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**NUCLEAR SAFETY AND RADIATION PROTECTION ACT**
(1995 No. 19)

**Nigeria Basic Ionizing Radiation Regulations 2020 (DRAFT)**

***Commencement:* ..... 2020**

**In exercise of the powers conferred on it by section 47 of the Nuclear Safety and Radiation Protection Act 1995 and of all other powers enabling it in that behalf, the Nigerian Nuclear Regulatory Authority, with the approval of the President, hereby makes the following Regulations -**

## PART 1
## GENERAL PROVISIONS

### 1. Entry into Force

These Regulations shall enter into force on

### 2. Objectives

(1) These Regulations specify the basic requirements:

(a) For protection of people against exposure to ionizing radiation, for the safety of radiation sources, for the safety of radioactive waste management, and for protection of the environment, hereinafter termed 'protection and safety';
(b) To prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources, so as to reduce the likelihood of accidental harmful exposure to such sources;
(c) To implement the Country's international commitments relevant to radiation safety.

(2) They are not intended to relieve an authorized legal person from the duty to take any additional actions as may be appropriate and necessary to protect the health and safety of people.

### 3. Scope

(1) These Regulations shall apply to protection against ionizing radiation only, which includes gamma rays, X rays and particles such as beta particles, neutrons, protons, alpha particles and heavier ions etc.

(2) These Regulations shall apply to all situations involving radiation exposure that is amenable to control. Exposures deemed not amenable to control are excluded from the scope of these Regulations such as $^{40}K$ in the body or cosmic radiation at the surface of the Earth that are not feasible to control

(3) These Regulations establish requirements that shall be fulfilled in all facilities and activities giving rise to radiation risks. For certain facilities and activities, such as nuclear installations, radioactive waste management facilities and the transport of radioactive material, other safety requirements, complementary to these Regulations shall also apply.

(4) These Regulations shall apply to the three categories of exposure: occupational exposure, public exposure and medical exposure.

### 4. Application

(1) These Regulations apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice in a planned exposure situation and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, , locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage and recycling or disposal of a radiation source within a practice
(2) These Regulations apply to the following practices in planned exposure situations:

(a) The production, supply and transport of radioactive material and of devices that contain radioactive material, including sealed sources and unsealed sources, and of consumer products;
(b) The production and supply of devices that generate radiation, including linear accelerators, cyclotrons, and fixed and mobile radiography equipment;
(c) The use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes, and the use of associated equipment, software or devices where such use could affect exposure to radiation;
(d) The use of radiation or radioactive material for education, training or research, including any activities relating to such use that involve or could involve exposure to radiation or exposure due to radioactive material;
(e) Any other practice as specified by the regulatory body.

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

(a) Facilities that contain radioactive material and facilities that contain radiation generators, including medical radiation facilities and irradiation facilities;
(b) Individual sources of radiation, including sources within the types of facility mentioned in para. (a), as appropriate, in accordance with the requirements of the regulatory body;
(c) Exposure due to material in any practice where the activity concentration in the material of any radionuclide in the uranium decay chain or thorium decay chain is greater than 1 Bq/g or the activity concentration of 40K is greater than 10 Bq/g;
(d) Radioactive waste resulting from applications and to radioactive waste management facilities and activities including:

    (i) Effluent discharges;
    (ii) Waste that contains only naturally occurring materials, whatever the origin of that waste;
    (iii) Disused radioactive sources.

(e) Any other radiation source specified by the regulatory body, including sources in the environment such as radon.
(f) The specific radioactive waste provisions apply only to waste arising from medical, agricultural, industrial, research and education applications, mining and milling activities, including associated radioactive waste management activities such as collection, segregation, characterization, classification, treatment, conditioning, and storage.
(g) These Regulations shall apply to intervention by legal persons authorized to possess radiation sources in the event of radiological emergencies involving their sources.

**5. Application of the principles of radiation protection**

(1) Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied for all exposure situations.

(2) For planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless it is justified

(3) For emergency exposure situations and existing exposure situations, each party with

responsibilities for protection and safety shall ensure, when relevant Regulations apply to that party that protective actions or remedial actions are justified and are undertaken in such a way as to achieve the objectives set out in a protection strategy.

(4) For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant Regulations apply to that party, that protection and safety is optimized.

(5) For planned exposure situations other than for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant Regulations apply to that party, specified dose limits are not exceeded.

(6) The application of the Regulations for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

RESPONSIBLE PARTIES

**6. Responsibility of the Authority:**

(1) The Authority shall be responsible for radiological protection and nuclear safety, so as to ensure the protection of life, health, property and the environment from the harmful effect of ionizing radiation, by ensuring compliance with these regulations.

(2) The Authority shall be responsible for the enforcement of these Regulation using a graded approach, in-line with international best practices to verify that all activities satisfy regulatory requirements.

(3) The Authority shall ensure that an emergency management system is established and maintained in line with the provisions of the Nigerian Nuclear and Radiological Emergency Regulations, which shall be integrated, to the extent practicable into the national emergency management plan on the territories and within the jurisdiction of the Federal Republic of Nigeria for the purposes of emergency response to protect human life, health and the environment in the event of a nuclear or radiological emergency.

**7. Responsibilities of Persons and Organizations**

(1) The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety, which cannot be delegated. Other parties shall have specified responsibilities for protection and safety.

(2) The Persons and Organizations responsible for protection and safety are:

(a) Registrants or licensees, or persons or organizations responsible for notified or authorized practices or sources within practices
(b) Employers, in relation to occupational exposure;
(c) Radiological medical practitioners, in relation to medical exposure;
(d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

(3) Other parties shall have specified responsibilities in relation to protection and safety. These other parties include:

(a) Suppliers of sources, providers of equipment and software, and providers of consumer products;
(b) Radiation Safety officers;
(c) Referring medical practitioners;
(d) Medical physicists;
(e) Medical radiation technologists;
(f) Qualified experts or any other party to whom a principal party has assigned specific responsibilities;
(g) Workers other than those listed in (a)–(f) in this paragraph;
(h) Ethics committees.

(4) The Legal Person in collaboration with the Radiation Safety Officer shall establish and implement a protection and safety programme that is appropriate for the exposure situation. The protection and safety programme shall:

(a) adopt objectives for protection and safety in accordance with the requirements of these Regulations;
(b) apply measures for protection and safety that are commensurate with the radiation risks associated with the exposure situation and that are adequate to ensure compliance with the requirements of these Regulations.

(5) The Legal Person in implementing the protection and safety programme shall ensure that:

(a) measures and resources that are necessary for achieving the objectives of protection and safety programme have been determined and are duly provided;
(b) The programme is periodically reviewed to assess its effectiveness and its continued fitness for purpose;
(c) A failure or shortcomings in protection and safety are identified, corrected, documented and measures are taken to prevent their reoccurrence;
(d) interested parties are consulted when the needs arise;
(e) Appropriate records are maintained.

(6) The Legal Person shall ensure that:
(a) all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification to carry out their responsibilities effectively with appropriate judgement and in accordance with procedures.

(b) (Qualified Experts, such as Radiation Safety Adviser (RSA), Engineering Service provider, Environmental Monitors, Waste Management Consultant, Dosimetry Service Providers (DSP) and other authorized service providers, accredited by the Authority are identified and are consulted as necessary on the implementation of these Regulations.

(7) The Qualified Experts shall:
(a) develop a management system manual for Technical Services in Radiation Safety in line with the Authority's Management System Guide, and submit to the Authority for approval

(b) not provide services to persons or Organizations that are not authorized by the Authority

(8) (a) For the purpose of paragraph (7) of this regulation and subject to (c) of this paragraph, registrant and licensee shall consult such suitable Qualified Experts that are necessary for the purpose of advising the registrant and licensee with respect to compliance with these Regulations and shall, in any event, consult one or more suitable Qualified Experts with regard to those matters as are set out in the Sixth Schedule to these Regulations.

(b) Where a Qualified Expert is consulted pursuant to the requirements of (a) above, the registrant and licensee shall appoint that Qualified Expert in writing and shall include in that appointment the scope of the advice that the Qualified Expert is required to give.

(c) Nothing in (a) above of this paragraph shall be construed as requiring registrant and licensee to consult a Qualified Expert where the only work with ionizing radiation undertaken by that registrant and licensee is work specified in the First Schedule to these Regulations

**8. Regulatory Inspection of Premises and Information**

The relevant principal parties shall permit access to appointed inspectors of the Authority to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspections.

**9. Non-Compliance and Accidents**

(1) In the event of contravention of any applicable requirement of these Regulations, principal parties shall:

(a) Notify the Authority within 24 hours
(b) Investigate the breach, its causes, circumstances and consequences;
(c) Take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;
(d) Report to the Authority as required on the causes of the breach, its circumstances, consequences, and on the corrective or preventive actions taken or to be taken;
(e) Take whatever other actions that are necessary as required by these Regulations.

(2) The communication of such a breach to the Authority shall be timely and it shall be immediate whenever an emergency exposure situation has developed or is developing.

(3) Whenever a situation involving the loss of control (e.g. loss, theft) radioactive source has occurred, or is occurring, the Authority shall be informed as soon as practicable.

(4) Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for enforcement in accordance with these Regulations.

**10. Enforcement**

An authorization to use a radiation source may be revoked, suspended or modified, or the possession of a radiation source may be prohibited upon finding an undue threat to health and

safety or non-compliance with applicable regulatory requirements. Legal persons responsible for notified or authorized practices or sources within practices are subject to fines for noncompliance with applicable regulations and regulatory requirements commensurate with the nature of the infraction. Willful violations or attempted violations of the regulations or requirements may be referred to Federal Ministry of Justice for prosecution under national criminal statutes and codes.

## PART II
## ADMINISTRATIVE REQUIREMENTS

### 11. General Obligations

No person or organization shall adopt, introduce, conduct, discontinue or cease a practice, or shall, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, , import, export, supply, provide, , , site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source within a practice other than in accordance with these Regulations.

### 12. Graded Approach

(1) The application of the requirements of these Regulations in planned exposure situations shall commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.(2) The application of these Regulations shall be in accordance with the graded approach and conform to any regulations specified by the Authority

### 13. Notification and Authorization

(1) - (a) Any person or organization intending to operate a facility or to conduct an activity specified in Regulations 4(2), 4(3) and 11 shall submit to the Authority a notification and, as appropriate, an application for authorization.

(b) - (i) Notwithstanding the provisions of Paragraph (2) and (3) of this regulation, where a radiation employer has notified work in accordance with paragraph (1)(a) of this regulation and subsequently makes a material change in that work which would affect the particulars so notified, he shall forthwith notify the Authority of such changes.

(ii) Nothing in paragraph (1)(b)(i) of this regulation shall be construed as requiring the cessation of the work to be notified except where the site or any part of the site in which the work was carried on has been or is to be vacated.

**Notification**

(2) ( a ) Any person or organization intending to carry out any of the actions specified in Regulation 11 shall submit a notification to the Authority of such an intention.

(b) Sequel to paragraph (2) (a) of this regulation,

(i) Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the Authority , of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible.

(ii) Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal.

(c) Without prejudice to the provisions of paragraphs (2) (a and b) of this regulation, no notification shall be required for any work specified in First Schedule to these Regulations.

(d)- (i) where a person or organization has notified work in accordance with paragraph 2(b)(ii) of this regulation and subsequently makes a material change in that work which would affect the particulars so notified, he shall forthwith notify the Authority of that change.

(ii) Nothing in paragraph (2)(d) (i) of this regulation shall be construed as requiring the cessation of the work to be notified except where the site or any part of the site in which the work was carried on has been or is to be vacated.

(e) Where the work involves clinical treatment of a person with the use of a radioactive medicinal product, it shall be sufficient compliance with paragraph (2) (a) of this regulation if the notification required under that paragraph is given as soon as practicable before the carrying out of that work.

AUTHORIZATION: REGISTRATION OR LICENSING

(3) Any person or organization intending to carry out any of the actions specified in Regulation 11 shall, unless notification alone is sufficient, apply to the Authority for authorization, which shall take the form of either registration or licensing or both, the person or organization shall:

(a) submit a duly completed Authorization Application Form to the Authority for the specific practice;
(b) submit to the Authority the relevant Minimum Requirements, which shall be practice specific, and other relevant information necessary to support the application;
(c) refrain from carrying out any of the actions specified in Regulation 11 until the registration or the licence has been issued;
(d) assess the nature, likelihood and magnitude of the expected exposures due to the source and take all necessary measures for protection and safety;
(e) , have a safety assessment made and submitted to the Authority as part of the application, if there is a possibility for an exposure to be greater than a level as specified by the Authority;
(f) as required by the Authority, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity.

(4) The authorisation mentioned under Paragraph (3) of this regulation may be:

(a) refused due to non-compliance with the Minimum Requirement in respect to the specific practice;
(b) granted subject to such terms and conditions as the Authority may, from time to time, determine;
(c) revoked in writing at any time.

(5) Where any person or organization to whom the authorisation was granted under Paragraph 4 of this regulation subsequently makes a material change to the circumstances relating to the authorisation, the person or organization shall forthwith notify the Authority of such changes.

(6) Any radiation employer to whom paragraph 4 of this regulation applies and who is aggrieved by the decision of the Authority may appeal to the Governing Board of the Authority -

**14. Exemption of Practices and Sources**

(1) Without prejudice to the provisions of Regulation 13 (3):

(a) Practices or sources for any work specified in First Schedule to these Regulations shall be exempted from some or all of the requirements of these Regulations as the Authority shall deem appropriate;
(b) The Legal Person for Practices or sources for any work specified in First Schedule to these Regulations shall apply for Exemption Certificate to be issued by the Authority

(2) The Authority shall not grant exemption for practices that are not justified.

(3) The following practices and sources within a practice shall be considered exempted from the specific safety requirements of these Regulations

(a) Radioactive materials in a moderate amount for which the total activity of a given nuclide present on the premises at any time or its activity concentration does not exceed the applicable exemption levels;
(b) Radioactive material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table 1.2 of First Schedule;
(c) Equipment containing radioactive material exceeding the quantities or concentrations specified in (a) and (b) above, provided that:

(i) The equipment containing radioactive material is of a type approved by the Authority;
(ii) It is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage;
(iii) It is in the form of an unsealed source in a small amount such as sources 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 1μSv/h at a distance of 0.1m from any accessible surface of the apparatus; or
(v) Necessary conditions for disposal of the equipment have been specified in the Regulations.

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

(i) They do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1μSv/h at a distance of 0.1m from any accessible surface of the equipment; or
(ii) The maximum energy of the radiation generated is no greater than 5keV

**1 5 . Responsibilities of Registrants and Licensees in planned exposure situations**

(1) Registrants and Licensees shall be responsible for protection and safety in planned exposure situations.

(2) Registrants and Licensees:

(a) shall bear the responsibility for setting up and implementing the technical and organizational measures that are necessary for protection and safety for the practices and sources for which they are authorized.

(b) may designate suitably qualified persons to carry out tasks relating to these responsibilities, but they shall retain the prime responsibility for protection and safety.
(c) shall document the names and responsibilities of persons designated to ensure compliance with the requirements of these Regulations .

(3) Registrants and Licensees shall notify the Authority of any intention to introduce modifications to any practice or source for which they are authorized and they shall not carry out any such modification unless it is specifically authorized by the Authority

(4) Registrants and Licensees shall:

(a) establish clear lines of responsibility and accountability for protection and safety for the sources for which they are authorized, and shall establish organizational arrangements for protection and safety;
(b) ensure that any delegation of responsibilities by a principal party is documented;
(c) for the sources for which they are authorized and for which a safety assessment is required in Regulation 13(3)(e) conduct such a safety assessment and keep it up to date in accordance with Regulation 25
(d) for the sources for which they are authorized and for which the Authority requires a prospective assessment to be made for radiological environmental impacts (see Regulation 13(3)(f) ), conduct such an assessment and keep it up to date;
(e) assess the likelihood and magnitude of potential exposures, their likely consequences and the number of individuals who may be affected by them;
(f) have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;
(g) **establish procedures for reporting on and learning from accidents and other incidents**;
(h) establish arrangements for the periodic review of the overall effectiveness of the measures for protection and safety;
(i) ensure that adequate maintenance, testing and servicing are carried out as necessary so that sources remain capable of fulfilling their design requirements for protection and safety throughout their lifetime;
(j) ensure safe management and control of all radioactive waste that are generated, and dispose of such waste in accordance with the **regulatory requirements**.

(5) Licensees shall ensure that appropriate safety measures are implemented throughout the lifecycle of radiation sources, from manufacture to their final disposal (cradle to grave),

(6) Licensees shall ensure a multilevel defence in depth is in place as provided in Regulation 24(3)

(7) Licensees 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 so as to prevent accidents as far as reasonably practicable. In this regards, the licensee shall make suitable arrangements as provided in Regulation 24(5)

(8) The licensee shall ensure that the safety of the facility or the waste is not jeopardized by any provision made for the purpose of complying with national or international requirements concerning safeguards of the material.

**16. Reporting to the Authority**

(1) Registrant and Licensees shall:

(a) Notify the Authority immediately of any event in which the dose limit specified in Schedule III is exceeded either by phone, e-mail or any other means.

(b) Notify the Authority by phone, email or any other means promptly not later than 24 hours after occurrence, of any unintended or accidental medical, public or occupational exposures.

(c) Submit to the Authority, within 30 days after occurrence any unintended or accidental medical, public or occupational exposures, a written report which states the cause of accidental exposure to include information on the doses, corrective measures and any other relevant information;

(d) Report a summary of the public exposure monitoring results to the Authority at approved intervals and promptly inform the Authority of any abnormal results which led to, or could lead to an increase of public exposure;

(e) Report at intervals to the Authority of any discharges of radioactive waste to the environment as specified in the licence and relevant regulations and promptly report any discharges exceeding the authorized limits;

(f) Report promptly to the Authority any releases of radioactive material to the environment above the clearance criteria established by the Authority, and submit a written report within 30 days;

(2) In addition to Paragraph 1(a-f), licensees shall submit the following report to the Authority:

(a) Radioactive source inventory data and subsequent changes to those data, except for routine movements of the source allowed in the authorization;
(b) Unusual events or incidents, such as:

(i) Loss of control over a radioactive source;

(ii) Unauthorized access to, or unauthorized use of, a source;

(iii) Discovery of any orphan sources;

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

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

**17. Investigations and feedback of information on the facility operation experience**

(1) Registrants and Licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant for protection and safety.

(2) Registrants and Licensees shall ensure that information on both normal operation and abnormal conditions that are significant for protection and safety is disseminated or made available, to the **Authority and** relevant parties. This information shall include, but not limited to:

(a) details of doses associated with given activities;
(b) data on maintenance;
(c) descriptions of events and information on corrective actions; and
(d) operating experience from other relevant facilities and activities.

(3) Registrants and Licensees shall conduct investigations as specified by the Authority 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; or
(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.

(4) The Registrant or Licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of its causes, or suspected causes, including a verification or determination of any doses received or committed and recommendations for preventing the reoccurrence of the event and the occurrence of similar events.

(5) The Registrant or Licensee shall:

(a) communicate to the Authority and to any other relevant parties, as appropriate, a written report of any formal investigation relating to events as prescribed by the Authority , including exposures giving rise to doses exceeding a dose limit.
(b) immediately report, within Forty Eighty (48) hours, to the Authority any event in which a dose limit is exceeded.

(6) The licensee shall where applicable make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer of information to the supplier on the use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and fabrication of the sources they have supplied

## 18. Clearance

Radiation sources, including substances, materials, radioactive waste and objects within authorized practices may be released from further compliance with the radiation protection and safety requirements of these Regulations provided that they comply with:

(a) Criteria for clearance or clearance levels established in Table 1.2 of First Schedule to these Regulations.

(b) Nigerian Radioactive Waste and Spent Nuclear Fuel Management Regulations

## PART III
## REQUIREMENTS FOR RADIATION PROTECTION

### 19. Justification of practices

(1) The following practices shall be deemed not justified:

(a) Practices, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person; except for justified practices involving medical exposure
(b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;
(c) Human imaging using radiation that is performed as a form of art or for publicity purposes.
(d) any other practice determined by the Authority, from time to time, as unjustified.

(2) Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed not justified. However in exceptional circumstances, where the Authority decides that the justification of such human imaging for specific practices is to be considered, the requirements as established by the Authority shall apply.

(3) Human imaging using radiation for theft detection purposes and the detection of concealed objects for anti-smuggling purposes shall normally be deemed not justified. However, in exceptional circumstances, where the Authority decides that the justification of such human imaging is to be considered, the requirements of Regulations 28 - 29 shall apply.

(4) Human imaging using radiation for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, the requirements of Regulations 28 - 29 shall apply.

### 20. Optimization of protection and safety

(1) Registrants and Licensees shall ensure that protection and safety is optimized.

(2) For occupational exposure and public exposure, Registrants and Licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety, in order to achieve the following objectives:

(a) To determine measures for protection and safety 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) To establish criteria, 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 accidents and for mitigating the consequences of those that do occur.

(3) For occupational exposure and public exposure, Registrants and Licensees shall ensure, as appropriate, that relevant constraints on dose and on risk are used in the optimization of protection and safety for any particular source within a practice. The dose constraint for public exposure is established in Third Schedule of this Regulation and shall be as established by the Authority

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

(5) For the Optimization of protection and safety in medical exposure, Regulation 42 shall apply.

**21. Dose limits**

Registrants and Licensees shall ensure that the exposures of individuals due to the practices for which the Registrants and Licensees are authorized are restricted, so that neither the effective dose nor the equivalent dose to tissues or organs exceeds the relevant dose limit specified in Third Schedule of these Regulations.

**22. Management for protection and safety**

(1) The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible**.**

PROTECTION AND SAFETY ELEMENTS OF THE MANAGEMENT SYSTEM

(2) The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

(3) The principal parties shall ensure that the management system is designed **and applied to enhance protection and safety by**:

(a) Applying the requirements for protection and safety coherently with other requirements, including requirements for operational performance, and coherently with guidelines for security;
(b) Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are **fulfilled**;
(c) Ensuring that protection and safety are not compromised by other requirements;
(d) Providing for the regular assessment of performance for protection and safety, and the application of lessons learned from experience;
(e) Promoting safety culture.

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

(5) The principal parties shall be able to demonstrate the effective fulfillment of the requirements for protection and safety in the management system.

(6) The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

(7) Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:

(a) Policies and procedures that identify safety as being of the highest priority are established;
(b) Problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;
(c) The responsibilities of each individual for safety are clearly identified and each individual is suitably trained and qualified;
(d) Clear lines of authority for decisions on safety are defined;
(e) Organizational arrangements and lines of communications are established that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the licensee.

SAFETY CULTURE

(8) The principal parties shall promote and maintain safety culture by:

(a) Promoting 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, while taking account 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.

HUMAN FACTORS

(9) The principal parties and other parties having specified responsibilities in relation to protection and safety, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring among other things that:

(a) Sound ergonomic principles are followed in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment, to minimize the possibility that operator errors could lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions could be misinterpreted.
(b) Appropriate equipment, safety systems and procedural requirements are provided, and other necessary provision is made to:

(i) reduce, as far as practicable, the possibility that human errors or inadvertent actions could give rise to accidents or to other incidents leading to the exposure of any person;
(ii) provide means for detecting human errors and for correcting them or compensating for them;
(iii) facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

(c) All employees shall be informed at least annually of the importance of effective measures for protection and safety and be trained in their implementation as appropriate.
(d) Training programmes shall be routinely evaluated and updated as necessary.

CONFIDENTIALITY OF INFORMATION

(10) Licensees shall establish information management systems, commensurate with the size and nature of the authorized activity, which ensure that:

(a) the confidentiality of information that it receives in confidence from another party is protected;
(b) information received in confidence from another party is only provided to a third party with the consent of the first party;

**23. Qualified Experts and Radiation Safety Officers**

(1) Licensees shall arrange for Qualified Experts as required under paragraphs 6 – 8 of Regulation 7, and also designate Radiation Safety Officer

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

(3) A Radiation Safety Officer shall be technically competent in radiation protection matters relevant to a given type of practice.

(4) An applicant may propose to use a Radiation Safety Officer in place of a Qualified Expert in radiation safety on the basis of the relatively low risk of the practice. The Radiation Safety Officer oversees the application of the requirements of these Regulations to that practice.

(5) Licensees shall provide the Authority with the letter of engagement and qualifications of the Qualified Experts and Radiation Safety Officer

**24. Prevention and mitigation of accidents**

(1) Registrants and Licensees shall apply good engineering practice and take all practicable measures to prevent accidents and to mitigate the consequences of such accidents should they occur.

*Good engineering practice*

(2) The Registrant or Licensee shall cooperate with other responsible parties, to ensure that the siting, location, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof are based on good engineering practice which shall:

(a) Take account of international and national standards;
(b) Be supported by managerial and organizational features, with the purpose of ensuring 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, so as to ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating the consequences of those accidents that do occur and restricting any possible future exposures;
(d) 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**.

*Defence-in-depth*

(3) Registrants and Licensees shall ensure that a multilevel (defence-in-depth) system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and the magnitude of the potential exposures is applied to sources for which the licensees are authorized.

(4) Licensees 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 accidents;
(b) Mitigating the consequences of any accidents that do occur;
(c) Restoring the sources to safe conditions after any such accidents.

*Accident prevention*

(5) The Registrant or Licensee for any facility or activity shall make suitable arrangements to:

(a) prevent reasonably foreseeable accidents in the facility or the activity;
(b) mitigate the consequences of those accidents that do occur;
(c) provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;

(d) ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;
(e) ensure that significant safety 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) ensure that maintenance, inspection and testing are carried out without undue occupational exposure;
(g) 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) ensure that there is a system for detection and response to allow for corrective action in a timely manner, to any abnormal operating conditions that could significantly affect protection and safety
(i) ensure that all relevant safety documentation is available in the appropriate local languages.

*Emergency preparedness and response*

(6) (a) the Registrant or Licensee shall prepare an emergency plan for the protection of people and the environment.

(b) the Registrant or Licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response as part of the emergency plan

(c) Registrant or Licensee shall make arrangements for emergency response at the scene which shall include :

(i) Provision for individual monitoring and area monitoring,
(ii) arrangements for medical treatment;
(iii) Arrangements for assessing and mitigating any consequences of the emergency.

(7) (a) Registrants and Licensees shall be responsible for the implementation of their emergency plans and prepare necessary action for effective response.

(b) Registrants and Licensees shall prevent the occurrence of conditions that could lead to a loss of control over a source or to the escalation of such conditions by:

(i) Developing, maintaining and implementing procedures to provide the means for preventing loss of control over the source and for regaining control over the source as **necessary**;
(ii) Making available equipment, instrumentation and diagnostic aids that may be needed;
(iii) Training and periodically retraining personnel in the procedures to be followed and **exercise the procedures**.

(8) Each Registrant and licensee responsible for sources, including radioactive waste, for which prompt intervention may be required, shall ensure that the emergency plan defines at the scene responsibilities and takes account of off-site responsibilities of response organizations appropriate for implementation of the emergency plan. Such emergency plans shall:

(a) Characterize the content, features and extent of a potential emergency taking into account the results of any hazard assessment and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
(b) Identify the various operating and other conditions of the source which could lead to the need for intervention;
(c) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
(d) Provide for protective actions and mitigation actions, and assign responsibilities to initiate and discharging such actions;
(e) Provide for rapid and continuous assessment of the accident as it proceeds and determine the need for protective actions;
(f) Assign responsibilities for notifying the relevant authorities and for initiating intervention;
(g) Provide procedures, including communication arrangements for contacting any relevant response organization (e.g. civil defence) and for obtaining assistance from firefighting, medical, police and other relevant organizations;
(h) Provide for training personnel involved in implementing emergency plans, which be rehearsed at suitable intervals based on requirements defined in paragraph 9c of Regulation 7;
(i) Provide for periodic review and updating of the plan

*Implementation of Intervention*

(9) The licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.

(10) The form, scale and duration of any justified intervention shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(11) Registrants and Licensees shall promptly notify the Authority when an accidental situation requiring intervention has occurred or is expected to occur and shall inform the Authority of:

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

## PART IV
## VERIFICATION OF SAFETY

### 25. Safety assessment

(1) The person or organization, as required under Paragraph (3)(e) of Regulation 13, or Registrants and Licensees, shall conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible.

(2) Safety assessments shall be conducted at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof as appropriate, so as to:

(a) identify the ways in which exposures could be incurred, taken account of the effects of external events as well as of events directly involving the source and associated equipment;
(b) determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, to make an assessment of potential exposures;
(c) assess the adequacy of the provisions for protection and safety.

(3) The safety assessment shall include, a systematic critical review of the:

(a) operational limits and conditions for the operation of the facility;
(b) ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;
(c) ways in which external factors could affect protection and safety;
(d) ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;
(e) implications for protection and safety of any modifications;
(f) implications for protection and safety of security measures or of **any modifications to security measures**;
(g) uncertainties or assumptions and their implications for protection and safety.

(4) The Registrant or Licensee in carrying out the safety assessment shall take into account factors that:

(a) could give rise to a substantial release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;
(b) could give rise to a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;
(c) could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or to control such occurrences;
(d) And the extent to which the use of redundant and diverse safety features that are independent of each other, so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposures.

(5) Registrants and Licensees shall ensure that the safety assessment is documented and, that it is independently reviewed under the relevant management system.

(6) Registrants and Licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met when:

(a) Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;
(b) Significant changes occur on the site that could affect the safety of the facility or of activities on the site;
(c) Information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;
(d) Any significant changes in activities are envisaged;
(e) Any relevant changes in guidelines or standards have been made or are **envisaged**.

(7) 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 seems desirable, any consequential modifications shall be made cautiously and only after favourable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

**26. Monitoring for verification of compliance**

(1) Registrants, Licensees and Employers shall conduct monitoring to verify compliance with the requirements for protection and safety.

(2) Registrants, Licensees and Employers shall ensure that:

(a) Monitoring and measurements of parameters are performed as necessary for **verification of compliance with the requirements of these Regulations**;
(b) Suitable equipment is provided and procedures for verification are implemented;
(c) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference traceable to Secondary Standard Dosimetry Laboratory (SSDL);
(d) Records of the results of monitoring, a verification of compliance,, tests and calibrations are maintained in accordance with these Regulations;
(e) The results of monitoring and verification of compliance are submitted tothe **Authority**.

**27. Inventory and Records**

(1) Registrant and Licensees shall establish, maintain and be able to retrieve records relating to:

(a) Inventory of sealed sources and radiation generators
(b) doses from occupational exposures;
(c) facilities and activities;
(d) Inventory of radioactive waste;
(e) Environmental Radiological monitoring
(f) events including non-routine release of radioactive material to the environment;
(g) decommissioning or closure of facilities;
(h) The transfer of radioactive sources;
(i) The testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of these Regulations, and
(j) Any other records as required by the Authority

(2) Individual sealed source records shall include the:
(a) Location of the source;
(b) Radionuclide;
(c) Radioactivity on a specified date;
(d) Serial number or unique identifier;
(e) Chemical and physical form;
(f) Source use history, including recording all movements into and out of the storage location;
(g) Receipt, transfer or disposal of the source;
(h) Other information, as appropriate, to enable the source to be identifiable and traceable.

(3) Licensees shall check inventory periodically to confirm that radioactive sources and radiation generators are in their assigned locations and under control.

## PART V
## HUMAN IMAGING USING RADIATION FOR PURPOSES OTHER THAN MEDICAL DIAGNOSIS, MEDICAL TREATMENT OR BIOMEDICAL RESEARCH

### 28. Justification of practices of any type of human imaging using radiation

(1) The justification process applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or as part of a programme of biomedical research 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

(2) Human imaging that has been determined to be justified through the process specified in paragraph (1) shall be subject to regulatory control.

### 29. Optimization of protection and safety

(1) Registrant or Licensee shall ensure that the appropriate optimization requirements for medical exposure in Paragraphs 2 – 14 of Regulations 43 and Paragraphs 2 – 4 of Regulations 44 are applied for human imaging using radiation, performed by medical personnel using medical radiological equipment, that exposes people to radiation for employment related, education, legal or health insurance purposes without medical referrals , and with dose constraints as established by the Authority in consultation with the relevant Professional bodies for such human imaging from time to time, instead of diagnostic reference levels.

(2) Registrants and Licensees shall apply the requirements for public exposure in planned exposure situations for 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 considered to give rise to public exposure, and ensure that optimization of protection and safety is subject to any dose constraints for public exposure set by the Authority.
(3) Registrants and Licensees 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.

(4) The Registrant or Licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the body, conforms with the standards of the International Organization for Standardization or Standards Organization of Nigeria.

PART VI
OCCUPATIONAL EXPOSURE

**30. Responsibilities of Employers, Registrants and Licensees for the protection of workers**

(1) Employers, Registrants and Licensees shall **be responsible for** the protection of workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations **and ensure** compliance with relevant requirements of these Regulations.

(2) Employers, Registrants and Licensees shall ensure that:

(a) Occupational exposure is controlled such that the relevant dose limits for occupational exposure specified in Third Schedule are not exceeded;
(b) Protection and safety is optimized in accordance with the requirements of these Regulations;
(c) Decisions with regard to measures for protection and safety are recorded and made available to relevant parties, through their representatives where appropriate, as specified by the Authority;
(d) Policies, procedures and organizational arrangements for protection and safety are established for implementing the relevant requirements of these Regulations, with priority given to design and technical measures for controlling occupational exposure;
(e) Suitable and adequate facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of occupational exposure;
(f) Necessary workers' health surveillance and health services for workers are **provided**;
(g) Appropriate monitoring equipment and personal protective equipment is provided and arrangements are made for its proper use, calibration, testing and maintenance;
(h) Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level **of competence**;
(i) Adequate records are maintained in accordance with the requirements of these **Regulations**;
(j) Arrangements are made to facilitate consultation of and cooperation with workers, through their representatives where appropriate, with regard to protection and safety on all measures necessary to achieve the effective application of these Regulations;
(k) Necessary conditions for promoting safety culture are provided.

(3) Employers, Registrants and Licensees shall:

(a) Involve workers in optimization of protection and safety;
(b) Establish and use constraints as part of optimization of protection and safety.

(4) Employers, Registrants and Licensees shall ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public.

(5) Employers, Registrants and Licensees shall take necessary administrative actions as to ensure that workers are informed that ensuring protection and safety is an integral part of a general occupational health and safety programme, 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.

(6) Employers, Registrants and Licensees shall record any report received from a worker that identifies circumstances that could affect compliance with the requirements of these Regulations, and shall take appropriate action.

(7) Employers shall comply with applicable national and local laws and regulations governing hazards in the workplace for the purpose of ensuring protection and safety.

(8) Employers, Registrants and Licensees shall facilitate compliance by workers with the requirements of these Regulations.

**31. Compliance by workers**

(1) Workers shall fulfill their obligations and carry out their duties for protection and safety by:

(a) following any applicable rules and procedures for protection and safety as specified by the employer, Registrant or Licensee;
(b) proper use of the monitoring equipment and personal protective equipment provided;
(c) cooperating with the employer, Registrant or Licensee with regard to protection and safety, and programmes for workers' health surveillance and programmes for dose assessment;
(d) providing to the employer, Registrant or Licensee such information on their past and present work that is relevant for ensuring their effective and comprehensive protection and safety and that of others;
(e) abstaining from any willful action that could endanger them or others and that is in contravention with these Regulations;
(f) Accepting such information, instruction and training in protection and safety as will enable them to conduct their work in accordance with the requirements of these Regulations.

(2) A worker who identifies circumstances that could adversely affect protection and safety shall report such circumstances to the employer, Registrant or Licensee as soon as possible.

**32. Cooperation between Employers, Registrants and Licensees**

(1) Employers, Registrants and Licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements of these Regulations for protection and safety.

(2) Registrant or Licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of these Regulations, if workers are engaged in work that involves or that could involve a source that is not under the control of their employer,

(3) Employer shall cooperate with Registrant or Licensee in:

(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 Registrant or Licensee;
(b) Specific assessments of the doses received by workers as specified in (a) above;
(c) A clear allocation and documentation of the responsibilities of the employer and those of the Registrant or Licensee for protection and safety.

(4) Registrant or **Licensee responsible for the source or for the exposure shall**:

(a) obtain from the Employers, including self-employed persons, the previous occupational exposure history of workers as specified in Regulation 34(11), and **any other necessary information**;
(b) provide appropriate information to the employer, including any available information relevant for compliance with the requirements of **these Regulations that the employer requests**;
(c) Provide both the worker and the employer with the relevant exposure **records**.

**33. Classification of Areas**

Employers, Registrants and Licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, **to ensure adequate** arrangements under the radiation protection programme**,**

CONTROLLED AREAS

(1) Registrants and Licensees shall designate as a controlled area any area in which specific measures for protection and safety are or could be required for:

(a) Controlling exposures or preventing the spread of contamination in normal operation;
(b) Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditionsand
(c) Any person working in the area, who is likely to receive an effective dose greater than 6mSv a year, or an equivalent dose greater than three-tenths of any relevant dose limit referred to in the Third Schedule of these Regulations, and/or where Time Average Dose Rate (TADR) is expected to exceed 7.5 µSv/h.

(2) Registrants and Licensees shall take account of the magnitude of the exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions; and the type and extent of the procedures required for protection and safety in defining the boundaries of any controlled area.

(3) Registrants and Licensees shall:

(a) Delineate controlled areas by physical means or, where this is not reasonably **practicable, by** some other suitable means.
(b) 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 shall specify exposure times.
(c) Ensure suitable and sufficient signs are displayed in suitable positions indicating that the area is a controlled area, the nature of the radiation sources in that area and the risks arising from such sources;
(d) establish measures for protection and safety, including, as appropriate, physical measures to control the spread of contamination and local rules and procedures for

controlled areas.

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

(f) **provide** at entrances to controlled areas:

(i) Personal protective equipment;
(ii) Equipment for individual monitoring and workplace monitoring;
(iii) Suitable storage for personal clothing.

(g) provide at exits from controlled areas:

(i) Equipment for monitoring for contamination of skin and clothing;
(ii) Equipment for monitoring for contamination of any objects or material being removed from the area;
(iii) Washing or showering facilities and other personal decontamination facilities;
(iv) Suitable storage for contaminated personal protective equipment.

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

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

SUPERVISED AREAS

(4) Registrants and Licensees shall designate as a supervised area any area:

(a) not already designated as a controlled area but for which occupational exposure conditions need to be kept under review, even though specific measures for protection and safety are not normally needed, or

(b) in which any person is likely to receive an effective dose greater than 1mSv a year, or an equivalent dose greater than one-tenth of any relevant dose limit referred to in the Third Schedule to these Regulations, and/or where Time Average Dose Rate (TADR) is expected to exceed 2.5 µSv/h

(5) Registrants and Licensees, taking into account the nature, likelihood and magnitude of exposures or contamination in the supervised areas, shall:

(a) delineate the supervised areas by appropriate means;

(b) Display suitable and sufficient signs giving warning of the supervised area are displayed, where appropriate, in suitable positions indicating the nature of the radiation sources and the risk arising from such sources.

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

34 **Local Rules, Procedures and Personal Protective Equipment**

(1) Employers, Registrants and Licensees shall following hierarchy of preventive measures:

(i) **Engineered controls**;
(ii) **Administrative controls**;
(iii) **Personal protective equipment**.

(2) Employers, Registrants and Licensees, in consultation with workers, or **through their representatives** shall:

(a) establish in writing 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 in the event **that such level is exceeded**;
(c) make the local rules, procedures, the measures for protection and safety known to those workers to whom they apply and to other persons who may be affected by them;
(d) ensure that any work in which workers are or could be subject to occupational exposure is adequately supervised and shall take all reasonable steps to ensure that the rules, procedures, and measures for protection and **safety are observed**;
(e) designate a radiation safety officer in accordance with the criteria established by the Authority.

(3) Employers, Registrants and Licensees shall ensure that:

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

(i) Protective clothing;
(ii) Respiratory protective equipment, the characteristics of which are **made known to the users**;
(iii) Protective aprons, gloves and organ shields.

(b) workers receive adequate instruction in the proper use **of respiratory protective equipment**
(c) Tasks requiring the use of certain personal protective equipment are **assigned only to workers who on the basis of medical advice are capable of safely sustaining** the extra effort necessary.
(d) Where the use of personal protective equipment is considered for any given task, account shall taken of any additional exposure that could result owing to the additional time taken or the inconvenience, and of any non-radiological risks that might be associated with using personal protective equipment while performing the task.
(e) All personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and, is tested **at regular intervals**.

**35 Monitoring of the Workplace**

(1) Registrants and Licensees shall cooperate with Employers to establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation safety officer and a qualified expert authorized by the Authority.

(2) Registrants and Licensees shall institute the appropriate type and frequency of workplace monitoring:

(a) 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 concentration in air, surface contamination, and their expected fluctuations; and on the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

(3) **Registrants and Licensees shall**:

a) generate records of the results of the workplace monitoring carried out and of the tests of monitoring equipment;
b) ensure that the records of the test are authorized by a qualified person; and
c) keep the records for at least 2 years from the respective dates on which they were made.

(4) Registrants and Licensees, shall cooperate with Employers to maintain such records and available to workers through their representatives where appropriate.

**36. Classification of Workers, Assessment of Occupational Exposure and Workers' Health Surveillance**

(1) Employers, Registrants and Licensees shall be responsible for making arrangements for assessment and recording of occupational exposures and for workers' health surveillance.

CLASSIFICATION OF WORKERS

(2) Employers, as well as self-employed persons, Registrants and Licensees shall designate as classified persons, employees who are submitted to occupational exposure as a result of their work in controlled or supervised area such employees shall be informed of their designations.

(a) Category A - classified person who work in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure or who is likely to receive an effective dose in excess of 6mSv per year or an equivalent dose, which exceeds three-tenths of any relevant dose limits

(b) Category B - classified person who work in a supervised area, or who occasionally enters a controlled area, and is likely to receive an effective dose greater than 1mSv a year or an equivalent dose greater than one-tenth of any relevant dose limit

(3) Employer, Registrant or Licensee shall not designate an employee as a classified person unless such -

(a) employee is 18 years or above; and

(b) employee has been certified medical fit for the work by an appointed doctor or employment medical adviser

(4) Employer, Registrant or Licensee shall continue to treat an employee as a classified person until at the end of a calendar year and except where -

(a) an appointed doctor or employment medical adviser so requires; or

(b) the employee is no longer employed by the same employer that capacity, which is likely to result in significant exposure to ionizing radiation during the remainder of the relevant calendar year.

(5) Employers, self-employed persons, Registrant and Licensees shall make arrangements with authorized Dosimetry Service Providers (DSP) that operate a quality management system for assessment of occupational exposure of workers, and on the basis of individual monitoring where appropriate. Such arrangements shall be made for-

(a) systematic assessments of such doses by the use of suitable individual measurement for appropriate periods or, where individual measurement is inappropriate, by means of other suitable measurements; and
(b) Generating and maintenance of dose records relating to each classified person.

(6) Occupational exposure for any category A – classified worker, shall be assessed on the basis of individual monitoring where appropriate, adequate and feasible. In cases where individual monitoring of the worker is inappropriate, inadequate or not feasible, the occupational exposure shall be assessed on the basis of the results of workplace monitoring and information on the locations and durations of exposure of the worker.

(7) Occupational exposure For any category B – classified worker, shall be assessed on the basis of the results of workplace monitoring or individual monitoring, as appropriate

(8) Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment, arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety; and to assess intakes of radionuclides and the committed effective doses.

**(9)** Where a dosimeter or other device used to make any individual measurement is lost, damaged or destroyed or it is not practicable to assess the dose received by a classified person over any period the employer shall:

(a) make an adequate investigation of the circumstances of the case with a view to estimating the dose received by that person during that period and –

(i) in a case where there is adequate information to estimate the dose received by the classified person, the employer shall arrange for the authorized DSP to enter a notional dose in the dose records of that person which shall be the proportion of the total annual dose limit for the relevant period; and

(ii) in any other case, the employer shall take reasonable steps to inform the classified person of that entry and arrange for the authorized DSP to identify the person of such entry and arrange for the authorized DSP to identify the entry in the dose records as an estimated dose or a notional dose as the case may be.

(b) at the request of the classified person or a person formerly employed by that employer as a classified person to whom the investigation made under Paragraph 9 of this regulation relates and upon reasonable notice, make available to such person a copy of the summary sent to the authorized DSP under paragraph (a)(i) of this regulation.

(10) - (a) Subject to paragraphs 10 (c) and (f) of this regulation, where an employer has reasonable cause to believe that the dose received by a classified person is greater or much lesser than that shown in the relevant entry of the dose records, he shall conduct adequate investigation of the circumstances of the exposure of such person to ionizing radiation and, if that investigation confirms his belief, the employer shall, where there is adequate information to estimate the dose received by the employee -

(i) Send to the authorized DSP , the adequate summary of the information used to estimate such dose;

(ii) arrange for the authorized DSP to enter such estimated dose in the dose record of such person and for the authorized DSP to identify the estimated dose in records as a special entry; and

(iii) notify the classified person accordingly.

(b) The employer shall make a report of any investigation carried out under paragraph (a) of this regulation and shall preserve a copy of that report for a period of 5 years from the date it was made.

(c) The provisions of paragraph (1) of this regulation shall not apply –

(i) in respect of a classified person subject only to an annual dose limit, more than 12 months after the original entry was made in the records; and
(ii) in any other case, more than 5 years after the original entry was made in the records.

(d) Where a classified person is aggrieved by a decision to replace a recorded dose by an estimated dose pursuant to paragraph (b) of this regulation, he may, by an application in writing to the Authority made within 3 months of the date on which he was notified of the decision, apply for that decision to be reviewed.

(e) Where the Authority concludes whether as a result of a review carried out pursuant to paragraph (d) of this regulation or otherwise that -

(i) there is reasonable cause to believe the investigation carried out pursuant to sub-paragraph (a) was inadequate; or
(ii) a reasonable estimated dose has not been established, the employer shall, if so directed by the Authority, re-instate the original entry in the dose record.

(f) The employer shall not, without the consent of the Authority, require the authorized DSP to enter an estimated dose in the dose record in any case where:

(i) the cumulative recorded effective dose is 20mSv or more in one calendar year; or
(ii) the cumulative recorded equivalent dose for the calendar year exceeds a relevant dose limit.

RECORDS OF OCCUPATIONAL EXPOSURE

(11) Employers, Registrants and Licensees shall maintain dose records for every worker for whom assessment of occupational exposure is required in Paragraph (2 - 10) of this regulation.

(12) Employers, Registrants and Licensees shall:

(a) ensure that each outside worker employed by him is provided with separate or individual radiation dose records; and
(b) make suitable arrangements to ensure that the particulars entered in the radiation records are kept up-to-date, during the continuance of the employment of the outside worker, and submitted to the Authority at such intervals as may be determined, from time to time, by the Authority.
(c) The radiation dose records shall include particulars provided in Fifth Schedule

(13) Records of occupational exposure for each worker shall be maintained 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 50 years after cessation of the work in which the worker was subject to occupational exposure.

(14) Records of occupational exposure shall include:

(a) Information on the general nature of the work in which the worker was subject to occupational exposure;
(b) Information on dose assessments, exposures and intakes at or above the relevant recording levels specified by the Authority and the data upon which the dose assessments were based;
(c) information on the dates of employment, doses, exposures and intakes for each employment where the worker was employed by more than one employer;
(d) Records of any assessments made of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, shall be distinguished from assessments of doses, exposures and intakes due to normal conditions of work and shall include references to reports of any relevant investigations.

(15) Employers, Registrants and Licensees shall:

(a) provide workers with access to records of their own occupational exposure;
(b) provide workers' health surveillance, to the supervisor of the programme, the Authority and the relevant employer with access to workers' dose records;
(c) facilitate the provision of copies of workers' dose records to new Employers when workers change employment;
(d) make arrangements for the retention of dose records for former workers
(e) In complying with (a)–(d) above, maintain the confidentiality of records.

(16) For the purposes of paragraph (5) of this regulation the employer, Registrant or Licensee shall make arrangements with the authorized DSP to include requirements for that service to:

(a) keep and submit to the Authority, quarterly records made and maintained pursuant to the arrangements or a copy thereof until the person to whom the records relates has or would have attained the age of 75 years or for at least 50 years from when they were made, whichever is earlier;

(b) provide the employer, Registrant or Licensee:

(i) at appropriate intervals with suitable summaries of the dose records maintained in accordance with sub-paragraph (a) of this paragraph;

(ii) such copies of the dose records relating to any of his employees as may be required from time to time;

(iii) when required, a record of the information concerning the dose assessment relating to a classified person who ceases to be an employee and to send such record to the Authority and a copy sent to the employer, Registrant and Licensee, and a record so made is referred to in this regulation as a "termination record";

(iv) provide summaries of all current dose records relating to the preceding year to the Authority on or before 31st March of the following year

(c) where a dose is estimated pursuant to paragraph (8) of this regulation, make an entry in a dose records and retain the summary of the information used to estimate that dose;

(d) Where the employer, Registrant or Licensee employs an outside worker, provide a dose records in respect of that outside worker to the Authority.

(17) If Employers, Registrants and Licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' dose records by the Authority or by a relevant employer, Registrant or Licensee, as appropriate.

WORKERS' HEALTH SURVEILLANCE

(18) Programmes for workers' health surveillance as required in Regulation 30(4)(f) shall be:

(a) based on the requirements in the health surveillance records;
(b) designed to assess the initial and continuing fitness of workers for their intended tasks.

(19) 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 Registrant or Licensee responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the regulatory requirements and other rules established by the Authority.

**37. Information, instruction and training**

(1) Employers, Registrants and Licensees shall provide workers with adequate information, instruction and training for protection and safety. Such information shall:

(2) (a) provide all workers with adequate information on:

(i) health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;
(ii) adequate instruction and training and periodic retraining in protection and safety;
(iii) adequate information on the significance of their actions for protection and safety;

(b) appropriate information, and adequate instruction and training and periodic retraining, for protection and safety to workers who could be involved in or affected by the response to an emergency with;

(c) records of the training provided to individual workers.

**38. Conditions of service**

(1) The conditions of service offered by Employers, Registrants and Licensees to 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 in accordance with the requirements of these Regulations.

(2) Employers shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the Authority or in the framework of the programme for workers' health surveillance in accordance with the requirements of these Regulations, that workers, for health reasons, may no longer continue in employment in which they are or could be subject to occupational exposure.

**39. Special arrangements for protection and safety for female workers and for persons under 18 years of age undergoing training**

(1) Employers, Registrants and Licensees shall make special arrangements for female workers, as necessary, for protection of the embryo or fetus and breastfed infants; And for protection and safety for persons under 18 years of age who are undergoing training.

(2) Employers, Registrants and Licensees, shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on the:

(a) risk to the embryo or fetus due to exposure of a pregnant woman;
(b) importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant or if she is breast-feeding;
(c) risk of health effects for a breastfed infant due to ingestion of radioactive substances.

(3) For female worker:

(a) Notification of the employer by the female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude the female worker from work.

(b) it shall be obligatory for such employee in pursuant to paragraph (a) of this regulation to inform the employer in writing as soon as possible after becoming aware of her pregnancy;

or if she is breast feeding.

(c) The employer of a female worker, who has been notified of her condition in pursuant to paragraph 3(a) – (b) of this regulation, 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.

(4) Employers, Registrants and Licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

(5) Employers, Registrants and Licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under 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.

## PART VII
## MEDICAL EXPOSURE

### 40. Responsibilities of Registrants and Licensees

(1) Registrants and Licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral from a medical practitioner, responsibility has been assumed for ensuring protection and safety; and the person subject to exposure has been informed of the expected benefits and risks.

(2) Registrants and Licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

(a) It is a radiological procedure that 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 programme;
(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 programme;
(c) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in paragraph 5a of this Regulation;
(d) The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

(3) Registrants and Licensees shall ensure that:

(a) No individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) as required in paragraph 8 of Regulation 41 and a radiological medical practitioner has assumed responsibility as specified in paragraph 5a of this Regulation.

(b) The requirements specified in paragraph 14 of Regulation 42 are fulfilled for the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

(4) Registrants and Licensees shall ensure that:

(a) No individual incurs a medical exposure as a carer or comforter unless he or she has received relevant information on radiation protection and has indicated an understanding of the associated radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure.

(b) The requirements specified in paragraph 13 of Regulation 42 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

(5) Registrants and Licensees 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 Paragraphs (2 – 8) of Regulation 41 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist as required in Paragraphs (2 – 4) of Regulation 2;
(b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure are specialized in the appropriate area;
(c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;
(d) For therapeutic radiological procedures, the requirements of these Regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Paragraphs 7, 8, 10 and 11 of Regulation 42, are fulfilled by or under the supervision of a medical physicist;
(e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Regulations for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Paragraphs 7, 8(a – b), 9, 10 and 11 of Regulation 42 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;
(f) Any delegation of responsibilities by a principal party is documented.

**41. Justification of medical exposures**

(1) Registrants and Licensees shall ensure that medical exposures are justified.

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

(3) Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, taking account of advances in knowledge and technological developments.

(4) The justification of medical exposure for an individual patient shall be carried out by the radiological medical practitioner in consultation with the referring medical practitioner as appropriate, and particularly taking account of, patient who are pregnant breast-feeding and paeadiatric to establish:

(a) The appropriateness of the request;
(b) The urgency of the radiological procedure;
(c) The characteristics of the medical exposure;
(d) The characteristics of the individual patient;
(e) Relevant information from the patient's previous radiological procedures.

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

(6) Justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.

(7) 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 programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

(8) The medical exposure of volunteers as part of a programme of biomedical research is deemed not justified unless it is in accordance with the provisions of the it is subject to approval by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority, board or council), and subject to dose constraints as specified in Second Schedule of these Regulations.

**42. Optimization of protection and safety**

(1) Registrants, Licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

DESIGN CONSIDERATIONS

(2) Registrants and Licensees, in cooperation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Standards Organization (ISO), International Electro-technical Commission (IEC) and the Standards Organization of Nigeria (SON), in addition to ensuring that the responsibilities stated in paragraph 1 of Regulation 51 are discharged. or other.

OPERATIONAL CONSIDERATIONS

(3) For diagnostic radiological procedures and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical radiation technologist, the medical physicist, and if appropriate with the radiopharmacist or radiochemist, shall ensure the use of: :

(a) An appropriate medical radiological equipment and software; and appropriate radiopharmaceuticals for nuclear medicine,;
( b ) Appropriate techniques and parameters to deliver the minimum necessary medical exposure that is required to fulfill the clinical purpose of the radiological procedure, taking account of relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels established by the Authority.

(4) For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient, the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

(5) For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist, d the medical radiation technologist and if appropriate with the radiopharmacist or radiochemist, shall ensure that for each patient, the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

(6) Registrants and Licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:

(a) Peadiatric patients subject to medical exposure;
(b) Individuals subject to medical exposure as part of an approved health screening programme;
(c) Volunteers subject to medical exposure as part of a programme of biomedical research;
(d) Relatively high doses to the patient;
(e) Exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant 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 breastfeeding patient having undergone a radiological procedure with radiopharmaceuticals.

CALIBRATION

(7) In accordance with paragraphs 5d and 5e of Regulation 40 the medical physicist shall ensure that:

(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;
(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the Authority;

(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;
(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a Secondary Standards Dosimetry Laboratory (SSDL).

DOSIMETRY OF PATIENTS

(8) Registrants and Licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

(a) Typical doses to patients for diagnostic radiological procedures;
(b) Typical doses to patients for image guided interventional procedures;,;
(c) 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, for therapeutic radiological procedures,;
(d) Typical absorbed doses to patients for therapeutic radiological procedures with unsealed sources.

DIAGNOSTIC REFERENCE LEVELS

(9) Registrants and Licensees shall ensure that:

(a) Local assessments, on the basis of the measurements required in Regulation 42 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**.

QUALITY ASSURANCE FOR MEDICAL EXPOSURES

(10) Registrants and Licensees, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of the Medical Physicists, Radiological Medical Practitioners, Medical Radiation Technologists and, for complex nuclear medicine facilities, Radiopharmacists and Radiochemists; and in conjunction with other health professionals as appropriate in applying the requirements of these Regulations in respect of management systems,.

(11) Registrants and Licensees shall ensure that programmes 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 thereafter;
(iii) After any major maintenance procedure that could affect protection and safety of patients;
(iv) After any installation of new software or modification of existing software that could affect protection and safety of patients.

(b) Implementation of corrective actions if measured values of the physical parameters mentioned in paragraph (a) of this regulation 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.

(12) Registrants and Licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

DOSE CONSTRAINTS

(13) Registrants and Licensees shall ensure that relevant dose constraints established by the Authority in consultation with the health Authority and relevant professional bodies are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

(14) Registrants and Licensees shall ensure that dose constraints specified or approved by the ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) on a case by case basis as part of a proposal for biomedical research **(paragraph 8 of Regulation** 41**)** are used in the optimization of protection and safety for **persons subject to exposure as part of a programme of biomedical research**.

**43. Pregnant or Breast-Feeding Patients**

(1) Registrants and Licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient might be pregnant or is breast-feeding.

(2) Registrants and Licensees shall ensure that signs in English and any local languages are placed in public areas, 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 medical practitioner, medical radiation **technologist or other 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.

(3) Registrants and Licensees 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 (paragraphs 2 and 3 of Regulations 41) and in **the optimization of protection and safety (paragraph 6 of Regulation** 42**)**.

(4) Registrants and Licensees 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 (paragraphs 2 and 4 of Regulations 41) and in the optimization of protection **and safety (paragraph 6 of Regulation 4**2**).**

**44. Release of patients after radionuclide therapy**

(1) Registrants and Licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

(2) The radiological medical practitioner 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 either a medical physicist or the facility's radiation protection officer that:

(a) The activity of radionuclides in the patient is such that doses that could be received by family members and the public would be in compliance with the criteria and guidelines established by the Authority for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or implanted sealed sources; and

(b) The patient, carer, comforter 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.

**45. Unintended and accidental medical exposures**

(1) Registrants and Licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures; and promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.

(2) Registrants and Licensees, in accordance with the relevant requirements of paragraph 8 of Regulations 21, paragraphs 5 – 6 of Regulation 24 and Regulations 50 -51, shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

INVESTIGATION OF UNINTENDED AND ACCIDENTAL MEDICAL EXPOSURES

(3) Registrants and Licensees shall promptly investigate any of the following **unintended or accidental medical exposures where**:

(a) medical treatment delivered to the wrong individual or to the wrong tissue or orga of a patient, using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from the values (over or under) prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;
(b) 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) exposure for diagnostic purposes is substantially greater than was **intended**;
(d) Any exposure arising from an image guided interventional procedure is **substantially greater than was intended**;
(e) there is inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;
(f) there is failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

(4) Registrants and Licensees shall, with regard to any unintended or accidental medical exposures investigated as required in Paragraph (3) of this regulation:

(a) Calculate or estimate the doses received and the dose distribution within the patient;
(b) Indicate the corrective actions required to prevent the reoccurrence 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 Authority , a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) – (c) of this regulation , **or any other** information as required by the Authority;
(e) Submit such written record to the Authority as soon as possible for significant unintended or accidental medical exposures and to the **relevant health authority**.
(f) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient, or the patient's carer, comforter, legal guardian of the unintended or accidental medical exposure.

**46. Reviews and records**

(1) Registrants and Licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.

RADIOLOGICAL REVIEWS

(2) Registrants and Licensees 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. 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.

RECORDS

(3) Registrants and Licensees shall maintain personnel records during the period of employment and shall make available to the authority, as required:

(a) Records of any delegation of responsibilities by a principal party (**as required in Paragraph (5)(f) of Regulation** 40**)**;
( b ) Records for education, training and competence of personnel in radiation protection.

(4) Registrants and Licensees shall maintain for a period as specified by the Authority and shall make available, as required,:

(a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;
(b) Records of dosimetry of patients, as required in Paragraph (8) of Regulation 42;
(c) Records of local assessments and reviews made with regard to diagnostic reference levels, as required in Paragraph (9) of Regulation 42;
(d) Records associated with the quality assurance programme, as required in Paragraph (11d) of Regulation 42.

(5) Registrants and Licensees shall maintain for a period as specified by the Authority and shall make available, as required, the following records for medical exposure:

(a) information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures for diagnostic radiology
(b) information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of **images acquired for** image guided interventional procedures
(c) the types of radiopharmaceuticals administered and their activity for nuclear medicine,;
(d) a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and **minimum** absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time for external beam radiation therapy or brachytherapy
(e) Exposure records for volunteers subject to medical exposure as part of **a programme of biomedical research**;
(f) Reports on investigations of unintended and accidental medical exposures **(as required in Paragraph (4d) of Regulation 4**8).

## PART VIII
## PUBLIC EXPOSURE

### 4 7 . Responsibilities of relevant parties specific to public exposure

GENERAL CONSIDERATIONS

(1) Registrants and Licensees, in cooperation with suppliers and providers of consumer products, shall apply the requirements of these Regulations, verify and demonstrate compliance as specified by the Authority, in relation to any public exposure for which they have

responsibility.

(2) Registrants and Licensees, in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source (or for closure and the post-closure period for waste disposal facilities), shall take into account the following:

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

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

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

(d) Uncertainties in the assessment of doses, especially in contributions to doses where the source and the representative person are separated in space and in time.

(3) Registrants and Licensees shall establish, implement and maintain:

(a) Policies, procedures and organizational arrangements for protection and safety in relation to public exposure, in accordance with the requirements of these Regulations;

(b) Measures for ensuring:

(i) Optimization of protection and safety;
(ii) Limitation of exposure of members of the public from such sources, in accordance with the authorization.

(c) Measures for ensuring the safety of such sources;
(d) **Provision for suitable and adequate** resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of exposures;
(e) Programmes for appropriate training of personnel having functions relevant to protection and safety of members of the public, as well as periodic retraining as required, to ensure the necessary level of competence;
(f) Provision for **appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure**;
(g) Adequate records of monitoring programmes;
(h) Emergency plans, procedures and arrangements, in accordance with the nature and magnitude of the radiation risks associated with the sources.

VISITORS

(4) Registrants and Licensees, **in cooperation with Employers shall**:

(a) apply the relevant requirements of these Regulations in respect of public **exposure for visitors to a controlled area or a supervised area**;
(b) 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 for protection and safety for visitors and for 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.

EXTERNAL EXPOSURE AND CONTAMINATION IN AREAS ACCESSIBLE TO MEMBERS OF THE **PUBLIC**

(5) Registrants and Licensees **that possess a source** that give rise to external exposure of members of the public shall ensure:

(a) The floor plans and arrangements of equipment for all new installations utilizing such sources, and all significant modifications to existing installations, are subject, to review and approval by the Authority prior to commissioning;
(b) Shielding and other measures for protection and safety, including access control, are provided for restricting public exposure, at open sites for some applications of industrial radiography.

(6) Registrants and Licensees 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.

**48. Consumer products**

(1) Providers of consumer products shall ensure that:

(a) the products are not made available to the public unless their use has been justified,
(b) their use has been exempted on the basis of the criteria specified in First Schedule or their provision to the public has been authorized.

(2) Providers **of the consumer** products shall provide documents to demonstrate compliance with the requirements in Regulations 34(2 – 8), during application for authorization;

(3) 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 these Regulations;
(c) plan for appropriate arrangements for the servicing, maintenance, **recycling or disposal of consumer products**.

(4) The designers, manufacturers and providers of consumer products shall ensure that **the concept of** optimization of protection and safety are applied on the design and manufacture of consumer products, with features that are likely to affect exposure during normal handling, transport and use, in the event of mishandling, misuse, accident or disposal. **The following shall be taken into consideration**:

(a) The various radionuclides that could be used in consumer products and their radiation types, energies, activities and half-lives;
(b) The chemical and physical forms of the radionuclides that could be used in consumer products and their significance for protection and safety in normal and abnormal conditions;
(c) The containment and shielding of radioactive substances in consumer products and access to these radioactive substances in normal **and abnormal conditions**;
(d) The need for servicing or repair of consumer products and ways in which **this could be done**;
(e) Relevant experience with similar consumer products.

(5) Providers of consumer products shall ensure that:

(a) a legible label is firmly affixed to a visible surface of each consumer product that states:

(i) that the consumer product contains radioactive substances and **identifies the** radionuclides and their activities;
(ii) that the provision of the consumer product to the public has **been authorized by the Authority**;
(iii) information on required or recommended options for **recycling or disposal**.

(b) information specified in paragraph (a) of this regulation is also printed legibly on the retail packaging of the consumer product.

(6) Providers of consumer products shall provide clear and appropriate information and instructions for each consumer product on:

(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**.

(7) Providers of consumer products shall provide information on safety and instructions on their transport and storage to product retailers.

**(8)** Providers of consumer products, who import consumer products, as exempt products, for sale and distribution shall include in the application to the Authority, a copy of manufacture authorization issued by regulatory authority in the country of manufacturer to distribution to members of the public in that country

**49. Monitoring and reporting**

(1) The Registrants and Licensees shall ensure that programmes for source monitoring and environmental radiological monitoring are in place and that the results from the monitoring are recorded and are made available.

(2) (a) Registrants and Licensees shall Establish and implement source and environmental **radiological monitoring** programmes to ensure that public exposure due to sources under their responsibility are adequately assessed to verify and demonstrate compliance with the authorization. These programmes shall include monitoring of the following, as appropriate:

(i) External exposure due to such sources;
(ii) Discharges;
(iii) Radioactivity in the environment;
(iv) Other parameters important for the assessment of public exposure.

(b) Maintain appropriate records of the results of the **radiological monitoring** programmes **and estimated doses to members** of the public.

(c) Report and make available to the Authority:

(i) the results of the **radiological** monitoring programme at approved intervals, including, 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 **radiological monitoring and retrospective assessments of doses to** the **representative person**.
(ii) any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the Authority.
(iii) any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with reporting criteria established by the Authority.

(d) Establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increase in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorized source or facility.

(e) Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts.

(f) Publish and make available on request, results from source and environmental **radiological monitoring programmes** and assessments of doses from public exposure.

## PART IX
## RADIATION GENERATORS AND RADIOACTIVE SOURCES

### 50. General Responsibilities

(1) The Registrant and licensee, in cooperation with other responsible parties, shall ensure that the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof are based on good engineering practice, which shall:

(a) Take account of national and international standards;
(b) Be supported by managerial and organizational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;
(c) Include adequate safety margins in the design, construction of the facility, and in operations involving the facility, to ensure reliable performance in normal operation, and

take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating the consequences of those accidents should they occur and also restricting any possible future exposures;

(d) Take account of relevant developments concerning technical criteria, including the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

(2) Registrants and Licensees shall make suitable arrangements with suppliers of radiation generators and radioactive sources, the Authority and other relevant parties 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 **is likely to** have implications for protection and safety for other users and possibility for improvements in protection and safety for radiation generators and radioactive sources.

(3) Registrants and Licensees in choosing a location to use or to store a radiation generator or radioactive source shall consider:

(a) Factors that could affect the safe management of and control over the **radiation generator or radioactive source**;
(b) Factors that could affect occupational and public exposure due to the radiation generator or radioactive source;
(c) The feasibility of Paragraphs 4(a) and 4(b) of this regulation in engineering **design.**

(4) In selecting a site for a facility that will contain large amount of radioactive material and with potential for the release of significant amounts of radioactive material, Registrants and Licensees shall take into account:

(a) features that might affect protection and safety;
(b) features that might affect the integrity or functioning of the facility; and
(c) the feasibility of carrying out off-site protective actions where necessary.

(5) Registrants and Licensees shall maintain an inventory that includes records **of the**:

(a) location and description of each radiation generator or radioactive **source for which they are responsible**;
(b) activity, form and other description specified in paragraph 2 of Regulation 27 of each radioactive source for which they are responsible.

(6) Registrants and Licensees shall provide appropriate information from their inventory records of radiation generators and radioactive sources to the Authority bi-annually.

(7) Registrants and Licensees shall keep radiation generators and radioactive sources under control to prevent loss or damage and unauthorized persons from carrying out any of the activities in Regulation 11, by ensuring that:

(a) Control over a radiation generator or radioactive source is **not relinquished except in compliance** with all relevant requirements specified in the registration or licence;
(b) The information Authority is promptly **provided with** information regarding a radiation generator or radioactive source that is lost, missing or not under control;

(c) A radiation generator or radioactive source is not transferred **unless the recipient** possesses the necessary authorization;
(d) An inventory, of radiation generators or radioactive sources is checked periodically in line with paragraph 6 of this regulation, to confirm that they are in their assigned locations and are under control.

**51. Design of Radiation Generators and Radioactive Sources**

(1) Registrants and Licensees who are manufacturers or suppliers of radiation generators and radioactive sources shall:

(a) Supply a well designed, manufactured and constructed radiation generator or radioactive source and device such that it;
  (i) Provide for protection and safety in accordance with the requirements of these Regulations;
  (ii) Meet engineering, performance and functional specifications;
  (iii) Meet quality standards commensurate with the significance for protection and safety of systems and components, including software;
  (iv) Provide clear displays, gauges and instructions on operating consoles in English language understandable to users.

(b) Ensure that radiation generators and radioactive sources are tested to demonstrate compliance with the relevant specifications.
(c) Make information available, in English and/or any local language understandable to users, on the proper installation and use of the radiation generator or radioactive source and its associated radiation risks, including performance specifications, instructions for operating and maintenance; and instructions for protection and safety.
(d) Ensure that the protection provided by shielding and by other protective **devices is optimized.**

(2) Registrants and Licensees shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in Second Schedule of these regulations and in accordance with the requirements of the Authority.

(3) The manufacturer of a radioactive source or a device containing a radioactive source shall ensure that, the source and its container are marked with the symbol recommended by the International Organization for Standardization (ISO) or Standard Organization of Nigeria (SON)

(4) Registrants and Licensees, in cooperation with manufacturers, shall ensure that, where practicable, sealed sources are identifiable and traceable.

(5) Registrants and Licensees shall ensure that:

(a) Radioactive sources are stored in an appropriate manner for protection and safety; when not in use
(b) arrangements for safe management and control are made before purchasing, or acquiring radiation generators and radioactive sources, including adequate financial provisions for its management where appropriate, **once it is has become disused or out of its useful life**.
(c) details of the arrangements in paragraph 5 (b) of this regulation , including copies of any contractual arrangements are submitted to the Authority.

**52. Supply and Procurement of Radioactive Sources**

(1) Licensee supplying and distributing of radioactive sources shall ensure that they only supply and distribute to authorized recipients.

(2) Licensees supplying radioactive sources or devices incorporating radioactive sources shall provide the recipient with all relevant technical information to permit their safe management.

## PART X
## RADIOACTIVE WASTE AND DISCHARGES

**53. Radioactive waste and discharges**

(1) Radioactive materials no longer in use shall be managed in compliance with the *Nigerian Radioactive Waste and Spent Nuclear Fuel Management Regulations* and any other relevant regulations.

(2).Registrants and Licensees shall ensure that radioactive waste and discharges to the environment are managed in accordance with the **Terms and Conditions of the authorization and any other relevant regulations**

**54. Radioactive Waste**

(1) Registrants and Licensees, in cooperation with suppliers shall:

(a) have the primary responsibility for the safe management of radioactive waste and shall take all necessary actions to ensure the safety of radioactive waste unless such responsibility has been transferred to another person or organization with the approval of the Authority;

(b) be responsible for on-site segregation, collection, characterization, and temporary storage of the radioactive waste arising from activities and discharge of exempt waste; and shall notify the Authority of all radioactive wastes that are not expected to decay to clearance levels within one year from the time of their generation.

(c) ensure that there is separate processing of radioactive waste of different types, where necessary by differences in factors such as radionuclide content, half-life, activity concentration, volume, and physical and chemical properties, taking into account the available options for storage and disposal of radioactive waste, without precluding the mixing of radioactive waste for purposes of protection and safety;

(d) ensure that activities for the predisposal management of and for the disposal of radioactive waste are conducted in accordance with the Terms and Condition of the authorization;

(e) not dispose of any radioactive waste unless the disposal facility designed and constructed specifically for this purpose is available and licensed by the Authority;

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

(g) maintain an inventory of all radioactive waste that is generated, stored, transferred or disposed of;
(h) develop and implement a strategy for radioactive waste management which shall include appropriate evidence for **optimization of** protection and safety.

**55. Discharges**

(1) Registrants and Licensees, in cooperation with suppliers, in applying for an authorization for discharges shall:

(a) determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;
(b) determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;
(c) assess the doses to the representative person due to the planned discharges;
(d) consider the environmental radiological impacts in an integrated manner with features of the system of protection and safety, as required by the Authority;
(e) submit to the Authority the findings of (a)–(d) above in accordance with, authorized limits on discharges and conditions for implementation as contained in the Nigerian Radioactive Waste and Spent Nuclear Fuel Management Regulations.

(2) Registrants and Licensees in relation to operational limits and conditions relating to public exposure outside the territory or other area under the jurisdiction or control of Nigeria shall:

(a) ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of Nigeria;

(b) comply with the Authority's established requirements for the control of discharges;
(c) arrange with the affected State the means for the exchange of information and consultations, with the Authority's approval,

(3) Registrants and Licensees shall review and modify their discharge control measures, in agreement with the Authority, 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.

(4) Registrants and Licensees who intend to import a sealed source containing any radioactive material for any practice shall:

(a) require the supplier, to receive the source back within six months after its useful lifetime as a condition of any contract for the purchase or transfer
(b) submit to the Authority a copy of relevant parts of the purchase or transfer document and obtain its authorization prior to entering the contract in force or accepting the source; and

## PART XI
## DECOMMISSIONING OF FACILITIES AND ACTIVITIES

**56. Decommissioning of facilities and activities**

(1) A graded approach shall be applied to the planning, conduct and completion of decommissioning.

(2) The Registrant and Licensee shall prepare and maintain a decommissioning plan throughout the lifetime of the facility, unless otherwise approved by the Authority, in order to show that the decommissioning can be accomplished safely to meet the defined end state. In this regard, the Registrant and Licensee shall:

(a) Prepare and submit an initial decommissioning plan in support of the licence application for the construction of the facility or at the time of applying for an authorization to operate the facility;
(b) Review and update periodically the initial decommissioning plan during operation, as prescribed by the Authority;
(c) Prepare without undue delay the initial decommissioning plan for facilities where one has not yet been prepared.

(4) The Registrant and Licensee shall retain the necessary resources, expertise and knowledge for decommissioning and shall keep records and documentation relevant to the design, construction, operation and decommissioning process during transition from operation to decommissioning.

(5) Registrant and Licensee shall prepare and submit a final decommissioning plan to the Authority for approval prior to the conduct of decommissioning phase and shall:

(a) ensure that the facility is maintained in a safe configuration until approval of the decommissioning plan;
(b) Ensure that the decommissioning plan states the methodology and criteria to demonstrate that the proposed end state has been achieved which include unrestricted use for most medical, industrial and research facilities;

(6) After shutdown, the responsibility for the facility may be transferred to a different organization which becomes the operating organization of the facility for decommissioning. Knowledge of the operational history of the facility shall be maintained and passed to the new operating organization. For such transfer of responsibility, the new operating organization shall have the necessary resources, expertise and knowledge.
(7) The Registrant and Licensee shall ensure adequate financial provisions are available to decommissioning the facility including the management of the resulting waste when needed, even in the event of premature shutdown in accordance with the national regulatory framework. The decommissioning cost for the facility shall be calculated.

(8) Financial assurance for decommissioning shall be included as part of the license application, and needs to be in place prior to initiation of construction or operation of the facility.

(9) If financial assurance for decommissioning an existing facility has not been obtained, appropriate funding provisions should be put in place as soon as possible. In any event, financial assurance shall be in place prior to approval of license renewal or license extension.

(10) Decontamination and dismantling techniques shall be chosen such that the protection of workers, the public and the environment is optimized and the generation of waste is minimized.

(11) Prior to using any new or untried methods for decommissioning, it shall be demonstrated that the use of such methods is justified and is addressed within the optimization analysis supporting the decommissioning plan. Such analyses shall be subject to review and approval by the Authority.

(12) On completion of decommissioning, the Registrant and Licensee shall demonstrate that the end state criteria as defined in the decommissioning plan and any additional regulatory requirements have been met. In this regards the Registrant and Licensee shall consider that:

(a) They could only be relieved of further responsibility for the facility after approval by the Authority;
(b) The facility shall not be released from regulatory control, nor shall authorization be terminated, until the Registrant and Licensee has demonstrated that the end state in the decommissioning plan has been reached and that any additional regulatory requirements have been met;
(c) On completion of decommissioning, appropriate records should be retained as specified by the Authority. A system shall be established to ensure that all records are maintained in accordance with the records retention requirements of the management system and the regulatory requirements;
(d) If waste is stored on the site, a revised or new, separate authorization, including requirements for decommissioning, shall be requested by the Registrant and Licensee and issued for the facility.

(13) The Registrant and Licensee shall prepare and submit to the Authority a final decommissioning report. This report shall document, in particular, the end state of the facility or site.

(14) If a facility cannot be released for unrestricted use, appropriate controls shall be maintained to ensure the protection of human health and the environment. In this case, Registrant and Licensee shall:

(a) Specify these controls which shall be subject to approval by the Authority. Clear responsibility shall be assigned for implementing and maintaining these controls;
(b) Ensure that in the case of restricted release of the facility or site from the regulatory control, appropriate arrangements for continuous controls are established to guarantee the protection of the workers, the public and the environment.

## PART XII
## TRANSPORT OF RADIOACTIVE MATERIALS

### 57. Transport of Radioactive Materials

Registrants and Licensees transporting radioactive sources, radioactive waste or any other radioactive material, either domestically or internationally shall do so in compliance with all applicable transport requirements of the *Nigerian Transport of Radioactive Materials Regulations and other relevant Regulations.*

## P A R T X I I I
## EMERGENCY EXPOSURE SITUATIONS

GENERIC REQUIREMENTS

### 58. Responsibilities of Licensees

(1) If an authorized practice or source including radioactive waste within a practice has a potential for an emergency affecting either workers or members of the public, the licensee shall prepare an emergency plan for the protection of people and the environment. As part of this emergency plan, the licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response. In relation to the arrangements for the emergency response at the scene by the licensee, the emergency plan shall include, in particular:

(a) Provision for individual monitoring, area, and arrangements for medical treatment;
(b) Arrangements for assessing and mitigating any consequences of an emergency.

(2) Licensees shall be responsible for the implementation of their emergency plans and shall be prepared to take any necessary action for effective response. To prevent the occurrence of conditions that could lead to a loss of control over a source or to the escalation of such conditions, licensees shall:

(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.

### 59. Emergency Preparedness and Response

Each licensee responsible for sources, including radioactive waste, for which prompt intervention may be required, shall ensure that the emergency plan defines at the scene responsibilities and takes account of off-site responsibilities of response organizations appropriate for implementation of the emergency plan. Such emergency plans shall:

(a) Characterize the content, features and extent of a potential emergency taking into account the results of any hazard assessment and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
(b) Identify the various operating and other conditions of the source which could lead to the need for intervention;

(c) Describe the methods and instruments for assessing the accident and its consequences on and off the site;
(d) Provide for protective and mitigation actions and assignment of responsibilities for initiating and discharging such actions;
(e) Provide for rapid and continuous assessment of the accident as it proceeds and determine the need for protective actions;
(f) Allocate responsibilities for notifying the relevant authorities and for initiating intervention;
(g) Provide procedures, including communication arrangements for contacting and obtaining assistance any relevant response organization such as civil defence, fire-fighting, medical, police and other relevant organizations;
(h) Provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals based on requirements defined in Regulation 22(9) in conjunction with designated authorities;
(i) Provide for periodic review and updating of the plan.

**60. Implementation of Intervention**

(1) The licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.

(2) The form, scale and duration of any justified intervention shall be optimized so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) Licensee shall promptly notify the Authority when an accidental **situation** requiring intervention arises or is expected to arise and shall keep the Authority informed of:

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

**61. Protection of Emergency Workers in an Emergency Exposure Situation**

(1) The response organization and employers responsible for ensuring compliance with the requirements in paragraphs (2) – (8) below shall be specified in the emergency plan

(2) In an emergency exposure situation, the relevant requirements for occupational exposure in planned exposure situations (Regulations 30- 40) shall be applied for emergency workers, in accordance with a graded approach, except as required in para. (3) of this Regulation.

(3) Response organizations and employers shall ensure that no emergency worker is subject to exposure in excess of 50 mSv other than:

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

(4) In the exceptional circumstances of Paragraph (3) of this Regulation, response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values set out in Table 4.2 of Fourth Schedule …..{*Schedule IV, Table IV-2 of GSR Part 3 [3]*}. In addition, emergency workers undertaking actions that doses could approach or exceed the values set out in Table 4.2 of Fourth Schedule …..{*Schedule IV, Table IV-2 of GSR Part 3 [3]*} shall do so only when the expected benefits to others clearly outweigh the risks to the emergency workers.

(5) Response organizations and employers shall ensure that emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily; have been clearly and comprehensively informed of the associated health risks in advance, available measures for protection and safety; and to the extent possible, trained in the actions that they may be required to take.

(6) 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 shall be subject to the relevant requirements for occupational exposure specified in these Regulations.

(7) Response organizations and employers shall take all reasonable steps to assess and record the doses received by emergency workers. Information of the doses received and information concerning the associated health risks shall be communicated to the workers involved.

(8) Workers who receive doses in an emergency exposure situation shall not normally be precluded from incurring further occupational exposure. However, qualified medical advice

## PART XIV
## EXISTING EXPOSURE SITUATIONS

### PUBLIC EXPOSURE

### 62. Responsibilities for remediation of areas with residual radioactive material

(1) The persons or organizations responsible for the planning, implementation and verification of remedial actions shall, ensure that:

(a) A remedial action plan, supported by a safety assessment, is prepared and is submitted to the Authority for approval.
(b) The remedial action plan is aimed at the timely and progressive reduction of the radiation risks and possible eventual removal of restrictions on the use or access to the area.
(c) Any additional doses received by members of the public as a result of the remedial actions are justified on the basis of the resulting net benefit, including consideration of the consequent reduction of the annual dose.
(d) In the choice of the optimized remediation option:

(i) Radiological impacts on people and the environment are considered together with non-radiological impacts on people and the environment, and with 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 radioactive waste, and any subsequent public exposure associated with its disposal are all taken into account.

(e) A mechanism for public information is in place and interested parties are involved in the planning, implementation and verification of the remedial actions, including any monitoring following remediation.
(f) A monitoring programme is established and implemented.
(g) A system for maintaining adequate records relating to the existing exposure situation and to actions taken for protection and safety is in place.
(h) Procedures are in place for reporting to the Authority on any abnormal conditions relevant to protection and safety.

(2) The person or organization 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 conduct of a safety assessment;
(c) monitor the area regularly during the remediation to verify levels of contamination, compliance with the requirements for radioactive waste management, and to enable the detection of any unexpected levels of radiation and the need for modification of the remedial action plan subject to the Authority's approval ;
(d) perform a radiological monitoring after completion of remedial actions to demonstrate that the end point conditions, as established in the remedial action plan, have been met;
(e) prepare and retain a final remediation report and submit a copy to the Authority.

(3) The person or organization responsible for post-remediation control measures shall establish and maintain, for as long as required by the Authority, an appropriate programme, including any necessary provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

(4) The conditions prevailing after the completion of remedial actions, if the Authority has imposed no restrictions or controls, shall be considered as background conditions for any new facilities and activities or for habitation on the land.

OCCUPATIONAL EXPOSURE

**63. Exposure in workplaces**

(1) The requirements in respect of public exposure stated in Regulation 62 shall be applied for protection and safety for workers in existing exposure situations, other than in those specific situations identified in Paragraph (2 – 6) of this regulation

REMEDIATION OF AREAS WITH RESIDUAL RADIOACTIVE MATERIAL

(2) Employers shall ensure that the exposure of workers undertaking remedial actions is controlled in accordance with the relevant requirements on occupational exposure in planned exposure situations as established in Part VI.

EXPOSURE DUE TO RADON IN WORKPLACES

(3) Employers shall ensure that activity concentrations of $^{222}Rn$ in workplaces are as low as reasonably achievable below the reference level established by the Authority, and protection is optimized.

(4) Employer shall ensure that relevant requirements for occupational exposure in planned exposure situations as stated in Part II of these regulations apply, where activity concentration of $^{222}Rn$ in workplaces remains above the reference level established by the Authority despite all reasonable efforts to reduce it.

EXPOSURE OF AIRCREW AND SPACE CREW DUE TO COSMIC RADIATION

(5) Where assessment of the exposure of aircrew due to cosmic radiation is necessary, the doses received by aircrew from occupational exposure to cosmic radiation shall not exceed the dose limits for occupational exposures given in Third Schedule to these Regulations

(6) In accordance to the framework established by the Authority for assessment of occupational exposure to cosmic radiation:

(a) Where the doses of aircrew are likely to exceed the reference level, as established by the Authority, Employers of aircrew shall:

(i) implement a personnel monitoring in pursuance to Regulation 30;
(ii) assess and keep records of doses;
(iii) make records of doses available to aircrew; and
(iv) make records of doses available to the Authority.

(b) Employers shall:

(i) 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;
(ii) apply the requirements of Regulation 40(1-3) in respect of notification of pregnancy.

## PART XV
## MISCELANEOUS PROVISIONS, OFFENCES AND PENALTIES

### 64. Applicability of other Regulations and Requirements, and Resolution of Conflicts

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

(2) Nothing in these Regulations shall be construed as relieving Employers from complying with applicable national and local laws and regulations governing safety.

(3) If a conflict exists between requirements contained herein and other laws or regulations, the Authority shall be notified of such conflict in order to initiate steps towards resolution.

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

### 65. Additional Requirements

The Licensee shall comply with additional requirements imposed by the Authority by other Regulations, order, or conditions of an authorization, in addition to those established in these Regulations, as deemed appropriate or necessary to:

(a) Protect health;
(b) Protect the environment; or
(c) Minimize risk from radiation hazards

### 66. Authorization Fees

The Authority, with the approval of the Board, may prescribe -

(a) the fees payable in respect of any licence;

(b) the classification of licences;

(c) the inspection, at any such interval as may be deemed necessary, of any irradiating device or radioactive materials and the fees to be paid in respect of such inspections; and

(d) (d) any other actions, including changes to fees charged, that may be deemed necessary in order to meet the needs of the time, to carry out the provisions of these Regulations.

### 67. Enforcement

(1) Any person or organization who -

(a) without reasonable excuse, fails to produce a licence which he is required by these Regulations to have; or

(b) willfully obstructs a Radiation Protection/Safety Officer or any other authorized officer in the exercise of his duties under these Regulations; or

(c) contravenes any other provisions of these Regulations, commits an offence under these Regulations.

(2) Pursuant to paragraph (1) of this regulation, Legal persons responsible for notified or authorized practices or sources within practices are subject to fines for non-compliance with applicable regulations and regulatory requirements commensurate with the nature of the infraction, in line with the Enforcement Policy of the Authority, and shall be liable on conviction to a fine or Penalty prescribed in the Enforcement Policy of the Authority.

(3) Willful violations or attempted violations of the regulations or requirements may be referred to the Nuclear Security Council.

(4) Where the offence under these Regulations is committed by a body corporate, the offender shall on conviction be liable a fine or Penalty prescribed in the Enforcement Policy of the Authority and every director, secretary or manager of the body corporate shall be proceeded against accordingly unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regards to the nature of his functions and the circumstances of the case.

**68**. **Citation**

These Regulations may be cited as the Nigeria Basic Ionizing Radiation Regulations 2020

**DEFINITIONS**

*The following definitions apply for the purposes of these Regulations.*

**"the Act**" means the Nuclear Safety and Radiological Protection Act No. 19, 1995;

**"absorbed dose, *D"*** The fundamental dosimetric quantity *D*, defined as:

$$D = \frac{d\varepsilon}{dm}$$

**where** dε 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 matter by irradiation of that matter.

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

$$A(t) = \frac{dN}{dt}$$

where d*N* is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval d*t*.

**"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.

**"approval"** The granting of consent by the Authority.

**"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.

**"the Authority" means the Nigerian Nuclear Regulatory Authority established under Section 1 of the Act**;

**"authorized limit***" means* A limit on a measurable quantity, established or formally accepted by a Authority.

**"authorization"** The granting by a Authority or other governmental body of written permission for a person or organization (the operator) to conduct specified activities.

**"bioassay"** Any procedure used to determine the nature, activity, location or retention of radionuclides in the body by direct (in vivo) measurement or by in vitro analysis of material excreted or otherwise removed from the body.

**"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 regulatory control by the Authority from radioactive material or radioactive objects within notified or authorized practices.

**"clearance level"** A value, established by the Authority and expressed in terms of activity 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 dose"*** committed equivalent dose or committed effective dose

**"committed effective dose, $E(\tau)$"** The quantity E(τ), defined as:

$$E(\tau) = \sum_T W_T H_T(\tau)$$

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

**"committed equivalent dose, $H_T(\tau)$" The quantity HT(τ) defined as**:

$$\boldsymbol{H_T(\tau) = \int_{t_0}^{t_0+\tau} H_T(t).\, dt}$$

where $t_0$ is the time of intake, $H_T(t)$ is the equivalent dose rate at time $t$ in tissue or organ T and $\tau$ is the integration time elapsed after an intake of radioactive **substances.** When $\tau$ is not specified, it will be taken to be 50 years for adults and **the time to age 70 years for intakes by children**.

**"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.

**"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.

**"decorporation"** The biological processes, facilitated by a chemical or biological agent, by which incorporated radionuclides are removed from the human body.

"**deterministic effect"** A radiation induced health effect for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose.

> ***severe deterministic effect.*** A deterministic effect that is fatal or life threatening or results in a permanent injury that reduces quality of life.

**"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**.

"**disposal"** Emplacement of waste in an appropriate facility without the intention of retrieval

.**“Dose”** A measure of the energy deposited by radiation in a target.

- 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 constrain” Mean a prospective and 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 the effective dose or the equivalent dose to individuals in **planned exposure situations that is not to 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:

$$E = \sum_T W_T H_T$$

where $H_T$ is the equivalent dose in tissue or organ T and $w_T$ is the tissue weighting factor for tissue or organ T. From the definition of equivalent dose, it follows that:

$$E = \sum_T W_T \sum_R W_R D_{T,R}$$

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.

**“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 action level (EAL)”** A specific, predetermined, observable criterion used to detect, recognize and determine the emergency class.

**“emergency arrangements”** The integrated set of infrastructural elements necessary to provide the capability for performing a specified function or task required in response to a nuclear or radiological emergency. These elements may include authorities and responsibilities, organization, coordination, personnel, plans, procedures, **facilities, equipment** or **training**.

**“emergency class”** A set of conditions that warrant a similar immediate emergency response.

**“emergency exposure situation”** A situation of exposure that arises as a result of an accident, a

malicious act or other unexpected event, 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 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 or organization with recognized responsibilities, commitments and duties towards a worker in the employment of the person or organization 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.

"**equilibrium equivalent concentration (EEC)"** The activity concentration of $Rn^{222}$ or $Rn^{220}$ in radioactive equilibrium with its short lived progeny that would have the same potential alpha energy concentration as the actual (non-equilibrium) mixture.

**"equilibrium factor"** The ratio of the equilibrium equivalent activity concentration of $^{222}$Rn to **the actual 222Rn activity concentration**.

**"equivalent dose, $H_T$" The quantity** $H_{T,R}$, defined as:

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

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 values of $w_{R,}$ the equivalent dose is:

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

"**event"** In the context of the reporting and analysis of events, an event is any occurrence unintended by the operator, including operating error, equipment failure or other 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"** The determination by the Authority that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection **irrespective of the actual level of the doses or risks**.

**"exemption level"** A value, established by the Authority and expressed in terms of activity concentration, total activity, 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**.

***"external exposure"*** means Exposure to radiation from a source outside the body.

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

**"facilities and activities"** A general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be subject to exposure to radiation from naturally occurring or artificial sources.

**"feed" Any single material or multiple materials, whether processed,** semi-processed or raw, that is or are intended to be fed directly to food **producing animal**

**"food"** Any substance, whether processed, semi-processed or raw, that is intended **for human consumption**.

**"graded approach"** For a system of control, such as a regulatory system or a safety system, 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.

**"hazard assessment"** Assessment of hazards associated with facilities, activities or sources within or beyond the borders of a State in order to identify:

(a) Those events and the associated areas for which protective actions may be **required within the State**;
(b) The actions that would be effective in mitigating the consequences of such events.

"**health authority"** A governmental authority (at the national, regional or local level) that is responsible for policies and interventions, including the development of standards and the provision of guidance, for maintaining or improving human health, and **that has the legal power** of **enforcing such policies and interventions**.

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

**"health screening programme"** A programme in which health tests or medical examinations are performed **for the purpose of early detection of disease**.

**"health surveillance"** See workers' health surveillance.

**"hereditary effect"** A radiation induced health effect that occurs in a descendant of the exposed person.

"**ICRU sphere"** International Commission on Radiation Units sphere is used as a reference phantom in defining dose equivalent quantities. A sphere of 30 cm diameter made of tissue equivalent material with a density of 1 g/cm$^3$ and a mass composition of 76.2% oxygen, 11.1% carbon, **10.1% hydrogen and 2.6% nitrogen**.

"**incident"** Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

**"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 for the purpose of detecting concealed objects on or within the human body or within cargo or a vehicle.

**"intake"** The act or process of taking radionuclides into the body by inhalation or ingestion or **through the skin. Also, the activity of a radionuclide taken into the body in a given time period** or **as a result of a given event**

**"interested party"** A person, company, etc., with a concern or interest in the activities and performance of an organization, business, system, etc.

***"internal exposure"*** means exposure to radiation from a source within the body

**"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.

**“ionizing radiation”** See radiation.

**“justification” (**1) 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) 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.

“**kerma, *K*”** The quantity *K*, defined as:

$$K = \frac{dE_{tr}}{dm}$$

where d$E_{tr}$ is the sum of the initial kinetic energies of all charged ionizing particles liberated by uncharged ionizing particles in a material of mass d*m*.

“legal person” means any person , organization, corporation, partnership, firm, association, trust, estate, public or private, or other persons designated in accordance with national legislation who or which has responsibility as authority for any action having implications for protection and safety.

**“licence”** A legal document issued by the Authority granting authorization to perform specified activities relating to a facility or activity.

“**Licensee” The holder of a current licence, a person or organization having overall responsibility for a facility or activity**

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

***“*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 Authority for safe operation of an authorized facility.

**“linear–no threshold (LNT) hypothesis”** The hypothesis that the risk of stochastic effects is directly proportional to the dose for all levels of dose and dose rate below those levels at which deterministic effects occur.

**“lung absorption type”** A classification used to distinguish between the different rates at which inhaled radionuclides are transferred from the respiratory tract to the blood.

"**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 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 programme of biomedical research.

**"medical physicist"** A health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the subfields (specialties) of medical physics.

**"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[60] that either delivers an exposure to 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 $^{60}$Co 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 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 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 Authority by a person or organization to notify an intention to carry out a practice or other use of a source.

**“nuclear fuel cycle”** All operations associated with the production of nuclear energy.

**“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”** “ An emergency in which there is, or is perceived to be, a hazard due to: The energy resulting from a nuclear chain reaction or from the decay **of the products of a chain reaction; or** Radiation exposure

**“(nuclear) safety”** The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the **public and the environment from undue radiation hazards.**

**“(nuclear) security”** The prevention of, detection of, and response to, criminal or intentional unauthorized acts involving or directed at nuclear material, radioactive material, associated facilities, or associated activities.

**“occupancy factor”** A typical fraction of the time for which a location is occupied by an **individual or group**.

**“occupational exposure” Exposure of workers incurred in the course of their work**.

**“operator”** means Any person or organization applying for authorization or authorized and/or responsible for *safety* when undertaking *activities* or in relation to any *nuclear facilities* or *sources* of *ionizing radiation*

**“operational intervention level (OIL)”** set level of a measurable quantity that corresponds to a generic criterion.

**“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 radiation dose to the patient commensurate with **the medical purpose**.

**“personal dose equivalent, $H_p(d)$”** the dose equivalent in soft tissue below a specified point on the body at **an appropriate depth d**.

**“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 introduces additional sources of exposure or additional exposure pathways, or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure **of people or the number of people exposed**.

**"Principal parties"** means the person having the main responsibilities for the application of these regulations. These include registrants, licensees, employers

**"projected dose"** the dose that would be expected to be received if planned protective actions were not taken.

**"protection (against radiation)"** *radiation protection (also radiological protection).* The protection of people from harmful effects of exposure to ionizing radiation, and the means **for achieving this**.

**"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**.

"**protective task"** means the generation of at least those *protective actions* necessary to ensure **that the safety task required by a given initiating event is accomplished**

**"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, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, 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 term 'radiation' refers only to ionizing radiation unless otherwise stated.

*ionizing radiation.* For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s).

**"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" -** *means* 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"** See protection.

**"radiation protection officer"** a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the Registrant, Licensee or employer to oversee the application of regulatory requirements.

"**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.

"**radioactive (adjective)"**

1. Exhibiting radioactivity; emitting or relating to **the emission of ionizing radiation or particles**.

2. Designated in national law or by the Authority as being subject to regulatory control because of its radioactivity.

**"radioactive discharges"** - *Radioactive substances* arising from *sources* within *facilities and activities* which are discharged as gases, aerosols, liquids or solids to the *environment*, generally with the purpose of dilution and *dispersion*

**"radioactive material"** material designated in national law or by a Authority as being subject to regulatory control because of its radioactivity.

**"radioactive source"** a source containing radioactive material that is used as a source of radiation.

"**radioactive substance"** means any substance, which contains one or more radionuclides whose activity cannot be disregarded for the purposes of radiation protection;

**"radioactive waste"** for legal and regulatory purposes, material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater

than clearance levels as established by the Authority;

**"radioactive waste management"** all administrative and operational activities involved in **the handling, pretreatment, treatment, conditioning, transport, storage and disposal of** radioactive waste.

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

**"radiological medical practitioner"** a health professional with specialist 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 education and training in** radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy.

"**radon" any combination of isotopes of the element radon.**

"**radon progeny" the short lived radioactive decay products of** $^{220}$Rn and of $^{222}$Rn.

"**reference level"** for an emergency exposure situation or an existing exposure situation, the level of dose, risk or activity 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.

**"Registrant" the holder of a current registration**

**"registration"** a form of authorization for practices of low or moderate risks whereby the person or organization responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the Authority. The practice or **use is authorized with conditions or limitations as appropriate**.

"**regulatory control":** Any form of control or regulation applied to facilities and activities by a Authority for reasons relating to nuclear safety and radiation protection or to nuclear security.

**"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 end point.

"**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:

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

**"remedial action"** the removal of a source or the reduction of its magnitude (in terms of activity 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**.

**"residual dose"** the dose expected to be incurred after protective actions have been terminated (or after a decision has been taken not to take protective actions).

**"response organization"** an organization designated or otherwise recognized by a State 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.

**See radiation risks**.

**"risk constraint" See constraint**.

**"safety"** see (nuclear) safety, protection and safety.

**"safety assessment"** assessment of all aspects of a practice 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, 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"** see (nuclear) security.

**"somatic effect"** a radiation induced health effect that occurs in the exposed person.

**"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. Radioactive material used as a source of radiation.

*dangerous source.* A source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. This categorization is used for determining the need for emergency arrangements and is not to **be confused with categorizations of sources for other purposes**.

*radioactive source.* A **source containing radio**active material that is used as a source **of** radiation**.**

*sealed source.* A radioactive source in which the radioactive material is (a) permanently sealed in a capsule, or (b) closely bonded and in a solid **form**.

*spent source.* A source that is no longer suitable for its intended purpose as a result of radioactive decay.

*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.

**"source monitoring"** the measurement of activity in radioactive material being released to the environment or of external dose rates due to sources within a facility or activity.

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

"**standards dosimetry laboratory"** a laboratory, designated by the relevant national authority, that possesses certification or accreditation necessary for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

**"stochastic effect"** a radiation induced health effect, the probability of occurrence of which is

greater for a higher radiation dose and the severity of which (if it occurs) is **independent of dose**.

**"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 a facility or activity 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 or organization to whom a Registrant or Licensee assigns duties, totally or partially, in relation to the design, manufacture, production or **construction of a source**.

"**tissue weighting factor,** $W_T$**"** 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.

"**transboundary exposure"** exposure of members of the public in one State due to radioactive material released via accidents, discharges or waste disposal in another State.

**"transport"** the deliberate physical movement of radioactive material (other than that forming part of the means of propulsion) from one place to another

**"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.