and which shall include a reference to any relevant report of an investigation.

(89) Employers shall:

(a) provide for access by any Worker to the Worker's own dose records;

(b) make dose records available to the approved supervising physician, the Regulatory Authority and the Operator when appropriate;

(c) when a Worker changes employment, communicate his or her dose records to the new Employer; and

(d) when the Employer ceases his activities or a Worker ceases to work, retain the Worker's dose records or transfer them to any relevant Operator, to the Regulatory Authority or, if required, to a relevant dose registry, as appropriate.

(90) Employers and Operators who retain dose records shall preserve them during the working life of the Worker and afterwards not less than 30 years after the termination of the work involving exposure to radiation and until the Worker attains or would have attained the age of 75 years.

2.8.13 Control of Natural Sources of Radiation in Workplaces

(91) Operators shall:

(a) apply these Standards when undertaking any work in a practice involving exposure to Natural Sources where such practice is expected to cause occupational exposures in addition to the background exposure that the worker receives and whenever such additional exposure can be reasonably regarded as being under the control of the employer; and

(b) observe, when designing and constructing any new workplace, the requirements of any code of practice approved by the Regulatory Authority

for the purpose of ensuring an adequate degree of occupational radiation protection against radon.

2.8.14 Radiation Protection in Uranium and Thorium Mines and Mills

(92) For the purposes of these Standards:

(a) A uranium or thorium mine (hereinafter generally called a mine) is any mine that yields ore containing uranium or thorium in sufficient quantities or concentrations to warrant exploitation, either for uranium or thorium alone or in conjunction with other substances which may be recovered in processing;

(b) A uranium or thorium mill (hereinafter generally called a mill) is uranium or thorium ore to produce a physical or chemical concentrate.

(93) The provisions for optimization, dose assessment, reporting, quality assurance and other requirements specified in other parts of these Standards also apply to mining and milling, as appropriate. Additional requirements are included in this section because the radiological conditions in mines and mills and the radiation safety requirements are substantially different than in other practices and covered by the Standards. Greater quantities of radioactive material are handled and the radiological hazards are dominated by the inhalation of radioactive substances. Consequently, ventilation and measure for the control of radioactive dust play a relatively greater role. Another peculiarity of mining is that the workplace and their radiological conditions change continually as mining proceeds.

General requirements

(94) The operator of each mine and mill shall:

(a) have available, at the design development and operating stages, the services of qualified experts in radiation protection, ventilation and dust control;

(b) give priority to protective measures incorporated into the design, construction and layout of mines and mills;

(c) establish good radiation protection and operating procedures and provide for the use of protective equipment as necessary;

(d) establish reference levels at which specified corrective actions are to be taken in the event of shortcomings in radiation safety measures and which are appropriate for the conditions peculiar to each mine and mill; and

(e) ensure that any rotation of workers to different working areas in order to limit their exposure is not done in place of providing properly designed and ventilated workplaces nor instead of using good radiation control procedures.

Design requirements for radiation safety in mines

(95) With regard to the design of ventilation systems, the Operator shall ensure, to the extent reasonably feasible, that:

(a) exploratory development workings are located in barren rock adjacent to ore bodies if such workings are to be used as fresh airways during ore removal operations;

(b) the layout of working areas in a mine is planned so as to minimize the number of working areas to be mined at the same time and so as to facilitate the provision of good ventilation in each working area;

(c) the quantity and quality of air provided to each working area are sufficient to ensure that exposures to radon and thoron daughters and ore dust are as low as reasonably achievable;

(d) air is supplied directly to each working area, preferably through airways that are outside the ore;

(e) ventilation flows are single-pass such that the air supplied to each working area has not already passed through another working area, and such that the residence time of radon and thoron in working areas is minimized;

(f) air pumped into rather than extracted from a mine so as to keep the pressure above atmospheric and so minimize the diffusion of radon and thoron from the rock into the mine;

(g) air inlet points to the mine are located so as to prevent possible contamination by air exhausted from the mine;

(h) fixed working stations are located in return airways or in areas with high levels of gamma radiation; and

(i) mine water with a high radon or thoron content is confined as close as possible to its source and routed to a sump or other convenient location for pumping to the surface, air from the sump is exhausted to the return air system, and water is piped from each level and not be allowed to fall to the bottom of the shaft, especially if the shaft conveys fresh air.

(96) With regard to the control of radioactive dust, the Operator shall insure that:

(a) the generation of dust is minimized by providing appropriate dust suppression and control devices on each piece of dust-generating equipment and in each working area;

(b) any dust that is generated is controlled by means such as ventilated enclosures and filtration as appropriate, and by keeping dust generating surfaces wetted with water;

(c) ore transport equipment is designed so as to minimize spills;

(d) where ore is to be dumped, that the free-fall distance is minimized so as to limit dust dispersal;

(e) the number of transfer points for broken rock is as small as reasonably achievable; and where feasible, loading and transfer of ore is done within an enclosure from which the air is exhausted directly to the return airway or scrubbed before release to working areas.

Operating requirements for radiation safety

(97) With regard to the operation of ventilation systems, the Operator shall ensure that:

(a) ventilation equipment is operated properly and under the supervision of the Ventilation Officer, and such as to ensure an adequate supply of fresh air to each working area and an adequate air velocity at each working face;

(b) the main ventilation systems are operated continuously while mining is in progress, with no substantial changes unless authorized by the Regulatory Authority or in case of emergency;

(c) in the event of shutdown of the ventilation system for any workplace, workers leave that workplace, go to an adequately ventilated area, and use respiratory protective equipment as appropriate;

(d) workers do not resume their regular work in their regular workplaces until adequate ventilation has been restored and radon and thoron daughters and dust are at acceptable levels as confirmed by appropriate monitoring;

(e) The flow of contaminated air from abandoned or unoccupied working areas into occupied areas is prevented by means such as sealed bulkheads or appropriate ventilation;

(f) mining is conducted towards the fresh-air supply with the air being exhausted through worked-out or abandoned areas and such as to prevent recirculation of the contaminated air leaving the working place;

(g) where ventilation or dust suppression measures are insufficient for maintaining adequate air quality in a working area, that enclosed operating booths with filtered air supplies are provided.

(98) With regard to the control of radioactive dust during mining, the operator shall ensure that:

(a) the generation of dust is minimized at the source by the proper operation of equipment and dust-suppression devices and by proper operating procedures;

(b) the amount of broken one in workplaces is kept as small as reasonably achievable so as to minimize the surface area of ore exposed to the atmosphere;

(c) before igniting a blast, that the surrounding area is thoroughly wetted with water so as to minimize dust dispersal, and that workers do not reenter an area after blasting until the dust from blasting has settled or been removed;

(d) the generation of dust during ore crushing is minimized by keeping all ... surfaces wetted with water;

(e) if wetting with water is insufficient to control dust at crushers, crushers are enclosed and exhausted such that unacceptable quantities of dust do not escape from the crusher enclosure;

(f) continuous or frequent re-wetting of broken rock is carried out during loading to ensure that the rock remains wet, and that it is rewetted at each handling point;

(g) spillage of ore during transport is cleaned up before the ore dries out;

(h) workers stay on the air-supply side of loading, dumping and transfer operations; and

(i) fine rock particles and dust are cleaned from returning conveyor belts.

(99) With regard to monitoring, the operator shall ensure that radiological conditions and worker exposure are monitored as required by other parts of these standards, and that:

(a) monitoring locations and frequencies are such as to provide information necessary for ensuring the proper operation of the ventilation and dust control systems;

(b) the radon and thoron concentrations in any source of water encountered in the course of mining are determined;

(c) the monitoring programmes are established in consultation with appropriate Qualified Experts and conducted under their supervision;

(d) the locations and frequencies of monitoring are modified as appropriate in the event of:

- measured concentrations exceeding the usual range in any working area,
- substantial changes in the ventilation system, mine layout or mining method,
- a reference level being reached, or
- a suspected increase in the rate of entry of radon or thoron into a working area.

Requirements for Radiation Safety in Mills

(100) The ventilation, confinement and dust control requirements specified for mines are also generally applicable in mills, although the relatively high concentrations of uranium or thorium

and their decay products in mills must be taken into account, as well as their chemical toxicity. In addition, shielding against beta and gamma radiation is generally more important and feasible in mills than is mines.

(101) The Operator shall ensure that:

(a) product packaging and sampling areas of the mill are enclosed, with the exhausted air passed through a scrubber to remove radioactive dust, and, to the extent reasonably feasible, other concentrated radioactive and toxic materials are handled with automated equipment in enclosures where negative air pressure is maintained;

(b) gloves are worn as appropriate for protection against contamination of the skin with uranium and thorium, against absorption of these materials through the skin and protection of the skin from irradiation by beta particles;

(c) good housekeeping is maintained and spills of concentrate are cleaned up with vacuum cleaners so as to minimize the suspension of dust;

(d) respirators are worn during abnormal conditions involving dusty operations;

(e) strict personal hygienic is enforced and smoking and eating are prohibited in the drying and packaging areas;

(f) contamination monitoring is done in areas where concentrates are handled in order to assess the effectiveness of the measures for controlling radioactive dust, and the colour of walls and equipment in such areas is such as to contrast with the colour of the concentrates.

Instruction and Training of Mine and Mill Workers

(102) The Employer shall ensure that all workers who are liable to be exposed to radiation and radioactive substances in a mine or mill receive appropriate instruction regarding:

(a) the radiological risks they may encounter during their work;

(b) the importance of following all the safety procedures, including the suppression of dust and the maintenance of an adequate supply of fresh air to workplaces;

(c) the main features of the ventilation system, the importance of its proper operation, and the need for immediate reporting of any break-down of the system to the supervisor or the Ventilation Officer;

(d) the reasons for abstaining from eating and smoking in working areas and the importance of personal hygiene;

(e) the importance of cleaning of any wounds caused in areas where concentrated radioactive substances are present and of wounds caused by contaminated equipment, and the need for properly dressing any cuts or wounds, with waterproof dressings before entering working areas.

2.8.15 Exposure of Workers Not Involved in Radiation Work

(103) Where a source of exposure is unconnected with the work, or the work is in premises not containing the radiation source giving rise to the exposure, Employers shall for dose limitation purposes treat the workers concerned as if they were members of the public.

2.8.16 Reference Exposure Levels for Workers Undertaking Protective Actions

(104) Reference levels of exposure of individual Workers undertaking protective actions shall not exceed the dose limits for Workers specified in Annex II, except:

(a) for the purpose of saving life or preventing serious injury; and

(b) while undertaking actions intended to avert a large collective dose or extensive property damage.

(105) Reference levels, as well as any procedure whereby exposures in excess of dose limits may be authorized, shall be specified in relevant emergency plans and shall be subject to approval by the Regulatory Authority.

(106) All reasonable steps shall be taken to assess the doses received by workers involved in interventions, and the assessed doses shall be entered:

(a) in the records for normal exposure; or

(b) where no records exist, in a special record set up for the purpose.

2.9 REQUIREMENTS FOR CONTROLLING MEDICAL EXPOSURES

2.9.1 Responsibilities

(107) The Licensee shall be responsible for overseeing the operation of the relevant sources for medical exposure under his administrative control and shall ensure that the following requirements are met.

2.9.2 Requirements

(108) No person shall receive a medical exposure unless such exposure is authorized by a Practitioner holding the appropriate licence.

(109) No person shall be exposed intentionally to radiation or radioactive substances for demonstration, training or any other similar non-medical purpose unless such exposure is an occupational exposure or a public exposure from a practice or an intervention situation.

(110) Individuals operating sources for medical exposures shall be adequately instructed in safe operating procedures and be competent in the safe use of the source.

(111) Written safety procedures shall be provided to each person operating a source for medical exposure which include any restrictions on the operating technique required for the safe operation of the particular system.

(112) For the therapeutic use of radiation the calibrations required by these Standards shall be performed under the supervision of a Qualified Expert in Radiotherapy Physics who is present

during such calibration; and treatment planning shall be performed under the supervision of a Qualified Expert who is present during such treatment planning.

2.9.3 Justification of Medical Exposures

(113) Medical exposures shall be subject to justification by weighing the benefits they produce against the radiation detriment caused, taking into account the feasibility of using alternative techniques that do not require exposure to radiation and following the principles established in 'A Rational Approach to Radiodiagnostic Investigations', WHO Technical Report Series 689[12], and 'Rational Use of Diagnostic Imaging in Paediatrics', WHO Technical Report Series 757.[13]

(114) Radiological examinations for occupational purposes undertaken without reference to clinical indications are deemed to be unjustified unless they provide useful information on the health of the examined individual.

(115) The medical exposure of population groups for purposes of mass screening is deemed to be unjustified unless based on a positive balance between the advantages implied for the individuals examined or of the population as a whole, taking into account the economic and social costs including radiation detriment. In general, the advantages will depend on the detection potential of the screening procedure, the possibility of effective treatment of cases detected and, for certain diseases, the advantages to the community of the control of the disease.

(116) The medical exposure of individuals or population groups for obtaining health information for legal purposes or for assessing health for insurance purposes is deemed to be unjustified.

(117) The exposure of human subjects for medical research is deemed to be unjustified unless:

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[12] World Health Organization, Technical Report Series 689, Geneva, 1983

[13] World Health Organization, Technical Report Series 757, Geneva, 1987

(a) it is in accordance with the provisions of the Helsinki Declaration[14];

(b) it is undertaken with the consent of the health authorities responsible for the institutions where the exposures occur;

(c) it is subject to the advice of an Ethical Review Committee and to local and national regulations and follows the principles established in 'Use of Ionizing Radiation and Radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes', WHO Technical Report Series 611.[15]

(118) The medical exposure of persons under the age of 18 years for research purposes shall be deemed not justified unless the project is specific to their age group.

2.9.4 Optimization of Protection for Medical Exposures

(119) In diagnostic medical exposures, in addition to the requirements of optimization of protection in other parts of these Standards, the following requirements for keeping medical exposures as low as reasonably achievable and in accordance with good clinical practice shall apply:

(a) the exposure of patients shall be the minimum required to produce good diagnostic images, following the principles established in 'Effective Choices for Diagnostic Imaging in Clinical Practices', WHO Technical Report Series 795[16];

(b) image receptors, including film or screen and film combinations, shall be of the highest sensitivity consistent with the diagnostic objectives of the examinations;

(c) standards of acceptable image quality established by appropriate professional bodies shall be used by the responsible medical or dental practitioner;

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[14] Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1974, and as amended by the 29th World Medical Assembly, Tokyo, Japan. 1975. and the 35th World Medical Assembly. Venice. Italy, 1983. and the 41st World Medical Assembly, Hong Kong, 1989; available from the World Medical Association Inc., 01210 Ferney-Voltaire, France

[15] World Health Organization, Technical Report Series 611, Geneva 1977

[16] World Health Organization, Technical Report Series 795, Geneva 1990

(d) diagnostic X ray systems other than fluoroscopic, dental, intraoral, or computed tomographic shall not be used in procedures where the source to patient distance is less than 0.3 m;

(e) portable or mobile X ray equipment shall be used only for examinations where it is not feasible to transfer patients to a stationary X ray installation;

(f) guidelines for achieving diagnostic effectiveness for common diagnostic techniques should be developed in collaboration with the appropriate professional bodies and the Regulatory Authority;

(g) particular attention should be given to the available options such as type of image receptor (e.g. high versus low speed screens), and operational factors such as tube potential, current and time, and image processing;

(h) the Practitioner who undertakes a radiological examination shall optimize the protection of the patient, taking into account relevant information from previous examinations and considering whether the necessary information can be obtained with less risk by other techniques;

(i) particular attention shall be paid to the diagnostic exposure of those sectors of the population that may be more sensitive to radiation, such as women who might be pregnant, nursing mothers and children, and avoidance or delay of exposure or use of alternative procedures that do not involve exposure to radiation should be considered, in consultation with specialists in obstetric and pediatric radiology;

(j) any radiological examination of the abdomen or pelvis of women of reproductive capacity shall be planned so as to deliver the minimal dose to any foetus or embryo that might be present;

(k) whenever feasible and appropriate, gonad shielding shall be used to protect the germinal tissue of patients undergoing radiodiagnostic procedures;

(l) the dose to the conceptus during exposures for diagnostic purposes shall be minimized.

(120) For therapeutic medical exposures, the following requirements shall apply, with due account taken of the fact that the primary consideration in therapy is to provide optimal treatment for the patient:

(a) exposure of normal tissue during radiotherapy shall be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume;

(b) all the requirements of optimization of protection for diagnostic medical exposures shall apply whenever feasible.

2.9.5 Exposure Constraints and Reference Levels

(121) The limits and constraints prescribed in Appendices II and III do not apply to medical exposures.

(122) For patients undergoing diagnostic medical exposures, dose or dose rate reference levels such as those presented in Appendix V shall be developed for common diagnostic procedures in consultation with the appropriate professional bodies and shall be applied by the Practitioner.

(123) Dose constraints shall apply to persons exposed for biomedical research purposes when there is no direct benefit to the exposed individual. The dose constraints shall be specified by the Ethical Review Committee on a case by case basis.

(124) The Licensee shall apply dose constraints to medical exposures incurred knowingly and voluntarily by any individual helping in the care, support or comfort of patients undergoing diagnosis or treatment [when giving such care, support or comfort is not part of the individual's occupation]. The projected effective dose for any adult helping in the care, support, or comfort of patients undergoing diagnosis or treatment or for visitors of patients who have received therapeutic amounts of radionuclides or who have been treated with brachytherapy sources should not exceed five times the dose limits for public exposure.

(125) Dose constraints shall apply to members of the households of patients who have undergone therapeutic procedures with sealed or unsealed radionuclides. Such patients shall not be discharged from treatment until the projected effective dose for any adult member of the

household is unlikely to exceed five times the dose limit for public exposure. The projected effective dose for children in the household should not exceed the dose limit for public exposure.

2.9.6 Potential Medical Exposures

(126) The requirements of these Standards shall apply for the safety of sources shall apply to sources used for medical exposure. In particular:

(a) the probability of equipment failure leading to unplanned exposure of patients shall be minimized by reducing the probability of occurrence of sequences of events leading to potential exposures;

(b) the Licensee shall identify possible equipment failures and human errors that could result in unplanned medical exposure and shall:

- take all reasonable measures to prevent the failures or errors;
- take all reasonable measures to minimize the consequences of failures and errors that do occur;
- develop appropriate emergency plans.

(c) the incidence of human error in delivering medical exposures shall be minimized by the selection of suitably trained personnel who shall be given periodic instruction in radiological procedures and in radiation protection and safety.

2.9.7 Training

(127) All clinicians, physicists, engineers, technicians, nurses and other persons involved in medical exposures shall be suitably instructed and trained in those aspects of protection and safety relevant to medical exposures. The training shall be updated periodically.

(128) Training courses and curricula shall be subject to approval by the Regulatory Authority in consultation with relevant professional bodies.

2.9.8 Design Requirements related to Medical Exposures

(129) All radiological equipment and other sources for medical exposures, [whether manufactured in the country where they are used or imported,] shall conform to the relevant standards of the International Electrotechnical Commission (IEC) and to any relevant design requirement in these Standards. In addition they shall be designed in compliance with the following requirements:

(a) Diagnostic radiography devices and accessories shall be designed and manufactured so as to reduce medical exposures to values as low as reasonably achievable consistent with obtaining adequate diagnostic information.

(b) Diagnostic radiography devices shall include provisions for setting operational parameters such as tube potential (kV), filtration, focal spot size, source-image receptor distance, field size indication and either tube current (mA) and time(s) or their product (mAs), except equipment values of such operational factors as source image receptor distance, filtration, antiscatter grids and focal spot size; and all operational factors shall be accurately indicated.

(c) Exposure from radiation sources other than radiotherapy simulators or electron accelerator portal imaging devices shall be limited to the area being examined or treated by using collimating devices aligned with the radiation source.

(d) Exposure outside the examination or treatment field due to radiation leakage or scattering shall be as low as reasonably achievable and consistent with national or IEC standards agreed to by the Regulatory Authority.

(e) The radiation field uniformity within the examination or treatment area shall conform to national or IEC standards agreed to by the Regulatory Authority.

(f) Diagnostic radiography devices and therapeutic equipment shall be provided with reliable radiation beam control mechanisms including reliable devices that indicate clearly to the operator whether the beam is on or off.

(g) Radiography devices shall be provided that automatically terminate the irradiation after a preset time, tube current time product or dose.

(h) High energy therapy equipment shall have at least two independent systems for terminating the irradiation and shall comply with IEC Standards 601-1-2.

(i) Radiotherapy equipment shall be designed and constructed so that the radiation beam intensity or energy may be modified as required for clinical applications. Beam parameters for radiation generators shall be clearly indicated and reliable interlocks shall be provided to prevent accidental exposures or to preclude excessive beam energies.

(j) Radiation generators used for radiotherapy shall include provisions for setting and accurate indication of operational parameters such as type of radiation, modality, nominal energy, radiation beam modifiers, treatment distance, field size, beam orientation and either treatment time or preset dose.

(k) High energy radiotherapy equipment shall be provided with interlocks designed so as to prevent the use of the machine in conditions other than those selected at the control panel.

(l) The design of safety interlocks shall be such that operation from the control panel is prevented during maintenance.

(m) Equipment that uses radioactive sources shall be fail-safe in the sense that the source will be automatically shielded in the event of a power interruption and will remain shielded until the beam control mechanism is reactivated from the control panel.

(n) Radioactive teletherapy sources shall be sealed in welded capsules housed in welded containers.

(130) The performance specifications and protection and safety features of any equipment used for medical exposure shall be clearly stated and shall be made available in a major world language acceptable to the user.

2.9.9 Clinical Dosimetry

(131) Representative entrance surface doses to patients undergoing radiodiagnostic procedures shall be determined and evaluated to facilitate comparison with reference levels such as those presented in Appendix V.

(132) For radiotherapeutic treatments with either radiation generators or sealed sources, the internal dose distribution for each patient shall be calculated and an optimal treatment plan developed such that:

(a) the prescribed dose at the prescribed energy and is delivered to the planning target volume;

(b) other tissues receive doses within the ranges accepted in good clinical practice.

(133) Representative doses to patients from unsealed sources used in diagnosis or treatment shall be estimated.

(134) Patient dose records shall be kept as follows:

(a) for diagnostic radiology, surface entrance doses for a standard size patient;

(b) for nuclear medicine, activities administered;

(c) for radiation therapy, the doses actually delivered to the planning target volume and their fractionation.

2.9.10 Calibration

(135) The following routine calibrations shall be done for sources used for medical exposure and the calibrations shall be traceable to a Primary or Secondary Standards Dosimetry Laboratory:

(a) linear accelerators and other radiation generators used for medical exposures for therapeutic purposes shall be calibrated in terms of absorbed dose and beam energy delivered at the treatment distance under specified conditions and following the recommendations given in IAEA Technical Reports Series No. 188[17];

(b) radionuclide teletherapy units shall be calibrated in terms of absorbed dose rate at the treatment distance under specified conditions;

(c) sealed radioactive sources shall be calibrated in terms of activity and absorbed dose rate at a specified distance;

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[17] International Atomic Energy Agency, Radiological Safety Aspects of the Operation of Electron Linear Accelerators, Technical Reports Series No. 188, IAEA, Vienna (1976)

(d) unsealed radioactive sources shall be calibrated in terms of activity;

(e) the instrumentation used in quality assurance procedures, such as activity and dose meters, shall be calibrated at approved intervals.

2.9.11 Quality Assurance for Medical Exposures

(136) The [relevant] requirements on quality assurance elsewhere in these Standards also apply to medical exposures and the following additional requirements apply:

(a) Equipment and safety features shall be checked against the supplier's performance specifications on installation and periodically thereafter.

(b) A comprehensive quality assurance programme for medical exposures with the participation of [competent] experts in relevant fields shall be established, following the principles established in 'Quality Assurance in Diagnostic Radiology'[18], 'Quality Assurance in Nuclear Medicine'[19], and 'Quality Assurance in Radiotherapy'[20], and Control de Calidad en Radioterapia:Aspectos Clinicos y Fisicos, PAHO Publication Cientifica 499'.[21]

(c) The quality assurance programme shall include measurements of the physical parameters of the radiation sources in use as well as verification of the physical and clinical factors used in each patient diagnosis or treatment.

(d) Sealed sources shall be checked periodically for leakage.

2.9.12 Investigations of Medical Exposures

(137) The licensee shall thoroughly investigate any of the following incidents as soon as possible and prepare a written report which states the cause of the occurrence, presents calculations or

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[18] World Health Organization, Geneva, 1982

[19] World Health Organization Geneva 1982

[20] World Health Organization, Geneva, 1988

[21] Pan American Health Organization, Publication Cientifica 499, Washington D.C., 1986

estimates of the doses received and gives recommendations for preventing recurrence of such an incident, and shall submit a summary report on the investigation to the Regulatory Authority as soon as possible:

(a) any therapeutic dose exceeding the intended dose by 10% or more;

(b) any diagnostic exposure significantly greater than intended;

(c) doses repeatedly exceeding established dose constraints or reference levels;

(d) any equipment failure, accident, error, mishap or other unusual incident with the potential for causing a significant overexposure of a patient.

2.10 REQUIREMENTS FOR PUBLIC EXPOSURE

(138) These requirements may be applied either to individual members of the public or to critical groups, where a critical group is representative of the individuals most exposed to radiation and is fairly homogeneous in respect of the parameters influencing the dose received.

2.10.1 Control of External Radiation

(139) No Operator shall use a beam of radiation that delivers public exposure unless specifically authorized by the Regulatory Authority.

(140) Prior to construction, the floor plans and equipment arrangements of all new installations or modifications of existing installations utilizing beams of radiation that may deliver public exposure shall be submitted to the Regulatory Authority for review and approval.

(141) No Operator shall transfer a generator able to deliver public exposure to any other person until it has been established that the receiver of the generator possesses a valid authorization or licence.

(142) The Operator shall notify the Regulatory Authority upon disposal of a non-functional generator that may deliver public exposure or upon the transfer of a functional generator to another authorized user.

2.10.2 Control of Radioactive Effluents

(143) For the purpose of these Standards radioactive effluents are those radioactive substances arising from a source within a practice which are released into the environment with the intention of dilution and dispersal, regardless of the physical state of those substances.

(144) Radioactive effluents from sources shall be limited following the principles established in IAEA Safety Series No. 77[22].

(145) Whenever a source may release radioactive substances that can deliver doses on a regional or global scale, specific dose constraints shall be established following the principles established in IAEA Safety Series 92[23].

(146) In addition, the Operator shall:

(a) determine:
- all significant pathways by which discharged radionuclides could reach humans, taking into account any preoperational studies;
- the critical groups for important pathways;
- the transfer parameters in the important pathways;

(b) use, in the absence of sufficient information regarding the transfer parameters for the local environment into which radionuclides are discharged, conservative values of transfer parameters such that the exposures due to the discharged radionuclides are not underestimated;

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[22] International Atomic Energy Agency, Principles for Limiting Releases of Radioactive Effluents into the Environment, Safety Series No. 77, IAEA, Vienna (1986)

[23] International Atomic Energy Agency, Principles for the Establishment of Upper Bounds to Individuals from Global and Regional Sources, Safety Series No 92, IAEA, Vienna (1989)

(c) optimize the effluent treatment processes and control devices, and in so doing:
- constrain the annual effective dose commitment to members of the public to the levels specified by these Standards;
- where the optimization analysis is based on differential cost-benefit analysis, use the monetary value for the unit collective effective dose stipulated by the Regulatory Authority and apply the requirements established in IAEA Safety Series No. 67 [24], for any transboundary component of the collective dose, 'Assigning a Value to Transboundary Radiation Exposure';

(d) submit for the approval of the Regulatory Authority, authorized limits for annual discharges and for discharges over shorter periods, on the basis of optimization analysis, taking into account the expected variability of dispersion of the discharged radionuclides into the local environment;

(e) monitor discharges of radionuclides so as to verify compliance with the authorized release limits and estimate the dose to members of the public due to discharged nuclides;

(f) record the monitoring results and estimated doses;

(g) report a summary of the monitoring results and dose estimates to the Regulatory Authority at approved intervals;

(h) report promptly to the Regulatory Authority any substantial deviation from normal discharges and any circumstances that indicate that substantial deviations might occur.

2.10.3 Management of Radioactive Wastes other than Effluents

(147) For the purpose of these Standards, the term radioactive waste is used to mean those radioactive materials arising from a source within a practice that are retained for the purpose of isolation from the biosphere, regardless of the physical state of those materials.

(148) The Operator shall ensure that:

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[24] International Atomic Energy Agency, IAEA Safety Guide, Safety Series No. 67, Vienna, 1985

(a) an integrated strategy is developed for the management of radioactive waste that includes collection, handling, treatment, conditioning, storage, transport and disposal of the waste;

(b) where a multiple barrier waste management system is required, reliable containment of radioactive waste in both normal conditions and potential disruptive events is demonstrated.

(149) The Operator shall ensure that its radioactive wastes are so managed such that:

(a) the amount of wastes is minimized by appropriate use of materials, methods, processes and management practices;

(b) where substantially different types of radioactive waste are produced, the different types are segregated and treated separately, taking into account radionuclide content, half-life, concentration, physical and chemical properties;

(c) no unauthorized amounts of radioactive substance reach humans under normal conditions;

(d) the risks to future generations from radioactive wastes do not exceed the risks that are acceptable at the time the wastes are disposed of, taking into account foreseeable events that could disrupt the waste management or disposal arrangements;

(e) the probability of disruptive events is constrained as prescribed in Appendix IV;

(f) the availability of natural resources is not unduly restricted by the construction or location of waste management facilities.

2.10.4 Environmental Monitoring

(150) Those licensees or registrants specified by the Regulatory Authority shall:

(a) carry out sufficient environmental monitoring and assessment to ensure that the conditions assumed in deriving the release limits remain valid;