NRRC Technical Regulations

Radiation Safety

NRRC-R-01

2022

هيئة الرقابة النووية والإشعاعية

Nuclear and Radiological Regulatory Commission

Regulation
Radiation Safety

2022
NRRC-R-01

Preamble

In accordance with the provisions of the Law of Nuclear and Radiological Control issued by Royal Decree No. (M/82) dated 25/7/1439 AH, and NRRC's Statue issued by the Minsters' Cabinet Resolution No. (334) dated 25 /6/1439 AH, the NRRC prepared regulations that ensure control over radiological activities and practices as well as nuclear and radiological facilities.

This regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments. This Regulation has been presented in "the Public Consultation Platform" for the public review, comments, feedback.

This regulation has been approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20/04/2022.

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Chapter 1: Objective, Scope, Exclusions and Definitions

Section 1: Objective

1. This regulation shall set out the general safety requirements in ensuring protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources.

2. This regulation shall harmonize the requirements applicable in the Kingdom with the international best practices in order to achieve the highest standards of safety in activities and facilities that give rise to radiation risks.

Section 2: Scope

3. This regulation applies to all activities and facilities including practices, that are carried out in the Kingdom which involve, or could involve, risk from exposure to ionizing radiation in planned, emergency and existing situations.

4. This regulation shall be applicable to occupational, public and medical exposure in the Kingdom.

5. The safety requirements set forth in this regulation shall apply to any person involved in activities and facilities including practices defined under the Law as specified in this regulation.

6. Other safety requirements, complementary to this regulation shall apply for certain activities and facilities, such as for nuclear installations.

7. This regulation is complemented by specific requierment for radiation protection and safety as specified by NRRC.

Section 3: Exclusions

8. The following exposures are excluded from the scope of this regulation:

    a. Exposures from natural radioactivity in the body;

    b. Cosmic radiation at the surface of the earth;

    c. Any other radiation sources that are essentially unamenable to control as may be determined by the NRRC.

Section 4: Definitions

Absorbed dose, D

The fundamental dosimetric quantity D, defined as:

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where $\mathrm{d}\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element.

Accident

Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

Activation

The process of inducing radioactivity in the matter by irradiation of that matter.

Activity

The production, use, possession, storage, transport, import, or export of radioactive, nuclear or nuclear-related items; the siting, construction, commissioning, operation or decommissioning of facilities; radioactive waste management and site rehabilitation; or any other act specified by the Commission in accordance with its laws.

Activity (A)

The quantity A, for an amount of radionuclide in a given energy state at a given time, defined as:

$$A(t) = \frac{\mathrm{d}N}{\mathrm{d}t}$$

where dN is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval dt.

Ambient dose equivalent, H*(d)

The dose equivalent that would be produced by the corresponding aligned and expanded field in the International Commission on Radiation Units and Measurements (ICRU) sphere at a depth d on the radius vector opposing the direction of the aligned field.

Annual dose

The dose from external exposure in a year plus the committed dose from intakes of radionuclides in that year.

Applicant

Any person applying to the NRRC for authorization to undertake specified activities and facilities including practices. Strictly, an applicant would be

such from the time at which an application is submitted until the requested authorization is either granted or refused.

Area monitoring

A form of workplace monitoring in which an area is monitored by taking measurements at different points in that area.

Assessment

The process, and the result, of analyzing systematically and evaluating the hazards associated with sources and practices, and associated protection and safety measures.

Authorization

The granting by the NRRC of written permission for a person to conduct specified activities.

Authorized limit

A limit on a measurable quantity, established or formally accepted by the NRRC.

Authorized person

Person granted authorization under this regulation and/or the relevant NRRC Laws.

Carers and comforters

Persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment.

Clearance

The removal of radioactive material or radiation source subject to the Law from the control imposed thereon by the NRRC because the radiation exposure resulting therefrom is too small to warrant the application of such control.

Clearance level

A value, established by the NRRC and expressed in terms of activity (A) concentration, at or below which regulatory control may be removed from a source of radiation within a notified or authorized practice.

Committed dose

The lifetime dose expected to result from an intake.

Committed effective dose, $E(\tau)$

The quantity $E(\tau)$, defined as:

$$E(\tau) = \sum_{\mathrm{T}} w_{\mathrm{T}} \cdot H_{\mathrm{T}}(\tau)$$

where $H_{\mathrm{T}}(\tau)$ is the committed equivalent dose to tissue or organ T over the integration time τ elapsed after an intake of radioactive substances and w_{T} is the tissue weighting factor for tissue or organ T. When τ is not specified, it will be taken to be 50 years for adults and the time to age 70 years for intakes by children or as specified by the NRRC.

Confinement

Prevention or control of releases of radioactive material to the environment in operation or in accidents.

Constraint

A prospective and source related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

Consumer product

A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale or any product as determined by NRRC.

Containment

Methods or physical structures designed to prevent or control the release and the dispersion of radioactive substances.

Contamination

Radioactive substances on surfaces, or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or the process giving rise to their presence in such places.

Control

The function or power or (usually as controls) means of directing, regulating or restraining.

Controlled area

A defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential exposures.

Decontamination

The complete or partial removal of contamination by a deliberate physical, chemical or biological process.

Deterministic effect

A radiation induced health effect for which generally a threshold level of dose exists above which the severity of the effect is more significant for a higher dose.

Diagnostic reference level

A level used in medical imaging to indicate whether in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

Directional dose equivalent $H'(d,\Omega)$**,**

The dose equivalent that would be produced by the corresponding expanded field in the International Commission on Radiation Units and Measurements ICRU sphere at a depth d on a radius in a specified direction Ω.

Dose

1. A measure of the energy deposited by radiation in a target.

2. Absorbed dose, committed equivalent dose, committed effective dose, effective dose, equivalent dose or organ dose, as indicated by the context.

Dose assessment

Assessment of the dose(s) to an individual or group of people.

Dose constraint

A prospective and radiation source related value of individual dose that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

Dose limit

The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

Effective dose, E

The quantity E, defined as a summation of the tissue or organ equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_{T} w_T \cdot H_T$$

where H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor or tissue or organ T.

From the definition of equivalent dose, it follows that:

$$E = \sum_{T} w_T \cdot \sum_{R} w_R \cdot D_{T,R}$$

where w_R is the radiation weighting factor for radiation type R and $D_{T,R}$ is the average absorbed dose in the tissue or organ T delivered by radiation type R. The SI unit for effective dose is joule per kilogram (J/kg), termed the sievert (Sv).

Emergency

A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear or radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situation

A situation of exposure that arises as a result of an accident, a malicious act or other unexpected events, and requires prompt action in order to avoid or reduce adverse consequences.

Emergency plan

A description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists.

Emergency preparedness

The capability to take actions that will effectively mitigate the consequences of an emergency for human health and safety, quality of life, property and the environment.

Emergency procedures

A set of instructions describing in detail the actions to be taken by the response personnel in an emergency.

Emergency response

The performance of actions to mitigate the consequences of an emergency for human health and safety, quality of life, property and the environment. It may also provide a basis for the resumption of normal social and economic activity.

Emergency worker

A person having specified duties as a worker in response to an emergency.

Employer

A person with recognized responsibilities, commitments and duties towards a worker in the employment of the person by virtue of a mutually agreed relationship.

Environment

The conditions under which people, animals and plants live or develop and which sustain all life and development; especially such conditions as affected by human activities.

Environmental monitoring

The measurement of external dose rates due to sources in the environment or of radionuclide concentrations in environmental media.

Equivalent dose, H_T

The quantity $H_{T\,R,}$ defined as:

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

where $D_{T\,R}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and w_R is the radiation weighting factor for radiation type R. When the radiation field is composed of different radiation types with different values of w_R , the equivalent dose is:

$$H_T = \sum_R w_R \cdot D_{T\,R}$$

The SI unit for equivalent dose is joule per kilogram (J/kg), termed the sievert (Sv).

Exemption

The NRRC's decision that a radiation source or certain radiation practice need not be subject to its partial or full control on the basis that the exposure to radiation resulting from such source or practice is too low to warrant application of such control, or that this is the optimum option available after taking necessary preventive measures for minimizing the risks of exposure to ionizing radiation.

Event

In the context of the reporting and analysis of events, an event is any oc-

currence unintended by the worker, including operating error, equipment failure or another mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

Exemption level

A value, established by the NRRC and expressed in terms of activity (A) concentration, total activity (A), dose rate or radiation energy, at or below which a source of radiation need not be subject to some or all aspects of regulatory control.

Existing exposure situation

A situation of exposure that already exists when a decision on the need for control needs to be taken.

Exposure

The state or condition of being subject to irradiation.

Exposure pathway

A route by which radiation or radionuclides can reach humans and cause exposure.

Facility

This shall include a nuclear facility; installation where a radiation source is used; mining and raw materials processing facilities, such as uranium mines; radioactive waste management facilities; and any other locations where radioactive materials are produced, processed, used, handled, stored or disposed of to the extent warranted by safety and security.

Graded approach

For a system of control a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.

Health professional

An individual who has been formally recognized through appropriate national procedures to practice a profession related to health (e.g. medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health).

Health screening program

A program in which health tests or medical examinations are performed for the purpose of early detection of disease.

Human factors

Engineering in which factors that could influence human performance and that could affect safety are understood and are taken into account, especially in the design and operation of facilities.

Individual monitoring

Monitoring using measurements by equipment worn by individuals, or measurements of quantities of radioactive substances in or on, or taken into, the bodies of individuals, or measurements of quantities of radioactive substances excreted from the body by individuals.

Inspection imaging device

An imaging device designed specifically for imaging persons or cargo conveyances to detect concealed objects on or within the human body or within cargo or a vehicle.

Intake

1. The act or process of taking radionuclides into the body by inhalation or ingestion or through the skin.

2. The activity (A) of a radionuclide taken into the body in a given period or as a result of a given event.

Investigation level

The value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation would be conducted.

Justification

1. Justification for a planned exposure situation

The process of determining for a planned exposure situation whether a practice is, overall, beneficial, i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

2. Justification for a existing or emergency situation

The process of determining for an emergency exposure situation or an existing exposure situation whether a proposed protective action

or remedial action is likely, overall, to be beneficial; i.e., whether the expected benefits to individuals and to society (including the reduction in radiation detriment) from introducing or continuing the protective action or remedial action outweigh the cost of such action and any harm or damage caused by the action.

Limit

The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

Management system

A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and an effective manner.

Medical exposure

Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a program of biomedical research.

Medical physicist

A Health professional recognized by the competent authority of the Kingdom.

Medical radiation facility

A medical facility in which radiological procedures are performed.

Medical radiation technologist

A health professional, with specialist education and training in medical

radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology.

Medical radiological equipment

Radiological equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure of an individual or directly controls or influences the extent of such exposure. The term applies to radiation generators, such as X ray machines or medical linear accelerators; to devices containing sealed sources, such as 60Co teletherapy units; to devices used in medical imaging to capture images, such as gamma cameras, image intensifiers or flat panel detectors, and to hybrid systems such as positron emission tomography-computed tomography scanners.

Member of the public

For purposes of protection and safety, in a general sense, any individual in the population except when subject to occupational exposure or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, this is the representative person.

Monitoring

The measurement of dose, dose rate or activity (A) for reasons relating to the assessment or control of exposure to radiation or exposure due to radioactive substances, and the interpretation of the results.

Natural background

The doses, dose rates or activity (A) concentrations associated with natural

sources, or any other sources in the environment that are not amenable to control.

Natural source

A naturally occurring source of radiation, such as the sun and stars (sources of cosmic radiation) and rocks and soil (terrestrial sources of radiation), or any other material whose radioactivity is for all intents and purposes due only to radionuclides of natural origin, such as products or residues from the processing of minerals; but excluding radioactive material for use in a nuclear installation and radioactive waste generated in a nuclear installation.

Notification

A document submitted to the NRRC by a person intending to carry out any activity or practice or to establish a radiation facility involving radiation sources.

Nuclear fuel cycle

All operations associated with the production of nuclear energy. These include:

a. Mining and processing of uranium ores or thorium ores;

b. Enrichment of uranium;

c. Manufacture of nuclear fuel;

d. Operation of nuclear reactors (including research reactors);

e. Reprocessing of spent fuel;

f. All waste management activities (including decommission-

ing) relating to operations associated with the production of nuclear energy;

g. Any related research and development activities.

Nuclear installation

Any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and radioactive waste disposal facilities.

Nuclear or radiological emergency

Any emergency, which results or is likely to result in exposure risk to ionizing radiation

Occupational exposure

Exposure of workers incurred in the course of their work.

Operational limits and conditions

A set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel approved by the NRRC for safe operation of an authorized facility.

Optimization of protection and safety

The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being "as low as reasonably achievable, economic and social factors being taken into account" (ALARA). For medical exposures of patients, the optimization of protection and safety is the management of the radia-

tion dose to the patient commensurate with the medical purpose.

Planned exposure situation

The situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source.

Planning target volume

A geometrical concept used in radiation therapy for planning medical treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissues, and variations in beam geometry such as beam size and beam direction.

Potential exposure

Prospectively considered exposure that is not expected to be delivered with certainty but that may result from an anticipated operational occurrence or accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Practice

Any human activity that causes or is likely to cause exposure to ionizing radiation, excluding procedures of medical diagnosis or treatment of patients by healthcare practitioners.

Projected dose

The dose that would be expected to be received if planned protective actions were not taken.

Protection (against radiation)

See Radiation Protection.

Protection and safety

The protection of people against exposure to ionizing radiation or exposure due to radioactive material and the safety of sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents if they do occur.

Protective action

An action for the purposes of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation.

Providers of consumer products

Designers, manufacturers, producers, constructors, installers, distributors, sellers, and importers and exporters of consumer products.

Public exposure

Exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure.

Qualified expert

An individual who is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty.

Quality assurance

The function of a management system that provides confidence that specified requirements will be fulfilled.

Radiation

The ionizing radiation as defined in the Law.

Radiation detriment

The total harm that would eventually be incurred by a group that is subject to exposure and by its descendants as a result of the group's exposure to radiation from a source.

Radiation generator

A device capable of generating ionizing radiation, such as X rays , neutrons, electrons or other charged particles, that may be used for scientific, industrial or medical purposes.

Radiation protection

The protection of people from the harmful effects of exposure to ionizing radiation and the means for achieving this.

Radiation source

Any radiation generator, radioactive source, or any other radioactive material outside the nuclear fuel cycles of research and power reactors.

Radiation safety officer (RSO)

A competent person certified by the NRRC in radiation safety matters relevant for a given type of practice who is designated by the authorized person or employer to oversee the application of regulatory requirements.

Radiation protection program

Systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Radiation risks

Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring), and any other safety related risks (including those to the environment) that might arise as a direct consequence of:

a. Exposure to radiation;

b. The presence of radioactive material (including radioactive waste) or its release to the environment;

c. A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

Radiation weighting factor, w_R

A number by which the absorbed dose in a tissue or organ is multiplied to reflect the relative biological effectiveness of the radiation in inducing stochastic effects at low doses, the result being the equivalent dose.

The radiation weighting factor values* are:

Type of radiation	W_R
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20

Neutrons	A continuous function of neutron energy: $w_R =$ $\begin{cases} 2{,}5 + 18{,}2e^{-[\ln(E_n)]^2/6} & E_n < 1\ MeV \\ 5{,}0 + 17e^{-[\ln(2E_n)]^2/6} & 1\ MeV \le E_n \le 50 MeV \\ 2{,}5 + 3{,}25e^{-[\ln(0\,04E_n)]^2/6} & E_n > 50\ MeV \end{cases}$

Note: All values relate to radiation incident on the body or, for internal radiation sources, radiation emitted from the incorporated radionuclide(s).

[*] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Elsevier (2007).

Radioactive material

Any material from which ionizing radiation is emitted, whether spontaneously or within other equipment, and which is designated as subject to the control of the NRRC, including naturally occurring radioactive materials.

Radioactive Source

Any radioactive material permanently sealed in a capsule or closely bonded and in a solid form.

Radioactive substance

Any substance that contains radioactivity, and gives no indication of the magnitude of the hazard involved that may be designated by the NRRC as being subject to regulatory control.

Radioactive waste

Any material, regardless of its physical form, resulting from activities, practices or interventions such as decontamination, for which no further use is foreseen and which contains or is contaminated with radioactive substances, and has radiological activity (A) or concentration higher than the level set for clearance from regulatory control.

Radioactive waste management

All administrative and operational activities involved in the handling, pretreatment, treatment, conditioning, transport, storage and disposal of radioactive waste.

Radiological medical practitioner

A health professional with Specialist in education and training in the medical uses of radiation, who is competent to perform independently or to oversee radiological procedures in a given specialty.

Radiological procedure

A medical imaging procedure or therapeutic procedure that involves ionizing radiation, such as a procedure in diagnostic radiology, nuclear medicine or radiation therapy, or a planning procedure, image guided interventional procedure or other interventional procedure involving radiation delivered by a radiation generator, a device containing a sealed source or an unsealed source, or by means of a radiopharmaceutical administered to a patient.

Radionuclides of natural origin

Radionuclides that occur naturally on Earth in significant quantities.

Radiopharmacist

A health professional, with Specialist in Education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy.

Reference level

For an emergency exposure situation or an existing exposure situation, the level of risk or activity (A) concentration above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented.

Referring medical practitioner

A health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure.

Regulatory control

Any form of control or regulation applied to activities and facilities including practices by the NRRC for reasons relating to nuclear safety and radiation protection or nuclear security or safeguards.

Relative biological effectiveness (RBE)

A relative measure of the effectiveness of different radiation types at inducing a specified health effect expressed as the inverse ratio of the absorbed doses of two different radiation types that would produce the same degree of a defined biological endpoint.

Relative biological effectiveness (RBE) weighted absorbed dose, AD_T

The quantity $AD_{T,R}$, defined as:

$$AD_{T,R} = D_{T,R} \times RBE_{T,R}$$

where $D_{T,R}$ is the absorbed dose delivered by radiation of type R averaged over a tissue or organ T and $RBE_{T,R}$ is the relative biological effectiveness for radiation of type R in the production of severe deterministic effects in a tissue or organ T.

When the radiation field is composed of different radiation types with different values of $RBE_{T,R}$ the RBE weighted absorbed dose is given by:

$$AD_T = \sum_R D_{T,R} \times RBE_{T,R}$$

Remedial action

The removal of a source or the reduction of its magnitude (in terms of activity (A) or amount) for the purposes of preventing or reducing exposures that might otherwise occur in an existing exposure situation.

Remediation

Any measures that may be carried out to reduce the radiation exposure due to existing contamination of land areas through actions applied to the contamination itself (the source) or to the exposure pathways to humans.

Representative person

An individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population.

Response organization

An organization designated or otherwise recognized by the Kingdom as

being responsible for managing or implementing any aspect of an emergency response.

Risk

A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with exposures or potential exposure. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

Safety assessment

Assessment of all aspects of an activity that are relevant to protection and safety; for an authorized facility. This includes siting, design and operation of the facility.

Safety culture

The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Safety measure

Any action that might be taken, a condition that might be applied or procedure that might be followed to fulfill the requirements of Safety Requirements.

Scenario

A postulated or assumed set of conditions and/or events.

Security

Prevention and detection of any theft, sabotage, unauthorized access, illegal transfer (or any other criminal act) involving nuclear, nuclear-related or radioactive materials and associated facilities.

Source

Anything that may cause radiation exposure such as by emitting ionizing radiation or by releasing radioactive substances or radioactive material and can be treated as a single entity for purposes of protection and safety.

Sealed source

Radioactive source in which the radioactive material is permanently sealed in a capsule or closely bonded and in a solid form.

Source monitoring

The measurement of activity (A) in radioactive material being released to the environment or of external dose rates due to sources within an activity or a facility.

Standards dosimetry laboratory

A laboratory, designated by the NRRC that possesses the recognition necessary for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

Storage

The holding of radioactive sources, radioactive material, spent fuel or radioactive waste in a facility that provides for their/its containment, with the intention of retrieval.

Structures, systems and components

A general term encompassing all of the elements (items) of an activity or a facility that contribute to protection and safety, except human factors.

Supervised area

A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures or safety provisions are not normally needed.

Supplier (of a source)

Any person to whom the authorized person assigns duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

Technical Services Organizations

An organization that provide expertise and services to support nuclear and radiation safety and all related scientific and technical issue.

Tissue weighting factor, w_T

The multiplier of the equivalent dose to a tissue or organ used for purposes of radiation protection to account for the different sensitivities of different tissues or organs to the induction of stochastic effects of radiation.

Transport

All operations and conditions associated with the movement of nuclear and radioactive material, whether through, from or into the territory of the Kingdom.

Unsealed source

A radioactive source in which the radioactive material is neither (a) permanently sealed in a capsule nor (b) closely bonded and in a solid form.

Worker

Any person who works, whether full time, part-time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection.

Workers' health surveillance

Medical supervision intended to ensure the initial and continuing fitness of workers for their intended tasks.

Workplace monitoring

Monitoring using measurements made in the working environment.

Chapter 2: General Requirement on the Application of System of Protection

Section 5: Justification

9. Not any practice that alters or could alerts the radiation exposure situation by introducing a new radiation source, by reducing existing exposure or by reducing the risk of potential exposure shall be engaged in unless such practice yields a benefit to all persons exposed to radiation or the community as a whole which justifies the radiation harm that it might cause, taking into account social, economic and other relevant factors.

10. The following practices are deemed to be not justified, unless the applicant demonstrates, by a due process, that concerned practice meet general justification criteria as in Article 9 above:

    a. The practices whose implementation would result in increasing the volume of the radioactive substance (through addition or activation) in the commodities or products are considered among not justified practices. Such practices shall include the following:

        (i) Fabrication, production, importation or sales of foodstuffs, drinks or other products intended for ingestion, inhalation or penetration of the skin or use by humans in general.

        (ii) Utilization of radioactive substances in the products or commodities.

    b. Human imaging using radiation that is performed as a form of art or for publicity purposes;

    c. Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication;

    d. Human imaging using radiation for theft detection purposes;

    e. Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes;

f. Human imaging using radiation for the detection of concealed objects that can be used for criminal acts or to pose a national security threat;

g. Other activities and practices as determine by the NRRC.

Section 6: Demonstration of the justification of practices

11. Any person intending to conduct a practice shall demonstrate the justification when:

    a. The practice has not been previously considered as justified.

    b. The NRRC requests for reviewing the existing type of practice in the light of new information about its efficacy or consequences.

    c. The concerned practice is one of those mentioned in Section 5, that are deemed to be not justified.

12. The demonstration of justification shall include:

    a. A description of the type of practice.

    b. A full characterization of the radiation sources that will be used and the measures that will be taken to ensure safety and to reduce the radiological consequences.

    c. An appraisal of the benefits and detriments, including radiation detriments. This appraisal should include economic, social, health and safety, waste management, recycling, radiological environmental impact and decommissioning aspects.

The assessment of the radiation detriment should cover both the magnitude and the likelihood of expected exposures and an assessment of the potential exposures.

d. An indication of the expected extent of use of the type of practice.

13. In the case of practices involving the deliberate exposure of humans for non-medical imaging purposes, when evaluating the justification of the concerned practice, considerations listed in Section 40 shall be taken into account.

14. The demonstration of justification by the applicant, if required, is part of the authorization process referenced in Sections 21 and 22.

Section 7: Optimization of Protection and Safety

15. The authorized person and any other responsible person shall ensure that the system of protection implemented over activities and facilities under its responsibility guarantees the application of:

a. Measures for protection that are optimized 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. Measures, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing radiation safety deviations and for mitigating the consequences of those that do

occur;

c. Dose constraints for occupational and public exposure.

16. For occupational exposure and public exposure, the authorized person and any other responsible person shall ensure that the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed are kept as low as reasonably achievable, taking economic and societal factors into account.

17. For the protection of individuals subject to medical exposure, the authorized person and any other responsible person shall ensure that medical exposure is limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure.

18. Measures for the optimization of the protection and safety shall be re-evaluated, by the authorized person on a periodical and timely basis or at any time deem necessary as determine by the NRRC.

Section 8: Dose Constraints

19. The authorized person shall establish dose constraints, as appropriate according to the category of exposure individuals to be approved by the NRRC for the following types of exposure:

a. Occupational and public exposures - Where relevant, the doses constraints shall be established in co-operation with the employer of the outside worker.

b. Medical exposure - Dose constraints shall apply only with regard to the protection of carers and comforters and volun-

teers participating in medical or biomedical research.

20. The authorized person shall ensure that the dose constraints are:

    a. Established in terms of individual effective or equivalent doses over a defined appropriate time period.

    b. Remained below the generic values defined by the NRRC for similar types of practices.

    c. Established so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits for the public or any lower values established by the NRRC for any source that can release radioactive material to the environment.

Section 9: Reference Levels

21. Any person that are involved in any activity concerning emergency or existing exposure situations shall use the relevant References Levels, established by the NRRC, as a boundary condition in identifying the range of options for optimization in implementing protective actions.

Section 10: Dose Limits

22. In planned exposure situations, the authorized person shall ensure that the exposures of individuals due to the activities and practices for which they are authorized are restricted so that the following relevant dose limits:

a. For occupational exposure of worker over the age of 18 years:

(i) 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;

(ii) 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;

(iii) An equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

b. 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:

(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 (hands and feet) or to the skin of 150 mSv in a year.

23. For a female worker who has notified pregnancy or is breast-feeding, the expected dose for the embryo or fetus or the breastfed infant shall be limited to 1 mSv.

24. For public exposure, the dose limits shall be:

    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.

25. The verification of compliance with the dose limit shall consider the criteria, conversion factors and other references values specified by the NRRC which allow to get the best estimation of the quantities used for controlling the dose limits.

26. Whenever the NRRC deems necessary to revise the established dose limits the authorized person shall implement all the necessary corrective actions to ensure compliance with the revised dose adopted limits.

Chapter 3: Responsibilities for Protection and Safety

Section 11: General Responsibilities

27. The authorized person or any responsible person for the activity or at the facility, shall have the prime responsibility for protection and safety, which cannot be delegated.

28. Any responsible person for the management of an existing exposure situation or involved in the emergency situation shall have specified responsibilities for the application of relevant requirements specified in this regulation.

29. The authorized person and any other person accountable for any practices shall be responsible for:

    a. Establishing a radiation protection program that is appropriate for exposure situation that:

        (i) Adopt objectives for protection and safety in accordance with the requirements of this regulation;

        (ii) Apply measures for protection and safety that are commensurate with the radiation risks associated with the exposure situation that ensures compliance with the requirements of this regulation.

    b. (b) Implementation of the radiation protection program that ensures:

        (i) Measures and resources necessary for achieving the objectives for protection and safety have been determined and are duly provided;

        (ii) Program that is periodically reviewed to assess its effectiveness and its continued fitness for purpose;

        (iii) Any failures or shortcomings in protection and safety

that are identified and corrected, and steps are taken to prevent their recurrence;

(iv) Any concern that is related to radiation protection and safety are addressed;

(v) Appropriate records are maintained.

30. The authorized person and any other person having responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification, so that they understand their responsibilities and able to perform their duties competently, with appropriate judgment and in accordance with the approved procedures.

Section 12: Management System

31. The authorized person and any other person having responsibilities in relation to protection and safety, shall ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible.

32. The authorized person and any other person accountable for the operation of the facility shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible for.

33. The management system shall be designed and applied to enhance protection and safety that:

a. Applies the requirements for protection and safety coherently with other requirements;

b. Describes the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;

c. Ensures protection and safety are not compromised by other requirements;

d. Provides for the regular assessment of performance for protection and safety, and the application of lessons learned from experience;

e. Promotes safety culture;

f. Establishes clear lines of responsibility, authority for decisions on safety and accountability for protection and safety for the sources for which they are authorized;

g. Ensures that problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;

h. Establishes organizational arrangements and lines of communications that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the authorized person.

34. The protection and safety elements of the management system shall commensurate with the complexity and the radiation risks associated with the activity.

35. The authorized person shall establish procedures for reporting on and learning from accidents and other incidents.

Section 13: Safety Culture

36. The authorized person and any other person having responsibilities in relation to protection and safety shall promote and maintain a safety culture through:

    a. Inculcating individual and collective commitment to protection and safety at all levels of the organization;

    b. Ensuring a common understanding of the key aspects of safety culture within the organization;

    c. Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;

    d. Encouraging the participation of workers and 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 organization and of individuals at all levels for protection and safety;

    f. Encouraging open communication with regard to protection and safety within the organization and with relevant parties, as appropriate;

g. Encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety;

h. Providing means by which the organization continually seeks to develop and strengthen its safety culture.

Section 14: Human Factors

37. The authorized person and any other person accountable for the operation of the facility, shall take into account human factors, support good performance and good practices to prevent human and organizational failures.

38. Sound ergonomic principles in the design of equipment and the development of operating procedures shall be ensured to:

a. Facilitate the safe operation and use of equipment;

b. Minimize the possibility of operator error that could lead to accidents; and

c. Reduce the possibility that indications of normal conditions and abnormal conditions to be misinterpreted.

39. Appropriate equipment, safety systems and procedural requirements shall be provided to:

a. Reduce, as far as practicable, the possibility that human errors or inadvertent actions that could give rise to accidents or to other incidents leading to the exposure of any person;

b. Provide means for detecting human errors and for correcting them or compensating for them; and

c. Facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

Chapter 4: Bases of Protection in Planned Exposure Situations

Section 15: General Requirement

40. Radiation protection shall be ensured for any activity and facility authorized by the NRRC.

41. No person shall adopt, introduce, conduct, discontinue or cease a practice, unless the requirements of this regulation, including requirements of notification and authorization, are met.

42. No person shall conduct any activity or practice with radiation source other than in accordance with the requirements of this regulation.

43. The control over any radiation sources within any activity and facility authorized by the NRRC shall be ensured by the authorized person.

44. Any responsible person at facility with existing exposure situations, as specified in Article 287, which are of concern from a radiation protection point of view shall be subject to regulatory control and planned exposure situations requirements.

Section 16: Categorization of Sealed Sources

45. The categorization of sealed sources as specified in Appendix 1 shall be used for the purpose of applying a graded approach for radiation protection prescribed in this regulation.

Section 17: Prohibition of Practices

46. Practices that deem to be not justified, taking into account principles provided in Section 5, shall be prohibited.

Section 18: Requirements for Notification

47. Unless exempt from requirements in accordance with Section 19, any person:

    a. Who, on the effective date of the publication of this regulation, is responsible for an activity, a facility or a practice involving radiation source, shall immediately submit a notification to the NRRC.

    b. Who intends to initiate an activity, a facility or a practice shall submit a prior notification to the NRRC of such an intention or to apply for an authorization.

48. Notwithstanding the exemption criteria prescribed in Section 19, in situations where there is concern that a practice involving naturally occurring radioactive material may lead to the presence of such radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the person responsible for such practice shall submit a notification to the NRRC.

49. For those activities where an application for an authorization is submitted, no separate notification shall be required.

50. After submission of notification, any person who is required to apply to the NRRC for an authorization and who submits such an application in accordance with Section 22 is permitted to continue existing activities specified in the notification, in conformance with the applicable requirements of this Regulation, until the NRRC revokes such permission or grants the authorization.

Section 19: Exemption of Practices and Sources

51. The activities involving the following radiation sources are automatically exempted from requirements of this regulation, including the requirements for notification and authorization with prior evaluation:

    a. Radioactive materials in quantities not greater than one tonne for which either the total activity (A) of a given nuclide present on the premises at any one time or its activity (A) concentration does not exceed the levels specified by NRRC.

    b. Radioactive materials in quantities greater than one tonne for which the activity (A) concentration of a given radionuclide of artificial origin used in the practice does not exceed the levels specified by NRRC.

    c. Equipment containing radioactive material exceeding the quantities or concentrations specified in Article 51(a), provided that:

        (i) The equipment containing radioactive material is of a type approved by the NRRC.

(ii) Where the radioactive material is in the form of a sealed source the safety features of the equipment effectively prevent any contact with the radioactive material and prevent its leakage.

(iii) Where the radioactive material is in the form of an unsealed source the total amount of involved activity (A) shall be as small as those used for radioimmunoassay.

(iv) 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 apparatus.

(v) Necessary conditions for later management of the equipment have been specified by the NRRC.

d. Radiation generators of a type approved by the NRRC, or in the form of an electronic tube, 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 or as specified by the NRRC

52. The practices involving the following radiation sources are exempted from requirements of this Regulation, including the requirements for notification and authorization with prior evaluation:

    a. A practice in which the radioactive substance derives from discharges of radioactive substances permitted in accordance with Section 102;

    b. A practice in which the radioactive substance derives from material that has been cleared for reuse, recycling or disposal in accordance with Section 103;

    c. The use of building materials when the activity (A) concentration of the relevant natural radionuclides is not liable to give doses exceeding the reference level defined by the NRRC.

Section 20: Exemption Under a Decision by the NRRC

53. Exemptions shall not be granted for practices deemed not to be justified as specified in Sections 5.

54. The NRRC may exempt a practice or a source within a practice from the authorization or any other requirement of this regulation provided that the practice is justified and the following general criteria are met:

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

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.

55. The NRRC may exempt a practice or a source within a practice from any requirement of this regulation provided that:

a. The effective dose expected to be incurred by any individual is of the order of 10 μSv or less in a year or as specified by NRRC; and

b. The effective dose expected to be incurred by any individual for low probability scenarios does not exceed 1 mSv in a year or as specified by the NRRC.

56. The authorized person shall meet the specific conditions defined by the NRRC when approving an exemption.

57. The NRRC has the right to cancel and withdraw the decision if the prerequisites for exemption are not met or if the conditions for exemption have not been complied with and the deficiencies are not remedied within a prescribed period of time despite a request to do so.

Section 21: Requirements for Authorization

58. Except for the conditions as provided in Section 19 of this Regulation, the person or entity responsible for facilities or activities which has plans to implement any practice that results in an exposure due to a source shall file, prior to proceeding with the practice or acquisition

of the radioactive source, an application to the NRRC for obtaining an authorization.

59. No practice shall be authorized unless it would be considered justified according to criteria prescribed in Section 5.

60. Any person who has filed an application for an authorization to the NRRC shall proceed with the activity or facility only after securing that the relevant authorization has been issued by the NRRC.

61. The authorized person shall not engage in any activity or facility, nor shall use any radiation source that is different other than that authorized by the NRRC.

62. Any person applying for authorization shall:

    a. Submit to the NRRC the relevant information necessary to support the application.

    b. Assess the nature, likelihood and magnitude of the expected exposures due to the source and shall take all necessary measures for protection and safety.

    c. If considered by the NRRC, have a safety assessment made and submitted to the NRRC as part of the application.

    d. As required by the NRRC, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the activity or facility.

63. The application for authorization shall be submitted by the applicant, as per requirements provided in the Regulation on Notification on and Authorization of Facilities and Activities with Radiation Sources (NRRC-R-02). The information shall be commensurate with the nature of the practice and the radiological risks involved.

Section 22: Authorization Process

64. At any situation, all requirement for completing authorization process described in Regulation on Notification on and Authorization of Facilities and Activities with Radiation Sources (NRRC-R-02) shall be complied.

Section 23: Release From Regulatory Control

65. The removal of radioactive materials or radioactive substances within authorized practices from any further regulatory control by the NRRC is subject to authorization requirement.

66. Radioactive materials or objects in solid form can be released from regulatory control provided that they do not exceed the clearance levels given by NRRC.

67. The NRRC may approve the removal of specific materials or objects that are not covered in Article 66, from the system of regulatory control on the basis of an assessment showing that the following clearance criteria are met:

    a. The effective dose expected to be incurred by any individual is of the order of 10 μSv or less in a year or as specified by NRRC; and

b. The effective dose expected to be incurred by any individual for low probability scenarios does not exceed 1 mSv in a year or as specified by the NRRC.

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 or as specified by the NRRC.

68. The deliberate dilution of radioactive materials for the purpose of them being released from regulatory control is prohibited.

Chapter 5: Requirements for the Management of Protection and Safety

Section 24: Prime Responsibility for Protection and Safety

69. The authorized person shall retain the prime responsibility for protection and safety throughout the lifetime of the practice, and this responsibility cannot be delegated.

70. The responsibilities of the authorized person are not diminished by the appointment of a radiation safety officer, or by the use of qualified experts or technical support organization.

71. The authorized person shall ensure that any delegation of responsibly for the implementation of this regulation is documented.

72. The authorized person shall notify the NRRC of any intention to introduce modifications to any activity or practice for which they are authorized and shall not carry out any such modification unless it is authorized by the NRRC.

Section 25: Radiation Protection Program

73. The authorized person shall design and implement a Radiation Protection Program capable of ensuring that:

    a. Responsibilities assigned to authorized person and other person in Section 11 are met.

    b. An effective integration into the overall management system of the organization, as required in Section 12, is achieved.

    c. Measures, arrangements and processes required to guarantee compliance with the requirements in this regulation are implemented.

    d. Relevant instructions established by the NRRC in relation to the content and scope of the Program are met.

74. The documentation of the Radiation Protection Program shall be submitted by the applicant for assessment and approval by the NRRC, as part of the documentation required for authorization process.

75. The authorized person shall ensure that the documentation of the Radiation Protection Program is reviewed and updated in such a way as to reflect the actual state of the implemented measures, arrangements and processes.

Section 26: Radiation Safety Officer

76. The authorized person shall appoint a Radiation Safety Officer in accordance with criteria established by the NRRC.

77. The Radiation Safety Officer shall be tasked with assisting the authorized person in the implementation of radiation protection, overseeing the implementation of the radiation protection program and as official liaison with the NRRC for implementation of other requirement prescribed by the NRRC.

78. The appointment or replacement of the Radiation Safety Officer shall require approval from the NRRC.

79. The authorized person shall define the duties, responsibilities and powers of the radiation safety officer in writing.

80. The authorized person shall ensure that the radiation safety officer has sufficient authority to carry out the appointed tasks, that includes the authority to discontinue the authorized activity if safety or other operational requirement prescribed by the NRRC is compromised.

81. For any activity involving radioactive material of Category 1, the authorized person shall ensure the continuous presence of the approved Radiation Safety Officer throughout the duration of practice.

Section 27: Qualified Expert

82. The authorized person shall identify and made available the qualified experts for providing advice on the observance of this regulation when so required by the NRRC.

83. The qualifications of qualified experts shall be compatible with the assigned tasks and the levels of risks associated with the authorized activity or sources within the relevant practice.

84. When required by the NRRC, the authorized person shall inform about the arrangements made with respect to Articles 82 and 83 above.

Section 28: Technical Service Organization

85. The authorized person are fully liable for any safety implication that may arise from the authorized activities, and the liability is not transferable to any party including to their appointed Technical Support Organization.

86. The authorized person shall ensure that the appointed Technical Support Organization having appropriate recognition from the NRRC.

Section 29: Investigations and feedback of information on operating experience

87. The authorized person shall ensure that information on both normal operation and abnormal conditions that are significant for protection and safety is made available to the NRRC.

88. The authorized person shall conduct an investigation as specified by the NRRC in the event that:

    a. A quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions;

b. Any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed any relevant limit or operating restriction;

c. The security of the radiation sources could be jeopardized by an unusual event or failures of protective measures and arrangements implemented to guarantee the security of radiation sources as provided in Regulation on Security of Radioactive Materials (NRRC-R-17).

89. The authorized person shall conduct an investigation immediately after an event and shall prepare a written record of its causes, or suspected causes, including verification or determination of any doses, received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.

90. The authorized person shall communicate to the NRRC a written report of any formal investigation relating to events as prescribed by the NRRC, including exposures giving rise to doses exceeding a dose limit.

91. The authorized person shall immediately report to the NRRC any event in which a dose limit is exceeded.

Section 30: Regulatory Inspection of Facility

92. The authorized person shall permit access by authorized representatives of the NRRC to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspections.

Section 31: Information Requested by the NRRC

93. The authorized person shall provide NRRC with any requested information in matters related to radiation protection and safety, following the specific requirements in the relevant instructions.

Chapter 6: Prevention and Mitigation of Accidents

Section 32: Good Engineering Practice

94. The authorized person shall ensure good engineering practice for the activity of the facilities that:

    a. Take account of national legal requirements and international and national standards;

    b. Supported by managerial and organizational features, to ensure protection and safety throughout the lifetime of the facility;

    c. Include adequate safety margins in the design and construction of the facility, and in operations involving the facility, to ensure:

        (i) Reliable performance in normal operation;

        (ii) The necessary quality, redundancy and capability for inspection, with emphasis on preventing potential exposure;

    d. Capable to mitigate the consequences of those radiation safety deviations that do occur and restricting any possible future exposures;

e. Take account of relevant developments concerning technical criteria, as well as, the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

Section 33: Defence in Depth

95. The authorized person shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety is applied to radiation sources under its responsibility. The system shall be commensurate with the likelihood and magnitude of potential exposures.

96. The authorized person shall ensure that if one level of protection were to fail, the subsequent independent level of protection would be available. Such defence in depth shall be applied for the purposes of:

    a. Preventing radiation safety deviations;

    b. Mitigating the consequences of any radiation safety deviations that do occur;

    c. Restoring the sources to safe conditions after any such radiation safety deviations.

Section 34: Prevention of Radiation Safety Deviations

97. The authorized person shall ensure that structures, systems and components, including software, that are related to protection and safety for facilities and activities are designed, constructed, commissioned,

operated and maintained to prevent radiation safety deviations as far as reasonably practicable.

98. The authorized person for any activity or facility shall make suitable arrangements:

    a. To prevent reasonably foreseeable radiation safety deviations;

    b. To mitigate the consequences of those radiation safety deviations that do occur;

    c. To provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;

    d. To ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable radiation safety deviations;

    e. To ensure that safety significant structures, systems and components, including software, and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;

    f. To ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;

    g. To provide, wherever appropriate, automatic systems for safely shutting off or reducing the release of radiation from facilities in the event that operating conditions are outside the stipulated ranges;

h. To ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner;

i. To ensure that all relevant safety documentation is available in the appropriate languages understandable to users.

Chapter 7: Verification of Safety

Section 35: Safety Assessment

99. The authorized person shall carry out, and if pertinent review, a safety assessment for the activity or facility under its responsibility, following the requirements prescribed by the NRRC.

100. The safety assessment shall be consistent with the magnitude of the possible radiation risks arising from the activity or facility, and is conducted, at different stages throughout the lifetime of the facility, so as:

a. To identify how 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. To determine the expected magnitudes and likelihood of exposures in normal operation and, to the extent reasonable and practicable, make an assessment of potential exposures;

c. To assess the adequacy of the provisions for protection and safety.

101. The authorized person shall ensure that the safety assessment, and its reviews are:

    a. Documented and made available to NRRC.

    b. Reviewed under the relevant management system.

    c. Independently reviewed by a qualified expert or technical support organization, if so required by the NRRC.

102. If, as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seem desirable, any significant modifications shall be made cautiously and only after favorable assessment of all the implications for protection and safety having approval from the NRRC. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

Section 36: Monitoring, Testing and Verification of Compliance

103. The authorized person shall establish and perform a monitoring and measurement program commensurate with the risks associated with the activity or facility in order to verify compliance with the requirements for protection and safety.

104. As part of the monitoring and measurement program, the authorized person shall ensure that:

    a. Suitable equipment is provided and procedures for verification are implemented;

b. Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;

c. Records are maintained of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with this regulation ;

d. The results of monitoring and verification of compliance are submitted to the NRRC.

105. The monitoring and measurement programs either as part of granting the authorization for practice or separately shall be submitted for approval to the NRRC.

Chapter 8: Emergency Preparedness and Response

Section 37: Emergency Planning

106. The authorized person shall establish organizational arrangements consistent with its Management System for coping with the emergencies.

107. The authorized person shall prepare an Emergency Plan for the protection of people and the environment reflecting findings from the safety assessment taking into consideration the likelihood of an emergency affecting either workers or members of the public as part of emergency preparedness and response.

108. The authorized person shall prepare and document a proposal of such plan for approval by the NRRC as part of the documentation required

in support of the authorization process. The content and scope of the Emergency Plan shall satisfy the requirements specified by the NRRC.

109. The authorized person shall ensure periodic review and updating of the emergency plan to guarantee that resources, arrangements, and procedures, to give the necessary response, are consistent with any change that is produced within the facility or at external organizations supporting the Emergency Plan.

110. In regard to the arrangements for the emergency response at the scene by the authorized person, 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.

Section 38: Implementation of the Emergency Plan

111. The authorized person shall be responsible for the implementation of their Emergency Plans and be prepared to take any necessary action for effective response.

112. To prevent the occurrence of conditions that could lead to a loss of control over a source or to the escalation of such conditions, authorized person 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.

Section 39: Action in an Emergency Situation

113. In an emergency situation, the authorized person shall take the measures prescribed under the approved emergency plan without delay in order to control the situation and prevent or limit radiation exposure and immediately notify the NRRC of any declaration of an emergency situation and the classification of the emergency situation.

Chapter 9: Human Imaging for Purposes other than Medical Diagnosis, Medical Treatment or Biomedical Research

Section 40: Justification of Practices Involving the Deliberate Exposure of Humans for Non-Medical Imaging Purposes

114. Not any practice involving the deliberate exposure of humans for non-medical imaging purposes shall be engaged in unless justified.

115. The process of evaluating the justification of conducting the justifiable practice shall include the consideration of:

a. The benefits and detriments of implementing the type of human imaging procedure;

b. The benefits and detriments of not implementing the type of human imaging procedure;

c. Any legal or ethical issues associated with the introduction of the type of human imaging procedure;

d. The effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;

e. The availability of sufficient resources to conduct the human imaging procedure safely throughout the intended period of the practice.

116. Any person responsible for a practice involving deliberate exposure of humans for non-medical imaging purposes, which has been determined through the due process as justified, shall apply for an authorization from the NRRC as referenced in Sections 21 and 22.

Section 41: Optimization of Protection and Safety

117. The authorized person responsible for a practice involving human imaging using radiation conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for employment related, legal or health insurance purposes without reference to clinical indication, shall ensure that the appropriate optimization requirements for medical exposure in Section 72 are applied, with dose constraints defined by the NRRC instead of diagnostic reference levels.

118. Procedures with inspection imaging devices in which radiation is used to expose persons for the purpose of detection of concealed weapons, contraband or other objects on or within the body shall be considered

to give rise to public exposure. The authorized person shall apply the requirements for public exposure and dose constraints for public exposure prescribed by the NRRC.

119. The authorized person shall ensure that all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available.

120. At all time, the authorized person shall ensure that any inspection imaging device used for the detection of concealed objects on or within the body, whether it is manufactured in the Kingdom or imported, conforms to NRRC's requirements.

Chapter 10: Occupational Exposure

Section 42: Principal Responsibilities

121. The authorized person shall be responsible for workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations, by ensuring:

    a. Protection of workers against occupational exposure;

    b. Compliance with relevant requirements of this regulation.

122. The authorized person shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:

a. Relevant dose limits for occupational exposure are not exceeded;

b. Protection and safety is optimized in accordance with the requirements of this regulation;

123. The authorized person shall ensure that workers exposed to radiation from sources within a practice that is not required by or directly related to their work have the same level of protection against such exposure as members of the public.

124. Nothing in this Regulation shall be construed as relieving the authorized person from complying with applicable national and local laws and regulations governing hazards in the workplace.

125. The authorized person shall ensure compliance by workers with the requirements prescribed in this regulation.

126. The authorized person shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well-engineered controls and satisfactory working conditions.

127. The authorized person shall ensure protection and safety in accordance with the following hierarchy of preventive measures:

a. Engineered controls;

b. Administrative controls;

c. Personal protective equipment.

Section 43: Management Requirements for the Protection of Workers, Apprentices, and Students

128. The authorized person shall adopt the necessary arrangements, within the management system, that ensure:

a. Decisions related to measures for protection and safety are recorded and made available as specified by the NRRC;

b. Policies, procedures and organizational arrangements for protection and safety are established for implementing the relevant requirements of this regulation, with priority given to design measures and technical measures for controlling occupational exposure;

c. 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 occupational exposure;

d. Arrangements are made to facilitate consultation of and co-operation with workers, through their representatives where appropriate, with regard to protection and safety on all measures necessary to achieve the effective application of these regulation;

e. Necessary conditions for promoting safety culture are provided;

f. Workers are involved, through their representatives where appropriate, in the optimization of protection and safety;

g. Workers are informed that ensuring protection and safety is an integral part of a general occupational health and radiation protection 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;

h. Any work in which workers are or could be subject to occupational exposure is adequately supervised and reasonable steps are taken to ensure that the rules, procedures, measures for protection and safety provisions are observed;

i. Any report received from a worker that identifies circumstances that could affect compliance to this regulation are recorded and appropriate actions are take;

j. All the information, procedures, instructions, warning signals and of that concern safety matters are managed or delivered in a language appropriated to the audience addressed.

Section 44: Controlling occupational exposure for outside workers

129. If workers are engaged in work that involves or that could involve a source that is not under the control of their employer, the authorized person responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of this regulation.

130. The authorized person shall ensure:

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 at least as good as those for employees of the authorized person;

b. Availability of specific assessments and monitoring of the doses received by workers;

c. A clear allocation and documentation of responsibilities of their employer and those of the authorized person for protection and safety.

131. In controlling occupational exposure for outside workers, the cooperation between the employer and the authorized person responsible for the source or for the exposure shall include:

a. The provision on previous occupational exposure history of workers and any other necessary information from the employers, including from the self-employed individuals;

b. The provision of appropriate information from the authorized user to the employer, including any available information relevant for compliance with the requirements of this regulation that the employer requests;

c. The provision of both the worker and the employer with the relevant exposure records.

132. The authorized person responsible for the source shall include in its radiation protection program when pertinent, measures, specific safe-

ty arrangements and the administrative basis on the cooperation with employers that will lead the involvement of workers not employed by the authorized person.

Section 45: Responsibilities of Workers

133. The workers shall be made liable for applying radiation protection and safety measures through ensuring:

a. Compliance to any applicable rules and procedures for protection and safety as specified by the authorized person;

b. The proper use of the provided monitoring equipment and personal protective equipment;

c. Involvement with the authorized person with regard to protection and safety, and programs for workers' health surveillance and programs for dose assessment;

d. Provision to the authorized person of such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others;

e. Abstention from any willful action that could put themselves or others in situations that would not be in accordance with the requirements of this regulation;

f. Acceptation of such information, instruction and training in protection and safety as will enable them to conduct their work in accordance with the requirements of this regulation.

Section 46: Classification of Areas

134. The authorized person shall ensure that arrangements in workplaces include a classification into controlled and supervised areas, based on an assessment of the expected annual doses, the probability and magnitude of potential exposures, and the type and extent of the procedures required for protection and safety including any other requirement as determined by the NRRC.

135. The authorized person shall designate a controlled area in which specific measures for protection and safety are or could be required for:

    a. Controlling exposures in normal operation;

    b. Preventing the spread of contamination in normal operation;

    c. Preventing or limiting the likelihood and magnitude of potential exposures.

136. The authorized person shall designate a supervised area that is not already designated as a controlled area, but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.

137. The authorized person shall periodically review conditions to assess whether there is any need for changes to the boundaries of controlled and supervised areas.

Section 47: Requirements for Controlled Areas

138. The authorized person with respect to controlled areas shall:

    a. Determine the boundaries of any controlled area on the basis

of the likelihood and magnitude of expected exposures and 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 energized or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;

d. Display a warning symbol, as prescribed by the NRRC, and display 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 local rules and procedures for controlled areas;

f. Restrict access to controlled areas by means of administrative procedures, such as the use of work permission, and/ or physical barriers. The degree of restriction shall be commensurate with the likelihood and magnitude of exposures;

g. Provide, at entrances to the controlled areas:

(i) Personal protective equipment;

(ii) Equipment for individual monitoring and workplace monitoring;

(iii) Suitable storage for personal clothing.

h. Provide, at exits from the 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 area;

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

(iv) Suitable storage for contaminated personal protective equipment.

i. Provide appropriate information, instruction and training for persons working in controlled areas.

Section 48: Requirements for Supervised Areas

139. The authorized person, taking into account the nature, likelihood and magnitude of exposures or contamination in the supervised areas shall:

(i) Delineate the supervised areas by appropriate means;

(ii) Display warning signs as prescribed by the NRRC, at access points to supervised areas;

(iii) Provide working instructions appropriate to the radiological risk associated with the sources and the operations involved.

Section 49: Local Rules and Procedures

140. The authorized person shall, in consultation with workers:

a. Establish written local rules and procedures that are necessary for protection and safety for workers and other persons;

b. Include in the local rules and procedures any relevant investigation level or authorized level, and the procedures to be followed if any such level is exceeded;

c. Make the local 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.

Section 50: Personal Protective Equipment

141. The authorized person shall provide the workers with suitable and adequate personal protective equipment that meets relevant standards or specifications prescribed by the NRRC.

142. The authorized person shall ensure that:

a. Workers receive adequate instruction in the proper use of personal protective equipment, including testing for good fit;

b. All personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and tested at regular intervals.

Section 51: Workplace Monitoring

143. The authorized person shall establish, maintain and keep under review a program for workplace monitoring.

144. The type and frequency of workplace monitoring shall be:

a. Sufficient to enable:

(i) Evaluation of the radiological conditions in all workplaces;

(ii) Assessment of exposures in controlled areas and supervised areas;

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

b. Based on dose rate, activity (A) concentration in air and surface contamination, and their expected fluctuations, and on the likelihood and magnitude of exposures in anticipated radiation safety deviations.

145. The authorized person shall maintain records of the findings of the workplace monitoring program and make the findings available to workers.

Section 52: Individual Monitoring and Assessment of Occupational Exposure

146. The authorized person shall be responsible for making arrangements for the assessment of the occupational exposure of workers based on individual monitoring.

147. The authorized person shall ensure that individual monitoring is performed, in a manner adequate and feasible, for any worker who normally works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure.

148. For a worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results of workplace monitoring or individual monitoring.

149. In cases where the individual monitoring is required or recommended, the type of dosimetry method to be used and the frequency of measurements shall be commensurate with the nature and expected level of exposure, as well as, the likelihood and magnitude of potential exposure.

150. The individual monitoring shall be performed by a dosimetry service that operates under a quality management system, and is recognized by the NRRC.

151. In cases where individual monitoring is not inappropriate, inadequate, or not feasible, the individual dose assessment shall be based on any of the following tools or a combination of them:

    a. Individual measurements made on other exposed workers,

    b. Workplace monitoring and information on the locations and durations of exposure of the worker,

c. Applying calculation methods previously approved by the NRRC.

152. For a worker who could be subject to exposure due to contamination, the authorized person shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and, where appropriate, to assess intakes of radionuclides and the committed effective doses.

Section 53: Records of Occupational Exposure

153. The authorized person shall maintain records of occupational exposure for every worker for whom assessment of occupational exposure is required as prescribed in Section 52.

154. The authorized person shall maintain records of occupational exposure during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work or for the period that will be determined by the NRRC in which the worker was subject to occupational exposure.

155. Records of occupational exposure managed by the authorized person shall include:

a. Information on the practice or exposure situation and the characteristics of the exposure, including the tasks of the worker;

b. Data on the employer when the authorized person does not employ the worker;

c. Information on dose assessments, estimated exposures and intakes, at or above the relevant recording levels specified by the NRRC that applies accepted physical quantities and units;

d. Information and data upon which the dose assessments were based and references to reports of any relevant investigations on radiation safety deviations;

e. Records of any assessment of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.

156. The authorized person that ceases to conduct activities in which workers are subject to occupational exposure, shall make arrangements for the retention of workers' records of occupational exposure by the NRRC and by relevant employer or other authorized person.

157. The authorized person shall implement the necessary arrangements to ensure the submission of relevant individual occupational exposure data to the centralized national database established by the NRRC.

Section 54: Access to Records of Occupational Exposure and Reporting of Dosimetry Results

158. The authorized person shall make data contained in the records of occupational exposure available to:

a. The concerned worker;

b. The NRRC;

c. The relevant employer;

d. The physician responsible for the health surveillance of the worker;

e. The new employer when worker changes employment.

159. In addition to the data registered in the records of occupational exposure, the authorized person, upon request, shall provide workers with the results of the direct measurements or the workplace monitoring results which may have been used in estimating their doses.

160. The authorized person shall inform the worker of any exposure exceeding the dose constraints.

161. In the case of accidental exposure, the authorized person shall communicate the results of individual monitoring and dose assessments to the concerned worker and the NRRC without delay.

162. The authorized person shall give due care and attention to maintaining the confidentiality of records.

Section 55: Workers' Health Surveillance for Radiation Exposure

163. The authorized person, in accordance with the requirements set by the NRRC, shall make arrangements for appropriate health surveillance.

164. The authorized person shall ensure that the workers' health surveil-

lance program is based on the general principle of occupational health and provides:

a. A medical examination prior to employment to determine the worker's fitness for a post for which the worker is being considered;

b. Periodic reviews of health at least once (1) every three (3) years, in order to determine whether the workers remain fit to perform their duties.

165. If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the authorized person responsible for the source shall, as a precondition for the engagement of such workers, check that worker concerned has been passed as medically fit for the activities to be assigned and make with the employer any special arrangements for workers' health surveillance that are needed to comply with the requirements set by the NRRC.

166. As part of the workers' health surveillance arrangements, the authorized person shall:

a. Provide the organization responsible for the health surveillance, upon request, with dosimetry and operational information on the concerned workers that may contribute to support the medical examination and further evaluation.

b. Record the information delivered by the health surveillance program on pre-employment, periodic and termination ex-

amination, as well as those resulting from any special assessments.

c. Maintain medical records during and after the worker's working life, at least until the former 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.

Section 56: Special Health Surveillance

167. The authorized person shall ensure that special health surveillance is performed in each case where any of the dose limits for occupational exposure has been exceeded.

168. In the case referred to in above Section 55, the physician responsible for workers' health surveillance shall decide on:

a. Necessary action for the health protection of the exposed individual, such as further examinations, decontamination, urgent treatment or other action identified by it;

b. Subsequent exposure conditions in which the worker can continue to work.

169. The authorized person shall ensure that recommendations raised by the physician responsible for workers' health surveillance are properly implemented.

Section 57: Information, Instruction, and Training

170. The authorized person shall:

a. Provide all workers with:

(i) Information on health risks due to their occupational exposure in normal operation anticipated operational occurrences and accident conditions;

(ii) Training and periodic retraining in protection and safety;

(iii) Instruction on radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;

(iv) Information and instruction on the relevant parts of the emergency response plans formation on the significance of their actions for protection and safety.

b. Provide those workers who could be involved in or affected by the response to an emergency with appropriate information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event, and adequate instruction and training and periodic retraining, for protection and safety;

c. Maintain records of the training provided to individual workers.

171. The authorized person shall ensure that actions providing workers with information, instruction, and training in protection and safety are:

    d. Conducted in compliance with specific requirements issued by the NRRC on its content and scope;

    e. Managed through a formal training program;

    f. Properly recorded.

Section 58: Conditions of Service

172. The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for measures for protection and safety.

173. The authorized person shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the NRRC or in the framework of the program for workers' health surveillance in accordance with the requirements of this regulation, that workers, for health reasons, may no longer continue in employment in which they are or could be subject to occupational exposure.

174. The authorized person shall not terminate an employment on the basis of the worker being exposed to a radiation dose exceeding the dose limit for occupational exposure.

Section 59: Age Limits for Occupational Exposure and Special Arrangements for Persons Under 18 Years of Age

175. The authorized person shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

176. The authorized person shall ensure that persons under the age of 18 years are allowed access to a controlled area only under the supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used unless determined otherwise by the NRRC.

Section 60: Protection of Pregnant and Breastfeeding Workers

177. The authorized person shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with 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 authorized person 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 breastfed infant due to ingestion of radioactive substances.

178. Notification of the authorized person by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be con-

sidered a reason to exclude the female worker from work.

179. The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public.

Chapter 11: Public Exposure

Section 61: Responsibilities for the Protection of the Members of the Public

180. The authorized person, in cooperation with suppliers and providers of consumer products shall apply the requirements of this regulation in relation to any public exposure delivered from a source for which they have responsibility.

181. The authorized person in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source shall take into account:
    a. Possible changes in any conditions that could affect the 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;

d. Uncertainties in the assessment of doses, especially uncertainties in contributions to doses if the source and the representative person are separated in space or in time.

182. The authorized person shall consider, in the safety assessment that supports the authorization process and when conducting any further safety evaluation, all aspects relevant for the public exposure, including those related to the siting of the facility from a radiation protection point of view.

183. The authorized person shall establish, implement, maintain and adequately document within the radiation protection program the following matters:

a. Policies, procedures and organizational arrangements for protection and safety related to public exposure, in accordance with the requirements of this regulation;

b. Measures for ensuring:

(i) Optimization of protection and safety;

(ii) Limitation of exposure of members of the public from such sources, so that the total exposure is not higher than the dose limits for members of the public as specified in Section 10;

c. 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;

d. Provision for controlling radioactive discharges and ensuring compliance with the discharge conditions established by the NRRC.

e. Provision for appropriate implementation of the waste management requirements, including the application of the clearance levels.

f. Programs for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as required, to ensure the necessary level of competence;

g. Provision for appropriate monitoring equipment, monitoring programs and methods for measuring and assessing public exposure and radioactive contamination of the environment;

h. Adequate records of monitoring programs.

Section 62: Control of Visitors

184. The authorized person shall:

a. Apply the relevant requirements of this regulation in respect of public exposure for visitors to a controlled area or a supervised area;

b. Ensure that 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 area or a supervised area so as to provide protection and safety for visitors and other individuals who could be affected by their actions;

d. Ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas;

e. Ensure that appropriate records on relevant information concerning the control of visitors are implemented.

Section 63: External Exposure and Contamination in Areas Accessible to Members of the Public

185. In a situation when a source is deemed to give rise to external exposure of members of the public, the authorized person shall ensure that:

a. The floor plans and arrangements of equipment for all new installations utilizing such sources, as well as all significant modifications to existing installations, are subject to review and approval by the NRRC prior to commissioning;

b. Shielding and other measures for protection and safety, including access control, are provided for restricting public exposure in particular at open sites.

186. The authorized person shall ensure that:

a. Specific provisions for confinement are established for the design and operation of a source that could cause the spread of contamination in areas that are accessible to members of the public;

b. Measures for protection and safety are implemented for restricting public exposure due to contamination in areas within a facility that are accessible to members of the public.

Section 64: Assessment of Doses to a Member of the Public

187. The authorized person shall ensure that arrangements are made for the assessment of doses to the member of the public to the extent necessary for verifying and demonstrating compliance with the authorization conditions.

188. The assessment of doses to members of the public shall be based on the proven identification of the representative person and the estimation of exposure doses due to external radiation and the intake of radionuclides.

189. The authorized person shall verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts.

190. The authorized person shall maintain appropriate records of the assessed doses to members of the public.

Section 65: Monitoring Programs

191. The authorized person shall establish and implement monitoring programs to ensure that the exposure of the representative person due to radiation sources under their responsibility and the radioactive contamination of the environment is adequately assessed.

192. The monitoring programs shall include monitoring of the following:

    a. External exposure due to radiation sources;

    b. Discharges;

    c. Radioactivity in the environment;

    d. Other parameters important for the assessment of public exposure.

193. The authorized person shall ensure that the monitoring program is reviewed and updated when changes in the source, the environment or along the exposure pathways are jeopardizing the capacity of the program to assess the public exposure.

194. The authorized person shall establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to a radiation safety event.

195. The authorized person shall maintain appropriate records of the results from the monitoring programs.

Section 66: Reporting and Publishing of Monitoring Results

196. The authorized person shall report or make available to the NRRC the results of the monitoring programs referred to in Section 65 at approved intervals. The reporting shall include, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments of doses to the representative person.

197. The authorized person shall report promptly to the NRRC, in accordance with reporting criteria established by the NRRC:

    a. Any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges;

    b. Any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the practice.

198. The authorized person shall publish or make available results from monitoring programs and assessments of doses from public exposure.

Chapter 12: Medical Exposure

Section 67: Regulatory Control for Medical Exposure

199. This regulation shall apply to the following medical exposures, including intended, unintended, and accidental exposures:

a. To patients as part of their medical diagnosis or treatment;

b. To individuals as part of a health screening program;

c. To patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programs;

d. To carers and comforters;

e. To asymptomatic individuals;

Section 68: Justification of medical exposures

200. The medical exposure is justified if it can be proved that the total potential diagnostic or therapeutic benefits to the health of an individual and the benefits to society are higher than the radiation detriment the exposure might cause. The benefits and risks connected to available alternative techniques with the same objective, involving less or no exposure to ionizing radiation, shall be evaluated.

201. The authorized person for the proper implementation of the justification principle, as outlined in Article 200, when considering the use of a radiological procedure on patients, shall ensure that:

a. The concerned radiological procedure with a specified objective is justified;

b. The justification for an individual patient is carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appro-

priate, with account taken, in particular for patients who are pregnant or breast-feeding or are pediatric, of:

(i) The appropriateness of the request;

(ii) The urgency of the radiological procedure;

(iii) The characteristics of medical exposure;

(iv) The characteristics of the individual patient;

(v) Relevant information from the patient's previous radiological procedures.

202. Where there is to be an exposure to a carer or comforter, the authorized person shall ensure a sufficient net benefit of exposure, taking into account:

a. The likely direct health benefits to a patient;

b. The possible benefits to the carer or comforter;

c. The detriment that the exposure might cause.

203. Where radiological procedures are planned to be performed as part of a health screening program for asymptomatic populations, the authorized person responsible for such studies shall ensure that the relevant program and involved procedures are documented and justified.

204. The authorized person shall ensure that any 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, is previously documented, evaluated, and justified by the radiological medical practitioner and the referring medical practitioner, in accordance with the defined requirements.

205. Whether a program of biomedical research that includes medical exposure of volunteers is considered justified by the authorized person responsible for such a program, this authorized person shall apply for a specific authorization before starting its implementation.

Section 69: General Requirements for the Personnel with Responsibilities for Medical Radiological Exposures

206. The authorized person shall allow health professionals to assume responsibilities for medical exposure at a particular medical radiation facility as prescribed in this regulation only if they:

a. Posses degree of specialization in the appropriate area according to the established national criteria;

b. Posses the respective requirements for education, training and competence in radiation protection prescribed by the NRRC;

c. Named and listed in the updated list of qualified personnel.

Section 70: Primary Requirements for the Control of the Medical Radiological Exposures of a Patient

207. The authorized person shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

a. The radiological procedure has been requested by a referring medical practitioner and information on the clinical context 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 overall protection and safety for the patient in the planning and delivery of the medical exposure specified by the relevant competent authority.

d. The patient or the patient's legally authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

Section 71: Involvement of Medical Personnel in Medical Exposures

208. The authorized person shall ensure that:

a. The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in Section 68 and the optimization of protection and safety, in

cooperation with the medical physicist and the medical radiation technologist as required in Section 72;

b. Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in regard to protection and safety for patients in a given radiological procedure are specialized in the appropriate area;

c. For therapeutic radiological procedures, the requirements of this Regulation for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 216, 219 (c), 224 and 225, are fulfilled by or under the supervision of a medical physicist;

d. For diagnostic radiological procedures and image-guided interventional procedures, the requirements of this regulation for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Articles 216, 219 (a) and (b), 220, 224 and 225 are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks.

209. For the proper performance of all medical exposures, the authorized person shall ensure the availability of sufficient medical personnel.

210. The authorized person shall ensure that the management system clearly defines the assignment of individual responsibilities with the medical exposure and that any delegation of responsibilities for the protection of the patient by an authorized person is appropriately documented.

Section 72: Optimization of Protection and Safety

211. In relation to all exposures to which this Regulation apply except radiotherapeutic exposures, the authorized person shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with obtaining the required medical information, taking into account economic and societal factors.

212. The authorized person shall ensure that diagnostic reference levels, are appropriately used for the optimization of the medical exposures of patients in diagnostic radiological procedures and image-guided interventional procedures.

213. In relation to all radiotherapeutic exposures, the authorized person shall ensure that exposures of target volumes are individually planned, their delivery appropriately verified taking into account that doses to non-target volumes and tissues is kept as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.

214. The authorized person shall ensure that the particular aspects of medical exposures are considered in the optimization process for the following situation:

a. Pediatric patients subject to medical exposure;

b. Individuals subject to medical exposure as part of an approved health screening program;

c. Volunteers subject to medical exposure as part of a program of biomedical research;

d. Exposure arising from therapeutic radiological procedures, image-guided interventional procedures, computed tomography and other 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;

f. Exposure of a breastfed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Section 73: Procedures

215. The authorized person shall establish written procedures for every type of radiological procedure that ensures the safety of the patient. The procedures shall describe the methods and apparatus settings for the accomplishment of examinations and treatment for relevant categories of patients.

Section 74: Calibration

216. The authorized person shall ensure in accordance with Articles 207 (c) and (d) that:

a. All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using an accepted procedure.

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 defined by the relative authority;

c. The radiation therapy doses are calibrated by a standard dosimetry laboratory prior to clinical use;

d. Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standard dosimetry laboratory.

217. In the case of radiotherapy procedures, the authorized person shall have a reference instrument for dose measurement. This reference instrument shall be calibrated every second year against the requirement as prescribed by the NRRC.

218. The authorized person shall ensure that, on the intervals defined by the NRRC, necessary arrangements are made for calibrating all devices that show a measure of radiation dose in X-ray diagnostics and nuclear medicine procedures.

Section 75: Patients Dosimetry

219. The authorized person shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and accepted protocols, including dosimetry to determine the following:

a. For diagnostic radiological procedures, typical doses to patients for common procedures;

b. For image-guided interventional procedures, typical doses to patients;

c. For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;

d. For therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients.

Section 76: Use of Diagnostic Reference Levels

220. The authorized person shall ensure that:

a. Local assessments based on the measurements required in Section 75, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established.

b. A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or

whether corrective action is required if, for a given radiological procedure:

(i) Typical doses or activities exceed the relevant diagnostic reference level; or

(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Section 77: General Requirements for the Control of the Medical Radiological Equipment

221. In addition to ensuring that the responsibilities stated in Section 70 are discharged, the authorized person shall ensure that medical radiological equipment and software that could influence the delivery of medical radiological exposure are in compliance with national standards.

222. The authorized person shall establish and maintain organizational, procedural, and technical arrangements for ensuring that no medical radiological equipment and software are used unless they are incompliance with national standards

223. The authorized person shall establish and keep up-to-date an inventory of the medical radiological equipment for each medical radiological installation for approval by the NRRC.

Section 78: Quality Assurance for Medical Exposure

224. The authorized person, in applying the requirements of this regulation in respect of management systems, shall establish a comprehensive program of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radio pharmacists and radiochemists, and in conjunction with other health professionals as appropriate.

225. The authorized person shall ensure that programs of quality assurance for medical exposure include, as appropriate to the medical radiation facility:

a. Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of a medical physicist:

(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;

(ii) Periodically after that;

(iii) After any major maintenance procedure that could affect the protection and safety of patients;

(iv) After any installation of new software or modification of existing software that could affect the protection and safety of patients.

b. Implementation of corrective actions if measured values of

the physical parameters mentioned in (a) above are outside established tolerance limits.

c. Verification of the appropriate physical and clinical factors used in radiological procedures.

d. Maintaining records of relevant procedures and results.

e. Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

226. The authorized person shall ensure that regular and independent audits are made of the program of quality assurance for medical exposures, and that their frequency is in accordance with the requirements established by NRRC.

Section 79: Special Protection of Pregnant or Breast-feeding Female Patients

227. The authorized person shall ensure that understandable signs are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological personnel in the event that:

a. She is or might be pregnant;

b. She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.

228. The authorized person shall ensure that there are procedures in place for 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, so that this information can be considered in the justification for the radiological procedure and in the optimization of protection and safety.

229. The authorized person shall ensure that there are arrangements in place for 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 breastfed infant, so that this information can be considered in the justification for the radiological procedure and in the optimization of protection and safety.

Section 80: Release of Patients After Radionuclide Therapy

230. The authorized person shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by the medical physicist and the facility's radiation safety officer that:

    a. The activity (A) of radionuclides in the patient is such that doses that could be received by members of the public and family members would comply with the requirements established by the NRRC; and

    b. The patient or the legal guardian of the patient is provided with:

(i) 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;

(ii) Information on the radiation risks.

Section 81: Medical Exposures as Part of a Research Program

231. The authorized person shall ensure that the research program involving medical exposures is conducted in accordance with the relevant national laws.

232. For a research program the authorized person shall ensure that:

a. The radiological medical practitioner has assumed responsibility as specified in Section 71;

b. The individuals concerned participate voluntarily;

c. These individuals are informed about the risks of exposure;

d. Dose constraints, are used in the optimization of protection and safety for persons subject to exposure;

e. In the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

Section 82: Protection of Carers and Comforters

233. The authorized person shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she 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.

234. The authorized person shall ensure that relevant dose constraints specified in Section 8 are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

Section 83: Prevention of Unintended and Accidental Medical Radiological Exposure

235. The authorized person, in accordance with the relevant requirements of Sections 13, 34 and 87, shall ensure that all practicable measures are taken to minimize the likelihood and magnitude 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.

Section 84: Investigation of Unintended and Accidental Medical Radiological Exposures

236. The authorized person shall promptly investigate any of the following unintended or accidental medical exposures:

    a. Any medical treatment delivered to the wrong individual or

to the wrong tissue or organ of the patient or using the wrong radiopharmaceutical, or with an activity (A), a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or 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;

f. Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrences with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

237. The authorized person shall, with regard to any unintended or accidental medical exposures investigated as required in Article 236:

a. Calculate or estimate the doses received and the dose distribution within the patient;

b. Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;

c. Implement all the corrective actions that are under their own responsibility;

d. Produce and keep, as soon as possible after the investigation or as otherwise required by the NRRC, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c) above, as relevant, and any other information as requested by the NRRC;

e. For significant unintended or accidental medical exposures or as otherwise required by the NRRC, submit the written record specified in (d) above, immediately to the NRRC;

f. Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legally authorized representative of the unintended or accidental medical exposure.

238. The authorized person shall cooperate with the NRRC for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Section 85: Radiological Reviews

239. The authorized person shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation

technologists and the medical physicists.

240. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.

Section 86: Records

241. The authorized person shall maintain and make available the following personnel records for a duration of the period specified by the NRRC:

    a. Any delegation of responsibilities by the authorized person.

    b. Training of personnel in radiation protection.

242. The authorized person shall maintain and make available the following records of calibration, dosimetry and quality assurance for a duration of the period specified by the NRRC:

    a. Results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;

    b. Dosimetry of patients, as required in Section 75;

    c. Local assessments and reviews made with regard to diagnostic reference levels, as required in Section 76;

    d. The associate quality assurance program, as required in Section 78.

243. The authorized person shall maintain and make available the following records for medical exposure for a duration of the period specified by the NRRC:

a. For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;

b. For image-guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;

c. For nuclear medicine, the types of radiopharmaceutical administered and their activity (A);

d. For external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the center of the planning target volume, and the maximum and minimum absorbed doses delivered absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and also, for external beam radiation therapy, the dose fractionation and the overall treatment time;

e. Exposure records for volunteers subject to medical exposure as part of a program of biomedical research;

f. Reports on investigations of unintended and accidental medical exposures as required in Section 84.

Chapter 13: Safety of Radiation Generators and Radioactive Sources

Section 87: General Design Requirements

244. The authorized person shall ensure that radiation sources authorized for their activities or/and at their facilities are:

a. Supplied based on a well-designed, well manufactured and well-constructed radiation generator or radioactive source and device in which the radiation generator or radioactive source is used that:

(i) Provides for protection and safety in accordance with the requirements of this regulation;

(ii) Meets engineering, performance and functional specifications;

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

(iv) Provides clear displays, gauges and instructions on operating consoles in the appropriate language understandable to users.

b. Tested to demonstrate compliance with the relevant specifications.

c. Provided with information in the appropriate language un-

derstandable to users, on the proper installation and use of the radiation source and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety.

d. Ensured that the protection provided by shielding and by other protective devices is optimized.

245. The authorized person shall ensure that supplied radioactive source and a radiation appliance containing a radioactive source including the source itself is marked as "Radioactive", where technically possible, and the radiation appliance is equipped with the symbol indicating radiation hazard in accordance with the national requirements.

246. The authorized person shall ensure that the authorized sealed sources are identifiable and traceable.

Section 88: The commitment of a Supplier for Accepting the Return of a Disused Sealed Source

247. Prior to the acquisition of radioactive sources, the authorized person shall arrange for and require a written commitment of the supplier for the return of the source once it becomes disused. The commitment of the supplier shall specify:

a. The assurance to take the disused source within a specified time period;

b. The arrangements for transport and associated conditioning

of the disused source in connection with its return, including the provision of a transport package certified in accordance with transport regulations and the maintenance of the source special form certificate as applicable;

c. The initial estimation and allocation of the costs of return between the authorized person and the supplier. This estimation and allocation of the costs shall be revised every five (5) years or as determined by the NRRC.

Section 89: Requirements for the Management of Radiation Generators and Radioactive Sources

248. Where applicable, the authorized person shall make suitable arrangements for the purposes of:

a. Obtaining information on conditions of use and operating experience that may be important for protection and safety;

b. Providing feedback and information that may have implications for protection and safety for other users, or that may have implications for the possibility for improvements in protection and safety for radiation generators and radioactive sources.

249. When implementing requirements in this regulation and other relevant regulations for sealed sources, the authorized person shall categorize its sources as set out in Appendix 1.

250. The authorized person shall ensure that when radioactive sources are not in use they are stored appropriately for protection and safety.

251. The authorized person shall review their radioactive source inventory at least every six (6) months or as determined by the NRRC to identify any sources that have become disused.

252. The authorized person shall ensure that when a radioactive source is declared disused, arrangements are made to ensure that within a period of two (2) years or as determined by the NRRC after this declaration, the source is transferred upon approval from the NRRC to the manufacturer, supplier, another authorized person or authorized waste management facility.

253. The authorized person shall ensure that the inventory of radiation generators or radioactive sources is checked periodically to confirm that they are in their assigned locations and are remained under control.

254. The applicant for an authorization for practices that involve the use of radioactive sources shall demonstrate that adequate provision has been made for the safe management of concerned sources when they become disused sources, including the case where the authorized person becomes insolvent or ceases its activities.

Section 90: Locations to Use or Storage of Radiation Sources

255. The authorized person shall ensure the safety and security of the place of use and storage of a radiation source. For the purpose of ensuring security of radioactive material, the authorized person shall ensure compliance with the relevant security requirements prescribed by the NRRC.

256. When choosing a location to use or to store a radiation generator or radioactive source, the authorized person shall take into account:

a. Factors that could affect the safe management of and control over the radiation generator or radioactive source including the relevant security requirement;

b. Factors that could affect occupational exposure and public exposure due to the radiation generator or radioactive source;

c. The feasibility of taking the foregoing factors into account in engineering design.

257. In selecting a site for a facility that will contain a large amount of radioactive substances and that will have the potential for the release of significant amounts of radioactive substances, the authorized person shall take into account:

a. Features that might affect protection, safety and security;

b. Features that might affect the integrity or functioning of the facility;

c. The feasibility of carrying out off-site protective actions if they become necessary.

Section 91: Record-keeping

258. The authorized person shall maintain an inventory of radiation sources that include records with the following information:

a. The location and description of each radiation source for which they are responsible;

b. The activity (A) and form of each radioactive source for which they are responsible.

259. The content of source records implemented by the authorized person for each type of radiation source shall comply with the relevant requirements established by the NRRC.

Section 92: Reporting to the NRRC

260. The authorized person shall implement necessary arrangements to ensure compliance with the instructions issued by the NRRC aiming to keep updated the national database on radiation sources.

261. The authorized person shall promptly notify the NRRC of pertinent information regarding a radiation generator or radioactive source that is lost, missing, theft, unauthorized used, or not under control.

Chapter 14: Consumer Products

Section 93: Authorization of Consumer Products

262. No consumer products shall be provided to the public unless the justification of their use by members of the public has been approved by the NRRC, and either their use has been exempted on the basis of the criteria specified in Sections 19 and 20.

263. Providers of consumer products shall request NRRC for an authorization following requirements specified in Sections 21, 22 and other relevant regulation.

Section 94: Responsibilities of Providers of Consumer Products

264. Providers of consumer products shall:

a. Comply with the conditions of the authorization to provide consumer products to the public;

b. Ensure that consumer products comply with the requirements of this regulation;

c. Plan for appropriate arrangements for the servicing, maintenance, recycling or disposal of consumer products.

Section 95: Labeling of Consumer Products

265. Providers, in cooperation with the manufacturer of consumer products, shall ensure that:

a. Where practicable, a legible label is firmly affixed to a visible surface of each consumer product with the following information:

(i) The consumer product contains radioactive substances with detail of radionuclides and their activities;

(ii) The provision of the respective consumer product to the public has been authorized by the NRRC;

(iii) The required or recommended options for recycling or disposal.

b. The information specified in (a) above is also printed legibly on the retail packaging of the consumer product.

Section 96: Information and Instructions to Users of Consumer Products

266. Providers of consumer products shall provide clear and appropriate information and instructions with each consumer product related to:

a. Correct installation, use and maintenance of the consumer product;

b. Servicing and repair;

c. The radionuclides and their activities at a specified date;

d. Dose rates in normal operation and during servicing and repair;

e. Required or recommended options for recycling or disposal.

Section 97: Information and Instructions to Consumer Product Retailers

267. Providers of consumer products shall provide the consumer product retailers with appropriate information on safety and instructions on their transport and storage.

Chapter 15: Radioactive Waste Management

Section 98: General Responsibilities for the Management of Radioactive Wastes

268. The authorized person shall be responsible for the safe management of the radioactive waste generated by the activity or sources for which they are authorized with.

269. The authorized person shall ensure that radioactive waste is managed and discharges are conducted in accordance with the requirements of this regulation and other applicable regulations, and in accordance with the relevant authorization.

270. The authorized person shall ensure that the management of radioactive waste, including disused sources, is conducted in such a manner that relevant requirements derived from the national policy on this matter are met.

271. The authorized person shall establish appropriate policies, technical procedures, and organizational arrangements and measures for ensuring the safe management of radioactive waste that are formally included in the overall management system and documented as part of the radiation protection program.

272. Before generating radioactive waste that may require subsequent management, the authorized person shall ensure the availability of suitable resources and facilities within their organization. When the subsequent management requires involvement of another organization, necessary arrangements shall be guaranteed.

Section 99: Control of Radioactive Waste Generation

273. The authorized person generating radioactive waste shall ensure that appropriate measures are taken to keep the generation of radioactive waste to the minimum practicable in terms of both activity (A) and volume.

Section 100: Characterization, Classification, and Collection of Radioactive Waste

274. The authorized person shall characterize radioactive waste in terms of its physical, mechanical, chemical, radiological and biological properties.

275. The authorized person shall classify the radioactive waste according to the waste classification scheme established by the NRRC.

276. The authorized person shall ensure that the collection of radioactive waste and its ulterior management until final clearance or transferring to another organization is conducted in such a manner that wastes are always adequately segregated according to the relevant classification.

Section 101: Acceptance Criteria for Radioactive Waste

277. The authorized person shall ensure that an appropriate control system is established to provide confidence that the radioactive waste under its responsibility meets the applicable waste acceptance criteria defined by the organization responsible for the subsequent step in the management.

Section 102: Discharge of Radioactive Materials to the Environment

278. Planned discharges to the sewer system, air, rivers, lakes, sea or elsewhere to the environment shall be subject to authorization by the NRRC.

279. Before initiating the discharge to the environment, the authorized person in applying for an authorization for discharges shall:

a. Determine the characteristics and activity (A) of the material to be discharged, and the possible points and methods of discharge;

b. Demonstrate how good practices in the operation of similar facilities or activities have been taken into account when designing the discharge control measures;

c. Determine by an appropriate pre-operational study all significant exposure pathway by which discharged radionuclides could give rise to exposure of members of the public;

d. Assess doses to the representative person due to the planned discharges;

e. Submit the source and environmental monitoring program for approval from the NRRC aiming to verify compliance with the limits and conditions established by the NRRC for controlling planned discharges;

f. Consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the NRRC;

g. Include assessment of impacts from the discharges that could cause public exposure outside the Kingdom;

h. Submit to the NRRC the findings of (a) to (g) as an input to

the establishment by the NRRC of authorized limits on discharges and conditions on their implementation.

280. The authorized person shall ensure that radioactive materials from authorized practices are not discharged to the environment unless such discharges are within the limits and conditions on their implementation specified by the NRRC.

281. The authorized person shall review and modify their discharges, control measures as appropriate and in agreement with the NRRC, taking into account:

a. Operating experience;

b. Any changes in exposure pathways or in the characteristics of the representative person that could affect the assessment of doses due to the discharges.

Section 103: Clearance and its Control

282. In an application for authorization, the applicant shall declare its intention to clear materials from regulatory control during the operational phase.

283. In regard to clearance and its control, the authorized person shall adopt provisions to ensure that:

a. The clearance of radioactive waste complies with the requirements and conditions prescribed by the NRRC;

b. A formal system is in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of clearance;

c. Deliberate dilution of material, other than the dilution that takes place in normal operations shall not be carried out;

d. Any radiation markings will be removed from any material of which regulatory controls no longer apply.

Section 104: Radioactive Waste records and Report

284. The authorized person shall develop a suitable and comprehensive recording system for radioactive waste management activities under its responsibility with information related to the inventory and management of all radioactive waste that is generated, stored, transferred, discharged, cleared and disposed. The system shall allow for traceability of radioactive waste from the point of its collection through to its long-term storage and its disposal.

285. When waste is being transferred, associated records shall be provided to the authorized person of the subsequent step.

286. The authorized person shall provide reports on its radioactive waste management activities to the NRRC.

Chapter 16: Existing Exposure Situations

Section 105: Regulatory Requirement for Existing Exposure Situation

287. The requirements for existing exposure situations apply to the following:

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 this regulation;

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

b. Exposure due to commodities, including food, feed, drinking water and construction materials, that incorporate radionuclides deriving from residual radioactive material as stated in Article 287 (a).

c. Exposure due to natural sources, including:

(i) Rn-222 and its progeny and Rn-220 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 (A) concentration, in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction materials, and residual radioactive material in the environment;

(iii) Materials, other than those stated in 287 (c)(i) and (c)(ii) above, in which the activity (A) concentration of no radionuclide in either the uranium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity (A) concentration of K-40 does not exceed 10 Bq/g;

(iv) Exposure of aircrew and space crew to cosmic radiation.

Section 106: General Responsibilities for the Management of Existing Situations

288. Any person responsible for an exposure which, according to the criteria issued by the NRRC, is considered an existing exposure situation, shall arrange for the implementation of all appropriate measures for ensuring compliance with relevant requirements in this regulation.

289. Any person responsible for the management of an existing exposure situation shall ensure that all necessary arrangements for the proper radiological characterization of the exposure situation, including dose evaluations, are conducted, and a report following the relevant regulatory requirements is made available to the NRRC.

290. When the NRRC considers that the exposure situation cannot be disregarded from a radiation protection point of view, the responsible person shall ensure that the protection strategy for controlling the public exposure, prescribed by the NRRC is implemented.

291. Remedial and protective actions aiming to implement the protection strategy shall be subject to authorization by the NRRC.

292. In the implementation of the protection strategy, the responsible person shall:

a. Use the relevant references levels for public exposure, established by the NRRC, when planning and implementing remedial and protective actions;

b. Comply with the objectives and protection strategy approved by the NRRC to reduce public exposure when remedial and protective actions are determined to be justified;

c. Provide individuals subject to exposure with the information on potential health risks and on the means available for reducing their exposures and the associated risks.

Section 107: Specific Requirements for the Remediation of Areas with Residual Radioactive Material

293. Any person 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 for approval by the NRRC;

b. The remedial action plan ensures that the radioactive wastes arising from remedial actions are managed according to the relevant strategy approved by the NRRC for controlling and optimizing the public exposure in such a situation;

c. The remedial action plan is aimed at the timely and progressive reduction of the radiation risks and eventually, if possible, the removal of restrictions on the use of or access to the area;

d. Any additional dose received by members of the public as a result of the remedial actions is justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose;

e. In the choice of the optimized remediation option:

(i) The radiological impacts on people and the environment are considered together with non-radiological impacts on people and the environment, and technical, societal and economic factors;

(ii) The costs of the transport and management of radioactive waste, the radiation exposure of and health risks to the workers managing the waste, and any subsequent public exposure associated with its disposal are all taken into account;

f. A mechanism for public information is in place and any person affected by the existing exposure situation are involved in the planning, implementation and verification of the remedial actions, including any monitoring and surveillance

following remediation;

g. A monitoring program is established and implemented;

h. A system for maintaining adequate records relating to the existing exposure situation and actions taken for protection and safety is in place;

i. Procedures are in place for reporting to the NRRC on any abnormal conditions relevant to protection and safety.

294. Any person 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, to verify compliance with the requirements for waste management, and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the NRRC or other relevant authority;

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 shall submit a copy to the NRRC.

295. Any person responsible for post-remediation control measures shall establish and maintain for as long as required by the NRRC or other relevant authority 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.

Section 108: Occupational Exposure

296. Any responsible person shall ensure that the protection and safety of workers in existing situations comply with the appropriate reference levels and protection strategy approved by the NRRC for the radiological protection of the public in such exposure situations.

297. In cases where for a specific existing situation has been identified by the NRRC, the responsible person for the management of the existing situation shall ensure compliance with the relevant requirements with regards to occupational exposure.

Section 109: Control of the Aircrew Exposure Due to Cosmic Radiation

298. The aircraft company regulated by designated authority in the Kingdom shall ensure that the following measures are conducted to monitor the effective dose received by the air crew:

a. Assess the exposure of the crew concerned;

b. Keep the relevant personal dose records;

c. Take into account the assessed exposure when organizing working schedules to comply with the dose constraint established by the NRRC;

d. Inform female aircrew of the risk to the embryo or fetus due to exposure to cosmic radiation and of the need for early notification of pregnancy;

e. Apply the requirements of Section 79 in respect of notification of pregnancy.

299. In the event where the effective dose to the air crew from cosmic radiation is liable to exceed the reference level established by the NRRC, the relevant requirements set out in Chapter 10 shall apply.

Chapter 17: Emergency Exposure Situations

Section 110: General Responsibilities for the Emergency Response

300. Any person responsible for workers potentially involved in emergency response shall ensure for the protection and safety of the emergency worker as provided in this regulation.

Section 111: Protection of Workers in Emergency Exposure Situations

301. In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations shall be applied for emergency workers, in accordance with a graded approach, except

as required in Article 302 of this Section.

302. During emergency situation, no person shall be subject to exposure over 50 mSv other than the following situation:

a. For the purposes of saving a life or preventing severe injury;

b. When undertaking actions to avert a large collective dose; or

c. When taking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment.

303. In the exceptional circumstances of Article 302 of this Section, all reasonable efforts shall be taken to keep doses to emergency workers below the values prescribed by NRRC. Emergency workers undertaking actions due to which their doses could approach or exceed the values prescribed by NRRC shall do so only when the expected benefits to others clearly outweigh the risks to the emergency workers.

304. Emergency workers who undertake actions in which the doses received might exceed 50 mSv shall be ensured:

a. to perform their tasks voluntary;

b. to have been clearly and comprehensively informed in advance of the associated health risks, as well as of available measures for protection and safety;

c. to the extent possible, trained in the actions that they may be required to take.

305. All reasonable steps shall be taken to assess and record the doses received in an emergency by emergency workers. Information on the doses shall be obtained before any further occupational exposure if a worker has received a dose exceeding 200 mSv or at the request of the worker.

306. Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure. However, qualified medical advice shall be obtained before any additional occupational exposure if a worker has received a dose exceeding 200 mSv or at the request of the worker.

Section 112: Protection of Workers Involved in the Transition from an Emergency Exposure Situation to an Existing Exposure Situation

307. Workers undertaking work such as repairs to plant and buildings or activities for radioactive waste management or remedial work for the decontamination of the site and surrounding areas, including when the contamination is associated with an existing situation, shall be subject to the relevant requirements for occupational exposure specified in this regulation.

Appendix 1 :Categorization of Radioactive Sources[1]

For the categorization of a radioactive source the activity ratio A/D should be calculated. This should be done by taking the activity A of the concerned source (in TBq) and dividing it by the D value. The resulting ratio A/D should then be compared with the values tabulated in the right-hand

(1) NRRC is responsible to amend these classifications based on world best practices and evaluation of international norms.

column of Table 1. Table 2 shows the activity corresponding to a dangerous source (D value) for selected radionuclides used in common practices. The D values for additional radionuclides are specified by the NRRC.

Table 1. Categories for sealed sources used in common practices

Category	Ratio of activity in the source to activity that is considered dangerous (A/D)
1	A/D≥1000
2	1000> A/D≥10
3	10 > A/D≥1
4	1 > A/D≥0.01
5	0.01 > A/D and A > level for exemption[a]

[a] *Levels for exemption are specified by the NRRC*

For short half-life radionuclides and unsealed sources, the above method for the categorization may be applied, but the NRRC will determine the category of the concerned source on a case by case basis.

For situations in which radioactive sources are in close proximity to each other, such as in manufacturing processes (e.g. in the same room or building) or in storage facilities (e.g. in the same enclosure) the activity in the source shall be aggregated. In such situations, the summed activity of the radionuclide should be divided by the appropriate D value and the calculated ratio A/D compared with the ratios A/D given in Table 1. If sources with various radionuclides are aggregated, then the sum of the ratios A/D should be used in determining the category, in accordance with

the formula:

$$\text{Aggregate } A/D = \Sigma_n \frac{\Sigma_i Ai\, n}{Dn}$$

where

$A_{i,n}$ = activity of each individual source *i* of radionuclide *n*;

D_n = D value for radionuclide *n*.

Table 2. Activity [a] corresponding to a dangerous source (D value) for selected radionuclides.

Radionuclide	D value (TBq)	Radionuclide	D value (TBq)
Am-241	6×10^{-2}	Mo-99	3×10^{-1}
Am-241/Be	6×10^{-2}	Ni-63	6×10^{1}
Au-198	2×10^{-1}	P-32	1×10^{1}
Cd-109	2×10^{1}	Pd-103	9×10^{1}
Cf-252	2×10^{-2}	Pm-147	4×10^{1}
Cm-244	5×10^{-2}	Po-210	6×10^{-2}
Co-57	7×10^{-1}	Pu-238	6×10^{-2}
Co-60	3×10^{-2}	Pu-239/Be	6×10^{-2}
Cs-137	1×10^{-1}	Ra-226	4×10^{-2}
Fe-55	8×10^{2}	Ru-106 (Rh106)	3×10^{-1}
Gd-153	1×10^{0}	Se-75	2×10^{-1}
Ge-68	7×10^{-2}	Sr-90 (Y-90)	1×10^{0}
H-3	2×10^{3}	Tc-99m	7×10^{-1}
I-125	2×10^{-1}	Tl-204	2×10^{1}
I-131	2×10^{-1}	Tm-170	2×10^{1}
Ir-192	8×10^{-2}	Yb-169	3×10^{-1}
Kr-85	3×10^{1}		

[a] Since this table does not state which dose criteria were used, these D values cannot be used 'in reverse' to derive possible doses from exposure due to sources of known activity.

(a) with the new regulations.

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