context that has been provided, or it is part of an approved health screening program;

(b) the medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening program;

(c) a radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure; and

(d) the patient or the patient's legal authorised representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure and radiation risks.

(2) A licensee and registrant shall ensure that-

(a) an individual shall not incurs a medical exposure as part of a program of biomedical research unless the exposure has has followed ethical conduct approved by relevant institutional and a radiological medical practitioner have assumed responsibility;

(b) the requirements are met for the optimisation of protection and safety for persons subject to exposure as part of a program of biomedical research;

(c) an individual shall not incurs a medical exposure as a carer or comforter unless has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure;

(d) the requirements for optimisation of protection and safety for any radiological procedure in which an individual acts as a carer or comforter are complied;

(e) the radiological medical practitioner while performing or overseeing the radiological procedure has the overall responsibility for protection and safety of patients;

(f) the radiological medical practitioners, medical physicists, radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure are specialised in the appropriate area;

(g) for therapeutic radiological procedures; calibration, dosimetry, quality assurance, acceptance and commissioning of medical radiological equipment are conducted by a medical physicist;

(h) for diagnostic radiological procedures and image guided interventional procedures; calibration, dosimetry, quality assurance, acceptance and commissioning of medical radiological equipment are conducted and documented by medical physicist.

Justification of medical exposure

47.-(1) Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

(2) The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner with account taken for patients who are pregnant or breast-feeding or paediatric of-

(a) the appropriateness of the radiological procedure equest;

(b) the urgency of the radiological procedure;

(c) the characteristics of the medical exposure;

(d) the characteristics of the individual patient;

(e) relevant information from the patient's previous radiological procedures.

(3) Relevant national or approved international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

(4) A radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening program, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant

professional body or the health authority.

(5) For the purpose of subregulation (4), the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(6) The exposure of volunteers as part of a program of biomedical research is deemed to be justified where it is subject to approval by an institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority, subject to dose constraints specified under these Regulations.

Optimisation of protection for medical exposures

48.-(1) A registrant, licensee and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

(2) A registrant and licensee shall ensure that design of sources equipment, and its operational aspects are optimized as prescribed in the Third Schedule to these Regulations.

(3) A registrant, licensee and suppliers shall ensure that medical radiological exposure equipment and software conforms to the national standards.

(4) For diagnostic radiological procedures and image guided interventional procedures, registrant and licensee shall ensure that the following are used-

(a) appropriate medical radiological equipment and software and, for nuclear medicine, appropriate radiopharmaceuticals;

(b) appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfill the clinical purpose of the radiological procedure.

(5) For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planned target volume is kept as low as reasonably achievable.

(6) For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and radiopharmacist or radiochemistry ensures that each patient is administered with the appropriate radiopharmaceutical so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

(6) Licensees shall ensure that the particular aspects of medical exposures are considered in the optimisation process for-

(a) paediatric patients subject to medical exposure;
(b) individuals subject to medical exposure as part of a health screening program;
(c) volunteers subject to medical exposure as part of a program of biomedical research;
(d) relatively high doses to the patient;
(e) exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose; and
(f) exposure of a breast-fed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Calibration

49. The licensee and registrant shall ensure that-

(a) all sources giving rise to medical exposure are calibrated;
(b) calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the Commission;
(c) calibrations of radiotherapy units are subject to independent verification prior to clinical use;
(d) calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.

Dosimetry of patients

50. A licensee and registrant shall ensure that-

(a) dosimetry of patients is performed by a medical physicist and documented;
(b) typical doses to patients undergoing diagnostic and image guided interventional procedures;
(c) absorbed doses to the planned target volume for each patient treated with external beam therapy or brachytherapy are as prescribed by the radiological medical practitioner;
(d) typical absorbed doses to patients treated with unsealed sources.

Diagnostic

51. A registrant andlicensees shall ensure that-

reference levels

(a) assessments on the basis of the measurements required in these Regulations are made at approved intervals;

(b) a review is conducted to determine whether the optimisation of protection and safety for patients is in accordance with the relevant diagnostic reference levels prescribed in the Fourth Schedule to these Regulations.

Quality assurance for medical exposure

52.-(1) A registrant and licensee shall establish a comprehensive quality assurance program that ensures optimisation of medical exposures.

(2) The quality assurance program for medical exposures include:

(a) major maintenance procedure that may affect protection and safety of patients;

(b) installation of new software or modification of existing software;

(c) verification of the appropriate physical and clinical factors used in radiological procedures;

(d) maintaining records of relevant procedures and results; and

(e) periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

(3) A registrant and licensees shall ensure that quality assurance program is audited regular, and that frequency is in accordance with the complexity of the radiological procedures and the associated risks.

Dose constraints

53.-(1) A registrant and licensee shall ensure that relevant dose constraints are used in the optimisation of protection and safety in radiological procedure in which an individual acts as a carer or comforter.

(2) A registrant and licensees shall ensure that dose constraints approved by the Commission are used in the optimisation of protection and safety for persons subject to exposure as part of biomedical research program as prescribed in Sixth Schedule to these Regulations.

Pregnant or breast-feeding female

54.-(1) A licensee and registrant shall ensure that-

(a) appropriate radiation protection procedures are in place where a female patient is pregnant or breast-

patients

feeding;

(b) appropriate warning notices and signs in appropriate languages are placed in waiting rooms for patients, cubicles and other appropriate places informing female patients who are to undergo a radiological procedure to notify the radiological medical personnel in the event that-

(i) she is pregnant;

(ii) she is breast-feeding;

(c) there are procedures in place for-

(i) ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus; and

(ii) establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breast-fed infant.

Release of patients after radionuclide therapy

55. A registrant and licensees shall ensure that-

(a) there are procedures in place for radiation protection of members of the public before a patient is released after radionuclide therapy;

(b) no patient who has undergone a therapeutic radiological procedure is discharged from a medical radiation facility unless it has been established by either a medical physicist or the facility's radiation protection officer that-

(i) the activity of radionuclides in the patient is such that doses that could be received by members of the public from the patient would be in compliance with these Regulation;

(ii) the patient or the guardian of the patient is provided with written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination and information on the radiation risks.

Unintend

56. A registrant and licensee shall ensure that all

ed and accidental medical exposures

practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

Investigation of unintended and accidental medical exposures

57.-(1) A registrant and licensee shall promptly investigate any of the following unintended or accidental medical exposure:

(a) any medical treatment delivered-

(i) to the wrong individual or to the wrong tissue or organ of the patient;

(ii) using the wrong radiopharmaceutical;

(iii) with an activity, a dose or dose fractionation differing substantially from the values prescribed by the radiological medical practitioner, that could lead to unduly severe secondary effects;

(b) any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;

(c) any exposure for diagnostic purposes that is substantially greater than was intended;

(d) any exposure arising from an image guided interventional procedure that is substantially greater than was intended;

(e) any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure; and

(f) any failure of medicalradiological equipment, failure of software or system failure, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

(2) With regard to any unintended or accidental medical exposures investigation the registrant and licensee shall-

(a) calculate or estimate the doses received and the dose distribution within the patient;

(b) indicate the corrective actions required to prevent recurrence of such an unintended or accidental exposure;

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

(d) produce and keep a written report that states the cause of the unintended or accidental medical exposure and submit it to the Commission;

(e) ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorised representative of the unintended or accidental medical exposure.

Radiological reviews

58. A registrant and licensee shall ensure that radiological reviews-

(a) are performed periodicall as provided in the guidelines issued by the Commission; and

(b) includes an investigation and critical review of the current practical application of the radiation protection principles.

Records of medical exposures

59.-(1) A registrant and licensee shall maintain records of medical exposure for a period as specified by the Commission.

(2) The record for medical exposure under this regulation shall include:

(a) records of calibration, dosimetry and quality assurance;

(b) records of calibrations reports;

(c) records of dosimetry of patients;

(d) records of assessments and reviews made with regard to diagnostic reference levels;

(e) records associated with the quality assurance program;

(f) information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures and number of images acquired;

(g) for nuclear medicine, the types of radiopharmaceutical administered and their activity;

(h) for external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the Centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as

determined by the radiological medical practitioner;

(i) for external beam radiation therapy, the dose fractionation and the overall treatment time;

(j) exposure records for volunteers subject to medical exposure as part of a program of biomedical research; and

(k) reports on investigations of unintended and accidental medical exposures as required in these Regulations.

(c) Public Exposure

General responsibilities

60.-(1) A registrant, licensee and supplier in applying the principle of optimisation of protection and safety in the design, planning, operation and decommissioning of a source or for closure and the post-closure period for waste disposal facilities, shall take into account-

(a) possible changes in any conditions that could affect exposure of members of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person;

(b) good practice in the operation of similar sources or the conduct of similar practices;

(c) possible buildup and accumulation in the environment of radioactive substances from discharges during the lifetime of the source; and

(d) uncertainties in the assessment of doses.

(2) A licensee and registrant for radiation sources under their responsibility, shall establish, implement and maintain-

(a) policies, procedures and organisational arrangements for protection and safety in relation to public exposure;

(b) measures for ensuring:

(i) optimisation of protection and safety; and

(ii) limitation of exposure of members of the public from such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in the Second Schedule of these Regulations;

(c) measures for ensuring the safety of such sources;

(d) provision for suitable and adequate resources including facilities, equipment and services for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;

(e) programs for appropriate training of personnel having functions relevant to the protection and safety of the public, and periodical training as required, to ensure the necessary level of competence;

(f) provision for appropriate monitoring equipment, monitoring programs and methods for assessing public exposure;

(g) emergency preparedness and response plan in accordance with the nature and magnitude of the radiation risks associated with the sources; and

(h) adequate records of monitoring programs.

(3) The Commission shall-

(a) establish or approve dose constraints of risks to be used in the optimisation of protection and safety for members of the public;

(b) enforce compliance with the dose limits and reference levels specified in Second and Eighth Schedules to these Regulations for public exposure;

(c) provide information on levels of radon indoors and the associated health risks; and

(d) implement an action plan for controlling public exposure due to radon indoors.

(4) Before authorisation of a new or modified practice, a registrant and licensee shall submit the safety assessments and other design related documents for exposure and potential exposure of members of the public.

(5) The reference levels and conditions specified in these Regulations shall-

(a) be used by registrant and licensee as the criteria for demonstration of compliance after the commencement of operation of a source;

(b) correspond to doses below the dose limits with account taken of the results of optimisation of protection and safety;

(c) reflect good practice in the operation of similar facilities or activities;

(d) allow for operational flexibility;

(e) take into account the results of the prospective assessment for radiological environmental impacts

that is undertaken in accordance with requirements of these Regulations.

Exposure from multiple sources

61. A licensee and registrant shall ensure that public exposed to multiple sources, total dose rate shall not exceed 1mSv per year.

Control of visitors

62. For the purpose of controlling visitors, registrant and licensee shall-

(a) apply the relevant requirements of these Regulations in respect of public exposure for visitors to a controlled area or a supervised area;

(b) visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;

(c) provide adequate information and instructions to visitors before they enter a controlled or supervised area; and

(d) adequate control is maintained over the entry of visitors to a controlled or supervised area.

Sources of external irradiation

63. For sources that may give rise to external exposure to the members of the public, a registrant and licensee shall ensure that-

(a) the floor plans, arrangements of equipment for all new installations and significant modifications to the existing installations utilizing such sources are subject to review and approval under these Regulations;

(b) shielding, access control and other measures for protection and safety, are provided as appropriate for restricting public exposure.

Control of discharge and contaminatio n of radioactive materials accessible to members of public

64. For the purpose of control of discharge of radioactive materials and contamination of areas accessible to the members of the public, a registrant and licensee shall ensure-

(a) radioactive materials from authorised practices are not discharged to the environment unless the requirements of these Regulations are complied;

(b) specific provisions for confinement are established for the design and operation of a source that may

cause the spread of contamination in areas that are accessible to members of the public; and

(c) measures for protection and safety are implemented for restricting public exposure.

Monitoring of public exposure

65.-(1) For the purpose of monitoring public exposure a registrant and licensee shall-

(a) establish and implement monitoring programs to ensure that sources under their responsibility are adequately assessed;

(b) maintain appropriate records of the results of the monitoring programs and estimated doses to the public;

(c) report to the Commission results of the levels and composition of discharges, dose rates at the site boundary and in premises open to the public, environmental monitoring and retrospective assessments made for doses to the representative person at authorised intervals;

(d) report promptly to the Commission any levels exceeding the reference levels;

(e) report promptly to the Commission any significant increase in dose rate or concentrations of radionuclides in the environment;

(f) establish and maintain capability to carry out monitoring in an emergency situation;

(g) verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts;

(h) make available upon request the results from public dose assessments.

(2) The monitoring programs in this regulation shall include-

(a) external exposure from such sources;

(b) discharges;

(c) radioactivity in the environment; and

(d) other parameters for the assessment of public exposure as may be specified by the Commission.

Consumer products

66. Providers of consumer products shall ensure that products-

(a) are not made available to the public unless the

justification of their use by the public has been approved by the Commission;

(b) have clear and appropriate information and instructions on-

(i) use, maintenance, servicing, repair and correct installation;

(ii) the radionuclides and their activities;

(iii) dose rates in normal operation and during servicing and repair;

(iv) required or recommended options for recycling or disposal; and

(v) safe and secure transport and storage.

(d) Existing Exposures

Management of existing exposure situations

67.-(1) A registrant and licensee shall develop and implement a radiation protection program to manage existing exposure situations including remediation of areas contaminated with residual radioactive material.

(2) The Commission shall-

(a) specify the exposure situations that are included in the scope of existing exposure situations;

(b) specify the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified;

(c) assign responsibilities for the establishment and implementation of protection strategies to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions;

(d) provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate.

(3) The Commission shall establish protection strategies for existing exposure situations which include the objectives to be achieved by means of the protection and appropriate reference levels.

(4) The Commission shall implement the protection strategy, including:

(a) arranging for evaluation of the available remedial actions and protective actions for achieving the

objectives;

(b) evaluation of the efficiency of the actions planned and implemented;

(c) ensuring that information is available to subject to exposure on potential health risks.

(5) The Commission shall ensure that the protection strategy for the management of existing exposure situations is established and commensurate with the radiation risks associated with the existing exposure situation.

(6) The licensee or registrant shall be responsible for remedial or protective actions to ensure that the form, scale and duration of such actions are optimised.

Remediation of areas with residual radioactive materials

68.-(1) Licensee or registrant responsible for the planning, implementation and verification of remedial actions shall ensure that-

(a) a remedial action plan, supported by a safety assessment, is prepared and is submitted to the Commission;

(b) a mechanism for public information is in place and the interested parties affected by the existing exposure situation;

(c) a monitoring program is established and implemented;

(d) system for maintaining adequate records relating to the existing exposure situation and actions taken for protection and safety is in place;

(e) procedures are in place for reporting to the Commission on any abnormal conditions relevant to protection and safety.

(2) Licensee or registrant responsible for carrying out the remedial actions shall-

(a) ensure that the work, including management of the radioactive waste arising, is conducted in accordance with the remedial action plan;

(b) take responsibility for all aspects of protection and safety, including the performance of a safety assessment;

(c) monitor and perform a radiological survey of the area regularly during the remediation work so as to verify levels of contamination as specified by the Commission;

(d) perform a radiological survey after completion of remedial actions to demonstrate that the end point

conditions, as established in the remedial action plan, have been met;

(e) prepare and retain a final remediation report and submit a copy to the Commission.

(3) Licensee or registrant responsible for post-remediation control measures shall establish and maintain for as long as required by the Commission, an appropriate program, including any necessary provisions for monitoring and surveillance, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation has been completed.

(4) The Commission shall take responsibility for-

(a) review of the safety assessment submitted by the licensee or registrants;

(b) approval of the remedial action plan and of any subsequent changes to the remedial action plan, and granting of any necessary authorisation;

(c) establishment of criteria and methods for assessing safety;

(d) review of work procedures, monitoring programs and records;

(e) review and approval of significant changes to procedures or equipment that may have radiological environmental impacts or that may alter the exposure conditions for workers taking remedial actions or for members of the public;

(f) where necessary, establishment of regulatory requirements for control measures following remediation.

(5) After the remedial actions have been completed, the Commission shall-

(a) review, amend as necessary and formalize the type, extent and duration of any post-remediation control measures already identified in the remedial action plan, with due consideration of the residual radiation risks;

(b) identify the person or organisation responsible for any post-remediation control measures;

(c) where necessary, impose specific restrictions for the remediated area to control-

(i) access by unauthorised persons;

(ii) removal of radioactive material or use of such material, including its use in commodities;

(iii) future use of the area, including the use of

water resources and its use for the production of food or feed, and the consumption of food from the area; and

(d) periodically review conditions in the remediated area and, if appropriate amend or remove any restrictions.

(6) For the remediation of areas with residual radioactive material deriving from past activities or from a nuclear or radiological emergency, the Commission shall-

(a) identify persons or organisations responsible for the contamination of areas and those responsible for financing the remediation program, and the determination of appropriate arrangements for alternative sources of funding if such persons or organisations are no longer present or are unable to meet their liabilities;

(b) designate persons or organisations responsible for planning, implementing and verifying the results of remedial actions;

(c) establish any restrictions on the use of or access to the areas concerned before, during and, if necessary, after remediation;

(d) establish an appropriate system for maintaining, retrieval and amendment of records that cover the nature and the extent of contamination; the decisions made before, during and after remediation; and information on verification of the results of remedial actions, including the results of all monitoring programs after completion of the remedial actions.

Protection of emergency workers in emergency exposure situation

69. The Commission shall establish a program for managing, controlling and recording the doses received in an emergency by emergency worker, which shall be implemented by response organisations and employers.

PART VIII
RADIATION GENERATORS AND RADIOACTIVE SOURCES

General responsibilities

70. A licensee and registrant with regard to activities related to radiation generators and sources including locating, siting, designing, construction, assembly, commissioning, use,

maintenance and decommissioning or closure of facilities shall-

(a) take account of national standards;

(b) be supported by managerial and organisational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;

(c) observe adequate safety margins in the design, construction and in operations involving the facility including safety warning notices and symbols;

(d) take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection, safety and feedback of information on lessons learned from experience; and

(e) do such other things as may be specified by the Commission.

Design of radiation generators and radioactive sources

71.-(1) A licensee and registrant who deals with radiation generators and radioactive sources shall ensure that-

(a) the radiation generator or radioactive source and device in which the radiation generator or radioactive source is used are well-designed, manufactured and constructed in a manner that-

(i) provides for protection and safety in accordance with the requirements of these Regulations;

(ii) meets engineering, performance and functional specifications that conform to technical standards of national and approved International Standards;

(iii) meets quality standards commensurate with the significance for protection and safety of systems and components, including software;

(iv) provides clear displays and instructions on operating consoles in a Swahili and English language;

(b) radiation generators and radioactive sources are tested to demonstrate compliance with the relevant specifications;

(c) information is available, in English or Swahili, on the proper installation and use of the radiation generator or radioactive source and its associated radiation risks; and

(d) protection provided by shielding and by other

protective devices is optimised;

(e) the radioactive source itself and its container are marked with applicable symbols;

(f) sealed sources are identifiable and traceable;

(g) where radioactive sources are not in use they are stored in an appropriate manner for protection and safety; and

(h) where the sealed radioactive sources have become spent or disused, a registrant and licensee shall make arrangement for safe management and control of the spent or disused sources until it has been returned to the country of origin.

(2) For the purposes of this regulation "disused source" means a radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorisation has been granted.

Supply and acquisition of radioactive sources

72.-(1) A licensee and registrant who supply or distribute radioactive sources shall ensure that those persons to whom the sources are being supplied are authorised to receive the sources.

(2) Prior to acquisition of sources a licensee and registrant shall-

(a) ensure equipment containing sources conform to applicable national standards and approved international standards; and

(b) enter into an agreement that the supplier shall take back the source when no longer in use and submit to the Commission copy of the agreement.

(3) A registrant and licensee supplying sources or devices incorporating radioactive sources shall provide the recipient with all relevant technical information to permit their safe management.

Storage of radioactive sources

73.-(1) A registrant and licensee shall ensure storage of radioactive materials, interim storage of sources on entry points or on transit are authorised by the Commission.

(2) A registrant and licensee shall ensure packages of radioactive materials are stored in separate transit area for a short time as practicable and far from other hazardous materials.

(3) A registrant and licensees shall ensure that the following requirements with regards to storage of radiation sources are met:

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(a) where the sources are not in use shall be stored in a place assigned for the purpose of storage only;

(b) the storage shall be adequately shielded such that at the outside surface of its walls or containment the radiation dose shall not exceed 0.5 µSv per hour, and shall be chosen so as to minimise 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;

(e) if the place of storage is to contain either sealed or unsealed radiation sources that are liable to release a radioactive gas, the store shall be continuously vented to the open air;

(f) all radiation sources stored shall be clearly labeled, giving information on their activity and physical form;

(g) the containers for beta emitting radionuclides shall have adequate thickness to reduce the primary radiation to a safe level:

Provided that, bremsstrahlung radiation that may arise from high intensity sources shall be provided with additional shielding;

(h) gamma 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;

(i) appropriate equipment shall be provided for storing unsealed radiation sources to prevent external irradiation and internal contamination hazards;

(j) records shall be kept of all stored radiation sources and inventories shall be updated periodically;

(k) records of the stored sources 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; and

(l) 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.

Accountability on radioactive sources

74.-(1) A licensee and registrant shall maintain an accountability system that includes:

(a) records of the location and description of each source;

(b) records of the activity and form of each radioactive substance;

(c) arrangements of sources to be secured by ensuring that-

(i) 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;

(ii) a source is not transferred unless the receiver possesses a valid authorisation;

(iii) 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.

(2) A licensee and registrant shall maintain an accountability system of nuclear materials as prescribed in the regulations relating to nuclear non-proliferation safeguards.

Export of category 1 or 2 radioactive sources

75.-(1) A licensee intending to export category 1 or 2 radioactive sources shall apply to the Commission for an export authorisation.

(2) The application for authorisation to export category 1 or 2 radioactive sources shall include a copy of the recipient authorisation to receive and possess the sources to be exported that includes at least the following information:

(a) name of the recipient;

(b) recipient location and legal address or principal place of business;

(c) relevant radionuclides and radioactivity;

(d) uses of the source;

(e) recipient authorisation expiration date;

(f) copies of relevant parts of any contractual agreements to re-import the source; and

(g) justification or explanation of any need to use the exceptional circumstances.

(3) After receiving authorisation to export the source, licensee shall ensure that-

(a) the export of the source is conducted in compliance with the requirements as prescribed in the Atomic Energy (Packaging and Transport of Radioactive Materials) Regulations, 2011;

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(b) the importing state is notified in advance of each shipment with the following information in writing:

(i) the estimated date of export;
(ii) exporting facility;
(iii) recipient;
(iv) radionuclides and radioactivity;
(v) aggregate activity level;
(vi) the number of radioactive sources and, if available, their unique identifiers; and

(c) for category 1 radioactive sources only, the notification described above should be accompanied by a copy of the importing states consent to import the sources.

Import of category 1 or 2 radioactive sources

76.-(1) A licensee intending to import category 1 or 2 radioactive sources shall apply to the Commission for an import authorisation.

(2) The application for authorisation to import sources shall include the following information:

(a) name of the exporter;
(b) exporter location and legal address or principal place of business;
(c) name of the recipient;
(d) recipient location and legal address or principal place of business;
(e) relevant radionuclides and radioactivity;
(f) uses of the sources;
(g) details of the arrangements for the safe management of the source, including financial provisions where appropriate, once they have become disused, including copies of any contractual agreements;
(h) justification or explanation of any need to use the exceptional circumstances.

(3) After receiving authorisation to import the sources, licensees shall ensure that the importation is in compliance with

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the requirements as prescribed in the Packaging and Transport of Radioactive Materials Regulations.

PART IX
RADIOACTIVE WASTE MANAGEMENT

General responsibilities

77. A licensee and registrant shall ensure that generation, storage, development, operation, management of radioactive waste and decommissioning of radioactive waste facilities are managed as follows:

(a) any radioactive waste generated is kept to the minimum practicable in terms of both activity and volume;

(b) ensure that there is separate processing of radioactive waste of different types, for their storage and disposal half-life, activity concentration, volume, physical and chemical properties, taking into account the available options for storage and disposal of radioactive waste;

(c) ensure that activities for the predisposal management of and for the disposal of radioactive waste are conducted in accordance with the authorisation;

(d) maintain a waste inventory of all radioactive waste that is generated, stored, transferred or disposed of, including particulars on Quantity, radionuclide, activity, form and characteristics of waste under their responsibilities;

(e) develop and implement a strategy for radioactive waste management and shall include appropriate evidence that protection and safety is optimised.

Radioactive waste management facility or activities

78.-(1) A licensee and registrant shall be responsible for the safety of the predisposal radioactive waste management facility or activities.

(2) Any person, organisation, licensee or registrant shall submit to the Commission for approval, a safety case which include the following:

(a) all safety aspects of the site, the design of the facility, and the managerial and regulatory controls;

(b) the level of protection provided and assurance that safety requirements will be met;

(c) an integrated approach to safety, nuclear security and if applicable nuclear safeguards in the management

and disposal of radioactive waste, spent nuclear fuel and disused sealed radiation sources;

(d) the level and complexity of safety and security measures which commensurate with the degree of hazard posed by the radioactive waste, spent nuclear fuel or disused sealed radiation sources;

(e) management systems to provide for assurance of quality; and

(f) safety related activities, systems and components throughout all the steps of the development and operation of a radioactive waste, spent nuclear fuel or disused sealed radiation source management or disposal facility.

(3) A licensee and registrant shall take into account the interdependences among all steps in the predisposal management of radioactive waste, spent nuclear fuel and disused sealed radiation sources as well as the impact of the anticipated disposal option.

(4) A licensee or registrant shall determine an authorised destination for all of their radioactive waste, spent nuclear fuel and disused sealed radiation sources generated in consultation with Central Radioactive Waste Management Facility.

Radioactive waste generation, characterisation and control

79.-(1) A licensee and registrant of a radioactive waste management facility shall have a waste management plan approved by the Commission.

(2) The waste management plan in subregulation (1) shall aim to-

(a) minimise the generation of radioactive waste;

(b) manage and control different radioactive waste types so as to optimise treatment and conditioning processes;

(c) ensure that radioactive waste or disused sealed radioactive source are characterised at the various steps in its predisposal management;

(d) maintain records of all types of radioactive waste generated and treated; and

(e) ensure that the final radioactive waste is suitable for disposal.

(2) Radioactive waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in case of accident.

(3) Radioactive waste shall be stored in such a manner that it can easily be inspected, monitored, retrieved and preserved

in a condition suitable for its subsequent management.

(4) Predisposal radioactive waste management facilities shall-

(a) be located and designed so as to ensure safety for the expected operating lifetime under both normal and in case of accident and for their decommissioning;

(b) be constructed in accordance with the design as described in the safety case and approved by the Commission;

(c) be verified during commissioning to ensure that the equipment, structures, systems and components perform as planned;

(d) be operated in accordance with the conditions prescribed under these Regulations.

(5) A licensee and registrant shall develop, in the design stage, an initial plan for the end of operations and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period.

(6) The decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the Commission and sufficient funds shall be available to carry out shutdown and decommissioning.

Control of radioactive waste generation

80. A licensee and registrant shall ensure that-

(a) the generation of radioactive waste and its impact to the environment is kept as minimum as possible; and

(b) disused sealed radiation source is not dismantled without authorisation.

Reuse and recycle

81. A licensee and registrant shall, before declaring radioactive material as radioactive waste, consider whether the radioactive material may be reused or recycled.

Discharge of radioactive effluents

82.-(1) A licensee and registrant shall not discharge radioactive effluents into the environment unless-

(a) the request for discharge has been approved by the Commission;

(b) it is in accordance with the prescriptions set out in the First Schedule of these Regulations;

(c) resulting doses are kept as low as reasonably achievable.

(2) Prior to initiating the discharge of radioactive

effluents into the environment a licensees and registrants shall-

(a) determine the characteristics, potential points, methods and activity of the materials to be discharged;
(b) determine any significant exposure pathway by which discharged radionuclides could deliver exposure;
(c) assess the doses likely to be incurred by the environment and public due to planned discharges; and
(d) submit the requisite reports as contained in paragraphs (a) to (c) to the Commission for approval.

Radioactive waste not qualified for release, discharge or disposal

83. Where radioactive waste is not suitable to be released, discharged or disposed to the environment within one year of its creation or any greater time as the Commission may approve, the licensee and registrant shall-

(a) submit a proposal and obtain approval from the Commission for disposal of the radioactive waste; and
(b) comply with any requirements made by the Commission with regards to further treatment and disposal of the radioactive waste.

Classification and segregation of radioactive waste

84.-(1) A licensee and registrant shall-

(a) classify the radioactive waste based on their radiological, physical, chemical and biological properties as prescribed in the Seventh Schedule to these Regulations; and
(b) segregate the radioactive waste in manner prescribed in regulations 88 and keep the segregated radioactive waste in a separate container.

(2) The segregated radioactive waste container shall-

(a) be clearly and uniquely marked with the details such as activity, types of radionuclides, half-life, physical and chemical form and non-radiological hazard;
(b) bear a radiation symbol as prescribed in the Fifth Schedule to these Regulations;
(c) be robust;
(d) be compatible with the radioactive waste; and
(e) be able to be filled and emptied safely throughout the expected period in storage including the provision of

adequate shielding as appropriate.

Container labelling

85.-(1) A licensee shall ensure a container that contains radioactive waste bears a durable clearly visible label with the radiation symbol which is legible for the whole period of storage.

(2) The label shall provide the following information:

(a) nature and date of the radioactive waste generated;
(b) commencement date of storage;
(c) content of major radionuclides;
(d) external surface dose rates;
(e) radioactive waste category;
(f) biological, chemical or other hazardous material if they exist;
(g) name of person responsible for the waste generation; and
(h) any information that may be required by the Commission.

(3) A registrant and licensee shall, prior to removal of empty container to unrestricted areas-

(a) ensure that the container is not contaminated; and
(b) remove or deface the label or otherwise clearly indicate that the container no longer contains radioactive waste as specified in these Regulations.

Location of radioactive waste storage

86. A registrant and licensee shall ensure that radioactive waste-

(a) is stored in such a way that protects human health and the environment;
(b) is not stored in the vicinity of corrosive, explosive or easily flammable materials; and
(c) is not stored in areas that are prone to natural disasters.

Interim storage facility

87.-(1) A registrant and licensee shall provide for interim storage facility of radioactive waste or disused sealed radioactive sources prior to its clearance, discharge, transfer or disposal.

(2) The interim storage facilities shall-

(a) be authorised by the Commission;
(b) store radioactive wastes or disused radioactive sources for a maximum period of six months prior to deportation to the country of origin or to the designated central radioactive waste management facility;

(c) be properly designed and constructed with at least one physical barrier between the radioactive waste and the other materials in the source;
(d) be adequately shielded;
(e) prevent deterioration of radioactive waste packages;
(f) have ability to handle and retrieve of radioactive waste packages; and
(g) have conventional safety and physical protection.

Packaging of radioactive waste

88. For the purpose of ensuring safe packaging of radioactive waste a registrant and licensee shall ensure that-

(a) the materials and production of radioactive waste storage container shall guarantee the integrity of the radioactive waste package throughout its expected period of storage;
(b) the types of radioactive waste are stored in outer container with puncture proof inner linings;
(c) where radioactive waste may corrode or disintegrate within the container or where storage is likely to be prolonged, a suitable lining shall be used in order to maintain the integrity of the contents throughout its expected period of storage;
(d) disused sealed radioactive sources are stored in their immediate shielding within containers to reduce exposure and assist future handling; and
(e) internal and external surfaces of all containers are checked for contamination each time before the containers are used or reused.

Disposal of radioactive materials

89.-(1) Where any radioactive waste does not qualify for discharge into the environment, or clearance within a reasonable time, the licensee managing the waste shall dispose it in approved disposal facility.

(2) A person or organisation shall not dispose radioactive waste in a repository unless the requirements for acceptance of radioactive waste for disposal approved by the Commission are satisfied.

(3) The responsibility for verification of compliance of radioactive waste package with the acceptance criteria rests with the disposing organisation.

Screening of scrap metals

90.-(1) A person shall screen all scrap metals for radioactive contamination before smelting, shipment, export or

import.

(2) The radioactive contaminated scrap metal shall not be smelted, exported or imported without the approval of the Commission.

(3) Employers, licensee or registrant who discovers radioactivity of scrap metal shall immediately inform the Commission for further verification.

Quality assurance

91.-(1) A licensee and registrant shall establish a comprehensive quality assurance program that ensures optimisation of medical exposures.

(2) Licensee applying for a license relating to the management of radioactive waste shall submit a written quality assurance program which is commensurate with the scale of intended operations to the Commission for approval.

(3) The quality assurance program shall be designed to ensure that the facilities and equipment are designed, constructed and operated in accordance with specified requirements for operation, all regulations and conditions in a license are complied with, and the radioactive waste, packages produced meet the waste acceptance requirements.

(4) Each licensee shall develop and maintain an accurate documentation system to cover all stages of radioactive waste management from its generation to disposal, and quality assurance program shall provide for controlled approval, receipts, retention, distribution and disposition of all records important for safety in accordance with the Commission's requirements.

(5) A licensee shall maintain adequate safeguard against tempering with and loss of records.

(6) The effectiveness of the quality assurance program shall be verified by the Commission or approved independent auditors to ensure that a radioactive waste management program meets specific requirements.

Physical protection of radioactive wastes

92.-(1) A licensee shall ensure adequate physical protection measures of all radioactive wastes in his possession or under his control to prevent unauthorised access to the radioactive waste.

(2) A licensee shall report to the Commission forthwith after its occurrence becomes known to him, any loss, stolen or missing radioactive waste and the circumstances under which such an occurrence took place and within thirty days after such occurrence, the licensee shall make a written report with a

description of the radioactive material involved, it's probable disposition, the circumstance under which the loss occurred, actions that have been taken.

(3) A licensee shall-

(a) report to the Commission any loss of, stolen or missing radioactive waste within 24 hours after such occurrence; and

(b) shall make a written report within a description of the radioactive material involved, its probable disposition, the circumstance under which the loss occurred, actions that have been taken.

(4) Each licensee shall immediately report to the Commission any event involving waste possessed by the licensee that may have caused or threaten to cause the release of radioactive materials, inside or outside of a restricted area, where an individual could have received an intake excess of one occupational annual limit on intake as specified by the Commission.

Financing

93.-(1) The waste generator shall secure adequate finances of management of radioactive waste.

(2) The waste generator dispatching a radioactive waste to the Central Radioactive Waste Management Facility for treatment, conditioning and storage services and further disposal may be charged for such service as determined by the Commission.

(3) For purposes of this regulation, "waste generator" means the operating organisation of a facility or activity that generates waste.

Decommissioning of facilities and activities

94.-(1) The Commission shall-

(a) establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall prepare associated guides;

(b) take actions to ensure that the Commission's regulatory requirements are met.

(2) The licensee shall plan for decommissioning and shall conduct the decommission actions in compliance with the authorisation for decommissioning and with requirements provided by the Commission.

(3) A licensee shall ensure the protection of people and environment are optimised during decommissioning of the radiation facilities.

(4) A licensee shall use the graded approach in all aspects of decommissioning in determining the scope and level of detail for any particular facility, consistent with the magnitude of the possible radiation risks arising from the decommissioning.

(5) Licensee shall ensure the integrated management system covers all aspects of decommissioning.

(6) The integrated management system for decommission shall enable the planning and implementation of decommissioning actions with the prime goal of ensuring that decommissioning is conducted safely.

PART X
REQUIREMENTS FOR EMERGENCY PREPAREDNESS AND RESPONSE

Responsibilities of registrants and licensees

95.-(1) A licensee and registrant shall prepare an emergency plan for the protection of people and the environment.

(2) As part of this emergency plan, the licensee and registrant shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response.

(3) In relation to the arrangements for the emergency response at the scene by the licensee and registrant, the emergency plan shall include:

(a) provision for individual monitoring and area monitoring and arrangements for medical treatment;

(b) arrangements for assessing and mitigating any consequences of an emergency.

(4) The licensee and registrant shall be responsible for the implementation of their emergency plan.

(5) The licensee and registrant shall, as appropriate-

(a) develop, maintain and implement procedures to provide the means for preventing loss of control over the source and for regaining control over the source as necessary;

(b) make available equipment, instrumentation and diagnostic aids that may be needed;

(c) train and periodically retrain personnel in the procedures to be followed and exercise the procedures.

Emergency

96.-(1) Each licensee responsible for sources, including radioactive waste, for which prompt intervention may be

preparedness and response

required, shall ensure that the emergency plan defines at the scene responsibilities and takes account of off-site responsibilities of response organisations appropriate for implementation of the emergency plan.

(2) Such emergency plans shall-

(a) characterise the content, features and extent of a potential emergency taking into account the results of any hazard assessment 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 protective actions 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 response authorities as for obtaining assistance from firefighting, medical, police and other relevant authorities;

(h) provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in these Regulation;

(i) provide for periodic review and updating of the plan.

Implementation of intervention

97.-(1) The licensee and registrant shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified.

(2) The form, scale and duration of any justified intervention shall be optimised.

(3) A licensees and registrant shall promptly notify the Commission when an accidental situation requiring intervention has arisen or is expected to arise and shall keep the Commission informed of-

(a) the current situation and its expected evolution;
(b) the measures taken to terminate the accident and to protect workers and members of the public;
(c) the exposures that have been incurred and that are expected to be incurred.

Protection of emergency workers in emergency exposure situation

98.-(1) The Commission shall establish a program for managing, controlling and recording the doses received in an emergency by emergency worker, which shall be implemented by response organisations and employers.

(2) The licensee shall specify in the emergency plan the response organisation in averting the emergence exposure.

(3) In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations as provided in these Regulations shall be applied for emergency workers, in accordance with a graded approach.

(4) The Licensee shall ensure that no emergency worker is subject to exposure in excess of 50 mSv other than-

(a) for the purposes of saving life or preventing serious injury;
(b) when undertaking actions to avert a large collective dose; or
(c) when undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment.

(5) In the exceptional circumstances specified in these Regulations, micensee shall make all reasonable efforts to keep doses to emergency workers below the values set out in these Regulations.

(6) Licensees shall ensure that emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily.

(7) Licensees shall ensure that emergency workers are clearly and comprehensively informed in advance of the associated health risks, as well as of available measures for protection and safety.

(8) Licensee shall ensure that emergency workers are trained in the actions that they may be required to take.

(9) Workers undertaking repairs of plant and buildings, activities for radioactive waste management, remedial work for the decontamination of the site and surrounding areas, shall be

subject to the relevant requirements for occupational exposure specified in these Regulations.

(10) Licensees shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers.

(11) Licensee shall provide information of the doses received concerning the associated health risks to the workers involved.

(12) Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure.

(13) Workers undertaking repairs to plant and buildings, activities for radioactive waste management, remedial actions for the decontamination of the site, shall be subject to the relevant requirements for occupational exposure in planned exposure situations specified in these Regulations.

PART XI
GENERAL PROVISIONS

Cooperation between licensees, registrants and workers

99.-(1) A licensee, registrant and a worker shall cooperate to the extent necessary for compliance by all responsible parties with the requirements of these Regulations.

(2) Where the workers are engaged in work that involves or that could involve a source that is not under the control of the registrant or licensee shall cooperate to the extent necessary for compliance by both parties with the requirements of these Regulations.

(3) Cooperation between a registrant, licensee shall include-

(a) the development and use of specific restrictions on exposure and other means of ensuring that the measures for protection and safety for workers who are engaged in work that involves or could involve a source that is not under the control of their employer are as good as those for employees of the registrant or licensee;

(b) specific assessments of the doses received by workers as specified in these Regulation;

(c) a clear allocation and documentation of the responsibilities of the employer and those of the registrant or licensee for protection and safety.

(4) As part of the cooperation between parties, a registrant or licensee responsible for the source or for the

exposure shall, as appropriate-

(a) obtain from the employers, including self-employed individuals, the previous occupational exposure history of workers as specified in these Regulations, and any other necessary information;

(b) provide appropriate information to the employer, including any available information relevant for compliance with the requirements of these Regulations that the employer requests; and

(c) provide both the worker and the employer with the relevant exposure records.

Transport of radioactive materials requirements

100. Licensees transporting radioactive sources, radioactive waste or any other radioactive material or nuclear material shall do so in compliance with all applicable domestically or internationally transport requirements of regulations relating to safe transport of radioactive materials.

Revocation GN. No. 209 of 2004 279 of 1999

101. The Radioactive Waste Management for the Protection of Human Health and Environment Regulations**,** 1999 and the Atomic Energy (Protection from Ionising) Regulations, 2004 are hereby revoked.

FIRST SCHEDULE

(Made under regulations 7(1) and (3), 21(1) and 82(1)(b))

EXEMPTION AND CLEARANCE CRITERIA

CRITERIA FOR EXEMPTION

1. The generic criteria for exemption are:

(a) radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control of the Commission, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or

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(b) regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

2. A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Regulations under the terms of paragraph 1(a) of this Schedule provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3. Under the criteria set out in paragraph 1 and 2 of this Schedule, the following sources within justified practices are automatically exempted without further consideration from the provisions requirements of these Regulations, including requirements for notification, registration or licensing:

(a) material in a moderate amount for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration as used in the practice does not exceed the applicable exemption level given in Table 1.

(b) material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table 2.

(c) radiation generators of a type approved by the Commission, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:

(i) they do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; or

(ii) the maximum energy of the radiation generated is no greater than 5 keV.

4. For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation.

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5. Exemption may be granted subject to conditions specified by the Commission, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal.

6. In particular, such an exemption may be granted for equipment containing radioactive material that is not otherwise automatically exempted without further consideration from some or all of the requirements of these Regulations provided that:

(a) the equipment containing radioactive material is of a type approved by the Commission.

(b) the radioactive material-

  (i) is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or

  (ii) is in the form of an unsealed source in a small amount such as sources used for radioimmunoassay.

(c) in normal operating conditions, the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment.

(d) necessary conditions for disposal of the equipment have been specified by the Commission.

7. For exemption of radioactive material containing more than one radionuclide on the basis of the levels given in **Tables 1 and 2,** the conditions for exemption from some or all of the requirements of these Regulations is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture (Xm), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where

f(i) is the fraction of activity or activity concentration, as appropriate, of radionuclide i in the mixture;

X(i) is the applicable level for radionuclide i as given in Table 1 or Table 2;

and n is the number of radionuclides present.

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8. Radioactive material arising from authorised discharges is exempted from any requirements for notification, registration or licensing unless otherwise specified by the Commission.

9. The values provided in Tables I and 2 are not intended to be applied to the control of discharges or to the control of residual radioactive material in the environment

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
H-3	1×10^6	1×10^9	Sc-45	1×10^2	1×10^7
Be-7	1×10^3	1×10^7	Sc-46	1×10^1	1×10^6
Be-10	1×10^4	1×10^6	Sc-47	1 × 102	1×10^6
C-11	1×10^1	1×10^6	Sc-48	1×10^1	1×10^5
C-14	1×10^4	1×10^7	Sc-49	1×10^3	1×10^5
N-13	1×10^2	1×10^9	Ti-44	1×10^1	1×10^5
Ne-19	1×10^2	1×10^9	Ti-45	1×10^1	1×10^6
O-15	1×10^2	1×10^9	V-47	1×10^1	1×10^5
F-18	1×10^1	1×10^6	V-48	1×10^1	1×10^5
Na-22	1×10^1	1×10^6	V-49	1×10^4	1×10^7
Na-24	1×10^1	1×10^5	Cr-48	1×10^2	1×10^6
Mg-28	1×10^1	1×10^5	Cr-49	1×10^1	1×10^6
Al-26	1×10^1	1×10^5	Cr-51	1×10^3	1×10^7
Si-31	1×10^3	1×10^6	Mn-51	1×10^1	1×10^5
Si-32	1×10^3	1×10^6	Mn-52	1×10^1	1×10^5
P-32	1×10^3	1×10^5	Mn-52m	1×10^1	1×10^5
P-33	1×10^5	1×10^8	Mn-53	1×10^4	1×10^9
S-35	1×10^5	1×10^8	Mn-54	1×10^1	1×10^6
Cl-36	1×10^4	1×10^6	Mn-56	1×10^1	1×10^5
Cl-38	1×10^1	1×10^5	Fe-52	1×10^1	1×10^6
Cl-39	1×10^1	1×10^5	Fe-55	1×10^4	1×10^6
Ar-37	1×10^6	1×10^8	Fe-59	1×10^1	1×10^6
Ar-39	1×10^7	1×10^4	Fe-60	1×10^2	1×10^5
Ar-41	1×10^2	1×10^9	Co-55	1×10^1	1×10^6
K-40	1×10^2	1×10^6	Co-56	1×10^1	1×10^5
K-42	1×10^2	1×10^6	Co-57	1×10^2	1×10^6
K-43	1×10^1	1×10^6	Co-58	1×10^1	1×10^6
K-44	1×10^1	1×10^5	Co-58m	1×10^4	1×10^7
K-45	1×10^1	1×10^5	Co-60	1×10^1	1×10^5

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Ca-41	1×10^5	1×10^7	Co-60m	1×10^3	1×10^6
Ca-45	1×10^4	1×10^7	Co-61	1×10^2	1×10^6
Ca-47	1×10^1	1×10^6	Co-62m	1×10^1	1×10^5
Sc-43	1×10^1	1×10^6	Ni-56	1×10^1	1×10^6
Sc-44	1×10^1	1×10^5	Ni-57	1×10^1	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Ni-59	1×10^4	1×10^8	As-72	1×10^1	1×10^5
Ni-63	1×10^5	1×10^8	As-73	1×10^3	1×10^7
Ni-65	1×10^1	1×10^6	As-74	1×10^1	1×10^6
Ni-66	1×10^4	1×10^7	As-76	1×10^2	1×10^5
Cu-60	1×10^1	1×10^5	As-77	1×10^3	1×10^6
Cu-61	1×10^1	1×10^6	As-78	1×10^1	1×10^5
Cu-64	1×10^2	1×10^6	Se-70	1×10^1	1×10^6
Cu-67	1×10^2	1×10^6	Se-73	1×10^1	1×10^6
Zn-62	1×10^2	1×10^6	Se-73m	1×10^2	1×10^6
Zn-63	1×10^1	1×10^5	Se-75	1×10^2	1×10^6
Zn-65	1×10^1	1×10^6	Se-79	1×10^4	1×10^7
Zn-69	1×10^4	1×10^6	Se-81	1×10^3	1×10^6
Zn-69m	1×10^2	1×10^6	Se-81m	1×10^3	1×10^7
Zn-71m	1×10^1	1×10^6	Se-83	1×10^1	1×10^5
Zn-72	1×10^2	1×10^6	Br-74	1×10^1	1×10^5
Ga-65	1×10^1	1×10^5	Br-74m	1×10^1	1×10^5
Ga-66	1×10^1	1×10^5	Br-75	1×10^1	1×10^6
Ga-67	1×10^2	1×10^6	Br-76	1×10^1	1×10^5
Ga-68	1×10^1	1×10^5	Br-77	1×10^2	1×10^6
Ga-70	1×10^2	1×10^6	Br-80	1×10^2	1×10^5
Ga-72	1×10^1	1×10^5	Br-80m	1×10^3	1×10^7
Ga-73	1×10^2	1×10^6	Br-82	1×10^1	1×10^6
Ge-66	1×10^1	1×10^6	Br-83	1×10^3	1×10^6
Ge-67	1×10^1	1×10^5	Br-84	1×10^1	1×10^5
Ge-68b	1×10^1	1×10^5	Kr-74	1×10^2	1×10^9
Ge-69	1×10^1	1×10^6	Kr-76	1×10^2	1×10^9
Ge-71	1×10^4	1×10^8	Kr-77	1×10^2	1×10^9
Ge-75	1×10^3	1×10^6	Kr-79	1×10^3	1×10^5
Ge-77	1×10^1	1×10^5	Kr-81	1×10^4	1×10^7

Ge-78	1×10^2	1×10^6	Kr-81m	1×10^3	1×10^{10}
As-69	1×10^1	1×10^5	Kr-83m	1×10^5	1×10^{12}
As-70	1×10^1	1×10^5	Kr-85	1×10^5	1×10^4
As-71	1×10^1	1×10^6	Kr-85m	1×10^3	1×10^{10}

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Kr-87	1×10^2	1×10^9	Y-94	1×10^1	1×10^5
Kr-88	1×10^2	1×10^9	Y-95	1×10^1	1×10^5
Rb-79	1×10^1	1×10^5	Zr-86	1×10^2	1×10^7
Rb-81	1×10^1	1×10^6	Zr-88	1×10^2	1×10^6
Rb-81m	1×10^3	1×10^7	Zr-89	1×10^1	1×10^6
Rb-82m	1×10^1	1×10^6	Zr-93[b]	1×10^3	1×10^7
Rb-83[b]	1×10^2	1×10^6	Zr-95	1×10^1	1×10^6
Rb-84	1×10^1	1×10^6	Zr-97[b]	1×10^1	1×10^5
Rb-86	1×10^2	1×10^5	Nb-88	1×10^1	1×10^5
Rb-87	1×10^3	1×10^7	Nb-89	1×10^1	1×10^5
Rb-88	1×10^2	1×10^5	Nb-89m	1×10^1	1×10^5
Rb-89	1×10^2	1×10^5	Nb-90	1×10^1	1×10^5
Sr-80	1×10^3	1×10^7	Nb-93m	1×10^4	1×10^7
Sr-81	1×10^1	1×10^5	Nb-94	1×10^1	1×10^6
Sr-82[b]	1×10^1	1×10^5	Nb-95	1×10^1	1×10^6
Sr-83	1×10^1	1×10^6	Nb-95m	1×10^2	1×10^7
Sr-85	1×10^2	1×10^6	Nb-96	1×10^1	1×10^5
Sr-85m	1×10^2	1×10^7	Nb-97	1×10^1	1×10^6
Sr-87m	1×10^2	1×10^6	Nb-98	1×10^1	1×10^5
Sr-89	1×10^3	1×10^6	Mo-90	1×10^1	1×10^6
Sr-90[b]	1×10^2	1×10^4	Mo-93	1×10^3	1×10^8
Sr-91	1×10^1	1×10^5	Mo-93m	1×10^1	1×10^6
Sr-92	1×10^1	1×10^6	Mo-99	1×10^2	1×10^6
Y-86	1×10^1	1×10^5	Mo-101	1×10^1	1×10^6
Y-86m	1×10^2	1×10^7	Tc-93	1×10^1	1×10^6
Y-87[b]	1×10^1	1×10^6	Tc-93m	1×10^1	1×10^6
Y-88	1×10^1	1×10^6	Tc-94	1×10^1	1×10^6
Y-90	1×10^3	1×10^5	Tc-94m	1×10^1	1×10^5
Y-90m	1×10^1	1×10^6	Tc-95	1×10^1	1×10^6
Y-91	1×10^3	1×10^6	Tc-95m	1×10^1	1×10^6

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Y-91m	1×10^2	1×10^6	Tc-96	1×10^1	1×10^6
Y-92	1×10^2	1×10^5	Tc-96m	1×10^3	1×10^7
Y-93	1×10^2	1×10^5	Tc-97	1×10^3	1×10^8

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Tc-97m	1×10^3	1×10^7	Ag-106m	1×10^1	1×10^6
Tc-98	1×10^1	1×10^6	Ag-108m	1×10^1	1×10^6
Tc-99	1×10^4	1×10^7	Ag-110m	1×10^1	1×10^6
Tc-99m	1×10^2	1×10^7	Ag-111	1×10^3	1×10^6
Tc-101	1×10^2	1×10^6	Ag-112	1×10^1	1×10^5
Tc-104	1×10^1	1×10^5	Ag-115	1×10^1	1×10^5
Ru-94	1×10^2	1×10^6	Cd-104	1×10^2	1×10^7
Ru-97	1×10^2	1×10^7	Cd-107	1×10^3	1×10^7
Ru-103	1×10^2	1×10^6	Cd-109	1×10^4	1×10^6
Ru-105	1×10^1	1×10^6	Cd-113	1×10^3	1×10^6
Ru-106[b]	1×10^2	1×10^5	Cd-113m	1×10^3	1×10^6
Rh-99	1×10^1	1×10^6	Cd-115	1×10^2	1×10^6
Rh-99m	1×10^1	1×10^6	Cd-115m	1×10^3	1×10^6
Rh-100	1×10^1	1×10^6	Cd-117	1×10^1	1×10^6
Rh-101	1×10^2	1×10^7	Cd-117m	1×10^1	1×10^6
Rh-101m	1×10^2	1×10^7	In-109	1×10^1	1×10^6
Rh-102	1×10^1	1×10^6	In-110	1×10^1	1×10^6
Rh-102m	1×10^2	1×10^6	In-110m	1×10^1	1×10^5
Rh-103m	1×10^4	1×10^8	In-111	1×10^2	1×10^6
Rh-105	1×10^2	1×10^7	In-112	1×10^2	1×10^6
Rh-106m	1×10^1	1×10^5	In-113m	1×10^2	1×10^6
Rh-107	1×10^2	1×10^6	In-114	1×10^3	1×10^5
Pd-100	1×10^2	1×10^7	In-114m	1×10^2	1×10^6
Pd-101	1×10^2	1×10^6	In-115	1×10^3	1×10^5
Pd-103	1×10^3	1×10^8	In-115m	1×10^2	1×10^6
Pd-107	1×10^5	1×10^8	In-116m	1×10^1	1×10^5
Pd-109	1×10^3	1×10^6	In-117	1×10^1	1×10^6
Ag-102	1×10^1	1×10^5	In-117m	1×10^2	1×10^6
Ag-103	1×10^1	1×10^6	In-119m	1×10^2	1×10^5
Ag-104	1×10^1	1×10^6	Sn-110	1×10^2	1×10^7
Ag-104m	1×10^1	1×10^6	Sn-111	1×10^2	1×10^6

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Ag-105	1×10^2	1×10^6	Sn-113	1×10^3	1×10^7
Ag-106	1×10^1	1×10^6	Sn-117m	1×10^2	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Sn-119m	1×10^3	1×10^7	Te-123m	1×10^2	1×10^7
Sn-121	1×10^5	1×10^7	Te-125m	1×10^3	1×10^7
Sn-121m[b]	1×10^3	1×10^7	Te-127	1×10^3	1×10^6
Sn-123	1×10^3	1×10^6	Te-127m	1×10^3	1×10^7
Sn-123m	1×10^2	1×10^6	Te-129	1×10^2	1×10^6
Sn-125	1×10^2	1×10^5	Te-129m	1×10^3	1×10^6
Sn-126[b]	1×10^1	1×10^5	Te-131	1×10^2	1×10^5
Sn-127	1×10^1	1×10^6	Te-131m	1×10^1	1×10^6
Sn-128	1×10^1	1×10^6	Te-132	1×10^2	1×10^7
Sb-115	1×10^1	1×10^6	Te-133	1×10^1	1×10^5
Sb-116	1×10^1	1×10^6	Te-133m	1×10^1	1×10^5
Sb-116m	1×10^1	1×10^5	Te-134	1×10^1	1×10^6
Sb-117	1×10^2	1×10^7	I-120	1×10^1	1×10^5
Sb-118m	1×10^1	1×10^6	I-120m	1×10^1	1×10^5
Sb-119	1×10^3	1×10^7	I-121	1×10^2	1×10^6
Sb-120	1×10^2	1×10^6	I-123	1×10^2	1×10^7
Sb-120m	1×10^1	1×10^6	I-124	1×10^1	1×10^6
Sb-122	1×10^2	1×10^4	I-125	1×10^3	1×10^6
Sb-124	1×10^1	1×10^6	I-126	1×10^2	1×10^6
Sb-124m	1×10^2	1×10^6	I-128	1×10^2	1×10^5
Sb-125	1×10^2	1×10^6	I-129	1×10^2	1×10^5
Sb-126	1×10^1	1×10^5	I-130	1×10^1	1×10^6
Sb-126m	1×10^1	1×10^5	I-131	1×10^2	1×10^6
Sb-127	1×10^1	1×10^6	I-132	1×10^1	1×10^5
Sb-128	1×10^1	1×10^5	I-132m	1×10^2	1×10^6
Sb-128m	1×10^1	1×10^5	I-133	1×10^1	1×10^6
Sb-129	1×10^1	1×10^6	I-134	1×10^1	1×10^5
Sb-130	1×10^1	1×10^5	I-135	1×10^1	1×10^6
Sb-131	1×10^1	1×10^6	Xe-120	1×10^2	1×10^9
Te-116	1×10^2	1×10^7	Xe-121	1×10^2	1×10^9
Te-121	1×10^1	1×10^6	Xe-122[b]	1×10^2	1×10^9
Te-121m	1×10^2	1×10^6	Xe-123	1×10^2	1×10^9

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Te-123	1×10^3	1×10^6	Xe-125	1×10^3	1×10^9

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	**Activity Concentration (Bq/g)**	**Activity (Bq)**	**Radionuclides**	**Activity Concentration (Bq/g)**	**Activity (Bq)**
Xe-127	1×10^3	1×10^5	La-131	1×10^1	1×10^6
Xe-129m	1×10^3	1×10^4	La-132	1×10^1	1×10^6
Xe-131m	1×10^4	1×10^4	La-135	1×10^3	1×10^7
Xe-133m	1×10^3	1×10^4	La-137	1×10^3	1×10^7
Xe-133	1×10^3	1×10^4	La-138	1×10^1	1×10^6
Xe-135	1×10^3	1×10^{10}	La-140	1×10^1	1×10^5
Xe-135m	1×10^2	1×10^9	La-141	1×10^2	1×10^5
Xe-138	1×10^2	1×10^9	La-142	1×10^1	1×10^5
Cs-125	1×10^1	1×10^4	La-143	1×10^2	1×10^5
Cs-127	1×10^2	1×10^5	Ce-134	1×10^3	1×10^7
Cs-129	1×10^2	1×10^5	Ce-135	1×10^1	1×10^6
Cs-130	1×10^2	1×10^6	Ce-137	1×10^3	1×10^7
Cs-131	1×10^3	1×10^6	Ce-137m	1×10^3	1×10^6
Cs-132	1×10^1	1×10^5	Ce-139	1×10^2	1×10^6
Cs-134m	1×10^3	1×10^5	Ce-141	1×10^2	1×10^7
Cs-134	1×10^1	1×10^4	Ce-143	1×10^2	1×10^6
Cs-135	1×10^4	1×10^7	Ce-144[b]	1×10^2	1×10^5
Cs-135m	1×10^1	1×10^6	Pr-136	1×10^1	1×10^5
Cs-136	1×10^1	1×10^5	Pr-137	1×10^2	1×10^6
Cs-137[b]	1×10^1	1×10^4	Pr-138m	1×10^1	1×10^6
Cs-138	1×10^1	1×10^4	Pr-139	1×10^2	1×10^7
Ba-126	1×10^2	1×10^7	Pr-142	1×10^2	1×10^5
Ba-128	1×10^2	1×10^7	Pr-142m	1×10^7	1×10^9
Ba-131	1×10^2	1×10^6	Pr-143	1×10^4	1×10^6
Ba-131m	1×10^2	1×10^7	Pr-144	1×10^2	1×10^5
Ba-133	1×10^2	1×10^6	Pr-145	1×10^3	1×10^5
Ba-133m	1×10^2	1×10^6	Pr-147	1×10^1	1×10^5
Ba-135m	1×10^2	1×10^6	Nd-136	1×10^2	1×10^6
Ba-137m	1×10^1	1×10^6	Nd-138	1×10^3	1×10^7
Ba-139	1×10^2	1×10^5	Nd-139	1×10^2	1×10^6
Ba-140[b]	1×10^1	1×10^5	Nd-139m	1×10^1	1×10^6
Ba-141	1×10^2	1×10^5	Nd-141	1×10^2	1×10^7
Ba-142	1×10^2	1×10^6	Nd-147	1×10^2	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Nd-149	1×10^2	1×10^6	Eu-155	1×10^2	1×10^7
Nd-151	1×10^1	1×10^5	Eu-156	1×10^1	1×10^6
Pm-141	1×10^1	1×10^5	Eu-157	1×10^2	1×10^6
Pm-143	1×10^2	1×10^6	Eu-158	1×10^1	1×10^5
Pm-144	1×10^1	1×10^6	Gd-145	1×10^1	1×10^5
Pm-145	1×10^3	1×10^7	Gd-146[b]	1×10^1	1×10^6
Pm-146	1×10^1	1×10^6	Gd-147	1×10^1	1×10^6
Pm-147	1×10^4	1×10^7	Gd-148	1×10^1	1×10^4
Pm-148	1×10^1	1×10^5	Gd-149	1×10^2	1×10^6
Pm-148m	1×10^1	1×10^6	Gd-151	1×10^2	1×10^7
Pm-149	1×10^3	1×10^6	Gd-152	1×10^1	1×10^4
Pm-150	1×10^1	1×10^5	Gd-153	1×10^2	1×10^7
Pm-151	1×10^2	1×10^6	Gd-159	1×10^3	1×10^6
Sm-141	1×10^1	1×10^5	Tb-147	1×10^1	1×10^6
Sm-141m	1×10^1	1×10^6	Tb-149	1×10^1	1×10^6
Sm-142	1×10^2	1×10^7	Tb-150	1×10^1	1×10^6
Sm-145	1×10^2	1×10^7	Tb-151	1×10^1	1×10^6
Sm-146	1×10^1	1×10^5	Tb-153	1×10^2	1×10^7
Sm-147	1×10^1	1×10^4	Tb-154	1×10^1	1×10^6
Sm-151	1×10^4	1×10^8	Tb-155	1×10^2	1×10^7
Sm-153	1×10^2	1×10^6	Tb-156	1×10^1	1×10^6
Sm-155	1×10^2	1×10^6	Tb-156m (24.4 h)	1×10^3	1×10^7
Sm-156	1×10^2	1×10^6	Tb-156m′ (5 h)	1×10^4	1×10^7
Eu-145	1×10^1	1×10^6	Tb-157	1×10^4	1×10^7
Eu-146	1×10^1	1×10^6	Tb-158	1×10^1	1×10^6
Eu-147	1×10^2	1×10^6	Tb-160	1×10^1	1×10^6
Eu-148	1×10^1	1×10^6	Tb-161	1×10^3	1×10^6
Eu-149	1×10^2	1×10^7	Dy-155	1×10^1	1×10^6
Eu-150	1×10^1	1×10^6	Dy-157	1×10^2	1×10^6
Eu-150m	1×10^3	1×10^6	Dy-159	1×10^3	1×10^7
Eu-152	1×10^1	1×10^6	Dy-165	1×10^3	1×10^6
Eu-152m	1×10^2	1×10^6	Dy-166	1×10^3	1×10^6
Eu-154	1×10^1	1×10^6	Ho-155	1×10^2	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Ho-157	1×10^2	1×10^6	Lu-172	1×10^1	1×10^6
Ho-159	1×10^2	1×10^6	Lu-173	1×10^2	1×10^7
Ho-161	1×10^2	1×10^7	Lu-174	1×10^2	1×10^7
Ho-162	1×10^2	1×10^7	Lu-174m	1×10^2	1×10^7
Ho-162m	1×10^1	1×10^6	Lu-176	1×10^2	1×10^6
Ho-164	1×10^3	1×10^6	Lu-176m	1×10^3	1×10^6
Ho-164m	1×10^3	1×10^7	Lu-177	1×10^3	1×10^7
Ho-166	1×10^3	1×10^5	Lu-177m	1×10^1	1×10^6
Ho-166m	1×10^1	1×10^6	Lu-178	1×10^2	1×10^5
Ho-167	1×10^2	1×10^6	Lu-178m	1×10^1	1×10^5
Er-161	1×10^1	1×10^6	Lu-179	1×10^3	1×10^6
Er-165	1×10^3	1×10^7	Hf-170	1×10^2	1×10^6
Er-169	1×10^4	1×10^7	Hf-172[b]	1×10^1	1×10^6
Er-171	1×10^2	1×10^6	Hf-173	1×10^2	1×10^6
Er-172	1×10^2	1×10^6	Hf-175	1×10^2	1×10^6
Tm-162	1×10^1	1×10^6	Hf-177m	1×10^1	1×10^5
Tm-166	1×10^1	1×10^6	Hf-178m	1×10^1	1×10^6
Tm-167	1×10^2	1×10^6	Hf-179m	1×10^1	1×10^6
Tm-170	1×10^3	1×10^6	Hf-180m	1×10^1	1×10^6
Tm-171	1×10^4	1×10^8	Hf-181	1×10^1	1×10^6
Tm-172	1×10^2	1×10^6	Hf-182	1×10^2	1×10^6
Tm-173	1×10^2	1×10^6	Hf-182m	1×10^1	1×10^6
Tm-175	1×10^1	1×10^6	Hf-183	1×10^1	1×10^6
Yb-162	1×10^2	1×10^7	Hf-184	1×10^2	1×10^6
Yb-166	1×10^2	1×10^7	Ta-172	1×10^1	1×10^6
Yb-167	1×10^2	1×10^6	Ta-173	1×10^1	1×10^6
Yb-169	1×10^2	1×10^7	Ta-174	1×10^1	1×10^6
Yb-175	1×10^3	1×10^7	Ta-175	1×10^1	1×10^6
Yb-177	1×10^2	1×10^6	Ta-176	1×10^1	1×10^6
Yb-178	1×10^3	1×10^6	Ta-177	1×10^2	1×10^7
Lu-169	1×10^1	1×10^6	Ta-178	1×10^1	1×10^6
Lu-170	1×10^1	1×10^6	Ta-179	1×10^3	1×10^7
Lu-171	1×10^1	1×10^6	Ta-180	1×10^1	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Ta-180m	1×10^3	1×10^7	Os-191	1×10^2	1×10^7
Ta-182	1×10^1	1×10^4	Os-191m	1×10^3	1×10^7
Ta-182m	1×10^2	1×10^6	Os-193	1×10^2	1×10^6
Ta-183	1×10^2	1×10^6	Os-194[b]	1×10^2	1×10^5
Ta-184	1×10^1	1×10^6	Ir-182	1×10^1	1×10^5
Ta-185	1×10^2	1×10^5	Ir-184	1×10^1	1×10^6
Ta-186	1×10^1	1×10^5	Ir-185	1×10^1	1×10^6
W-176	1×10^2	1×10^6	Ir-186	1×10^1	1×10^6
W-177	1×10^1	1×10^6	Ir-186m	1×10^1	1×10^6
W-178[b]	1×10^1	1×10^6	Ir-187	1×10^2	1×10^6
W-179	1×10^2	1×10^7	Ir-188	1×10^1	1×10^6
W-181	1×10^3	1×10^7	Ir-189[b]	1×10^2	1×10^7
W-185	1×10^4	1×10^7	Ir-190	1×10^1	1×10^6
W-187	1×10^2	1×10^6	Ir-190m (3.1 h)	1×10^1	1×10^6
W-188[b]	1×10^2	1×10^5	Ir-190m′ (1.2 h)	1×10^4	1×10^7
Re-177	1×10^1	1×10^6	Ir-192	1×10^1	1×10^4
Re-178	1×10^1	1×10^6	Ir-192m	1×10^2	1×10^7
Re-181	1×10^1	1×10^6	Ir-193m	1×10^4	1×10^7
Re-182	1×10^1	1×10^6	Ir-194	1×10^2	1×10^5
Re-182m	1×10^1	1×10^6	Ir-194m	1×10^1	1×10^6
Re-184	1×10^1	1×10^6	Ir-195	1×10^2	1×10^6
Re-184m	1×10^2	1×10^6	Ir-195m	1×10^2	1×10^6
Re-186	1×10^3	1×10^6	Pt-186	1×10^1	1×10^6
Re-186m	1×10^3	1×10^7	Pt-188[b]	1×10^1	1×10^6
Re-187	1×10^6	1×10^9	Pt-189	1×10^2	1×10^6

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Re-188	1×10^2	1×10^5	Pt-191	1×10^2	1×10^6
Re-188m	1×10^2	1×10^7	Pt-193	1×10^4	1×10^7
Re-189[b]	1×10^2	1×10^6	Pt-193m	1×10^3	1×10^7
Os-180	1×10^2	1×10^7	Pt-195m	1×10^2	1×10^6
Os-181	1×10^1	1×10^6	Pt-197	1×10^3	1×10^6
Os-182	1×10^2	1×10^6	Pt-197m	1×10^2	1×10^6
Os-185	1×10^1	1×10^6	Pt-199	1×10^2	1×10^6
Os-189m	1×10^4	1×10^7	Pt-200	1×10^2	1×10^6

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)	Radionuclides	Activity Concentration (Bq/g)	Activity (Bq)
Au-193	1×10^2	1×10^7	Pb-201	1×10^1	1×10^6
Au-194	1×10^1	1×10^6	Pb-202	1×10^3	1×10^6
Au-195	1×10^2	1×10^7	Pb-202m	1×10^1	1×10^6
Au-198	1×10^2	1×10^6	Pb-203	1×10^2	1×10^6
Au-198m	1×10^1	1×10^6	Pb-205	1×10^4	1×10^7
Au-199	1×10^2	1×10^6	Pb-209	1×10^5	1×10^6
Au-200	1×10^2	1×10^5	Pb-210[b]	1×10^1	1×10^4
Au-200m	1×10^1	1×10^6	Pb-211	1×10^2	1×10^6
Au-201	1×10^2	1×10^6	Pb-212[b]	1×10^1	1×10^5
Hg-193	1×10^2	1×10^6	Pb-214	1×10^2	1×10^6
Hg-193m	1×10^1	1×10^6	Bi-200	1×10^1	1×10^6
Hg-194[b]	1×10^1	1×10^6	Bi-201	1×10^1	1×10^6
Hg-195	1×10^2	1×10^6	Bi-202	1×10^1	1×10^6
Hg-195m[b]	1×10^2	1×10^6	Bi-203	1×10^1	1×10^6
Hg-197	1×10^2	1×10^7	Bi-205	1×10^1	1×10^6
Hg-197m	1×10^2	1×10^6	Bi-206	1×10^1	1×10^5
Hg-199m	1×10^2	1×10^6	Bi-207	1×10^1	1×10^6
Hg-203	1×10^2	1×10^5	Bi-210	1×10^3	1×10^6
Tl-194	1×10^1	1×10^6	Bi-210m[b]	1×10^1	1×10^5
Tl-194m	1×10^1	1×10^6	Bi-212[b]	1×10^1	1×10^5
Tl-195	1×10^1	1×10^6	Bi-213	1×10^2	1×10^6
Tl-197	1×10^2	1×10^6	Bi-214	1×10^1	1×10^5
Tl-198	1×10^1	1×10^6	Po-203	1×10^1	1×10^6
Tl-198m	1×10^1	1×10^6	Po-205	1×10^1	1×10^6
Tl-199	1×10^2	1×10^6	Po-206	1×10^1	1×10^6
Tl-200	1×10^1	1×10^6	Po-207	1×10^1	1×10^6

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Tl-201	1×10^{2}	1×10^{6}	Po-208	1×10^{1}	1×10^{4}
Tl-202	1×10^{2}	1×10^{6}	Po-209	1×10^{1}	1×10^{4}
Tl-204	1×10^{4}	1×10^{4}	Po-210	1×10^{1}	1×10^{4}
Pb-195m	1×10^{1}	1×10^{6}	At-207	1×10^{1}	1×10^{6}
Pb-198	1×10^{2}	1×10^{6}	At-211	1×10^{3}	1×10^{7}
Pb-199	1×10^{1}	1×10^{6}	Fr-222	1×10^{3}	1×10^{5}
Pb-200	1×10^{2}	1×10^{6}	Fr-223	1×10^{2}	1×10^{6}

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	**Activity Concentration (Bq/g)**	**Activity (Bq)**	**Radionuclides**	**Activity Concentration (Bq/g)**	**Activity (Bq)**
Rn-220[b]	1×10^{4}	1×10^{7}	U-235[b]	1×10^{1}	1×10^{4}
Rn-222[b]	1×10^{1}	1×10^{8}	U-236	1×10^{1}	1×10^{4}
Ra-223[b]	1×10^{2}	1×10^{5}	U-237	1×10^{2}	1×10^{6}
Ra-224[b]	1×10^{1}	1×10^{5}	U-238[b]	1×10^{1}	1×10^{4}
Ra-225	1×10^{2}	1×10^{5}	U-239	1×10^{2}	1×10^{6}
Ra-226[b]	1×10^{1}	1×10^{4}	U-240	1×10^{3}	1×10^{7}
Ra-227	1×10^{2}	1×10^{6}	U-240[b]	1×10^{1}	1×10^{6}
Ra-228[b]	1×10^{1}	1×10^{5}	Np-232	1×10^{1}	1×10^{6}
Ac-224	1×10^{2}	1×10^{6}	Np-233	1×10^{2}	1×10^{7}
Ac-225[b]	1×10^{1}	1×10^{4}	Np-234	1×10^{1}	1×10^{6}
Ac-226	1×10^{2}	1×10^{5}	Np-235	1×10^{3}	1×10^{7}
Ac-227[b]	1×10^{-1}	1×10^{3}	Np-236	1×10^{2}	1×10^{5}
Ac-228	1×10^{1}	1×10^{6}	Np-236m	1×10^{3}	1×10^{7}
Th-226[b]	1×10^{3}	1×10^{7}	Np-237[b]	1×10^{0}	1×10^{3}
Th-227	1×10^{1}	1×10^{4}	Np-238	1×10^{2}	1×10^{6}
Th-228[b]	1×10^{0}	1×10^{4}	Np-239	1×10^{2}	1×10^{7}
Th-229[b]	1×10^{0}	1×10^{3}	Np-240	1×10^{1}	1×10^{6}
Th-230	1×10^{0}	1×10^{4}	Pu-234	1×10^{2}	1×10^{7}
Th-231	1×10^{3}	1×10^{7}	Pu-235	1×10^{2}	1×10^{7}
Th-232	1×10^{1}	1×10^{4}	Pu-236	1×10^{1}	1×10^{4}
Th-234[b]	1×10^{3}	1×10^{5}	Pu-237	1×10^{3}	1×10^{7}
Pa-227	1×10^{1}	1×10^{6}	Pu-238	1×10^{0}	1×10^{4}
Pa-228	1×10^{1}	1×10^{6}	Pu-239	1×10^{0}	1×10^{4}
Pa-230	1×10^{1}	1×10^{6}	Pu-240	1×10^{0}	1×10^{3}
Pa-231	1×10^{0}	1×10^{3}	Pu-241	1×10^{2}	1×10^{5}
Pa-232	1×10^{1}	1×10^{6}	Pu-242	1×10^{0}	1×10^{4}
Pa-233	1×10^{2}	1×10^{7}	Pu-243	1×10^{3}	1×10^{7}
Pa-234	1×10^{1}	1×10^{6}	Pu-244	1×10^{0}	1×10^{4}

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U-230[b]	1×10^{1}	1×10^{5}	Pu-245	1×10^{2}	1×10^{6}
U-231	1×10^{2}	1×10^{7}	Pu-246	1×10^{2}	1×10^{6}
U-232[b]	1×10^{0}	1×10^{3}	Am-237	1×10^{2}	1×10^{6}
U-233	1×10^{1}	1×10^{4}	Am-238	1×10^{1}	1×10^{6}
U-234	1×10^{1}	1×10^{4}	Am-239	1×10^{2}	1×10^{6}

TABLE I. LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (cont....)

Radionuclides	**Activity Concentration (Bq/g)**	**Activity (Bq)**	**Radionuclides**	**Activity Concentration (Bq/g)**	**Activity (Bq)**
Am-240	1×10^{1}	1×10^{6}	Bk-247	1×10^{0}	1×10^{4}
Am-241	1×10^{0}	1×10^{4}	Bk-249	1×10^{3}	1×10^{6}
Am-242	1×10^{3}	1×10^{6}	Bk-250	1×10^{1}	1×10^{6}
Am-242m[b]	1×10^{0}	1×10^{4}	Cf-244	1×10^{4}	1×10^{7}
Am-243[b]	1×10^{0}	1×10^{3}	Cf-246	1×10^{3}	1×10^{6}
Am-244	1×10^{1}	1×10^{6}	Cf-248	1×10^{1}	1×10^{4}
Am-244m	1×10^{4}	1×10^{7}	Cf-249	1×10^{0}	1×10^{3}
Am-245	1×10^{3}	1×10^{6}	Cf-250	1×10^{1}	1×10^{4}
Am-246	1×10^{1}	1×10^{5}	Cf-251	1×10^{0}	1×10^{3}
Am-246m	1×10^{1}	1×10^{6}	Cf-252	1×10^{1}	1×10^{4}
Cm-238	1×10^{2}	1×10^{7}	Cf-253	1×10^{2}	1×10^{5}
Cm-240	1×10^{2}	1×10^{5}	Cf-254	1×10^{0}	1×10^{3}
Cm-241	1×10^{2}	1×10^{6}	Es-250	1×10^{2}	1×10^{6}
Cm-242	1×10^{2}	1×10^{5}	Es-251	1×10^{2}	1×10^{7}
Cm-243	1×10^{0}	1×10^{4}	Es-253	1×10^{2}	1×10^{5}
Cm-244	1×10^{1}	1×10^{4}	Es-254	1×10^{1}	1×10^{4}
Cm-245	1×10^{0}	1×10^{3}	Es-254m	1×10^{2}	1×10^{6}
Cm-246	1×10^{0}	1×10^{3}	Fm-252	1×10^{3}	1×10^{6}
Cm-247	1×10^{0}	1×10^{4}	Fm-253	1×10^{2}	1×10^{6}
Cm-248	1×10^{0}	1×10^{3}	Fm-254	1×10^{4}	1×10^{7}
Cm-249	1×10^{3}	1×10^{6}	Fm-255	1×10^{3}	1×10^{6}
Cm-250	1×10^{-1}	1×10^{3}	Fm-257	1×10^{1}	1×10^{5}
Bk-245	1×10^{2}	1×10^{6}	Md-257	1×10^{2}	1×10^{7}
Bk-246	1×10^{1}	1×10^{6}	Md-258	1×10^{2}	1×10^{5}

a. m and m′ denote metastable states of the radionuclide. The metastable state m′ is of higher energy than the metastable state m.

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b. Parent radionuclides and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered) are listed here:

Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Ag-108m	Ag-108
Sn-121m	Sn-121 (0.776)
Sn-126	Sb-126m
Xe-122	I-122
Cs-137	Ba-137m
Ba-140	La-140
Ce-134	La-134
Ce-144	Pr-144
Gd-146	Eu-146
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m (0.241)
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195 (0.542)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-210m	Tl-206
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Po-213 (0.978), Tl-209 (0.0216), Pb-209 (0.978)
Ac-227	Fr-223 (0.0138)
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212,Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np-237	Pa-233

Po-212 (0.64)	Am-242m	Am-242
	Am-243	Np-239

TABLE 2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclides	**Activity Concentration (Bq/g)** (Bq/g)	**Radionuclides**	**Activity Concentration** (Bq/g)
H-3	100	Co-58	1
Be-7	10	Co-58m	10 000
C-14	1	Co-60	0.1
F-18	10	Co-60m	1 000
Na-22	0.1	Co-61	100
Na-24	1	Co-62m	10
Si-31	1 000	Ni-59	100
P-32	1 000	Ni-63	100
P-33	1 000	Ni-65	10
S-35	100	Cu-64	100
Cl-36	1	Zn-65	0.1
Cl-38	10	Zn-69	1 000
K-42	100	Zn-69ma	10
K-43	10	Ga-72	10
Ca-45	100	Ge-71	10 000
Ca-47	10	As-73	1 000
Sc-46	0.1	As-74	10
Sc-47	100	As-76	10
Sc-48	1	As-77	1 000
V-48	1	Se-75	1
Cr-51	100	Br-82	1
Mn-51	10	Rb-86	100
Mn-52	1	Sr-85	1
Mn-52m	10	Sr-85m	100
Mn-53	100	Sr-87m	100
Mn-54	0.1	Sr-89	1 000
Mn-56	10	Sr-90a	1
Fe-52a	10	Sr-91a	10
Fe-55	1 000	Sr-92	10

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Fe-59	1	Y-90	1 000
Co-55	10	Y-91	100
Co-56	0.1	Y-91m	100
Co-57	1	Y-92	100

TABLE 2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclides	**Activity Concentration (Bq/g)**	**Radionuclides**	**Activity Concentration** (Bq/g)
Y-93	100	In-111	10
Zr-93	10	In-113m	100
Zr-95[a]	1	In-114m[a]	10
Zr-97[a]	10	In-115m	100
Nb-93m	10	Sn-113[a]	1
Nb-94	0.1	Sn-125	10
Nb-95	1	Sb-122	10
Nb-97[a]	10	Sb-124	1
Nb-98	10	Sb-125[a]	0.1
Mo-90	10	Te-123m	1
Mo-93	10	Te-125m	1 000
Mo-99[a]	10	Te-127	1 000
Mo-101[a]	10	Te-127m[a]	10
Tc-96	1	Te-129	100
Tc-96m	1 000	Te-129m[a]	10
Tc-97	10	Te-131	100
Tc-97m	100	Te-131m[a]	10
Tc-99	1	Te-132[a]	1
Tc-99m	100	Te-133	10
Ru-97	10	Te-133m	10
Ru-103[a]	1	Te-134	10
Ru-105[a]	10	I-123	100
Ru-106[a]	0.1	I-125	100
Rh-103m	10 000	I-126	10
Rh-105	100	I-129	0.01

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Pd-103[a]	1 000	I-130	10
Pd-109[a]	100	I-131	10
Ag-105	1	I-132	10
Ag-110m[a]	0.1	I-133	10
Ag-111	100	I-134	10
Cd-109[a]	1	I-135	10
Cd-115[a]	10	Cs-129	10
Cd-115m[a]	100	Cs-131	1 000

TABLE 2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (cont..)

Radionuclides	**Activity Concentration (Bq/g)**	**Radionuclides**	**Activity Concentration** (Bq/g)
Cs-132	10	Er-171	100
Cs-134	0.1	Tm-170	100
Cs-134m	1 000	Tm-171	1 000
Cs-135	100	Yb-175	100
Cs-136	1	Lu-177	100
Cs-137[a]	0.1	Hf-181	1
Cs-138	10	Ta-182	0.1
Ba-131	10	W-181	10
Ba-140	1	W-185	1 000
La-140	1	W-187	10
Ce-139	1	Re-186	1 000
Ce-141	100	Re-188	100
Ce-143	10	Os-185	1
Ce-144[a]	10	Os-191	100
Pr-142	100	Os-191m	1 000
Pr-143	1 000	Os-193	100
Nd-147	100	Ir-190	1
Nd-149	100	Ir-192	1
Pm-147	1 000	Ir-194	100
Pm-149	1 000	Pt-191	10
Sm-151	1 000	Pt-193m	1 000
Sm-153	100	Pt-197	1 000
Eu-152	0.1	Pt-197m	100
Eu-152m	100	Au-198	10
Eu-154	0.1	Au-199	100
Eu-155	1	Hg-197	100
Gd-153	10	Hg-197m	100
Gd-159	100	Hg-203	10

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Tb-160	1	Tl-200	10
Dy-165	1 000	Tl-201	100
Dy-166	100	Tl-202	10
Ho-166	100	Tl-204	1
Er-169	1 000	Pb-203	10

TABLE 2. LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION AND FOR CLEARANCE OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN (cont.)

Radionuclides	**Activity Concentration (Bq/g)**	**Radionuclides**	**Activity Concentration** (Bq/g)
Bi-206	1	Pu-241	10
Bi-207	0.1	Pu-242	0.1
Po-203	10	Pu-243	1 000
Po-205	10	Pu-244[a]	0.1
Po-207	10	Am-241	0.1
At-211	1 000	Am-242	1 000
Ra-225	10	Am-242m[a]	0.1
Ra-227	100	Am-243[a]	0.1
Th-226	1 000	Cm-242	10
Th-229	0.1	Cm-243	1
Pa-230	10	Cm-244	1
Pa-233	10	Cm-245	0.1
U-230	10	Cm-246	0.1
U-231	100	Cm-247[a]	0.1
U-232[a]	0.1	Cm-248	0.1
U-233	1	Bk-249	100
U-236	10	Cf-246	1 000
U-237	100	Cf-248	1
U-239	100	Cf-249	0.1
U-240[a]	100	Cf-250	1
Np-237[a]	1	Cf-251	0.1
Np-239	100	Cf-252	1
Np-240	10	Cf-253	100
Pu-234	100	Cf-254	1
Pu-235	100	Es-253	100
Pu-236	1	Es-254[a]	0.1
Pu-237	100	Es-254m[a]	10
Pu-238	0.1	Fm-254	10 000
Pu-239	0.1	Fm-255	100
Pu-240	0.1		

a. Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered), are listed here:

Fe-52	Mn-52m
Zn-69m	Zn-69
Sr-90	Y-90
Sr-91	Y-91m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
Cs-137	Ba-137m
Ce-144	Pr-144, Pr-144m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240m, Np-240
Np-237	Pa-233
Pu-244	U-240, Np-240m, Np-240 Am-242m Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250
Es-254m	Fm-254

CRITERIA FOR CLEARANCE

1. The general criteria for clearance are that:

(a) radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

2. Material may be cleared without further consideration under paragraph of 1(a) of this Schedule provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective

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dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3. Radioactive material within a notified practice or an authorised practice may be cleared without further consideration provided that:

(a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Table 2; or

(b) the activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table 3; or

(c) for radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1 mSv in a year, which is commensurate with typical doses due to natural background levels of radiation.

4. Clearance may be granted by the Commission for specific situations, on the basis of the criteria of 1 and 2, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance levels may be specified in terms of activity concentration per unit mass or activity concentration per unit surface area.

5. For clearance of radioactive material containing more than one radionuclide of artificial origin, on the basis of the levels given in Table 2, the conditions for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (Xm), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where

f(i) is the fraction of activity concentration of radionuclide i in the mixture;

X(i) is the applicable level for radionuclide i as given in Table 2; and n is the number of radionuclides present.

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5 For clearance of bulk quantities of material containing a mixture of radionuclides of natural origin and radionuclides of artificial origin, the conditions given in criteria 12 and 14 both have to be satisfied.

TABLE 3. LEVELS FOR CLEARANCE OF MATERIAL: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF NATURAL ORIGIN

Radionuclide	Activity concentration (Bq/g)
K-40	10
Each radionuclide in the uranium decay chain or the thorium decay chain	1

SECOND SCHEDULE

(Made under regulations 6(g), 24(2), 25(1), 38(2)(a) and 60(2)(b)(ii))

DOSE LIMITS FOR PLANNED EXPOSURES SITUATIONS

OCCUPATIONAL EXPOSURE.

1. For occupational exposure of over the age of 18 years, the dose limits are:

(a) An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;

(c) An equivalent dose to the extremities namely hands and feet or to the skin of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified that is pregnant or is breast-feeding.

2. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:

(i) An effective dose of 6 mSv in a year;

(ii) An equivalent dose to the lens of the eye of 20 mSv in a year;

(iii) An equivalent dose to the extremities namely hands and feet or to the skin of 150 mSv in a year.

SPECIALCIRCUMSTANCES

1. When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to regulation 50:

(a) the dose average period mentioned in paragraph (a) above may exceptionally be up to 10 consecutive years as specified by the Commission, 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 the temporary change in dose limitation shall be as specified by the Commission, but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed 5 years.

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PUBLIC EXPOSURE

3. For public exposure, the dose limits are:

(a) an effective dose of 1 mSv in a year;

(b) in special circumstances, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;

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

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

VERIFICATION OF COMPLIANCE WITH DOSE LIMITS

4. The effective dose limits specified in this schedule apply to the sum of the relevant doses from external exposure in the specified period and the relevant committed doses from intakes in the same period; the period for calculating the committed dose shall normally be 50 years for intakes by adults and shall be up to age 70 years for intakes by children.

5. For occupational exposure, the personal dose equivalent Hp(10) may be used as an approximation of the effective dose from external exposure to penetrating radiation.

INTERNAL

EXPOSURE

6. Internal exposure caused by inhalation or ingestion of radioactive substances shall be estimated in accordance with the methodologies, parameters and value contained in the current IAEA GSR-Part 3

DOSE LIMITATION FOR COMFORTERS AND VISITORS OF PATIENTS

7. The dose limits set out in this part shall not apply to comforters or visitors of patients. However, the dose of any such comforter or visitor shall be

constrained so that it is unlikely that the dose will exceed 5 mSv during the period of the diagnostic examination or treatment. The dose to children visiting patients who have ingested or have been injected radioactive materials shall be similarly constrained to less than 1 mSv.

THIRD SCHEDULE

(Made under regulation 48(2))

MEDICAL EXPOSURE - DESIGN AND OPERATIONAL REQUIREMENTS

Design of sources and equipment

1. The requirements for the safety of sources specified in Regulation 58 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 be 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:
   (i) ensure that radiation generators, sources and accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information or therapeutic results;
   (ii) ensure that equipment containing sources for medical exposure conform to applicable international such as International Electrotechnical Commission (IEC) , International Standards Organisation (ISO) and national standards;
   (iii) ensure that performance specifications and operating and maintenance instructions, including radiation safety aspects, are provided in a major world language understandable to the users as well as in the language;

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(iv) identify and take all reasonable measures to prevent failures and human error that could result in unplanned medical exposures, including the establishment of adequate procedures for calibration, quality assurance and operation of diagnostic and therapeutic equipment as well as the selection, training and periodic retraining of suitably qualified personnel;

(v) ensure that any radiation emitting equipment is provided with radiation beam control mechanisms, including safety interlocks and clear and fail-safe "on-off" indicators;

(vi) ensure that devices are provided to limit the exposure to the area being examined or treated and keep exposure rates outside this area, due to radiation leakage or scattering, as low as reasonably achievable;

vii. ensure that, when appropriate, monitoring equipment is installed or is available to give warning of an unusual situation or trend in the use of radiation emitting equipment for diagnostic or therapeutic applications.

OPERATIONAL ASPECTS

Diagnostic exposure

1. 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 diagnostic reference 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 pediatric radiology and interventional radiology:

(i) the area to be examined, the number and size of views per examination .*example number of films or computed tomography slices* or the time per examination *example fluoroscopic time);*

(ii) the type of image receptor such as high versus low speed screens;

(iii) the use of anti-scatter 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 such as tube generating potential current and time or their product);

(vi) appropriate image storage techniques in dynamic imaging *example number of images per second*; and

(vii) adequate image processing facilities such as developer, temperature control device and image reconstruction algorithms

4. **Nuclear medicine**

Licensees shall make sure that:

(a) the medical 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 diagnostic reference 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;

(iv) avoid administration of radionuclides for diagnostic procedure to pregnant women or who are likely to be pregnant unless there are strong clinical indications to justify such procedures;

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(v) 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 nursing; and

(vi) 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;

(vii) the medical practitioner, the technologist, radiologist or other imaging staff, as appropriate,

(viii) endeavor to achieve the minimum patient exposure consistent with acceptable image quality by:

(a) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;

(b) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable; and

(c) appropriate image acquisition and processing.

5. **Therapeutic exposure**

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

(a) the prescribed absorbed dose is delivered to the planning target volume or organ;

(b) 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.

FOURTH SCHEDULE

(Made under regulations 25(1) and 51(b))

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
Skull	AP	5
	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] Delivered 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.

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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			
	$^{99}Tc^{m}$	Phosphate and	600
Bone imaging		Phosphate compounds	
Bone imaging by single	$^{99}Tc^{m}$	Phosphate and	
Photon emission computerized		Phosphate compounds	800
Tomography (SPECT)			
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	800
		glucoheptonate	
	$^{99}Tc^{m}$	Exametazime	500
Cerebral blood flow	^{133}Xe	In isotonic sodium	400
		Chloride solution	
	$^{99}Tc^{m}$	Hexamethyl propylene	500
		amine oxime (HM-PAO)	
Cisternography	^{111}In	DTPA	40

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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	^{131}I	I^{-}	400
(after ablation)			
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

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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

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Myocardial imaging	$^{99}Tc^{m}$	Phosphonate and	
		Phosphate	
		Compounds	
600			
Myocardial imaging	$^{99}Tc^{m}$	Isonitriles	
300			
(SPECT)			
	^{201}TI	TI^{+} chloride	
100			
	$^{99}Tc^{m}$	Phosphonate and	
		phosphate	
		compounds	
800			
	$^{99}Tc^{m}$	Isonitriles	
600			

Stomach,			
Gastrointestinal tract			
Stomach/salivary gland	$^{99}Tc^{m}$	TcO^{-}_{4}	
40			
Imaging			
Meckel's diverticulum	$^{99}Tc^{m}$	TcO^{-}_{4}	
400			
Imaging			
Gastrointestinal bleeding	$^{99}Tc^{m}$	labeled colloid	400
	$^{99}Tc^{m}$	labeled normal	
		red blood cells	400
Oesophageal transit and	$^{99}Tc^{m}$	labeled colloid	
40			
Reflux			
	$^{99}Tc^{m}$	non-absorbable	
		compounds	
40			
Gastric emptying	$^{99}Tc^{m}$	non-absorbable	
		Compounds	
12			

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	^{111}In	non-absorbable compounds	12
	$^{113}In^{m}$	non-absorbable compounds	12
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	^{67}Ga	Citrate	300
Or abscess			
Imaging	^{201}TI	Chloride	100

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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)**	**Dose rate at 1 m (mSv/h)**
Gold-198	3500	0.21
Gallium-67	8700	0.18
Iodine -123	6000	0.26
Iodine -131	1200	0.07
Indium-111	2400	0.2
Phosphorus -32	*	*
Rhenium-186	28,000	0.15
Rhenium-188	29,000	0.20
Samarium-153	5000–26000	0.06–0.3
Strontium-89	*	
Technetium-99m	28,000	0.58
Thallium-201	16,000	0.19
Yttrium-90	*	
Ytterbium-169	370	0.02

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* No value given because of minimal exposures of the public.

FIFTH SCHEDULE

(Made under regulations 39(2)(d) and 84(2)(b))

RADIATION SYMBOLS

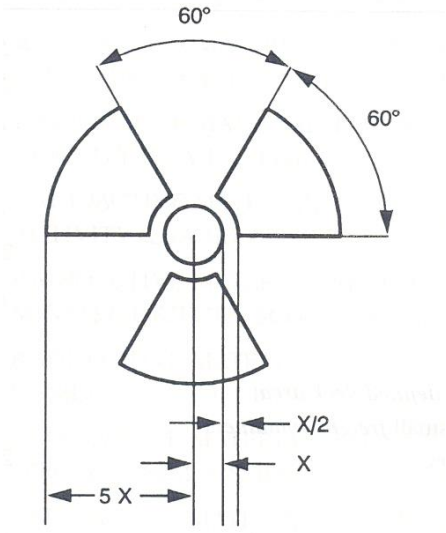

Figure 1. Basic trefoil symbol with proportions based on a central circle of radius X. The minimum allowable size of X shall be 4 millimeters. The symbol shall be in black colour and should be placed on yellow or white background.

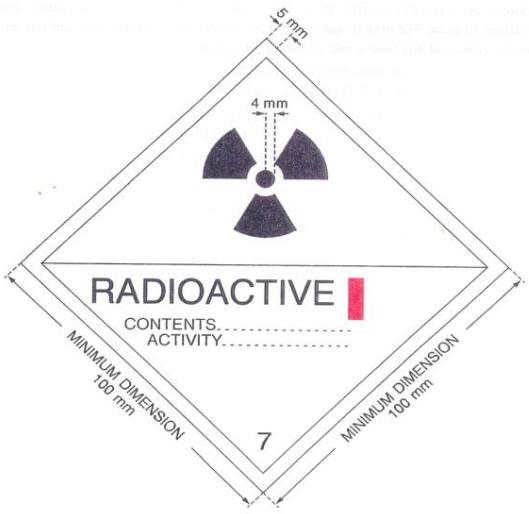

Figure 2 Category I-WHITE label. The background colour of the label shall be white, the colour of the trefoil and the printing shall be black, and the colour of the category bar shall be red.

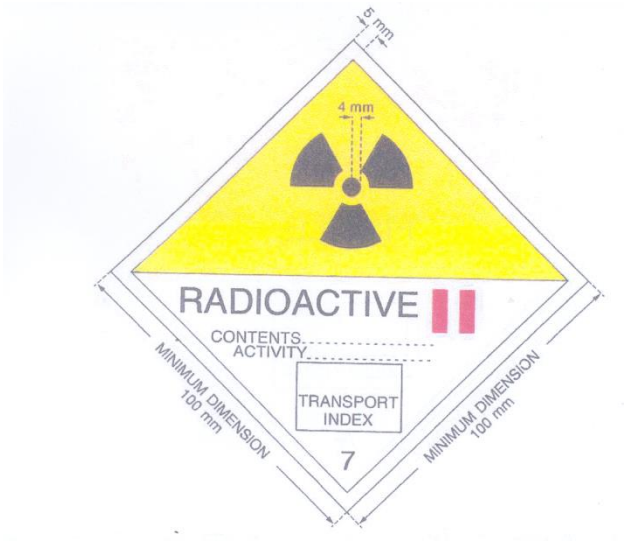

Figure 3. Category II-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

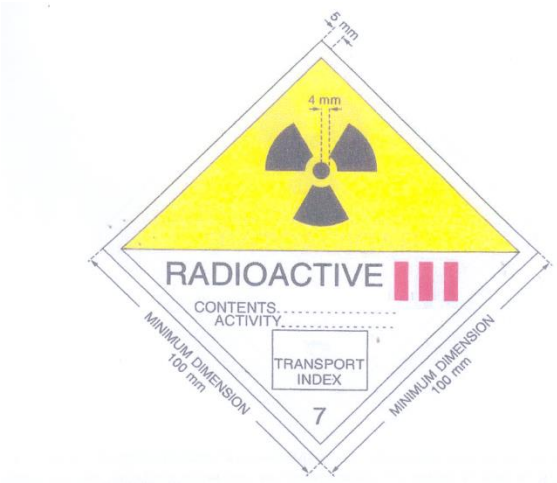

Figure 4. Category III-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

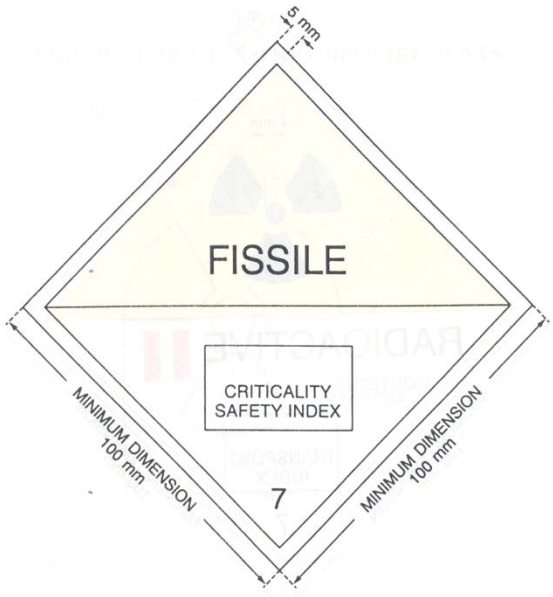

Figure 5. Criticality safety index label. The background colour of the label shall be white, the colour of the printing shall be black.

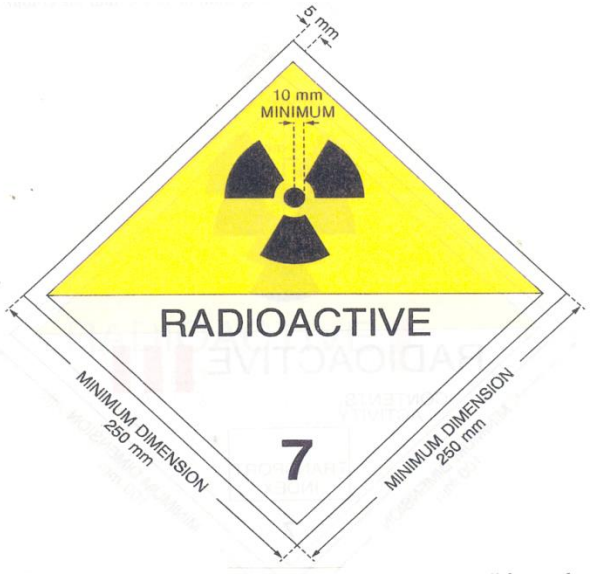

Figure 6. Placard. Minimum dimensions shall be as shown; when different dimensions are used the relative proportions must be maintained. The number '7' shall not be less than 25 millimeters high. The background colour of the upper half of the placard shall be yellow and of the lower half white, the colour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

SIXTH SCHEDULE

(Made under regulation 53(2))

HELSINKI DECLARATION

HELSINKI DECLARATION (1964/96)

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

GN NO. 480 (Contd)

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.
INTROD
UCTION

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 etiology 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 recognised 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.

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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 acceptable 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 of a clinically competent medical person. 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. 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.

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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 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.

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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).

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.

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30. The investigator or the investigating team should discontinue the research if in his or their judgement it may, if continued, be harmful to the individual.

31. In research of a man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

SEVENTH SCHEDULE

A. RADIOACTIVE WASTE CLASSIFICATION

(Made under regulation 84(1)(a))

Six classes of waste are derived and used as the basis for the classification scheme:

(1) Exempt waste (EW): Waste that meets the criteria for clearance, exemption or exclusion from Commission for radiation protection purposes

(2) Very short lived waste (VSLW): Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared by Commission according to arrangements approved by the for uncontrolled disposal, use or discharge. VSLW includes waste primarily containing radionuclides with very short half-lives often used for research and medical purposes.

(3) Very low level waste (VLLW): Waste that does not necessarily meet the criteria of EW, but which does not need a high level of containment and isolation and, therefore, is suitable for disposal in near surface landfill type facilities with limited regulatory control. Such landfill type facilities may also contain other hazardous waste. Typical waste in this class includes soil and rubble with low levels of activity concentration.

(4) Low level waste (LLW): Waste that is above clearance levels, but with limited amounts of long lived radionuclides. Such waste requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near surface facilities.. Typical waste in this class include short lived radionuclides at higher levels of activity concentration and long lived radionuclides, but only at relatively low levels of activity concentration.

(5) Intermediate level waste (ILW): Waste that, because of its content, particularly of long lived radionuclides, requires a greater degree of containment and isolation than that provided by near surface disposal. Typical waste in this class contain long lived Radioactive waste containing radionuclides with activity concentrations more than LILW-SL but which generate heat at above 2 kW/m^3.

B. RADIATION DOSE LIMITATION

(a) The dose limit for members of the public for doses from all planned exposure situations is an effective dose of 1 mSv in a year. This and its risk equivalent are considered criteria that are not to be exceeded both now and in the future. The dose constraint for an individual facility is 0.3 mSv in a year.

(b) To comply with this dose limit, a disposal facility (considered as a single source) is so designed that the calculated dose or risk to the representative person who might be exposed in the future as a result of possible natural processes affecting the disposal facility does not exceed a dose constraint of 0.3 mSv in a year or a risk constraint of the order of 1 in 10,000 per year. Natural processes include the range of conditions anticipated over the lifetime of the facility and events that could occur with a lesser likelihood. However, extremely low probability events would be outside the scope of consideration. Risk due to the disposal facility in this context is to be understood as the probability of fatal cancer or serious hereditary effects.

(c) In relation to the effects of inadvertent human intrusion after closure, if such intrusion is expected to lead to an annual dose of less than 1 mSv to those living around the site, then efforts to reduce the probability of intrusion or to limit its consequences are not warranted.

(d) If human intrusion were expected to lead to a possible annual dose of more than 20 mSv to those living around the site, then alternative options for waste disposal are to be considered, for example, disposal of the waste below the surface, or separation of the radionuclide content giving rise to the higher dose.

(e) If annual doses in the range 1 – 20 mSv are indicated, then reasonable efforts are warranted at the stage of development of the facility to reduce the probability of intrusion or to limit its consequences by means of optimisation of the facility's design.

(f) Similar considerations apply where the relevant thresholds for deterministic effects in organs may be exceeded. Radiation doses to people in the future can only be estimated and that uncertainties associated with these estimates will increase for periods farther into the future. Caution needs to be exercised in applying criteria for periods far into the future. Beyond such timescales, the uncertainties associated with dose estimates become so large that the criteria might no longer serve as a reasonable basis for decision-making.

EIGHTH SCHEDULE

(Made under regulations 6(g), 25(1), 38(2)(a) and 60(3)(b))

A. EXPOSURE LIMITS

The exposure limits for the general public are five (5) times lower than for occupational workers. This is due to the fact that such workers are normally persons who may have been trained to be aware of Radiofrequency (RF) hazards and have been medically assessed to be fit for work in RF environment.

Table 1: Basic restrictions for time varying electric and magnetic fields for frequencies up to 10 GHz

Type of exposure	Frequency range	Current density for head & trunk (mA/m^2) (rms)	Whole-body average SAR (W/kg)	Localized SAR (head & trunk) (W/kg)	Localized SAR (limbs) (W/kg)
Occupational exposure	Up to 1 HZ	40	Not determined	Not determined	Not determined
	1 – 4 Hz	40/*f*	Not determined	Not determined	Not determined
	4 Hz – 1 kHz	10	Not determined	Not determined	Not determined
	1 – 100 kHz	*f*/100	Not determined	Not determined	Not determined
	100 kHz – 10 MHz	*f*/100	0.4	10	20
	10 MHz – 10 GHz	Not determined	0.4	10	20
General public exposure	Up to 1 Hz	8	Not determined	Not determined	Not determined
	1 – 4 Hz	8/*f*	Not determined	Not determined	Not determined
	4 Hz – 1 kHz	2	Not determined	Not determined	Not determined
	1 – 100 kHz	*f*/500	Not determined	Not determined	Not determined
	100 kHz – 10 MHz	*f*/500	0.08	2	4

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	10 MHz – 10 GHz	Not determined	0.08	2	4

Note*:*

1. ***f*** is the frequency in hertz.
2. Because of electrical inhomogeneity of the body, current densities should be averaged over a cross-section of 1 cm^2 perpendicular to the current direction.
3. For frequencies up to **100 kHz**, peak current density values can be obtained by multiplying the **rms** value by **$\sqrt{2}$(~1.414).** For pulses of duration t_p the equivalent frequency to apply in the basic restrictions should be calculated as ***f*=1/(2t_p).**
4. For frequencies up to **100 kHz** and for pulsed magnetic fields, the maximum current density associated with the pulses can be calculated from the rise/fall times and the maximum rate of change of magnetic flux density. The induced current density can then be compared with the appropriate basic restriction.
5. All **SAR** values are to be averaged over any **6-min** period.
6. Localized **SAR** averaging mass is any **10g** of contiguous tissue; the maximum **SAR** so obtained should be the value used for the estimation of exposure.
7. For pulses of duration t_p the equivalent frequency to apply in the basic restrictions should be calculated as $f = 1/(2t_p)$. Additionally, for pulsed exposures in the frequency range **0.3 to 10 GHz** and for localized exposure of the head, in order to limit or avoid auditory effects caused by thermo elastic expansion, an additional basic restriction is recommended.
   This is that the SAR should not exceed **10 mJ/kg** for workers and **2mJ/kg** for the general public, averaged over **10 g tissues**.

Table 2: Basic restrictions for power density for frequencies between 10 GHz and 300 GHz

Exposure characteristics	**Power density (W/m^2)**
Occupational exposure	50
General public exposure	10

Note:

1. Power densities are to be averaged over any **20 cm^2** of exposed area and any **68/*f* 1.05-min** period (**where *f* is in GHz**) to compensate for progressively shorter penetration depth as the frequency increases.

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2. Spatial maximum power densities, averaged over **1 cm^2**, should not exceed **20 times** the values above.

Table 3: Ranges of threshold currents for indirect effects, including children, women, and men

Indirect effect	Threshold current (mA) at frequency	
	100kHz	**1 MHz**
Touch perception	25 - 40	25 - 40
Pain on finger contact	33 - 55	28 - 50
Painful shock/let-go threshold	112 - 224	Not determined
Severe shock/breathing difficulty	160 - 320	Not determined

B. REFERENCE LEVELS

Table 1: Reference levels for occupational and general public exposure to time-varying electric and magnetic fields (unperturbed rms values)

Type of exposure	Frequency range	Electric (E) field strength (V/m)	Magnetic (H) field strength (A/m)	B-field (μT)	Equivalent plane wave power density S_{eq} (W/m^2)
Occupational exposure	Up to 1Hz	Not determined	1.63×10^5	2×10^5	Not determined
	1 – 8Hz	20,000	$1.63 \times 10^5/f^2$	$2 \times 10^5/f^2$	Not determined
	8 Hz – 25Hz	20,000	$2 \times 10^4/f$	$2.5 \times 10^4/f$	Not determined
	0.025 – 0.82 kHz	$500f$	$20/f$	$25/f$	Not determined
	0.82 – 65 kHz	610	24.4	30.7	Not determined
	0.065 – 1MHz	610	$1.6/f$	$2.0/f$	Not determined
	1 – 10 MHz	$610f$	$1.6/f$	$2.0/f$	Not determined
	10 – 400 MHz	61	0.16	0.2	10
	400 – 2000MHz	$3f^{1/2}$	$0.008f^{1/2}$	$0.01f^{1/2}$	$f/40$
	2 – 300 GHz	137	0.36	0.45	50
General public exposure	Up to 1Hz	Not determined	3.2×10^4	4×10^4	Not determined
	1 – 8Hz	10,000	$3.2 \times 10^4/f^2$	$4 \times 10^4/f^2$	Not determined
	8 Hz – 25Hz	10,000	$4000/f$	$5000/f$	Not determined

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Type of exposure	Frequency range	Electric (E) field strength (V/m)	Magnetic (H) field strength (A/m)	B-field (μT)	Equivalent plane wave power density S_{eq} (W/m^2)
	0.025 – 0.8 kHz	250/*f*	4/*f*	5/*f*	Not determined
	0.8 – 3 kHz	250/*f*	5	6.25	Not determined
	3 – 150 kHz	87	5	6.25	Not determined
	0.15 – 1MHz	87	0.73/*f*	0.92/*f*	Not determined
	1 – 10 MHz	$87/f^{1/2}$	0.73/*f*	0.92/*f*	Not determined
	10 – 400 MHz	28	0.073	0.092	2
	400 – 2000MHz	$1.375f^{1/2}$	$0.0037f^{1/2}$	$0.0046f^{1/2}$	*f*/200
	2 – 300 GHz	61	0.16	0.20	10

Note:

1. ***f*** as indicated in the frequency range column.
2. Provided that basic restrictions are met and adverse indirect effects can be excluded, field strength values can be exceeded.
3. For frequencies between **100 kHz** and **10 GHz, S_{eq}, E2, H2**, and **B2** are to be averaged over any 6-min period.
4. For peak values at frequencies up to **100 kHz** see Appendix 7.
5. Between **100 kHz** and **10 MHz**, peak values for the field strengths are obtained by interpolation from the 1.5-fold peak at **100 kHz** to the 32-fold peak at **10 MHz**. For frequencies exceeding **10 MHz** it is suggested that the peak equivalent plane wave power density, as averaged over the pulse width, does not exceed 1,000 times the S_{eq} restrictions, or that the field strength does not exceed 32 times the field strength exposure levels given in the table.
6. For frequencies exceeding 10 GHz, *S*eq, E2, H2, and B2 are to be averaged over any $68/f^{1.05}$-min period (*f* in GHz).
7. No E-field value is provided for frequencies <1 Hz, which are effectively static electric fields. Electric shock from low impedance sources is prevented by established electrical safety procedures for such equipment. Perception of surface electric charges will not occur at field strengths less than 25 kV/m. Spark discharges causing stress or annoyance should be avoided.

C. GUIDELINES FOR LIMITING EXPOSURE TO TIME-VARYING ELECTRIC AND MAGNETIC FIELDS (1Hz – 100 kHz)

Table 1: Basic Restrictions (General Public) for human exposure to time-varying electric and magnetic fields

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Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz – 100 kHz)	
Magnetic Induction (Magnetic fields)	Electric fields
field actually required: 606 µT	**20 mV/m in the head (*brain & retina*)** **400 mV/m in the whole body**
Guidelines for limiting exposure to time-varying electric and magnetic fields (up to 300 GHz)	
Specific Absorption Rate (SAR)	Electric fields
	20 mV/m in the head (*brain & retina*) **400 mV/m in the whole body**

Table 2: Reference Levels (General Public) for human exposure to time-varying electric and magnetic fields

Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz – 100 kHz)	
Magnetic Induction (Magnetic fields)	Electric fields
ICNIRP reference level: 200 µT (160 A/m) **field actually required: 606 µT**	**ICNIRP reference level: 5 kV/m** **field actually required: 9.9 kV/m**
Guidelines for limiting exposure to time-varying electric and magnetic fields (100 kHz - 300 GHz)	
Magnetic Induction (Magnetic fields)	Electric fields

Table 3: **Basic Restrictions (Occupational) for human exposure to time-varying electric and magnetic fields**

Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz – 100 kHz)	
Magnetic Induction (Magnetic fields)	Electric fields
field actually required: 3.03 mT	**100 mV/m in the head (*brain & retina*)** **800 mV/m in the whole body**
Guidelines for limiting exposure to time-varying electric and magnetic fields (up to 300 GHz)	
Specific Absorption Rate (SAR)	Electric fields
0.4 W/kg	

Table 4: **Reference Levels (Occupational) for human exposure to time-varying electric and magnetic fields**

Guidelines for limiting exposure to time-varying electric and magnetic fields (1Hz – 100 kHz)	
Magnetic Induction (Magnetic fields)	Electric fields
ICNIRP reference level: 1 mT (800 A/m)	**ICNIRP reference level: 10 kV/m**

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field actually required: 3.03 mT	**field actually required: 24.2 kV/m**
Guidelines for limiting exposure to time-varying electric and magnetic fields (up to 300 GHz)	
Magnetic Induction (Magnetic fields)	Electric fields

Note: **Basic restrictions for 50 Hz fields are the values of the electric field strength considered as acceptable for people's well-being.**

D. MAXIMUM PERMISSIBLE EXPOSURE

The maximum permissible exposure (MPE) emission limits for laser radiation for Occupational

Frequency Range (MHz)	**Electric Field Strength (V/m)**	**Magnetic Field Strength (A/m)**	**Power Density (mW/cm^2)**	**Averaging Time (minutes)**
0.3-3.0	614	1.63	100 †	6
3.0-30	842/f	4.89/f	$900/f^2$ †	6
30-300	61.4	0.163	1.0	6
300-1500	-	-	f/300	6
1500-100,000	-	-	5	6

The maximum permissible exposure (MPE) emission limits for laser radiation for the General Public

Frequency Range (MHz)	**Electric Field Strength (V/m)**	**Magnetic Field Strength (A/m)**	**Power Density (mW/cm^2)**	**Averaging Time (minutes)**
0.3-3.0	614	1.63	100 †	30
3.0-30	842/f	2.19/f	$180/f^2$ †	30
30-300	27.5	0.073	0.2	30
300-1500	-	-	f/500	30
1500-100,000	-	-	1.0	30

f = frequency in MHz
† = plane-wave equivalent power density (see note)
Note: Equivalent far field strength that would have the E-field or H-field components calculated or measured. Equivalent far field density for near and far fields can be calculated using Power Density = $|E_{total}|^2/3770$ mW/cm^2 or Power Density = $|H_{total}|^2/37.7$ mW/cm^2

E. EXPOSURE LIMITS VALUES (ELVs) AND ESTIMATED EXPOSURES IN MRI

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Table 1: Exposure Limit Values (ELVs) and Estimated Exposures in MRI

Field	Frequency	ELV	Estimated maximum occupational exposure in MRI
Static magnetic field (always present for most scanners)	0 Hz	None (action value 200mT)	3 T (clinical) 9.4 T (research)
	< 1 Hz (typical) (generated by movement of subject)	Current density 40mA/m^2 head & trunk	200 – 400 mA/m^2 (Central Nervous System); limit exceed 0.5 – 1.0m from magnet if moving at 1m/s
Switched gradients (present only during imaging)	1 kHz (typical)	Current density 10mA/m^2 head and trunk	>200 mA/m^2 (Central Nervous System); limit exceeded ≈ 1m from end of scanner bore.
RF (present only during imaging)	10 – 100s MHz	Specific absorption rate (SAR) ▪ 0.4W/kg whole body ▪ 10 W/kg head & trunk ▪ 20W/kg limbs; all SAR values averaged over 6 min, localized SAR averaged over 10g tissue.	Not exceeded in normal circumstances

Note 1: For whole-body exposures, no adverse health effects are expected if the increase in body core temperature does not exceed 1°C. In the case of infants and persons with cardio circulatory impairment, the temperature increase should not exceed 0.5°C. With regard to localized heating, it seems reasonable to assume that adverse effects will be avoided with a reasonable certainty if temperatures in localized regions of the head are less than 38°C, of the trunk less than 39°C, and in the limbs less than 40°C.

Note 2: For the purposes of these Regulations Adverse health effect means a biological effect that has a detrimental effect on mental, physical and/ or general well-being of exposed people, either in the short-term or long term.

Table 2: Basic restrictions for body temperature rise and partial-body temperatures

Operating mode	**Rise of body core temperature (ºC)**	**Spatially localized temperature limits**		
		Head (ºC)	**Trunk (ºC)**	**Extremities (ºC)**
Normal	0.5	38	39	40
Controlled	1	38	39	40
Restricted	>1	>38	>39	>40

Table 3: SAR levels valid at environmental temperatures below 24ºC

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	Averaging time: 6 minutes					
	Whole body SAR (W/kg)	Partial-body SAR (W/kg)		Local SAR (averaged over 10g tissue)		
Body region → Operating mode ↓	Whole body	Any, except head	Head	Head	Trunk	Extremities
Normal	2	2 – 10[a]	3	10[b]	10	20
Controlled	4	4 – 10[a]	3	10[b]	10	20
Restricted	>4	>(4 – 10[a])	>3	10[b]	>10	>20
Short term SAR	The SAR limit over any 10s period should not exceed 3 times the corresponding average SAR limit					

Note:

- [a] Partial-body SARs scale dynamically with the ratio *r* between the patient mass exposed and the total patient mass:
  - ✓ normal operating mode: SAR = (10–8 **.** *r*) W/kg
  - ✓ controlled operating mode: SAR = (10–6 **.** *r*) W/kg
- The exposed patient mass and the actual SAR levels are calculated by the SAR monitor implemented in the MR system for each sequence and compared to the SAR limits.
- [b] In cases where the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1°C

F. EXPOSURE LIMITS TO AIRBORNE ULTRASOUND

Frequency (kHz)	Sound pressure level (dB)
20	75
25	110
31.5	110
40	110
50	110

Note: The majority of the wave energy from airborne ultrasound is deflected by the skin rather than absorbed and therefore the effects on the skin can be considered negligible under 'normal' exposure conditions. There is some evidence however, to suggest that slight heating of the skin can occur when we are exposed to high sound pressure levels (SPLs) of between 140 -150 dB at ultrasonic frequencies.

NINTH SCHEDULE

(Made under regulation 7(3)(d))

Radiation generators emitting non-ionizing radiation

i. Devices emitting electromagnetic radiation in the UV, IR and RF, and laser source in these spectral regions, will be exempted from the regulations provided that they comply with Tanzania standard for free use. The last condition applies only if the said standards relate to the radiation emitted.

ii. Devices that do not comply with Tanzania standards(or even if they comply, but the specific standards does not relate to radiation hazards) will be exempted from the present regulations, provided they comply with the following:

   a. Ultra violet (UV) radiation: any device emitting electromagnetic radiate in the spectral region 180-400 nm will be exempted from the present regulations, provided that the weighted power density emitted (as measured at a distance of 5 cm from any accessible point on the device) does not exceed 3X 10-8 W/cm2 *A, where A is weighting factor given in table 1 below:

Table 1: Weighting factor A

Wavelength (nm)	A
180	0.012
200	0.030
210	0.075
230	0.190
240	0.300
250	0.430
270	1.000
300	0.300
305	0.060
313	0.006
315	0.003
325	0.005
350	0.002
400	0.00003

Notes to use of Table 1:

1) Use linear interpolation for wavelength of intermediate values.

2) For devices emitting at more than one wavelength, the weighted contributions from each wavelength should be summed up. Alternatively, measurements can be conducted by instruments with a spectral response which is tailored in accordance with the weighting factors of Table 1.

b. Infra red (IR) radiation:

Any device emitting in spectral range 780nm -1mm, with a power density lower than 10Mw/cm2, as measured at a distance of 5cm from any accessible point on the device, shall be exempted from the present regulations.

c. Radiation frequencies (RF):

Any device emitting RF radiation, in the spectral range 1mm-1000km, shall be exempted from the present regulations, provided that its power density, as measured at a distance of 5cm from any accessible point on the device, complies with the following:

In frequency range: 3 kHz-450 MHz-7W

In frequency range: 0.4 GHz-1.5 GHz-7W- 7.(0.45/f, where f is the frequency in GHz.

In frequency range: 1.5 GHz-300 GHz-2.1W

Dodoma,
27th October, 2023

ADOLF F. MKENDA
Minister of Education, Science, and Technology