

**REGULATION No. 307/2002 Coll.  
of the State Office for Nuclear Safety  
of 13 June 2002  
on Radiation Protection**

The State Office for Nuclear Safety sets out pursuant to Section 47 paragraph 7 to carry out Section 2 h) point 4, Section 2 letter gg), Section 4 paragraphs 4, 5, 6, 7, 11 and 12, Section 6 paragraphs 2, 3, 4, 5 and 6, Section 7 paragraph 3, Section 8 paragraph 1, Section 9 paragraph 1 h) i) j) and r), Section 13 paragraph 3 d), Section 17 paragraph 1 d), Section 18 paragraph 1 a) c), Section 22 e), Section 24 paragraph 4 and points I.6, I.7, I.8, I.12 and I.13 of Annex of the Act No. 18/1997 Coll., on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on amendments and alterations to some acts as amended by the Act No. 83/1998 Coll. and the Act No. 13/2002 Coll., (hereinafter referred to as „Act“):

**PART ONE  
INTRODUCTORY AND GENERAL PROVISIONS**

Chapter I

§ 1  
Scope

- (1) This regulation in compliance with the European Community law<sup>1)</sup> regulates
- a) details of the method and the scope of radiation protection during work at the workplaces where radiation activities shall be performed including the details related to delineation, identification, notification and approval of supervised and controlled areas at the workplaces;
  - b) details referred to performance of work activities associated with an increased presence of natural radionuclides or increased influence of cosmic radiation which lead or may lead to a significant increase in exposure of individuals (hereinafter referred to as „work activities with the increased exposure to natural sources“) in such a way that the affected workplaces and individuals, measurement scope and guidance levels for interventions to reduce the increased exposures to natural sources shall be set out;

---

<sup>1)</sup> Council Directive 96/29/Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.  
Council Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers arising from ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom.

- c) details on the rules for preparation or implementation of remedial actions to avert or reduce exposures as well as the guidance levels for the interventions shall be laid down;
- d) exemption levels, clearance levels, exposure limits, dose constraints, maximum permitted levels of natural radionuclide concentrations in building materials and maximum permitted levels of radioactive contamination of foodstuffs;
- e) details about the classification of ionising radiation sources, the categorisation of exposed workers and the categorisation of workplaces where radiation activities shall be performed;
- f) technical and organisational requirements, procedures and guidance levels to demonstrate the radiation protection optimisation;
- g) the scope and the method of ionising radiation source management, handling of radioactive waste and radionuclide discharge into the environment for which the licence shall be required, and it regulates the details for ensuring radiation protection during the radiation activities;
- h) conditions of medical exposures, diagnostic reference levels and usually the rules for exposure of physical persons who voluntarily help the persons undergoing medical exposure;
- i) technical and organisational conditions for safe operation of ionising radiation sources and workplaces with ionising radiation; and
- j) quantities, parameters and the facts impacting radiation protection and sets out the scope of monitoring, measurements, evaluation, verification, recording, keeping records and the method of data transfer to the State Office for Nuclear Safety (hereinafter referred to as „Office“).

(2) This Regulation shall not apply to natural background exposures, that is, to the radionuclides which are naturally contained in human body, to cosmic radiation prevailing normally at ground level, and radiation caused by the radionuclides present in the earth's crust undisturbed by human activities, and the other natural ionising radiation sources not modified by human activities.

## § 2 Basic Terms

For the purpose of this Regulation, the following terms have the meaning hereby assigned to them:

- a) **activation:** the process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy gamma radiation;
- b) **practitioner:** a medical practitioner, dentist or other medical personnel who in the scope of his qualification set out in the special legal regulation<sup>2)</sup> ensures the medical exposure application considering the principle of radiation protection optimisation;

---

<sup>2)</sup> Regulation No. 77/1981 Coll., on Medical Workers in Health Service. Binding Provision of MH ČSR, Directive No. 10/1981, 29 January 1986.

- c) **normal operation:** operation of ionising radiation source under the conditions that are laid down in the licence for operation or the licence for ionising radiation source management and in approved documentation as well;
- d) **radiation generator:** the equipment or device emitting ionising radiation and containing components operating at potential difference higher than 5 kV, especially x-ray units<sup>3)</sup> and particle accelerators;
- e) **prescriber:** a medical doctor who in compliance with the special legal regulations<sup>4)</sup> is entitled to refer individuals for medical exposure to a practitioner;
- f) **clinical responsibility:** the responsibility regarding individual medical exposures or its parts involving justification, optimisation and clinical evaluation of medical exposures; this is based on practical cooperation among other specialists and personnel, and/or based on information arising from previous examinations, and giving information about a specific medical examination, and offering the records to the other practitioners and prescribers on their request, and/or giving information to affected patients and the other persons about a risk arising from ionising radiation;
- g) **clinical audit:** a systematic verification and review of medical radiological procedures for the purpose of improving the quality and the outcome of patient care, while the radiological practices, procedures and results are compared with the released medical radiological procedures;
- h) **cosmic radiation:** ionising radiation of a cosmic origin;
- i) **medical supervision:** an observation of health capability and state of health development of category A workers from the point of view of possible effects of ionising radiation on their health performed as a part of preventive medical care;<sup>5)</sup>
- j) **monitoring:** a set of aimed measurements of the quantities characterising exposure, radiation field or radionuclides as well as the evaluation of measurement results for the purpose of exposure regulation;
- k) **approved dosimetric service:** a body who performs readouts and explanation of the values that are registered by personal dosimeters as well as the other evaluation of external exposures at own responsibility, or the body who performs radioactivity measurements in human bodies and in biological samples, evaluation of internal exposure which allows the annual effective dose and committed dose to determine (hereinafter referred to as „personal dosimetric service“); the body shall be the licensee in accordance with the Act, Section 9, paragraph 1 r);
- l) **approved medical practitioner:** a medical practitioner of a medical facility responsible to the employer for preventive medical care of category A workers;
- m) **personal doses:** a general term for the quantities characterising a measure of external and internal exposures of individuals, especially effective dose, committed effective dose and committed equivalent dose in individual organs and tissues; personal doses are measured by personal dosimeters;
- n) **unsealed radionuclide source:** a radionuclide that is not a sealed radionuclide source;

---

<sup>3)</sup> ČSN IEC 788 Standard: Medical Radiobiology – Terminology.

<sup>4)</sup> Act No. 20/1966 Coll., on Public Health Care, as amended.

<sup>5)</sup> Act No. 20/1966 Coll., Section 18 a), as amended.

- o) **workplace with unsealed sources:** a workplace where unsealed radionuclide sources are handled;
- p) **working spot:** a part of workplace that is clearly characterised by its protective properties (i.e. insulation, ventilation and shielding), delineated by an area and technology (i.e. a work desk, an application and examination box, a fume chamber, a sealed vacuum box, etc.) where separate work with ionising radiation sources can be performed; more than one working spot can be placed in one room if each place is an independent unit from the organisational point of view;
- q) **practical aspects of medical exposure:** a particular medical exposure and all supporting operations including handling and use of the medical devices for medical exposure, evaluation of technical and physical parameters including exposure doses, calibration, maintenance, preparation and administration of radiopharmaceutical preparations and film development;
- r) **natural ionising radiation source:** an ionising radiation source of terrestrial and cosmic origin;
- s) **radioactive contamination:** contamination of any material and its surface, the environment or any person by a radioactive substance; if a surface of human body is contaminated, this involves both external skin contamination and internal contamination regardless of intake pathways;
- t) **medical physics expert:** a medical worker having a university degree who fulfils the requirements of special legal regulations<sup>2)</sup> and who participates, either directly or indirectly, in consultancy, ionising radiation application in radiodiagnostics, radiotherapy and nuclear medicine;
- u) **radiological equipment:** a medical device<sup>6)</sup> that is used for examinations and treatment in nuclear medicine, radiotherapy or radiodiagnostics, and which is also a source of ionising radiation or which can also affect exposure of patients or other persons subjected to medical exposure;
- v) **radiological procedures:** any procedures pertaining to medical exposure in nuclear medicine, radiotherapy and radiodiagnostics;
- w) **radionuclide:** a kind of atoms having the same number of protons and neutrons, the same energy state and which are subjected to a spontaneous change of their composition or the state of atomic nuclei;
- x) **radionuclide source:** is an ionising radiation source that contains a radioactive substance for which the sum of the quotients of radionuclide activities and exemption levels for these radionuclides is higher than 1 and simultaneously for which the sum of the quotients of radionuclide mass activities and exemption levels of radionuclide mass activities is higher than 1;
- y) **radiodiagnostic:** pertaining to radiodiagnostics in nuclear medicine in vivo, medical diagnostic radiology and dental diagnostic radiology;
- z) **radiotherapeutic:** pertaining to radiotherapy including nuclear medicine for therapeutical purposes;
- aa) **particle accelerator:** a radiation generator with the energy higher than 1 MeV in which the particles are accelerated;

---

<sup>6)</sup> Act No. 123/2000 Coll., on Medical Devices and amendments to some related acts.

- bb) **artificial ionising radiation source:** an ionising radiation source which is not a natural source of ionising radiation;
- cc) **sealed radionuclide source:** a radionuclide source which is modified, for example, by either encapsulation or being protected by a shield, to secure its tightness that is verified by tests eliminating release of radionuclides from the source under predictable conditions of its use and wear;
- dd) **internal exposure:** exposure of a person to ionising radiation from the radionuclides that are present in his or her body, usually as a consequence of radionuclide intake by ingestion or inhalation;
- ee) **health screening:** a procedure using medical radiodiagnostic devices for early diagnosis in risk groups of the population;
- ff) **discharge:** liquid or a gaseous substance that is discharged into the environment and which contains radionuclides in the amount not exceeding clearance levels or which is discharged into the environment under the terms that are laid down in the licence for radionuclide discharge into the environment;
- gg) **internal exposure:** exposure of a person to ionising radiation sources placed outside the body of person; and
- hh) **radioactive waste disposal:** a dislocation of radioactive waste to a radioactive waste repository or to a certain place without intention of its further retrieval; the disposal also involves the authorised release of radioactive waste directly into the environment and its consecutive dispersion.

### § 3

#### Quantities in Radiation Protection

For the purpose of this Regulation, the following quantities in radiation protection have the meaning hereby assigned to them:

- a) **equivalent dose  $H_T$ :** the product of the radiation weighting factor  $w_R$  that is given in Annex 5, Table 1 and the absorbed dose<sup>7)</sup>  $D_{TR}$  averaged over organ or tissue T due to ionising radiation R, or the sum of such products if the radiation field is composed of more than one kind of radiation or more than one energy;
- b) **effective dose E:** the sum of products of tissue weighting factors  $w_T$  that are given in Annex 5, Table 2 and the equivalent dose  $H_T$  in exposed tissues or organs T;
- c) **collective effective and/or equivalent dose S:** the sum of effective and/or equivalent doses to all individuals in a certain group;
- d) **committed effective dose  $E(\tau)$  and/or committed equivalent dose  $H_T(\tau)$ :** the time integral of effective dose rate and/or equivalent dose rate over the period  $\tau$  from radionuclide intake; unless otherwise specified, the period is 50 years for radionuclide intake for adults, and up to age 70 years for radionuclide intake for children; collective committed effective doses and/or collective committed equivalent doses are defined similarly;

---

<sup>7)</sup> ČSN ISO 31-9 Standard: Quantities and Units. Part 9: Atomic and Nuclear Physics. ČSN ISO 31-10 Standard: Quantities and Units. Part 10: Nuclear Reactions and Ionising Radiation.

- e) **dose equivalent H:** the product of the absorbed dose in a point of tissue and the quality factor Q that is given in Annex 5, Table 3 and which expresses a different biological efficiency for different kinds of radiation;
- f) **personal dose equivalent  $H_p(d)$ :** the dose equivalent in a point of tissue under body skin in a depth of  $d$ ;
- g) **equivalent-equilibrium radon concentration  $a_{ekv}$ :** the weighted sum of volume activity<sup>7)</sup>  $a_1$  of polonium 218, volume activity  $a_2$  of lead 214 and volume activity  $a_3$  of bismuth 214 defined by the formula of  $a_{ekv} = 0.106 \times a_1 + 0.513 \times a_2 + 0.381 \times a_3$ ;
- h) **mass activity index I:** the number based on mass activities of K-40, Ra-226 and Th-228 and determined by the formula  $I = a_K/3000 \text{ Bq kg}^{-1} + a_{Ra}/300 \text{ Bq kg}^{-1} + a_{Th}/200 \text{ Bq kg}^{-1}$ ;
- i) **intake:** radionuclide activity that enters a human body from the environment, usually by ingestion or ingestion; and
- j) **conversion factor of intake:** the coefficient that gives the effective dose per a unit intake; conventional values of the conversion factors for ingestion  $i_{ing}$ , and inhalation  $i_{inh}$  that are calculated on the basis of the standard models are given in tables in Annex 3.

## Chapter II

### Classification of Ionising Radiation Sources

[For the implementation the Act, Section 4, paragraph 12]

#### § 4

#### Criteria for Ionising Radiation Source Classification

(1) The ionising radiation sources according to their ascending significance of hazard to health and the environment shall be classified as insignificant, minor, simple, significant and very significant on the basis of:

- a) dose equivalent rate;
- b) technical modification and the method of arrangement;
- c) activity and mass activity of radionuclide sources, usually in relation to the exemption levels;
- d) possibility of releasing radionuclides from radionuclide sources;
- e) possibility of generating radionuclide waste and demands of its disposal;
- f) typical way of handling and a related measure of possible exposure;
- g) potential hazard arising from predictable malfunctions and deviations from normal operation; and
- h) risk of a radiological incident or accident, importance of its consequences, and possibility of interventions.

(2) With respect to a typical method of ionising radiation source management, a related measure of possible exposure and a potential risk arising from predictable malfunctions and deviations from normal operation, the Office can assign a different

classification as a part of the type-approval under the Act, Section 23, or as a part of the issue of the licence for ionising radiation source management under the Act, Section 9, paragraph 1i), or in case of consumables as a part of the issue of the licence for their production and preparation, or their import or export under the Act, Section 9, paragraph 1s) in contrast with Sections 6 to 10.

## § 5 Exemption Levels

(1) The exemption levels for particular radionuclides shall be defined by the values of activity<sup>7)</sup> set out in Annex 1, Table 1, the second column, and the exemption levels of mass activities shall be defined by the values of mass activity<sup>7)</sup> set out in Annex 1, Table 1, the third column. The exemption levels shall be related to a total amount of radioactivity in possession<sup>8)</sup> of one person as a part of certain radiation activity.

(2) For radionuclides listed in Annex 1, Table 1, the first column and defined in Annex 1, Table 2, the exemption levels under paragraph 1 shall relate not only to the radionuclide themselves, but also to the products of radioactive decay in radioactive equilibrium which are listed in Annex 1, Table 2, the second column.

(3) For a mixture of radionuclides, the exemption levels shall not demonstrably be exceeded provided that:

- a) the sum of the quotients of activities for particular radionuclides and the appropriate exemption levels is not higher than 1; or
- b) the sum of the quotients of mass activities for particular radionuclides and the appropriate exemption levels of mass activities is not higher than 1.

For the sums under a) and b) the quotients for all the radionuclides contained in the mentioned substance are added, with the exception of the radionuclides defined in Annex 1, Table 2, the second column.

(4) The exemption levels shall not refer to a discharge of radionuclides into the environment. To discharge the radionuclides from permitted radiation activities into the environment, clearance levels shall apply under Section 57. Clearance levels under Section 89 shall refer to the discharge of radionuclides into the environment for work activities with an increased exposure to natural sources.

## § 6 Insignificant Sources

The insignificant source of ionising radiation shall be:

- a) electrical equipment emitting ionising radiation, provided it does not contain the components operating at potential difference higher than 5 kV;
- b) cathode-ray tube working as a display, or other electrical equipment operating at potential difference not exceeding 30 kV and for which dose rate equivalent at any accessible point at a distance of 0.1 m from its surface is lower than 1 µSv/hr;
- c) radioactive substance for which the sum of the quotients of radionuclide activities and the appropriate exemption levels is not higher than 1 or the sum of the

---

<sup>8)</sup> Civil Code, Act No. 40/1964 Coll., Section 129, as amended.

quotients of radionuclide mass activities and the appropriate exemption levels of mass activities is not higher than 1;

- d) sealed radionuclide source for which the sum of the quotients of radionuclide activities and the appropriate exemption levels or the sum of the quotients of radionuclide mass activities and the appropriate exemption levels of mass activities is not higher than 10;
- e) the equipment containing a sealed radionuclide and constructed in such a way that dose equivalent rate at any accessible point at a distance of 0.1 m from its surface is lower than 1  $\mu\text{Sv/hr}$ , and at the same time, with respect to a typical method of equipment management, a related measure of possible exposure and a potential risk arising from predictable malfunctions and deviations from normal operation the equipment was classified into this category within type-approval under Section 23 of the Act or as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1 i) of the Act for production, import or distribution of this equipment;
- f) radionuclide contaminated material arising from the approved discharge of radionuclides into the environment under Section 9, paragraph 1 h) of the Act unless otherwise stated by the Office under the terms laid down in the appropriate licence; and
- g) fire detector or similar consumer products containing radionuclide unless otherwise stated in the licence for their production or preparation, or import and export under Section 9, paragraph 1s) of the Act.

## § 7

### **Minor Sources**

The minor source of ionising radiation shall be:

- a) radiation generator provided it is not an insignificant source and constructed in such a way that dose equivalent rate at any accessible point at a distance of 0.1 m from the equipment surface is lower than 1  $\mu\text{Sv/hr}$ , with the exception of the points that are exclusively intended for handling and operating by hands under normal operating conditions, where dose equivalent rate can be up to 250  $\mu\text{Sv/hr}$ ;
- b) sealed radionuclide source provided it is not an insignificant source and for which the sum of the quotients of radionuclide activities and the appropriate exemption levels or the sum of the quotients of radionuclide mass activities and the appropriate exemption levels of mass activities is lower than 100 in case of long-lived alpha sources including alpha-neutron sources, and lower than 1000 in all other cases;
- c) the equipment containing a sealed radionuclide source provided it is not an insignificant source and constructed in such a way that dose equivalent rate at any accessible point at a distance of 0.1 m from the equipment surface is lower than 1  $\mu\text{Sv/hr}$ , with the exception of the points which are exclusively intended for handling and operating by hands under normal operating conditions, where dose equivalent rate can be up to 250  $\mu\text{Sv/hr}$ , and for which with respect to a typical method of equipment handling, a related measure of possible exposure and a potential risk arising from predictable malfunctions and deviations from normal operation the equipment was classified into this category within type-approval under Section 23 of the Act or as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1 i) of the Act for production, import or distribution of this equipment;



- d) unsealed radionuclide source provided it is not an insignificant source and for which the sum of the quotients of activities or mass activities of particular radionuclides and the values of activity or mass activity of the radionuclides defined in Table 1 of the Annex 1 is lower than 10; and
- e) more than 20 fire detectors or other consumer products containing radionuclides which at the same time are located in one building and in possession of one person unless otherwise stated in the licence for their production and preparation, or import or export under Section 9, paragraph 1 s) of the Act.

§ 8  
**Simple Sources**

The simple sources of ionising radiation shall be all ionising radiation sources which are not classified as insignificant, minor, significant and very significant ionising radiation sources.

§ 9  
**Significant Sources**

The significant source of ionising radiation shall be:

- a) radiation generator intended for radiotherapy and radiodiagnostics in human medicine, with the exception of bone densitometers, cabin x-ray units and dental x-ray units;
- b) particle accelerator which with respect to a typical method of its handling, a related measure of possible exposure and a potential risk arising from predictable malfunctions and deviations from normal operation was classified into this category within type-approval under Section 23 of the Act or as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1 i) of the Act;
- c) ionising radiation source intended for proton, neutron and other heavy particle radiotherapy;
- d) the equipment containing sealed radionuclide sources intended for radiotherapy including brachytherapy, with the exception of the equipment which with respect to a typical method of its handling, a related measure of possible exposure and a potential risk arising from predictable malfunctions and deviations from normal operation was classified into the other category within its type-approval under Section 23 of the Act or as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1 i) of the Act;
- e) irradiators and other equipment that contain sealed radionuclide sources including food irradiators and the other stationary industrial irradiators which with respect to their radionuclide concentration, dose rate and with respect to the typical method of their management, a related measure of possible exposure and a potential risk arising from predictable malfunctions and variations from normal operation were classified into this category within type-approval under Section 23 of the Act or as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1 i) of the Act; and
- f) mobile flaw detector incorporating sealed radionuclide sources.

§ 10  
**Very Significant Sources**

The very significant ionising radiation source shall be a nuclear reactor.

**Chapter III**  
**Categorisation of Workplaces Performing Radiation Activities**  
[For the implementation of the Act, Section 4, paragraph 12]

§ 11  
**Criteria for Workplace Categorisation**

(1) The workplaces which perform radiation activities, with the exception of the workplaces using only insignificant source, shall be categorised in the ascending order according to a hazard caused by ionising radiation to health and the environment into categories I, II, III and IV on the basis of:

- a) classification of ionising radiation sources to be handled at the workplaces;
- b) expected normal operation of the workplace and a related measure of possible occupational and public exposures;
- c) orientation of radiation activity and difficulties of ensuring radiation protection and quality during this activity;
- d) the equipment and methods of work safety at the workplace with ionising radiation sources, especially by use of protective aids, insulation and shield equipment, ventilation and drainage;
- e) possible radioactive contamination of the workplace or its vicinity by radionuclides;
- f) possible generation of radioactive waste and difficulties of its disposal;
- g) potential risk arising from the predictable malfunctions and deviations from normal operation; and
- h) risk of a radiation incident or radiation accident, magnitude of consequences of such event and the possibilities of interventions.

(2) The workplaces not mentioned in Sections 12 to 15 shall be classified into category II unless the Office takes a decision on a different categorisation as a part of the licence proceedings for ionising radiation management under Section 9, paragraph 1i) of the Act. With respect to a typical method of workplace operation and a related measure of possible occupational and public exposures and a potential risk arising from the predictable malfunctions and deviations from normal operation the Office can take a decision on a different categorisation in contrast with Section 12 to 15 as a part of the licence proceedings for workplace operation under Section 9, paragraph 1 d) of the Act or the licence for ionising radiation source management under Section 9, paragraph 1i) of the Act.

§ 12  
**Category I Workplace**

The category I workplace shall be a:

- a) workplace handling minor ionising radiation sources;
- b) workplace with a bone densitometer;
- c) workplace with veterinary, dental or cabin x-ray units;
- d) workplace with a compact blood irradiator containing a sealed source;
- e) workplace with gauges containing sealed radionuclide sources;
- f) workplace with industrial x-ray unit for which the nature of radiation activity does not require a delineation of controlled area; and
- g) workplace with unsealed radionuclide sources provided that insulation and ventilation equipment and a level of drainage system shall comply with the appropriate minimum requirements laid down under Annex 4, Table 1 and the classification into this category shall be approved by the Office as a part of the issue of the licence for ionising source management under Section 9, paragraph 1 i) of the Act.

### § 13

#### **Category II Workplace**

The category II workplace shall be a:

- a) workplace handling simple ionising radiation sources not classified as the category I workplace;
- b) workplace with an x-ray unit intended for radiodiagnostics and radiotherapy, with the exception of bone densitometers, cabin and dental x-ray units including veterinary x-ray units;
- c) workplace with a mobile flaw detector containing a sealed radionuclide source;
- d) workplace with a mobile irradiator containing a sealed radionuclide source, with the exception of the workplaces which with respect to a typical method of workplace operation, a related measure of possible exposure, and a potential risk arising from the predictable malfunctions and deviations from normal operation have been classified into a different category as a part of the licence proceedings for workplace operation under Section § 9, paragraph 1d) of the Act or the licence for ionising source management under Section 9, paragraph 1i) of the Act to handle these irradiators;
- e) workplace with the gauges containing sealed radionuclide sources for which the nature of radiation activity requires a delineation of controlled area;
- f) workplace with industrial x-ray units for which the nature of radiation activities requires the delineation of a controlled area; and
- g) workplace with unsealed radionuclide sources provided that insulation and ventilation systems and a level of drainage system shall comply with the minimum requirements according to Annex 4, Table 1 and the classification into this category shall be approved by the Office as a part of the issue of the licence for ionising radiation source management under Section 9, paragraph 1i) of the Act.

### § 14

#### **Category III Workplace**

The category III workplace shall be a:

- a) workplace with a particle accelerator, with the exception of the workplaces which with respect to a typical method of workplace operation, a related measure of possible exposure, and a potential risk arising from predictable malfunctions and deviations from normal operation shall be classified into the other category as a part of the issue of the licence proceedings under Section 9, paragraph 1 d) of the Act or the licence for ionising radiation management under Section 9, paragraph 1 i) of the Act to handle these irradiators;
- b) workplace with an installation containing a sealed radionuclide source intended for radiotherapy, including brachytherapy, classified as a significant source;
- c) workplace with a stationary radionuclide irradiator or another stationary installation containing a sealed radionuclide source classified as a significant ionising radiation source;
- d) workplace with unsealed radionuclide sources provided that insulation and ventilation systems and a level of drainage system shall comply with the appropriate minimum requirements laid down under Annex 4, Table 1 and the classification into this category shall be approved by the Office as a part of the issue of the licence for ionising radiation management under Section 9, paragraph 1 i) of the Act;
- e) workplace with a stationary industrial irradiator intended for irradiation of foodstuffs, objects of standard use and other materials; and
- f) workplace for mining and treatment of uranium ore including mining, treatment, and uranium concentrate handling, decontamination station operation, collection of mining products at spoil heaps and tailing dumps.

#### § 15

#### **Category IV Workplace**

The category IV workplace shall be a:

- a) nuclear installation pursuant to Section 2, paragraph h) of the Act;
- b) radioactive waste repository pursuant to Section 2, paragraph u) of the Act,
- c) workplace with unsealed radionuclide sources which with respect to high activities treated at the same time at one working spot and with respect to the typical method of workplace operation, a related measure of possible exposure and a potential risk arising from predictable deviations from normal operation, and based on incidents and accidents, cannot be classified into category III.

#### § 16

#### **Categorisation of Exposed Workers**

[For the implementation of the Act, Section 4, paragraph 12]

(1) For the purpose of monitoring and medical supervision, a distinction shall be made between two categories, A and B, of exposed workers depending on a measure of risk to health caused by ionising radiation and based on the expected exposure under normal operation and predictable malfunctions and deviations from normal operation, except the exposure as a consequence of a radiation incident or accident.

(2) Category A workers shall be those workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 3/10 of the exposure limit

for lens of the eye, skin and extremities laid down under Section 20, paragraph 1a) to c); the other exposed workers shall be classified as category B workers.

## Chapter IV Optimisation and Exposure Limits

[For the implementation of the Act, Section 4, paragraph. 4 and 6]

### § 17

#### **Optimisation of Radiation Protection**

- (1) The optimisation of radiation protection shall be performed
- a) in advance of a commencement of radiation practices by assessing and comparing with radiation protection variants which for the intended activities should be taken into consideration, by assessing of necessary costs for the appropriate remedial measures, and by assessing of collective doses and doses in appropriate critical groups of the public;
  - b) during radiation practices by a regular analysis of doses received in respect of working operations, by taking into account all possible other measures to ensure radiation protection, and by comparing with similar already practised and socially acceptable activities;
  - c) in advance of the commencement of any intervention to avert or reduce exposure by assessing of all possible variants and by selecting of such a variant which with its method of performance, scope and duration shall bring the most net benefit; and
  - d) during implementing of intervention by the analysis of doses received in relation to the countermeasures being performed and by considering of a possible change of selected countermeasures and procedures.

(2) As a part of the optimisation of radiation protection, all exposures shall be planned and kept as low as reasonably achievable, taking into account economic and social factors. The variants of radiation protection assessed as a part of the optimisation of radiation protection shall not lead to exposure which exceeds the exposure limits or the dose constraints if these limits and dose constraints are laid down for this case. If dose constraints for particular radiation practices or a particular ionising radiation source are to be set out, the Office shall take into account all existing experience of similar radiation practices and handling of the sources so that the level of radiation protection shall not be lower than achieved in practice so yet, and the Office shall also consider a possible effect of the other activities and sources to avoid the limit exceeding.

(3) While optimising radiation protection, the costs of different remedial measures to improve radiation protection, for example, a relocation of individuals or a construction of additional barriers, etc., shall be usually compared with a financial appraisal of expected exposure reduction (hereinafter referred to as “the benefits of remedial measures”). A reasonably achievable level of radiation protection shall be considered to be proved and the remedial measures need not be implemented if the costs are higher than the benefits of such remedial measures and if implementation of the remedial measures does not require special social conditions. The benefits of remedial measures shall be calculated in such a way that a reduction of collective effective dose for a group of individuals being assessed shall be multiplied by a factor of:

- a) 0.5 million CZK / Sv for radiation activities when an average effective dose to individuals shall not exceed one tenth of appropriate exposure limits;
- b) 1 million CZK / Sv for radiation activities when an average effective dose to individuals shall exceed one tenth of appropriate exposure limits but not three tenths of the appropriate exposure limits;
- c) 2.5 million CZK / Sv for radiation activities when an average effective dose to individuals shall exceed three tenths of appropriate exposure limits;
- d) 1 million CZK / Sv for medical exposures;
- e) 0.5 million CZK / Sv for the exposure to natural radionuclides which are not intentionally utilised; and
- f) 2.5 million CZK / Sv for emergency exposure.

(4) A reasonably achievable level of radiation protection shall be also considered to sufficiently proved if an annual effective dose of the exposed workers arising from a certain radiation activity does not exceed 1 mSv for each exposed worker even for predictable deviations from normal operation, and an annual effective dose to the public does not exceed 50 µSv for each individual, and a collective effective dose at a category IV workplace does not exceed 1 Sv. In such cases, it is not necessary to optimise radiation protection in accordance with paragraph 3.

(5) A dose constraint for a nuclear installation operation shall be a collective effective dose of 4 Sv per year for each gigawatt being installed in the nuclear installation related to the exposure of all exposed workers who undergo personal monitoring in compliance with the monitoring programme.

## § 18

### **Limit System and Exposure Reduction**

(1) The reduction of occupational and public exposures to ionising radiation shall be ensured by:

- a) exposure limits which are established as binding quantitative measures to indicate a total exposure arising from radiation activities and their exceeding is not permitted in the cases laid down herein; the exposure limits shall be divided into:
  - 1. general limits;
  - 2. exposure limits of exposed workers; and
  - 3. limits of apprentices and students;
- b) derived limits as subsidiary quantitative measures which are expressed in measurable quantities and which serve in special cases to demonstrate that the limits of exposed workers have not been exceeded; and
- c) authorised limits as binding quantitative measures established by the Office in the appropriate licence, usually as a result of the optimisation of radiation protection for a particular radiation activity or a particular ionising radiation source.

(2) The occupational exposure shall not exceed the exposure limits if it is sufficiently demonstrated that the derived limits established under Section 22 are not exceeded.

(3) For radiation activities and ionising radiation sources for which the authorised limits are laid down by the Office under Section 4, paragraph 6 of the Act in the licence for a

particular activity or a source, the exposure limits shall not be exceeded if it is sufficiently demonstrated that the authorised limits are not exceeded.

(4) The exposure to natural sources shall not be included in total exposure, with the exception of exposure to natural source intentionally utilised, and except the cases laid down in Section 91.

## § 19

### **General Limits**

(1) The general limits shall be:

- a) 1 mSv per calendar year for the sum of effective doses from external exposure and committed effective doses from internal exposure, or exceptionally 5 mSv for a period of five consecutive calendar years under the conditions laid down in the licence for category III and IV workplace operation;
- b) 15 mSv per calendar year for an equivalent dose for lens; and
- c) 50 mSv per calendar year for an average equivalent dose for 1 cm<sup>2</sup> of skin.

(2) The general limits shall relate to total exposure caused by all radiation activities except:

- a) occupational exposure under Section 2, letter x), point 1 of the Act;
- b) exposure to which the individuals who intentionally, voluntarily and after being instructed on the risks related to such activities are exposed over a period of their specialised training for their work activities with ionising radiation sources;
- c) medical exposure under Section 2, letter x), point 2 of the Act;
- d) emergency exposure under Section 2, letter x) 3 of the Act;
- e) emergency exposure of intervening individuals under Section 2, letter x) 4 of the Act; and
- f) special cases under Section 23;

(3) The general limits shall relate to a calculated average exposure of the critical group of the public from all exposure pathways, all ionising radiation sources, and all radiation practices being considered. If no direct calculation data is available, a conservative estimate of variations of the factors that affect a radionuclide release or the exposure of individuals in the critical group shall be applied in compliance with the procedures under Section 74.

## § 20

### **Limits for Exposed Workers**

(1) The limits for exposed workers shall be:

- a) 100 mSv for a period of five consecutive calendar years as the sum of effective doses from external exposure and committed effective doses from internal exposure;
- b) 50 mSv per calendar year as the sum of effective doses from external exposure and committed effective doses from internal exposure;
- c) 150 mSv per calendar year for an equivalent dose for lens,

- d) 500 mSv per calendar year for an average equivalent dose for 1 cm<sup>2</sup> of skin,
- e) 500 mSv per calendar year for an equivalent dose in upper extremities from fingers to forearms and in lower extremities from feet to ankles.

(2) The limits of exposed workers shall relate to occupational exposure, that is the exposure which is directly related to work activity of the exposed workers.

(3) The limits of exposed workers shall relate to the sum of all doses from all exposure pathways and all radiation activities which the exposed worker performs individually or simultaneously for one or more licensees of ionising radiation source management, or he or she also performs as an independent licensee for ionising radiation source management.

## § 21

### **Limits for Apprentices and Students**

(1) The limits for apprentices and students aged from 16 to 18 years shall be:

- a) 6 mSv per calendar year as the sum of effective doses from external exposure and committed effective doses from internal exposure;
- b) 50 mSv per calendar year for an equivalent dose for lens;
- c) 150 mSv per calendar year for an average equivalent dose for 1 cm<sup>2</sup> of skin;  
and
- d) 150 mSv per calendar year for an equivalent dose in upper extremities from fingers to forearm and in lower extremities from feet to ankles.

(2) The limits for apprentices and students under the age mentioned in paragraph 1 shall be the same as the general limits and over the age mentioned in paragraph 1 shall be the same as the limits for exposed workers.

(3) The limits for apprentices and students shall relate to the exposure to which the individuals who intentionally, voluntarily and after being instructed on the risks related to such activities are exposed over a period of their specialised training for their work activities with ionising radiation sources.

## § 22

### **Derived Limits**

(1) The derived limits for external exposure shall be:

- a) 500 mSv per calendar year for the annual personal dose equivalent in a depth of 0.07 mm; and
- b) 20 mSv per calendar year for the annual personal dose equivalent in a depth of 10 mm.

(2) The derived limits for internal exposure per calendar year, except the cases laid down in paragraphs 4 and 5, shall be for radionuclide intake:

- a) by ingestion a value of the quotation of 20 mSv and the conversion factor  $h_{\text{ing}}$  for intake of a particular radionuclide by ingestion by an exposed worker according to tables in Annex 3; and



b) by inhalation a value of the quotation of 20 mSv and the conversion factor  $h_{inh}$  for intake of a particular radionuclide by inhalation by an exposed worker according to tables in Annex 3.

(3) For simultaneous external and internal exposures over a calendar year, except the cases mentioned in paragraphs 4 and 5, the limits for exposed workers shall not be exceeded if

$H_p(0.07) \leq 500$  mSv and simultaneously  $H_p(10) + \sum h_{j,inh} I_{j,inh} + \sum h_{j,ing} I_{j,ing} \leq 20$  mSv, where

$H_p(0.07)$  and/or  $H_p(10)$  is annual personal dose equivalent in a depth of 0.07 mm and/or 10 mm,

$I_{j,inh}$ , and/or  $I_{j,ing}$  is annual intake of a particular radionuclide by inhalation and/or ingestion, and

$h_{j,inh}$ , and/or  $h_{j,ing}$  is the conversion factor according to tables in Annex 3 for intake of a particular radionuclide by inhalation or ingestion by the exposed worker; for unidentified radionuclides, unidentified chemical forms and properties of aerosol being inhaled, the activity shall be determined for radionuclides, chemical forms and properties of the aerosol with the highest conversion factor for intake by inhalation and/or ingestion according to Annex 3.

(4) For exposure to radon daughters, the derived limit shall be a value of 3 MBq for the annual intake of equivalent-equilibrium radon concentration, which corresponds to intake of the latent energy of radon daughters of 17 mJ, or exposure to radon products of 2.5 MBq.h.m<sup>-3</sup>, or the annual average equivalent-equilibrium radon concentration of 1260 Bq.m<sup>-3</sup>.

(5) For exposure to a mixture of long-lived radionuclides that emit the alpha particles of the uranium-radium series nuclides, the derived limit shall be intake of 1850 Bq by inhalation per calendar year.

## § 23

### Exposure Reduction in Special Cases

(1) The exposure of the individuals who knowingly and willingly beyond their working obligations help to patients undergoing medical exposure and visit the patients or live in one household with the patients who were discharged after radionuclide application from a medical facility shall be reduced in such a way that the sum over a calendar year shall not exceed 1 mSv for the individuals younger than 18 years and 5 mSv for the others.

(2) The exposure of foetus in pregnant women, on becoming aware that she is pregnant and notifying this her employer, who work at category I to category IV workplaces shall be immediately reduced by a modification of working conditions so that the sum of effective doses from external exposure and committed effective doses from internal exposure of the foetus shall not exceed 1 mSv at least over the remaining period of pregnancy.

(3) After notifying the employer that a woman breastfeeds the infant, the exposure of a breastfed infant by intake of radionuclides from contaminated breast milk shall be immediately reduced by a modification of working conditions of the breastfeeding woman working at the category I to category IV workplaces or her suspension from work in the controlled area with unsealed radionuclide sources.

(4) The exposure of exposed workers during single, short-term or other exceptional work with ionising radiation sources limited to a small number of individuals and to

delineated areas, with the exception of work during radiation accidents or radiological emergencies (hereinafter „specially authorised exposure“), shall be reduced in such a way that effective dose from repeated specially authorised exposures shall not exceed 500 mSv in five consecutive calendar years. The specially authorised exposures can be applied only in the scope and under the terms which are laid down in the licence for such methods of ionising radiation source management. The specially authorised exposure can be only applied to category A workers who perform this work voluntarily and after the foregoing instructions on the risks related to this work. This specially authorised exposure shall be inadmissible for the individuals younger than 18 years, apprentices and students, pregnant and breastfeeding women, and the individuals who received the effective dose that exceeds 500 mSv in five consecutive calendar years during interventions in case of radiation accidents. All personal doses from specially authorised exposures as well as the personal doses from emergency exposures and the emergency exposures of intervening individuals shall be recorded separately and for planning the other radiation activities the doses from specially authorised exposures shall not be added to doses received under normal operation.

## **PART TWO RADIATION ACTIVITIES**

### **Chapter I Conditions of Safe Operation of Workplaces Performing Radiation Activities**

[for the implementation of the Act, Section 4 paragraph 11, Section 13 paragraph 3 (d) and section 17 paragraph 1]

#### **§ 24**

#### **General Conditions of Safe Operation**

(1) Operation safety of workplaces performing radiation activities and radiation protection of the personnel shall always be ensured by:

- a) justification of the radiation activity and the optimisation of radiation protection for all working conditions including the previous assessment of the character and scope of a potential risk to health of the exposed workers and of the risks related to the radiation activity being prepared, and regular reviews based on the operating experience;
- b) introduction of a quality system complying with the requirements set out in the implementing legal regulation <sup>9)</sup>;
- c) classification of the ionising radiation sources used, categorisation of workplaces and categorisation of exposed workers,

---

<sup>9)</sup> Regulation No. 214/1997 Coll., on Quality Assurance in Activities Related to the Utilisation of Nuclear Energy and in Radiation Activities, and Laying Down Criteria for the Assignment and Categorisation of Classified Equipment into Safety Classes.

- d) instructing the personnel on the risks from their work and on the arrangements for their educational system and examination of their qualification in conformity with the importance of the work duties performed;
- e) delineation of supervised and controlled areas with regard to the estimate of exposure anticipated under normal operation, and to the probability and scope of potential exposure;
- f) implementation of regulatory measures and monitoring of work conditions and/or personal monitoring;
- g) medical supervision of the exposed workers;
- h) arrangements for systematic supervision over radiation protection;
- i) providing the workplace with devices, equipment and aids in such quantities and quality that are sufficient to ensure all measurements specified in the monitoring programme, the on-site emergency plan and the quality assurance programme, as well as all measurements performed within the constancy tests, or any measurements in accordance with the conditions specified in a licence for management issued by the Office, and the maintenance thereof in a proper technical condition; and
- j) providing the exposed workers with personal protection means of appropriate shielding effect and with appropriate protective aids.

(2) The supervised and controlled areas at workplaces performing radiation activities shall be delineated in such a way as to ensure, by restricting person access to such areas, by creating protective barriers and/or constructional modifications, by work regime, and by the scope of monitoring and other measures appropriate with the sources used and their handling methods, that the sources will only be handled by individuals who have sufficient professional competence, are fit in terms of health, instructed on a potential risk involved by their work and appropriately equipped, and that the consequences of a potential radiation incident will be reduced as much as possible.

(3) During professional training involving work with ionising radiation sources, no person who has not reached 18 years of age shall be assigned to any work which may subject such a person to exposure above the limits for apprentices and students pursuant to Section 21; and such working conditions shall be created and such radiation protection level shall be ensured for them as for category B workers. Under no other circumstances may persons under 18 years of age be assigned to work tasks that may subject them to exposure above the general limits pursuant to Section 19; and the same working conditions shall be created for them and the same radiation protection level shall be ensured for them as for the exposed workers. During their professional training for work with ionising radiation sources, pupils, apprentices and students may only use ionising radiation sources under the supervision of appointed exposed workers.

(4) For category A workers, the following shall be ensured:

- a) regular replacement and evaluation of personal dosimeters, in accordance with the monitoring programme approved by the Office;
- b) immediate replacement and evaluation of personal dosimeters in case of a suspicion or occurrence of a radiation incident; and
- c) acquaintance of workers with the results of dose evaluation from their personal dosimeters.

(5) Radioactive contamination of body surface, clothes, equipment or constructional elements of the workplaces shall be maintained below the guidance levels for radioactive contamination as set out in Annex 2, Table 1. Shall radioactive contamination exceed the mentioned limits, an effective decontamination shall be performed, while the values stipulated for radioactive contamination of surfaces within the controlled area, occurring as a consequence of anticipated ways of the ionising radiation source usage, shall only be related to detachable parts.

(6) The impact of the workplace operation on the vicinity shall be kept as low as reasonably achievable, not only to avoid exceeding the limits, but to ensure the maximum possible protection of the public in the vicinity of the workplace.

## § 25

### **Justification of Radiation Activities**

(1) All new categories and types of radiation activities shall be justified, prior to their first introduction into practice or their first authorisation, from the point of view of their economic, social or other benefits, compared to the health detriment they may cause.

(2) Justification of existing categories or types of radiation practices must be reviewed upon a revelation of any new and significant knowledge of their effects.

## § 26

### **Informing and Preparing the Workers**

(1) A person operating a workplace where a supervised area is delineated (hereinafter referred to as the "supervised area operator") and a licensee operating a workplace where a controlled area is delineated (hereinafter referred to as the "controlled area operator") shall instruct, demonstrably and in advance, any exposed workers who are to work in such areas, as well as any individuals using the ionising radiation sources therein during their professional training, on the following:

- a) on the character and scope of a potential hazard to health, the risks from their work, and a potential health detriment related thereto;
- b) on general procedures of radiation protection and measures to be taken, in particular, on measures appropriate to the operating and work conditions related both to given activity in general and to individual workplaces and work tasks to which they may be assigned;
- c) on the importance to meet the requirements of health protection as well as of any technical and administrative requirements aimed at ensuring radiation protection; and,
- d) in case of women, on the importance of a timely notification of pregnancy with regard to the exposure risk for the foetus and to radioactive contamination of a breastfed infant in the event of internal contamination of mother with radionuclides.

(2) A supervised or controlled area operator shall arrange the educational programme for the exposed workers to make them fully acquainted with general rules and radiation protection procedures, and in particular, with radiation protection measures for work with particular ionising radiation sources at the workplace, both under normal operating conditions and under predictable deviations from normal operation, or during an occurrence of a radiological emergency. The knowledge of the exposed workers as well as their professional

competence for safe handling of ionising radiation sources within their work assignment shall be verified before they start to work in their position, and subsequently, on a regular basis by examinations, no less than once a year. Records shall be kept on the examinations taken. The knowledge of the supervising persons, pursuant to the Act, Section 10, paragraph 2, as well as of other individuals performing activities especially important from the radiation protection viewpoint shall be verified by the Office examining board, proving their special professional competence under the Act, Section 18, paragraph 4.

## § 27

### **Systematic Supervision of Radiation Protection Observance**

(1) A systematic supervision of radiation protection observance under the Act, Section 18, paragraph 1i), shall be ensured in the scope commensurate with the ionising radiation sources handled at a workplace, as well as with the methods of their handling, and the related level of potential exposure, including exposure from predictable malfunctions and deviations from normal operation and taking into account the risk of a radiation incident or accident occurring. The supervising persons and/or other persons specified in the quality assurance programme shall ensure systematic supervision of radiation protection observance. For the purposes of the systematic supervision of radiation protection observance, the operator may establish an independent specialised unit which is provided with necessary means. In such installations where the Office shall deem it necessary to establish such a specialised radiation protection unit to provide specific consultancy for the given installation, the unit, if it is an internal organisational unit of the given installation, shall be separate from the production and operation units from the organisational point of view. Such a unit may serve several workplaces.

(2) To ensure systematic supervision at workplaces operated based on a licence under the Act, Section 9, paragraph 1d), or at workplaces where ionising radiation sources are managed based on a licence under the Act, Section 9, paragraph 1i), the operator shall appoint a supervising person. The supervising person shall have a special professional competence<sup>10)</sup> corresponding to the requirements for the activity undertaken and given ionising radiation sources. If the operator is a natural person having the appropriate special professional competence, the operator may carry out the activities of the supervising person him or herself.

(3) The licensee shall enable the supervising person to get acquainted with all documents related to radiation protection and to participate in meetings related to radiation protection.

(4) The activities of the supervising person shall include:

- a) supervision and assessment that the licensee observations to implement all measures of safe management of ionising radiation sources are met; and
- b) assistance to the management to meet the licensee observations to ensure radiation protection, bringing to their attention any shortcomings ascertained, as well as submitting proposals for correction thereof.

---

<sup>10)</sup> Regulation No. 146/1997 Coll., Specifying Activities Directly Affecting Nuclear Safety and Activities Especially Important from Radiation Protection Viewpoint, Requirements on Qualification and Professional Training, on Method to be Used for Verification of Special Professional Competency and for Issue Authorisations to Selected Personnel, and the Form of Documentation to be Approved for Licensing of Expert Training of Selected Personnel.

(5) The licensee shall consult with the supervising person the delineation of supervised and controlled areas and the application of appropriate requirements for such areas, including tests and inspection of protective aids and measuring instruments, in particular during the following:

- a) comprehensive assessment of individual installation projects from the radiation protection point of view;
- b) commissioning of new or modified ionising radiation sources,
- c) regular inspections of efficiency of protective aids and technical procedures;  
and
- d) regular calibrations of measuring instruments and regular inspections of proper operation and correct use thereof.

(6) The supervising person usually provides the operator with the following activities from the area of radiation protection:

- a) instruction of personnel on work with ionising radiation sources;
- b) education of the exposed workers on safe handling of sources;
- c) verification of the professional competence for safe handling of ionising radiation sources by regular examinations;
- d) preparation of the monitoring program, or participation in measurements and evaluation according to the approved monitoring programme;
- e) proper record keeping, required with regard to the radiation protection at the workplace;
- f) keeping records on movement and conditions of ionising radiation sources, equipment and devices affecting radiation protection;
- g) organisation of acceptance tests, status tests and constancy tests for the ionising radiation sources;
- h) investigation of radiological emergencies or radiation incidents, loss or theft of a ionising radiation source, and implementation of remedial measures; and,
- i) supervision of personnel attendance to prescribed preventive medical examinations.

(7) Besides the supervising persons, other persons shall participate in the systematic supervision of radiation protection whose direct responsibility to ensure radiation protection at work with ionising radiation sources shall be defined, in the scope specified by the quality assurance programme.

## § 28

### **Medical Surveillance of Exposed Workers**

(1) Medical surveillance of exposed workers is based on the general principles governing health protection at work. It is carried out in the framework of industrial preventative care of personnel by approved medical practitioners of medical establishments that provide such a care to the employer under special regulations.<sup>11)</sup>

---

<sup>11)</sup> Act No. 20/1966 Coll., Section 40, amended.

(2) Within the medical surveillance, the state of health of category A workers is assessed from the point of view of their physical and mental capability for tasks performed within radiation activities. For this purpose, the approved medical practitioner shall have access to all significant information related to exposure evaluation, including monitoring data and data on the working conditions.

(3) Medical surveillance includes the following preventative medical examinations:

- a) medical examination prior to employment, and taken always before classification of a worker in the category A, which aims at assessing the worker's fitness for contemplated position as the category A worker;<sup>12)</sup>
- b) periodic examination, taken by category A workers once a year, which shall check up whether the workers remain fit and able to fulfil their duties within the radiation activities;
- c) extraordinary examination, taken whenever there is a reasonable suspicion that the state of health of an category A worker has changed; the approved medical practitioner shall determine an earlier examination date than a periodic check-up; or whenever, according to the assessment of exposure by the Office, the exposure limits were exceeded and the conditions for further radiation exposure at work need to be assessed; and
- d) leaving examination.<sup>13)</sup>

(4) The approved medical practitioner shall be entitled to recommend upon the worker's leaving examination that a registering approved medical practitioner can continue medical surveillance by subsequent examinations<sup>14)</sup> to ensure a timely ascertainment of potential changes in the state of health related to exposure during work performance, particularly, for long-term work close to the limits, even after the termination of given work and for such a long time as the approved medical practitioner may consider necessary for health of the given person.

(5) To describe physical and mental capability of category A workers, the medical finding uses the following classification:

- a) fit for performance of the category A worker activities;
- b) fit for performance of the category A worker activities under certain conditions specified in the medical report; and
- c) unfit for performance of the category A worker activities.

(6) The worker must be acquainted with the results and the expert opinion formed based on medical examination conclusions of the approved medical practitioner. If the worker disagrees with the medical findings or the medical examination conclusions, the worker may apply for remedies under the special legal regulation.<sup>15)</sup> The medical establishment shall immediately send the medical report with its findings on worker fitness for performance of the category A worker activities to the appropriate licensees authorised for ionising radiation source management.

---

<sup>12)</sup> Labour Code, Section 133, paragraph 1a).

<sup>13)</sup> Directive of Ministry of Health of the CR No. 49/67, Section 17, paragraph 2, Gazette of MH CR.

<sup>14)</sup> Act No. 48/1997 Coll., Section 21, paragraph 3, Section 35 paragraph d), on Public Health Insurance and on amendments and alterations to some related acts, as amended.

<sup>15)</sup> Act No. 20/1966 Coll., Section 77, as amended.

(7) No person may be employed or assigned to work as a category A worker for any period of time at a specific workplace if deemed and classified unfit in the medical findings for performing such a specific position. Shall exposure limits be exceeded, a person may only be subject to further occupational exposure under the conditions determined by the approved medical practitioner, based on an extraordinary examination. The worker shall be obliged to keep their employer informed of any changes that may render them unfit for performance of category A worker activities.

(8) For each category A worker and the time when the worker is classified in this category, the approved medical practitioner shall keep records, as a part of the medical reports, on the character of work activities ascertained in the framework of medical surveillance, on the results of preventive medical examinations, including diagnostic conclusions drawn from the results of previous medical examinations, and on the results of personal monitoring. Any personal doses from specially authorised exposures under Section 23 paragraph 4, from emergency exposures under the Act, Section 2 x), point 3, and from emergency exposures of intervening persons under the Act, Section 2 x), point 4, shall be recorded separately. The documents shall be kept until the person reaches, or would have reached, the age of 75, in any case no shorter than 30 years after the termination of the work activity during which the worker was subjected to the ionising radiation exposure.

## § 29

### **Supervised Area**

(1) A supervised area shall be delineated at workplaces where radiation activities are performed wherever it is expected that exposure under normal operation or under predictable deviations from normal operation might exceed general limits.

(2) As a rule, the supervised area shall be delineated at all workplaces of categories I through IV, with the exception of workplaces with type-approved minor ionising radiation sources. The supervised area is not delineated either if its area would not be larger than a controlled area.

(3) The supervised area shall be delineated as an integral and unambiguously delimited part of a workplace, usually partitioned off. The entries or boundaries of the supervised area shall be marked with a radiation warning sign<sup>16)</sup> and a notice "Supervised Area with Ionising Radiation Sources"; the notice may also provide data on the character of sources and related risks.

(4) Within the supervised area, only workplace monitoring is secured unless otherwise specified in the monitoring programme.

(5) A supervised area operator shall notify to the Office, without any delay, of any workplace where the supervised area has been delineated, furnishing a description of the radiation activity contemplated and ionising radiation sources to be used. The supervised area operator shall also immediately inform the Office of any modifications to the delineation of the supervised area or cancellation thereof.

---

<sup>16)</sup> ČSN 01 8015 Standard: Radiation Warning Sign. Shape and Size.



§ 30  
**Controlled Area**

(1) A controlled area shall be delineated wherever it is expected that under normal operation or predictable deviations from normal operation exposure might exceed three tenths of the limits set out for exposed workers. Unless otherwise justified by a specific method of handling the ionising radiation sources, e.g. by their time-limited usage, it is purposeful to delineate the controlled area wherever expected that

- a) effective dose equivalent of external exposure at a workplace will exceed an average of 2.5  $\mu\text{Sv/hr}$  per year under normal operation of the radiation source,
- b) the sum of products of volume activities of individual radionuclides in the air at the workplace and the conversion factors  $h_{\text{inh}}$  for intake by inhalation by an exposed worker under Annex 3 will exceed an average of 2.5  $\mu\text{Sv.m}^{-3}$  per year; and
- c) radioactive contamination of the surfaces at workplaces will exceed the guidance levels of surface contamination in the controlled area of workplaces which use unsealed sources, as laid down by Annex 2, Table 1.

(2) The controlled area shall be delineated as an integral and unambiguously delimited part of the workplace, usually partitioned off and properly secured against unauthorised access. The entries or boundaries of the controlled area shall be marked with the radiation warning sign<sup>16)</sup> and a "Controlled Area with Ionising Radiation Sources. No Admittance for Unauthorised Persons" notice; the notice may also contain information on the character of the sources and the related risks.

(3) A proposal for delineation of the controlled area, which shall be submitted to the Office under the Annex to the Act, point D.b.5 or I.7, as one of the documents to be approved by the Office and required to be enclosed with the application form for the corresponding licence, shall include:

- a) the area of the controlled area, usually presented as a list of rooms concerned and a schematic plan thereof; for contemplated temporary field workplaces (e.g. defectoscopic or logging), a dose rate constraint to be used for the delimitation of the controlled area of such workplaces shall be determined;
- b) justification of the controlled area proposed, in particular, by calculations and other evidence provided, demonstrating the fulfilment of the requirements specified in paragraph 1;
- c) description of constructional or technical security of the controlled area, preventing access of unauthorised individuals; and
- d) anticipated number of persons to work in the controlled area, and the method of their instructing on the risks from work in the controlled area, e.g. by submitting sample instructions for entry and work in the controlled area.

(4) Only such persons shall be permitted to enter the controlled area that have been instructed as to their conduct inside to avoid threatening their own health as well as the health of other persons. For exposed workers, such an instruction shall take place at least once a year in the framework of their preparation in accordance with Section 26, in a provable way.

(5) Pregnant women and persons aged under 18 shall not be admitted to enter the controlled area, except patients who are to undertake medical exposure at such workplaces and except persons who work at such workplaces or receive professional training for work with ionising radiation sources.

(6) Only category A workers shall be assigned to work duties in the controlled areas. The time when persons other than exposed workers are present in the controlled area and the conditions of such presence shall be limited in such a way as to make an excess of general limits of the exposure unlikely.

(7) For the stay in the controlled area, each exposed worker shall be equipped with protective aids, commensurate with the method of the ionising radiation source management.

(8) Individual monitoring shall be performed for the stay of exposed workers in the controlled area in the scope stipulated by the monitoring programme. Each category A worker shall be equipped with personal dosimeters. If the dose equivalent rate might exceed 1 mSv/hr, the exposed workers shall also be equipped with operative personal dosimeters (for example, signal dosimeters, direct-reading dosimeters or other dosimeters approved in the monitoring programme); these provisions shall apply to each individual at category III and IV workplaces, except the individuals entering the controlled area of a medical workplace to undergo a treatment or examination with the use of ionising radiation sources.

(9) Unless otherwise specified in the licence, workers shall enter and work in the controlled area of category IV workplaces and the controlled area of category III and II workplaces with unsealed radionuclide sources, after changing their clothes; and upon leaving the aforementioned areas, radioactive contamination shall be checked up, and if necessary, personal decontamination shall be carried out.

## § 31

### **Preparation and Commissioning of a Workplace where Radiation Activities Are to Be Undertaken**

(1) A workplace where radiation activities are to be undertaken shall be designed, constructed and commissioned in such a way as to ensure that a ionising radiation source will be handled in a safe way during operation, ensuring sufficient radiation protection for any persons at the workplace as well as any persons in the vicinity thereof, while

- a) the building material used in workplace construction, the construction of walls and shielding, the ionising radiation source shields, the equipment and the internal arrangement of the workplace shall ensure that during all radiation practices undertaken at the workplace as well as during eventual radiation incidents such a radiation protection is ensured which is appropriate to the conditions expected from the operation of such a workplace;
- b) the walls, the ceiling and the floor of a room where radionuclide sources are to be stored when not in use shall be protected by sufficient shielding layers; and
- c) fast and effective personal decontamination shall be possible when needed at workplaces with unsealed radionuclide sources.

(2) Further requirements concerning the methods and scope of radiation protection to be arranged for siting, building, commissioning and operation of nuclear installations are set out in special legal regulations.<sup>17)</sup>

---

<sup>17)</sup> Regulation No. 215/1997 Coll., on Criteria for Siting Nuclear Facilities and Very Significant Ionising Radiation Sources.  
Regulation No. 106/1998 Coll., on Nuclear Safety and Radiation Protection Assurance during Commissioning and Operation of Nuclear Facilities.

§ 32

**Special Conditions of Safe Operation of Workplaces with Radiation Generators**

(1) A radiation generator may only be switched on and used for an indispensable time.

(2) For irradiation with radiation generators, measuring or signalling before entry into the delineated or shielded irradiation room and after the work is finished shall verify that the radiation generator is off.

(3) Stationary x-ray units as well as other stationary radiation generators shall be placed in independent irradiation rooms or examination rooms and shall be operated from shielded control rooms, except such x-ray units whose construction or purpose of use eliminate the exceeding of exposure limits. As regards x-ray units for radiodiagnostics that need to be operated directly from within the examination room, fixed or movable protective shields shall be installed, preventing exposure limits from being exceeded.

(4) Any device or equipment that contains a radiation generator and a protective shield may only be used on condition that the device or equipment cannot be turned on while the protective shield is removed and will automatically stop when the protective shield is open.

(5) A radiation generator may only be used on condition that it has passed successfully an acceptance test or a status test, and no longer period elapsed since the last successful long-term stability test than is laid down for its periodic performance, or no other reason for such testing has arisen.

§ 33

**Special Conditions of Safe Operation of Workplaces with Sealed Radionuclide Sources**

(1) If a sealed source is not accompanied with the certificate of sealed source as stipulated by Section 82, or its tightness is not otherwise proven as stipulated in the licence, or its untightness is revealed, the sealed source shall be handled as an unsealed source.

(2) A sealed source, except for an insignificant or type-approved minor source, may only be physically taken over by such a person who is authorised to use, or at least to store it based on a licence for ionising radiation source management under the Act, Section 9, paragraph 1i). This provision shall not be applicable to source takeover by a carrier for transport.

(3) A sealed source may only be used for an absolutely indispensable period of time, while otherwise it shall be stored in a protective shield or otherwise shielded, as a rule, in such a way as to prevent dose equivalent rate from exceeding 100  $\mu\text{Sv/hr}$  on the surface of shield, container, shielded storage rooms, vaults and shielded boxes and from exceeding 10  $\mu\text{Sv/hr}$  at a distance of 1 m from the surface, and while moving the sources at the workplace from exceeding 100  $\mu\text{Sv/hr}$  at a distance of 1m from the surface of the transport cover.

(4) For irradiation with a sealed source, it shall be verified by measuring or signalling after the finished work or before entering the delineated or shielded irradiation room whether the sealed source is properly shielded or inserted in a shield. For handling such a sealed source where loosening thereof from the irradiation apparatus or its loss may not be excluded, such a measuring instrument shall be used which is able to indicate the source location under all circumstances.

(5) It is prohibited to use a sealed source until it has successfully passed the acceptance test or the status test and if no longer period since the last successful status test elapsed than is stipulated for its periodic performance, or no other reason for such testing has arisen. Upon any suspicion of untightness, the use of the sealed source shall immediately be discontinued.

(6) It is prohibited to use the equipment containing a sealed source until it has successfully passed the acceptance test or the status test and if no longer period since the last successful status test elapsed than is stipulated for its periodic performance, or no other reason for such testing has arisen.

#### § 34

### **Special Conditions for Safe Operation of Workplaces with Unsealed Sources**

(1) An unsealed source, except for an insignificant or type-approved minor source, may only be taken over physically by such a person who is authorised to use, or at least to store it, based on a licence for ionising radiation source management under the Act, Section 9, paragraph 1i), or a licence for workplace operation under the Act, Section 9, paragraph 1d), or a licence for radioactive waste management under the Act, Section 9, paragraph 1j).

(2) The maximum activity of unsealed sources which may concurrently be processed at individual workplaces with unsealed sources of category I, II or III, categorised on the basis of the equipment of the workplace and the working spots, shall be determined based on the criteria which take into account the contiguity of equipment of the working spots and the whole of the workplace with ventilation, insulation and shielding equipment, sewer system, physical properties of materials to be processed, in particular, their volatility and dust content, difficulties and potential risks from the contemplated work operations. Namely, the corresponding maximum activity shall be determined by selecting a value from Table 4, Annex 4, which corresponds to the given category of workplace with unsealed sources and to material properties and work therewith, and this value shall be multiplied by the equipment coefficient of working spot of given workplace as per Annex 4, Table 2. If several radionuclides are used concurrently at one workplace, the sum of quotients of processed activities of individual radionuclides and the maximum activity determined in the above-mentioned method must not be greater than 1.

(3) When the unsealed sources are not in use and while the sources are not included in technological units or media of the workplace, the sources shall be placed in protective shields or containers, as a rule in such a way as to prevent dose equivalent rate from exceeding 100  $\mu\text{Sv/hr}$  on the surface of shield, container, shielded storage rooms, vaults and shielded boxes, and 10  $\mu\text{Sv/hr}$  at a distance of 1 m from the surface, and when moving the sources at the workplace, the dose equivalent rate at a distance of 1 m from the surface of the transport package shall not exceed 100  $\mu\text{Sv/hr}$ .

(4) At category III and II workplaces with unsealed sources, unless otherwise stipulated in the licence, a separate sewer must be installed for discharge of radioactive wastewater from the workplace, connected to an independent catch basin.

(5) While handling unsealed sources, appropriate personal protective means shall be used, such as shielding coats, aprons, goggles, gloves, and appropriate protective aids, such as tweezers, pliers, shielding protective packages, containers and so on. Unsealed sources shall not be taken with hands, and solutions containing these sources shall not be pipetted with mouth; activities during which radioactive substances may be released into air shall be performed in closed spaces, such as a laboratory hood, hermetic box and the like.

(6) It shall be prohibited to smoke in the controlled areas of workplaces with unsealed sources; it may be allowed to eat and drink only under the conditions stipulated by given licence issued by the Office.

## § 35

### **Decommissioning**

(1) A workplace where radiation activities were performed may only be decommissioned after the removal of all ionising radiation sources, or their securing against unauthorised utilisation, and decontamination of the workplace from radionuclides, which shall be carried out in such a way and scope that the clearance levels stated in Section 57 paragraph 1 a) or stipulated in given licence issued by the Office are not exceeded anywhere at the workplace.

(2) Further requirements for the method and scope of radiation protection to be ensured for the termination or cancellation of operation and decommissioning of category III and IV workplaces are stipulated by the special legal regulation.<sup>18)</sup>

## Chapter II

### **Ionising Radiation Source Management**

[for the implementation of the Act, Section 4, paragraph 11, Section 9, paragraph 1i), Section 13, paragraph 3d) and the Annex to the Act, points I.6, I.7, I.8, I.12 and I.13]

## § 36

### **Methods of Ionising Radiation Source Management Requiring a Licence**

(1) The methods of ionising radiation source management which require a licence to be issued for the ionising radiation sources management under the Act, Section 9, paragraph 1i) shall include:

- a) manufacture of ionising radiation sources under the conditions stipulated by Section 37, except the manufacture of the following:
  1. radiation generators which are deemed insignificant sources;
  2. ionising radiation sources produced for own needs; and
  3. consumer goods with radioactive substances added whose production or export have been authorised by the Office under the Act, section 9, paragraph 1 s);
- b) import of ionising radiation sources under the conditions stipulated by Section 38, except the import of the following:
  1. radiation generators which are deemed insignificant sources;
  2. ionising radiation sources imported for own needs; and
  3. consumer goods with radioactive substances added whose production or import have been authorised by the Office under the Act, Section 9, paragraph 1 s); and

---

<sup>18)</sup> Regulation No. 196/1999 Coll., on Decommissioning of Nuclear Installations and Working Places with Important and Very Important Sources of Ionising Radiation.

- c) export of ionising radiation sources under the conditions laid down by Section 39, except export of
  - 1. insignificant and minor sources; and
  - 2. consumer goods with radioactive substances added whose production or import have been authorised by the Office under the Act, Section 9, paragraph 1 s);
- d) distribution of ionising radiation sources under the conditions stipulated by section 40, except distribution of
  - 1. radiation generators which are deemed to be insignificant sources; and
  - 2. consumer goods with radioactive substances added whose production or import have been authorised by the Office under the Act, section 9, paragraph 1s);
- e) installation or commissioning of ionising radiation sources under the conditions laid down in Section 41;
- f) storage of radionuclide sources under the conditions laid down in Section 42, except for necessary storage of ionising radiation sources during transport thereof;
- g) usage of ionising radiation sources under the conditions laid down in Section 43, except for the usage of
  - 1. insignificant or type-approved minor sources;
  - 2. consumer goods with radioactive substances added whose production or import have been authorised by the Office under the Act, Section 9, paragraph 1 s);
  - 3. ionising radiation sources which are a part of the equipment, technological assembly, equipment or operation media at a workplace for the operation of which the user is authorised based on a licence issued under the Act, Section 9, paragraph 1 d); and
  - 4. ionising radiation sources used exclusively in such a scope as authorised for the user under other licences;
- h) evaluation of ionising radiation source properties under the conditions laid down in Section 44;
- i) ionising radiation sources under the conditions laid down in Section 45, except for repairs
  - 1. of radiation generators which do not require the generator to be switched on or cannot in whatsoever manner pose any exposure hazard to the individuals carrying out the repair; and
  - 2. carried out by a licensee authorised to use such a source unless the repair poses a potential exposure in excess of normal operation;
- j) handling of mining products from mining and uranium ore treatment, such as tailings stored in spoil heaps and dumps that are not radioactive wastes.

(2) The following activities shall not be considered ionising radiation source management for which a licence authorising to handle the ionising radiation sources is required:

- a) management of ionising radiation sources in such a way that in no calendar year may the collective effective dose exceed 1 Sv and effective dose for no individual can exceed 10  $\mu$ Sv;
- b) taking and usage of solid shielding materials containing solely natural or depleted uranium or natural thorium;

- c) taking and usage of natural curative waters containing only radionuclides of natural origin;
- d) work activities with increased exposure from natural sources, except activities listed in paragraph 1j);
- e) operation of a nuclear installation or a radioactive waste repository operated based on and under the conditions of a licence issued under the Act, Section 9, paragraph 1 d);
- f) mining and treatment of radioactive minerals, performed based on and under the conditions of a licence under the Act, Section 9, paragraph 1 d); and
- g) usage of consumer goods with radioactive substances added whose production or import has been authorised by the Office under the Act, Section 9, paragraph 1s).

(3) An application for the licence to handle ionising radiation sources shall be accompanied with documents stipulated by the Annex to the Act, point I, and submitted in full scope for category II workplaces and higher operated by the applicant, and for the ionising radiation sources which are intended to be in the applicant possession. For a category I workplace operated by the applicant, the monitoring programme, the proposal for delineation of a controlled area and the on-site emergency plan are not required and not subject to approval, provided that such operating rules are submitted which, in the Office's view, include a sufficient description of workplace monitoring and instructions for the event of deviations from normal operation. For other ionising radiation sources to be handled and for work duties at workplaces operated by other persons, the scope and method of the ionising radiation source management shall be taken into account. Shall several persons use a single ionising radiation source or a single workplace, they may submit the aforesaid documents jointly.

### § 37

#### **Manufacture**

(1) A licence to manufacture ionising radiation sources also entitles the manufacturer<sup>19)</sup> to store them and to carry out necessary testing and verification of the properties and parameters of the ionising radiation sources produced, but it does not replace any other licence needed for the intended use of sources.

(2) Produced radionuclide sources shall be stored safely in accordance with Section 42.

(3) The manufacturer shall only deliver the ionising radiation sources to a person authorised to handle them, that is the person shall be at least authorised to store them.

### § 38

#### **Import**

(1) Imported radionuclide sources shall be transported safely under the Act, Section 20, and stored safely in accordance with Section 42.

---

<sup>19)</sup> Act No. 22/1997 Coll., Section 2, on Technical Requirements for Products and on amendments and alterations to some acts, as amended.

(2) The importer<sup>19)</sup> shall ensure that during import only authorised persons will handle the ionising radiation sources and that the ionising radiation sources will only be delivered to a person authorised to handle them, that is to at least be authorised to store them.

(3) The importer who will not physically use the imported ionising radiation source for own purpose nor, for radionuclide sources, will the importer store them, need not submit along with a licence application for import of ionising radiation sources the monitoring programme, the proposal of controlled area delineation or the on-site emergency plan under the Annex to the Act, points I.6 through I.8, if the importer completes the licence application with a list of all workers who will handle the ionising radiation sources during import on the territory of the Czech Republic, providing evidence that they are authorised to such handling.

### § 39

#### **Export**

(1) Exported radionuclide sources shall be transported safely under the Act, Section 20, and stored safely in accordance with Section 42.

(2) The exporter shall ensure that during export only authorised persons will handle the ionising radiation sources and that the ionising radiation sources will only be delivered to a person authorised to handle them. A certificate pursuant to the Annex to the Act, point I.13, stating that the recipient meets the conditions of ionising radiation source management, confirmed by a competent body of the recipient's country, shall only be required for radionuclide source export.

(3) The exporter who will not physically use the exported ionising radiation source for own purpose nor, for radionuclide sources, will the exporter store them, need not submit along with a licence application for export of ionising radiation sources the monitoring programme, the proposal of controlled area delineation or the on-site emergency plan under the Annex to the Act, I.6 through I.8, if the exporter completes the licence application with a list of all workers who will handle the ionising radiation sources exported during the export on the territory of the Czech Republic, providing evidence that they are authorised to such handling.

### § 40

#### **Distribution**

(1) The ionising radiation sources that are subject to type-approval under the Act, Section 23, may only be introduced in the market after their type-approval and if conditions have been created for:

- a) verification and evaluation of properties and parameters of individual manufactured ionising radiation sources with an approved type; and
- b) giving evidence that individual ionising radiation sources conform to the type approved.

(2) The distributor<sup>19)</sup> shall ensure that the documentation for the ionising radiation sources distributed includes their classification, proposed scope of acceptance tests as set out in Section 70 and status tests set out in Section 71, and the standard document for unsealed sources and the valid certificate of sealed source issued by an authorised person, and operating instructions approved by the Office for minor sources.



(3) The distributed radionuclide sources shall be transported in a safe and secure manner stipulated by the Act, Section 20, and stored safely in accordance with Section 42.

(4) The distributor shall ensure that during distribution only authorised persons handle the ionising radiation sources and that the ionising radiation sources will only be delivered to a person authorised to handle them, that is to at least store them.

(5) The distributor who will not physically use the distributed ionising radiation sources for own purpose nor, for radionuclide sources, will the distributor store them, need not enclose the monitoring programme, the proposal of controlled area delineation and the on-site emergency plan as set out in the Annex to the Act, points I.6 through I.8, to the licence application for ionising radiation source distribution, if the distributor completes the licence application with a list of all workers who will handle the ionising radiation sources during the distribution on the territory of the Czech Republic, providing evidence that they are authorised for such handling.

#### § 41

#### **Installation or Commissioning**

(1) A licence shall be required for such a specific way of ionising radiation source management as ionising radiation source installation or commissioning from anyone who is not otherwise duly authorised to handle given source, if he or she uses it during the ionising radiation source installation or commissioning in order to perform necessary testing of the ionising radiation source functionality and related shielding and protective equipment, or to verify whether the ionising radiation source is suitable for its intended purpose. If the installation or commissioning are not related to a greater exposure hazard than that posed by normal operation, e.g. by removing shielding or safety elements, such a person who is authorised to use given ionising radiation source shall not need a licence for installation or commissioning.

(2) Ionising radiation sources, except insignificant and minor sources, may only be installed and commissioned at such workplaces that comply with the technical and organisational conditions of safe operation set out in Sections 24 through 34; provided that

- a) if the ionising radiation sources used are subjected to type-approval under Section 23, they have been type-approved and evidence is provided, proving conformity with the approved type;
- b) if it is an installation of radionuclide sources or commissioning of equipment containing them, the operator of the workplace where the ionising radiation sources are to be installed is authorised to store given radionuclide sources; and
- c) conditions are created at the workplaces as to prevent ionising radiation source theft or handling by unauthorised persons, which also applies to the time when they are not in use.

(3) A proposal for the controlled area delineation and the on-site emergency plan need not be enclosed with the application for installation or commissioning of ionising radiation sources under the Annex to the Act, points I.7 and I.8, if these activities are exclusively performed at a workplace of another licensee.

## § 42

### **Storage of Radionuclide Sources**

(1) A licence shall be required for such a specific way of ionising radiation source management as radionuclide source storage from anyone who stores radionuclide sources which he or she is not authorised to manufacture, import, distribute or use, e.g. due to not having created or having lost the conditions for their usage. The licence for radionuclide source storage is not required from a carrier for storing ionising radiation sources which is necessary to carry out the transportation in accordance with safe transport under the Act, Section 20.

(2) Ionising radiation sources shall be stored in such a way as to prevent any unauthorised persons from handling them.

(3) The documents to be enclosed with the storage licence application, unless otherwise agreed with the Office, shall only include the documents specified in the Annex to the Act, points I.2 and I.5, i.e. the quality assurance programme, monitoring description and instructions for the event of a radiation incident.

## § 43

### **Usage**

(1) If explicitly stated in a licence, the ionising radiation sources for the usage whereof a licence is required may be used also at previously unspecified workplaces designed for work with ionising radiation sources for a short period of time not longer than 30 days (hereinafter referred to as the "temporary workplace").

(2) The Office shall be notified in writing, by telegraph or by e-mail, no later than one day in advance of the date of work start-up, of the anticipated period of time of work at a temporary workplace, of its location, of work duties description and an overview of the ionising radiation sources used. Working teams at temporary workplaces shall comprise at least two members, while at least one person shall have a special professional competence. The Office shall be notified without any delay of work termination at the temporary workplace. The aforesaid provisions shall not apply to such temporary workplaces where at most simple sources will be used.

(3) Such ionising radiation sources for the usage whereof a licence is required under paragraph 1 may only be used at such workplaces that meet the technical and organisational conditions of safe operation set out in Sections 24 through 34; provided that

- a) ionising radiation sources are secured against theft and handling by unauthorised persons, including the time when the sources are not directly in use; and,
- b) ionising radiation sources are only used or switched on to perform the work tasks.

## § 44

### **Property Evaluation**

(1) A licence shall be required under the Act, Section 9 paragraph 1i), for such a specific way of ionising radiation source management as evaluation of the ionising radiation sources properties from anyone who carries out the evaluation of the ionising radiation source properties:

- a) during ionising radiation source testing for type-approval under the Act, Section 23 paragraph 3; and
- b) during conformity assessment if ionising radiation source properties match the requirements of legal regulations, and during verification of ionising radiation source properties against the approved type; or
- c) during acceptance tests of ionising radiation sources, except unsealed sources; or
- d) during status tests of ionising radiation sources.

(2) For property evaluation of ionising radiation source during acceptance tests and status tests and for other purposes of paragraph 1, the following conditions shall be required:

- a) to ensure a sufficient expert level in relation to the evaluation process of the ionising radiation source properties including a sufficient number of personnel with specialised training, knowledge and skills;
- b) to provide own equipment for technical and administrative tasks, accessibility of the equipment for special evaluations;
- c) to use such methods which correspond with the requirements of model methods set out in Annex 6;
- d) to prepare test record sheets complying with a sample record sheet provided in Annex 6; and
- e) to arrange for the presence of qualified representatives in comparison measurements organised by the Office or carried out with the Office consent.

(3) A licence application for the evaluation of ionising radiation source properties need not be accompanied with a proposal of controlled area delineation or the on-site emergency plan pursuant to the Annex to the Act, points I.7 and I.8, if this activity is carried out exclusively at the undertaking workplace of evaluated ionising radiation source.

(4) Natural persons performing the evaluation of properties of ionising radiation sources at the undertaking workplaces of the sources being evaluated shall adhere to the on-site emergency plan approved for the undertaking of the source being evaluated.

#### § 45 **Repairs**

(1) A licence application for ionising radiation source repairs need not be accompanied with a proposal for the controlled area delineation and the on-site emergency plan pursuant to the Annex to the Act, points I.7 and I.8, if these activities are carried out exclusively at a undertaking workplace of the source being repaired.

(2) Natural persons performing the repairs of ionising radiation sources at undertaking workplaces of the sources being repaired shall adhere to the on-site emergency plan approved for the undertaking of the source being repaired.

## Chapter III Radioactive Waste Management

[For the implementation of the Act, Section 2h), point 4, Section 9 paragraph 1j), Section 13 paragraph 3d) and Section 24 paragraph 4]

### § 46

#### **General Requirements for Radioactive Waste Management**

(1) The methods of radioactive waste management that require a licence under the Act, section 9 paragraph 1j) include collection, sorting, processing, treatment, storage and disposal. Collection, sorting and storage of radioactive waste on the site of its generator who is authorised to manage it as unsealed sources shall not be considered radioactive waste management requiring a licence under the Act, section 9 paragraph 1j). Recycling, release or other discharge of radioactive waste into the environment shall be governed by Sections 56 and 57 including a licence under the Act, Section 9 paragraph 1h). Radioactive waste shall be transported in accordance with the requirements of the Act, Section 20.

(2) For radioactive waste management, radiation protection shall be ensured in the same way and scope as for other radionuclide sources unless expressly specified otherwise in a licence.

(3) In addition to radioactivity, all hazardous properties of radioactive waste that may impact security of waste management, namely its toxicity, flammability, explosiveness, spontaneous fissility, and formation of critical mass or residual heat shall be taken into account during radioactive waste management. In relation to the hazardous properties, radioactive waste management shall be carried out in accordance with general legal regulations on waste management.<sup>20)</sup>

(4) The licensee shall define procedures for individual activities undertaken within radioactive waste management in the licensee's operating instructions under the Act, Section 9 paragraph 1j) and h).

### § 47

#### **Requirements for Facilities Used in Radioactive Waste Management**

(1) The facilities used in radioactive waste management shall enable:

- a) collection and storage of radioactive waste;
- b) good accessibility for maintenance, repairs and easy decontamination;
- c) maximum prevention of clogging, and easy removal of any deposits or sediments; and
- d) prevention of radioactive waste release, and collection and return of any release.

(2) The facilities used in radioactive waste management shall enable continuous or, at least, regular measurement of quantities that prove its correct functioning, as set out by the project. The licensee shall define and document the measurement methods for such quantities.

---

<sup>20)</sup> For example Regulation No. 383/2001 Coll., on Details of Waste Management.

(3) The facilities used in processing and treatment of radioactive waste containing explosive or flammable substances shall be capable of withstanding the effects of a potential explosion or fire. Quantities impacting explosiveness or inflammation shall be monitored.

#### § 48

### **Radioactive Waste Collection and Sorting**

(1) Radioactive waste or mixtures thereof with other substances shall be collected at the place of their origin, in particular, in relation to the methods of processing and treatment used, and, so far as reasonably practicable sorted as well.

(2) Radioactive waste or mixtures thereof with other substances shall be sorted according to the methods of processing and treatment used. Radioactive waste shall be sorted by its physical and chemical properties.

(3) The licensee authorised for radioactive waste management shall document the types and methods of radioactive waste sorting and keep records on the waste sorted.

(4) Radioactive waste is classified as gas, liquid and solid. Solid radioactive waste shall be classified into three basic categories, namely temporary, low-level and intermediate-level, and high-level wastes.

(5) Temporary radioactive waste shall be such waste whose radioactivity after long-term storage (maximum 5 years) does not exceed the clearance levels. High-level radioactive waste shall be waste for which heat generation from radionuclide decay of the radionuclides contained must be taken into account during its storage and disposal. Other radioactive waste shall be classified as low-level and intermediate-level waste.

(6) Low-level and intermediate-level waste is classified into two subcategories. The first subcategory is short-lived waste, in which the half-life of radionuclides contained is shorter than 30 years (including Cs-137) with a limited mass activity of long-lived alpha emitters (in individual packages a maximum of 4000 kBq/kg, and a mean value of 400 kBq/kg in the total volume of waste produced in a calendar year). The other subcategory is long-lived waste, that is waste not ranking in the short-lived radioactive waste subcategory.

(7) The packages containing radioactive waste shall be labelled in such a way as to clearly indicate what type of waste is being collected and how it is sorted. The licensee shall establish his or her own transparent system for container and package labelling.

#### § 49

### **Radioactive Waste Processing**

(1) Radioactive waste processing means that the maximum quantity of usable substances is separated and returned for reuse so that the quantity of resulting waste and radioactive waste is minimised.

(2) Before radioactive waste processing, consideration shall be given to the impact of the processed and arising substances on the reliability of the technological equipment used for waste processing, as well as the impact on the technologically related systems to avoid any adverse impact on nuclear safety or radiation protection.

(3) If radioactive waste processing makes use of ion exchangers, filtration or other separating substances of a limited life, their function shall be inspected on a regular basis, and the licensee shall determine the highest values upon the exceeding of which these shall be

refurbished or replaced. The licensee shall specify the aforementioned values in the corresponding operating instructions.

(4) If radioactive waste is incinerated, a technological incineration procedure shall be set out and documented for each type thereof, which the licensee shall specify in corresponding operating instructions.

## § 50

### **Radioactive Waste Treatment**

(1) Radioactive waste shall be treated by changing its physical or chemical properties, or by enclosure in a container; this shall be carried out in such a way as to ensure safe transport, storage and disposal thereof. Radioactive waste treatment usually includes radioactive waste solidification and filling in packages.

(2) For radioactive waste solidification by hardeners, which may be, in particular, cement, solid bitumen or vitreous matter, the licensee shall determine a technological procedure for treatment in the operating instructions, which shall include, among other things, the blending ratio or specific hardener consumption and hardening conditions. The operating instructions shall also set out the acceptance criteria for hardeners and a method of verification thereof to assure their desired quality.

(3) If the treated radioactive waste is filled in packages, provisions shall be made to avoid their overfilling.

(4) If radioactive waste treatment includes packaging, such packages shall be selected which can reliably withstand stress resulting from subsequent manipulation and transport, ensuring their safe handling. Consideration shall be given both to a potential effect of the radioactive waste on the package from the inside caused by the presence of corrosive substances, expansion, gas formation, heat generation, etc., and to the impact of external influences.

## § 51

### **Radioactive Waste Storage**

(1) The equipment of a radioactive waste storage facility shall be adequate for the type of radioactive waste stored, namely:

- a) tanks for liquid radioactive waste shall be ensured against overflow and their filling shall be controlled; the tanks shall be placed in protective reservoirs that can safely accommodate the tank content; the protective reservoirs shall be waterproof, equipped with a tank leakage signalling equipment and pumping equipment; vapours from the tanks and reservoirs shall be drained away and processed as radioactive waste;
- b) it shall be possible to pump out the content of the storage and collecting tanks; each system of storage or collecting tanks shall always be backed up by an emergency redundancy for the event of an accident by an empty tank of a capacity corresponding to the system's largest tank;
- c) if liquid radioactive waste is stored in vessels, the floor and the walls of the storage facility shall be leakproof to such a height as to minimise, to a maximum extent, any leakage of the stored liquid radioactive waste into the environment; the floor shall be inclined towards a no-outlet leakproof sump; and

- d) the radioactive waste storage facility shall be protected against adverse weather conditions, in particular, against precipitation; the licensee shall control the state and equipment of the storage on a regular basis.
- (2) It shall be required for a radioactive waste storage that:
- a) treated radioactive waste is stored in such a way that prevents any changes of properties which might adversely affect its disposal;
- b) the licensee determines the maximum acceptable quantity of radioactive waste stored; and
- c) radioactive waste is safely stored at the place of its origin or a workplace if it cannot be treated and transported to a long-term storage facility or a radioactive waste repository.
- (3) Radioactive waste shall not be stored jointly with other waste or materials.
- (4) The facilities in which the total activity of the radioactive waste stored containing radionuclides of a half-life longer than 75 days and alpha-particle emission in excess of  $10^{15}$  Bq shall be considered a nuclear installation under the Act, Section 2h), point 4.

## § 52

### **Radioactive Waste Disposal**

- (1) Apart from general conditions for nuclear installations and category IV workplaces, it shall be required for a radioactive waste repository that
- a) the storage areas of the repository are protected against two-way infiltration of water, and that extended contact of the deposited radioactive waste with water is avoided until the repository is closed; and
- b) the repository is secured against flooding, especially with precipitation and mine waters.
- (2) The operation of a radioactive waste repository shall be terminated by its closure. A proposal for a method of closure shall be derived from safety analyses, which shall be enclosed with the documentation required for a licence for its operation.
- (3) A supervision system for a repository and its vicinity, shall not ensure only monitoring, but it shall also provide sufficient indication of potential water infiltration into the repository during its filling and of radionuclide release from the repository into the environment; while such a supervision system shall not impair the tightness and integrity of the repository.
- (4) If a draining system is a part of the repository, it shall be constructed in such a way as to prevent its clogging or choking. If despite that water penetrates into the storage area of the repository during its filling, its pumping and safe handling shall be ensured. Correct function of the draining system shall be reviewed at least once a year throughout the service life of the repository.
- (5) The fulfilment of the requirements for radiation protection in radioactive waste disposal shall be demonstrated by safety analyses of potential hazards of radioactive waste disposal. Based on the knowledge of the site where the repository shall be built, safety analyses shall demonstrably and plausibly assess the potential risks during the operating period as well as during the period after the repository is closed. Based on the safety analyses, acceptance criteria for radioactive waste disposal shall be determined.

(6) The dose constraint for safe disposal of radioactive waste shall be an effective dose of 0.25 mSv per calendar year and individual from the critical group of the population.

#### § 53

#### **Limits and Conditions for Safe Radioactive Waste Management**

(1) The limits and conditions for safe radioactive waste management approved under the Annex to the Act, point J.9 shall be determined based on safety analyses and include namely:

- a) data on admissible parameters which ensure nuclear safety and radiation protection for a given type of management;
- b) methods and terms for measurement and evaluation thereof;
- c) requirements for serviceability of facilities for radioactive waste management;
- d) requirements for a set-up of safety systems of such facilities;
- e) limits for conditioning quantities; and
- f) requirements for the personnel activities and for the organisational measures ensuring that all defined conditions are met for projected operating states.

(2) The limits and conditions for storage shall specify the maximum admissible quantities of radionuclide sources for storage. The limits and conditions for radioactive waste disposal in a repository shall include appropriate acceptance criteria, specifying the conditions and limits for characteristic properties of radioactive waste being disposed of, in particular, radionuclide content, the maximum admissible quantity of radionuclide sources, structural stability, leachability, heat and radiation effects, possibility of gas generation, possibility of microbial decomposition and origination of critical state, content of corrosive substances, explosive and spontaneous-combustion substances, combustibles, free liquids and complex-forming agents, corrosion resistance and surface contamination of packages, and a dose rate or a justification why a limit for a characteristic property of radioactive waste disposed of is not provided. The acceptance criteria may also specify the requirements for usual dimensions, weight, design and labelling of casks, containers and other packages for radioactive waste disposal.

(3) A licensee authorised for radioactive waste management shall furnish the Office on a regular basis, at least once a year, with a report on fulfilling the limits and conditions for safe radioactive waste management.

#### § 54

#### **Radioactive Waste Records**

(1) Quantity and specific activities of radionuclides in radioactive waste shall be recorded during its collection, sorting, processing, treatment, storage, transportation and disposal. These records shall serve to control the licensee's radioactive waste flow under the Act, Section 9 paragraph 1j).

(2) A licensee authorised for radioactive waste management shall keep and archive operating records on the management thereof, containing data:

- a) on weight (volume);



- b) on activity of those radionuclides whose content shall be limited by the acceptance criteria, as well as of those radionuclides whose content is greater than 1 percent of the total activity;
- c) on chemical and physical form of radioactive waste, including data on the generator of the waste consigned;
- d) on the method of waste management, and for stored or disposed radioactive waste, data on the location and time of its emplacement;
- e) on the results of waste analyses and packages;
- f) on the operation of facilities, including data on time-utilisation of the facility and/or its shutdown, on the maintenance of the facility carried out and on operational failures and breakdowns and the method of their repair; and
- g) on the first names and surnames of the personnel members responsible for the operation.

## § 55

### **Standard Document for Radioactive Waste**

(1) A standard document for radioactive waste shall accompany radioactive waste for any physical consignment to a licensee under the Act, Section 9 paragraph 1j). The standard document for radioactive waste shall be issued by the consigner and shall be signed by authorised persons of the consigner and the consignee. The standard document shall be issued for all types of radioactive waste and for each radioactive waste package that is an independent manipulation unit, such as a cask.

(2) The standard document for radioactive waste shall contain the following:

- a) indication of physical and chemical form and properties of radioactive waste, or a code characterising radioactive waste, and for solid waste, its category according to Section 48 as well;
- b) description of the package type and an external label or marking, identifying the package (identification number);
- c) mass activity of those radionuclides whose content shall be limited by the acceptance criteria and of those radionuclides whose quantity is greater than 1 percent of the total activity;
- d) dose equivalent rate on the package surface;
- e) data on surface contamination of the package with radionuclides;
- f) magnitude of the leachability coefficient of radioactive waste treated for disposal if the coefficient is limited by the acceptance criteria of the repository;
- g) total weight of radioactive waste;
- h) weight of the radioactive waste package if it is to be stored prior to disposal and when it is being disposed of;
- i) the packaging filling date or period;
- j) the issue date of the standard document;
- k) business company and identification number (if it has been assigned) of a person who is consigning radioactive waste as well as the first name, surname, job position and signature of an authorised representative of this person; and

l) business company and identification number (if it has been assigned) of a person who is receiving radioactive waste, and the first name, surname, job position and signature of an authorised representative of this person.

(3) The standard document for treated radioactive waste shall be completed with copies of the original standard documents for radioactive waste or the certificates of sealed source that are contained in the radioactive waste package; other documents may be enclosed as well, describing the properties of radioactive waste and the handling methods thereof.

(4) An integral part of the standard document for radioactive waste conveyed for disposal or storage shall be a written statement of the generator of the treated radioactive waste, stating that radioactive waste was treated in accordance with approved limits and conditions for treatment thereof and that it complies with the acceptance criteria for given repository or storage facility, for example that no free liquids, pyrophoric substances, toxic or explosive substances are present.

(5) The data in the standard document shall comply with the operating records of the generator or of an administrator of storage facility or repository. The standard document shall be executed in three copies, while the original and the copies shall be filed in different fire cells.<sup>21)</sup> The standard document for radioactive waste shall be permanently archived by the Radioactive Waste Repository Authority; and other licensees authorised for radioactive waste management or the generators shall archive the same for the minimum of 10 years from consignment or disposal of given radioactive waste.

## Chapter IV Discharge of Radionuclides into the Environment

[For the implementation of the Act, Section 8, paragraph 1, and Section 9 paragraph 1 h)]

### § 56

#### **General Rules for Radionuclide Discharge into the Environment**

(1) The radionuclides may be discharged into the environment only if the radionuclide discharge is reasonable under Section 4 paragraph 2 of the Act. The methods of discharge must be chosen in such a way that human health and the environment shall not be endangered by radionuclide accumulation before the activity is naturally reduced by spontaneous radioactive decay to a level of insignificant exposure.

(2) If a collective effective dose might exceed 1 Sv or the exposure in a critical group might exceed one twentieth of the general limits during a radionuclide discharge, the optimisation of radiation protection shall be demonstrated by a quantitative study in which the benefits and risks of the procedure being chosen shall be evaluated and a comparison with possible alternatives shall be performed.

(3) The dose constraint for a total discharge of radioactive substances from a workplace where radiation activities are performed shall be an average effective dose of 250  $\mu$ Sv per calendar year for the appropriate critical group of the public, from which 200  $\mu$ Sv shall be for discharges into the atmosphere and 50  $\mu$ Sv for discharges into watercourses from nuclear installations.

---

<sup>21)</sup> CSN 73 0802 Standard: Fire Security of Buildings – Non-production Structures.

(4) Substances, materials and objects with the radionuclide content or surface radionuclide contamination that exceeds the clearance levels may be discharged into the environment in the scope and under the terms laid down in the licence for radionuclide discharge into the environment issued by the Office under Section 9 paragraph 1 h) of the Act and/or the other licences issued with the approval of the Office in compliance with the special legal regulations.<sup>22)</sup>

## § 57

### Clearance Levels

(1) Materials, substances and objects containing radionuclides or having been contaminated by radionuclides can be discharged into the environment without a foregoing approval issued by the Office under Section 9 paragraph 1h) of the Act under the terms that:

- a) during a discharge of solids and other objects to be used out of category I to IV workplaces the sum of the quotients of average mass activities of particular radionuclides in each kilogram of the material being discharged and the clearance levels of mass activities of the appropriate radionuclides mentioned in Annex 2, Table 1 shall not be higher than 1, and the sum of the quotients of average surface activities of particular radionuclides on each 100 cm<sup>2</sup> of the surface of the material being discharged and the clearance levels of surface activities of the appropriate radionuclides mentioned in Annex 2, Table 1 shall not be higher than 1;
- b) during a discharge of waste water into surface water the sum of the products of average volume activities of particular radionuclides being discharged and the maximum conversion factors  $h_{ing}$  according to tables in Annex 3 for intake of the radionuclides ingested by adult individuals in each cubic metre of water being discharged shall not be higher than  $10^{-4}$  Sv.m<sup>-3</sup>;
- c) during a discharge of waste water into public sewerage the sum of the products of average volume activities of particular radionuclides being discharged and the maximum conversion factors  $h_{ing}$  according to tables in Annex 3 for intake of the radionuclides ingested by adult individuals in each cubic metre of water being discharged shall not be higher than  $10^{-2}$  Sv.m<sup>-3</sup>;
- d) during a discharge into the atmosphere the sum of the products of average volume activities of the particular radionuclides being discharged and the conversion factors  $h_{inh}$  according to tables in Annex 3 for intake of the radionuclides inhaled by adult individuals in each cubic metre of gaseous substance being discharged shall not be higher than  $10^{-7}$  Sv.m<sup>-3</sup>;
- e) during a disposal at waste dumps<sup>23)</sup> disposed material shall comply with the requirement under a), and the disposal shall be implemented in such a way that dose equivalent rate shall not increase by more than 0.1 µSv/hr at a distance of 1 m from the waste dump surface compared with the original natural background in the given point, and total dose equivalent rate shall not exceed a value of 0.4 µSv/hr; and

---

<sup>22)</sup> For example, the Act No. 254/2001 Coll., on Water and alternations to some acts (the Water Act), as amended by the Act No. 76/2002 Coll., Act No. 309/1991 Coll., on Air Protection against Pollutants (the Air Act), as amended.

<sup>23)</sup> Section 4 of the Act No. 185/2001 Cool, on Waste and alternations to some acts, as amended.

f) during combustion in incineration plants combustion gases discharged into the atmosphere shall comply with the requirement under d), and ash generated by incineration shall comply with the requirement under a), or if the ash is disposed at municipal waste dumps it shall comply with the requirement under e).

(2) The clearance levels under paragraph 1 shall not relate to a discharge of radionuclides into the environment which is not reasonable by the benefits under Section 4 paragraph 2 of the Act. The clearance levels shall not also relate to a discharge of radionuclides into water and into the atmosphere from nuclear installations as well as to the utilisation of aggregates from uranium mine spoil heaps.

(3) Materials, substances and objects containing radionuclides or contaminated by radionuclides can be also discharged into the environment without a licence issued by the Office under Section 9 paragraph 1h) of the Act when such activity is reasonable by the benefits under Section 4 paragraph 2 of the Act, and a collective effective dose related to the discharge shall not exceed 1 Sv per each calendar year, an effective dose to individuals shall not exceed 10  $\mu$ Sv, and the Office shall be informed at least 60 day beforehand about the kind of radionuclides, activities, location, date and method of the discharge into the environment as well as about an estimate of the related exposure.

## Chapter V Other Radiation Activities

[For the implementation of Section 4 paragraph 11 and Section 9 paragraph 1r) of the Act]

### § 58

#### **Adding of Radioactive Substances into Consumer Products**

(1) Adding of radioactive substances into consumer products shall be justified and the amount of radioactive substances added into consumer products shall be as low as reasonably achievable to keep the purpose of the consumer product.

(2) Consumer product with added radioactive substances introduced on the market shall be provided with the accompanying documentation informing the consumers about the radioactive substances added, their kinds and activities, and a possible health detriment related to the product utilisation as well as provided with the instructions for safe use. Unless otherwise stated in the terms of the licence, the object shall be visibly marked with the warning sign of radiation danger,<sup>16)</sup> the identification of radionuclides used and possibly with their activities.

(3) Consumer product with radioactive substances added, of which production and import is permitted by the Office under Section 9 paragraph 1s) of the Act, can be used even out of supervised and controlled areas if the product is used in compliance with the instructions of use (the instructions for safe product use) approved by the Office.

### § 59

#### **Services Significant from Radiation Protection Viewpoint**

(1) Services significant from the point of view of radiation protection which require the licence under Section 9 1 r) of the Act shall be:

- a) personal dosimetric services including the services for the purposes under Section 6 paragraph 3 b) of the Act;
- b) monitoring of a workplace and its vicinity in the scope that is laid out in the monitoring programme and ensured as the service for the operator of category III and IV workplaces;
- c) services related to the systematic supervision for the purposes of radiation protection;
- d) services during which the materials of the controlled areas at the workplaces handling unsealed sources, for example washing clothes taken from these workplaces, are maintained or handled by a different person than the operator of the controlled area;
- e) services during which ionising radiation sources are not handled, but the work shall be performed in the controlled areas of the workplaces handling unsealed sources, for example, cleaning, maintenance and repair of other equipment at these workplaces that are performed by a different person than the operator of the controlled area;
- f) measurement and evaluation of radon and its daughters in buildings and the determination of radon-related index of a building site for the purposes under Section 6 paragraphs 4 and 5 of the Act; and
- g) measurement and evaluation of natural radionuclide concentration in building materials and in water under Section 6 paragraph 6 of Act.

(2) The following activities shall be considered regular and qualified performance of services under paragraph 1 a), b), e) and f) depending upon the type of services:

- a) use of the methods that comply with the requirements of the model methods described in Annex 6;
- b) elaboration of test protocols that comply with the requirements of the model protocol enclosed in Annex 6; and
- c) participation of the qualified representatives in the comparison measurement meetings that are organised by the Office or approved by the Office.

(3) A provider of services in controlled areas under 1 d) shall follow the appropriate documentation approved for the operator of the controlled area. The employees who perform such services in controlled areas shall be classified into category A.

(4) The licence for performance of the other services that are significant from radiation protection point of view under Section 9 paragraph 1 r) of the Act shall not be necessary if clearly agreed in the contract of work activity for the services provided under paragraph 1 c) to e) that the licensee who operates the controlled area where the services shall be done shall undertake the full responsibility for radiation protection of all physical persons who perform such work activities.

## Chapter VI Particulars for Medical Exposure

[For the implementation of the Act, Section 4, paragraph 7a) and Section 7, paragraph 3]

### § 60

#### **Justification of Medical Exposure**

(1) Medical exposure of individuals shall be justified by the expected health benefits for a patient. As regards preventive healthcare, including health screening, medical exposure may only be carried out if justified by an anticipated benefit for the individual whose illness will be discovered, taking into account a potential curative effect on the disease. In some cases, health screening may be justified by protection of population groups.

(2) The process of justifying medical exposure under the Act, Section 4, paragraph 2, shall involve, in accordance with the principles of clinical responsibility, both a prescriber and a practitioner who

- a) shall always consider the effects, benefits and risks of other methods available leading to the same goal without exposure to ionising radiation;
- b) shall ascertain, prior to each use of a ionising radiation source for medical exposure, any previous significant applications of radionuclides and ionising radiation to the patient which might be of importance for the examination or treatment contemplated; for women in child-bearing age, they shall verify if the woman is not pregnant or breastfeeding a baby; this data shall be recorded in the patient's medical file; and
- c) shall only carry out examination involving exposure to pregnant women for urgent reasons or for reasons of obstetric indication; while it shall always be necessary to carefully consider the necessity of acquisition of the information required by means of ionising radiation sources and to select only such a technique which ensures the maximum protection for the foetus; for nuclear medicine examination of breastfeeding women, alike attention shall be paid to the justification and assessment of the urgency thereof.

(3) Such exposures that are not related to direct health benefit for the persons subject to exposure, such as verification of new knowledge, including application of methods that have not been introduced so far into clinical practice pursuant to the Act, Section 2x), point 2cc), shall require special justification and application of adequate techniques to avoid exceeding the following dose constraints:

- a) diagnostic reference levels if they are set out for given medical exposure in Annex 9;
- b) an effective dose of 1 mSv per individual in a calendar year, or under the conditions stipulated by the Office in its decision under the Act, Section 7, paragraph 2, exceptionally a value of 10 mSv for 10 successive calendar years for such exposures in which the research outcome only aims at advancing knowledge, but not at life saving or at preventing serious diseases; and
- c) dose constraint stipulated by the Office in its decision under the Act, Section 7, paragraph 2, based on a submitted study on the expected doses and assumed benefit from such exposures where the research is aimed at life saving or at preventing serious diseases, and an effective dose for an individual might exceed 1 mSv per calendar year.

§ 61

**Verification of New Knowledge**

(1) The Office shall issue its decision under the Act, Section 7, paragraph 2, for verification of new findings on human beings or for application of methods not introduced so far into the clinical practice involving exposure after the assessment of the following:

- a) assurance of radiation protection during exposure;
- b) special professional competence of the persons performing the given activity;
- c) exposure programme including the data on the number, age and sex of the persons planned to be exposed as well as the magnitude of planned exposure;
- d) data on quality assurance and control during exposure;
- e) description of an assumed professional or social benefit of the planned exposure if there is no direct health benefit for the persons subject to such exposure and an effective dose for an exposed individual does not exceed 1 mSv per calendar year; and
- f) an optimisation study for such exposures where there is no direct health benefit for the persons subject to exposure and an effective dose for an exposed individual might exceed 1 mSv per calendar year.

(2) While performing exposure within the verification of new knowledge including application of the methods that have not been introduced into clinical practice so far, it shall be ensured that the persons concerned participate in the exposure voluntarily and after provable instructing on the risks of such exposure. For those persons who are assumed to have diagnostic or therapeutic benefit from the treatment, the target dose levels shall be planned individually.

(3) Within one calendar month after the exposure is terminated, the Office shall be furnished with a report on the progress of the investigation carried out and with the relevant facts from the point of view of radiation protection.

§ 62

**Radiation Protection Optimisation in Medical Exposure**

(1) Radiation protection optimisation in medical exposure shall be ensured in particular by establishing a quality system.<sup>9)</sup> The aim of the optimisation is:

- a) to apply an appropriate imaging method in radiodiagnostic examination so as to minimise the doses in tissues, not limiting the acquisition of necessary radiodiagnostic information;
- b) to apply only an indispensable amount of a radioactive substance of desired purity and activity in nuclear medicine examination which shall ensure sufficient diagnostic information at the lowest possible burden for the patient; and
- c) in radiotherapeutic treatment, exposure to a target volume, towards which the medical exposure aims, in the scope necessary to achieve the effect desired while the exposure of other tissues shall be as low as reasonably achievable without limiting the treatment.

(2) Diagnostic reference levels as set out in Annex 9 shall be dose levels and/or applied activity levels used in diagnostic procedures in the framework of medical exposure,

whose exceeding is not expected in examination of an adult patient of 70 kg weight during the application of standard procedures and proper practice. Repeated exceeding of diagnostic reference levels in routine clinical practice requires the healthcare facility to inspect the conditions of medical exposure and, if radiation protection is not optimised, to take corrective measures.

### § 63

#### **Procedures for Medical Exposure**

(1) For all standard types of medical exposure, a written procedure (a standard) shall be drawn up, and the adherence thereto by individual radiological workplaces shall be assessed by a clinical audit. The procedure shall specify a method of dose determination and evaluation for patients.

(2) During medical exposure, all reasonable steps shall be taken to minimise the likelihood of accident occurrence or of application of an unplanned dose to a patient.

### § 64

#### **Requirements for Workplace Equipment**

(1) New X-ray units shall be equipped, wherever technically practicable, with complementary outfit and accessories to provide quantitative information on the exposure to which the examined person is subject. Skiascopy without an image intensifier is prohibited. The use of skiascopic X-ray units without automatic regulation of dose rate shall only be permitted in exceptional and justified cases.

(2) Any use of new therapeutic radiological machines shall be prohibited without appropriate dosimetric equipment for the testing of the ionising radiation source properties or without a simulator.

(3) A medical workplace where medical exposure is performed shall be equipped with personal protective means and aids for radiation protection for all personnel, persons subject to medical exposure as well as persons voluntarily helping them. Personal protective means and aids shall be used in such a scope as is appropriate to the character of the examination.

### § 65

#### **Therapeutic Application of Radionuclides**

(1) Therapeutic application of radionuclides that are unsealed sources shall only be performed in such inpatient wards of healthcare facilities that are specially adapted and equipped to meet the requirements for workplaces with unsealed sources. At the same time, it shall be ensured that the patients must not use their own clothing and, upon the patients' discharge, all personal articles shall be controlled for potential radionuclide contamination, and, if applicable, decontaminated or disposed of as items contaminated with radionuclides or as radioactive waste. Therapeutic application of radionuclides to outpatients, such as palliative therapy of osteometastasis, may only be performed if the respective licence issued by the Office stipulates so. Therapeutic application of radionuclides to outpatients is inadmissible for incontinent patients or patients unable to stick to the basic hygienic rules.

(2) Patient discharge to home care after a therapeutic application of radionuclides shall be regulated to avoid exceeding the limits set out under Section 23, paragraph 1. The



said limits shall also apply to the regulation of exposure for the patients' visitors after a therapeutic application of radionuclides. The data shall be recorded in the patient's medical file. If a patient undergoes a radionuclide therapy, the licensee shall provide the patient or his or her statutory representative prior to leaving the healthcare facility with a written notice on the risks from ionising radiation, as well as with written instructions on how to minimise the doses to a level as low as reasonably achievable for persons who come in touch with the patient. Should exposure of persons in a household come close to the general limits, the written instructions shall also be provided to the patients who undergo examination with the use of radionuclides.

## § 66

### **Requirements for Workers**

(1) Radiotherapeutic units and therapeutic units of nuclear medicine shall engage a medical physics expert.<sup>2)</sup> For other radiodiagnostic and nuclear medicine activities, except workplaces with dental and cabin X-ray units and bone densitometers, a medical physics expert shall work in a scope appropriate to his or her role within an approved quality assurance programme.

(2) Within the performance of work duties, a medical physics expert shall be responsible for accuracy and safety of ionising radiation application in clinical practice and for the introduction of new radiological equipment and physical methods into clinical practice. He or she shall also be responsible for establishing and evaluating a quality assurance system, and in particular, for managing the testing of ionising radiation sources and other medical devices which might influence exposure of patients or other persons subject to medical exposure as well as for applying and optimising radiation protection in clinical practice of the healthcare facility.

(3) Special attention shall be paid to the training of practitioners, professionally qualified competent medical personnel and medical physics experts involved in exposure of children, exposures that are a part of screening programs and exposures related to high doses to patients, in particular in radiotherapy, interventional radiology and computed tomography.

(4) In clinical application of new techniques, practitioners, professionally qualified competent medical personnel and medical physics experts shall continue their professional education and undergo practical training related to the new techniques and other new requirements for radiation protection assurance.

(5) Requirements for special professional competence of selected personnel participating in the performances related to medical exposure are stipulated by the special legal regulation.<sup>10)</sup>

## § 67

### **Further Conditions for Medical Exposure**

(1) Radiation protection for persons who knowingly and voluntarily help individuals undergoing medical exposure shall be optimised in accordance with the Act, Section 4 paragraph 4, while exposure of such persons shall be minimised in accordance with the requirements set out in Section 23 paragraph 1. Such persons shall be older than 18 years and provably instructed on the risks arising from exposure, while their approval of such exposure shall be confirmed in writing.

(2) Medical exposure under the Act, Section 2, paragraph x), point 2, without clinical indication, such as for insurance or legal purposes, shall only be carried out by application of well-established clinical procedures.

(3) Special attention shall be given to the selection of medical devices and the selection of procedures which are designed for medical exposure of children, exposure within screening examinations, and exposure involving high doses to patients undergoing radiotherapy, interventional radiology and computed tomography. For such activities, maximum attention shall be given to the evaluation of exposure of patients or other persons subject to medical exposure.

(4) A record shall be kept on each medical exposure to facilitate an assessment of exposure of an individual examined or treated person. For each radiodiagnostic procedure, reasons for exposure as well as the following data shall be recorded for dose estimate:

- a) for radiotherapeutic exposure, target dose and time schedule of exposures;  
and
- b) for nuclear medicine, in particular, specification of the radiopharmaceuticals administered, their application form and activity.

(5) The undertakings of a healthcare facility shall furnish the Office, upon request, with the data pursuant to paragraph 4 as well as with the data used for the determination of dose distribution to the public.

## Chapter VII

### Monitoring, Measurement, Evaluation, Verification and Recording of Quantities, Parameters and Facts Impacting on Radiation Protection

[For the implementation of the Act, Section 2 paragraph gg), and Section 18, paragraph 1a)]

#### § 68

#### **Quantities, Parameters and Facts Impacting on Radiation Protection**

(1) Quantities impacting on radiation protection shall be the quantities which are defined in the monitoring programme approved by the Office:

(2) The parameters and facts impacting on radiation protection shall be:

- a) parameters and properties of ionising radiation sources;
- b) parameters and protective properties of personal protective means and other protective aids and equipment used for work with ionising radiation sources (hereinafter referred to as “protective aids”);
- c) parameters and properties of packaging assemblies for radionuclide sources;
- d) parameters and properties of other equipment intended for direct work with ionising radiation sources having a construction that can affect a level of radiation protection, for example, a quality of X-ray films and developers;
- e) conformity declaration for type-approved ionising radiation sources submitted by a producer or an importer of the installation and/or a written statement demonstrating that the conformity declaration has been issued, and the certificate of sealed source in case of sealed sources, and the standard document in case of unsealed source; and

- f) monitoring results and the methods used including:
  - 1. personal doses of category A workers including part-time workers,
  - 2. quantities and parameters that characterise a ionising radiation field and an occurrence of radionuclides at a workplace;
  - 3. quantities and parameters that characterise radionuclide releases into the atmosphere in the vicinity of a workplace;
  - 4. quantities and parameters that characterise a ionising radiation field and the occurrence of radionuclides in the vicinity of the workplace;
- g) records demonstrating that the exposed workers have been informed on the risks of their work;
- h) records on the verification of professional competence of the exposed workers for safe management of ionising radiation sources by regular tests;
- i) documents on the conclusions of preventive medical examinations verifying the physical and mental capability of category A workers;
- j) facts demonstrating a violation of the principles of radiation protection identified in the framework of the systematic supervision of the observance of radiation protection; and
- k) the other data recorded in a personal radiation passport.

#### § 69

#### **Scope of Monitoring, Measurement, Evaluation, Verification and Records of Quantities, Parameters and Facts Impacting on Radiation Protection**

(1) The parameters and properties under Section 68 paragraph 2 a) shall be monitored, measured, evaluated, verified and recorded:

- a) during production, import and distribution in the scope which is needed for the assessment of conformity with the approved type;
- b) during acceptance of a ionising radiation source before commencement of its use in the scope laid down by the acceptance test; and
- c) during utilisation of the ionising radiation source in the scope that is laid down by the status test and the constancy test.

(2) The parameters and properties under Section 68 paragraph 2 b), c) and d) shall be monitored, measured, evaluated, verified and recorded during acceptance and purchase of appropriate objects in the scope that is laid down in the quality assurance programme or according to that programme.

(3) The parameters and protective properties under Section 68 paragraph 2b) shall comply with the requirements for radiation protection set out in the Czech technical standards.<sup>24)</sup>

---

<sup>24)</sup> For example, the ČSN IEC 1331-1 Standard: Protective Aids against a Medical Diagnostic X-ray Unit - Part 1: Determination of Attenuation Properties of Materials.

ČSN IEC 1331-2 Standard: Protective Aids against a Medical Diagnostic X-ray Unit - Part 2: Protective Glasses.

(4) The documents according to Section 68 paragraph 2 e) shall be verified and recorded in the scope necessary for the registration of sources.

(5) The parameters and properties of a sealed radionuclide source after verifying its tightness shall be recorded in the certificate of sealed source in the scope laid down under Section 82. The parameters and properties of an unsealed source during transfer to another licensee shall be recorded in the standard document of unsealed source in the scope laid down under Section 83 and/or in case of radioactive waste in the standard document of radioactive waste.

(6) The quantities, parameters and facts under Section 68 paragraph 2 f) shall be monitored, measured, evaluated, verified and recorded in the scope defined under Section 74 to 79 as specified in the monitoring programme for a given workplace or a ionising radiation source.

(7) Personal doses to the external workers shall be recorded in their personal radiation passports. Details shall be laid down in a special legal regulation.

## § 70

### Acceptance Test

(1) The acceptance test shall include:

- a) classification of a ionising radiation source under Section 4 to 10 unless done earlier by a producer, importer or distributor, or during a type-approval;
- b) for unsealed radionuclide sources the verification of the data given in the standard document for unsealed radionuclide source being handed over, at least the data laid down under Section 83 paragraph 2 b);
- c) for sealed radionuclide sources the test of tightness<sup>25)</sup> and the verification of the data given in the certificate of sealed radionuclide source, at least the data under Section 82 paragraph 2 b) by a visual method and according to paragraph 2 d) and e) by measurement; if the certificate of sealed source is not older than six months, the test of tightness shall be satisfactory; and
- d) for an installation that contains a sealed radionuclide source:
  1. test of the sealed source under letter b) by methods demonstrating the required data indirectly if the installation is delivered with a source that cannot be dismantled, while the verification of the serial number is not performed;
  2. verification of installation functionality and the quality of control, safety, signalling and indication systems and/or other mechanical and operational systems laid down in the decision on type-approval;
  3. verification if specified operational parameters do not deviate from the limits for the expected purpose of the use laid down in the Czech technical standards and technical documentation supplied by a producer or an importer;
  4. determination of dosimetric quantities and their precision from the purpose of use viewpoint;
- e) for radiation generators and the installation which generate radionuclides:

---

<sup>25)</sup> ČSN 40 4302 Standard: Sealed Radionuclide Sources. Resistance Grades and Testing Methods.

1. verification of installation functionality and the quality of control, safety, signalling, indication and imaging systems or other mechanical systems laid down in the decision on type-approval;
2. verification if specified operational parameters and properties of the installation do not deviate from the limits for the purpose of their use laid down in the Czech technical standards<sup>26)</sup> and in the accompanying technical documentation supplied by a producer; and
3. determination of dosimetric quantities and their precision from the purpose of use viewpoint.

(2) The acceptance tests shall be performed in the scope laid down in the Czech technical standards or in the scope set out by a type-approval of a ionising radiation source based on a proposal of the producer or importer of this installation. During the acceptance test, the scope and frequency of measurements as well as the verification of properties of ionising radiation sources for their expected way of use in the framework of status tests and constancy tests shall be proposed.

(3) Only the persons furnished with the appropriate licence issued by the Office can perform the acceptance tests as a specific method of ionising radiation sources management, with the exception of the acceptance tests for unsealed sources, while only physical persons with a special professional competence in compliance with special legal regulations<sup>10)</sup> can manage and perform acceptance tests as the activities impacting on radiation protection. The results of the acceptance test shall be recorded in a test protocol of which the copies get both a sender and a consignee.

(4) For technological sections of nuclear installations, their parts and nuclear fuel, the acceptance tests shall be replaced by the tests performed as a part of individual phases of the commissioning.

(5) The acceptance tests shall not apply to:

- a) insignificant and minor ionising radiation sources and to such simple sources if those are specified in the terms of a licence for ionising radiation source management or in the terms of a decision on type-approval;
- b) radioactive waste during its acceptance by the Radioactive Waste Repository Authority to be disposed;
- c) ionising radiation sources during acceptance only for their storing, transport and distribution; and
- d) ionising radiation sources produced by their undertaking for own use, prototypes and unique installations.

## § 71

### **Status Test**

(1) A status test for particular ionising radiation sources shall be performed in the scope laid down in a type-approval for ionising radiation source and in the way that corresponds to the Czech technical standards<sup>26)</sup>, based on a proposal submitted by a producer

---

<sup>26)</sup> For example, the ČSN IEC 1223 Standard: Evaluation and Operational Tests for Processing Medical Image Information.

or an importer of installation. The scope of the test shall be specified during the acceptance test or during the first status test called the initial status test.

(2) Unless otherwise stated by the Office or as a part of the inspection activity, the status test shall be performed:

- a) if there is a reasonable suspicion of improper functionality of the installation in which the ionising radiation source is assembled;
- b) after maintenance or repair which can affect a property or a parameter verified during the status test;
- c) whenever the results of the constancy test indicate that characteristic operational properties and parameters of the ionising radiation source deviate for a specific purpose of use from the limits laid down in the Czech technical standards or technical documentation supplied by a producer or an importer, and
- d) at most before the date of expiry of the last test:
  1. 12 months for significant sources;
  2. 12 months for dental x-ray units or 24 months if the results of an independent test performed by the Office by means of a set of thermoluminescent dosimeters sent by mail (TLD audit) verifies the proper functionality of the installation;
  3. for sealed radionuclide sources in the scope and frequency according to Annex 7; and
  4. 24 months for other simple sources;

(3) The licensee of ionising radiation source management who has the source in possession shall ensure status tests. Only the persons furnished with the appropriate licence issued by the Office can perform the status tests as a specific method of ionising radiation source management, and only physical persons with the special professional competence in compliance with the special legal regulations<sup>10)</sup> can manage and perform the status tests. Results of the status test shall be recorded in a test protocol and each licensee who manages the given ionising radiation source shall get its counterpart. The copy of the protocol shall be sent to the Office within 1 month from the date of the test by the person who performed the test.

(4) The status tests shall not apply to insignificant and minor ionising radiation sources, unsealed radionuclide sources, technological units of nuclear installations and their parts, nuclear fuel and radioactive waste. The status tests of a ionising radiation source produced by the undertaking for its own purpose, prototype or unique installation shall be replaced by constancy tests in the scope approved by the Office.

## § 72

### **Constancy Test**

(1) A constancy test for particular ionising radiation sources shall involve the verification of characteristic properties and parameters in the scope laid down in the Czech technical standards or in the scope set out during a type-approval of the source under Section 23 of the Act, based on the proposal of a producer or an importer of the installation. The scope of the constancy test shall be specified in detail during the acceptance test and during status tests.

(2) The constancy test shall be performed periodically in the intervals set out during the acceptance test or based on the recommendation specified by a producer in technical

documentation of the source, and always after maintenance or repair which could affect a tested property or parameter.

(3) The constancy test for sealed radionuclide sources shall usually be performed indirectly by the measurement of abrasion according to the method specified in the Czech technical standard<sup>25</sup>) on the parts of installation which are in contact with the source, at least once per 12 months during cleaning, and at least one per 3 months if the installation is used in the chemical aggressive environment and if there is an increased risk of mechanical damage unless otherwise stated in the terms of the licence or in the decision about type-approval.

(4) A registrant or a licensee for ionising radiation source management who has the source including other tested equipment in his or her possession shall perform or ensure the constancy tests. Results of the constancy test shall be recorded in a test protocol and filed by the licensee for ionising radiation source management who has the source in his or her possession. The other users of the source shall be informed about the results of the constancy tests.

(5) The constancy tests shall not apply to insignificant sources, unsealed sources, technological units of nuclear installations and their parts, nuclear fuel and radioactive waste.

### § 73

#### **Requisites of Monitoring Programme**

(1) The monitoring programme, according to the scope and the method of ionising radiation source and/or radioactive waste management, usually consists of the following parts:

- a) monitoring of workplace;
- b) personal monitoring;
- c) monitoring of discharges; and
- d) environmental monitoring.

(2) The monitoring programme shall involve the monitoring under normal operation, the monitoring for predictable deviations from normal operation as well as the monitoring during radiation incidents and radiation accidents:

- a) determination of the quantities to be monitored including the method, scope and frequency of their measurements;
- b) instructions for the evaluation of measurement results;
- c) reference levels and the overview of appropriate countermeasures if the reference levels are exceeded;
- d) specification of the methods of measurement; and
- e) specification of the types of gauges used for measurement including other aids and their parameters.

(3) The monitoring programme shall be established in such a way and such a scope as to verify the requirements of exposure limitation during operation of the workplace and to demonstrate the optimisation of radiation protection and other requirements for safe operation of workplaces, especially early detection of deviations from normal operation. Depending upon the nature of work, the monitoring shall be established either as routine, that is continuous or periodic, or as operative during a certain activity aimed at evaluating and ensuring the acceptability of this activity from the point of view of the limitation system. If the arrangement of workplace, sources, methods and/or the conditions of ionising radiation

source management and/or monitoring methods are changed, the monitoring programme shall be updated.

#### § 74

#### **Uniform Procedures for Evaluation of Quantities Measured as a Part of Monitoring**

(1) The conversion factors given in the appropriate tables in Annex 3 shall be used to convert the activities of inhaled or ingested radionuclides to a committed effective dose. For unidentified radionuclides, unknown chemical forms and properties of inhaled aerosols, activity shall be assigned to radionuclides and their forms and/or to an aerosol for which the highest conversion factor for inhalation or ingestion is set in Annex 3.

(2) If the data that better describes a given situation is not available, intake of radionuclides by ingestion shall be calculated on the basis of consumption of a given kind of foodstuffs, especially determined from statistical overviews, separately for each age category.

(3) If the data that better describes a given situation is not available, it shall be assumed that a worker being at work 2000 hours per year inhales 2000 m<sup>3</sup> of the air and ingests 1 m<sup>3</sup> of water, of which 0.7 m<sup>3</sup> in liquid form. For other members of the public, the volume of inhaled air shall be 1000 m<sup>3</sup> per year for individuals at the age up to 1 year inclusively, 2000 m<sup>3</sup> at the age from 1 to 2 years inclusively, 4000 m<sup>3</sup> at the age from 2 to 7 years inclusively, 6000 m<sup>3</sup> at the age from 7 to 12 years inclusively, 8000 m<sup>3</sup> at the age from 12 to 17 let inclusively and 8500 m<sup>3</sup> for the individuals older than 17 years. For other members of the public, it shall be assumed that the adult man shall ingest 1 m<sup>3</sup> of water per year, of which 0.7 m<sup>3</sup> in liquid form, and the adult woman or a child older than 10 years shall ingest 0.7 m<sup>3</sup> water, of which 0.45 m<sup>3</sup> in liquid form.

(4) For external exposure to radioactive noble gases dispersed in the atmosphere at a workplace, the conversion factors given in Annex 3, Table 1 shall be used to convert average volume activities of gases to an effective dose rate.

#### § 75

#### **Reference Levels**

(1) Reference levels shall be defined in the monitoring programme, which are the critical values or criteria defined in advance for certain procedures or measures.

(2) Recording levels shall be such reference levels upon the exceeding of which the values shall be recorded and filed. The recording levels shall separate the values being worth of attention from insignificant ones. The recording levels shall usually be defined as one tenth of limits, and monitoring methods shall be chosen in such a way that the minimum detectable activity of a radiation protection quantity measured shall be lower than the recording level defined in this way.

(3) Investigation levels shall be such reference levels for which their exceeding shall lead to a consecutive investigation of causes and possible consequences of the deviation of monitored quantity in radiation protection. The investigation levels shall usually be defined as three tenths of the exposure limit or as the upper limit of normally monitored values.

(4) Intervention levels shall be such reference levels for which their exceeding shall commence or introduce the remedial measures to change the deviation of a quantity monitored in radiation protection. For intervention levels specified in the monitoring programme, the interventions and decisive procedures shall be specified exactly. For a



particular quantity or a parameter, more than one intervention level related progressively may be defined which corresponds to related interventions more and more significant depending upon a rising significance of the deviation of monitored quantity.

## § 76

### **Monitoring of Workplace**

(1) The monitoring of workplace shall be realised by monitoring, measurement, evaluation and recording of the quantities and parameters which characterise an ionising radiation field and an occurrence of radionuclides at the workplace, namely equivalent dose rates at the workplace, volume activities in the air and surface activities at the workplace. The monitoring shall be introduced at all workplaces of categories I to IV, with the exception of the category I workplaces where only minor ionising radiation sources shall be used.

(2) While commencing work activities, changing operational procedures or radiation protection methods, the effectiveness of radiation protection against external and internal exposures shall be verified by detailed measurements of a dose equivalent rate, volume activities and other quantities of ionising radiation sources at working spots and at the places of possible worker's stay.

(3) The monitoring of surface radionuclide contamination shall be realised at the workplaces with unsealed sources so that operational variations from normal operation, insufficient functionality and radionuclide dispersion barrier failures shall be indicated. If a permanent high surface contamination is detected, the monitoring of volume activities in the air and regular personal monitoring of radionuclide intake shall be introduced.

(4) The regular monitoring of the air by systematic measurements shall always be introduced at the working spots with unsealed radionuclide sources and at category IV workplaces.

## § 77

### **Personal Monitoring**

(1) Personal monitoring shall serve for the determination of personal doses by monitoring, measurement and evaluation of individual external and internal exposures, usually by personal dosimeters. At category II workplaces with a controlled area and at workplaces of category III and IV, a monitoring period of personal dosimeters shall be one month.

(2) The personal monitoring by personal dosimeters shall be ensured for all category A workers including external workers as well as for persons intervening during radiation accidents or natural disasters in compliance with an on-site emergency plan unless otherwise stated under the terms of the licence and of an approved monitoring programme.

(3) Personal dosimeter shall be worn on the front left part of chest (hereinafter referred to as "reference point") unless otherwise stated in a monitoring programme. If a protective shielding apron is used, the dosimeter shall be placed outside the apron. If an intervention level or an investigation level laid down in the approved monitoring programme is exceeded, a personal dose equivalent measured outside the apron shall be reduced by a value which corresponds to attenuation in the apron. If the dosimeter placed at the reference point does not permit an estimate of an effective dose and an equivalent dose in organs and tissues for which the limits have been determined, a worker shall be provided with another dosimeter which due to either its properties or its position can determine such an estimate.

(4) Personal dosimeter shall measure all kinds of radiation which contribute to the worker's external exposure during ionising radiation source management. If the dosimeter does not comply with such a condition, the worker shall be provided with other dosimeters unless another method of monitoring is specified in the monitoring programme.

(5) At the workplaces where a radiation accident as a consequence of single external exposure due to a loss of control over a source may be possible, exposed workers shall be provided with operative dosimeters which can directly indicate the exceeding of a preset level. If single exposure caused by a source can exceed five-times the occupational limit for exposed workers, the monitoring shall determine doses and their distribution in the worker's bodies including the reconstruction of accident.

(6) At the workplaces with a possibility of internal occupational exposure, radionuclide intakes and/or committed effective doses caused by internal exposure shall usually be determined by radionuclide activity measurements in a worker's body or the worker's excretes and activities shall be converted to an intake by means of a respiratory tract model and by the kinetics of appropriate elements. At work with unsealed sources, the measurements of radionuclide activity in a worker's body or the worker's excretes shall always be required at category IV workplace, and at category III workplace only if stated in the monitoring programme.

(7) In case of a suspicion of an uncontrolled single occupational exposure, personal dosimeters shall be immediately evaluated and a dosimetric evaluation of the event shall be performed.

(8) An employer shall be obliged to make the results of personal monitoring available to exposed workers on request including their dose estimates based on such measurement results or the monitoring of workplace.

## § 78

### **Monitoring Discharges**

(1) The monitoring of discharges shall be realised by monitoring, measurement, evaluation and recording of the quantities and parameters which characterise radionuclide discharges to the vicinity of a facility, namely gross activities and volume activities of the discharges. The monitoring shall be introduced at all workplaces where a disposal of radionuclide-contaminated substances is carried out by a controlled discharge or where a release of significant radionuclide amount into the environment is possible. The monitoring of discharges shall serve to check if admissible discharge limits are met as well as to provide early detection and evaluation of possible releases and their consequences to the public in the vicinity of the facility and to the environment.

(2) The monitoring of discharges into the atmosphere and watercourses from category IV workplaces, and from category III workplaces if laid down in the terms of the licence issued by the Office, shall involve both a systematic balance measurement of all radionuclides, which significantly contribute to exposure of the public, and continuous measurements of representative radionuclides which can quickly indicate deviations from normal operation. If there is a possibility of inadmissible radionuclide releases into the atmosphere, the systematic monitoring of all potential pathways shall be ensured.

§ 79

**Monitoring of Workplace Vicinity**

(1) The monitoring of workplace vicinity shall be realised by monitoring, measurement, evaluation and recording of the quantities and parameters that characterise the ionising radiation field and an occurrence of radionuclides in the vicinity of the workplace, namely dose rates, activities, volume activities and mass activities. The monitoring shall be introduced at all workplaces with a possible release of a significant amount of radionuclides into the environment. The monitoring shall serve to check if admissible discharge limits are met as well as to provide early detection and evaluation of possible releases and their consequence to the public in the vicinity of the facility and to the environment, and it shall serve to confirm safety operation under normal operation in relation to the environment.

(2) The monitoring of the environment shall be ensured by a network of pre-selected monitoring points and routes at which a magnitude and a distribution of effective doses and committed doses shall be calculated, based on measurements of dose equivalent from external exposure as well as environmental sampling and the determination of radionuclides in the air, watercourses, and in selected components of the environment and foodstuffs.

(3) The monitoring in the environment of very significant ionising radiation sources shall commence 1 to 2 years before its putting into operation. The goal of this pre-operational monitoring is to get the data on the original condition in the vicinity of the future source and to verify the monitoring programme in advance of the source operation. The scope and the content of the pre-operational monitoring shall be a part of the preliminary safety analysis report.

(4) The monitoring which is realised in the framework of the National Radiation Monitoring Network shall be laid down in a special legal regulation.

**Chapter VIII**

**Accounting for Ionising Radiation Sources  
and Records of Other Facts Relevant for Radiation Protection**

[For the implementation of the Act, Section 18, paragraph 1c), and Section 22 e)]

§ 80

**Licensees' Accounting for Ionising Radiation Sources**

(1) A licensee shall keep the following records and data on each ionising radiation source which he or she manages:

- a) source description enabling its unambiguous identification, namely its name, type designation, manufacturer's name, serial or identification number;
- b) purpose of source management;
- c) all licences and other decisions concerning the ionising radiation source management;
- d) operational records characterising the method and scope of ionising radiation source management; and for an unsealed source, its purpose and consumption balance; and

e) records concerning the ionising radiation source management, acquired in the framework of a systematic surveillance of radiation protection observance, and records of inspection activities.

(2) For each ionising radiation source in his or her possession, a licensee shall further keep these documents and data

- a) the date of physical acceptance of the ionising radiation source;
- b) a document on the ionising radiation source acquisition;
- c) for a ionising radiation source that is subjected to a type-approval, except radionuclide sources, a conformity statement issued by its manufacturer, importer or distributor;
- d) for a sealed source, a certificate of sealed source;
- e) for an unsealed source, a standard document issued upon the transfer of the source by its previous owner;
- f) a protocol on an acceptance test, protocols on status tests and protocols on constancy tests;
- g) if a ionising radiation source is transferred to another person, data indicating to whom and when the source was transferred; and for unsealed sources, also an accompanying document issued upon such a transfer;
- h) if a radionuclide source is discharged into the environment, the records on its discharge into the environment; and
- i) if a radionuclide source is disposed of as radioactive waste, the data indicating to whom and when the source was transferred, and a standard document for radioactive waste issued upon such a transfer.

(3) The data under the paragraphs 1 and 2 shall be preserved at least for 10 years after the termination of the ionising radiation source management.

(4) Unless otherwise stipulated in a licence, the licensees authorised for ionising radiation source usage or storage shall furnish the Office in writing or another agreed form with the below data on the ionising radiation sources in their possession, except insignificant and type-approved minor sources, to be recorded in the national system of accounting for ionising radiation sources:

- a) for radiation generators, the data in the scope of items on a source generator registration card specified in Annex 12, within 1 month of:
  - 1. successful acceptance tests performed;
  - 2. alternation of registration card data;
  - 3. transfer to possession of another person; and
  - 4. decommissioning;
- b) for sealed sources, the data in the scope of items on the sealed source registration card specified in Annex 12, within 1 month of:
  - 1. a physical acceptance of the sealed source;
  - 2. alternation of the registration card data;
  - 3. transfer to the possession of another person; and
  - 4. its disposal as radioactive waste or its other disposal;

- c) for equipment with sealed sources, the data in the scope of items on a registration card for the equipment with sealed radionuclide sources specified in Annex 12, within 1 month of:
1. successful acceptance tests performed;
  2. alteration of registration card data;
  3. equipment transfer to the possession of another person; and,
  4. equipment decommissioning;
- d) for unsealed sources with a half-life of the radionuclides contained therein longer than 60 days:
1. a copy of the standard document of the received unsealed source within 1 month of its physical acceptance;
  2. a copy of the standard document of the consigned unsealed source within 1 month of its transfer to the possession of another person;
  3. a copy of the standard document of radioactive waste within 1 month of its disposal as radioactive waste; and
  4. the data on the discharge into the environment or other disposal within 1 month thereof.

(5) The licensees authorised for manufacture, import, distribution and export of ionising radiation sources shall furnish the Office in writing or another agreed form, unless otherwise specified in the licence, always by the end of January and by the end of June of a current year with a summary for the preceding six months of the manufactured, imported, distributed and exported ionising radiation sources in the scope specified in Annex 13.

(6) The Radioactive Waste Repository Authority shall furnish the Office in writing or another agreed form by the end of February of a current year with a summary for preceding calendar year of the data concerning the mass (volume), the total activity of such radionuclides whose content is limited by the acceptance criteria for disposal, and also of such radionuclides whose content exceeds one percent of the total activity including the data on the waste generator.

(7) The provisions of paragraphs 1 through 3 shall be applicable to radioactive waste accounting for as well. Accounting for radioactive waste by a licensee under the Act, Section 9, paragraph 1j), shall also be subjected to the provisions of Section 54.

## § 81

### **Registrants' Accounting for Minor Ionising Radiation Sources**

(1) A registrant pursuant to the Act, Section 21, paragraph 2, who uses type-approved minor sources, shall keep and preserve the following documents and the data on each type-approved minor source:

- a) specification of the source facilitating its unambiguous identification, namely its name, type designation, name of the manufacturer, serial or identification number;
- b) purpose of the ionising radiation source use;
- c) user manual for the ionising radiation source approved by the Office; and
- d) set scope of constancy tests.

(2) For each type-approved minor ionising radiation source in the registrant's possession, the registrant authorised for the use of the type-approved minor source shall keep and preserve the following documents and data:

- a) date of purchase or transfer of the ionising radiation source;
- b) documents on the acquisition of the ionising radiation source;
- c) conformity statement issued by its manufacturer, importer or other person introducing the ionising radiation source into circulation;
- d) for sealed sources, the certificate of sealed source;
- e) for unsealed sources, the standard document; and
- f) data on the location of the ionising radiation source.

(3) The recorded data shall be preserved for 5 years after the transfer or disposal of the ionising radiation source.

(4) The registrants shall furnish the Office with the data under the Act, Section 21, paragraph 2, in writing or another agreed form, to be filed in the national system of accounting for ionising radiation sources.

## § 82

### **Certificate of Sealed Source**

(1) A certificate of sealed source shall indicate its grade of resistance and other properties thereof verified by tests carried out.<sup>25)</sup>

(2) The certificate of sealed source shall include the following:

- a) certificate identification number;
- b) serial number of the sealed source;
- c) designation of the approved type with whose properties the source's properties are in conformance;
- d) the data on the radionuclide type;
- e) the data on the activity of the sealed source, stating the reference date, the data on the maximum content of the basic radionuclide; for significant and very significant sources, a kerma rate in the air, stating the reference date;
- f) the data on chemical and physical form of the radionuclide and its carrier;
- g) the data on the dimensions of the sealed source;
- h) the data on encapsulation or a protective cover (material, thickness, design and seal);
- i) grade of resistance of a sealed source<sup>25)</sup> of given type;
- j) results of the tests performed<sup>25)</sup> for radioactive contamination and tightness of the sealed radionuclide source;
- k) recommended time of usage of the sealed radionuclide source and/or other materials for a systematic verification of its tightness by the operator;
- l) issue date of the certificate of sealed source; and

m) business company and identification number (if assigned) of the person who issued the certificate, and the first name, surname, job position and signature of an authorised representative of this person.

(3) For sealed sources that for technical reasons cannot be identified with a mark and a serial number, a mass certificate shall be issued. This mass certificate shall be issued for all sources of identical type and size, containing identical volume of the same radionuclides and in possession of the same owner. The mass certificate shall contain the data specified in paragraph 2; instead the serial number of the source, a number of individual sealed sources shall be stated for which the mass certificate is issued.

(4) Determining or verifying a resistance class of sealed sources and issuing sealed source certificates shall be deemed specific methods of ionising radiation source management requiring an appropriate licence from the Office, and their performance may only be managed, as activities significant from the point of view of radiation protection, by the natural persons with special professional competence. For sealed sources classified as insignificant sources, the data stated in a certificate issued by a manufacturer of the source, which is no older than 6 months, shall suffice for the issue of the certificate of sealed source.

(5) If a sealed source is not accompanied with a certificate, or its tightness is not demonstrated in another way specified in the licence conditions, it shall be handled as an unsealed source. A sealed source whose tightness has been proved by a status test performed in terms according to Annex 7, but whose certificate validity expired, may be considered a sealed source and it may remain in use for the recommended time of use stated in the certificate of sealed source; if the recommended time of use is unknown or has expired, it may only be used until June, 30, 2007, unless otherwise specified by the Office in the licence for given source management.

### § 83

#### **Standard Document of Unsealed Source**

(1) Upon transfer to possession of another person, an unsealed source shall be accompanied with the standard document of unsealed source, which shall indicate parameters and properties thereof, relevant for radiation protection during its management.

(2) The standard document of unsealed source shall contain:

- a) specification or identification number of the source;
- b) for the sources subjected to a type-approval, designation of the approved type with whose properties the source's properties are in conformance;
- c) the data on the radionuclide type;
- d) the data on chemical and physical form of the radionuclide and its carrier;
- e) the data on activity and mass activity of the radionuclide stating the reference date;
- f) the data on its chemical and radio-chemical purity;
- g) the data on the type of unsealed source packaging;
- h) issue date of the standard document; and
- i) business company and identification number (if assigned) of a person who issued the standard document, and the first name, surname, job position and signature of an authorised representative of this person.

(3) For jointly transferred identical unsealed radionuclide sources, a common standard document shall be issued, which shall contain, apart from the data as per paragraph 2 for an individual source, the total number of the sources transferred.

(4) Objects or substances contaminated with the radionuclides which originated during operation of nuclear installations or other facilities, during whose operation radionuclides are generated, shall not be considered further unsealed sources as long as they remain at the workplace where radioactive contamination or a generation of the objects or substances occurred. If such objects or substances are transferred to possession of another person, the standard document of such sources need not contain the data according to paragraph 2c) through f) if the maximum dose equivalent rate at a distance of 0.1 m from the surface and the maximum surface activity for 100 cm<sup>2</sup> on the surface in the event of surface contamination with radionuclides are specified.

(5) For radioactive waste, the standard document for unsealed source shall not be issued and it shall be replaced with the standard document for radioactive waste.

#### § 84

#### **Licensees' Record Keeping of Personal Doses**

(1) To record personal doses, a licensee shall keep the following documents and data:

- a) first names, surnames, birth registration numbers, if assigned, of all category A workers who are his or her employees;
- b) his or her own first name, surname and birth registration number, if assigned, if the licensee is a natural person who is also a category A worker; and
- c) personal doses for all category A workers and other data to characterise the exposures of such workers as set out by the Office in the licence conditions or approved by the Office as a part of the monitoring programme.

(2) Documents and data according to paragraph 1 shall be kept throughout the time of performing the work activity involving ionising radiation exposure, and subsequently until the time when the person reaches or would have reached 75 years of age, however no shorter than 30 years after the termination of the work activity during which the worker was subject to the ionising radiation.

(3) The operator of a controlled area shall keep records on all persons other than those stated in paragraph 1 who have entered the controlled area, on the time of stay of such persons therein and an estimate of an effective dose for such persons. This data shall be preserved for 10 years.

(4) Personal doses from specially authorised exposures in the sense of Section 23, paragraph 4, from emergency exposures under the Act, Section 2x), point 3, and from emergency exposures of intervening persons under the Act, Section 2x), point 4, shall be recorded separately.

(5) A licensee shall furnish, directly or by means of a person who performs personal dosimetry for him or her, the Office with the following for inclusion in the national system for exposure registration of exposed workers:

- a) personal data on each category A worker and the data characterising his or her expected exposure in the scope and form stipulated by the Office within 1 month of the commencement of employment and upon each change in such data;



- b) the data on personal doses of all of his or her category A workers within 2 months of the end of a monitoring period;
- c) annual summary of personal doses for all of his or her category A workers by the end of April of a current year for the preceding year;
- d) effective doses of external exposure in excess of 20 mSv or equivalent doses from external exposure in excess of 150 mSv, along with an evaluation of the causes of such a situation and the conclusions made, immediately after their revelation; and
- e) a committed effective dose from internal exposure exceeding 6 mSv, along with an evaluation of the causes of such a situation and the conclusions made, immediately after their revelation.

#### § 85

##### **Keeping Records on Personal Doses by Approved Dosimetric Services**

(1) An approved dosimetric service shall archive the data on personal doses for category A workers for the minimum of 1 year following the year to which the data is related.

(2) The approved dosimetric service shall submit the results of exposure evaluation in a form stipulated under the terms of a licence or agreed with the Office to the respective licensee and to the Office as well:

- a) immediately after dosimeter evaluation due to an unplanned single exposure;
- b) immediately upon identification of an effective dose of external exposure in excess of 20 mSv and an equivalent dose from external exposure in excess of 150 mSv;
- c) immediately upon identification of a committed effective dose from internal exposure in excess of 6 mSv.

(3) The approved dosimetric service shall inform the Office within 1 month of a signature or termination of a contract with a licensee authorised for ionising radiation source management on the performance of personal dosimetry at a given workplace.

(4) Doses received by exposed workers of the A category in specially authorised exposures as per Section 23 and doses received in radiological emergencies shall be recorded separately, without being added to the doses received in normal operation.

#### § 86

##### **Keeping Records on Other Quantities, Parameters and Facts Relevant for Radiation Protection**

(1) Documents on the conclusions of preventive medical examinations to verify health fitness of the category A workers shall be preserved until the time when the person reaches or would have reached 75 years of age; however, for the minimum of 30 years from the termination of a work activity during which the worker was subject to the ionising radiation.

(2) Other quantities, parameters and facts relevant from the point of view of radiation protection, including records on the radionuclide discharge into the environment, monitoring programme, methods for monitoring, and monitoring results other than personal doses, shall be kept for the minimum of 10 years.

## **PART THREE**

### **WORK ACTIVITIES ASSOCIATED WITH INCREASED EXPOSURE TO NATURAL SOURCES**

[For the implementation of the Act, Section 4 paragraph 7) b), Section 6 paragraph 2, 3 b), c) and d), Section 8 and Section 9 paragraph 1 h)]

#### § 87

#### **Workplaces with a Possibility of Significantly Increased Exposure to Natural Sources**

Workplaces where an increased exposure to natural radiation sources may be expected are as follows:

- a) aircraft boards in flights at an altitude over 8 km;
- b) mines, caves and other underground workplaces;
- c) workplaces, namely pumping stations, spa facilities, filling rooms, water treatment plants where underground water is handled by pumping, collecting or by other method;
- d) all workplaces where radon concentration of 1000 Bq/m<sup>3</sup> has demonstrably been exceeded; and
- e) workplaces performing:
  1. primary coal treatment and its utilisation as energy raw material including energy by-product treatment and production of building materials thereof;
  2. mining, transport piping and petroleum and gas treatment;
  3. phosphate raw material treatment;
  4. pigment production based on titanium dioxide;
  5. production of refractory and corrosion resistant materials based on zirconium oxide;
  6. treatment of raw materials based on rare earths;
  7. metallurgical metal production of primary raw materials;
  8. production and utilisation of materials containing thorium and uranium, for example welding electrodes, high-resistant materials and admixtures in glass; and
  9. underground water treatment.

#### § 88

#### **Scope of Measurements and Keeping Records on Results**

(1) Measurements which can determine an effective dose per year shall only be done by an approved dosimetric service in compliance with the methods given in a quality assurance programme approved by the Office as a part of the issue of a licence under Section 9, paragraph 1 r) of the Act at the following relevant physical persons:

- a) by monitoring of average radon concentrations at the workplaces and by keeping records on stay times at physical persons performing work at the workplaces laid down under Section 87 b), c) and d) at which the exposure to radon and its decay products as a consequence of inhalation may be expected;

- b) by monitoring of gamma-radiation dose rates, airborne radionuclide volume activities, surface contamination and by keeping records on stay times at the workplace at the physical persons who handle substances or residua at the workplaces laid down under Section 87 e);
- c) at aircrew members operating on airplane boards at an altitude over 8 km by determining an aircrew flight schedule, flight parameters and other parameters which are important for calculation of an effective dose in compliance with the approved methods and by calculation of an effective dose per calendar year;
- d) at other persons laid down by the Office as a part of inspection activity by the manner set out by the Office.

(2) Requirements for monitoring during radiation activities laid down in Sections 73 through 79 shall adequately be applied for measurements under paragraph 1.

(3) At workplaces where a significant increase of exposure to natural sources may be expected, however the guidance levels under Section 90 paragraph 2 a) and b) have not been exceeded, and at workplaces laid down under Section 87 letters b), c) and d) where it has been demonstrated that an effective dose per calendar year caused by inhalation of radon decay products due to a short stay of the persons performing work is lower than 1 mSv, measurements shall not be done over the next calendar years and effective dose per calendar year shall not be determined provided that no change of work conditions, production procedures and raw materials occurs. In the opposite case, the measurements and the annual effective dose calculation shall be performed each year.

(4) The data measured and the annual effective doses per calendar year for the persons performing work at the workplaces where the guidance levels under Section 90 paragraph 2 a) and b) have been exceeded, as well as for the aircrew members operating on airplane boards at an altitude over 8 km, shall be filed during the whole period of their working life and afterwards until the persons have or would have attained the age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure.

(5) The Office's state system of records of exposure of individuals shall be notified once a year in summary directly or through a person who performs the approved dosimetric service of the names, surnames, birth registration numbers, if assigned, and the data of effective doses of all the persons performing work activities in the environment with a significantly increased exposure to natural radiation sources under Section 91.

## § 89

### **Release of Natural Radionuclides from Workplaces with a Possibility of Significantly Increased Exposure to Natural Sources**

(1) During release of natural radionuclides from the workplaces with a possibility of significantly increased exposure to natural sources, the following shall preferably be monitored:

- a) sediments and sludge in piping and storage systems, for example, in pumps, fittings, valves, collectors and separators;
- b) filters and materials separated from separators installed at power plants, water supply stations, and in chemical and petrochemical industry;
- c) waste from technological systems generated during their reconstruction, demolition and disposal; and

d) waste and secondary raw materials generated in plants, for example, energy by-products, phosphogypsum, etc.

(2) For solid and insoluble substances and low-extraction substances in which it is assumed that long-term decay chain radionuclides are approximately in equilibrium, the clearance level for a discharge of natural radionuclides into the environment from the workplaces with a possibility of significantly increased exposure to natural sources shall be a magnitude of mass activity index equal to 2.

(3) In case of other substance types, namely for soluble, liquid and gaseous substances in which the equilibrium of long-term decay chain radionuclides is substantially disturbed, clearance levels for a discharge of natural radionuclides into the environment from workplaces with a possibility of significantly increased exposure to natural sources shall be laid down under Section 57, paragraph 1.

(4) For a release of natural radionuclides into the environment, and in accordance with Section 6 paragraph 3 c) of the Act based on the assessment of exposure in a critical group (optimising study), the Office can specify the clearance levels in a licence under Section 9, paragraph 1 h) that differs from those laid down in paragraphs 2 and 3.

## § 90

### Guidance Levels

(1) For the members of aircrews who operate on airplane boards at an altitude over 8 km, the guidance level for the reduction of exposure to cosmic rays shall be an effective dose of 1 mSv per calendar year. If this guidance level might be exceeded, the members of aircrews shall be informed on the magnitude of their exposure and the health risk, and radiation protection optimisation shall be performed. For this purpose, the exposure of individual aircrew members shall be evaluated, and based on this evaluation their flight schedules shall be prepared and/or modified.

(2) For other work activities with increased exposure to natural sources the following guidance levels shall be laid down:

- a) 1 mSv for an effective dose per calendar year above the natural background or an outdoor radon concentration of 1000 Bq/m<sup>3</sup> during a work activity at the workplaces laid down under Section 87, e);
- b) average outdoor radon concentration of 1000 Bq/m<sup>3</sup> for a work activity of the persons performing work at the workplaces laid down under Section 87 b) c) and d); and

If the values of effective doses per calendar year measured in compliance with the requirements under Section 88 paragraph 1 are higher than 6 mSv, the optimisation of radiation protection shall be done and the measures to reduce such exposure based on this optimisation shall be accepted.

(3) Working conditions of pregnant women shall be modified in accordance to Section 23 paragraph 2 for work activities with an increased exposure to natural sources.

## § 91

### Significantly Increased Exposure to Natural Sources

(1) For persons performing work activities at the workplace laid down under Section 87 b), c), d) and e) and if after applying countermeasures corresponding to the optimisation of

radiation protection it shall not be possible to reduce effective doses per calendar year for such persons below 6 mSv, and as well as for aircrews members if it is not possible to reduce an effective dose below 1 mSv, radiation protection shall be ensured in the scope and the manner that is applied for controlled areas of the workplaces where radiation activities are performed, namely:

- a) by delineation of the workplace or its parts where the persons performing work may exceed three tenths of the limits stipulated under Sections 20 and 22, by its identification and by securing against unauthorised access;
- b) by determining of the persons who can perform work at such a workplace, and by determining of the method and the scope of their annual demonstrable instructions on radiation risks at such workplaces;
- c) by securing of prior to employment examinations, annual periodic and extraordinary preventive examinations for the persons performing work at such a workplace;
- d) by drawing up the instructions for work at the workplace including the instructions for safe work performance as well as the instructions for entry of persons to such a workplace;
- e) by determining of protective work aids with which the persons performing work activities shall be provided;
- f) by securing of the monitoring in accordance with Section 88 paragraph 2 including drawing up the monitoring programme and by determining of the method of handling of radionuclide contaminated materials; and
- g) by keeping records on the above-mentioned scope and the method of ensuring radiation protection.

(2) Exposures of the persons performing work activities in accordance with paragraph 1 shall be ranked among the cases of significantly increased exposure to natural ionising radiation sources for which the exposure limits under Section 4 paragraph 7 b) of the Act shall apply, namely the limits mentioned in Sections 20 and 22.

## **PART FOUR**

### **INTERVENTIONS TO AVERT OR REDUCE EXPOSURE**

[For the implementation of the Act, Section 4 paragraph 5, Section 6 paragraph 4, 5 and 6]

#### Chapter I

##### § 92

#### **General Rules for Preparation and Implementation of Interventions**

- (1) Interventions shall be prepared and implemented to avert and reduce:

- a) exposure to natural sources if it is ascertained that as a consequence of human activity a significant increase in health detriment occurs or might occur from this exposure;
- b) emergency exposure; and
- c) lasting exposure.

(2) An intervention shall be implemented only if the reduction in health detriment due to radiation is sufficient to justify costs including social costs and harm related to the intervention.

(3) The form, scale and duration of the intervention shall be optimised so as the benefit of the reduction in health detriment shall be maximised after subtraction of costs and harm related to the intervention.

(4) Exposure limits shall not apply to a decision on the intervention implementation, however intervention levels or a span of guidance levels for the intervention levels can be established. If the intervention levels are established, their exceeding shall justify to implement, or at least to consider, appropriate countermeasures. If detailed data is not available to assess the optimisation of radiation protection and to establish the intervention levels for such an event, the span of guidance levels for intervention levels shall apply to assess the implementation of intervention and its extent. If the lower limit of the span of guidance levels is exceeded, the implementation of intervention shall be considered with respect to its scope, feasibility, expensiveness and possible consequences; if the upper limit of the span of guidance levels is exceeded, the intervention shall usually be implemented.

(5) Emergency exposure of intervening physical persons shall be kept as low as reasonably achievable taking into account economic and social factors. The intervention shall be organised so that the exposure limits or at least the maximum permitted levels laid down under Section 4 paragraph 7 c) of the Act are not exceeded. To prevent from exceeding the limits multiplied by a factor of ten which are laid down for occupational exposure of exposed workers, 200 mSv for a personal dose equivalent in a depth of 10 mm shall not be exceeded per calendar year. The persons performing intervention shall demonstrably be informed about the risks related to the intervention in accordance with Section 4 paragraph 7c) of the Act, and they shall participate in such an intervention on a voluntary basis only.

## Chapter II

### Interventions to Reduce Exposure to Natural Ionising Radiation Sources

#### § 93

#### **Rules for Preparation and Implementation of Interventions to Reduce Exposure to Natural Ionising Radiation Sources**

(1) The interventions to reduce exposure to natural ionising radiation sources shall be implemented in cases which ascertain that, as a consequence of human activity, a significant increase in health detriment occur or might occurs due to this exposure, including the events when the exposure occurs unintentionally. The interventions to reduce exposure to natural ionising radiation can involve elimination, reduction and/or modification of a certain activity or the realisation of technical remedial measures.

(2) Maximum permitted values and guidance levels of the intervention levels for exposure to natural ionising radiation sources in respect of building construction, building material deliveries and water supply are laid down under Section 94 through 97. In other justified cases, the Office shall lay down the intervention levels in accordance with Section 40 paragraph 1 of the Act in respect of inspection activities performed.

(3) Unless otherwise stated, the values of 5 mSv to 50 mSv shall apply as the span of guidance levels for average effective doses per calendar year in individuals from a critical group of the population for preparation and implementation of an intervention to avert or reduce exposure to natural ionising radiation sources. If it is expected that an averted effective dose due to intervention shall exceed 5 mSv per year, the implementation of intervention shall be considered with respect to its scope, feasibility, expensiveness and possible consequences. If it is expected that an averted effective dose due to intervention shall exceed 50 mSv per year, the intervention shall usually be implemented.

#### § 94

##### **Radon-related Index of Site**

(1) A radon-related index of a site laid down under Section 6 paragraph 4 of the Act shall be intended to assess and regulate a possible radon penetration from geological subsoil into houses. To determine the radon-related index of a site, the following measurements and factors shall be used:

- a) representative set of measurements of outdoor radon <sup>222</sup> concentration in soil air;
- b) assessment of a soil gas permeability in contact area between building foundations and geological subsoil; and
- c) assessment of other factors and properties of geological subsoil affecting radon transport into foundations.

(2) The details for determination of the radon-related index of a site are given in Annex 11. During measurements and assessment to determine the radon-related index of a site, the methods shall be followed which are set out in a quality assurance programme approved by the Office as a part of the issue of an appropriate licence under Section 9, paragraph 1 r) of the Act.

#### § 95

##### **Buildings**

(1) The guidance levels applied after the approval of building for making decision in living and accommodation rooms to implement an intervention to reduce the existing exposure to natural radionuclides shall be:

- a) 400 Bq/m<sup>3</sup> for indoor radon concentration in living and accommodation rooms; this value shall relate to an average value of airshift under normal use; and
- b) 1 µSv/hr for the maximum photon dose equivalent rate in living and accommodation rooms;

(2) The intervention to reduce the existing exposure mentioned in paragraph 1 means, in particular, a room usage adaptation, airshift adaptation, building adaptations and other suitable measures. If no data for the optimising analysis better corresponding to the situation is available, it shall be assumed that a reduction of radon concentration by 100 Bq/m<sup>3</sup> in a

room for the annual stay of 7000 hours for an individual should avert the effective dose for one individual approximately by 2 mSv per year; the value under Section 17 paragraph 3 e) shall be applied to calculate the financial equivalent of health detriment.

(3) The maximum permitted levels for exposure to natural radionuclides in approved buildings with living and accommodation rooms shall be:

- a) 4000 Bq/m<sup>3</sup> for indoor radon concentration in living and accommodation rooms; this value shall relate to an average value of airshift under normal use, and
- b) 10 µSv/hr for the maximum photon dose equivalent rate in living and accommodation rooms.

(4) The guidance levels for making decision whether the countermeasures against radon penetration from subsoil, building materials and supplied water and against external gamma radiation from building materials are to be prepared and implemented in the houses being designed and built with living and accommodation rooms shall be as follows:

- a) 200 Bq/m<sup>3</sup> for indoor radon concentration in living and accommodation rooms; this value shall relate to an average value of airshift under normal usage;
- b) 0.5 µSv/hr for the maximum photon dose equivalent rate in living and accommodation rooms.

(5) The methods set out in the quality assurance programme approved by the Office as a part of the issue of the appropriate licence under Section 9 paragraph 1 r) of the Act shall apply during measurements and evaluation whether the guidance levels and the maximum permitted levels are exceeded.

## § 96

### **Building Materials**

(1) The guidance levels of natural radionuclide content in selected input raw materials and selected products for constructions (hereinafter referred to as „building materials“) shall be determined by the magnitudes of mass activity indices which are given in Annex 10, Table 1. If these values are exceeded, building materials can be introduced into circulation only in the justified cases when the costs related to an intervention to reduce radionuclide concentration, namely by a change of raw materials or their origin, by sorting raw materials, by a change of technology and other suitable intervention, would be demonstrably higher than the risks in health detriment.

(2) The maximum permitted levels of the natural radionuclide content which may not be exceeded during introducing building materials into circulation are set out by mass activities given in Annex 10, Table 2.

(3) The measurement of mass activities in building materials in the scope according to Annex 10, Table 3 shall be regarded as a systematic measurement and evaluation of natural radionuclide content in building materials.

(4) The methods set out in the quality assurance programme approved by the Office as a part of the issue of the appropriate licence under Section 9 paragraph 1 r) of the Act shall apply during measurements and evaluation whether the guidance levels and the maximum permitted levels are exceeded.

(5) The keeping records on results shall include:



- a) identification or type of building materials measured including raw materials for production and their origin;
- b) annual production capacity and annual import amount;
- c) the data which describes the expected scope and the method of building material use in constructions;
- d) location, date and method of sampling;
- e) measurement results of individual samples; and
- f) identification of laboratory performing measurements.

(6) The data laid down in paragraph 5 shall be kept at least for a period of 5 years after the termination of production or material import, and the Office shall be notified of the data within 1 month from receiving the measurement results.

## § 97 Supplied Water

(1) The guidance levels for natural radionuclide content in packaged water and water intended for public supply of drinking water<sup>27)</sup> shall be specified by the values of volume activities given in Annex 10, Table 4. If the values are exceeded, packaged water can be introduced into circulation and drinking water can be supplied to the public water supply only in justified cases if the costs related to an intervention to reduce the radionuclide content, namely by a selection of other water sources or a radon removal or another appropriate intervention, would be demonstrably higher than the risks in health detriment.

(2) The maximum permitted levels of natural radionuclide content in drinking water supplied to the public water supply as well as packaged water shall be specified by volume activities given in Annex 10, Table 5. If more than one natural radionuclide is present, the sum of the quotations of volume activities for particular radionuclides and the corresponding values specified in Annex 10, Table 5 shall not be higher than 1.

(3) The measurements of volume activities carried out in the scope according to Annex 10, Table 6 shall be regarded as a systematic measurement and evaluation of natural radionuclide content in water. The basic analysis according to Annex 10, Table 6 shall be regarded as a systematic measurement in water mains for which the optimised radiation protection is proved even if the guidance levels have been exceeded.

(4) The methods set out in the quality assurance programme approved by the Office as a part of the issue of the appropriate licence under Section 9 paragraph 1 r) of the Act shall apply during measurements and evaluation whether the guidance levels and the maximum permitted levels are exceeded.

(5) The keeping records on results shall involve:

- a) water source identification;
- b) marking and type of packaged water;
- c) water source yield and annual water volume supplied;
- d) annual production or import capacity of packaged water;

---

<sup>27)</sup> Section 2 of Regulation No. 376/2000 Coll. which sets out the requirements for drinking water and the scope and frequency of its inspections.

- e) in case of public water supply the names of villages and the number of inhabitants supplied with water;
- f) place, date and method of sampling;
- g) measurement results of individual samples; and
- h) laboratory identification which performed the measurement.

(6) The recorded data in accordance with paragraph 5 shall be kept at least for a period of 5 years from the termination of drinking water supply for the public water supply or the production and import of packaged water, and the data shall be notified to the Office within one month from receiving the measurement results.

(7) The guidance levels and the maximum permitted levels for packaged infant water set out in Annex 10, Tables 4 and 5 shall apply for packaged infant water in making decision whether packaged water or drinking water supplied to the public water supply may be used for infant food preparation.

(8) The guidance levels and the maximum permitted levels for drinking water supplied to the public water supply set out in Annex 10, Tables 4 and 5 shall apply in making decision on water usage in case of individual supply.

## Chapter III Interventions in Radiological Emergencies

### § 98

#### **Countermeasures**

(1) The reduction of both personal and environmental exposures during a radiological emergency shall be applied by the following protective measures:

- a) early countermeasures involving sheltering, stable iodine administration, and evacuation; and
- b) recovery countermeasures involving relocation, control of radionuclide contaminated foodstuffs and water and control of radionuclide contaminated fodder.

(2) The countermeasures in radiological emergencies shall always be implemented if these are justified by a greater benefit compared to the costs and damage caused by emergencies, and they shall be optimised in their form, scope and duration to bring the most reasonably achievable benefit as possible.

(3) As a basic guidance for making decision on implementing the countermeasures, the guidance levels shall be applied which reflect a current status of knowledge and international experience about the facts that a given countermeasure brings a greater benefit than damage. For particular radiation activities and ionising radiation sources to which a risk of radiological emergency is related, the intervention levels specific for a given radiation activity or a ionising radiation source shall be set out in emergency plans based on the optimisation of radiation protection and the data specific for each particular event.

(4) The data specific for determining the intervention levels in accordance with paragraph 3 shall involve the data on settlement and infrastructure in the vicinity of the ionising radiation source that affect the expected collective doses and the feasibility of countermeasures, namely:

- a) presence of specific groups of the population, namely in hospitals, old people's homes, community care homes, and prisons;
- b) traffic situations;
- c) high density of population; and
- d) presence of a large city.

(5) During making decision on the acceptance of countermeasures in a radiological emergency, it shall be necessary to take into account the fact that a current situation shall not remarkably differ from the conditions when the intervention levels were laid down. For a simultaneous occurrence of a radiological emergency and a radiological emergency after different accident, for example, an accident with leakage of chemical harmful substance, or after a natural disaster, it shall be necessary to consider whether the introduction of countermeasure increases or not the damage arising from the other accidents or disasters in a scope greater than the benefit from exposure reduction.

## § 99

### **Early Countermeasures**

(1) An early countermeasure shall always be considered reasonable if the expected exposure of an individual might directly lead to his and her health damage, and hence the countermeasures will always be introduced if it is expected that absorbed doses might exceed the levels given in Table 1 of Annex 8 during less than 2 days for any person.

(2) If a countermeasure might avert or reduce in the critical group of the population for the time not longer than 7 days the exposure exceeding the lower maximum permitted level of the span of guidance levels of intervention levels as laid down in Table 2 of Annex 8, the implementation of countermeasures shall be considered with respect to its scope, feasibility, and expensiveness of countermeasures and its possible consequences; if the upper maximum permitted level is exceeded, the countermeasures shall usually be implemented.

(3) To implement and evaluate the scope of early countermeasures, the following guidance levels shall be followed as a specifying guidance:

- a) for sheltering, an averted effective dose of 10 mSv for a period of sheltering equal or shorter than 2 days;
- b) for stable iodine administration, an averted committed equivalent dose of 100 mSv in thyroid gland induced by iodine radioisotopes; and
- c) for evacuation, an averted committed effective dose of 100 mSv over a period of evacuation not longer than 1 week.

## § 100

### **Recovery Countermeasures**

(1) For recovery countermeasures, the guidance levels of intervention levels shall be laid down in Table 3 of Annex 8. Projected effective or equivalent doses which, if the corresponding remedial measures are not implemented, would be received from all pathways of external exposure and radionuclide intake by inhalation and ingestion over the first year after the radiation accident, and for the control of contaminated foodstuffs and water only due to radionuclide intake by ingestion over the first year after the radiation accident shall be compared to these guidance levels.

(2) For the control of foodstuffs production and import, and the introduction of foodstuffs into the market according to the special act<sup>28)</sup>, the maximum permitted limits of radioactive contamination of foodstuffs given in Table 4 of Annex 8 shall be effective for radioactive foodstuffs contamination during a radiation accident or a radiological emergency until the admission date of the Czech Republic to the European Union.

(3) To make a decision on relocation, the following guidance levels of intervention levels shall be accepted as a specifying guidance:

- a) for commencement of a temporary relocation, an averted effective dose shall be 30 mSv for a period of 1 month;
- b) for termination of the temporary relocation, a projected effective dose shall be 10 mSv for a period of 1 month. If it is proved within 1 up to 2 years that the total effective dose within 1 month shall not drop below the intervention level for the termination of temporary relocation, permanent relocation shall be considered;
- c) for permanent relocation the projected lifetime effective dose shall be 1 Sv.

## Chapter IV Interventions during Lasting Exposure

### § 101

#### **Scope of Lasting Exposure Regulation**

Lasting exposure shall be regulated in the cases when a significant increase of health detriment, without any change of status and usually by a long-term effect, might be expected either directly or even indirectly due to water and food chain contamination.

### § 102

#### **Intervention Levels for Lasting Exposure**

(1) Unless otherwise stated, the values of 5 mSv and 50 mSv shall apply as the span of guidance levels for preparation and implementation to avert or reduce lasting exposure for average effective doses to individuals in the critical group per calendar year. If it is expected that due to intervention the averted effective dose shall exceed 5 mSv per year, the implementation of an intervention shall be considered with respect to its scope, feasibility, expensiveness and its possible consequences. If it is expected that due to the intervention the averted effective dose shall exceed 50 mSv per year, the intervention shall usually be implemented.

(2) After assessment of lasting exposure, and based on the optimisation of radiation protection, the Office may lay down specific intervention levels for a specific situation and to order implementing either remedial measures according to Section 40, paragraph 1 of the Act or preliminary measures according to Section 40 paragraph 2 of the Act.

---

<sup>28)</sup> Section 3 and 10 of the Act No.110/1997 Coll., on Foodstuffs and Tobacco Products, as amended by the Act No. 306/2000 Coll.

§ 103

**Lasting Foodstuffs Radioactive Contamination from the Chernobyl Accident**

For foodstuffs radioactive contamination from lasting exposure after the Chernobyl power plant accident, the maximum permitted limits of radioactive contamination of foodstuffs given in Table 5 of Annex 8 shall be effective until the admission date of the Czech Republic to the European Union. The maximum permitted levels shall apply for regulation of production, import and introduction into the food market according to the special act,<sup>28)</sup> except for a period of radiological emergency when the values according to Section 100 paragraph 2 are applied.

**CHAPTER FIVE  
GENERAL, TEMPORARY AND FINAL PROVISIONS**

§ 104

**General Provisions**

The special legal regulations laying down the requirements for ionising radiation sources that are classified as nuclear materials, and the requirements for the workplaces that are classified as nuclear installations<sup>29)</sup> as well as the requirements for underground workplaces, namely uranium mines and underground radioactive waste repositories<sup>30)</sup> shall not be changed.

§ 105

**Temporary Provisions**

The first five-year period for assessment of an effective dose limit of exposed workers, which in compliance with the current regulations was related to the date of 1 January 2000, shall be considered as the first five-year period for the purpose in compliance with Section 20 paragraph 1 a).

---

<sup>29)</sup> For example, Regulation No. 144/1997 Coll., on Physical Protection of Nuclear Materials and Nuclear Facilities and their Classification, Regulation No. 145/1997 Coll., on Accounting for and Control of Nuclear Materials and their Detailed Specification.

<sup>30)</sup> Order of the Czech Mining Office No. 8/1987 Coll., on the Plans to Solve Serious Operational Accidents in Underground Mines.  
Regulation No. 99/1992 Coll., on the Establishment, Operation, Securing and Disposal of Facilities for Waste Disposal in Underground Areas.  
Regulation No. 340/1992 Coll., on the Requirements on Qualification and Qualification Verification for Mining Activity and the Activities Performed by Mining Methods, as amended.

§ 106  
**Repeal Provisions**

This Regulation shall repeal the Regulation of the SÚJB No. 184/1997 Coll. on Radiation Protection Requirements.

§ 107  
**Entry into Force**

This regulation shall come into force on the date of its declaration, with the exception of the provision of Section 63 paragraph 1 which shall come into force on 1 January 2005, and the provision of Section 66 paragraph 2, clause 2, which shall come into force on 1 January 2007.

Chairman:  
Dana **Drábová**