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PART II

Statutory Notifications (SRO)

GOVERNMENT OF PAKISTAN

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATIONS

Islamabad, the 5th October, 2004

S.R.O. 837(I)/2004. — In exercise of the powers conferred by Section 56 of the Pakistan Nuclear Regulatory Authority Ordinance, 2001(III of 2001), the Pakistan Nuclear Regulatory Authority is pleased to make and promulgate the following regulations:—

1. Short title and commencement. — (1) These regulations may be called "Regulations on Radiation Protection (PAK/904)".

(2) These regulations extend to the whole of Pakistan.

(3) These regulations shall come into force at once.

2. Definitions.— In these regulations, unless there is anything repugnant in the subject or context, —

- (a) "accident" means any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.
- (b) "applicant" means any person who applies to the Authority for a license or/and authorization to under take specified activities.
- (c) "Authority" means the Pakistan Nuclear Regulatory Authority established under section 3 of the Ordinance.
- (d) "authorization" means an authorization granted under section 20 or, as the case may be, sections 21, 22 or 23 of the Ordinance.
- (e) "clearance" means the removal of radioactive materials or radioactive objects within licensed/authorized practices from any further regulatory control by the Authority.

- (f) "consumer product" means device such as smoke detector, luminous dial or ion generating tube that contains a small amount of radioactive substance.
- (g) "controlled area" means a defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures or preventing the spread of contamination during normal working conditions, and preventing or limiting the extent of potential exposures.
- (h) "critical group" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathway and is typical of individuals receiving the highest effective dose or equivalent dose (as applicable) by the given exposure pathway from the given source.
- (i) "defence in depth" means a hierarchical deployment of different levels of equipment and procedures in order to maintain the effectiveness of physical barriers placed between a radiation source or radioactive materials and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions.
- (j) "dose constraint" means a prospective restriction on the individual dose delivered by a source, which serves as an upper limit on the dose in optimization of protection and safety for the source.
- (k) "dose limit" means the value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.
- (l) "effective dose, E" means the quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T \cdot H_T$$

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

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

where w_R is the radiation weighting factor for radiation R and $D_{T,R}$ is the average absorbed dose in the organ or tissue T.

- (m) "equivalent dose, H_T " means the quantity $H_{T,R}$, defined as:

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

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

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

- (n) "Exposure" means the act or condition of being subject to irradiation. Exposure can be either external exposure (irradiation by source outside the body) or internal exposure (irradiation by source inside the body). Exposure can be classified as either normal exposure or potential exposure; occupational, medical or public exposure; and, in intervention situations, either emergency exposure or chronic exposure. The term exposure is also used in radiodosimetry to express the amount of ionization produced in air by ionizing radiations.
- (o) "guidance level" means a level of a specified quantity above which appropriate actions shall be considered. In some circumstances, actions may need to be considered when the specified quantity is substantially below the guidance level.
- (p) "health professional" means an individual who has been accredited through appropriate national procedures to practice a profession related to health (e.g. nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).
- (q) "health surveillance" means medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.
- (r) "intervention" means any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.
- (s) "licensee" means the holder of a current license.
- (t) "limit" means the value of a quantity used in certain specified activities or circumstances that must not be exceeded.
- (u) "medical exposure" means exposure incurred by patients as part of their own medical or dental diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly exposed while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.
- (v) "medical professional" means an individual who: (a) has been accredited through Pakistan Medical and Dental Council (PMDC) as a registered medical practitioner or registered dental surgeon; and (b) fulfills the requirements of training and experience as approved by the Authority;
- (w) "member of the public" means, in a general sense, any individual in the population except, for protection and safety purposes, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.
- (x) "monitoring" means the measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

- (y) "normal exposure" means exposure which is expected to occur under the normal operating conditions of a facility or activity, including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences.
- (z) "occupational exposure" means all exposure of workers incurred in the course of their work, with the exception of excluded exposures and exposures from exempt practices or exempt sources.
- (aa) "optimization" means the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, "as low as reasonably achievable, economic and social factors being taken into account" (ALARA).
- (bb) "Ordinance" means the Pakistan Nuclear Regulatory Authority Ordinance, 2001(III of 2001).
- (cc) "potential exposure" means exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.
- (dd) "practice" means any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.
- (ee) "protection and safety" means the protection of people against exposure to ionizing radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents should they occur.
- (ff) "protective action" means an intervention intended to avoid or reduce doses to members of the public in chronic exposure or emergency exposure situations.
- (gg) "public exposure" means exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.
- (hh) "qualified expert" means an individual who, by virtue of certification by appropriate boards or societies, professional licences 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 assurance or any relevant engineering or safety speciality.
- (ii) "quality assurance (QA)" means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example, those specified in the licence.
- (jj) "Radiation Protection Officer (RPO)" means an individual technically

competent in radiation protection matters relevant for a given type of practice who is designated by the licensee to oversee the application of the requirements of these regulations.

- (kk) "reference level" means action level, intervention level, investigation level or recording level.
- (ll) "safety assessment" means assessment of all aspects of the siting, design and operation of an authorized facility which are relevant to protection and safety.
- (mm) "safety culture" means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.
- (nn) "sealed source" means radioactive material that is (i) permanently sealed in a capsule or (ii) closely bonded and in a solid form.
- (oo) "security" means measures to prevent unauthorized access to, and loss, theft or unauthorized transfer of radiation sources or radioactive material.
- (pp) "source" means anything that may cause radiation exposure, such as by emitting ionizing radiation or by releasing radioactive substances or materials, and can be treated as a single entity for protection and safety purposes.
- (qq) "supervised area" means a defined area not designated a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures and safety provisions are not normally needed.
- (rr) "unsealed source" means a source that does not meet the definition of a sealed source.
- (ss) "worker" means any individual 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. (A self-employed person is regarded as having the duties of both an employer and a worker).

GENERAL PROVISION

3. Scope.—These regulations shall apply to the following activities:

- (a) acquisition, design, manufacture, construction, installation or operation of any device that contains any radioactive material or produce ionizing radiation including consumer products, sealed sources, unsealed sources and radiation generators including, mobile radiography equipment;
- (b) establishment of installations and facilities which contain radioactive materials or devices which produce radiation including irradiation facilities, mines and mills processing radioactive ores, installations processing radioactive substances, nuclear installations and radioactive waste management facilities;
- (c) exploration for mining and milling, extraction, acquisition, handling, use for medical, industrial, veterinary, or agriculture purposes, or for

education, training or research, etc., selling, leasing, lending, buying, transferring, import, export, conversion, enrichment, production, storage, processing, reprocessing, fabrication, transportation, disposal of any radioactive ores, radioactive material, nuclear substance or any other substance as the Authority may, by notification in the official Gazette, specify;

- (d) treatment of food by ionizing radiation; and
- (e) any other source or practice as specified by the Authority.

4. Interpretation.—The decision of Chairman, PNRA regarding the interpretation of any word or phrase of these regulations or applicability of these regulations shall be final and binding on the licensee.

5. Exclusions.— The following exposures are excluded from the requirements of these regulations:

- (a) exposures from natural radioactivity in the body;
- (b) exposures from cosmic radiation at the surface of the earth;
- (c) exposures from unmodified concentrations of radionuclides in raw materials; and
- (d) exposures from any other sources that are essentially unamenable to control as may be determined by the Authority.

6. Non-compliance.— (1) In the event of a breach of any applicable requirement of these regulations, the licensee shall, as appropriate:

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

(2) The communication of a breach to the Authority shall be timely (within 24 hours) and it shall be immediate whenever an emergency exposure situation has developed or is developing.

(3) Failure to take corrective or preventive actions within a reasonable time in accordance with these regulations shall be grounds for modifying, suspending or withdrawing any license or/and authorization that has been granted by the Authority.

ADMINISTRATIVE REQUIREMENTS

7. Exemptions.— (1) Practices and sources within practices may be exempted from the requirements of these regulations if the Authority is satisfied that the sources meet the exemption criteria:

- (a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μ Sv or less in a year,

- (b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option.

or the exemption levels specified in Annex I or other exemption levels specified by the Authority on the basis of these exemption criteria.

- (2) Exemptions shall not be granted for practices deemed not to be justified.
- (3) The following practices and sources within a practice are automatically exempted from the requirements of these regulations, including the requirement for notification, licensing and authorization
 - (a) radioactive substances for which the total activity of a given nuclide present on the premises at any one time or its activity concentration contained in a mass of 1000 kg or less of material does not exceed the exemption levels specified in Annex I;
 - (b) apparatus containing radioactive substances exceeding the quantities or concentrations specified above, provided that:
 - (i) it is of a type approved by the Authority; and
 - (ii) it is constructed in the form of a sealed source, and it does not cause, in normal operating conditions, a dose rate exceeding $1 \mu\text{Sv}\cdot\text{h}^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus nor a dose to any member of the public exceeding 10 μSv in a year; or
 - (c) the operation of any electrical apparatus to which these regulations apply, other than that referred in sub-clause (d) below, provided that:
 - (i) it is of a type approved by the Authority; and
 - (ii) it does not cause in normal operating conditions a dose rate exceeding $1 \mu\text{Sv}\cdot\text{h}^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; or
 - (d) the operation of any cathode ray tube intended for the display of visual images or other electrical apparatus operating at a potential difference not exceeding 30 kV, provided that it does not cause in normal operating conditions a dose rate exceeding $1 \mu\text{Sv}\cdot\text{h}^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus.

8. Licensing. — The applicant shall fulfill the requirements specified in the ‘Regulations for the Licensing of Nuclear Installations in Pakistan- PAK/909’ or ‘Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s)- PAK/908’.

9. Designation/Employment of RPO/ Health Professional/ Medical Professional.— ~~The licensee shall designate/employ an RPO/Health Professional/Medical Professional as deems necessary and fulfilling the basic qualification criteria established by the Authority for the accomplishment of the requirement of these regulations.~~ The licensee shall designate/employee a Radiation Protection Officer (RPO)/Health Professional/ Medical Professional as deems necessary fulfilling the basic qualification and training criteria given in Annexure-VII of these regulations.

10. Responsibilities of the licensee.— (1) The licensee shall bear the responsibility for establishing and implementing the technical and organizational measures that are needed for

ensuring protection and safety for the practices and sources for which they are licensed and for compliance with all applicable requirements of these regulations. They may appoint and shall specifically identify other people to carry out actions and tasks related to these responsibilities, but they shall retain the responsibility for the actions and tasks themselves.

(2) The licensee shall notify to the Authority of their intentions to introduce modifications to any practice or source for which they are licensed whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modification unless specifically authorized by the Authority.

(3) The licensee shall ensure that only workers who are designated in the application by name and qualification credentials and permitted by reference in the license, as having key assignments related to protection and safety, and other workers assigned tasks involving operation or handling of radiation sources which could substantially affect protection and safety shall be permitted to undertake and fulfill such required assignments and tasks.

11. Clearance.— The licensee can apply for the clearance of sources, including substances, materials and objects within licensed or authorized practices from further compliance with the requirements of these regulations provided that they comply with the exemption criteria as specified in regulation no. 7 or approved by the Authority.

12. Radionuclide contamination levels in edible goods.— (1) No person shall import any edible goods without a certificate from the relevant authority of the country of origin of the goods to the effect that the radionuclide levels in the goods are not more than those specified in Annex II.

(2) No person shall produce, manufacture or otherwise prepare, store, sell or offer for sale any edible goods in which the radionuclide levels are more than the levels prescribed in Annex II.

RADIATION PROTECTION PERFORMANCE REQUIREMENTS

13. Justification of practices.— (1) No practice shall be licensed or authorized unless it produces sufficient benefit to individuals to be exposed or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors. For this decision, the applicant for a license or authorization shall provide sufficient information and evidence on the benefits and the harm to support the justification of the practice.

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

- (a) except for justified practice involving medical exposures, practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being;
- (b) practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments; and
- (c) any other practice so determined by the Authority.

14. Dose limitation.— The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused

by the possible combination of exposures from licensed or/and authorized practices, exceeds any relevant dose limit specified in Annex III except in the special circumstances considered in regulation no. 34. Dose limits shall not apply to medical exposures from authorized practices.

15. Optimization of protection and safety.— In relation to exposures from any particular source within a practice, radiation safety shall be optimized in order that the magnitude of individual doses, except for therapeutic medical exposures, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable (ALARA), economic and social factors being taken into account, within the restriction that the dose to individuals delivered by the source be subject to dose constraints. The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation safety principles to achieve this objective.

16. Dose constraints.— (1) Except for medical exposure, the optimisation of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses to the individuals of the critical group do not exceed dose constraints which are equal to the dose limits specified in Annex III or any lower values agreed by the Authority.

(2) In case of any source that can release radioactive substances to the environment, the dose constraints (fraction of the dose limit) 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 contribution by other practices and sources, are unlikely to exceed the dose limits specified in Annex III.

MANAGEMENT AND TECHNICAL REQUIREMENTS

17. Safety Culture.— The licensee shall establish a management system, commensurate with the size and nature of the licensed/authorized activity, which ensures that:

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

18. Quality Assurance.— The licensee shall establish quality assurance programmes that provide, as appropriate:

- (a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and
- (b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

19. Human Factors.— (1) The licensee shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their

responsibilities and perform their duties with appropriate judgement and according to defined procedures, and are periodically retrained or re-qualified as may be appropriate.

(2). The licensee, in co-operation with suppliers as appropriate, shall follow sound ergonomic principles in designing equipment and preparing operating procedures, in order to facilitate the safe use of equipment and minimize the contribution of human errors to accidents or incidents.

(3) The licensee shall provide appropriate equipment, safety systems and procedures which:

- (a) reduce, as far as practicable, the possibility of human errors leading to unplanned exposure of any person;
- (b) provide means to detect human errors and correct or compensate for them; and
- (c) facilitate intervention in the event of an accident.

20. Security and Accountability of Sources.— (1) Sources shall be kept secure so as to prevent loss, theft, damage and to prevent any unauthorized transfer or access to the sources.

(2) The licensee shall maintain an accountability system that includes records of:

- (a) the location and description of each source for which they are responsible; and
- (b) the activity and form of each radioactive substance for which they are responsible.

(3) The licensee shall make arrangements for the sources under their responsibility to be kept secure by ensuring that:

- (a) control of a source is not relinquished without compliance with all relevant requirements specified in the license and without immediate communication to the Authority of information regarding any decontrolled, lost, stolen or missing source;
- (b) a source is not transferred unless the receiver possesses a valid license or authorization from the Authority;
- (c) records are maintained of source inventory, including records of receipt, transfer and disposal of sources; and
- (d) a periodic inventory of sources is conducted at intervals specified in the license to confirm that they are in their assigned locations and are secure.

21. Defence in depth.— A multilayer (defence in depth) system of provisions for protection and safety shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers.

VERIFICATION OF PROTECTION AND SAFETY

22. Safety assessments.— Safety assessments related to protection and safety measures for sources within practices shall be made by the licensee at different stages, including siting, design, manufacture, construction, installation, commissioning, operation, maintenance and decommissioning.

23. Monitoring and verification of compliance.— (1) The licensee shall conduct monitoring and measurements of the parameters necessary for verification of compliance with the requirements of these regulations and licence.

(2) For the purposes of monitoring and verification of compliance, suitable equipment shall be provided and verification procedures introduced by the licensee. The equipment shall be properly maintained and tested and shall be calibrated at appropriate intervals with reference to standards traceable to national or international standards.

24. Records.— Records shall be maintained by the licensee of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with requirements of these regulations.

OCCUPATIONAL EXPOSURE PROTECTION

25. General responsibilities.— (1) The licensee who is engaged in activities that involve or could involve occupational exposure shall be responsible for the protection of the workers against any occupational exposure which is not excluded from these regulations.

(2) The licensee shall ensure, for all workers engaged in activities that involve or could involve occupational exposure that:

- (a) occupational exposures are limited as specified in Annex III;
- (b) radiation safety is optimized in accordance with regulation nos. 15 and 16;
- (c) policies, procedures and organizational arrangements for occupational protection and safety are established to implement the relevant requirements of these regulations and the resulting decisions on measures to be adopted for this purpose are recorded and made available to relevant parties including workers;
- (d) suitable and adequate facilities for radiation safety are provided, including personal protective devices and radiation monitoring equipment, and arrangements are made for their proper use;
- (e) radiation safety and health surveillance services are provided through qualified experts;
- (f) arrangements are made to facilitate better coordination with workers on all measures which are needed to achieve adequate radiation safety by an effective implementation of these regulations; and
- (g) necessary conditions are provided and arrangements are made to promote a safety culture in the work force and achieve adequate training of workers on radiation safety matters.

(3) If workers are to be engaged in work that involves or could involve a source which is not under the control of their employer, the licensee responsible for the source shall:

- (a) obtain from the employer, as a pre-condition for engagement of such workers, information on their previous occupational exposure history and other information as may be necessary to provide protection and safety in compliance with these regulations;
- (b) provide such workers with protective measures and safety provisions which are at least as good as those provided for employees of the licensee; and

- (c) make dosimetric and other appropriate information available to the employer for the purpose of demonstrating that the level of protection provided to such workers is compatible with the requirements of these regulations.

(4) The licensee shall ensure that workers under their responsibility who are exposed to radiation from sources, other than natural sources, that are not directly related to or required by their work receive the same level of protection as if they were members of the public.

(5) The licensee shall ensure that workers are informed of their obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources. In particular, the licensee shall ensure that workers:

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

(6) The licensee shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of these regulations, and shall take appropriate remedial action.

26. Conditions of service.— (1) The conditions of service of workers shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of these regulations.

(2) Female workers shall be advised by the licensee that it is desirable to notify the licensee of pregnancy. Once a female worker has notified the licensee that she is pregnant, the licensee shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection which is required for members of the public, as is specified in Annex III. The notification of pregnancy shall not be considered a reason to exclude a female worker from work.

(3) The licensee shall make every reasonable effort to provide workers with suitable alternative workplace or employment in circumstances where it has been determined either by the Authority or in the framework of health surveillance programme required by these regulations that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

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

27. Classification of areas.— (1) Controlled area: The licensee shall designate an area as controlled area where there is a likelihood of receiving an effective dose greater than 6 mSv in a year or an equivalent dose greater than three tenths of any relevant dose limit specified

in Annex III and in which specific protective measures or safety provisions are or could be required for:

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

(2) The licensee shall:

- (a) determine the boundaries of any controlled area on the basis of the magnitude and likelihood of expected exposure and the nature and extent of the required protection and safety provisions;
- (b) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
- (c) where a source is brought into operation or energized only intermittently or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;
- (d) display internationally recognized warning symbols and appropriate instructions at access points and other appropriate locations within controlled areas;
- (e) establish occupational protection and safety measures, including local rules and procedures that are appropriate for controlled areas;
- (f) restrict access to controlled areas by means of administrative procedures, such as the use of work permits, and by physical barriers, which could include locks or interlocks; the degree of restriction being commensurate with the magnitude and likelihood of the expected exposures; and
- (g) provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.

(3) Supervised area: The licensee shall designate an area as a supervised area not already designated as a controlled area but where there is a likelihood of receiving an effective dose greater than 1 mSv in a year or an equivalent dose greater than one tenth of any relevant dose limit specified in Annex III and occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.

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

(5) The licensee shall periodically review conditions to determine the possible need to revise the protection measures or safety provisions, including the boundaries of controlled and supervised areas.

28. Rules, procedures and supervision.—(1) The licensee shall:

- (a) establish in writing such rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other individuals;
- (b) include in these rules and procedures the values of any relevant reference level or investigation level and the procedure to be followed in the event that any such value is exceeded;
- (c) ensure that any work involving occupational exposure be adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions are observed.

- (2) The licensee shall:
- (a) provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety, including information on general and local rules and procedures and on available protection and safety provisions, as well as adequate information on the significance for protection and safety of their actions;
 - (b) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on:
 - (i) the risk to the embryo or foetus due to exposure of a pregnant woman;
 - (ii) the importance for a female worker of notifying as soon as she suspects that she is pregnant; and
 - (iii) the risk to an infant ingesting radioactive substances by breast feeding;
 - (c) provide to those workers who could be affected by an emergency plan appropriate information, instruction and training; and
 - (d) keep records of the training provided to individual workers.

29. Personal protective equipment.— The licensee shall:

- (a) minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate protective well engineered controls and satisfactory working conditions;
- (b) if necessary, ensure that workers are provided with suitable and adequate personal protective equipment, including as appropriate:
 - (i) protective clothing;
 - (ii) protective respiratory equipment with information on its protection characteristics and instruction on its proper use; and
 - (iii) protective aprons, gloves and organ shields;
- (c) arrange for regular testing and maintenance to be carried out on all personal protective equipment, including, as required, special equipment for use in the event of accidents and interventions; and
- (d) take into account the following factors when assigning personal protective equipment for a given task:
 - (i) medical fitness to sustain possible extra physical effort while using the protective equipment; and
 - (ii) additional work time or inconvenience or additional non-radiological risks associated with the use of the protective equipment.

30. Individual monitoring and exposure assessment.— (1) The licensee shall arrange for the assessment of the occupational exposure of workers and shall ensure that adequate arrangements are made with appropriate dosimetry services under an adequate quality assurance programme.

(2) For any worker who works in controlled area individual monitoring shall be undertaken.

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

(4) The licensee shall ensure that workers who may be exposed to radioactive contamination, including workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses, as appropriate.

31. Monitoring of workplace.— (1) The licensee shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of and the risks associated with the source.

(2) The nature and frequency of monitoring of workplaces shall:

(a) be sufficient to enable:

- (i) evaluation of the radiological conditions in all workplaces;
- (ii) exposure assessment in controlled areas and supervised areas; and
- (iii) review of the designation of controlled and supervised areas;

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

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

- (a) the quantities to be measured;
- (b) where and when the measurements are to be made and at what frequency;
- (c) the most appropriate measurement methods and procedures; and
- (d) reference levels and the actions to be taken if these are exceeded.

(4) The licensee shall keep appropriate records of the findings of the workplace monitoring programme, which shall be made available to workers.

32. Records of worker exposure.— (1) The licensee shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under regulation no. 30. Such worker exposure records shall include information on:

- (a) the general nature of the work resulting in exposure, the doses and intakes and the data upon which the dose assessments are based;
- (b) the periods of employment with different licensees, if any, and the corresponding doses and intakes in each period of employment; and
- (c) the doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal condition.

(2) The licensee shall:

- (a) provide for access by workers to information in their own exposure records and workplace monitoring where appropriate; and
- (b) upon request of the Authority or other relevant persons or organizations with a demonstrated need for such records, including relevant employers and supervisors of the health surveillance programme, provide access to worker exposure records with due care and attention to the maintenance of appropriate confidentiality.

(3) Exposure records of each worker shall be retained by the licensee and supplied to the Authority if desired. These records shall be preserved at least until the worker attains or would have attained the age of seventy five (75) years, and for not less than thirty (30) years after the termination of the work involving occupational exposure.

33. Health surveillance.— The licensee, in accordance with the requirements established by the Authority (Annex VI), shall make arrangements for appropriate health surveillance based on general principles of occupational health and designed to assess the initial and continuous fitness of regular workers working in the controlled area for their intended tasks.

34. Special circumstances.— (1) If a practice which is justified and for which radiation safety is optimized presents special circumstances which require a temporary change in some dose limitation requirements of these regulations, the licensee shall not make any such temporary change without approval of the Authority.

(2) The application submitted by the licensee to obtain this approval shall include evidence to demonstrate that:

- (a) all reasonable efforts have been made to reduce exposures and optimize radiation safety provisions in accordance with the requirements of these regulations; and
- (b) workers have been consulted on the need for and the conditions of the temporary change in dose limitation requirements.

MEDICAL EXPOSURE PROTECTION

35. General responsibilities.— (1) The licensee shall ensure that:

- (a) no patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical professional;
- (b) medical professionals are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- (c) medical and health professionals are available as needed and have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedures that the medical professional prescribes;
- (d) for therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of these regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics; and
- (e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients are constrained as specified in Annex III.

(2) The licensee shall ensure fulfillment of quality assurance requirements as laid down under these regulations.

36. Justification of medical exposures.—(1) Medical professionals shall consider the justification of medical exposures that they prescribe by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

(2) Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications shall not be performed unless the specific type of examination is justified by medical professional.

(3) Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

37. Optimization of protection for medical exposures.— In addition to satisfying the general requirements for optimisation of radiation safety, the licensee shall satisfy the prescriptive design and operational requirements specified in Annex IV.

38. Dose Constraints.— The licensee shall constrain any dose to individuals incurred while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Annex III.

39. Calibration and clinical dosimetry for medical exposures.— (1) The licensee shall ensure that:

- (a) the calibration of sources used for medical exposure is traceable to a Standards Dosimetry Laboratory;
- (b) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;
- (c) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceutical to be administered; and
- (d) calibrations of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may effect the calibration, as well as at regular intervals approved by the Authority.

(2) The licensee shall ensure that the representative values of clinical dosimetry parameters are determined and documented.

40. Quality assurance for medical exposures.— Quality assurance programmes for medical exposures shall include:

- (a) measurements of the physical parameters of the radiation generators including therapeutic and diagnostic equipment at the time of commissioning and periodically (which period shall not be more than twelve calendar months) thereafter;

- (b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
- (c) written records of relevant procedures and results;
- (d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
- (e) as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

41. Guidance levels for medical exposure.— (1) Guidance levels for medical exposure (Annex V) shall be used by medical professionals in the conduct of diagnostic and therapeutic procedures involving exposure to radiation as well as in the optimisation of protection of patients.

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

42. Maximum activity for patients in therapy on discharge from hospital.— In order to restrict the exposure of any member of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Annex V unless otherwise justified and the justification is documented. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

43. Medical surveillance for abnormal situation.— (1) The licensee shall ensure that in case of radiation accident situations, adequate medical facilities and staff are available for the administration of first aid and for carrying out external decontamination of the affected persons without any delay.

(2) The adequacy of such facilities shall be regularly reviewed by the licensee.

(3) The licensee shall make necessary arrangements that in case of radiation injuries, affected persons are immediately transferred to hospitals designated to treat such injuries.

44. Investigation of accidental medical exposures.— (1) The licensee shall promptly investigate:

- (a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical professional;
 - (b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the specified guidance levels; and
 - (c) any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.
- (2) The licensee shall, with respect to any investigation required above:
- (a) calculate or estimate the doses received and their distribution within the patient;

- (b) indicate the corrective measures required to prevent recurrence of such an incident;
- (c) implement all the corrective measures that are under their own responsibility;
- (d) notify the Authority, by telephone or facsimile as soon as practicable, but not later than twenty four (24) hours after discovery, of any incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient;
- (e) submit to the Authority, within thirty (30) days after discovery of the incident, a written report which states the cause of the incident and includes the information on the doses, corrective measures and any other relevant information; and
- (f) Inform the patient and his/her doctor in confidence about the incident.

45. Records.— The licensee shall keep and make available, as appropriate, records of equipment calibration, clinical dosimetry and quality assurance, as well as any other necessary information to allow retrospective assessments of the doses received by patients.

PUBLIC EXPOSURE PROTECTION

46. General responsibilities.— (1) The licensee shall apply the requirements of these regulations to any public exposure delivered by a practice or source for which they are responsible, unless the exposure is excluded from these regulations or the practice or source delivering the exposure is exempted from the requirements of these regulations.

(2) The licensee shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:

- (a) radiation safety policies, procedures and organizational arrangements for control of public exposure;
- (b) measures for ensuring:
 - (i) the optimization of the protection, subject to constraints as may be appropriate, of members of the public whose exposure is attributable to such sources; and
 - (ii) the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is not higher than the dose limits for members of the public as specified in Annex III.
- (c) measures for ensuring the safety of such sources, in order that the likelihood of public exposures is controlled in accordance with the requirements of these regulations;
- (d) suitable and adequate facilities, equipment and services for the protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the exposure;
- (e) appropriate radiation safety training, and periodic retraining, to the personnel having functions such as that of RPO(s) relevant to the protection of the public;
- (f) appropriate monitoring equipment and surveillance programmes to assess public exposure; and
- (g) adequate records of the surveillance and monitoring.

47. Control of visitors.— The licensee shall:

- (a) ensure that visitors are accompanied in any controlled area by a person knowledgeable about the radiation safety measures for that area;
- (b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions; and
- (c) ensure that adequate control over entry of visitors to a supervised area are maintained and that cautionary/ warning signs be posted in such areas.

48. Monitoring of public exposure.— The licensee shall, as appropriate:

- (a) establish and carry out a monitoring programme, of magnitude and complexity commensurate with the type of and risks associated with the sources under their responsibilities, which is sufficient to ensure that the requirements of these regulations are satisfied and to assess the exposure of members of the public from sources of external irradiation and/or discharges of radioactive substances in to the environment, as appropriate;
- (b) keep appropriate records of the results of the monitoring programmes; and
- (c) report a summary of the monitoring results to the Authority on a yearly basis or such shorter intervals as approved by the Authority and promptly inform the Authority of any abnormal results which lead or could lead to an increase of public exposure.

49. Consumer products.— (1) Consumer products capable of causing exposure to radiation shall not be supplied to members of the public unless:

- (a) such exposure is excluded from these regulations under regulation no. 5; or
- (b) such products meet the exemption requirements specified in regulation no. 7 or have otherwise been exempted by the Authority; or
- (c) such products are authorized by the Authority for use by members of the public.

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

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

50. Repeal.— Regulation nos. 2, 22, 23, 26 to 32, 34 to 38, 43, 45 to 57 and 65 to 69 and Schedules II to XVI of Pakistan Nuclear Safety and Radiation Protection (PNSRP) Regulations, 1990 are hereby repealed.

EXEMPT CONCENTRATIONS AND QUANTITIES OF
RADIONUCLIDES

Table 1

EXEMPTION LEVELS: EXEMPT ACTIVITY CONCENTRATIONS AND
EXEMPT ACTIVITIES OF RADIONUCLIDES (ROUNDED)

| Nuclide | Activity Concentration (Bq/g) | Activity (Bq) | Nuclide | Activity Concentration (Bq/g) | Activity (Bq) |
|---------|-------------------------------------|---------------------|---------|-------------------------------------|----------------------|
| H-3 | 1 x 10 ⁶ | 1 x 10 ⁹ | Ni-63 | 1 x 10 ⁵ | 1 x 10 ⁸ |
| Be-7 | 1 x 10 ³ | 1 x 10 ⁷ | Ni-65 | 1 x 10 ¹ | 1 x 10 ⁶ |
| C-14 | 1 x 10 ⁴ | 1 x 10 ⁷ | Cu-64 | 1 x 10 ² | 1 x 10 ⁶ |
| O-15 | 1 x 10 ² | 1 x 10 ⁹ | Zn-65 | 1 x 10 ¹ | 1 x 10 ⁶ |
| F-18 | 1 x 10 ¹ | 1 x 10 ⁶ | Zn-69 | 1 x 10 ⁴ | 1 x 10 ⁶ |
| Na-22 | 1 x 10 ¹ | 1 x 10 ⁶ | Zn-69m | 1 x 10 ² | 1 x 10 ⁶ |
| Na-24 | 1 x 10 ¹ | 1 x 10 ⁵ | Ga-72 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Si-31 | 1 x 10 ³ | 1 x 10 ⁶ | Ge-71 | 1 x 10 ⁴ | 1 x 10 ⁸ |
| P-32 | 1 x 10 ³ | 1 x 10 ⁵ | As-73 | 1 x 10 ³ | 1 x 10 ⁷ |
| P-33 | 1 x 10 ⁵ | 1 x 10 ⁸ | As-74 | 1 x 10 ¹ | 1 x 10 ⁶ |
| S-35 | 1 x 10 ⁵ | 1 x 10 ⁸ | As-76 | 1 x 10 ² | 1 x 10 ⁵ |
| Cl-36 | 1 x 10 ⁴ | 1 x 10 ⁶ | As-77 | 1 x 10 ³ | 1 x 10 ⁶ |
| Cl-38 | 1 x 10 ¹ | 1 x 10 ⁵ | Se-75 | 1 x 10 ² | 1 x 10 ⁶ |
| Ar-37 | 1 x 10 ⁶ | 1 x 10 ⁸ | Br-82 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Ar-41 | 1 x 10 ² | 1 x 10 ⁹ | Kr-74 | 1 x 10 ² | 1 x 10 ⁹ |
| K-40 | 1 x 10 ² | 1 x 10 ⁶ | Kr-76 | 1 x 10 ² | 1 x 10 ⁹ |
| K-42 | 1 x 10 ² | 1 x 10 ⁶ | Kr-77 | 1 x 10 ² | 1 x 10 ⁹ |
| K-43 | 1 x 10 ¹ | 1 x 10 ⁶ | Kr-79 | 1 x 10 ³ | 1 x 10 ⁵ |
| Ca-45 | 1 x 10 ⁴ | 1 x 10 ⁷ | Kr-81 | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Ca-47 | 1 x 10 ¹ | 1 x 10 ⁶ | Kr-83m | 1 x 10 ⁵ | 1 x 10 ¹² |
| Sc-46 | 1 x 10 ¹ | 1 x 10 ⁶ | Kr-85 | 1 x 10 ⁵ | 1 x 10 ⁴ |
| Sc-47 | 1 x 10 ² | 1 x 10 ⁶ | Kr-85m | 1 x 10 ³ | 1 x 10 ¹⁰ |
| Sc-48 | 1 x 10 ¹ | 1 x 10 ⁵ | Kr-87 | 1 x 10 ² | 1 x 10 ⁹ |
| V-48 | 1 x 10 ¹ | 1 x 10 ⁵ | Kr-88 | 1 x 10 ² | 1 x 10 ⁹ |
| Cr-51 | 1 x 10 ³ | 1 x 10 ⁷ | Rb-86 | 1 x 10 ² | 1 x 10 ⁵ |
| Mn-51 | 1 x 10 ¹ | 1 x 10 ⁵ | Sr-85 | 1 x 10 ² | 1 x 10 ⁶ |
| Mn-52 | 1 x 10 ¹ | 1 x 10 ⁵ | Sr-85m | 1 x 10 ² | 1 x 10 ⁷ |
| Mn-52m | 1 x 10 ¹ | 1 x 10 ⁵ | Sr-87m | 1 x 10 ² | 1 x 10 ⁶ |
| Mn-53 | 1 x 10 ⁴ | 1 x 10 ⁹ | Sr-89 | 1 x 10 ³ | 1 x 10 ⁶ |
| Mn-54 | 1 x 10 ¹ | 1 x 10 ⁶ | Sr-90* | 1 x 10 ² | 1 x 10 ⁴ |
| Mn-56 | 1 x 10 ¹ | 1 x 10 ⁵ | Sr-91 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Fe-52 | 1 x 10 ¹ | 1 x 10 ⁶ | Sr-92 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Fe-55 | 1 x 10 ⁴ | 1 x 10 ⁶ | Y-90 | 1 x 10 ³ | 1 x 10 ⁵ |
| Fe-59 | 1 x 10 ¹ | 1 x 10 ⁶ | Y-91 | 1 x 10 ³ | 1 x 10 ⁶ |
| Co-55 | 1 x 10 ¹ | 1 x 10 ⁶ | Y-91m | 1 x 10 ² | 1 x 10 ⁶ |
| Co-56 | 1 x 10 ¹ | 1 x 10 ⁵ | Y-92 | 1 x 10 ² | 1 x 10 ⁵ |
| Co-57 | 1 x 10 ² | 1 x 10 ⁶ | Y-93 | 1 x 10 ² | 1 x 10 ⁵ |
| Co-58 | 1 x 10 ¹ | 1 x 10 ⁶ | Zr-93* | 1 x 10 ³ | 1 x 10 ⁷ |
| Co-58m | 1 x 10 ⁴ | 1 x 10 ⁷ | Zr-95 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Co-60 | 1 x 10 ¹ | 1 x 10 ⁵ | Zr-97* | 1 x 10 ¹ | 1 x 10 ⁵ |
| Co-60m | 1 x 10 ³ | 1 x 10 ⁶ | Nb-93m | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Co-61 | 1 x 10 ² | 1 x 10 ⁶ | Nb-94 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Co-62m | 1 x 10 ¹ | 1 x 10 ⁵ | Nb-95 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Ni-59 | 1 x 10 ⁴ | 1 x 10 ⁸ | Nb-97 | 1 x 10 ¹ | 1 x 10 ⁶ |

Table 1 (cont.)

| Nuclide | Activity concentration (Bq/g) | Activity (Bq) | Nuclide | Activity concentration (Bq/g) | Activity (Bq) |
|---------|-------------------------------------|---------------------|---------|-------------------------------------|----------------------|
| Nb-98 | 1 x 10 ¹ | 1 x 10 ⁵ | I-123 | 1 x 10 ² | 1 x 10 ⁷ |
| Mo-90 | 1 x 10 ¹ | 1 x 10 ⁶ | I-125 | 1 x 10 ³ | 1 x 10 ⁶ |
| Mo-93 | 1 x 10 ³ | 1 x 10 ⁸ | I-126 | 1 x 10 ² | 1 x 10 ⁶ |
| Mo-99 | 1 x 10 ² | 1 x 10 ⁶ | I-129 | 1 x 10 ² | 1 x 10 ⁵ |
| Mo-101 | 1 x 10 ¹ | 1 x 10 ⁶ | I-130 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Tc-96 | 1 x 10 ¹ | 1 x 10 ⁶ | I-131 | 1 x 10 ² | 1 x 10 ⁶ |
| Tc-96m | 1 x 10 ³ | 1 x 10 ⁷ | I-132 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Tc-97 | 1 x 10 ³ | 1 x 10 ⁸ | I-133 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Tc-97m | 1 x 10 ³ | 1 x 10 ⁷ | I-134 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Tc-99 | 1 x 10 ⁴ | 1 x 10 ⁷ | I-135 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Tc-99m | 1 x 10 ² | 1 x 10 ⁷ | Xe131m | 1 x 10 ⁴ | 1 x 10 ⁴ |
| Ru-97 | 1 x 10 ² | 1 x 10 ⁷ | Xe-133 | 1 x 10 ³ | 1 x 10 ⁴ |
| Ru-103 | 1 x 10 ² | 1 x 10 ⁶ | Xe-135 | 1 x 10 ³ | 1 x 10 ¹⁰ |
| Ru-105 | 1 x 10 ¹ | 1 x 10 ⁶ | Cs-129 | 1 x 10 ² | 1 x 10 ⁵ |
| Ru-106* | 1 x 10 ² | 1 x 10 ⁵ | Cs-131 | 1 x 10 ³ | 1 x 10 ⁶ |
| Rh-103m | 1 x 10 ⁴ | 1 x 10 ⁸ | Cs-132 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Rh-105 | 1 x 10 ² | 1 x 10 ⁷ | Cs-134m | 1 x 10 ³ | 1 x 10 ⁵ |
| Pd-103 | 1 x 10 ³ | 1 x 10 ⁸ | Cs-134 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Pd-109 | 1 x 10 ³ | 1 x 10 ⁶ | Cs-135 | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Ag-105 | 1 x 10 ² | 1 x 10 ⁶ | Cs-136 | 1 x 10 ¹ | 1 x 10 ⁵ |
| Ag-110m | 1 x 10 ¹ | 1 x 10 ⁶ | Cs-137* | 1 x 10 ¹ | 1 x 10 ⁴ |
| Ag-111 | 1 x 10 ³ | 1 x 10 ⁶ | Cs-138 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Cd-109 | 1 x 10 ⁴ | 1 x 10 ⁶ | Ba-131 | 1 x 10 ² | 1 x 10 ⁶ |
| Cd-115 | 1 x 10 ² | 1 x 10 ⁶ | Ba-140* | 1 x 10 ¹ | 1 x 10 ⁵ |
| Cd-115m | 1 x 10 ³ | 1 x 10 ⁶ | La-140 | 1 x 10 ¹ | 1 x 10 ⁵ |
| In-111 | 1 x 10 ² | 1 x 10 ⁶ | Ce-139 | 1 x 10 ² | 1 x 10 ⁶ |
| In-113m | 1 x 10 ² | 1 x 10 ⁶ | Ce-141 | 1 x 10 ² | 1 x 10 ⁷ |
| In-114m | 1 x 10 ² | 1 x 10 ⁶ | Ce-143 | 1 x 10 ² | 1 x 10 ⁶ |
| In-115m | 1 x 10 ² | 1 x 10 ⁶ | Ce-144* | 1 x 10 ² | 1 x 10 ⁵ |
| Sn-113 | 1 x 10 ³ | 1 x 10 ⁷ | Pr-142 | 1 x 10 ² | 1 x 10 ⁵ |
| Sn-125 | 1 x 10 ² | 1 x 10 ⁵ | Pr-143 | 1 x 10 ⁴ | 1 x 10 ⁶ |
| Sb-122 | 1 x 10 ² | 1 x 10 ⁴ | Nd-147 | 1 x 10 ² | 1 x 10 ⁶ |
| Sb-124 | 1 x 10 ¹ | 1 x 10 ⁶ | Nd-149 | 1 x 10 ² | 1 x 10 ⁶ |
| Sb-125 | 1 x 10 ² | 1 x 10 ⁶ | Pm-147 | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Te-123m | 1 x 10 ² | 1 x 10 ⁷ | Pm-149 | 1 x 10 ³ | 1 x 10 ⁶ |
| Te-125m | 1 x 10 ³ | 1 x 10 ⁷ | Sm-151 | 1 x 10 ⁴ | 1 x 10 ⁸ |
| Te-127 | 1 x 10 ³ | 1 x 10 ⁶ | Sm-153 | 1 x 10 ² | 1 x 10 ⁶ |
| Te-127m | 1 x 10 ³ | 1 x 10 ⁷ | Eu-152 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Te-129 | 1 x 10 ² | 1 x 10 ⁶ | Eu-152m | 1 x 10 ² | 1 x 10 ⁶ |
| Te-129m | 1 x 10 ³ | 1 x 10 ⁶ | Eu-154 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Te-131 | 1 x 10 ² | 1 x 10 ⁵ | Eu-155 | 1 x 10 ² | 1 x 10 ⁷ |
| Te-131m | 1 x 10 ¹ | 1 x 10 ⁶ | Gd-153 | 1 x 10 ² | 1 x 10 ⁷ |
| Te-132 | 1 x 10 ² | 1 x 10 ⁷ | Gd-159 | 1 x 10 ³ | 1 x 10 ⁶ |
| Te-133 | 1 x 10 ¹ | 1 x 10 ⁵ | Tb-160 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Te-133m | 1 x 10 ¹ | 1 x 10 ⁵ | Dy-165 | 1 x 10 ³ | 1 x 10 ⁶ |
| Te-134 | 1 x 10 ¹ | 1 x 10 ⁶ | Dy-166 | 1 x 10 ³ | 1 x 10 ⁶ |

Table 1 (cont.)

| Nuclide | Activity concentration (Bq/g) | Activity (Bq) | Nuclide | Activity concentration (Bq/g) | Activity (Bq) |
|---------|-------------------------------------|---------------------|---------------|-------------------------------------|---------------------|
| Ho-166 | 1 x 10 ³ | 1 x 10 ⁵ | Rn-220* | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Er-169 | 1 x 10 ⁴ | 1 x 10 ⁷ | Rn-222* | 1 x 10 ¹ | 1 x 10 ⁸ |
| Er-171 | 1 x 10 ² | 1 x 10 ⁶ | Ra-223* | 1 x 10 ² | 1 x 10 ⁵ |
| Tm-170 | 1 x 10 ³ | 1 x 10 ⁶ | Ra-224* | 1 x 10 ¹ | 1 x 10 ⁵ |
| Tm-171 | 1 x 10 ⁴ | 1 x 10 ⁸ | Ra-225 | 1 x 10 ² | 1 x 10 ⁵ |
| Yb-175 | 1 x 10 ³ | 1 x 10 ⁷ | Ra-226* | 1 x 10 ¹ | 1 x 10 ⁴ |
| Lu-177 | 1 x 10 ³ | 1 x 10 ⁷ | Ra-227 | 1 x 10 ² | 1 x 10 ⁶ |
| Hf-181 | 1 x 10 ¹ | 1 x 10 ⁶ | Ra-228* | 1 x 10 ¹ | 1 x 10 ⁵ |
| Ta-182 | 1 x 10 ¹ | 1 x 10 ⁴ | Ac-228 | 1 x 10 ¹ | 1 x 10 ⁶ |
| W-181 | 1 x 10 ³ | 1 x 10 ⁷ | Th-226* | 1 x 10 ³ | 1 x 10 ⁷ |
| W-185 | 1 x 10 ⁴ | 1 x 10 ⁷ | Th-227 | 1 x 10 ¹ | 1 x 10 ⁴ |
| W-187 | 1 x 10 ² | 1 x 10 ⁶ | Th-228* | 1 x 10 ⁰ | 1 x 10 ⁴ |
| Re-186 | 1 x 10 ³ | 1 x 10 ⁶ | Th-229* | 1 x 10 ⁰ | 1 x 10 ³ |
| Re-188 | 1 x 10 ² | 1 x 10 ⁵ | Th-230 | 1 x 10 ⁰ | 1 x 10 ⁴ |
| Os-185 | 1 x 10 ¹ | 1 x 10 ⁶ | Th-231 | 1 x 10 ³ | 1 x 10 ⁷ |
| Os-191 | 1 x 10 ² | 1 x 10 ⁷ | Th-nat | 1 x 10 ⁰ | 1 x 10 ³ |
| Os-191m | 1 x 10 ³ | 1 x 10 ⁷ | (incl.Th-232) | | |
| Os-193 | 1 x 10 ² | 1 x 10 ⁶ | Th-234* | 1 x 10 ³ | 1 x 10 ⁵ |
| Ir-190 | 1 x 10 ¹ | 1 x 10 ⁶ | Pa-230 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Ir-192 | 1 x 10 ¹ | 1 x 10 ⁴ | Pa-231 | 1 x 10 ⁰ | 1 x 10 ³ |
| Ir-194 | 1 x 10 ² | 1 x 10 ⁵ | Pa-233 | 1 x 10 ² | 1 x 10 ⁷ |
| Pt-191 | 1 x 10 ² | 1 x 10 ⁶ | U-230* | 1 x 10 ¹ | 1 x 10 ⁵ |
| Pt-193m | 1 x 10 ³ | 1 x 10 ⁷ | U-231 | 1 x 10 ² | 1 x 10 ⁷ |
| Pt-197 | 1 x 10 ³ | 1 x 10 ⁶ | U-232* | 1 x 10 ⁰ | 1 x 10 ³ |
| Pt-197m | 1 x 10 ² | 1 x 10 ⁶ | U-233 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Au-198 | 1 x 10 ² | 1 x 10 ⁶ | U-234 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Au-199 | 1 x 10 ² | 1 x 10 ⁶ | U-235* | 1 x 10 ¹ | 1 x 10 ⁴ |
| Hg-197 | 1 x 10 ² | 1 x 10 ⁷ | U-236 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Hg197m | 1 x 10 ² | 1 x 10 ⁶ | U-237 | 1 x 10 ² | 1 x 10 ⁶ |
| Hg-203 | 1 x 10 ² | 1 x 10 ⁵ | U-238* | 1 x 10 ¹ | 1 x 10 ⁴ |
| Tl-200 | 1 x 10 ¹ | 1 x 10 ⁶ | U-nat | 1 x 10 ⁰ | 1 x 10 ³ |
| Tl-201 | 1 x 10 ² | 1 x 10 ⁶ | U-239 | 1 x 10 ² | 1 x 10 ⁶ |
| Tl-202 | 1 x 10 ² | 1 x 10 ⁶ | U-240 | 1 x 10 ³ | 1 x 10 ⁷ |
| Tl-204 | 1 x 10 ⁴ | 1 x 10 ⁴ | U-240* | 1 x 10 ¹ | 1 x 10 ⁶ |
| Pb-203 | 1 x 10 ² | 1 x 10 ⁶ | Np-237* | 1 x 10 ⁰ | 1 x 10 ³ |
| Pb-210* | 1 x 10 ¹ | 1 x 10 ⁴ | Np-239 | 1 x 10 ² | 1 x 10 ⁷ |
| Pb-212* | 1 x 10 ¹ | 1 x 10 ⁵ | Np-240 | 1 x 10 ¹ | 1 x 10 ⁶ |
| Bi-206 | 1 x 10 ¹ | 1 x 10 ⁵ | Pu-234 | 1 x 10 ² | 1 x 10 ⁷ |
| Bi-207 | 1 x 10 ¹ | 1 x 10 ⁶ | Pu-235 | 1 x 10 ² | 1 x 10 ⁷ |
| Bi-210 | 1 x 10 ³ | 1 x 10 ⁶ | Pu-236 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Bi-212* | 1 x 10 ¹ | 1 x 10 ⁵ | Pu-237 | 1 x 10 ³ | 1 x 10 ⁷ |
| Po-203 | 1 x 10 ¹ | 1 x 10 ⁶ | Pu-238 | 1 x 10 ⁰ | 1 x 10 ⁴ |
| Po-205 | 1 x 10 ¹ | 1 x 10 ⁶ | Pu-239 | 1 x 10 ⁰ | 1 x 10 ⁴ |
| Po-207 | 1 x 10 ¹ | 1 x 10 ⁶ | Pu-240 | 1 x 10 ⁰ | 1 x 10 ³ |
| Po-210 | 1 x 10 ¹ | 1 x 10 ⁴ | Pu-241 | 1 x 10 ² | 1 x 10 ⁵ |
| At-211 | 1 x 10 ³ | 1 x 10 ⁷ | Pu-242 | 1 x 10 ⁰ | 1 x 10 ⁴ |

Table 1 (cont.)

| Nuclide | Activity concentration (Bq/g) | Activity (Bq) | Nuclide | Activity concentration (Bq/g) | Activity (Bq) |
|----------|-------------------------------------|---------------------|---------|-------------------------------------|---------------------|
| Pu-243 | 1 x 10 ³ | 1 x 10 ⁷ | Cf-246 | 1 x 10 ³ | 1 x 10 ⁶ |
| Pu-244 | 1 x 10 ⁰ | 1 x 10 ⁴ | Cf-248 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Am-241 | 1 x 10 ⁰ | 1 x 10 ⁴ | Cf-249 | 1 x 10 ⁰ | 1 x 10 ³ |
| Am-242 | 1 x 10 ³ | 1 x 10 ⁶ | Cf-250 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Am-242m* | 1 x 10 ⁰ | 1 x 10 ⁴ | Cf-251 | 1 x 10 ⁰ | 1 x 10 ³ |
| Am-243* | 1 x 10 ⁰ | 1 x 10 ³ | Cf-252 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Cm-242 | 1 x 10 ² | 1 x 10 ⁵ | Cf-253 | 1 x 10 ² | 1 x 10 ⁵ |
| Cm-243 | 1 x 10 ⁰ | 1 x 10 ⁴ | Cf-254 | 1 x 10 ⁰ | 1 x 10 ³ |
| Cm-244 | 1 x 10 ¹ | 1 x 10 ⁴ | Es-253 | 1 x 10 ² | 1 x 10 ⁵ |
| Cm-245 | 1 x 10 ⁰ | 1 x 10 ³ | Es-254 | 1 x 10 ¹ | 1 x 10 ⁴ |
| Cm-246 | 1 x 10 ⁰ | 1 x 10 ³ | Es-254m | 1 x 10 ² | 1 x 10 ⁶ |
| Cm-247 | 1 x 10 ⁰ | 1 x 10 ⁴ | Fm-254 | 1 x 10 ⁴ | 1 x 10 ⁷ |
| Cm-248 | 1 x 10 ⁰ | 1 x 10 ³ | Fm-255 | 1 x 10 ³ | 1 x 10 ⁶ |
| Bk-249 | 1 x 10 ³ | 1 x 10 ⁶ | | | |

* Parent nuclides and their progeny included in secular equilibrium are listed in the following:

| | |
|--------|--|
| Sr-90 | Y-90 |
| Zr-93 | Nb-93m |
| Zr-97 | Nb-97 |
| Ru-106 | Rh-106 |
| Cs-137 | Ba-137m |
| Ba-140 | La-140 |
| Ce-134 | La-134 |
| Ce-144 | Pr-144 |
| Pb-210 | Bi-210, Po-210 |
| Pb-212 | Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Bi-212 | Tl-208 (0.36), Po-212 (0.64) |
| Rn-220 | Po-216 |
| Rn-222 | Po-218, Pb-214, Bi-214, Po-214 |
| Ra-223 | Rn-219, Po-215, Pb-211, Bi-211, Tl-207 |
| Ra-224 | Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64) |
| Ra-226 | Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210 |
| Ra-228 | Ac-228 |

| | |
|---------|--|
| Th-226 | Ra-222, Rn-218, Po-214 |
| Th-228 | Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Th-229 | Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209 |
| Th-nat | Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Th-234 | Pa-234m |
| U-230 | Th-226, Ra-222, Rn-218, Po-214 |
| U-232 | Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| U-235 | Th-231 |
| U-238 | Th-234, Pa-234m |
| U-nat | Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210 |
| U-240 | Np-240m |
| Np-237 | Pa-233 |
| Am-242m | Am-242 |
| Am-243 | Np-239 |

Table 1

RADIONUCLIDE CONTAMINATION LEVELS IN FOOD ITEMS

| Radionuclide | Target Organ | Limits of radionuclide concentration level per Kg of Food (Bq/Kg) |
|---------------|-----------------------|---|
| Strontium-90 | Bone surface (infant) | 20 |
| Cesium-134 | Whole body (adult) | 50 |
| Cesium-137 | Whole body (adult) | 100 |
| Plutonium-239 | Bone surface (infant) | 2 |

Exception:

Milk powder shall be treated as being diluted 7 times with water when made ready for use, therefore, the limits of concentration as given above shall be multiplied by a factor of seven (07).

Formula for addition

This Annex shall be applicable to any of the above single radionuclide present in the food. When two or more radionuclides are found to be present, the formula applicable in such cases shall be worked according to the following sum(s):

S =

Actual level of radionuclide A

Limit for radionuclide A

+

Actual level of radionuclide B

Limit for radionuclide B

+

-----etc.

≤ 1

DOSE LIMITS FOR EXPOSURES INCURRED FROM PRACTICES

Table 1

ANNUAL DOSE LIMITS FOR RADIATION WORKERS
(Aged 18 years and above)

| Organ or Tissue | Dose Quantity | Dose Limits (mSv) |
|--|----------------------|------------------------------|
| Whole body | Effective dose | 20 [*] |
| Lens of the eye | Equivalent dose | 150 |
| Extremities (hands and feet) or Skin (average dose over 1 cm ² of the most highly irradiated area). | Equivalent dose | 500 |

* In special circumstances, an effective dose of up to 50 mSv in a single year provided that the average dose over five consecutive years does not exceed 20 mSv/year.

Table 2

ANNUAL DOSE LIMITS FOR APPRENTICES/STUDENTS
(16 to 18 years of age)

| Organ or Tissue | Dose Quantity | Dose Limits (mSv) |
|--|----------------------|------------------------------|
| Whole body | Effective dose | 6 |
| Lens of the eye | Equivalent dose | 50 |
| Extremities (hands and feet) or skin (average dose over 1 cm ² of the most highly irradiated area). | Equivalent dose | 150 |

Table 3

ANNUAL DOSE LIMITS FOR PUBLIC

| Organ or Tissue | Dose Quantity | Dose Limits (mSv) |
|------------------------|----------------------|------------------------------|
| Whole body | Effective dose | 1 [*] |
| Lens of the eye | Equivalent dose | 15 |
| Skin | Equivalent dose | 50 |

* In special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv/year.

Table 4

DOSE LIMITS FOR COMFORTERS/VISITORS OF PATIENTS

| Organ/Tissue | Dose Quantity | Dose Limits (mSv) |
|-----------------------|----------------|-------------------|
| Whole body (Adult) | Effective dose | 5 |
| Whole body (Children) | Effective dose | < 1 |

ANNEX IV

MEDICAL EXPOSURE: DESIGN AND OPERATIONAL REQUIREMENTS

DESIGN OF NUCLEAR MEDICINE, RADIOLOGY AND RADIOTHERAPY FACILITIES

- (1) The licensee shall ensure, in the design of radiology and radiotherapy facilities, that the treatment room is designed such that the dose level in the controlled and uncontrolled areas is within the limits as specified by the Authority. The provisions for safety systems or devices shall be inherent to the equipment or the room so as to reduce the occurrence of accidental radiation exposure.
- (2) Nuclear medicine: The licensee shall ensure that:
- (a) in the design of the facility the following factors have been taken into consideration:
 - (i) the classification of areas;
 - (ii) the type of work to be done; and
 - (iii) the radionuclides intended to be used and their activities;
 - (b) a safety assessment is performed in order to determine the special needs concerning ventilation, plumbing, materials used in walls, floor and benches;
 - (c) the floors of controlled areas are finished in an impermeable material, which is washable and resistant to chemical changes;
 - (d) source storage area is provided;
 - (e) area for temporary storage of radioactive waste is provided; and
 - (f) a separate room is provided for patients undergoing radionuclide therapy.
- (3) Diagnostic and interventional radiology: The licensee shall ensure that:
- (a) due consideration has been given to the:

- (i) classification of areas;
 - (ii) type of work to be done; and
 - (iii) X-ray system intended to be used;
- (b) the X-ray room is large enough to provide adequate shielding to the staff and to the persons in adjacent rooms;
- (c) the design of the room is such that the X-ray beam cannot be directed at any unshielded area or towards the doors;
- (d) the doors and electric switches are placed at an easily accessible point;
- (e) sufficient shielding with lead or equivalent material on walls, ceilings, doors and floors is incorporated in the design;
- (f) the ducts are designed in such a way that significant radiation cannot escape; and
- (g) the dark room, film storage and processing room, change room, waiting rooms and washrooms are located outside the X-ray exposure room.
- (4) External beam radiotherapy: The licensee shall ensure that the:
 - (a) facility includes examination rooms, simulator room, treatment planning room, mould room, treatment room and waiting areas.
 - (b) simulator room, treatment planning room and treatment room are designed in accordance with the design specification of the equipment.
 - (c) examination room is constructed in close proximity to the treatment room and the treatment planning room is located near the simulator room.
 - (d) power, air-conditioning and emergency system requirements are considered at the design stage.
- (5) Low dose-rate brachytherapy: The licensee shall make sure that:
 - (a) a source storage and preparation room, operating room, treatment planning room and patient room are incorporated in the design;
 - (b) these rooms are placed in close proximity so as to reduce distances over which the patient and source have to be transported; and
 - (c) the facility design incorporates features to avoid elevator transport of patients containing radioactive sources.
- (6) High dose-rate brachytherapy: The licensee shall make sure that:
 - (a) an operating room or outpatient surgery room, a radiographic imaging system room, treatment planning area and treatment room are incorporated in the design.
 - (b) all these rooms are constructed in close proximity to each other.

(7) The licensee shall ensure that the common space for all these modalities like office space for physicians and physicists, laboratories, dark room, patient registration and admission areas and file rooms are given due consideration while designing the facilities.

DESIGN OF SOURCES AND EQUIPMENTS

(8) The requirements for the safety of sources specified in regulation no. 20 of these regulations shall apply to sources used in medical exposure where relevant and, in particular, equipment used in medical exposure shall be so designed that:

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

OPERATIONAL ASPECTS

- (10) Diagnostic exposure: The licensee shall make sure that:
- (a) the medical practitioners who prescribe or conduct radiological diagnostic examinations:

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

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

(12) Therapeutic exposure: The licensee shall make sure that the medical practitioners who prescribe or conduct radiotherapy procedures with radiation sources or with radionuclides or radiation apparatus/generators:

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

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

TABLE 1

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

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

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

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

| <div> <div>TABLE 2</div> <div>DOSE GUIDANCE LEVELS FOR COMPUTED TOMOGRAPHY FOR A TYPICAL ADULT PATIENT</div> </div> | |
|---|--|
| Examination | Multiple scan average dose ^a (mGy) |
| Head | 50 |
| Lumbar spine | 35 |
| Abdomen | 25 |
| ^a Derived from measurements on the axis of rotation in water equivalent phantoms, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and abdomen) in diameter. | |

| <div> <div>TABLE 3</div> <div>DOSE GUIDANCE LEVELS FOR MAMMOGRAPHY FOR A TYPICAL ADULT PATIENT</div> </div> | |
|---|--|
| Average glandular dose per cranio-caudal projection ^a 1 mGy (without grid) 3 mGy (with grid) | |
| ^a Determined in a 4.5 cm compressed breast consisting of 50% glandular and 50% adipose tissue, for film -screen systems and dedicated Mo-target Mo-filter mammography units. | |

| <div> <div>TABLE 4</div> <div>DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT</div> </div> | |
|--|--|
| Mode of operation | Entrance surface dose rate ^a (mGy/min) |
| Normal | 25 |
| High level ^b | 100 |
| ^a In air with backscatter. ^b For fluoroscopes that have an optional 'high level' operational mode, such as those frequently used in interventional radiology. | |

TABLE 5

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

| Test | Radio-nuclide | Chemical form ^a | Maximum usual activity per test ^b (MBq) |
|--|-------------------------------|--|--|
| Bone | | | |
| Bone imaging | ⁹⁹ Tc ^m | Phosphonate and Phosphate compounds | 600 |
| Bone imaging by single photon emission computerized tomography (SPECT) | ⁹⁹ Tc ^m | Phosphonate and Phosphate compounds | 800 |
| Bone marrow imaging | ⁹⁹ Tc ^m | Labelled colloid | 400 |
| Brain | | | |
| Brain imaging (static) | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 500 |
| | ⁹⁹ Tc ^m | Diethylenetriaminepenta-acetic acid (DTPA), gluconate and glucoheptonate | 500 |
| Brain imaging (SPECT) | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 800 |
| | ⁹⁹ Tc ^m | DTPA, gluconate and Glucoheptonate | 800 |
| Cerebral blood flow | ⁹⁹ Tc ^m | Exametazime | 500 |
| | ¹³³ Xe | In isotonic sodium chloride solution | 400 |
| Cisternography | ⁹⁹ Tc ^m | Hexamethyl propylene amine oxime (HM-PAO) | 500 |
| | ¹¹¹ In | DTPA | 40 |
| Lacrimal | | | |
| Lacrimal drainage | ⁹⁹ Tc ^m | TcO ^l ₄ | 4 |
| | ⁹⁹ Tc ^m | Labelled colloid | 4 |
| Thyroid | | | |
| Thyroid imaging | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 200 |
| Thyroid metastases (after ablation) | ¹²³ I | I ⁻ | 20 |
| | ¹³¹ I | I ⁻ | 400 |
| Parathyroid imaging | ²⁰¹ Tl | Tl ⁺ , chloride | 80 |
| Lung | | | |
| Lung ventilation imaging | ⁸¹ Kr ^m | Gas | 6000 |
| | ⁹⁹ Tc ^m | DTPA –aerosol | 80 |
| Lung ventilation study | ¹³³ Xe | Gas | 400 |
| | ¹²⁷ Xe | Gas | 200 |
| Lung perfusion imaging | ⁸¹ Kr ^m | Aqueous solution | 6000 |

| Test | Radio-nuclide | Chemical form ^a | Maximum usual activity per test ^b (MBq) |
|--|-------------------------------|---|--|
| | ⁹⁹ Tc ^m | Human albumin (macroaggregates or microspheres) | 100 |
| Lung perfusion imaging (with venography) | ⁹⁹ Tc ^m | Human albumin (macroaggregates or microspheres) | 160 |
| Lung perfusion studies | ¹³³ Xe | Isotonic solution | 200 |
| | ¹²⁷ Xe | Isotonic chloride solution | 200 |
| Lung imaging (SPECT) | ⁹⁹ Tc | Macroaggregated albumin (MAA) | 200 |
| Liver and spleen | | | |
| Liver and spleen imaging | ⁹⁹ Tc ^m | Labelled colloid | 80 |
| Functional biliary system Imaging | ⁹⁹ Tc ^m | Iminodiacetates and equivalent agents | 150 |
| Spleen imaging | ⁹⁹ Tc ^m | Labelled denaturated red blood cells | 100 |
| Liver imaging (SPECT) | ⁹⁹ Tc ^m | Labelled colloid | 200 |
| Cardiovascular | | | |
| First pass blood flow Studies | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 800 |
| | ⁹⁹ Tc ^m | DTPA | 800 |
| | ⁹⁹ Tc ^m | Macroaggregated globulin 3 | 400 |
| Blood pool imaging | ⁹⁹ Tc ^m | Human albumin complex | 40 |
| Cardiac and vascular imaging/probe studies | ⁹⁹ Tc ^m | Human albumin complex | 800 |
| Myocardial imaging/probe studies | ⁹⁹ Tc ^m | Labelled normal red blood Cells | 800 |
| Myocardial imaging | ⁹⁹ Tc ^m | Phosphonate and Phosphate compounds | 600 |
| Myocardial imaging (SPECT) | ⁹⁹ Tc ^m | Isonitriles | 300 |
| | ²⁰¹ Tl | Tl ⁺ Chloride | 100 |
| | ⁹⁹ Tc ^m | Phosphonate and Phosphate compounds | 800 |
| | ⁹⁹ Tc ^m | Isonitriles | 600 |
| Stomach, gastrointestinal tract | | | |
| Stomach/salivary gland imaging | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 40 |
| Meckel's diverticulum Imaging | ⁹⁹ Tc ^m | TcO ⁻ ₄ | 400 |
| Gastrointestinal bleeding | ⁹⁹ Tc ^m | Labelled colloid | 400 |
| | ⁹⁹ Tc ^m | Labelled normal red blood Cells | 400 |
| Oesophageal transit and reflux | ⁹⁹ Tc ^m | Labelled colloid | 40 |
| | ⁹⁹ Tc ^m | Non –absorbable compounds | 40 |
| Gastric emptying | ⁹⁹ Tc ^m | Non –absorbable compounds | 12 |

| Test | Radio-nuclide | Chemical form ^a | Maximum usual activity per test ^b (MBq) |
|--|--------------------------------|-------------------------------------|--|
| | ¹¹¹ In | Non- absorbable compounds | 12 |
| | ¹¹³ In ^m | Non- absorbable compounds | 12 |
| Kidney, urinary system and adrenals | | | |
| Renal imaging | ⁹⁹ Tc ^m | Dimercaptosuccinic acid | 160 |
| Renal imaging/renography | ⁹⁹ Tc ^m | DTPA, glirconate and Glucoheptonate | 350 |
| | ⁹⁹ Tc ^m | Macroaggregated globulin 3 | 100 |
| | ¹²³ I | O-iodohippurate | 20 |
| Adrenal imaging | ⁷⁵ Se | Selenorcholesterol | 8 |
| Miscellaneous | | | |
| Tumour or abscess | ⁶⁷ Ga | Citrate | 300 |
| Imaging | ²⁰¹ Tl | Chloride | 100 |
| Tumour imaging | ⁹⁹ Tc ^m | Dimercaptosuccinic acid | 400 |
| Neuroectodermal tumour imaging | ¹²³ I | Meta -iodo –benzyl Guanidine | 400 |
| | ¹³¹ I | Meta-iodo-benzyl guanidine | 20 |
| Lymph node imaging | ⁹⁹ Tc ^m | Labelled colloid | 80 |
| Abscess imaging | ⁹⁹ Tc ^m | Exametazime labelled white Cells | 400 |
| | ¹¹¹ In | Labelled white cells | 20 |
| Thrombus imaging | ¹¹¹ In | Labelled platelets | 20 |

^a In some countries some of the compounds are considered obsolete.

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

TABLE 6

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

| Radionuclide | Activity (MBq) |
|--------------|-------------------|
| Iodine-131 | 1100 ^a |

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

ANNEX VI

MEDICAL TESTS FOR HEALTH SURVEILLANCE

- (1) General tests:
 - (a) Blood CP (Haemoglobin, ESR, TLC, DLC, RBC & WBC with Morphology)
 - (b) Urine (Routine) examination
 - (c) Chest X-Ray, if needed.

(2) If the working conditions are such that the doses are expected to be higher as in industrial radiography, in addition to above following tests may be required:

| <u>Blood tests</u> | <u>Urine examination</u> |
|--|--------------------------|
| (a) Clotting profile | (a) Routine examination |
| (b) Platelet counts | (b) Renal Function Tests |
| (c) HLA Typing | |
| (d) Serum Electrolytes (Sodium, Potassium etc) | |
| (e) Serum Proteins | |
| (f) Serum Urea/Creatinine | |

(3) If the nature of work is such that the possibility of exposure through ingestion or inhalation can be expected to occur like a nuclear medicine department, etc. in addition to blood & urine examinations, following tests are recommended:

- (a) Fecal examination (Routine & bioassay for radionuclides)
- (b) Bioassay of urine for radionuclides
- (c) Examinations of other body fluids like sweat, saliva, etc. for radionuclide detection
- (d) Thyroid function tests
- (e) Thyroid scan

(4) Psychiatric examination is required in case of reactor operators/supervisors

(5) In addition to above, if any test results indicate some kind of abnormality, the following tests can be conducted:

- (a) bone scanning,
- (b) serum electrophoresis,
- (c) blood cytogenic analysis & radionuclide detection tests on blood or urine or
- (d) any other special test as desired by the treating physician. "

Sd/
JAWAD A. HASHIMI,
Corporate member,
Pakistan Nuclear Regulatory Authority.

Annexure-VII

**QUALIFICATION & TRAINING CRITERIA FOR RPO/HEALTH PROFESSIONAL/
MEDICAL PROFESSIONAL OF RADIATION FACILITIES AND PRACTICES**

| Serial No. | Type of Facility | Qualification | [≠] Training Period (months) |
|------------|---|--|---------------------------------------|
| 01. | Radiotherapy/ Nuclear Medicine | 1. M.S. in Medical Physics or 2. M.B.,B.S. plus following qualification in order of preference: a) F.C.P.S./F.R.C.R.(Radiotherapy) or equivalent recognized by P.M.D.C. or b) Diplomate American Board (Radiotherapy) recognized by P.M.D.C. or c) D.M.R.T./M.C.P.S.(Radiotherapy) recognized by P.M.D.C. with 03 years practical experience in radiotherapy after post graduation | 03 |
| | | M.Sc. with Physics or Chemistry or *M.B.,B.S. | 06 |
| 02. | Radiology (Interventional Diagnostic, CT, Angiography, Fluoroscopy & Mammography) | 1. M.S. in Medical Physics/Health Physics or 2. M.B., B.S. plus following qualification in order of preference: a) F.C.P.S./F.R.C.R. or equivalent recognized by P.M.D.C. or b) Diplomate American Board (Radiology) recognized by P.M.D.C. or c) D.M.R.D./M.C.P.S. (Radiology) recognized by P.M.D.C. with 03 years practical experience in Radiology after post graduation | 03 |
| | | M.Sc. with Physics or Chemistry or *M.B., B.S. | 06 |
| | Conventional Diagnostic Radiology (X-ray) | *M.B.,B.S. or Certified Radiographer (Medical) | 03 |
| | | F. Sc. with Physics or Chemistry or equivalent (For small independent conventional diagnostic set-ups operating with one X-ray machine) | 06 |
| 03. | Irradiator (Sterilization/ Food processing) | M.Sc. with Physics or Chemistry | 03 |
| 04 | Irradiator (Blood/Research) | B.Sc. with Physics or Chemistry | 03 |
| | | F. Sc with Physics or Chemistry or equivalent | 06 |
| 05. | Industrial Radiography | F. Sc. with Physics or Chemistry or equivalent and Level-II radiography certification | 06 |
| 06. | Nuclear Gauges | M.Sc. with Physics or Chemistry | 03 |
| | | B.Sc. with Physics or Chemistry | 06 |

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| 07. | Oil Well Logging | M.Sc. with Physics or Chemistry | 03 |
| | | B.Sc. with Physics or Chemistry | 06 |
| 08. | Academic Research and Development | M.Sc. with Physics or Chemistry | 03 |
| | | B.Sc. with Physics or Chemistry | 06 |
| 09. | Gas Mantle Manufacturing | F. Sc. with Physics or Chemistry or equivalent | 03 |
| 10. | Importers (involved in installation, testing and maintenance) | F. Sc with Physics or Chemistry or equivalent | 03 |
| 11. | Scanning Machines (Baggage Scanners) | F. Sc with Physics or Chemistry or equivalent | 03 |
| | Scanning Machines (Industrial or Cargo Scanners) | F. Sc with Physics or Chemistry or equivalent | 06 |
| 12. | Radioimmunoassay (RIA) Labs | F. Sc with Physics or Chemistry or equivalent | 03 |

* Registered Medical Practitioner (RMP)

≠ On the job training in relevant radiation protection requirements

ABDUL MANNAN
Secretary

PAK/904 ammended vide S.R.O.(303)(I)/2012 dated the 28th March, 2012