

**ACT**  
**No. 263/2016 of Coll.**  
**Of 14th July 2016**  
**Atomic Act**

As amended by:

Act No. 183/2017 Coll.  
Act No. 403/2020 Coll.  
Act No. 261/2021 Coll.

The Parliament has adopted the following Act of the Czech Republic:

**PART ONE**

**INTRODUCTORY PROVISIONS**

Title I

**Introductory provisions**

Part 1

**Subject matter**

§ 1

(1) This Act incorporates the relevant legislation of the European Atomic Energy Community (hereinafter “Euratom”)<sup>1)</sup> and the European Union<sup>2)</sup>, follows on from directly applicable legislation of the Euratom<sup>3)</sup> and the European Union<sup>4)</sup>, and governs

- a) the conditions for the peaceful uses of nuclear energy,
- b) the conditions for performing activities in exposure situations,
- c) radioactive waste management and spent fuel,
- d) the type-approval of certain products in the area of peaceful utilization of nuclear energy and ionising radiation and the conditions for shipment of radioactive or fissile materials, radioactive waste or spent fuel,
- e) radiation situation monitoring,
- f) radiation extraordinary event management,
- g) the conditions for security of nuclear installations, nuclear materials and sources of ionising radiation (hereinafter “security”),
- h) the requirements for ensuring the non-proliferation of nuclear weapons,
- i) the exercise of state administration in the area of the peaceful utilization of nuclear energy and ionising radiation.

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<sup>1</sup> Directive of 5 March 1962 on freedom to take skilled employment in the field of nuclear energy.

Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel.

Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

<sup>2</sup> Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel.

Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

<sup>3</sup> Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency.

Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

<sup>4</sup> Commission Regulation (Euratom) No 302/2005 of 8 February 2005 on the application of Euratom safeguards.

Council Regulation (EEC) No 733/2008 of 15 March 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.

Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Council Regulation (EC) No 1048/2009 of 23 October 2009 amending Regulation (EEC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.

- (2) This Act shall not apply to exposure situations as a result of exposure from
- a) mineral water, which originates from a natural medicinal source or a source of natural mineral water for which a certificate has been granted under other legislation,
  - b) water intended for human consumption from an individual supply providing on average less than 10 m<sup>3</sup> a day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial activity or public service,
  - c) natural background radiation.

## Part 2

### Definition of certain terms

#### § 2

- (1) For the purposes of this Act, the following definitions shall apply
- a) source material means
    1. uranium containing the mixture of isotopes occurring in nature,
    2. uranium depleted in the isotope <sup>235</sup>U,
    3. thorium,
    4. an item referred to in Points 1 to 3, in the form of metal, alloy, chemical compound or concentrate, or
    5. material containing an element referred to in Points 1 to 3,
  - b) special fissile material means
    1. isotope <sup>239</sup>Pu,
    2. isotope <sup>233</sup>U,
    3. uranium enriched in the isotopes <sup>235</sup>U or <sup>233</sup>U, or
    4. material containing a radionuclide as referred to in Points 1 to 3, unless it is a source material,
  - c) nuclear material means any source material, special fissile material and other fissile material significant from a perspective of ensurance of non-proliferation of nuclear weapons,
  - d) selected nuclear item means material, equipment and technology, including software, designed and manufactured for use in the nuclear field,
  - e) dual-use nuclear item means material, equipment and technology, including software, which are not designed and manufactured for use in the nuclear field, but can be used in this field,
  - f) nuclear item means nuclear material, a selected nuclear item, a dual-use nuclear item, or another item significant from a perspective of ensurance of non-proliferation of nuclear weapons,
  - g) transfer means sending of radioactive waste, spent fuel or nuclear item between the Czech Republic and other Euratom member state or vice versa performed within business relations and aiming to supply the item into the market.
- (2) For the purposes of this Act, the following definitions shall apply
- a) ionising radiation means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nm or less and a frequency of  $3 \times 10^{15}$  Hz or more capable of producing ions,
  - b) radioactive substance means any substance that contains or is contaminated by a radionuclide at a level requiring regulation under this Act with a view to possible exposure,
  - c) source of ionising radiation means
    1. a radioactive substance or an article or facility containing or releasing it, or

2. a radiation generator, which is a device capable of generating ionising radiation,
- d) radionuclide source means a source of ionising radiation containing a radioactive substance, for which the sum of radionuclide activity ratios and activity exemption levels for these radionuclides is greater than one and, at the same time, the sum of radionuclide activity concentration ratios and activity concentration exemption levels for these radionuclides is greater than one,
  - e) exposure situation means any circumstance that may lead to exposure of a natural person or the environment to ionising radiation; exposure situations include
    1. planned exposure situations, which are associated with the deliberate use of a source of ionising radiation,
    2. emergency exposure situations, which may arise in the course of a planned exposure situation or arises as a result of a malicious act and requires immediate measures to avert or mitigate the consequences, or
    3. existing exposure situations, which already exist when a decision on the need for regulation thereof needs to be taken, including long-term consequences of an emergency exposure situation or a discontinued activity in the context of a planned exposure situation,
  - f) activity involving radiation means
    1. an activity involving an artificial source of ionising radiation in the context of a planned exposure situation, including the provision of services in the controlled area of a category IV workplace, or
    2. an activity in which a natural radionuclide is used in the context of planned exposure situations for its radioactive, fissile or fertile properties, including activity related to acquiring of radioactive minerals,
  - g) radiation protection means a system of technical and organisational measures to reduce exposure of natural persons and protect the environment from the effects of ionising radiation,
  - h) consumer product containing radionuclide means a product which may be sold or made available to the public without special regulation or control after sale, and which
    1. contains a radionuclide deliberately incorporated into the product,
    2. contains a radionuclide deliberately produced in the product by activation, or
    3. generates ionising radiation.

(3) For the purposes of this Act, the following definitions shall apply

- a) exposure means exposure of a natural person to ionising radiation, except exposure to natural background radiation,
- b) occupational exposure means exposure in connection with the performance of work in the course of activities in the context of a planned exposure situation,
- c) medical exposure means exposure in the context of
  1. diagnosis or treatment of a patient,
  2. occupational medicine services or preventive healthcare,
  3. voluntary participation by healthy natural persons or patients in a medical trial of a new method involving medical exposure, or
  4. provision of assistance to a natural person undergoing medical exposure referred to in § 64(1),
- d) accidental exposure means exposure received by an individual other than emergency worker as a consequence of an emergency exposure situation and exposure received by an emergency worker in an emergency exposure situation,
- e) public exposure means any exposure, except occupational exposure, medical exposure and accidental exposure in the event or as a consequence of an emergency exposure situation,

- f) exposure to natural background radiation means exposure of a natural person to ionising radiation
  1. caused by a radionuclide contained naturally in the human body,
  2. caused by cosmic radiation, which is common at ground level,
  3. caused by a radionuclide present in the Earth's crust undisturbed by human activity, or
  4. from a natural source of radiation, which has not been modified by human activity,
- g) potential exposure means exposure that is not expected to occur but may result from an event of a probabilistic nature,
- h) non-medical exposure means any deliberate exposure of a natural person for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the natural person being exposed; non-medical exposure includes
  1. non-medical exposure from medical radiological equipment, in particular for the purposes of immigration, insurance, evaluation of the physical development of children and adolescents with a view to a career in sports and dancing, age assessment, identification of concealed objects within the human body, or for the purposes of employment, except occupational medicine services, or
  2. non-medical exposure from another source of ionising radiation, namely for detection of concealed objects on or attached to the human body, for detection of concealed humans as part of cargo screening or for other security purposes,
- i) member of the public means a natural person subject to public exposure,
- j) representative person means a member of the public representing a model group of natural persons most highly exposed to a given source and route of exposure.

### § 3

(1) For the purposes of this Act, the following definitions shall apply

- a) exposed worker means any natural person subject to occupational exposure,
- b) emergency worker means a natural person who has a defined role in an emergency exposure situation and who might be exposed to radiation while taking action in response to a radiation extraordinary event,
- c) optimisation of radiation protection means an iterative process to achieve and maintain a level of radiation protection ensuring that exposure of natural persons and the environment is as low as reasonably achievable, taking all economic and societal aspects into account,
- d) activity related to acquiring of radioactive minerals means
  1. exploration of deposits of radioactive minerals at the stage of detailed and mining exploration,
  2. mining of radioactive minerals,
  3. carriage of radioactive minerals,
  4. treatment and processing of radioactive minerals,
  5. management of uranium concentrate,
  6. accumulation of extractive waste in tips and sludge lagoons that were created by mining activities during acquiring of radioactive minerals,
  7. operation of decontamination stations of mining works in operation,
  8. treatment of industrial waste water from workplaces that are part of facilities for the treatment of radioactive minerals,
  9. mining of radioactive material by chemical leaching,
  10. processing of leaching solutions used for mining of radioactive mineral,
  11. treatment of mine water from closed radioactive mineral deposits,
  12. sanation and recultivation of the consequences of activity related to acquiring of radioactive minerals,

- e) activity of particular relevance to radiation protection means activity ensuring fulfilment of the requirement on radiation protection as stipulated by this act, use of technical and organizational measures and procedures of safe operation of ionising radiation sources and workplaces with them or evaluation of properties of ionising radiation sources or managing of services relevant to radiation protection,
- f) personal dosimetry means the calibration of a device intended for individual monitoring, reading or interpretation of the values recorded by the device, measurement of radioactivity in the human body or biological samples, or assessment of doses.

(2) For the purposes of this Act, the following definitions shall apply

- a) radioactive waste means an item which is a radioactive substance or an article or equipment containing or contaminated by a radioactive substance, for which no further use is foreseen and which does not satisfy the conditions laid down in this Act for the discharge of radioactive substances from a workplace,
- b) radioactive waste management means all activities that relate to collection, segregation, treatment, conditioning, storage, or disposal of radioactive waste, excluding transportation from the site where these activities are carried out,
- c) radioactive waste disposal facility means a site, installation or facility used for the disposal of radioactive waste,
- d) spent fuel means irradiated nuclear fuel that has been permanently removed from the active zone of a nuclear reactor,
- e) nuclear installation means
  1. a facility or plant comprising a nuclear reactor using fission chain reaction or other nuclear chain reaction,
  2. a storage facility for spent fuel,
  3. a storage facility for fresh nuclear fuel, unless part of another nuclear installation,
  4. an enrichment plant, nuclear fuel fabrication plant or spent fuel reprocessing plant,
  5. a storage facility for radioactive waste, except installations for the storage of radioactive waste, which is part of another nuclear installation or workplace where activity involving radiation are performed,
  6. a radioactive waste disposal facility, except repositories containing exclusively natural radionuclides,
- f) complete decommissioning means putting a nuclear installation, a category III workplace or a category IV workplace into a state that allows its use for another purpose or use of the area where it was located without restrictions,
- g) decommissioning means the administrative and technical activities aimed at complete decommissioning or decommissioning of a nuclear installation, a category III workplace or a category IV workplace with restrictions on its use for other activities related to the use of nuclear energy or activities in exposure situations,
- h) closure of a radioactive waste disposal facility means the completion of all activities related to radioactive waste management and bringing it into a long-term safe state.

#### § 4

(1) For the purposes of this Act, the following definitions shall apply

- a) radiation extraordinary event means an event that leads or may lead to exceeding of exposure dose limits and requires action to prevent the exceeding of the limits or deterioration of the situation from the standpoint of radiation protection assurance,
- b) first degree radiation extraordinary event means a radiation extraordinary event that can be handled by forces and means of the operators or shift personnel of the person whose activities gave rise to the radiation extraordinary event,

- c) radiation incident means a radiation extraordinary event that cannot be handled by forces and means of the operators or shift personnel of the person whose activities gave rise to the radiation extraordinary event or has resulted from the finding, misuse or loss of a radionuclide source which does not require taking urgent action to protect the general public,
- d) radiation accident means a radiation extraordinary event that cannot be handled by forces and means of the operators or shift personnel of the person whose activities gave rise to the radiation extraordinary event or has resulted from the finding, misuse or loss of a radionuclide source which requires taking urgent action to protect the general public ,
- e) radiation extraordinary event management means a system of procedures and measures to ensure
  1. analysis and assessment of impacts of potential radiation extraordinary event which means; analysis of radiation extraordinary events coming into consideration and assessing their impact,
  2. radiation extraordinary event response preparedness,
  3. radiation extraordinary event response, and
  4. remedial action after a radiation accident,
- f) an inner area means an area used for the placement or storage of nuclear material of category I,
- g) a vital area means an area in which systems and equipment relevant to nuclear safety must be placed,
- h) a protected area means an area in which nuclear material of category II or an inner area or vital area is located,
- i) a guarded area means an area in which nuclear material of category III or a protected area is located,
- j) nuclear installation grounds means the guarded area of a nuclear installation and the area adjacent to it, which are used for ensuring the performance of the activities related to the use of nuclear energy and for which an on-site emergency plan is drawn up,
- k) emergency planning zone means the area surrounding the nuclear installation grounds or category IV workplace in which, based on radiation extraordinary event analysis and assessment, the requirements for preparation for taking urgent protective action under § 104(1)(a), other measures to protect the general public as a result of the expected exceedance of reference levels and other measures to protect the general public apply,
- l) national radiation emergency plan means a plan drawn up for the territory of the Czech Republic outside nuclear installation grounds or category IV workplaces to prepare for the management and implementation of a response to a radiation incident or radiation accident with an impact outside the emergency planning zone.

(2) For the purposes of this Act, the following definitions shall apply

- a) nuclear safety means the state and capability of nuclear installations and natural persons operating the installation to prevent uncontrolled self-sustaining fission chain reaction or release of radioactive substances or ionising radiation into the environment and to mitigate the consequences of accidents,
- b) activity related to the use of nuclear energy means
  1. designing, siting, building, commissioning, operating, modifying or decommissioning of nuclear installations,
  2. designing, manufacturing, assembling, maintaining, repairing and verifying the systems or components of nuclear installations, including the material for their manufacture,

3. designing, manufacturing, maintaining, repairing and verifying packaging assemblies for carriage, storage or disposal of fissile materials or radioactive substances,
  4. management of and undertaking of research and development related to a nuclear item,
  5. carriage of radioactive or fissile substances,
  6. closure of a radioactive waste disposal facility,
- c) activity of particular relevance to nuclear safety means an activity directly affecting nuclear safety, which is performed in the context of managing of a whole nuclear installation and its particular parts and of manipulation with nuclear fuel.

(3) For the purposes of this Act, the following definitions shall apply

- a) safety function means the functionality of a system, structure, component or other part of a nuclear installation relevant ensuring nuclear safety of the nuclear installation,
- b) selected equipment means a system, structure, component or other part of a nuclear installation affecting nuclear safety and the performance of safety functions,
- c) limits and conditions mean a set of requirements, compliance with which means that the performance of activities is considered safe,
- d) technical safety means the state of constant compliance of selected equipment with the technical requirements placed on it, in which there is no danger to human health and property,
- e) life cycle of a nuclear installation means the period of performing activities related to the use of nuclear energy, from siting a nuclear installation for the purposes of operating it to decommissioning of the nuclear installation or, in the case of a radioactive waste disposal facility, closure of the radioactive waste disposal facility,
- f) nuclear installation design means the documented design of a nuclear installation and the procedures and instructions for activities related to the use of nuclear energy in the course of the nuclear installation's life cycle.

(4) For the purposes of this Act, the following definitions shall apply

- a) physical protection means a system of technical and organisational measures preventing unauthorised activities involving a nuclear installation or nuclear material,
- b) design basis threat means a set of characteristics and abilities of a natural person who is present inside or outside a nuclear installation or near nuclear material which are subject of physical protection and who is capable of intentional illegal handling thereof,
- c) physical start-up means the stage of commissioning a nuclear installation consisting of loading nuclear fuel into the nuclear reactor and subsequent physical start-up tests of the nuclear installation; physical start-up commences upon the first handling of nuclear fuel with the aim of loading it into the nuclear reactor,
- d) power-generation start-up of a nuclear installation means a phase in the life cycle of a nuclear installation with a nuclear reactor, the purpose of which is to verify the design characteristics of the nuclear installation at the different output levels envisaged in the nuclear installation design,
- e) special professional competence means the ability to apply in practice the information and skills acquired in the context of the required education, professional experience and training, which are prerequisite for granting the authorisation for the performance of activities of particular relevance to nuclear safety or radiation protection.

### Part 3

## **Basic rules for the peaceful use of nuclear energy and ionising radiation**

### § 5



### **Principles of the peaceful use of nuclear energy and ionising radiation**

- (1) Anyone who uses nuclear energy or performs activities in exposure situations shall
- a) precede radiation extraordinary events and, if they occur, ensure that radiation extraordinary event management procedures are followed and minimise their consequences,
  - b) ensure the safe performance of these activities and protection of natural persons and the environment from the effects of ionising radiation and
  - c) act in a way ensuring that the risk to natural persons and the environment is kept as low as can reasonably be achieved taking into account the current state of technical knowledge and economic and societal aspects.
- (2) Anyone who uses nuclear energy, manages a nuclear item or performs activities in exposure situations shall
- a) as a matter of priority, ensure nuclear safety, safety of nuclear items and radiation protection, while respecting the present level of science and technology and good practice,
  - b) perform assessment of intention to perform activity and of its expected results from perspective of their benefits for the society and individuals (hereinafter „justification“),
  - c) within the justification take into consideration techniques which do not use nuclear energy and ionising radiation, but which can provide comparable results,
  - d) perform only activity with benefits for the society and individuals prevailing over a risk emerging from the activity or its consequences; such activity is considered as justified,
  - e) perform justification repeatedly whenever new and important evidence about the efficacy or potential consequences of the activities performed or new and important information about other techniques or technologies is available.
- (3) Compliance with requirements of paragraph (2)(d) may be reached
- a) in planned exposure situation by a measure with direct relation to a ionising radiation source ensuring benefit for the society and exposed individual prevailing over caused harm or potential harm and taking into consideration all aspects and states of activity with the ionising radiation source, or
  - b) in existing exposure situation or emergency exposure situation by a measure changing ways of exposure ensuring benefit for the society and exposed individual prevailing over caused harm or potential harm.
- (4) Obligation to ensure nuclear safety, radiation protection and safety of nuclear materials and other items in the nuclear field, which is important for ensuring the non-proliferation of nuclear weapons, cannot be transferred to another person.
- (5) Anyone who uses nuclear energy or performs activities in exposure situations shall
- a) when new relevant information is acquired about the risks and consequences of these activities, evaluate the level of nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security and take measures to satisfy the requirements under this Act and
  - b) continuously and comprehensively evaluate compliance with the principles of the peaceful uses of nuclear energy and ionising radiation from the perspective of the present level of science and technology and ensure that the results of the evaluation are applied in practice.
- (6) Anyone who uses nuclear energy or performs activities with nuclear material or performs activities in exposure situations shall ensure security.

(7) Anyone who uses nuclear energy shall collect, sort, analyse and document experience and safety-relevant information by a feedback system in ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security and take into account the importance of the interaction between personnel, technology and organisational arrangements.

(8) Anyone who uses nuclear energy or performs activities in exposure situations when ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security shall utilize a graded approach, depending on the magnitude of potential exposure and its possible consequences (hereinafter “graded approach”), shall be applied. The graded approach shall be commensurate to

- a) the type of the nuclear installation or category of the workplace with sources of ionising radiation,
- b) the type of nuclear material and radioactive waste present in the nuclear installation and
- c) the activities carried out.

## § 6

### **General obligations related to ensuring the peaceful use of nuclear energy and ionising radiation**

(1) In accordance with international commitments of the Czech Republic,<sup>5)</sup> nuclear energy and nuclear items may only be used for peaceful purposes.

(2) Anyone who finds a nuclear material or other source of ionising radiation or suspects that an article found is a source of ionising radiation shall immediately notify of the find the State Office for Nuclear Safety (hereinafter the “Office”) or the Police of the Czech Republic, which shall forthwith notify the Office of this fact.

(3) Anyone who becomes aware of a loss, theft or serious damage to a nuclear material or other source of ionising radiation or its container, or theft of a selected nuclear item or dual-use nuclear item, shall immediately notify of this fact the Office or the Police of the Czech Republic, which shall forthwith notify the Office.

(4) Anyone who becomes aware of the occurrence of an emergency exposure situation in the territory of the Czech Republic shall immediately notify of this fact the Office or the Police of the Czech Republic, which shall forthwith notify the Office.

(5) Anyone who manufactures packaging assemblies for irradiated nuclear fuel, builds hot cells, undertakes research and development activities related to the nuclear fuel cycle, or

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<sup>5)</sup> Treaty on the Non-Proliferation of Nuclear Weapons, promulgated under No 61/1974

Agreement between the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the European Atomic Energy Community and the International Atomic Energy Agency in implementation of Article III(1) and (4) of the Treaty on the Non-Proliferation of Nuclear Weapons, promulgated under No 35/2010.

Additional Protocol to the Agreement between the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland, the Federal Republic of Germany, the Hellenic Republic, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of Netherlands, the Portuguese Republic, the Kingdom of Spain, the Kingdom of Sweden, the European Atomic Energy Community and the International Atomic Energy Agency, in implementation of Article III(1) and (4) of the Treaty on the Non-Proliferation of Nuclear Weapons, promulgated under No 36/2010.

performs other activities set out in directly applicable Euratom regulation on the application of Euratom safeguards<sup>6)</sup> shall notify the Office of the commencement and scope of these activities.

(6) Anyone who mines or processes uranium or thorium ore in the territory of the Czech Republic shall retain and forward information about these activities to the office.

(7) Anyone who becomes aware of a fact that could lead or leads to exposure of a natural person placing the person's health or life at risk shall immediately notify the office of this fact.

(8) Implementing legislation shall establish

- a) the scope, method and period of notifying the Office of the commencement and scope of the activities referred to in paragraph 5,
- b) the scope, method and time of retaining and forwarding to the Office information about mining and processing of uranium or thorium ores in the territory of the Czech Republic.

### **Prohibited activities**

#### **§ 7**

(1) It shall be prohibited to manufacture or otherwise acquire nuclear weapons or other nuclear explosive devices and provide or seek any assistance in the development and manufacture of nuclear weapons or other nuclear explosive devices. It shall be prohibited to acquire any control over nuclear weapons or other nuclear explosive devices.

(2) It shall be prohibited to carry out any nuclear weapon test explosion or any other nuclear explosion and encourage or participate in the carrying out of any nuclear weapon test explosion or any other nuclear explosion.

(3) It shall be prohibited to import or transfer radioactive waste or spent fuel from a Member State of the Euratom to the Czech Republic, save in the case of

- a) re-import of radioactive waste produced during the processing of a material exported from the Czech Republic or re-transfer thereof from a Member State of the Euratom authorised under this Act, or
- b) import or transfer from a Member State of the Euratom under paragraph 4.

(4) Import or transfer of radioactive waste from a Member State of the Euratom for the purposes of processing or reusing it in the territory of the Czech Republic shall be allowed only if immediate export or transfer of the processed radioactive waste and radioactive waste produced during the processing of the imported or transferred radioactive waste to the country of origin is ensured.

(5) It shall be prohibited to transport radioactive waste to

- a) a place of destination located south of 60° South latitude,
- b) a State which is a signatory to the 4th Convention of the African, Caribbean and Pacific Group of States and the European Economic Community and which is not a Member State of the Euratom, unless it is an export of a used source of ionising radiation produced in this State or radioactive waste generated from material exported from this State for the purpose of processing or reprocessing it in the Czech Republic, or

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<sup>6)</sup> Commission Regulation (Euratom) No 302/2005 of 8 February 2005.

c) a State where, according to the opinion of the competent Authority of the State of origin of the radioactive waste, safe radioactive waste management is not regulated by law or where safe radioactive waste management is not ensured.

(6) It shall be prohibited to transfer a nuclear item in contradiction with international commitments of the Czech Republic.

## § 8

(1) It shall be prohibited to carry out an activity which could, after closure of a radioactive waste disposal facility, lead to disruption of the insulating barriers of storage areas of a radioactive waste disposal facility and contamination of a natural person or a component of the environment by a radioactive substance or their exposure to ionising radiation.

(2) It shall be prohibited to add radioactive substances to foodstuffs, feedingstuffs, toys, personal ornaments and cosmetic products, or import or export products modified in this manner.

(3) It shall be prohibited to sell or make available to the public consumer products containing radionuclide, unless these satisfy the conditions for exemption from notification, registration or license, under § 67.

(4) Practices causing activation of a material resulting in an increase in its activity, which cannot be disregarded from a radiation protection point of view when making available on the market or manufacturing the product from this material, and import or export of material or product from this material, shall be deemed not to be justified. In the case of toys and personal ornaments, the activities referred to in the first sentence shall be prohibited.

(5) It shall be prohibited, without permission by the Office, to dilute a radioactive substance being discharged from a workplace in order to reach radionuclide concentration at which the radioactive substance can be discharged from the workplace. Mixing that takes place in normal operations of the workplace shall not be deemed to be such dilution.

(6) It shall be prohibited to distribute or install autonomous ionisation fire alarms.

(7) Deliberate exposure of natural persons shall not be conducted unless its benefit for the society and the individual is considerably higher than the risk arising therefrom.

## Title II

### **Common prerequisites for the performance of activities in the area of the peaceful uses of nuclear energy and ionising radiation**

#### Part 1

### **Regulation of the use of nuclear energy and ionising radiation**

## § 9

### **Licence**

(1) A licence from the Office shall be required for performing the following activities related to the use of nuclear energy:

a) the siting of a nuclear installation,

- b) the construction of a nuclear installation,
- c) the first physical start-up of a nuclear installation with a nuclear reactor,
- d) the first power-generation start-up of a nuclear installation with a nuclear reactor,
- e) the commissioning of a nuclear installation without a nuclear reactor,
- f) the operation of a nuclear installation,
- g) the individual phases of decommissioning of a nuclear installation, and
- h) the carrying out of modifications affecting nuclear safety, technical safety and physical protection of a nuclear installation.

(2) A licence from the Office shall be required for carrying out the following activities in exposure situations:

- a) the construction of a category IV workplace, except workplaces with a nuclear installation,
- b) the operation of category III workplace or category IV workplace,
- c) the carrying out of reconstruction or other modifications affecting radiation protection, radiation situation monitoring and radiation extraordinary event management in a category III workplace or category IV workplace; implementing legislation shall establish list of modifications affecting radiation protection, radiation situation monitoring and radiation extraordinary event management in a category III workplace or category IV workplace,
- d) the individual phases of decommissioning of a category III workplace or a category IV workplace,
- e) the discharge of a radioactive substance from a workplace, if not set otherwise by this act,
- f) the management of a source of ionising radiation, namely
  1. the production of a source of ionising radiation, except the manufacture of a radiation generator which is an insignificant source of ionising radiation,
  2. the import of a source of ionising radiation, except the import of a source of ionising radiation for own use or import of a radiation generator,
  3. the export of a source of ionising radiation, except the export of a source of ionising radiation for own use, export of an insignificant or minor source, or export of a radiation generator,
  4. the distribution of a source of ionising radiation, except the distribution of a radiation generator,
  5. the installation or commissioning of a source of ionising radiation, except the installation or commissioning of a source of ionising radiation which is performed by a person authorised to use the source of ionising radiation and which is not associated with a risk of exposure greater than in normal use,
  6. the operation of a recognised storage facility for the purposes of storing a radionuclide source,
  7. the use of a source of ionising radiation, except the use of consumer products containing radionuclide, the production, import or export of which was authorised, a source of ionising radiation which is an integral part of technological systems or operating media in a workplace which the user is authorised to operate on the basis of a licence under (b), a source of ionising radiation used only to an extent falling within the user's authorisation under other licences, and the use of a source of ionising radiation, which has been registered by the office or of which the office has been notified,
  8. the evaluation of the characteristics of a source of ionising radiation by type-approval testing of the source of ionising radiation, conformity assessment of the properties of a source of ionising radiation pursuant to other legislation<sup>7)</sup>, acceptance testing of a

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<sup>7)</sup> For example, Act No 22/1997 on the technical requirements for products and on amendments to certain acts, as amended.

- source of ionising radiation, except unsealed radionuclide sources, and long-term stability testing of a source of ionising radiation,
9. the repair and servicing of sources of ionising radiation, except repair and servicing of radiation generators that cannot be associated with exposure of natural persons, and repair and servicing performed by the holder of a licence for using this source, unless the repair is associated with a risk of potential exposure greater than in normal use,
  10. the management of products of activity related to acquiring of radioactive minerals and deposited in tips and sludge lagoons,
- g) the addition of a radioactive substance to a consumer product when manufacturing or preparing it and for importing and exporting such a consumer product,
- h) the performance of services relevant to radiation protection, namely
1. the performance of personal dosimetry, including for own needs,
  2. the determination of personal doses of workers in a workplace with potentially increased exposure to a natural source of radiation and in a workplace with potentially increased exposure to radon,
  3. the monitoring of a category III workplace or category IV workplace, discharges from this workplace, the area surrounding it, the area surrounding a radioactive waste disposal facility after closure of the radioactive waste disposal facility, tips, settling ponds or other residues of activity related to acquiring of radioactive minerals or other mining activity accompanied by the occurrence of a radioactive mineral, and monitoring for the purposes of siting or constructing a nuclear installation,
  4. the continuous surveillance of radiation protection (hereinafter “continuous surveillance”) by the supervising person,
  5. the measurement and assessment of indoor exposure to natural sources of radiation for the purposes of preventing radon penetration indoors under § 100 or protection against natural indoor radiation under § 99 and determination of the building site radon index under § 98,
  6. the measurement and assessment of natural radionuclide content of water under § 100(2)(a) and of construction products and materials expected to have an increased natural radionuclide content, which are intended to be installed in structures with residential rooms or rooms intended to be occupied by persons (hereinafter “building materials”) under § 101(2)(a),
  7. the measurement and evaluation of the radionuclide content of a radioactive substance discharged from a workplace with potentially increased exposure to a natural source of radiation under § 95(1)(b),
- i) the provision of services in the controlled area to the operator of a category IV workplace, except cases where the activity is performed sporadically or there is danger in delay and where the operator of the controlled area has demonstrably satisfied all the requirements for radiation protection of the workers performing this activity,
- j) the making available on the market of building materials, if the effective dose to a representative person from using the building material exceeds 1 mSv per year from external exposure; a list of building materials shall be established by implementing legislation, and
- k) the mixing of radioactive substances discharged from a workplace under § 93(1)(b) for the purpose of reusing or recycling them.

(3) A licence from the Office shall be required for the following activities in the area of radioactive waste management:

- a) radioactive waste management, except collection, segregation and storage of radioactive waste directly by the radioactive waste producer, who is authorised to manage the waste as an unsealed radionuclide source,
- b) the closure of a radioactive waste disposal facility,
- c) the re-import of radioactive waste produced during the processing of a material exported from the Czech Republic or re-transfer thereof from a Member State of the Euratom, and
- d) the import or transfer of radioactive waste from a Member State of the Euratom to the territory of the Czech Republic for the purposes of processing or reusing it.

(4) A licence from the Office shall be required for carriage of radioactive or fissile materials, specifically for

- a) carriage of fissile material; implementing legislation shall establish the rules for determining fissile materials the carriage of which shall be subject to licensing, their categorization, requirements on them and the technical requirements for determining the packaging assembly for carrying fissile materials and requirements on it,
- b) carriage of radioactive substances; implementing legislation shall establish the rules for determining radioactive substances the carriage of which shall be subject to licensing, their categorization, requirements on them and the technical requirements for determining the packaging assembly for carrying radioactive substances and requirements on it,
- c) carriage of radioactive or fissile materials under special conditions if, taking into account the economic and societal circumstances, it is not possible to satisfy all the requirements under this Act or other legislation<sup>8)</sup> and these requirements are replaced by specific requirements, which ensure the same or higher level of nuclear safety, radiation protection, physical protection and radiation extraordinary event management during carriage and
- d) transboundary shipments of radioactive waste or spent fuel, if their activity and the activity concentration of radionuclides contained in them exceed the clearance levels established in implementing legislation and where the State of origin, State of destination or the first State of transit through the Euratom is the Czech Republic, except shipments of radioactive waste or spent fuel from a Member State of the Euratom to the Czech Republic or transit thereof through the Czech Republic, if the Czech Republic is not the first State of transit through the Euratom which the radioactive waste or spent fuel enters.

(5) A licence from the Office shall be required for the following activities in the area of non-proliferation of nuclear weapons:

- a) the management of nuclear material and
- b) the import or export of a nuclear item or transit of nuclear material and a selected nuclear item.

(6) A licence from the Office shall be required for

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<sup>8)</sup> Act No 111/1994 on road transport, as amended.

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), promulgated under No 64/1987, as amended.

Act No 266/1994 on railroads, as amended.

Convention concerning International Carriage by Rail (COTIF), promulgated under No 8/1985, as amended.

Act No 114/1995 on inland navigation, as amended.

Decree No 222/1995 on waterways, vessel traffic in ports, general average and transport of dangerous goods, as amended.

Act No 49/1997 on civil aviation and on amendments to Trading Act No 455/1991, as amended.

European Agreement concerning the international carriage of dangerous goods by inland waterways (ADN), promulgated under No 102/2011

- a) training and further training of workers performing activities of particular relevance to nuclear safety and radiation protection (hereinafter “selected worker”) and
- b) training of a natural person ensuring the radiation protection of a person who has been registered under this Act (hereinafter the “registered person”).

(7) A licence from the Office shall be required for complete decommissioning.

(8) Any activity for which a licence from the office is required, except the activities referred to in paragraph 2(h) and (i) and paragraph 6, shall not be a service as defined under the act on the free movement of services. A licence from the office shall also be required for an activity performed by a person with registered office or permanent residence in another Member State of the European Union who is a holder of authorisation for performing this activity in that State.

## § 10

### **Registration**

Dental or veterinary x-ray equipment or x-ray bone densitometers, which are the simplest sources of ionising radiation, may be used and radiation generators may be imported, exported or distributed only subject to registration of this activity.

## § 11

### **Notification**

The Office shall be notified in advance of

- a) the use of a type-approved minor source of ionising radiation, except the use of a source of ionising radiation for non-medical exposure or
- b) a transfer of a nuclear item.

## § 12

### **General exemption from license, registration and notification**

Urgent action to mitigate or avert a radiation extraordinary event or eliminate its consequences may be taken without licence, registration or notification.

## § 13

### **Licensing and registration prerequisites**

(1) An activity subject to licensing or registration may be performed under the prerequisite that

- a) the natural person has full legal capacity and good repute and is professionally competent,
- b) natural persons who are members of a statutory body of a legal person have full legal capacity and good repute and at least one of these persons is professionally competent,
- c) the legal person and the legal person who is a member of a statutory body of a legal person have good repute and
- d) natural persons, who are alternates of a legal person, which is a member of a statutory body of a legal person have full legal capacity and good repute.



(2) Compliance with the prerequisite of professional competence shall not be required for activities under § 9(6).

## § 14

### **Good repute**

(1) For the purposes of this Act, a person shall be considered to be of good repute if he or she

- a) has not been finally convicted of a criminal offence related to the activity subject to licensing or registration, or
- b) has not received an imprisonment sentence of more than three years, if applying for a license.

(2) For the purposes of this Act, a person considered as not having been convicted shall be considered to be of good repute.

(3) Natural persons shall demonstrate their good repute by

- a) an extract from the Criminal Records Register,
- b) an extract from the criminal register or an equivalent document issued by the State of which the person is a national or a solemn declaration of good repute, or
- c) an extract from the criminal register or an equivalent document issued by the last State of residence lasting more than three months in two consecutive years or a solemn declaration of good repute.

(4) Legal persons shall demonstrate their good repute by

- a) an extract from the Criminal Records Register,
- b) an extract from the criminal register or an equivalent document issued by the State in which the legal person has its registered office or a solemn declaration of good repute, or
- c) an extract from the criminal register or an equivalent document issued by the State in which the legal person carried on business in the last two consecutive years or a solemn declaration of good repute.

(5) Proof of good repute referred to in paragraph 3(b) and (c) and paragraph 4(b) and (c) shall not be older than three months.

(6) In order to determine good repute, the Office shall request an extract from the Criminal Records Register in accordance with other legislation<sup>9)</sup>. Applications for the issue of an extract from the Criminal Records Register and the extract from the Criminal Records Register shall be transmitted in electronic form, in a manner allowing remote access.

## § 15

### **Professional competence**

(1) Professional competence shall be demonstrated

- a) in the case of activities involving radiation, performance of services relevant to radiation protection and management of a nuclear items, by proof of completed secondary education with the 'maturitní zkouška' exam or proof of secondary education completed with an

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<sup>9)</sup> Act No 269/1994 on the Criminal Records Register, as amended.

apprenticeship certificate and experience in the field of at least three years; compliance with the condition of having at least three years of experience in the field shall not be required for activities involving radiation that are related to radiodiagnostics when providing dental care,

- b) in the case of activities related to the use of nuclear energy that are not listed under (a) and activities in the field of radioactive waste management, proof of completion of higher education in a study programme on technical sciences, technology or application of natural sciences and experience in the field of at least three years.

(2) As regards the recognition of professional qualifications obtained in another Member State of the European Union, another State that is a contracting party to the Agreement on the European Economic Area or in the Swiss Confederation for the performance of activities referred to in paragraph 1, the Office shall proceed in accordance with the act on the recognition of professional qualifications, unless the professional qualifications have already been recognised by another administrative Authority in accordance with other legislation<sup>10)</sup>. The office's decision to recognise professional qualifications shall serve as proof of professional competence under this Act.

(3) Evidence of education and training issued abroad shall be accompanied by a nostrification clause and evidence of higher education shall be accompanied by a certificate of recognition of equivalence of education in accordance with other legislation.

(4) The obligation to present evidence accompanied by a nostrification clause or certificate of recognition of equivalence of education referred to in paragraph 3 shall not apply to evidence of education and training issued in a Member State of the European Union, other Member State of the European Free Trade Association or in Swiss Confederation or presented by a natural person from that State.

## § 16

### **Licence application**

(1) The licence application shall contain

- a) the subject matter of the activity to be licensed,
- b) the scope of performance of the activity to be licensed,
- c) the place of performance of the activity to be licensed, if other than the applicant's place of residence or registered office,
- d) the period of performance of the activity to be licensed, if other than indefinite or longest possible pursuant to § 21(2)(a) to (h),
- e) the presumed method of discontinuation of the activity to be licensed,
- f) personal number, if assigned, name at birth, if different from current name, and the place and district of birth of the natural person who is
  1. the applicant,
  2. a member of a statutory body of an applicant who is a legal person, or
  3. an alternate of a legal person, which is a member of a statutory body of an applicant who is a legal person,

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<sup>10)</sup> Act No 95/2004 on the conditions for the acquisition and recognition of professional competence and specialist competence for the exercise of the medical profession of a physician, dentist and pharmacist, as amended.  
Act No 96/2004 on the conditions for the acquisition and recognition of qualifications for the exercise of paramedical professions and for the exercise of activities related to the provision of healthcare, and on amendments to certain related acts (Paramedical Professions Act), as amended.

g) the registration number of the holder of a licence granted by the office (hereinafter the “registration number”), if already assigned.

(2) In addition to other evidence of compliance with the conditions laid down by the Act, the licence application shall be accompanied by the following,

- a) a document certifying the professional competence for the activity to be licensed in case of a natural person or, where the applicant is a legal person, proof of professional competence for the activity to be licensed of at least one member of the statutory body,
- b) where a supervising person is designated, written consent of that person,
- c) where the nuclear damage liability insurance is required, a certificate of nuclear damage liability insurance or evidence of other financial collateral arrangements,
- d) the required documentation for the activity to be licensed, and
- e) if the activity to be licensed generates radioactive waste, a document demonstrating that safe radioactive waste management has been ensured, including the financing thereof.

(3) Licence holders shall forthwith notify the office of any changes in the facts referred to in paragraph 1(a) to (d).

## § 17

### **Registration application**

(1) Registration applications shall be filed using the registration form.

(2) In addition to other evidence of compliance with the conditions laid down by the Act, the registration application shall be accompanied by the following,

- a) a document certifying the natural person’s professional competence for the activity to be registered or, where the applicant is a legal person, proof of professional competence for the activity to be registered of at least one member of the statutory body,
- b) certificate of designation of a natural person ensuring radiation protection (hereinafter „person ensuring radiation protection of registered person”) and that person’s written consent to the designation and
- c) documentation for the activity to be registered.

(3) Implementing legislation shall establish

- a) registration form specimens,
- b) a list and content of the documentation for the activity to be registered.

## § 18

### **Notification of activities**

(1) Notification of the use of a type-approved minor source of ionising radiation shall contain

- a) specification and number of the sources of ionising radiation used,
- b) the address of the workplace where the source of ionising radiation is used and
- c) the presumed method of discontinuation of the use of the source of ionising radiation.

(2) Notification of the transfer of a nuclear item shall contain

- a) in the case of nuclear material, its quantity and category,
- b) in the case of a selected nuclear item or a dual-use nuclear item, its quantity, name and specifications in accordance with implementing legislation,

- c) the presumed method and date of the transfer of the nuclear item,
- d) name(s) and surname, in the case of a natural person, or, in the case of a legal person, the business name,
- e) address of the supplier and a person who shall manage the nuclear item (hereinafter the „end-user“), and
- f) end-use statement for the nuclear item.

(3) The notification of the transfer of a nuclear item shall be made at least 30 days prior to the expected date of commencement of the activity.

(4) If there is danger in delay, the notification of the transfer of a nuclear item intended for ensuring the operation of a nuclear installation, the failure to supply which could result in a threat to nuclear safety or reduction in the level of radiation protection or radiation extraordinary event management of a nuclear installation, shall be made no less than five working days prior to the expected date of commencement of the activity involving the nuclear item.

(5) Implementing legislation shall establish requisites of the end-use statement for the nuclear item.

## § 19

### **Procedure for issuing licences**

(1) Licences shall be issued on the basis of an application. The applicant shall be the sole party to the procedure.

(2) The Office shall issue a decision on the issue of a licence within

- a) 12 months of the commencement of a procedure to license the siting of a nuclear installation,
- b) 18 months of the commencement of a procedure to license the construction of a nuclear installation or a category IV workplace, except workplaces with a nuclear installation,
- c) 12 months of the commencement of a procedure to license the first physical start-up of a nuclear installation with a nuclear reactor,
- d) six months of the commencement of a procedure to license
  1. the first power-generation start-up of a nuclear installation with a nuclear reactor,
  2. the commissioning of a nuclear installation without a nuclear reactor,
  3. the operation of a nuclear installation,
  4. the operation of a category IV workplace, except workplaces with a nuclear installation,
  5. the individual phases of decommissioning of a nuclear installation,
  6. the closure of a radioactive waste disposal facility,
- e) 90 days of the commencement of a procedure concerning other licences.

(3) A licence for the activities under § 9(2)(h) and (i) and (6) shall also be deemed to have been granted upon fruitless expiry of the time limits, in the manner referred to in §§ 28 to 30 of the act on the free movement of services.

## § 20

### **Registration procedure**

(1) If the registration application meets requirements of § 17 and conditions laid down in this Act for exercising of an activity subject of registration have been satisfied, the office shall make the registration in 30 days after the day the delivery of application was done and confirm the registration on a registration form.

(2) If requirements of § 17 on the registration application have not been satisfied, the office shall call the applicant in a period of time set in paragraph (1) to remedy deficiencies and set adequate term for remediation, at least 15 days. In case of serious reasons the office may repeatedly, upon request of the applicant, make the set term for remediation longer. Terms for registration and its confirmation stops during the term for remediation.

(3) If the applicant remedies deficiencies in the set period of time or in the prolonged set period of time the registration application is considered as flawless from the very beginning. If the applicant does not remedy deficiencies in the set period of time or in the prolonged set period of time, the office shall reject the registration application. Decision on the rejection of the application is the first administrative act in the proceedings. If the applicant remedies deficiencies before the decision is adopted and the office acknowledges that conditions for a registration are met, the office shall provide the registration and confirm the registration on the registration form.

(4) If the applicant does not meet conditions laid down in this Act for exercising of an activity subject of registration, the office shall reject the registration application. Decision on the rejection of the application is the first administrative act in the proceedings.

## § 21

### **Particulars and period of validity of a licence**

(1) In its decision to issue a licence, the Office shall provide

- a) the registration number,
- b) the subject and scope of the licensed activity,
- c) conditions for the performance and discontinuation of the licensed activity, and
- d) the period for which the licence is issued, if the licence is issued for a definite period.

(2) The licence shall be issued for an indefinite period, except

- a) licences for the first physical start-up of a nuclear installation with a nuclear reactor, which shall be issued for a period not exceeding two years,
- b) licences for the first power-generation start-up of a nuclear installation with a nuclear reactor, which shall be issued for a period not exceeding two years,
- c) licences for the commissioning of a nuclear installation without a nuclear reactor, which shall be issued for a period not exceeding five years,
- d) licences for the individual phases of decommissioning of a nuclear installation, which shall be issued for a period not exceeding 10 years,
- e) licences for the individual phases of decommissioning of a category III workplace or a category IV workplace, which shall be issued for a period not exceeding 10 years,
- f) licences for the closure of a radioactive waste disposal facility, which shall be issued for a period not exceeding 20 years,
- g) licences for the carriage of radioactive and fissile material, which shall be issued for a period not exceeding five years,
- h) licences for transboundary shipments of radioactive waste and spent fuel, which shall be issued for a period not exceeding three years.

§ 22

**New decision on the issue of a licence and cancellation and lapse of a licence**

(1) The Office shall commence a new procedure and issue a new decision on the issue of a licence

- a) at the request of the licence holder,
- b) if there is a material change in the facts on the basis of which the original licence was issued or
- c) if there is a change in the performance of the originally licensed activity which is relevant to nuclear safety, radiation protection, technical safety, non-proliferation of nuclear weapons, radiation situation monitoring, radiation extraordinary event management or security.

(2) The original decision shall be cancelled by the new decision issued in accordance with paragraph 1.

(3) In proceedings under paragraph (1)(b) and (c) the participant is obliged to submit to the office upon request information needed for issuing the new decision on the issue of a licence, providing evidence on changes in comparison with original state and compliance with legal conditions.

(4) A licence shall lapse

- a) on the date of dissolution or transformation of a legal person, or death of a natural person,
- b) in the case of licences referred to in § 21(2), upon expiry of the period for which they were issued, or
- c) on the date a decision of the office to cancel a licence becomes final.

(5) If the licence holder does not intend to continue to perform the licensed activity, he or she shall notify the office of this fact without undue delay and concurrently request cancellation of the licence.

(6) The Office shall cancel the licence if

- a) the licence holder seriously fails in his or her obligations under this Act or fails to remedy serious deficiencies in the activities found by the Office,
- b) the licence holder no longer satisfies the conditions relevant for the issue of the licence, or
- c) the licence holder requests in writing that it be cancelled and provides evidence that nuclear safety, radiation protection, technical safety, safe management of nuclear materials and radiation extraordinary event management have been ensured.

(7) Prior to the lapse of the licence, the licence holder shall discontinue the licensed activity in compliance with this Act or, with the Office's consent find a person who intends to continue the licensed activity.

(8) The legal successor of a licence holder whose licence has lapsed under paragraph 4(a) and a legal person whose licence has lapsed due to its transformation shall ensure the immediate safe discontinuation of the licensed activity after cancellation of the license and until the safe discontinuation of the licensed activity they must ensure compliance with the obligations laid down in this Act. They may continue the licensed activity without a licence, if he or she ensures compliance with the obligations laid down in this Act and files an application for a licence for the activity within 30 days of the lapse of the licence.

§ 23

**Cancellation and lapse of registration**

(1) Registration shall lapse

- a) upon the death of the natural person who is the registered person,
- b) upon dissolution of a registered person who is a legal person, or
- c) on the date a decision of the office to cancel the registration becomes final.

(2) If the registered person does not intend to continue to perform the registered activity, he or she shall notify the office of this fact without undue delay and concurrently request cancellation of the registration.

(3) The Office shall cancel the registration if the registered person

- a) no longer satisfies the prerequisites relevant for registration or seriously fails in his or her obligations under this Act,
- b) fails to take corrective action imposed by the Office within the set period, or
- c) requests that the registration be cancelled.

(4) Prior to the lapse of the registration, the registered person shall discontinue the registered activity in compliance with this Act or, with the office's consent, find a person who intends to continue the registered activity.

(5) The legal successor of a registered person whose registration has lapsed due to death or dissolution of a registered person who is a legal person may continue the registered activity for a period of 30 days of the lapse of registration, provided that compliance with the conditions for the performance of the registered activity under this Act is ensured.

§ 24

**Documentation for a licensed activity and its amendment**

(1) Licence holders shall act in accordance with the documentation for the licensed activity.

(2) The list of documentation for a licensed activity is provided in Annex 1 to this Act.

(3) Where so required under this Act, the documentation for a licensed activity shall be subject to approval by decision of the Office. The applicant shall be the sole party to the procedure. The office shall approve a documentation for a licensed activity and issue the licence in combined proceedings if the proceedings are related in a matter of time.

(4) Licence holders shall file the documentation for the licensed activity during performing of licensed activity and keep it in compliance with the requirements under this Act, the principles of good practice and the actual status of the licensed activity.

(5) Licence holders shall notify the office of any amendments to documentation for a licensed activity which is not subject to approval within 30 days or, if there is danger in delay, 72 hours prior to the time he or she intends to act in accordance with them. Where the amendments to documentation for a licensed activity not subject to approval do not comply with the requirements under paragraph 4, the office shall request that the licence holder remedy the deficiencies and set a reasonable deadline for this. The licence holder may not act in

accordance with the amended documentation for the licensed activity unless it complies with the requirements under paragraph 4.

(6) At a request, the office shall decide on approval of amendments to documentation for a licensed activity which is subject to approval.

(7) Implementing legislation shall establish requirements for the content of documentation for licensed activities.

## § 25

### **Obligations common to licence holders and registered persons**

(1) Licence holders and registered persons shall

- a) notify the Office without delay of any changes or events relevant to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, security and management of nuclear materials and any changes in the facts relevant for the issue of the licence or for registration, except information identifiable from a public register,
- b) investigate without delay any breaches of this Act, take corrective action and prevent the recurrence of such situations,
- c) assess nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security within the scope of applicable requirements,
- d) ensure that activities of particular relevance to nuclear safety and radiation protection are performed by selected workers,
- e) comply with the technical and organisational conditions for the safe operation of nuclear installations and workplaces with a source of ionising radiation and technical and organisational conditions for the safe management of sources of ionising radiation and act in accordance with internal regulations,
- f) monitor, measure, evaluate, verify, and record quantities and facts relevant to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security and retain and forward information about them to the Office, as well as participate in comparative measurements organised by the Office and take corrective action if the participation in comparative measurements is not successful,
- g) ensure appropriate instrumentation for the measurement of quantities referred to in (f),
- h) keep and retain a register of sources of ionising radiation, radioactive waste and nuclear items and forward data from the register to the Office,
- i) forward information to the European Commission as required under this Act or Euratom legislation or European Union legislation, including identification data of natural persons, and provide this information to the Office,
- j) provide assistance to inspectors of the International Atomic Energy Agency and the European Commission and representatives of the European Commission in the performance of international controls referred to in § 205, and
- k) regularly verify that natural persons performing sensitive activities under this Act are authorised to perform these activities.

(2) Implementing legislation shall establish

- a) a list of quantities and facts relevant to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security,



- b) the scope, method and period of monitoring, measuring, evaluating, verifying, and recording quantities and facts relevant to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security, and period of retaining information about them,
- c) the scope, method and terms of forwarding information to the Office about quantities and facts relevant to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- d) the scope, method and period of retaining records on sources of ionising radiation, radioactive waste and nuclear items and period for forwarding them to the Office,
- e) the scope of information under paragraph (1)(i) and the method of forwarding them.

### **Maintaining lists and registers**

#### § 26

(1) The office shall draw up lists of

- a) nuclear installations and sources of ionising radiation,
- b) nuclear materials,
- c) data on exposure of exposed workers and emergency workers,
- d) data on medical exposure,
- e) individual radiological monitoring documents,
- f) approved types of packaging assemblies for carriage and storage of fissile or radioactive substances, sources of ionising radiation and other products,
- g) selected nuclear items that have been exported, imported or transferred,
- h) data from radiation situation monitoring in the territory of the Czech Republic,

(2) Radioactive waste repository authority (hereinafter the „Authority“) shall draw up list of radioactive wastes.

(3) The purpose of the lists referred to in paragraphs 1 and 2 shall be to collect and manage information needed for ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, non-proliferation of nuclear weapons, and security in the peaceful use of nuclear energy and ionising radiation.

(4) Lists referred to in paragraph 1(a), (d) through (f) and (h) are public. Lists referred to in paragraph 1(b), (c) and (g) and paragraph 2 are not public.

(5) At request, the office shall issue a full or partial extract from the lists referred to in paragraph 1(b), (c) and (g) to persons who can demonstrate their legal interest. The Authority shall issue a full or partial extract from the lists referred to in paragraph 2. Instead of issuing an extract, information from the information system may be provided in a manner allowing remote access.

(6) The personal data below will be processed in the lists referred to in paragraph 1, except the lists referred to in (d) and (h), and in paragraph 2:

- a) surname,
- b) name(s),
- c) personal number, if assigned,
- d) address of the place of residence.

(7) The data on legal persons referred to below will be processed in the lists referred to in paragraphs 1 and 2:

- a) business name,
- b) company registration number,
- c) address of registered office.

(8) The data contained in the lists referred to in paragraphs 1 and 2 shall be processed throughout the period of performing the activities that they concern and for 25 years after discontinuing them, except the data included in the lists under paragraph 1(c) and (e), which shall be processed until the natural person whom the data concern reaches the age of 75, but for no less than 30 years after discontinuing working activities during which this natural person was subject to occupational exposure.

#### § 27

(1) The office shall draw up registers of

- a) licence holders,
- b) registered persons,
- c) notifying persons,
- d) holders of authorisations for the performance of activities of particular relevance to nuclear safety and radiation protection.

(2) The Authority shall draw up registers of radioactive waste producers.

(3) The purpose of the registers referred to in paragraphs 1 and 2 shall be to collect and manage information needed for ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security in the peaceful use of nuclear energy and ionising radiation.

(4) The registers referred to in paragraphs 1 and 2 shall be public.

(5) The personal data below will be processed in the registers referred to in paragraphs 1 and 2:

- a) surname,
- b) name(s),
- c) personal number, if assigned,
- d) address of the place of residence.

(6) The data on legal persons referred to below will be processed in the registers referred to in paragraphs 1 and 2:

- a) business name,
- b) company registration number,
- c) address of registered office.

(7) The data contained in the registers referred to in paragraphs 1 and 2 shall be processed throughout the period of performing the activities that they concern and for 25 years after discontinuing them.

#### § 28

(1) The office shall make public, in a manner allowing remote access, information about

- a) the licences issued,
- b) authorisations granted for the performance of activities of particular relevance to safety and radiation protection,

- c) registrations made,
- d) notifications received,
- e) data from radiation situation monitoring in the territory of the Czech Republic.

(2) Information referred to in paragraph 1 shall be made public without providing the personal number and information about the place of residence.

(3) Information relating to a nuclear installation or a source of ionising radiation, including nuclear material, shall be made public in the form of summary information, without providing any personal data, similar data on legal persons, or data on the location of sources of ionising radiation.

(4) Anyone who obtains information relating to security and specifications of a source of ionising radiation or a nuclear item, the disclosure of which could lead to a misuse of the information and a threat to public order, public health or safety of the source of ionising radiation or nuclear item, shall keep this information confidential and not disclose it to the public under act on free access to information<sup>11)</sup>. The obligation of confidentiality shall continue to apply after the termination of the contract of employment or other similar arrangement.

## Part 2

### Management system

#### § 29

(1) With the aim of ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security, a management system shall be introduced and maintained by

- a) licence holders under
  - 1. § 9(1),
  - 2. § 9(2)(a) to (d),
  - 3. § 9(2)f), Point 7, if they operate a category III workplace,
  - 4. § 9(3) and (4),
  - 5. § 9(6)(a), if they provide training and further training to selected workers performing activities of particular relevance to nuclear safety,
- b) persons designing nuclear installations,
- c) persons who design or manufacture selected equipment or modify such equipment,
- d) persons who prepare, manage and carry out the construction of structures and technological systems, which are part of a nuclear installation,
- e) person conducting safety assessments under § 48, and
- f) person conducting site evaluation for a nuclear installation under § 47.

(2) When introducing and maintaining a management system, the graded approach shall be commensurate to

- a) the complexity of the processes and activities affecting nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security (hereinafter “processes and activities”), their inputs and outputs and their relevance to nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,

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<sup>11)</sup> § 11(3) of Act No 106/1999 on free access to information, as amended.

- b) potential consequences of non-conformity of the processes and activities performed with the documented requirements (hereinafter “non-conformity”) and its impact on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, security, and quality of the outputs of processes and activities and
- c) the need for and adequacy of resources for processes and activities and their inputs and outputs.

(3) In the context of their management systems, the persons referred to in paragraph 1 shall

- a) identify processes and activities, including processes that have outputs whose conformity with the requirements placed on them cannot be fully verified (hereinafter “special processes”),
- b) manage and perform processes and activities methodically so that they effectively contribute to ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security,
- c) document the management system, including processes and activities, and follow the management system documentation,
- d) determine the organisational structure and interactions between organisational units, personnel and other persons,
- e) provide the internal bodies or personnel with general obligation to ensure introducing and maintaining the management system,
- f) define the rights and obligations of personnel and methods of communication between them so that they effectively contribute to ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- g) create a plan for ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security, a document the planning,
- h) make changes to the management system in a manner ensuring integrity of all areas of the management system,
- i) assess the efficiency of the management system, including processes and activities and changes to them, and
- j) integrate all requirements that could be used for ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security.

(4) In the context of their management systems, the persons referred to in paragraph 1 shall ensure management of non-conformities, which means a set of measures to

- a) prevent non-conformities,
- b) detect non-conformities,
- c) remedy non-conformities immediately and
- d) prevent recurrence of non-conformities.

(5) In the context of their management systems, the persons referred to in paragraph 1 shall ensure and make use of the human, technical, material and financial resources, including suitable working environment, which are essential for ensuring and increasing the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security.

(6) In the context of their management systems, the persons referred to in paragraph 1 shall seek opportunities for improving the management system and based on the opportunities for improvement the management system shall be modified by means of an action the course of which shall be planned, monitored and documented and after the action verify its efficiency.

(7) Implementing legislation shall establish

- a) the requirements for the introduction, maintenance and improvement of the management system,
- b) the content and method of keeping the management system documentation ,
- c) rules for conducting and managing processes and activities, including special processes,
- d) the method of management system planning and the scope and method of documenting this planning,
- e) the method of implementing changes to the management system,
- f) rules for assessing the efficiency of the management system, including processes and activities and changes thereto,
- g) the method of managing non-conformities.

### § 30

(1) In the context of their management systems, the persons referred to in § 29(1) shall lay down the requirements for the selection and qualifications of suppliers of products or services and manage and monitor the supplies of products or services.

(2) Persons referred to in § 29(1) may only be supplied products or services by a person who has introduced and maintains a management system in compliance with the requirements under this Act or by other means ensuring the quality of processes and activities and their outputs comparable with the requirements under this Act.

(3) The processes and activities of a supplier of products or services shall meet a quality standard similar to that of the processes and activities of the persons referred to in § 29(1). The outputs of the processes and activities of a supplier of products or services may be used by a person referred to in § 29(1) only if they conform to the requirements placed on them under technical specifications.

(4) In the context of their management systems, the persons referred to in § 29(1) shall regularly evaluate their suppliers' management systems, including processes and activities and their outputs, as well as their efficiency in terms of ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security.

(5) In the context of their management systems, the persons referred to in § 29(1) shall make contractual arrangements with suppliers of products or services concerning

- a) the scope and method of communication with the supplier of the product or service,
- b) measures for supervision of the supplier of a product or service,
- c) requirements for the supplier's management system, including the requirements for processes and activities, and its efficiency in terms of ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security,
- d) requirements for the qualifications of the personnel conducting processes and activities within the supplier's management system,

- e) requirements for the regular evaluation of the supplier's management system, including the processes and activities and their outputs, and its efficiency in terms of ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- f) the method of dealing with the results of the evaluation of the processes and activities in the supplier's management system and their outcomes, and
- g) the scope and method of assessment of compliance of the products or services supplied with the agreed requirements.

(6) Processes and activities shall be performed by personnel with qualifications corresponding to the type and importance of the process and activity they perform so that nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security are ensured.

(7) The persons referred to in § 29(1) shall introduce the management system in a manner ensuring that through this system are permanently developed and regularly evaluated characteristics and attitudes of persons performing activities related to the use of nuclear energy and activities in exposure situations and of their personnel, which ensure that nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security are approached with a seriousness corresponding to their importance (hereinafter „safety culture“).

(8) The requirements referred to in paragraphs 1 to 5 shall not apply to licence holders who operate a category III workplace, carry out decommissioning of such a workplace or carry out reconstruction or other modifications affecting its radiation protection.

(9) Implementing legislation shall establish

- a) the method of ensuring appropriate qualification of the personnel conducting processes and activities,
- b) the scope and method of ensuring the permanent development and regular evaluation of safety culture.

### **Activities of particular relevance to nuclear safety and radiation protection and special professional competence**

#### § 31

(1) Activities of particular relevance to nuclear safety and radiation protection may be performed by a selected worker only on the basis of authorisation granted by the Office.

(2) The Office shall decide to grant authorisation for the performance of activities of particular relevance to nuclear safety or radiation protection at the request of the selected worker if he or she

- a) has obtained required education, professional experience and training,
- b) has appropriate personality characteristics for the activity performed and is medically fit under the act on specific health services, if the activity is of particular relevance to nuclear safety and
- c) has successfully passed the examination of special professional competence.

(3) As a person with appropriate personality characteristics for purposes under paragraph 2(b) is considered a selected worker with performative and personal characteristics that are prerequisite for performing the activities of particular relevance to nuclear safety.

(4) The Office shall recognise professional qualifications obtained in another Member State of the European Union, another State that is a contracting party to the Agreement on the European Economic Area or in the Swiss Confederation as special professional competence for the performance of activities of particular relevance to nuclear safety and radiation protection. When recognising professional qualifications, the Office shall proceed in accordance with the act on the recognition of professional qualifications.

(5) For activities of particular relevance to radiation protection, the training referred to in paragraph 2(a) may be substituted by completing a training course to acquire competence for the exercise of the paramedical profession of a radiological physicist.

(6) Implementing legislation shall establish

- a) the list of activities of particular relevance to nuclear safety and radiation protection,
- b) the type and level of education required for each activity,
- c) the type and length of professional experience for each activity,
- d) the content and method of provision of training for each activity,
- e) performative and personal characteristics that are prerequisite for performing the activities of particular relevance to nuclear safety and the method of verification of appropriate personality characteristics.

## § 32

(1) Applications for the granting of authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection shall be accompanied by

- a) proof of completion of the required education, professional experience and training, and
- b) if the activity is of particular relevance to nuclear safety, proof of appropriate personality characteristics and medical fitness within a scope corresponding to the activity to be performed.

(2) Evidence of education issued abroad, except evidence of education issued in a Member State of the European Union, shall be accompanied by a nostrification clause in accordance with other legislation; evidence of higher education shall be accompanied by a certificate of recognition of equivalence of education in accordance with other legislation.

(3) The applicant shall pass the examination of special professional competence within 12 months of filing the application before an examining board appointed by the office. An examining board has at least 3 members and its chairman is a state employee designated to serve at the Office.

(4) The applicant may repeat, no more than twice, the examination of special professional competence or part thereof within the period referred to in paragraph 3.

(5) Applicants who have obtained authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection based on the examination of special professional competence shall be issued a certificate of special professional competence by the Office.

(6) The certificate of special professional competence shall contain

- a) name(s), the surname, date of birth, and address of place of residence,
- b) specification of the scope of activities of particular relevance to nuclear safety and radiation protection which the authorisation holder is authorised to perform.

(7) Authorisations for the performance of activities of particular relevance to radiation protection shall be granted for an indefinite period of time.

(8) Authorisations for the performance of activities of particular relevance to nuclear safety shall be granted for a period of no more than eight years, depending on the number of preceding authorisations for the performance of the same activity granted to the same applicant and the result of the examination of special professional competence.

(9) A decision of the Office to recognise professional qualifications obtained in another Member State of the European Union, another State that is a contracting party to the Agreement on the European Economic Area or in the Swiss Confederation shall substitute the successful completion of the examination of special professional competence before an examining board appointed by the Office.

(10) Implementing legislation shall establish

- a) the scope, content and method of conducting and evaluating the examination of special professional competence for each activity,
- b) conditions for repeating the examination of special professional competence,
- c) the period of validity of the authorisation for the performance of activities of particular relevance to nuclear safety.

### § 33

(1) Holders of authorisations for the performance of activities of particular relevance to nuclear safety and radiation protection shall undertake further training.

(2) Where there is a reasonable suspicion that a holder of authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection does not maintain the required level of special professional competence, the office may order and conduct re-examination of the holder. When conducting re-examination, the office shall follow a procedure analogical to that applied when granting authorisations for the performance of activities of particular relevance to nuclear safety and radiation protection.

(3) Holders of authorisations for the performance of activities of particular relevance to nuclear safety shall subject themselves to regular verification of appropriate personality characteristics and medical fitness.

(4) The authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection shall lapse

- a) upon death of the authorisation holder,
- b) upon restriction of the legal capacity of the authorisation holder,
- c) in the case of an activity that is of particular relevance to nuclear safety, upon expiry of the period for which it was granted, or
- d) on the date the authorisation cancelling decision referred to in paragraph 5 or 6 becomes final.

(5) The Office shall cancel the authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection, if the authorisation holder

- a) seriously or repeatedly breaches this Act,
- b) violates the principles of the peaceful uses of nuclear energy and ionising radiation,
- c) fails to pass re-examination,



- d) in the case of an activity that is of particular relevance to nuclear safety lost the appropriate personality characteristics and medical fitness within a scope corresponding to the activity performed,
- e) does not perform, for a prolonged period of time, the activity for which the authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection has been granted, or
- f) requests that it be cancelled.

(6) The office shall cancel the authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection in the event of material changes to the conditions under which the authorisation for the performance of these activities was granted.

(7) An appeal against a decision to cancel the authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection shall not have suspensory effect.

(8) Implementing legislation shall establish

- a) the content and the method and frequency of providing further training,
- b) the interval of regular verification of appropriate personality characteristics of holders of authorisations for the performance of activities of particular relevance to nuclear safety,
- c) the period after which the authorisation for the performance of activities of particular relevance to nuclear safety and radiation protection shall be cancelled due to the fact that the activities are not performed.

### Part 3

#### **Fees for the Office's expert activities**

##### § 34

#### **Definition of the fees**

The fees for the Office's expert activities include

- a) the fee for the application for the issue of a licence (hereinafter the "application fee"),
- b) the renewal fee.

##### § 35

#### **Fee payers**

- (1) The application fee shall be paid by the applicant for the issue of a licence.
- (2) The renewal fee shall be paid by the licence holder.

##### § 36

#### **Object of the fees**

- (1) The object of the application fee are the Office's activities related to the issue of
  - a) a licence for the siting of a nuclear installation,
  - b) a licence for the construction of
    - 1. a nuclear installation, or
    - 2. a category IV workplace, except workplaces with a nuclear installation,

- c) the first licence for the operation of
  1. a nuclear installation,
  2. a category III workplace for activity related to acquiring of radioactive minerals, or
  3. a category IV workplace, except workplaces with a nuclear installation,
- d) a licence for the individual phases of decommissioning
  1. a nuclear installation,
  2. a category III workplace for activity related to acquiring of radioactive minerals, or
  3. a category IV workplace, except workplaces with a nuclear installation.

(2) The object of the renewal fee are the Office's activities related to the exercise of control over the activities of holders of a licence for

- a) the operation of
  1. a nuclear installation,
  2. a category III workplace for activity related to acquiring of radioactive minerals, or
  3. a category IV workplace, except workplaces with a nuclear installation,
- b) the individual phases of decommissioning
  1. a nuclear installation,
  2. a category III workplace for activity related to acquiring of radioactive minerals, or
  3. a category IV workplace, except workplaces with a nuclear installation.

### § 37

#### **Obligation to pay the renewal fee**

(1) The obligation to pay the renewal fee shall arise on the first day of the calendar month, in which the decision to grant the licence becomes final.

(2) The obligation to pay the renewal fee shall cease on the last day of the calendar month, in which the licence lapses.

### § 38

#### **Exemption from fees**

(1) The following shall be exempt from the fees for the Office's expert activities

- a) health establishments, which carry out activities under this Act in exchange for reimbursement from the public health insurance system,
- b) public higher education institutions,
- c) persons who carry out activities under this Act only in exchange for reimbursement from public research and development funding, including funding from European Union or Euratom funds.

(2) The grounds for exemption from the fees for the office's expert activities shall be demonstrated by the fee payer when filing the application for the issue of a licence or at the office's request.

(3) If there is a change in the grounds for exemption from the fees for the office's expert activities, the fee payer shall notify the office of this fact within 15 days of the occurrence of the change.

### § 39

### **Fee rates**

- (1) The following application fee rates shall apply to licence applications under
- a) § 36(1)(a), a maximum of CZK 30 000 000,
  - b) § 36(1)(b), a maximum of CZK 150 000 000,
  - c) § 36(1)(c), a maximum of CZK 60 000 000,
  - d) § 36(1)(d), a maximum of CZK 60 000 000.
- (2) If the issue of more than one licence is requested in the application, the application fee shall amount to the sum of the rates applicable to each licence application.
- (3) The renewal fee for each calendar month in which the obligation to pay the fee applies shall not exceed CZK 4 000 000.
- (4) The rates of the fees for the office's expert activities for each of the office's activities under § 36 shall be established by the government in a regulation.

### § 40

#### **Due dates of the fees**

- (1) The application fee shall be due within 30 days of the date of filing the licence application.
- (2) The renewal fee shall be due within 30 days of the end of the fee period, which shall be the calendar year.

### § 41

#### **Fee administrator**

The fees for the office's expert activities shall be administered by the office.

### § 42

#### **Budgetary distribution of the fees**

The fees for the office's expert activities shall be state budgetary revenue of budgetary chapter „State Office For Nuclear Safety“.

## PART TWO

# **PEACEFUL USES OF NUCLEAR ENERGY AND IONISING RADIATION**

## Title I

### **Use of nuclear energy**

## Part 1

### **General rules for the safe use of nuclear energy**

### § 43

### **Definition of certain terms in the area of the use of nuclear energy**

For the purposes of this Act, the following definitions shall apply

- a) trial operation of a nuclear installation means the phase of power-generation start-up of a nuclear installation, the purpose of which is to verify the design characteristics, reliability and stability of the nuclear installation over a longer time interval,
- b) operational occurrence means an occurrence at a nuclear installation in the course of the nuclear installation's life cycle that has actual or potential consequences for nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- c) defence-in-depth means a method of protection based on multiple independent levels providing a graded protection against the possibility of exposure of workers and the general public, propagation of ionising radiation and release of radioactive substances into the environment,
- d) research nuclear installation means a nuclear installation with a nuclear reactor, which is used as a source of ionising radiation for the purposes of research, education, production of radionuclides, neutron radiography, testing of materials, or the provision of health services, whose heat dissipation does not exceed 50 MW and whose main purpose is not electricity or heat production,
- e) design basis means a set of data characterising the functions provided by the systems, structures and components of a nuclear installation in the event of internal and external threats and occurrences, and the values or ranges of values of the control parameters of a nuclear installation that are used in designing of a nuclear installation,
- f) criterion of acceptability means a safety, technical or administrative condition or quantity limit determining its acceptability in terms of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, or security,
- g) other modification in the use of nuclear energy means
  1. a modification of selected equipment not affecting nuclear safety, technical safety and physical protection of a nuclear installation,
  2. an organisational modification in the organisation of a holder of a licence for an activity related to the use of nuclear energy,
  3. a change in the field of ensuring of physical protection of a holder of a licence for an activity related to the use of nuclear energy,
- h) a modifications in the use of nuclear energy means
  1. a modification affecting nuclear safety, technical safety and physical protection of a nuclear installation, in particular modification of selected equipment, including modification of a part of selected equipment or the medium in the systems of selected equipment involving a change in the method or scope of performance of a safety function of selected equipment or replacement of a security-relevant part of selected equipment classified in safety classes 1 or 2,
  2. other modification in the use of nuclear energy,
- i) deferred dismantling means decommissioning, where the decommissioning activities are divided into several successive phases with a defined scope and schedule between which there may be a time lag.

### **Categorisation in the area of the use of nuclear energy**

(1) In the case of activities related to the use of nuclear energy, safety functions shall be determined and divided into 3 categories in accordance with the graded approach principle.

(2) In the case of activities related to the use of nuclear energy, selected equipment shall be classified, for the purposes of applying the graded approach to ensuring its quality, into safety classes 1 to 3, depending on the safety functions to the performance of which its contributes.

(3) For the purposes of utilising the feedback system for activities related to the use of nuclear energy, operational occurrences shall be categorised as significant or less significant depending on their impact on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security.

(4) Implementing legislation shall establish

- a) a list of safety functions that must be performed by a nuclear installation and their classification into categories according to their relevance to nuclear safety,
- b) safety classes and the criteria for classifying selected equipment into these classes,
- c) criteria for classifying operational occurrences into categories.

#### § 45

### **Principles of the safe use of nuclear energy**

(1) Nuclear safety, radiation protection, radiation situation monitoring, radiation extraordinary event management, and security of nuclear installations shall be ensured throughout the life cycle of a nuclear installation by means of defence-in-depth.

(2) A nuclear installation with a nuclear reactor shall, from the commencement of construction to decommissioning,

- a) allow for, if necessary, immediate and safe shut-down of the nuclear reactor and for maintaining it in a subcritical state,
- b) prevent the uncontrolled development of a fission chain reaction,
- c) make it physically impossible for a critical or supercritical state to develop outside the inner part of a nuclear reactor,
- d) ensure dissipation of the heat produced by nuclear fuel and technological systems, and
- e) ensure shielding and prevent the release of a radioactive substance and propagation of ionising radiation into the environment.

(3) A nuclear installation without a nuclear reactor shall, from the commencement of construction to decommissioning or, in the case of a radioactive waste disposal facility, until the time fixed in the documentation for the activity to be licensed,

- a) make it physically impossible for a critical or supercritical state to develop,
- b) ensure dissipation of the heat produced, and
- c) ensure shielding and prevent the release of a radioactive substance and propagation of ionising radiation into the environment.

(4) Implementing legislation shall establish the method of ensuring defence-in-depth.

#### § 46

## **Requirements for nuclear installation design and the design process of nuclear installation**

(1) Nuclear installations shall be designed in a manner ensuring their nuclear safety, radiation protection, radiation situation monitoring, radiation extraordinary event management, security and non-proliferation of nuclear weapons throughout their life cycle.

(2) The nuclear installation design shall

- a) ensure compliance with safety objectives,
- b) ensure compliance with the principles of the safe use of nuclear energy,
- c) ensure performance of the safety functions in accordance with their categorisation,
- d) ensure compliance with the requirements for the application of defence-in-depth,
- e) ensure resilience and protection of the nuclear installation against the hazards resulting from the site characteristics of the site for a nuclear installation and from external influences,
- f) specify the requirements for the scope and method of evaluating the resilience and protection referred to under (e),
- g) ensure prevention, resilience and protection of the nuclear installation against internal influences,
- h) specify the requirements for the scope and method of evaluating the prevention, resilience and protection referred to under (g),
- i) specify the requirements for selected equipment in terms of the safety functions to the performance of which it contributes,
- j) classify selected equipment into safety classes,
- k) ensure compliance with the requirements for the technical means of radiation protection assurance,
- l) ensure compliance with the requirements for radiation extraordinary event management, and
- m) ensure compliance with the requirements for security.

(3) When designing a nuclear installation, a design basis shall be established and proven methods, procedures and technology shall be used.

(4) The nuclear installation design shall specify the requirements for technical procedures and organisational measures for the construction of the nuclear installation, the first physical start-up of a nuclear installation with a nuclear reactor, the first power-generation start-up of a nuclear installation with a nuclear reactor, the commissioning of a nuclear installation without a nuclear reactor, the operation of the nuclear installation, the decommissioning of the nuclear installation and, in the case of a radioactive waste disposal facility, for the closure of the radioactive waste disposal facility.

(5) The nuclear installation design process shall comprise an evaluation of compliance of the design with the requirements referred to in paragraphs 1 to 4.

(6) Any modification of a nuclear installation, including modification of its structural and technological parts, media parameters and technical procedures, shall be, prior to implementation, subject to the design process in accordance with paragraphs 1 to 4 and shall be documented in the design documentation for this modification. After implementation, any modification of a nuclear installation shall be incorporated into the as-built documentation of the nuclear installation.

(7) The as-built documentation of the nuclear installation shall correspond to the actual state of the nuclear installation throughout the life cycle of the nuclear installation. The evaluation of compliance of the design with the requirements referred to in paragraphs 1 to 4 shall be documented.

(8) Implementing legislation shall establish the content of the requirements for nuclear installation design referred to in paragraph 1, paragraph 2(a), (b), (e), (g), (i), (k), (l), and (m), and paragraph 3.

## § 47

### **Siting of a nuclear installation**

(1) The site for a nuclear installation shall be evaluated in terms of

- a) its characteristics that can affect nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security during the life cycle of the nuclear installation,
- b) the impact of the nuclear installation on individuals, the general public, the society and the environment.

(2) Siting of a nuclear installations is prohibited in the area, whose characteristics pursuant to paragraph 1 (a) reduce the required level nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security during the life cycle of the nuclear installation, so that in terms of current level of science and technology is not possible remedy in the form of technical or administrative measures.

(3) Prior to siting a nuclear installation, a baseline survey of site for a nuclear installation shall be conducted with regard to radiation situation monitoring by measuring and evaluating the baseline radionuclide content in the environment and food chain. The results of the baseline survey shall be retained for the needs of the complete decommissioning.

(4) Implementing legislation shall establish

- a) list of site characteristics of site for a nuclear installation evaluated pursuant to paragraph 1,
- b) features of site characteristics pursuant to paragraph 1 (a) excluding siting of a nuclear installation,
- c) the requirements for the scope and method of evaluation of site for a nuclear installation.

## § 48

### **Safety assessment**

(1) The level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security shall be regularly, systematically, comprehensively and verifiably assessed during the life cycle of a nuclear installation (hereinafter “safety assessment”) and documented.

(2) Safety assessment shall comprise the following types of assessment:

- a) deterministic safety assessment,
- b) probabilistic safety assessment, in the case of a nuclear installation which is not a research nuclear installation that has a nuclear reactor with heat dissipation exceeding lower than

2 MW and is not a radioactive waste storage facility, spent fuel storage facility or radioactive waste disposal facility,

- c) periodic safety assessment,
- d) continuous safety assessment, and
- e) special safety assessment.

(3) Special safety assessment shall be conducted

- a) prior to implementing a modification in the use of nuclear energy,
- b) in the case of a radiation extraordinary event at a nuclear installation or other nuclear installation of a similar type,
- c) if so required by the office in a decision made in accordance with the requirements under an international agreement binding on the Czech Republic or an Euratom regulation, or
- d) when it is suspected that the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security has been compromised.

(4) Safety assessment shall be used to evaluate relevant information about the risks associated with the use of nuclear energy and to adopt measures to prevent compromising the level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security.

(5) Safety assessment shall verify the implementation of measures to prevent the emergence of accident conditions and to mitigate their consequences, including defence-in-depth.

(6) Implementing legislation shall establish

- a) rules for conducting safety assessments and particular types of a safety assessment and terms in which they shall be conducted,
- b) the method of documenting safety assessment and particular types of a safety assessment and the content of safety assessment documentation and particular types of a safety assessment,
- c) the method of utilising safety assessments.

## Part 2

### **Obligations of holders of a licence for an activity related to the use of nuclear energy**

#### § 49

### **General obligations of holders of a licence for an activity related to the use of nuclear energy**

(1) Holders of a licence for an activity related to the use of nuclear energy shall

- a) provide for and maintain the financial and human resources necessary to fulfil the obligations related nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- b) ensure that, from the commencement of construction to decommissioning, the nuclear installation
  1. meets the safety objectives, safety functions and principles of the safe use of nuclear energy,
  2. reflects the site characteristics of the site for a nuclear installation under § 47 paragraph 1 and



3. meets the nuclear installation design requirements,
- c) if limits and conditions area breached, ensure, from the commencement of construction to decommissioning, that the nuclear installation is brought to a state in which nuclear safety is ensured,
- d) conduct safety assessment,
- e) based on the safety assessment, constantly increase the level of nuclear safety as far as reasonably practicable,
- f) ensure that where the safety assessment concerns facts that are of relevance to ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security of a nuclear installation, it is verified by persons who did not directly participate in the safety assessment,
- g) draw up and continuously update internal regulations according to the actual state of the nuclear installation to be in conformity with the nuclear installation design and cover all states of the nuclear installation envisaged in the nuclear installation design,
- h) prior to commencing a subsequent phase of the nuclear installation's life cycle, ensure, verify and document the readiness of the nuclear installation and its personnel for this phase,
- i) document the steps within the feedback system, retain this documentation throughout the nuclear installation's life cycle,
- j) execute an investigation of an operational occurrence, notify an operational occurrence to the office and take measures to prevent an operational occurrence and to remedy the state after an operational occurrence,
- k) ensure fire and explosion prevention, detection and elimination, as well as exclusion and limitation of their impact on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security,
- l) continuously evaluate the facts relevant to the assessment of the acceptability of the site for a nuclear installation and their effect on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and security,
- m) estimate developments in the facts relevant to the assessment of the acceptability of the site for a nuclear installation with a view to the expected length of the nuclear installation's life cycle,
- n) determine the qualification requirements for activities relevant to nuclear safety and provide for a system of education, training and practice for the personnel, including a register of the qualifications obtained and their verification with respect to the relevance of the activities performed,
- o) document and report to the Office the carrying out of other modifications in the use of nuclear energy,
- p) evaluate modifications in the use of nuclear energy made in the course of the nuclear installation's life cycle, except siting, in terms of their effect on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management, and physical protection,
- q) form a company fire and rescue brigade unit for nuclear installations that are not research nuclear installations in accordance with the fire protection act, available from the commencement of construction of the installation,
- r) ensure, maintain and practice radiation extraordinary event management measures and procedures set out in the on-site emergency plan and internal regulations,
- s) from the commencement of construction to decommissioning of the nuclear installation, continuously monitor the state of the nuclear installation and its systems, structures and

components in terms of the implementation of the controlled ageing process in accordance with the controlled ageing programme,

- t) prevent fission chain reaction and release into the environment when handling nuclear materials and radioactive waste and document this handling, and
- u) introduce processes and activities, the purpose of which is to prevent accident conditions at a nuclear installation from escalating and mitigate their consequences, document them and continuously update them.

(2) Implementing legislation shall establish

- a) terms for notifying an operational occurrence to the office,
- b) the method for investigation of an operational occurrence,
- c) scope of information utilised by the feedback system,
- d) list of other modifications in the use of nuclear energy,
- e) the scope and method of documenting and reporting to the office other modifications in the use of nuclear energy,
- f) the methods for the implementation of the controlled ageing process,
- g) the rules for preventing fission chain reaction and release into the environment when handling nuclear materials and radioactive waste and the method of documenting this handling,
- h) the methods of introducing processes and activities under paragraph 1(u) and their documenting and continuous updating.

## § 50

### **Obligations of holders of a licence for the construction of a nuclear installation**

(1) Holders of a licence for the construction of a nuclear installation shall

- a) ensure that already reached level of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security of another nuclear installation located in the site for a nuclear installation under constructions is sited does not degrade and
- b) perform testing of the nuclear installation and its parts in the course of construction of the nuclear installation, in accordance with the trials and testing programme.

(2) Holders of a licence for the construction of a nuclear installation with a nuclear reactor shall, in the context of ensuring the readiness of the nuclear installation and its personnel for the first physical start-up of a nuclear installation with a nuclear reactor,

- a) perform non-active testing of the nuclear installation without nuclear fuel, in accordance with the non-active testing programme,
- b) ensure and document compliance with the pass criteria under the non-active testing programme and
- c) verify and document the completeness and readiness of all systems necessary for the first physical start-up of a nuclear installation with a nuclear reactor.

(3) Holders of a licence for the construction of a nuclear installation without a nuclear reactor shall, in the context of ensuring the readiness of the nuclear installation and its personnel for active testing of the nuclear installation,

- a) perform non-active testing of the nuclear installation, in accordance with the non-active testing programme, and
- b) ensure and document compliance with the pass criteria under the non-active testing programme.

(4) Implementing legislation shall establish the method of performing non-active testing of nuclear installations.

§ 51

**Obligations of holders of a licence for the first physical start-up of a nuclear installation with a nuclear reactor**

(1) Holders of a licence for the first physical start-up of a nuclear installation with a nuclear reactor shall

- a) after loading nuclear fuel into the nuclear reactor
  1. perform a check of the loading of nuclear fuel into the nuclear reactor and
  2. verify the neutron-physical characteristics of the nuclear reactor's active zone and the related safety functions,
- b) in the context of ensuring the readiness of the nuclear installation and its personnel for the first power-generation start-up of the nuclear installation
  1. ensure, verify and document the successful testing of the first physical start-up of a nuclear installation with a nuclear reactor,
  2. ensure and document compliance with the pass criteria for the first physical start-up of a nuclear installation with a nuclear reactor,
  3. verify and document the existence and accuracy of documentation for the licensed activity and internal regulations, including emergency operating rules and internal regulations drawn up in accordance with the on-site emergency plan, and
  4. verify that radiation protection of the general public in the emergency planning zone has been ensured in accordance with § 156(2)(c) through (g).

(2) Holders of a licence for the first physical start-up of a nuclear installation with a nuclear reactor shall steadily accumulate decommissioning financial reserves, in accordance with the act concerning reserves and the calculation of the income tax base, if the total decommissioning cost estimate verified by the Authority exceeds CZK 300 000 so that the funding held in the blocked account is available for the needs of preparing and implementing decommissioning at the time and in the amount required, in accordance with the decommissioning plan approved by the office.

(3) Holders of a licence for the first physical start-up of a nuclear installation with a nuclear reactor shall deposit funds corresponding to the amount of the reserve referred to in paragraph 2 in a blocked account with a bank with a seat in the Czech Republic or with a branch of a foreign bank in the Czech Republic with a seat in other member state of the European Union; interests from a blocked account are incomes of this account. Proceeds from the funds in the blocked account shall be revenue of that account. The reserves shall be considered as expenditure incurred to achieve, secure and maintain income.

(4) The obligation to accumulate decommissioning reserves shall not apply to organisational units of the State and state contributory organisations, public higher education institutions, organisational units and contributory organisations established by regional authorities and state enterprises for which phase-out of operations has been declared by their founders.

(5) The funding held in the blocked account referred to in paragraph 3 may only be used for the preparation and implementation of decommissioning and with the approval by the Authority.

- (6) Implementing legislation shall establish the method of
- a) performing the first physical start-up of a nuclear installation with a nuclear reactor,
  - b) the scope and method of documenting the facts under paragraph 1(b)(1) through (3),
  - c) the method of accumulating decommissioning reserves.

§ 52

**Obligations of holders of a licence for the first power-generation start-up of a nuclear installation with a nuclear reactor**

(1) Holders of a licence for the first power-generation start-up of a nuclear installation with a nuclear reactor shall

- a) verify and document at different output levels the design characteristics of the nuclear installation and its compliance with the nuclear installation design,
- b) verify and document that the nuclear installation is capable of stable and safe operation,
- c) in the context of ensuring the operational readiness of the nuclear installation and its personnel
  1. ensure, verify and document the successful testing of the first power-generation start-up of a nuclear installation with a nuclear reactor and the trial operation,
  2. ensure and document compliance with the pass criteria for the first power-generation start-up of a nuclear installation with a nuclear reactor and for trial operation,
  3. verify and document the existence and accuracy of documentation for the licensed activity and internal regulations, including emergency operating rules and internal regulations drawn up in accordance with the on-site emergency plan, and
  4. verify that radiation protection of the general public in the emergency planning zone has been ensured in accordance with § 156(2)(c) through (g), and
- d) accumulate reserves for the decommissioning of the nuclear installation in accordance with § 51(2) to (4) and 6(c) and the funding of the reserve use only for the preparation and implementation of decommissioning and with the approval by the Authority.

(2) Implementing legislation shall establish

- a) the method of performing the first power-generation start-up of a nuclear installation with a nuclear reactor,
- b) the scope and method of documenting the facts under paragraph 1(a)(b) and (c)(1) through (3).

§ 53

**Obligations of holders of a licence for the commissioning of a nuclear installation without a nuclear reactor**

(1) Holders of a licence for the commissioning of a nuclear installation without a nuclear reactor shall

- a) prior to commencing active testing
  1. perform and document a check of the nuclear installation's readiness for this phase,
  2. verify the existence and accuracy of the active testing programme and sub-programmes, limits and conditions, internal regulations, including emergency operating rules and internal rules drawn up in accordance with the on-site emergency plan and the management system programme, and
  3. ensure and verify the overall readiness of the nuclear installation and its personnel for active testing,

- b) perform active testing,
- c) verify and demonstrate the design characteristics of the nuclear installation and its compliance with the nuclear installation design in trial operation under the actual future operational states, and
- d) accumulate the decommissioning reserves in accordance with § 51(2) to (4) and 6(c) and the funding of the reserve use only for the preparation and implementation of decommissioning and with the approval by the Authority.

(2) Implementing legislation shall establish

- a) rules for nuclear safety assurance when commissioning a nuclear installation without a nuclear reactor,
- b) the scope and method of documenting a check of the nuclear installation's readiness for active testing.

#### § 54

#### **Obligations of holders of a licence for the operation of a nuclear installation**

(1) Holders of a licence for the operation of a nuclear installation shall

- a) continuously ensure, verify and document that the nuclear installation is capable of stable and safe operation,
- b) inform the office of a planned permanent shutdown of a nuclear installation no less than two years prior to the planned permanent shutdown,
- c) accumulate the decommissioning reserves in accordance with § 51(2) to (4) and 6(c) and the funding of the reserve use only for the preparation and implementation of decommissioning and with the approval by the Authority,
- d) prior to entering the first phase of decommissioning of the nuclear installation, transport any spent fuel, if placed in the nuclear installation, to another nuclear installation intended for management of nuclear fuel,
- e) in the case of a research nuclear installation, perform a long-term shut-down of the nuclear reactor, if reasons exist for its temporary non-use, and
- f) ensure decommissioning of the nuclear installation or closure of the radioactive waste disposal facility without delay after their operation has been ceased.

(2) Holders of a licence for the operation of a nuclear installation shall, prior to bringing a nuclear reactor to criticality,

- a) ensure that the systems, structures and components necessary for the operation of the nuclear installation are in good working order to provide for reliable and safe operation, in compliance with the nuclear installation design,
- b) in the case that the shut-down is performed for a cause other than replacement of the fuel in the nuclear reactor,
  - 1. analyse and eliminate the causes that led to the shut-down and
  - 2. take corrective action to prevent the recurrence of operational occurrences, and
- c) ensure and verify the readiness of the nuclear installation and its personnel for bringing the nuclear reactor back to criticality and for further operation.

(3) After replacement of the fuel in the nuclear reactor, holders of a licence for the operation of a nuclear installation shall

- a) meet the pass criteria for works and tests relating to fuel replacement,
- b) perform a check of the loading of nuclear fuel into the nuclear reactor,

- c) perform physical start-up in accordance with internal regulations and demonstrate to the office compliance with the physical start-up criteria,
- d) during the physical start-up, verify the neutron-physical characteristics of the nuclear reactor's active zone and the related safety functions,
- e) ensure and verify the readiness of the nuclear installation for its first power-generation start-up,
- f) provide the office with evidence of the readiness of the nuclear installation and its personnel for bringing the nuclear reactor back to criticality after nuclear fuel replacement by presenting the following documents:
  - 1. information about the neutron-physical characteristics of the nuclear reactor's active zone,
  - 2. loading cartogram,
  - 3. updating statement with regard to updates to internal regulations made on the basis of modifications during the previous operation of the nuclear installation,
  - 4. evidence and reports on the testing of the readiness of equipment relevant to nuclear safety,
  - 5. evidence and reports from operational checks,
  - 6. evidence of compliance with acceptance criteria,
  - 7. a summary document on the results of the checks on the readiness of the nuclear installation and its personnel for further operation,
  - 8. timetable of further operation of the nuclear installation, including the programme for recommissioning of the nuclear installation and programmes for the physical and power-generation start-ups of the nuclear installation, and
- g) perform power-generation start-up of the nuclear installation.

(4) Implementing legislation shall establish

- a) the rules for continuously ensuring, verifying and documenting that the nuclear installation is capable of stable and safe operation,
- b) the reasons for the temporary non-use of a nuclear reactor leading to its long-term shut-down, in the case of a research nuclear installation,
- c) the method of performing the long-term shut-down of a nuclear reactor, in the case of a research nuclear installation,
- d) terms for presenting to the office the documentation for bringing a nuclear reactor back to criticality after nuclear fuel replacement and the requirements for its content.

## § 55

### **Obligations of holders of a licence for the decommissioning of a nuclear installation**

(1) Holders of a licence for the decommissioning of a nuclear installation shall

- a) have introduced a system of
  - 1. radioactive waste management,
  - 2. monitoring, which takes into account changes in the nuclear installation in the different phases of decommissioning,
  - 3. checks, testing and maintenance of systems, structures and components of the nuclear installation being decommissioned, with emphasis on their availability, functionality and reliability in the process of decommissioning, including in the periods between the different phases of decommissioning, and
  - 4. collection, evaluation and archiving of any data necessary for the purposes of decommissioning, including data on the quantities of substances released into the environment and radioactive waste stored of the site for a nuclear installation,

- b) once a year, draw up and forward to the office an evaluation of the different phases of decommissioning, including compliance with the timetable,
- c) in the case of deferred dismantling, ensure that passive safety features are used in the periods between the different phases of decommissioning,
- d) draw up a proposal for the use of the decommissioning reserves in accordance with the approved decommissioning plan,
- e) the funding of the decommissioning reserves use only for the preparation and implementation of decommissioning and with the approval by the Authority,
- f) retain the data under (a), Point 4), for a period of 20 years from the complete decommissioning or decommissioning with restrictions on its use for other activities related to the use of nuclear energy or activities in exposure situations (hereinafter the „completion of the decommissioning“), and
- g) where the installation is a radioactive waste disposal facility, complete the decommissioning of the nuclear installation by closure of the radioactive waste disposal facility.

(2) Implementing legislation shall establish the scope and method of decommissioning and completion of decommissioning of a nuclear installation.

### Part 3

#### **Selected equipment and technical safety**

##### § 56

#### **Quality assurance for selected equipment**

(1) Licence holders referred to in § 9(1)(b) to (h) shall ensure the quality of selected equipment so that the nuclear installation of which the selected equipment is part is capable of performing the safety functions and document the quality assurance for selected equipment by means of records.

(2) Implementing legislation shall establish

- a) the scope and method of quality assurance for selected equipment in the process of its design, manufacture, procurement, commissioning and operation,
- b) the types of records and the method of record-keeping of quality assurance for selected equipment.

##### § 57

#### **Technical safety**

(1) Anyone who designs, manufactures, assembles, puts into service, repairs or performs maintenance of selected equipment or its parts whose failure or wrong function may endanger technical safety of selected equipment (hereinafter “parts of selected equipment”) and licence holders referred to in § 9(1)(b) to (h) shall ensure compliance of selected equipment or parts of selected equipment with technical requirements and document how this compliance is ensured.

(2) The technical safety of selected equipment and parts of selected equipment shall be ensured throughout their expected life-span when used under reasonably foreseeable and technically justifiable conditions.

(3) Implementing legislation shall establish

- a) the technical requirements for selected equipment and parts of selected equipment,
- b) the requirements for the method of ensuring compliance of selected equipment and parts of selected equipment with technical requirements,
- c) the requirements for the documentation on ensuring compliance of selected equipment and parts of selected equipment with technical requirements.

§ 58

**Assessment of conformity of selected equipment with technical requirements**

(1) Anyone who designs, manufactures or performs assembly of selected equipment after manufacture shall ensure that this equipment is assessed for conformity with technical requirements.

(2) The conformity of selected equipment with technical requirements shall be assessed by

- a) a person authorised under the act on technical requirements for products,
- b) a person accredited under the act on technical requirements for products, or
- c) the manufacturer or importer of selected equipment.

(3) Authorisation for assessment of conformity of selected equipment with technical requirements may only be granted on the basis of a binding affirmative statement of the office.

(4) Anyone who imports selected equipment for the purposes of using it in the Czech Republic shall ensure that this equipment is assessed for conformity with technical requirements, except cases when, in the State in which it was manufactured, the selected equipment complies with

- a) technical regulations for nuclear installations that are binding for the manufacture of this selected equipment,
- b) technical standards or rules of good practice intended for nuclear installations, which are issued by a national standardisation Authority or a body of equivalent status,
- c) international technical standards for nuclear installations legitimately applied in that State, or
- d) manufacturing procedures which are applied for nuclear installations in accordance with the legislation of the State in which it was manufactured and for which sufficiently detailed technical documentation exists ensuring that this selected equipment may, if necessary, also be assessed for the given purpose of use based on additional testing of the selected equipment, provided that these technical regulations, technical standards, or rules or procedures of good practice guarantee a level of protection of legitimate interests corresponding to that guaranteed in the Czech Republic.

(5) Holders of a licence for the operation of a nuclear installation may use selected equipment only after it has passed conformity assessment, unless it has been imported and complies with the conditions referred to in paragraph 4.

(6) The cost of assessment of conformity of selected equipment with technical requirements shall be borne by the person for whose benefit it is performed.

(7) Implementing legislation shall establish

- a) the procedures and scope of assessment of conformity of selected equipment with technical requirements,



- b) the requirements for documenting the assessment of conformity of selected equipment with technical requirements,
- c) particular methods which may be used by the persons under paragraph 2 to assess conformity of selected equipment with technical requirements.

§ 59

**Verification of conformity of selected equipment with technical requirements**

(1) Holders of a licence for the operation of a nuclear installation shall ensure regular verification of the conformity of selected equipment in service with technical requirements.

(2) Anyone who repairs, maintains or reassembles selected equipment after repair or maintenance shall ensure that the conformity of this equipment with technical requirements is assessed before reuse.

(3) Holder of a licence for the operation of a nuclear installation shall ensure documenting of verification of conformity of selected equipment with technical requirements.

(4) Implementing legislation shall establish

- a) the scope and method of verification of conformity of selected equipment with technical requirements,
- b) the method of documenting and the content of the documentation on the verification of conformity of selected equipment with technical requirements.

Title II

**Radiation protection**

Part 1

**Principles and general rules of radiation protection**

§ 60

**Definition of certain terms in the area of ensuring radiation protection**

- (1) For the purposes of this Act, the following definitions shall apply
- a) sealed radionuclide source means a radionuclide source whose treatment using encapsulation or a protective cover ensures leak tightness, which has been verified by testing and precludes leakage of the radionuclide under foreseeable conditions of use and wear,
  - b) unsealed radionuclide source means a radionuclide source which is not a sealed radionuclide source,
  - c) supervised area means an area subject to supervision for the purposes of radiation protection,
  - d) controlled area means an area to which access is controlled and, in which specific rules are in place to ensure radiation protection and prevent the spread of contamination,
  - e) outside worker means any exposed worker, who is not employed by the operator of a supervised and controlled area, but performs activities in this area, including apprentice or student.
- (2) For the purposes of this Act, the following definitions shall apply

- a) dose constraint means a prospective upper bound of individual doses set out for the purposes of optimisation of radiation protection for a given source of ionising radiation in a planned exposure situation,
- b) reference level means the level of exposure or risk of exposure in an emergency exposure situation or in an existing exposure situation, the exceeding of which is undesirable; optimisation of radiation protection shall not be considered to have been achieved by reducing the level of exposure or risk of exposure to the reference level,
- c) interventional radiology means the use of X-ray imaging techniques to facilitate the introduction and guidance of a device or accessory in the human body for diagnostic or treatment purposes,
- d) diagnostic reference level means the dose level in radiodiagnostics or interventional radiology or, in the case of radio-pharmaceuticals, the level of activity for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment,
- e) radiological occurrence means an occurrence during medical exposure, which causes erroneous exposure of a patient,
- f) health detriment following exposure means reduction in length and quality of life occurring in a population, including reduction in length and quality of life arising from tissue reactions, cancer and severe genetic disorder.

(3) For the purposes of this Act, the following definitions shall apply

- a) orphan source means a radionuclide source which is not under regulatory control, especially because it has never been under regulatory control or because it has been abandoned or lost by its holder, stolen from the holder or acquired by the holder accidentally, or without notifying the Office,
- b) disused source means a radionuclide source which is no longer used or intended to be used for the practice for which licence was granted by the Office,
- c) recognised storage facility means a workplace authorised for the collection or storage of radionuclide sources, including high-activity sources,
- d) high-activity source means a sealed radionuclide source whose activity is equal to or exceeds that laid down for the given radionuclide in implementing legislation,
- e) building site radon index means an indicator of the degree of risk of radon migration from the subsoil; the building site radon index may be low, medium or high,
- f) exposure to radon means exposure to radon progeny.

(4) Implementing legislation shall establish

- a) exposure of a patient considered to be erroneous for the purposes of defining a radiological occurrence,
- b) radionuclide activity at which a sealed radionuclide source is a high-activity source.

## § 61

### **Categorisation in the area of ensuring radiation protection**

(1) For the purposes of a graded approach to the management of activities, sources of ionising radiation shall be categorised as insignificant, minor, simple, significant and very significant, depending on the degree of risk to health and to the environment posed by ionising radiation. In justified cases, the office may, by decision, change a category of a source of ionising radiation in a frame of categories set in the first sentence. When deciding on the classification of a source of ionising radiation in another category, the office shall take into consideration the typical method of management of the source of ionising radiation, the related

level of possible exposure of workers and the potential risk arising from foreseeable breakdowns and deviations from normal operation of the sources of ionising radiation.

(2) For the purposes of management of transboundary movement and security of radionuclide sources, radionuclide sources shall be classified in security categories 1 to 5 (hereinafter “security categories”) depending on their activity.

(3) Workplaces in which activities involving radiation are conducted shall be classified in categories I, II, III or IV. In justified cases, the office may, by decision, change a category of a workplace in a frame of categories set in the first sentence. When deciding on the classification of a workplace in another category, the office shall take into consideration the workplace’s typical method of operation, the related level of possible exposure of workers and the general public and the potential risk arising from foreseeable breakdowns and deviations from normal operation of the workplace.

(4) For the purposes of monitoring and occupational medicine services, exposed workers shall be classified in categories A or B depending on the degree of possible health risks associated with ionising radiation.

(5) Exposure to ionising radiation in the workplace shall be considered a risk factor of the working conditions in workplaces. Work which may only be performed by exposed workers of category A shall be considered second category work and risk-involving work pursuant to act on protection of a public health; other work involving exposure to ionising radiation in the workplace shall be considered first category work.

(6) Implementing legislation shall establish

- a) criteria for classifying sources of ionising radiation in categories,
- b) the method of classification of radionuclide sources in security categories,
- c) the criteria for classifying workplaces in the appropriate category,
- d) the rules for classifying exposed workers in categories A or B.

## § 62

### **Restriction of exposure**

Anyone who performs an activity in planned exposure situations shall restrict exposure of natural persons so that the total exposure resulting from a combination of exposures from these activities is justified, optimised and does not exceed in total the exposure limits.

## § 63

### **Exposure limits**

(1) An exposure limit is a quantitative indicator for the restriction of the total exposure of a natural person from activities in planned exposure situations.

(2) Exposure limits include

- a) general limits for the general public,
- b) limits for exposed workers,
- c) limits for apprentices and students.

(3) An authorised limit is a quantitative indicator which is a result of radiation protection optimisation for individual activities involving radiation or an individual source of ionising radiation and is usually lower than the dose constraint. Authorised limits shall be laid down by the Office in the licence for activities performed in exposure situations. If authorised limits are not exceeded, this demonstrates that exposure limits have not been exceeded.

(4) If it is found in the context of radiation protection optimisation that a limit for exposed workers set for a certain period cannot be complied with for a specific activity involving radiation, the Office may approve, by decision, on the basis of assessment of the level of radiation protection and risks arising from exposure, a different method of exhausting this limit over time.

(5) Medical exposure shall not be subject to exposure limits.

(6) Implementing legislation shall establish the exposure limit values and the method of managing them.

## § 64

### **Restriction of exposure in specific cases**

(1) Holders of a licence for the performance of activities in exposure situations who perform medical exposure shall restrict exposure of natural persons who

- a) voluntarily, outside their professional duties, provide care to patients exposed to medical exposure, visit these patients or live in a common household with patients who have been released from a health establishment following application of radionuclide, so that in total, over a calendar year, the effective dose constraint of 1 mSv for natural persons under the age of 18 and 5 mSv for other natural persons is not exceeded,
- b) voluntarily assist a natural person undergoing medical exposure, so that in total, over a calendar year, the effective dose constraint of 5 mSv is not exceeded; these natural persons shall
  1. be over 18 years of age,
  2. be instructed about the risks arising from exposure,
  3. be equipped with means of protection, and
  4. confirm in writing their consent to exposure.

(2) The exposure of natural persons referred to in paragraph 1 must show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the natural person providing care and assistance and the possible health detriments following exposure.

(3) As soon as holders of a licence for the performance of activities in exposure situations are informed by a pregnant woman working in their category I to IV workplace of her pregnancy, they shall adjust her employment conditions to restrict exposure of the unborn child so that the total of effective doses from external exposure and committed effective doses from internal exposure of the unborn child are unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

(4) As soon as holders of a licence for the performance of activities in exposure situations are informed by a breastfeeding woman working in their category I to IV workplace that she is breastfeeding a child, they shall adjust her employment conditions to restrict exposure of the

infant by the intake of radionuclide from contaminated mother's milk and reassign her from work in the controlled area of a workplace with an unsealed radionuclide source.

§ 65

**Exceptional exposure**

(1) If licence holders intend to perform work in a planned exposure situation in which the expected exposure of an exposed worker may exceed the limits for exposed workers (hereinafter "exceptional exposure"), they shall apply to the Office in advance for approval of exceptional exposure. The application for approval of exceptional exposure shall contain justification of the exceptional exposure and the radiation protection optimisation procedures for the exceptional exposure.

(2) Based on an assessment of the level of radiation protection and risks arising from the exceptional exposure, the Office may approve, by decision, exceptional exposure in the case of a one-off, short-term or other exceptional operation with a source of ionising radiation limited to a small number of natural persons and confined to certain areas, which is not performed in the context of an emergency exposure situation. In its decision approving exceptional exposure, the Office shall determine the level of approved exceptional exposure and the period for which the exposed worker may be subject to exceptional exposure.

(3) Holders of a licence for performing activities in exposure situations shall restrict exceptional exposure so that the effective dose from repeated exceptional exposures does not exceed 500 mSv over five consecutive calendar years.

(4) Only exposed workers of category A may be subject to exceptional exposure, and this with his/her consent, after having been instructed about the associated risks.

(5) Holders of a licence for performing activities in exposure situations shall in advance discuss work involving exceptional exposure and the conditions for such work with the representatives of employees subject to exceptional exposure and the provider of occupational medicine services.

(6) Exceptional exposure shall not be permissible in the case of natural persons who are under the age of 18 years, apprentices, students, and pregnant and breastfeeding women.

§ 66

**Radiation protection optimisation**

(1) Anyone who performs an activity in exposure situations shall take into account the extent of exposure, its likelihood and the number of natural persons exposed to radiation, when optimising radiation protection.

(2) Anyone who performs an activity in exposure situations shall optimise a radiation protection

a) before the start of activities in a planned exposure situation, by assessing alternative solutions to radiation protection that come into consideration, having regard to the costs, collective dose, doses received by representative persons and good practice,

- b) when performing activities in a planned exposure situations, by regularly analysing the relationship between the doses received and the operations performed, taking into account additional measures to ensure radiation protection, and by comparing it to a similar socially acceptable activity that is being carried out,
- c) before implementing measures to ensure radiation protection in an existing or emergency exposure situation and prior to the discharge of a radioactive substance from a workplace with potentially increased exposure to a natural source of radiation, by assessing possible alternative measures and choosing a measure which, due to its method of implementation, scope and period of duration, delivers the greatest net benefits,
- d) when implementing measures to ensure radiation protection in an existing or emergency exposure situation, by analysing the doses received in relation to the measures being taken and considering changes to the measures and procedures chosen.

(3) Anyone who performs an activity in planned exposure situations shall apply the dose constraints referred to in § 81(1) in order to optimise public exposure.

(4) In order to optimise the exposure of workers in planned exposure situations, licence holders shall determine the relevant dose constraints for a set period of time in the monitoring programme.

(5) Anyone who performs an activity in existing or emergency exposure situations shall use the reference levels in order to optimise radiation protection of the general public, exposed workers and emergency workers and optimisation shall, as a matter of priority, focus on exposure exceeding the reference level.

(6) Implementing legislation shall establish

- a) the reference levels,
- b) the method of application of the reference levels,
- c) the procedures used when optimising radiation protection, including the method of determination of dose constraints.

## Part 2

### **Regulation of planned exposure situations**

#### § 67

#### **Exemptions**

(1) Anyone can perform activities involving radiation without notification, registration or licence, if they are justified and performed with a source of ionising radiation,

- a) which is a radioactive substance whose activity is lower than the exemption level value or equipment containing or releasing such a substance,
- b) which is a radiation generator emitting ionising radiation with energy not exceeding 5 keV,
- c) which is a cathode-ray tube intended for the display of visual images or other electrical apparatus operating at a potential difference not exceeding 30 kV, which causes an equivalent dose rate of less than 0.001 mSv/h at any accessible place at a distance of 0.1 m from the surface of the apparatus, or
- d) which has been discharged from a workplace in compliance with this Act.

(2) Anyone may perform an activity with a ionising radiation source without notification, registration or license when the activity is justified and where is so established by the Office by

means of a general measure, if the health risk associated with exposure of a natural person caused by the activity is so low that regulation of the activity is not necessary.

(3) The exemption under paragraphs 1 or 2 shall not apply to the addition of a radioactive substance to consumer products when manufacturing or preparing them and when importing and exporting such consumer products, which may only be carried out on the basis of a licence under § 9(2)(g).

(4) Implementing legislation shall establish the value and method of application of the exemption level.

#### Subpart 1

### **Obligations of licence holders, registered persons and notifying persons in the area of ensuring radiation protection**

#### § 68

### **Obligations common to licence holders and registered persons in the area of ensuring radiation protection**

(1) Licence holders performing activities in planned exposure situations and registered persons shall

- a) ensure monitoring of the sum of doses from all work activities of their exposed workers and compare the sum of the doses with the limits for exposed workers,
- b) forward the results of individual monitoring of an exposed worker to another licence holder or registered person for whom the exposed worker also performs work activities and cooperate with this licence holder or registered person when determining the causes for exceeding the limits for the exposed worker, if the doses leading to the exceedance were received while working for multiple licence holders or registered persons,
- c) immediately notify the Office of an exceedance of the exposure limit,
- d) allow only persons authorised for the management of sources of ionising radiation under this Act to manage these sources,
- e) classify the source of ionising radiation used and the workplace operated in the appropriate category,
- f) ensure that the characteristics of sources of ionising radiation are evaluated by means of
  1. acceptance testing, unless these are insignificant or minor sources of ionising radiation, which is not ionising radiation source for non-medical exposure, bone densitometers, sealed radionuclide sources manufactured no more than six months ago or sources of ionising radiation received solely for storage, carriage or distribution, sources of ionising radiation manufactured by the users for their own use, prototypes or unique equipment, and
  2. long-term stability testing, unless these are insignificant or minor sources of ionising radiation, bone densitometers, unsealed radionuclide sources, sources of ionising radiation manufactured by the users for their own use, prototypes or unique equipment,
- g) perform verification of the characteristics of sources of ionising radiation by means of operational stability testing, unless these are insignificant sources of ionising radiation or unsealed radionuclide sources, evaluate the results of this testing and, in the event of unsatisfactory results, take corrective action,
- h) use sources of ionising radiation in accordance with the instructions for their use,
- i) not use a source of ionising radiation, if
  1. it has not passed acceptance testing, or

2. it has not passed long-term stability testing or the period elapsed since it last passed long-term stability testing is longer than that fixed for periodic testing or other reasons for performing this testing have arisen,
- j) in workplaces where activities involving radiation are performed, draw up and make permanently available intervention instructions and internal regulations; internal regulations shall lay down the procedures for the safe management of sources of ionising radiation, including procedures to prevent unauthorised handling of sources of ionising radiation, their loss, theft or damage, and including procedures for cases of deviations from normal operation,
  - k) if they import or distribute a source of ionising radiation, at the request of the user of the source of ionising radiation imported or distributed by them, take the source of ionising radiation back and ensure its safe delivery to the manufacturer or another person authorised for management of the source,
  - l) if a radioactive substance is added to a consumer product while it is manufactured or prepared or while it is imported or exported, ensure that the documentation provided to the user of the consumer product containing a radionuclide includes information about
    1. the added radioactive substance, its type and activity,
    2. the dose rate under normal conditions and in maintenance,
    3. possible health detriments following exposure,
    4. type-approval of the product,
    5. proper use, installation, maintenance and repair, and
    6. the recommended method of disposal,
  - m) if they import or distribute a source of ionising radiation, ensure that the documentation provided to the user of the imported or distributed source of ionising radiation includes
    1. information about the category classification of the source of ionising radiation,
    2. the proposed scope of acceptance testing, long-term stability testing and operational stability testing to be performed,
    3. a certificate, in the case of a sealed radionuclide source, or accompanying document, in the case of an unsealed radionuclide source,
    4. instructions for use, including instructions for the safe use and disposal of the source of ionising radiation by the user,
    5. information about the potential radiological risks associated with its use,
    6. evidence that the construction of its equipment makes it possible to restrict exposure to a level which is as low as reasonably achievable, and
    7. in the case of equipment used for medical exposure, information about the risks for patients and the available results of trials of a new method, including practical training,
  - n) inform exposed workers and natural persons undertaking occupational training in a controlled or supervised area about the facts relevant to radiation protection relating to the performance of their work,
  - o) ensure continuous training of exposed workers, verify their knowledge and document this continuous training,
  - p) equip exposed workers with personal protective equipment with a sufficient shielding effect and appropriate protective accessories, and
  - q) immediately report to the Office any case of unauthorised access or serious damage to a source of ionising radiation.

(2) Implementing legislation shall establish

- a) the scope and frequency of the testing referred to in paragraph 1(f),
- b) the scope and frequency of the operational stability testing executed by a registered person,



- c) rules for determination of the scope and frequency of the operational stability testing executed by a license holder,
- d) list of persons providing the operational stability testing,
- e) list of persons obliged to ensure fulfilling of obligations under paragraph 1(g),
- f) the method of assessment of the operational stability testing and utilizing of its results, including the method and term of filing of results,
- g) the criteria for evaluating long-term stability testing and the rules for eliminating defects detected by this testing and method for determination of terms for remedy of defects,
- h) the scope, content and method of providing the information provided under paragraph 1(n),
- i) the scope and method of continuous training for exposed workers, the method and frequency of verifying their knowledge and the method of documenting continuous training,
- j) the contents of intervention instructions.

## § 69

### **Special obligations of licence holders in the area of ensuring radiation protection**

- (1) Licence holders performing activities in planned exposure situations shall,
- a) if they manage a source of ionising radiation or provide a service in a controlled area to an operator of a category IV workplace, perform annually an evaluation of the method of radiation protection assurance for the activity performed and forward the evaluation to the Office by 30 April of the following calendar year,
  - b) if they manufacture a source of ionising radiation, at the request of its user, take back the source of ionising radiation that they manufactured and ensure its safe disposal or reuse,
  - c) perform inventory checks of sources of ionising radiation, including physical checks of their presence and report the results to the Office,
  - d) in the case of management of a sealed radionuclide source, manage it as if it were unsealed, if
    1. its leak tightness is not evidenced or
    2. leakage has been detected,
  - e) when decommissioning a category IV workplace with a radioactive waste disposal facility, complete the decommissioning by closing the radioactive waste disposal facility, and
  - f) document and report to the office the implementation of modifications related to radiation protection, radiation situation monitoring and radiation extraordinary event management in a workplace with a source of ionising radiation.
- (2) Implementing legislation shall establish
- a) the scope and method of evaluating the method of radiation protection assurance for the activities performed, as referred to in paragraph 1(a),
  - b) the types of sources of ionising radiation for which inventory checks shall be performed, the scope, method and frequency of inventory checks and the scope of results to be forwarded to the Office,
  - c) the methods of evidencing leak tightness of sealed radionuclide sources,
  - d) the list of modifications that relate to radiation protection, radiation situation monitoring and radiation extraordinary event management in a workplace with a source of ionising radiation,
  - e) the scope and method of documenting modifications related to radiation protection, radiation situation monitoring and radiation extraordinary event management in a workplace with a source of ionising radiation and the method and terms of its reporting to the office.

§ 70

**Special obligations of registered persons in the area of ensuring radiation protection**

(1) Registered persons shall

- a) if they use dental or veterinary x-ray equipment or an x-ray bone densitometer, designate a natural person ensuring radiation protection of the registered person and ensure that this person is trained and present in the workplace,
- b) follow the procedures for ensuring radiation protection by registered persons when using sources of ionising radiation, and
- c) immediately report to the Office any changes to the facts relevant to radiation protection and changes in information provided in the registration form.

(2) Implementing legislation shall establish

- a) the scope, method and frequency of providing training to the person ensuring radiation protection of the registered person,
- b) the job description of the person ensuring radiation protection of the registered person,
- c) the procedures for ensuring radiation protection by registered person when using sources of ionising radiation.

§ 71

**Special obligations of notifying persons in the area of ensuring radiation protection**

(1) Notifying persons using a type-approved minor source of ionising radiation shall

- a) ensure the safe discontinuation of the use of the source of ionising radiation,
- b) keep and retain a register of sources of ionising radiation and forward data from the register to the Office,
- c) inform exposed workers about facts relevant to radiation protection in relation to the activities they perform,
- d) verify the characteristics of the source of ionising radiation by means of operating stability testing in accordance with a manual, and
- e) use the source of ionising radiation in accordance with the instructions for its use.

(2) Implementing legislation shall establish the scope, method and period of retaining records on sources of ionising radiation and forwarding them to the Office.

§ 72

**Continuous surveillance of radiation protection**

(1) Holders of a licence for the management of a source of ionising radiation, management of radioactive waste, operation of a category III workplace or category IV workplace or the individual phases of decommissioning of a category III workplace or a category IV workplace shall ensure continuous surveillance of radiation protection by a supervising person and, in a workplace of category II or higher, by a person directly supervising radiation protection.

(2) Holders of a licence for the provision of services in a controlled area to an operator of a category IV workplace shall ensure continuous surveillance of radiation protection by a supervising person. When providing services in a controlled area to an operator of a category IV workplace, the operator of the controlled area in which the activities are performed shall

ensure continuous surveillance of radiation protection of natural persons providing services in a controlled area by a person directly supervising radiation protection.

(3) Continuous surveillance of radiation protection shall be ensured within a scope corresponding to the activities performed, the method of management of the source of ionising radiation and the level of possible exposure, including potential exposure.

(4) In order to perform continuous surveillance of radiation protection at an energy-generating nuclear installation, holder of a licence for operation of a category IV workplace shall set up a specialised radiation protection unit, which shall be organisationally independent of the licence holder's operating and production units.

(5) Implementing legislation shall establish

- a) the scope and method of performance of the activities of a supervising person,
- b) the category of exposed worker in the case of supervising persons,
- c) the scope and method of performance of the activities of a person directly supervising radiation protection,
- d) the category of exposed worker in the case of persons directly supervising radiation protection,
- e) the scope and method of performance of the activities of specialised radiation protection unit ensuring continuous surveillance of radiation protection at an energy-generating nuclear installation.

## Subpart 2

### **Requirements for the safe operation of a workplace with a source of ionising radiation**

#### § 73

#### **Controlled area**

(1) In a workplace with a source of ionising radiation where the effective dose can be expected to exceed 6 mSv per year or the equivalent dose to exceed three-tenths of the limit for exposed workers for the skin or limbs or 15 mSv for the lens of the eye, the holder of a licence referred to in § 9(2)(b) and (f) shall delineate a controlled area, document its operation and ensure radiation protection of natural persons entering it.

(2) Licence holders delineating a controlled area shall immediately report to the Office

- a) the delineation of a controlled area,
- b) a modification of the delineation of a controlled area and
- c) the cancellation of a controlled area.

(3) Implementing legislation shall establish

- a) the scope and method of delineating a controlled area,
- b) the scope of restrictions on entry into the controlled area,
- c) the conditions for the performance of work in a controlled area,
- d) the method of radiation protection assurance in a controlled area,
- e) the requirements for documenting the operation of a controlled area.

#### § 74

#### **Supervised area**

(1) In a workplace with a source of ionising radiation where the effective dose can be expected to exceed 1 mSv per year or the equivalent dose to exceed one-tenth of the exposure limit for exposed workers for the lens of the eye, skin or limbs, the licence holder or registered person shall delineate a supervised area, document its operation and ensure radiation protection of natural persons entering it.

(2) If the scope of the supervised area would not exceed the scope of the controlled area, it shall not be delineated.

(3) Licence holders or registered persons delineating a supervised area shall immediately report to the Office

- a) the delineation of a supervised area,
- b) a modification of the delineation of a supervised area and
- c) the cancellation of a supervised area.

(4) Implementing legislation shall establish

- a) the scope and method of delineating a supervised area,
- b) the method of radiation protection assurance in a supervised area,
- c) the requirements for documenting the operation of a supervised area.

## § 75

### **Safe operation of a workplace**

(1) Licence holders performing activities in planned exposure situations, registered persons or notifying persons using a type-approved minor source of ionising radiation

- a) shall ensure that the workplace where activities involving radiation are to be performed is designed, built and put into service in a manner enabling the safe management of sources of ionising radiation in operation and ensuring adequate radiation protection of natural persons in the workplace and natural persons present in the surrounding area,
- b) shall comply with the conditions for the safe operation of a workplace with a source of ionising radiation and
- c) may discontinue the operation of a category I workplace or category II workplace only after all sources of ionising radiation have been removed or after they have been secured against unauthorised use and after the workplace has been cleaned of radioactive substances; after the workplace has been cleaned, the clearance level shall not be exceeded in the workplace.

(2) Holders of a licence for the operation of a category III workplace or category IV workplace shall

- a) inform the Office of their decision to discontinue the operation of the workplace and, prior to discontinuing the operation, file a licence application for the individual phases of decommissioning of the workplace,
- b) accumulate reserves for the decommissioning of the workplace they operate in accordance with § 51(2) to (4) and 6(c) and the funding of the reserve use only for the preparation and implementation of decommissioning and with the approval by the Authority and
- c) decommission the workplace they operate.

(3) The obligation to accumulate decommissioning reserves for the decommissioning of category III workplaces and category IV workplaces shall not apply to organisational units of the State and state contributory organisations, public higher education institutions,

organisational units and contributory organisations established by regional authorities, and state enterprises for which phase-out of operations has been declared by their founders.

(4) Holder of a licence for the individual phases of decommissioning of a category III workplace or a category IV workplace shall prepare draft of using of decommissioning reserves for decommissioning in accordance with an approved plan of decommissioning and funds of the reserves use only for preparation and realisation of decommissioning and after the approval of the Authority.

(5) Implementing legislation shall establish

- a) the conditions for the safe operation of a workplace with a source of ionising radiation with regard to the type of the source of ionising radiation,
- b) the scope and method of decommissioning of a category III workplace or a category IV workplace,
- c) the scope and method of completing the decommissioning of a category III workplace or a category IV workplace,
- d) the method of setting reserves for the decommissioning of a category III workplace or a category IV workplace.

## § 76

### **Discharges from a workplace with radiation activity**

(1) A radioactive substance may be discharged from a workplace with radiation activity without a licence of the office if clearance levels as stipulated by the implementing legislation are not exceeded.

(2) Exemption under paragraph (1) shall not apply to

- a) workplace with a nuclear installation,
- b) workplace where an activity related to acquiring of radioactive minerals is performed, or
- c) workplace where stones from tips coming from activities related to acquiring of radioactive minerals are processed.

(3) Radioactive substances may be discharged from a workplace without a licence of the office also if the effective dose of each member of the public during a calendar year caused by a discharge is lower than 0,01 mSv.

(4) Exemption under paragraph (3) shall not apply to discharges of radioactive substances from a workplace with a nuclear installation to the air or waterstream.

(5) Anyone who discharges radioactive substances from a workplace under paragraph (3) shall inform the office at least 60 days in advance about

- a) type of discharged radioactive substances,
- b) activity of radionuclides in discharged radioactive substances,
- c) place, time and method of discharging and
- d) assessment of exposure to a member of the public confirming compliance with conditions under paragraph (3).

(6) Implementing legislation shall establish values of clearance levels for a workplace with radiation activity and conditions under which they are considered as exceeded.

§ 77

**Temporary workplace**

(7) Holders of a licence for the use of a source of ionising radiation may perform activities in a previously unspecified temporary workplace indented for the use of a source of ionising radiation (hereinafter “temporary workplace”) for a period not exceeding 30 days, provided that the radiation protection of the general public, workers and the area surrounding the temporary workplace is ensured. The performance of activities in a temporary workplace shall be reported to the office in advance by the holder of a licence for the use of a source of ionising radiation.

(8) Implementing legislation shall establish

- a) the scope and method of delineating a controlled area in a temporary workplace,
- b) the method of assurance of radiation protection of the general public, workers and the area surrounding the temporary workplace,
- c) the scope, method and period of reporting to the office the performance of activities in a temporary workplace.

Subpart 3

**Special requirements for radiation protection of workers, the general public and patients**

Section 1

**Radiation protection of workers**

§ 78

**Exposed workers**

(1) Holders of a licence for the performance of activities in exposure situations and registered persons shall

- a) classify exposed workers in categories A or B,
- b) maintain a list of their exposed workers,
- c) in the case of changes in working conditions that could lead to a change in the exposure of an exposed worker, verify the correct classification of the exposed worker in categories A or B,
- d) ensure individual monitoring of exposed workers and monitoring of the workplace depending on the scope and method of the activities performed,
- e) determine the monitoring levels and procedure in the event they are exceeded in accordance with general procedures for their exceeding set by the implementing legislation,
- f) in the event of exposure to external radiation, equip exposed workers of category A with personal dosimeters and ensure their evaluation,
- g) ensure that the level of radiation protection of apprentices and students is equivalent to that of other exposed workers, and
- h) provide exposed workers with the results of their individual monitoring.

(2) Only a worker aged 18 years or over may be an exposed worker, except apprentices and students aged between 16 and 18 years who are obliged to work with sources of ionising radiation in the course of their studies. Apprentices and students aged between 16 and 18 years may only be classified in category B. Apprentices and students aged 18 years or over may be classified in categories A or B, depending on the activity performed.

(3) Implementing legislation shall establish

- a) the requirements for individual monitoring of exposed workers,
- b) the requirements for the monitoring of the workplace,
- c) the types of monitoring levels for the evaluation of the results of monitoring and general procedures for their exceeding,
- d) the procedures for evaluation of the quantities measured in the context of monitoring,
- e) the rules of equipping exposed workers of category A with personal dosimeters and handling and evaluating them, including length of period for their evaluation,
- f) the method of providing the results of individual monitoring to exposed workers.

§ 79

**Outside workers**

(1) Outside workers of category A, who perform activities involving radiation in a controlled area, shall be provided with an individual radiological monitoring document.

(2) The persons below shall ensure the full scope of radiation protection of outside workers, including the provision of the individual radiological monitoring document, if so required under this Act

- a) employers of an outside worker who are licence holders,
- b) outside workers themselves, if they are licence holders and perform work in the supervised or controlled area of another licence holder in person or
- c) operators of a supervised or controlled area, in which work is performed by an outside worker, unless the employer of the outside worker or the outside worker himself is a licence holder.

(3) If the information necessary to ensure radiation protection of the outside worker is not available to operators of a supervised or controlled area in which work is performed by an outside worker, the employer of the outside worker shall provide them with this information. The scope of information to be provided by the employer of an outside worker to the operator of a supervised or controlled area in which work is performed by the outside worker shall be agreed between the employer and the operator.

(4) Operators of a controlled area in which work is performed by outside workers of category A shall

- a) verify that the outside workers have been correctly classified as exposed workers of category A,
- b) ensure that the level of radiation protection of outside workers when performing work in the controlled area is equivalent to that of their employees,
- c) before outside workers commence work in a controlled area, verify that they are medically fit for the work that they will perform in the controlled area,
- d) ensure evaluation of the personal doses received by outside workers in the controlled area in accordance with the monitoring programme,
- e) record the dose received in the outside worker's individual radiological monitoring document or, immediately after evaluation, forward the information to the relevant person obliged to ensure radiation protection of outside workers in this case in accordance with paragraph 2, who shall record it in that worker's individual radiological monitoring document, and
- f) instruct outside workers about the specific working conditions in the given controlled area.

(5) Operators of a supervised area in which work is performed by outside workers shall

- a) ensure that the level of radiation protection of outside workers when performing work in the supervised area is equivalent to that of their employees and
- b) give the outside workers working instructions appropriate to the risk associated with the activities which will be performed by the outside workers in the supervised area.

(6) The person obliged to ensure radiation protection of outside workers in accordance with paragraph 2 shall

- a) inspect and regularly update the information contained in their individual radiological monitoring documents, if provided to the outside worker,
- b) continuously monitor the total personal doses received by outside workers and compare them with the limits established for exposed workers,
- c) provide training and information to outside workers,
- d) ensure occupational medicine services for outside workers under § 80,
- e) in cooperation with the operator of the controlled area, determine the dose constraints for outside workers for a given period, unless the person him- or herself is the operator of the controlled area,
- f) as soon as informed by a woman who is an outside worker of her pregnancy, adjust her employment conditions to restrict exposure of the unborn child so that the total of effective doses from external exposure and committed effective doses from internal exposure of the unborn child are unlikely to exceed 1 mSv during the remainder of the pregnancy and
- g) as soon as informed by a woman who is an outside worker that she breast-feeds an infant, adjust her employment conditions to restrict exposure of the infant by the intake of radionuclide from contaminated mother's milk and reassign her from work in the controlled area of a workplace with an unsealed radionuclide source.

(7) Outside workers who have been provided the individual radiological monitoring document shall ensure that their individual radiological monitoring document is not damaged, lost or stolen.

(8) Outside workers shall report to the person obliged to ensure radiation protection of outside workers under paragraph 2(a) and (c) any fact that could reduce the level of assurance of their radiation protection, including that they have been provided with more than one individual radiological monitoring document or similar foreign document. In such a case, the person obliged to ensure radiation protection of outside workers in accordance with paragraph 2 shall immediately report this fact to the Office.

(9) Implementing legislation shall establish

- a) the rules for issuing individual radiological monitoring documents, period for submitting an application and term of validity of individual radiological monitoring documents,
- b) the rules for handling the individual radiological monitoring document,
- c) a specimen of the individual radiological monitoring document for outside workers,
- d) the scope and method of updating the information in the individual radiological monitoring document.

## § 80

### **Occupational medicine services provided to exposed workers**



(1) Employer of exposed workers shall ensure occupational medicine services in accordance with the legislation governing specific medicine services, unless otherwise provided below.

(2) Exposed workers who perform their work in a framework of other than a basic employment relationship shall ensure their own occupational medicine services by a provider of occupational medicine services with whom they shall enter into a contract on the provision of occupational medicine services. In order to ensure occupational medicine services to exposed workers who perform their work in a framework of other than an employment relationship occupational medicine services shall be ensured in accordance with the legislation governing specific medicine services, unless otherwise provided below

(3) Employers referred to in paragraph 2 or exposed workers referred to in paragraph 2 shall ensure that providers of occupational medicine services have access to all information necessary to ascertain the state of health of exposed workers in terms of their ability to perform the tasks assigned to them, including data on the working environment and the results of individual monitoring.

(4) Occupational medicine services to exposed workers shall comprise

- a) medical examination prior to classifying them as exposed workers of category A,
- b) periodic medical examination of exposed workers of category A, at least once a year,
- c) medical examination after completing high-risk work, if the effects of the occupational risks exist even after completing the high-risk work and the provider of occupational medicine services so determines when conducting a post-employment medical examination,
- d) extraordinary medical examination, if a limit for exposed workers has been exceeded or the exposed worker's state of health has changed; the provider of occupational medicine services may determine the conditions for further work with sources of ionising radiation by the medical fitness opinion, and
- e) post-employment medical examination of exposed workers of category A.

## Section 2

### **Radiation protection of the general public**

#### § 81

#### **Discharges**

(1) Anyone who performs activities in planned exposure situations shall ensure radiation protection of the general public against exposure as a result of managing a source of ionising radiation in the workplace or discharging radioactive substances into the area surrounding the workplace.

(2) Holders of a licence for the operation of a category IV workplace, holders of a licence for the individual phases of decommissioning of a category IV workplace, holders of a licence for the discharge of a radioactive substance from a category III workplace who discharge radioactive substances by means of discharges, and holders of a licence for the individual phases of decommissioning of a category III workplace who discharge a radioactive substance by means of discharges shall

- a) ensure monitoring of the discharges and the area surrounding the workplace,

- b) set the monitoring levels and procedures for the case of their exceeding in accordance with general procedures for the case of their exceeding established by implementing legislation,
- c) ensure monitoring of all potential leakage pathways, if there is a possibility of release of radioactive substances from the workplace, and
- d) evaluate doses received by the representative person, forward the results of the evaluation to the Office and, upon request, provide them to those concerned.

(3) Implementing legislation shall establish

- a) the scope and method of monitoring discharges and the area surrounding the workplaces referred to in paragraph 2(a),
- b) types of the monitoring levels for evaluating the results of monitoring of discharges and the area surrounding the workplaces referred to in paragraph 2(a), rules for their determination and general procedures for the case of their exceeding,
- c) the procedures for evaluating the quantities measured in the context of monitoring discharges and the area surrounding the workplaces referred to in paragraph 2(a),
- d) the rules for determination of the representative person and evaluating of his/her exposure.

## § 82

### **Optimisation of radiation protection of the general public**

(1) Anyone who performs an activity involving radiation shall ensure that, as a result of this activity, including in the case of accumulation of a radioactive substance discharged from the workplace, the dose constraints for the representative person of 0.25 mSv per year and, in the case of an energy-generating nuclear installation, simultaneously 0.2 mSv for discharges into the air and 0.05 mSv for discharges into surface waters, are applied in the optimisation of radiation protection.

(2) The dose constraint for discharging a radioactive substance from the workplace with potentially increased exposure to a natural source of radiation shall be established by the office in the conditions of the licence referred to in § 9(1)(e).

(3) The office may impose by a decision, for the purposes of establishing an authorised limit of exposure of the representative person, an optimisation study to be conducted by the applicant for a licence for discharging radioactive substances from the workplace.

(4) Implementing legislation shall establish the content of the optimisation study for establishing the authorised limit of exposure of the representative person.

## § 83

### **Non-medical exposure**

(1) Non-medical exposure shall be justified in advance, taking into account the specific nature of the purpose of this exposure, which is not a diagnostic or therapeutic benefit.

(2) Non-medical exposure by medical radiological equipment may be performed if

- a) it is performed by the provider of a health service which involves medical exposure authorised under other legislation,
- b) it is performed in accordance with scientific rules and recognised medical practices, while respecting the individuality of the natural person being exposed, taking into account the particular circumstances and objective possibilities,

- c) appropriate techniques are used, of which, techniques involving a low dose of exposure to the natural person involved are preferred,
- d) the specific purpose of this exposure has been taken into account,
- e) the characteristics and state of health of the natural person being exposed have been taken into account, and
- f) it is performed in compliance with the requirements on medical exposure under this Act and other legislation that are achievable with a view to the specific nature of non-medical exposure and its justification.

(3) Licence holders or registered persons who perform non-medical exposure shall keep records of exposures.

(4) Licence holders or registered persons who perform non-medical exposure using another source of ionising radiation shall comply with the dose constraints.

(5) Natural persons subjected to non-medical exposure shall be informed about the risk of exposure and the possibilities for using a method that does not involve ionising radiation, through which the same objective could be achieved.

(6) Natural persons subjected to non-medical exposure may undergo the exposure with own consent, unless other legislation provides otherwise.

(7) Implementing legislation shall establish content of records under paragraph 3.

### Section 3

#### **Radiation protection of patients**

##### § 84

#### **Optimisation of medical exposure**

(1) Diagnostic reference levels shall be used for the assessment of optimisation of medical exposure in medical radiodiagnostic and interventional radiology procedures and in diagnostic medical procedures in nuclear medicine.

(2) Licence holders or registered persons performing medical exposure shall establish a local diagnostic reference level for each medical radiodiagnostic and interventional radiology procedure commonly performed in their workplace and for diagnostic medical procedures in nuclear medicine commonly performed in their workplace.

(3) The local diagnostic reference level may exceed the national diagnostic reference level only in justified cases.

(4) Licence holders or registered persons shall investigate continuous deviations from the local diagnostic reference level in normal clinical practice, record the results of the investigation and, without delay, take measures to optimise radiation protection.

(5) If the local diagnostic reference level is significantly exceeded, licence holders or registered persons shall investigate this exceedance; in particular, they shall consider whether this does not constitute a radiological occurrence and record the results of the investigation.

(6) Implementing legislation shall establish

- a) the national diagnostic reference levels,
- b) content of the records under paragraph 3 and 4.

§ 85

**Monitoring of medical exposure doses**

(1) Licence holders or registered persons performing medical exposure shall record quantities and parameters making it possible to determine the doses received by each patient for a particular diagnostic procedure or treatment chosen and, upon request, forward them to the Office.

(2) When performing medical exposure of children, medical exposure involving high doses received by patients during radiotherapy, interventional radiology, computational tomography and nuclear medicine, and in the context of health screening, licence holders or registered persons performing medical exposure shall pay closer attention to the evaluation of patient exposure and to the choice of procedures intended for medical exposure.

(3) Health insurance companies shall, upon request, provide the Office with information about health services which involved ionising radiation and which were reported by the provider of health services and reimbursed by the health insurance companies. The information referred to in the first sentence shall be used for determining the distribution of medical exposure doses among the general public.

(4) Implementing legislation shall establish the scope, structure and method of providing information about health services by health insurance companies.

§ 86

**Workplace equipment and home care**

(1) Licence holders or registered persons performing medical exposure shall equip workplaces in which medical exposure is performed with apparatus to ensure radiation protection of the patient and the natural person providing assistance to the patient.

(2) After therapeutic or diagnostic application of radionuclides, patients may be released to home care only if

- a) the values laid down in § 64(1) are not exceeded,
- b) they have been instructed about risks and safe behaviour and
- c) they have been provided with written instructions on safe behaviour, if so required under implementing legislation.

(3) Implementing legislation shall establish

- a) the requirements for sources of ionising radiation used in medical exposure and workplace equipment for x-ray diagnostics and radiotherapy,
- b) the method of therapeutic or diagnostic application of radionuclides,
- c) the conditions for the release of a patient after therapeutic or diagnostic application of radionuclides,
- d) the cases in which patients shall be provided with written instructions on safe behaviour after therapeutic or diagnostic application of radionuclides.

§ 87

### **Radiological occurrences**

(1) Licence holders or registered persons shall perform medical exposure in a way that minimises the likelihood of a radiological occurrence. In the case of radiotherapeutic activities, licence holders or registered persons shall conduct an analysis of the risk of a radiological occurrence.

(2) In the event of a radiological occurrence, licence holders or registered persons shall proceed taking into account its severity so that the consequences are as minimal as possible.

(3) Licence holders or registered persons shall ensure investigation of radiological occurrences and of cases in which radiological occurrences could have arisen had the causes not been detected and eliminated in good time, and take measures to prevent the occurrences. The action taken by licence holders or registered persons shall be commensurate to the risks associated with the radiological occurrence. Licence holders or registered persons shall keep and retain records of investigations and records of the measures taken.

(4) The Office, the prescriber, the application expert and the patient or his or her legal representative shall be demonstrably informed about any serious radiological occurrences by the licence holder or the registered person.

(5) Implementing legislation shall establish

- a) the classification of radiological occurrences according to their severity,
- b) the procedures for the event of a radiological occurrence or a case in which a radiological occurrence could have arisen had the causes not been detected and eliminated in good time,
- c) the content and period for which the records of investigations and records of the measures taken under paragraph 3 shall be retained,
- d) the scope and the period for the provision of information about serious radiological occurrences.

#### Subpart 4

### **Conditions for the management of certain specific types of sources of ionising radiation**

#### § 88

#### **Activities related to acquiring of radioactive minerals**

(1) Products of mining works deposited in tips or settling ponds as extractive waste<sup>12)</sup> containing a natural radionuclide shall not be considered as radioactive waste.

(2) If extractive waste produced by activities related to acquiring of radioactive minerals contains a radioactive substance, it shall be managed in accordance with this Act as far as its radioactive properties are concerned.

(3) Work performed using underground mining techniques at a radioactive mineral deposit shall be performed under the same conditions as activities related to acquiring of radioactive minerals.

(4) The person who is the holder of a tip, settling pond or other residue of activities related to acquiring of radioactive minerals or other mining activity accompanied by the occurrence of

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<sup>12)</sup> Act No 157/2009 on the management of extractive waste and on amendments to certain acts, as amended.

a radioactive mineral shall ensure monitoring of these residues in accordance with § 149 and take remedial action if clearance levels are exceeded.

(5) The owner of the land on which monitoring or remedial action referred to in paragraph 4 is performed shall tolerate the measures associated with their implementation.

(6) Implementing legislation shall establish the radiation protection assurance requirements for activities related to acquiring of radioactive minerals.

## § 89

### **High-activity source**

(1) Holders of a licence for the manufacture or import of a high-activity source and persons holding a high-activity source shall ensure identification and marking of the high-activity source and its accessories, in particular the container, overpack and equipment in which the high-activity source is installed.

(2) Implementing legislation shall establish the method of identifying and marking a high-activity source and its accessories.

## § 90

### **Special obligations related to the management of a radionuclide source**

(1) Licence holders holding a radionuclide source for which they have no further use shall immediately transfer this source to its supplier, a recognised storage facility, a holder of a licence for the management of radioactive waste, or another authorised user.

(2) Holders of a licence for the management of a radionuclide source shall permanently generate funds for the safe discontinuation of this activity.

(3) Licence holders holding a simple or significant radionuclide source which is expected to be not used for a period longer than 12 months shall transfer this source, at their own cost, to a recognised storage facility for storage.

(4) Holders of a licence for the management of a radionuclide source who are subject to a bankruptcy decision shall, immediately after the bankruptcy decision becomes final, transfer, at their own cost, any radionuclide source for which they have no further use to a recognised storage facility for storage. The cost of storage of a radionuclide source and its final disposal shall be part of asset management expenditure.

## § 91

### **Orphan source**

(1) Operators of installations intended for melting, collecting or processing scrap metal shall take measures to detect any orphan sources and ensure that workers who can be exposed to a ionising radiation from an orphan source are

- a) informed about the effects of ionising radiation on the human body,
- b) advised on how an orphan source can be visually detected,

- c) informed of the actions to be taken in the event of the detection or suspected detection of an orphan source, and
- d) regularly trained in relation to the facts referred to in letters (a) to (c).

(2) If an orphan source is detected

- a) in an installation intended for melting, collecting or processing scrap metal, its operator shall
  1. ensure radiation protection of natural persons who could come into contact with the source of ionising radiation and secure the source of ionising radiation against access by unauthorised natural persons,
  2. become the owner of the source of ionising radiation, unless the original owner is identified within 60 days of detection, or
- b) outside an installation intended for melting, collecting or processing scrap metal,
  1. the Authority shall collect the source of ionising radiation and the Czech Republic shall become the owner of the source of ionising radiation, unless the original owner is identified within 60 days of detection, or
  2. the office shall decide to return the source of ionising radiation to the original owner, provided that conditions for further safe management of the source have been ensured, or decide to declare the source of ionising radiation as radioactive waste.

(3) The costs associated with the detection, safe transfer, storage, preparation for reuse or disposal of an orphan source shall be borne by the original owner, if known; otherwise, it shall be borne by the Czech Republic or the operator of the installation intended for melting, collecting or processing scrap metal, if he or she becomes the owner of the source of ionising radiation in accordance with paragraph 2(a)(2).

## § 92

### **Import and export of a radionuclide source**

- (1) Holders of a licence for importing radionuclide sources of security category 1 or 2 shall
- a) inform the Office of a planned import 30 days in advance; this information shall be accompanied by
    1. information about the type and activity of the radionuclide source to be imported,
    2. identification data of the supplier of the radionuclide source,
    3. information about the method of carriage, and
    4. the expected date of import,
  - b) at least three days prior to the date of import, inform the Office about its actual date and the unique identification of the radionuclide source to be imported.
- (2) Holders of a licence for exporting radionuclide sources of security category 1 or 2 shall
- a) only export a radionuclide source to a State that is able ensure continuous safe management of the radionuclide source,
  - b) inform the Office of a planned export 30 days in advance; this information shall be accompanied by
    1. the expected date of export,
    2. identification data of the consignee in the destination country, including the address of registered office or place of residence, and information about the existence and validity of the consignee's authorisation to manage the radionuclide source,
    3. information about the type and activity of the radionuclide source to be exported, and
    4. the number and total activity of the radionuclide sources to be exported,

- c) at least seven calendar days prior to the date of export, inform the Office about its actual date and the unique identification of the radionuclide source to be exported.

(3) It shall be prohibited to export a radionuclide source of security category 1 unless it can be demonstrated that the consignee or the receiving State are able to ensure the safe management of this resource.

#### Subpart 5

### **Planned exposure situations in a workplace with potentially increased exposure to a natural source of radiation**

#### § 93

#### **Workplace with potentially increased exposure to a natural source of radiation**

(1) Workplaces with potentially increased exposure to a natural source of radiation include

- a) on the board of an aircraft flying at an altitude of over 8 km,
- b) workplaces using a material with increased content of natural radionuclides.

(2) Anyone who performs activities involving the operation of a workplace with potentially increased exposure to a natural source of radiation shall

- a) make measurements to determine workers' individual doses and keep record of the results of the measurements and workers' individual doses,
- b) report to the Office information about the workplace, results of measurements and workers' individual doses,
- c) ensure optimisation of radiation protection of the workers, if the set level is exceeded,
- d) ensure protection of pregnant women as referred to in § 64(3), and
- e) inform the workers about
  - 1. the potentially increased exposure to a natural source of radiation,
  - 2. the results of the measurements in the workplace, individual doses established by the measurements and the related health detriments following exposure, and
  - 3. measures taken to reduce exposure.

(3) Anyone who operates a workplace with potentially increased exposure to a natural source of radiation which is on the board of an aircraft flying at an altitude of over 8 km, where the effective dose to an aircraft crew member may exceed 1 mSv per year shall evaluate the exposure of aircraft crew members and, on the basis of the results of this evaluation, consider adjusting the duty roster of aircraft crew members in order to reduce the exposure.

(4) Implementing legislation shall establish

- a) a list of workplaces using a material with increased content of natural radionuclides,
- b) the method, scope and frequency of the measurements to determine workers' individual doses, the method of establishing workers' individual doses and the scope, method and term of recording-keeping of workers' individual doses,
- c) the scope and content of information reported to the Office about workplaces, including identification data of the operator of the workplace, and frequency of their reporting,
- d) the level which, when exceeded, radiation protection optimisation shall be ensured in workplaces using materials with an increased content of natural radionuclide.

#### § 94

#### **Workplaces with increased exposure to a natural source of radiation**



(1) If the exposure of a worker in a workplace with potentially increased exposure to a natural source of radiation is liable to exceed the effective dose of 6 mSv per year after implementation of radiation protection optimisation referred to in § 93(2)(c), the workplace shall be considered to be a workplace with increased exposure to a natural source of radiation.

(2) Anyone who performs activities involving the operation of a workplace with increased exposure to a natural source of radiation shall

- a) delineate, mark and secure the workplace or part thereof where the effective dose to a worker is liable to exceed 6 mSv per year against access by unauthorised persons,
- b) classify their workers as exposed workers of category A,
- c) annually instruct the workers on the radiation risk in the workplace,
- d) ensure occupational medicine services to the workers in accordance with § 80,
- e) draw up instructions for work in the workplace, including instructions for the safe conduct of the work and entry to the workplace by natural persons who are not workers,
- f) provide the workers with personal protective equipment,
- g) ensure that a procedure for monitoring the workplace and the workers is drawn up, and
- h) ensure that documentation is maintained about the scope and method of radiation protection assurance.

## § 95

### **Conditions for discharging radioactive substances from certain workplaces with potentially increased exposure to a natural source of radiation**

(1) Anyone who discharges a radioactive substance from the workplace referred to in § 93(1)b) shall

- a) prevent unjustified accumulation of radioactive substances discharged from the workplace,
- b) ensure measurement and evaluation of the radionuclide content of the radioactive substance discharged from the workplace, including in cases where the radioactive substance being discharged is intended for reuse or recycling,
- c) record and report to the office the results of the measurements referred to in (b),
- d) draw up and act in compliance with internal regulations for the management of radioactive substances discharged from the workplace, and
- e) if the radioactive substance discharged from the workplace is to be used for the production of building materials, inform the manufacturer of the building material about the type and activity of the radioactive substance being discharged.

(2) Radioactive substance may be discharged from a workplace under § 93(1)(b) without a licence of the office if clearance levels as stipulated by the implementing legislation are not exceeded.

(3) Radioactive substance may be discharged from a workplace under § 93(1)(b) without a licence of the office also if the effective dose of each member of the public during a calendar year caused by a discharge is lower than 0,3 mSv.

(4) Anyone who discharges radioactive substances from a workplace under paragraph (3) shall inform the office at least 60 days in advance about

- a) type of discharged radioactive substances,
- b) activity of radionuclides in discharged radioactive substances,
- c) place, time and method of discharging and

- d) d) assessment of exposure to a member of the public confirming compliance with conditions under paragraph (3).

(5) Radioactive substance may be discharged from a workplace under § 93(1)(b) without a licence of the office also if the discharged radioactive substances are used for manufacturing of building materials. In this case of discharging of radioactive substances from a workplace is not allowed to use a procedure under paragraph (3). Anyone who discharges radioactive substances from a workplace with purpose to use it for manufacturing of building materials shall inform the office at least 60 days in advance about

- a) type of discharged radioactive substances,
- b) activity of radionuclides in discharged radioactive substances,
- c) time and scope of discharging of radioactive substances and
- d) identification data of building materials manufacturer.

(6) Implementing legislation shall establish

- a) the scope, method and frequency of measurements and evaluation of the radionuclide content of a radioactive substance discharged from the workplace,
- b) the method and term of record-keeping of, and frequency of reporting to the Office, the results of the measurements of the radionuclide content of radioactive substances discharged from the workplace,
- c) the content of internal regulations for the management of radioactive substances discharged from the workplace,
- d) values of clearance levels for workplaces with potentially increased exposure to a natural source of radiation and conditions under which they are considered as exceeded.

### Part 3

#### **Existing exposure situations**

##### Subpart 1

#### **Exposure to radon in the workplace**

##### § 96

#### **Workplace with potentially increased exposure to radon**

(1) Workplaces with potentially increased exposure to radon include

- a) underground workplaces,
- b) workplace in which water from an underground source is pumped, collected or otherwise similarly handled, in particular pumping stations, spa facilities, bottling facilities, water treatment facilities or water towers,
- c) workplaces located on an underground or first ground floor of a building which meets the conditions laid down in implementing legislation.

(2) Anyone who performs activities involving the operation of a workplace with potentially increased exposure to radon shall

- a) report to the Office information about the workplace,
- b) ensure measurements to establish the effective doses to workers in the workplace and record-keeping of the results of the measurements and effective doses to workers, except workplaces where the period of the workers' presence in the workplace does not exceed 100 hours per year,

- c) ensure optimisation of radiation protection, if the measurements referred to in (b) demonstrate that the reference levels set out in implementing legislation have been exceeded, and
  - d) inform the workers about
    - 1. the potentially increased exposure to radon,
    - 2. the results of the measurements in the workplace, effective doses and the related health detriments following exposure, and
    - 3. the measures taken to reduce exposure to radon.
- (3) Implementing legislation shall establish
- a) the conditions for classifying workplaces located on an underground or first ground floor of a building as workplaces with potentially increased exposure to radon,
  - b) the scope, method and frequency of performing the measurements to establish the effective doses to workers in the workplace and rules to establish the effective doses to workers,
  - c) the scope, method and term of record-keeping of results of the measurements and the effective doses to workers,
  - d) the scope and content of the information about the workplace to be reported to the office, including identification data of the workplace operator, and frequency of their reporting to the office.

§ 97

**Workplaces with increased exposure to radon**

(1) If the exposure of a worker in a workplace referred to in § 96(1) is liable to exceed the effective dose of 6 mSv per year, the workplace shall be considered to be a workplace with increased exposure to radon.

(2) Anyone who performs activities in a workplace with increased exposure to radon shall

- a) apply limits with regard to exposed workers,
- b) delineate the workplace or part thereof where the effective dose to a worker is liable to exceed 6 mSv per year,
- c) annually instruct the workers on the radiation risk in the workplace,
- d) draw up instructions for work in the workplace, including instructions for the safe conduct of the work,
- e) ensure that a monitoring procedure is drawn up, and
- f) ensure that documentation is maintained about the scope and method of radiation protection assurance.

Subpart 2

**Indoor exposure to natural sources of radiation**

§ 98

**Prevention of indoor penetration of radon**

(1) Anyone who proposes the siting of a new building or extension with residential rooms or rooms intended to be occupied by persons shall ensure that the building site radon index is determined.

(2) Anyone who reports, or applies for a permit to make modifications to a completed building that will newly comprise residential rooms or rooms intended to be occupied by

persons, or applies for, or notifies of, a modification in the use of a building that will newly comprise residential rooms or rooms intended to be occupied by persons shall ensure measurement of radon activity concentration in the existing building.

(3) It shall not be required to determine the building site radon index, if the building will be placed in the terrain in such a manner that all of its peripheral structures will be separated from the ground by an air layer through which air can flow freely or if a preventive anti-radon measure has been designed based on ventilation of radon from the ground outside of the structure.

(4) Implementing legislation shall establish the method of determining the building site radon index.

## § 99

### **Protection from natural indoor radiation**

(1) Owners of buildings with residential rooms or rooms intended to be occupied by persons in which the reference level was found to be exceeded shall endeavour to ensure that the indoor exposure of natural persons is as low as reasonably achievable, taking all economic and societal aspects into account.

(2) Owners of buildings used for schools or school facilities or buildings used for the provision of social or health services involving long-term residence of natural persons shall ensure measurement of the indoor air activity concentration of radon when putting them into service and always after making modifications to a completed building which could affect the indoor air activity concentration of radon, in particular after interfering with the insulation of the building to prevent radon penetration from the ground and modifications that could lead to reduced efficiency of indoor ventilation.

(3) If the indoor air activity concentration of radon in a building referred to in paragraph 2 exceeds the reference level, the owner of the building shall take measures to reduce the exposure to a level as low as reasonably achievable, taking all economic and societal aspects into account.

(4) Owners of buildings with residential rooms or rooms intended to be occupied by persons in which the set level of annual average radon activity concentration in the air was found to be exceeded shall take measures reducing the level of exposure.

(5) Implementing legislation shall establish

- a) the criteria for the preparation and evaluation of measures intended to reduce the level of indoor exposure to natural sources of radiation,
- b) the level of annual average radon activity concentration in the air which, when exceeded, owners of buildings with residential rooms or rooms intended to be occupied by persons shall take measures reducing the level of exposure.

## Subpart 3

### **Water and building materials**

## § 100

### **Water**

(1) Drinking water may not be made available for public use and bottled water may not be made available on the market in the Czech Republic, if

- a) the activity concentration of radon exceeds the maximum permissible value or
- b) its natural radionuclide content exceeds the reference level and no measures have been taken to reduce exposure to a level as low as reasonably achievable, taking all economic and societal aspects into account.

(2) Persons liable to ensure that the drinking water supplied meets the quality requirements under the act on the protection of public health (hereinafter the “water supplier”) and producers and importers of bottled water shall

- a) ensure systematic measurement and evaluation of the natural radionuclide content of water,
- b) keep a record of, and report to the Office, the results of the measurements of the natural radionuclide content of water and other data,
- c) if the maximum permissible value of radon activity concentration is exceeded, take measures reducing radon activity concentration below this value,
- d) if the reference level for natural radionuclide content is exceeded, take measures reducing exposure to a level as low as reasonably achievable, taking all economic and societal aspects into account, and
- e) if the reference level is exceeded, provide the public with information about the results of the measurements, the effective dose from water and the associated risks, as well as about the measures taken to reduce the level of exposure.

(3) Implementing legislation shall establish

- a) the maximum permissible value of radon activity concentration in drinking water for public use and for making bottled water available on the market,
- b) the reference levels for natural radionuclide content of drinking water for public use and for making bottled water available on the market,
- c) the scope, frequency and method of systematic measurement and evaluation of the natural radionuclide content of water,
- d) the scope, method and term of record-keeping, and frequency of reporting to the office, of the results of measurements and other data, including identification data of water supplier and manufacturer and importer of bottled water.

## § 101

### **Building materials**

(1) Building materials may not be made available on the market in the Czech Republic, if the effective dose to the representative person from external exposure to gamma radiation in the use of a building with residential rooms or rooms intended to be occupied by persons could exceed the reference level and its making available on the market has not been not authorised by the Office under § 9(2)(j).

(2) Manufacturers and importers of building materials shall

- a) ensure systematic measurement and evaluation of the natural radionuclide content of building materials,
- b) keep a record of, and report to the Office, the results of the measurements of the activity concentration index and other data and
- c) when making building materials available on the market, provide the public with information about the results of the systematic measurement and evaluation of their natural radionuclide content in the event the reference level is exceeded.

(3) If, based on measurements of the natural radionuclide content of building materials, a manufacturer or importer of building materials finds that the reference level is not exceeded, systematic measurements and evaluation of the natural radionuclide content of building materials shall not be required until a change occurs which could affect their natural radionuclide content.

(4) Implementing legislation shall establish

- a) the reference level for building materials,
- b) the method of calculating and the value of the activity concentration index for building materials,
- c) the scope, method and frequency of systematic measurement and evaluation of the natural radionuclide content of building materials,
- d) the scope, method and term of record-keeping of, and reporting to the Office, the results of measurements and other data, including identification data of manufacturer and importer of building materials.

#### Subpart 4

### **Other existing exposure situations and the provision of subsidies in some existing exposure situations**

#### § 102

### **Exposure situations existing as a result of emergency exposure situations or other circumstances**

(1) The Office may, by means of a general measure, take measures to regulate exposure in existing exposure situations resulting from an emergency exposure situation or a discontinued activity in a planned exposure situation (hereinafter “lasting exposure”), where a significant increase in health detriment to members of the public following exposure could occur unless an intervention is made.

(2) Lasting exposure shall be regulated by the Office in accordance with paragraph 1 by fixing reference levels for the average effective dose to the representative person per calendar year within the range of 1 to 20 mSv. Radioactive contamination of foodstuffs, feedingstuffs or water shall also be regulated by the Office by fixing maximum permissible levels of radioactive contamination for the relevant existing exposure situation.

(3) Existing exposure situations not referred to in §§ 96 to 101, which are relevant to radiation protection, shall be subject to notification to the Office in accordance with § 11 and these situations shall be governed by the requirements under this Act for planned exposure situations.

(4) Management of areas contaminated as a result of an emergency exposure situation, including measures allowing habitation and the resumption of social and economic activities, shall follow the optimised radiation protection strategy, which forms part of the national radiation extraordinary event plan.

#### § 103

### **Provision of subsidies in some existing exposure situations**

(1) The Ministry of Finance may provide subsidies for

- a) the identification of the risks arising from the presence of radon and its conversion products in indoor air of residential and public buildings,
- b) the adoption of a justified measure reducing the level of exposure due to the presence of radon and its conversion products in indoor air of residential and public buildings, or
- c) the adoption of measures reducing the natural radionuclide content of drinking water intended for public use.

(2) The subsidies under paragraph 1 may be granted on the basis of an application providing evidence of the facts referred to in paragraph 1.

(3) Granting of the subsidies shall be facilitated by the relevant regional body acting under delegated Authority.

(4) The subsidies referred to in paragraph 1 may only be granted on the basis of a previous consent of the office following assessment of the degree of risk and the expected efficiency of the proposed measures reducing the level of exposure after they have been implemented.

(5) Regional authority shall inform owners of the buildings on conditions of granting of the subsidies under paragraph 1(a) and (b), receive applications for providing the subsidies and submit them to the Ministry of Finance together with authority's opinion and consent of the office.

(6) Implementing legislation shall establish

- a) the conditions for granting the subsidies referred to in paragraph 1,
- b) the procedure for receiving applications for the granting of the subsidies referred to in paragraph 1,
- c) the procedure for facilitating subsidies by the region,
- d) the particulars of the application for the granting of the subsidies referred to in paragraph 1 and terms for its submitting.

#### Part 4

### **Emergency exposure situations**

#### § 104

(1) Exposure of natural persons in emergency exposure situations shall be restricted by any person who performs activities in emergency exposure situations by means of individual protection, restricting the movement and presence of natural persons in the affected area and

- a) implementing of urgent protective action, which comprises, in particular
  1. sheltering,
  2. the application of iodine prophylaxis,
  3. evacuation, and
- b) implementing of follow-up protective action, which comprises, in particular
  1. resettlement of the population,
  2. restriction of the use of radionuclide-contaminated food and water,
  3. restriction of the use of radionuclide-contaminated feedingstuffs.

(2) Any person who plans and prepares protective measures shall assess whether these are justified by the benefits, which shall exceed the cost of their implementation and the damage caused.

(3) Any person who plans and prepares protective measures shall act so that they provide as much reasonably achievable benefits as possible. Reference levels shall be taken into consideration when deciding on the introduction or withdrawal of protective measures.

(4) Limits shall be applied for exposed workers in order to restrict accidental exposure of emergency workers in an emergency exposure situation. In cases where it cannot be excluded that the exposure limits will be exceeded, accidental exposure of emergency workers shall be optimised using the reference levels of

- a) 100 mSv per year or
- b) 500 mSv per year, in the case of saving human lives or preventing the development of an emergency exposure situation that could have extensive social and economic consequences.

(5) The person sending emergency workers to a response action shall ensure, in respect of emergency workers who are expected to be sent to response actions,

- a) regular training, exercises and record-keeping of these workers,
- b) provision of information about the risks associated with response actions and about protective measures,
- c) monitoring and evaluation of the magnitude of exposure during response actions, retention of the data thus obtained and forwarding them to the Office, if individual monitoring is performed,
- d) a pre-employment medical examination, which takes into account the risk of ionising radiation, unless similar examination has been conducted under other legislation,
- e) personal protective equipment and accessories,
- f) an extraordinary medical examination, and
- g) maintenance of a list of emergency workers.

(6) Where the reference level referred to in paragraph 4(a) is liable to be exceeded, the participation by emergency workers in the response action shall only with his/her consent.

(7) The person sending emergency workers to a response action shall follow, by analogy, paragraph 5 in respect of workers who are not expected to be sent to response actions.

(8) The participation in response actions by emergency workers who are not expected to be sent to response actions shall only with his/her consent.

(9) Implementing legislation shall establish

- a) the conditions for the introduction and withdrawal of, and the requirements for, protective action,
- b) the method of informing emergency workers about the risks associated with response actions and the method of providing evidence of consent of the person with participation in a response action,
- c) the basic characteristics of personal protective equipment and accessories for emergency workers,
- d) the period for which the records and data referred to in paragraph 5(a) to (c) and (g) shall be retained,
- e) the scope and time of forwarding to the Office the data on the magnitude of exposure in response actions obtained from individual monitoring.



§ 105

(1) Holders of a licence for complete decommissioning shall retain the documentation referred to in Point 7 of Annex 1 to this Act for a period of 20 years after complete decommissioning.

(2) Where complete decommissioning is not carried out, licence applicants referred to in § 9(1)(g) or (2)(d) shall specify the conditions for further use of the site and systems, structures or components, including the scope and method of monitoring, measurement, evaluation, verification and recording of quantities and facts relevant to radiation protection and radiation situation monitoring.

Title IV

**Radioactive waste and spent fuel management**

§ 106

**Definition of certain terms in the area of radioactive waste management and spent fuel**

For the purposes of this Act, the following definitions shall apply

- a) storage of radioactive waste means in advance timely limited placement of radioactive waste in a site, facility or installation with the intention of its retrieval,
- b) disposal of radioactive waste means the permanent placement of radioactive waste in a site, facility or installation without the intention of retrieval,
- c) reprocessing of spent fuel means an activity performed with the aim of obtaining materials from spent fuel for further use,
- d) institutional control means a set of activities to ensure the maintenance and monitoring of a site and an actual radioactive waste disposal facility after the closure of the radioactive waste disposal facility, for a period set out in the documentation for the licensed activity,
- e) radioactive waste management means all activities that relate to collection, segregation, treatment, conditioning, storage, or disposal of radioactive waste, excluding transportation from the site where these activities are carried out.

§ 107

**Principles of radioactive waste management**

(1) If radioactive waste is sent for processing or reprocessing from the Czech Republic to another Member State of the European Union or a State that is not a Member State of the European Union, the Czech Republic shall continue to have obligation to ensure the safe and responsible disposal of this waste, including waste generated as a by-product of processing or reprocessing.

(2) Radioactive waste generated in the Czech Republic may be disposed of in another Member State of the Euratom or in a State that is not a Member State of the Euratom, if an agreement has been concluded between the Czech Republic and that State on the use of a radioactive waste disposal facility of that State. Prior to a shipment to a State that is not a Member State of the Euratom, the Office shall inform the European Commission of the content of this agreement.

(3) The agreement referred to in paragraph 2 between the Czech Republic and a State that is not a Member State of the Euratom may be entered into if this State

- a) has concluded an agreement with the European Union covering spent fuel and radioactive waste management or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and
- b) has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by Euratom legislation<sup>13)</sup>, and the radioactive waste disposal facility is
  - 1. a facility authorised for radioactive waste,
  - 2. operating prior to the shipment of radioactive waste to it and
  - 3. managed in accordance with the requirements set out in the radioactive waste management and disposal programme of that State.

(4) The Czech Republic shall ensure spent fuel and radioactive waste management produced under its jurisdiction, if it is not ensured under § 106 through 117, including monitoring of radiation situation in surroundings of radioactive waste disposal facility and institutional control after the closure of the radioactive waste disposal facility.

## § 108

### **Concept for radioactive waste and spent fuel management**

(1) In the interest of managing radioactive waste, including radioactive waste generated as a consequence of a radiation accident, and spent fuel, a concept for radioactive waste and spent fuel management shall be drawn by the Ministry of Industry and Trade; this concept shall be regularly evaluated, no less than once every 10 years, and, if necessary, updated. The Ministry of Industry and Trade shall inform the European Commission of the concept for radioactive waste and spent fuel management, as well as the evaluation and updates to the concept.

(2) Radioactive waste and spent fuel may only be managed so that it does not impose undue technical, economic and social burdens on current and future generations.

(3) Implementing legislation shall establish

- a) the content of the concept for radioactive waste and spent fuel management,
- b) the method of evaluating and updating the concept for radioactive waste and spent fuel management,
- c) the method of informing the European Commission of the evaluation and updates to the concept for radioactive waste and spent fuel management.

(4) Process of designation of an exploration area for the disposal of radioactive waste in underground repositories, designation of a protected area for the disposal of radioactive waste in underground repositories, authorizing of the operation of a radioactive waste disposal facility and ensuring of considering of interests of municipalities getting contributions from the nuclear account under § 117(1) and their citizens in these processes stipulates a special Act.

## § 109

### **Conditions for the radioactive waste management**

(1) The requirements for the radioactive waste management shall not apply to the management of residues from extraction of minerals containing a natural radionuclide and

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<sup>13)</sup> Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

waste containing a natural radionuclide which has not originated from an activity involving radiation.

(2) When managing radioactive waste, all of its physical, chemical and biological properties that could affect the safe management thereof shall be taken into account.

## § 110

### **Conditions for the spent fuel management**

(1) In addition to the requirements arising from other provisions of this Act, the same requirements as those applicable to radioactive waste shall apply to spent fuel until such time that it is declared radioactive waste by the producer in the radioactive waste accompanying document or by the Office by a decision.

(2) Spent fuel shall be managed by the producers thereof in such a manner that the possibility of its further transportation and further management is not rendered more difficult.

## § 111

### **Obligations of producers of radioactive waste and holders of a licence for the radioactive waste management**

(1) Holders of a licence for the radioactive waste management or producers of radioactive waste, if radioactive waste was not handed to the holder of a licence for the management of radioactive waste, shall

- a) draw up a strategy for the radioactive waste management which shall implement principles included in the concept for radioactive waste and spent fuel management,
- b) take technical and organisational measures to restrict the amount of radioactive waste generated,
- c) bear all the costs associated with the management of radioactive waste, from its generation to disposal; contracts for the transfer of the right of radioactive waste management or transfer of ownership of radioactive shall be made in writing,
- d) bear all the costs associated with the radioactive waste management after its disposal, including the monitoring of radioactive waste repositories after their closure and the necessary research and development activities; these costs shall be financed by fees paid to an account maintained by the Czech National Bank (hereinafter the “nuclear account”),
- e) take due account of the correlation between the individual steps of radioactive waste management, from its generation to disposal, and
- f) draw up and maintain the radioactive waste accompanying document.

(2) Holders of a licence for the radioactive waste management shall

- a) manage radioactive waste in such a manner that the quantity and activity of radioactive waste is maintained at a level as low as possible, taking all security, economic and societal aspects into account,
- b) manage radioactive waste only in workplaces meeting the technical requirements for the safe management of radioactive waste,
- c) follow procedures for the safe collection, segregation, treatment, processing, storage and disposal of radioactive waste, and
- d) maintain a register of radioactive waste by the type of waste and forward data from the register to the Authority.

- (3) Implementing legislation shall establish
- a) the technical requirements for equipment of radioactive waste management workplace,
  - b) the procedure for the collection, segregation, treatment, processing, storage and disposal of radioactive waste,
  - c) the scope and method of maintaining the register of radioactive waste and the radioactive waste accompanying document,
  - d) the scope and method of monitoring radioactive waste repositories.

§ 112

**Obligations of holders of a licence for the closure of a radioactive waste disposal facility**

- (1) Holders of a licence for the closure of a radioactive waste disposal facility shall
- a) perform institutional control for the period set out in the licence conditions,
  - b) take corrective measures in the event of a radionuclide release into the environment and
  - c) retain records of the storage areas and the quantity, radioactivity and form of radioactive waste disposed in them, for a time set in the documentation for the licensed activity.
- (2) Implementing legislation shall establish the method of carrying out the closure of a radioactive waste disposal facility.

§ 113

**The Authority and its activities and funding**

(1) The Authority is an organisational unit of the State established by the Ministry of Industry and Trade to ensure activities related to the disposal of radioactive waste. The Authority shall carry out activities on the basis of a licence under this Act.

(2) The Authority's activities shall be financed from the State budget using funds from the nuclear account. Any unused funds shall be subject to the annual settlement of the nuclear account by 31 January of the following calendar year.

(3) In respect of the funds in the nuclear account, the Authority shall not create claims on unused expenditure under budgetary rules<sup>14)</sup>.

- (4) The subject of the Authority's activities shall be
- a) preparation, construction, commissioning, operation and closure of radioactive waste repositories,
  - b) monitoring of the impact of radioactive waste repositories on their surrounding area,
  - c) institutional control of radioactive waste repositories,
  - d) management of radioactive waste,
  - e) treatment of spent fuel into a form suitable for disposal or subsequent use after it has been declared radioactive waste,
  - f) management of the fees for radioactive waste disposal,
  - g) control of the reserves held by holders of decommissioning licences, including the terms of the contracts for the maintenance of blocked accounts and approval of the use of funds from these reserves,

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<sup>14)</sup> § 47 of Act No 218/2000 on budgetary rules and on amendments to certain related acts (Budgetary Rules), as amended.

- h) provision of services in the area of radioactive waste management,
- i) radioactive waste management brought into the Czech Republic from abroad which cannot be returned,
- j) ensuring the safe management of nuclear materials or other sources of ionising radiation that have been found or seized, in accordance with the decision of the office,
- k) ensuring the safe performing of activities related to a management of nuclear materials or other sources of ionising radiation that are owned by the State,
- l) administration of radioactive waste and sources of ionising radiation seized in accordance with the Code of Criminal Procedure,
- m) provision of contributions to municipalities under § 117,
- n) provision of subsidies for the remediation of old radiation liabilities under § 114,
- o) approving a use of funds of decommissioning reserves,
- p) checking the demonstration on financial covering.

(5) The Authority shall carry out its activities on the basis of its government-approved statute and annual, three-year and long-term plans of activities.

(6) Funds in the nuclear account may not be used for financing the activities referred to in paragraph 4(i) and (k) and for the management of radioactive waste, which was generated before 1 July 1997 and which represents old radiation liabilities. The Authority shall use State budget funds for this purpose.

#### § 114

##### **Remediation of old radiation liabilities**

The Authority may provide subsidies

- a) for the elimination of radioactive waste generated before the producer of the radioactive waste was privatised,
- b) for the remediation of radioactive contamination of the environment, which occurred before the producer of the contamination was privatised,
- c) covering the proportionate share of the costs incurred for the elimination of radioactive waste generated from substances or articles contaminated by a radionuclide before the producer of the radioactive waste was privatised, or
- d) covering the proportionate share of decommissioning costs in the case of a facility put into service before it was privatised.

#### § 115

##### **Nuclear account**

(1) The Ministry of Finance shall administer the nuclear account. The nuclear account shall be one of the State financial assets accounts. The funds in the nuclear account may only be used in accordance with this Act.

(2) Nuclear account revenues shall comprise, in particular

- a) fees for radioactive waste disposal,
- b) earnings from financial market operations with nuclear account funds under § 116,
- c) revenues of the Authority,
- d) subsidies, financial gifts and grants.

#### § 116

### **Investments of the funds in the nuclear account**

(1) The funds in the nuclear account may be invested by the Ministry of Finance. The ministry shall invest the funds with expertise and in safe manner.

(2) The funds may be invested into

- a) state bonds issued by the Czech Republic,
- b) bonds issued by the Czech National Bank, or
- c) commercial papers or listed commercial papers representing a right for getting payment for obligation issued by
  - 1. a Member State of the European Union or Organisation for Economic Co-operation and Development, if the issuing state has a rating granted by a rating agency in accordance with paragraph (6),
  - 2. a central bank of the state under point (1),
  - 3. the European Union, European Central Bank, European Investment Bank, European Bank for Reconstruction and Development, European Financial Stability Facility or European Stability Mechanism,
  - 4. International Monetary Fund or International Bank for Reconstruction and Development,
  - 5. an international financial organization, which member is one or more states under point (1) and these states take a financial pledge for its obligations, or
  - 6. a person for whose obligations take a financial pledge for his/her obligations the Czech Republic, state under point (1) or a person under points (3) or (4).

(3) Commercial papers or listed commercial papers under paragraph (2) may be traded only at European regulated market or at foreign market similar to a regulated market.

(4) It is not allowed to invest more than 15 % of the funds in the nuclear account into commercial papers or listed commercial papers under paragraph (2) if they were issued by the same person. This rule shall not apply if they were issued by the person under paragraph (2)(a) or (b).

(5) The Ministry of Finance shall trade the investment tools under paragraph (2) on its own account, buy and sell them, independently or through a person with a sufficient knowledge of trading on a particular market.

(6) During the investments into commercial papers or listed commercial papers only a rating granted by a rating agency registered or certified according to European regulation on the rating agencies<sup>15)</sup> if the rating agency is included on a list published on the web page of the European Securities and Market Authority.

### § 117

#### **Contributions from the nuclear account**

(1) Contributions from the nuclear account may, be granted to municipalities in the administrative territory of which

- a) an exploration area for the disposal of radioactive waste in underground repositories has been designated,

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<sup>15)</sup> Regulation (EC) No 1060/2009 of the European Parliament and of the Council of 16 September 2009 on credit rating agencies.

- b) a protected area for the disposal of radioactive waste in underground repositories has been designated,
- c) the operation of a radioactive waste disposal facility has been authorised.

(2) Municipalities entitled to a contribution under paragraph 1(a) or (c) in a calendar year shall not be entitled to a contribution under paragraph 1(b).

(3) Any municipality shall receive a one-off contribution from the nuclear account amounting to

- a) CZK 1 000 000, if the Authority submits application for designation of an exploration area for the disposal of radioactive waste in the administrative territory of a municipality; the contribution shall not be granted repeatedly,
- b) CZK 60 000 000, if in the administrative territory of a municipality a protected area for the disposal of radioactive waste in underground repositories has been designated; in the same calendar year, when this contribution has been granted to a municipality, the contribution referred to in paragraph 1(b) shall not be granted.

(4) This Government shall establish in a regulation

- a) the method of calculation of the contribution under paragraph 1(a), taking into account the size of the exploration area intended for specific intervention in the Earth's crust for the purposes of disposal of radioactive waste in underground repositories,
- b) the rules for granting and the amount of the contribution referred to in paragraph 1(b) and (c),
- c) the rules for granting of the contribution referred to in paragraph 3.

## Title V

### **Fees for radioactive waste disposal**

#### Part 1

#### **Definition of the fees**

#### § 118

Fees for radioactive waste disposal include

- a) regular fees and
- b) one-off fees.

#### Part 2

#### **Regular fees**

#### § 119

#### **Fee payers**

Fee payers shall be producers of radioactive waste operating

- a) an energy-generating nuclear installation,
- b) a research nuclear installation with a nominal thermal output higher than 1 MW.

#### § 120

#### **Object of the fees**

The object of regular fees is a disposal of the radioactive waste produced from the spent fuel or its reprocessing.

§ 121

**Base for the fees**

Base for the fees is in the case of producers of radioactive waste operating

- a) an energy-generating nuclear installation amount of electricity in MWh as measured at the generator terminals,
- b) a research nuclear installation production of thermal energy in MWh.

§ 122

**Fees rates**

Rates of regular fees are

- a) 55 CZK in the case of the fee payer operating an energy-generating nuclear installation,
- b) 30 CZK in the case of the fee payer operating a research nuclear installation.

§ 123

**Fees calculation**

Regular fees shall be calculated as a multiple of base of fees rounded to whole MWh and fees rates.

§ 124

**Fees period**

Fees period of regular fees is a calendar year.

§ 125

**Registration**

Fees payer shall apply for a registration to pay a regular fee in one month from the day of entry into force of a decision on license to the first physical start-up of a nuclear installation with a nuclear reactor.

§ 126

**Fees return**

(1) Fees payer shall submit a fees return to a regular fee one month after the end of fees period at the latest.

(2) A fees return and additional fees return shall be submitted only on a form issued by the Authority or on print-out from a computer printer with information, content and structure of the data identical with the form.



§ 127

**Fees deposits**

- (1) Regular fees shall be paid through fees deposits for a deposit period of one month.
- (2) Fees deposits shall not be paid for the last deposit period for a fees period.
- (3) Fees deposits shall be calculated for a deposit period as a regular fee.
- (4) Fees deposits are payable one month after the end of a deposit period at the latest.

Part 3

**One-off fees**

§ 128

**Fee payers**

Fee payers shall be producers of radioactive waste. Producers paying regular fees cannot be fee payers of one-off fees.

§ 129

**Object of the fees**

- (1) The object of one-off fees is a disposal of the radioactive waste.
- (2) Obligation to pay fees begins with accepting a radioactive waste by the Authority.

§ 130

**Base for the fees**

Base for the fees is amount of the radioactive waste in cubic metres.

§ 131

**Fees rates**

- (1) Rates of one-off fees are up to
  - a) 200 000 CZK for a radioactive waste in a form of standard package meeting limits and conditions for radioactive waste management approved by the office, or
  - b) 200 000 CZK for a radioactive waste other than according to (a).
- (2) The government establishes by a regulation rates of one-off fees.

§ 132

**Fees calculation**

One-off fees shall be calculated as a multiple of base of fees rounded to two decimal places and fee rates.

§ 133

**Due dates of the fees**

The one-off fee shall be due within 15 days after delivery of payment order.

Part 4

**Common provisions**

§ 134

**Budgetary distribution of the fees**

- (1) The fees for a radioactive waste disposal shall be state budgetary revenue.
- (2) For the purposes of administration of the fees the nuclear account shall be considered a public budget.

§ 135

**Fees administrator**

The fees for a radioactive waste disposal shall be administered by the Authority.

Title VI

**Type-approval of certain products in the field of peaceful utilization of nuclear energy and ionising radiation and transport**

Part 1

**Definition of certain terms in the area of type-approval of products and transport**

§ 136

For the purposes of this Act, the following definitions shall apply

- a) criticality safety index means an indicator which is used to provide control over the accumulation of packaging assemblies or containers containing fissile material in order to maintain subcriticality of fissile material during transport and transport-related storage,
- b) packaging assembly means the assembly of components necessary to enclose the radioactive contents completely,
- c) carrier means the holder of a licence for carriage, if the carriage is subject to a licence under this Act, or the person referred to as the consignor in transport documents,
- d) transport index means the number assigned by the carrier to a packaging assembly, overpack, container, unpackaged substance with low activity concentration or unpackaged surface-contaminated articles and used to provide control over radiation exposure,
- e) consignee of radioactive waste or spent fuel means the person to whom radioactive waste or spent fuel is planned to be or being shipped,
- f) State of origin of radioactive waste or spent fuel means the State from which a shipment of radioactive waste or spent fuel is planned to be initiated or is initiated,
- g) State of destination of radioactive waste or spent fuel means the State to which a shipment of radioactive waste or spent fuel is planned or takes place,

- h) State of transit of radioactive waste or spent fuel means a State other than the State of origin or the State of destination, through the territory of which a shipment of radioactive waste or spent fuel is planned or takes place,
- i) fissile material means isotopes of uranium  $^{233}\text{U}$  or  $^{235}\text{U}$ , or isotopes of plutonium  $^{239}\text{Pu}$  or  $^{241}\text{Pu}$  or any combination of these radionuclides, except unirradiated natural uranium or depleted uranium and natural uranium or depleted uranium which have only been irradiated in thermal reactors only,
- j) surface contamination means the occurrence of a radioactive substance on a surface in a quantity exceeding  $0.4 \text{ Bq/cm}^2$  for radionuclide sources emitting beta or gamma exposure and for low toxic radionuclide sources emitting alpha exposure, or  $0.04 \text{ Bq/cm}^2$  for all other radionuclide sources emitting alpha exposure; surface contamination may be
  1. non-fixed, which means surface contamination that can be removed by normal means, or
  2. fixed, which means surface contamination other than non-fixed contamination,
- k) low dispersible radioactive material means a radioactive substance in solid form, which is not powder form and which, whether alone or in a sealed capsule, has limited dispersibility,
- l) special form radioactive material means an indispersible solid radioactive substance or a sealed capsule containing a radioactive substance,
- m) radioactive contents mean a radioactive substance together with any contaminated or activated solids, liquids and gases within a packaging assembly.

## Part 2

### **Type-approval of certain products**

#### § 137

#### **Products subject to type-approval**

(1) The products below may only be used if type-approved by the Office

- a) packaging assembly for the carriage, storage or disposal of a radioactive or fissile material,
- b) special form radioactive material, or
- c) low dispersible radioactive material.

(2) The products below may only be manufactured, imported, distributed or used if type-approved by the Office

- a) radiation generator which is not an insignificant source of ionising radiation,
- b) sealed radionuclide source and equipment containing a sealed radionuclide source,
- c) unsealed radionuclide source
  1. intended for use in medical exposures, which is not a radio-pharmaceutical registered under other legislation, or
  2. intended for use in industrial or other applications, or
- d) consumer product containing a radionuclide.

(3) Products referred to in paragraph 2, which are intended for demonstration or testing and, at the same time, are not intended to be placed on the market, may be manufactured, imported, distributed or used without type-approval by the office.

(4) If a product referred to in paragraph 1 or 2 has been manufactured or placed on the market in a Member States of the Euratom, in Turkey or in a Member State of the European Free Trade Association, which is simultaneously a party to the European Economic Area, in accordance with the legislation of that State, the results of the findings made in that State shall be recognised provided that they guarantee a standard comparable to that required under this

Act and that these findings are available to the Office. Such products shall be considered to be compliant to the product type-approved under this Act.

(5) The packaging assembly for the carriage of a radioactive or fissile material and low dispersible radioactive material subject to multilateral approval according to international agreements binding for the Czech Republic<sup>16)</sup> must be type-approved by the office even in the case when their type has been approved in similar manner by a respective authority of a Member States of the Euratom, Turkey or a Member State of the European Free Trade Association, which is simultaneously a party to the European Economic Area, where the product has been manufactured or introduced into the market. Results of findings performed in these states are recognized if ensure comparable level as requested by this act, if the results are available to the office.

(6) Implementing legislation shall provide a closer specification of the products referred to in paragraph 1 that shall be subject to type-approval.

## § 138

### **Application for product type-approval**

(1) The product type-approval procedure shall be initiated at the request of a manufacturer, importer, distributor or another person who provides evidence of a legal interest in the type-approval of a product.

(2) Applications for product type-approval referred to in § 137(1) shall contain

- a) identification of the manufacturer, if different from the applicant,
- b) product identification,
- c) description of use,
- d) a list of legislation and technical standards in accordance with which the product was designed and manufactured,
- e) proposal for the scope and method of implementation of operational controls,
- f) instructions for use in Czech, comprising rules for the safe handling and maintenance of the product and
- g) the requested period of validity of the type-approval of the product.

(3) Applications for product type-approval referred to in § 137(2) shall contain

- a) description of the intended use of the product,
- b) data on the nature, type, activity and chemical and physical form of the radionuclide,
- c) data on the technical parameters of the radiation generator and its accessories,
- d) in the case of products containing radioactive substances, information as to their means of fixation,
- e) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0.1 m from any accessible surface of the product and expected personal doses to regular users of the product,
- f) description of how the requirements for radiation protection have been met,

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<sup>16)</sup> E.g. Convention concerning International Carriage by Rail (COTIF), promulgated under No 8/1985, as amended.

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), promulgated under No 64/1987, as amended.

European Agreement concerning the international carriage of dangerous goods by inland waterways (ADN), promulgated under No 102/2011.

- g) evidence of manufacturing authorisation in the country of the manufacturer,
- h) accompanying letter issued by the manufacturer, if it is an unsealed radionuclide source,
- i) certificate, if it is a sealed radionuclide source,
- j) information about the resistance classification, sealing method, design description, recommended leakage checks and the period of usability of the radionuclide,
- k) concept for the decommissioning of the product and
- l) measurements report drawn up by the manufacturer, containing data on the actual operational parameters.

(4) Applications for product type-approval of referred to in § 137(1) shall be accompanied by the documentation set out in Annex 2 to this Act. The documentation for applications for the type-approval of a packaging assembly, special form radioactive materials and low dispersible radioactive materials shall comprise documentation of tests or calculations and analyses and their independent verification by authorised legal persons, which shall be ensured by applicants at their own cost, and detailed technical specifications of the packaging assembly.

(5) The documentation referred to in paragraph 4 shall not be required if it has already been presented to the office in a previous product type-approval procedure, provided that no changes have been made in the documentation. In cases covered by the first sentence, the applicant shall attach to the application a statement that no changes have been made in the documentation together with a list of documentation presented previously.

(6) Implementing legislation shall establish

- a) the scope, content and method of conducting the tests or calculations and analyses to be included in an application for product type-approval,
- b) the content of the documentation of tests or calculations and analyses to be included in an application for product type-approval,
- c) the requirements for authorised legal persons conducting tests and independent verification of tests or calculations and analyses to be included in an application for product type-approval,
- d) the scope and form of the documentation according to paragraph 4.

## § 139

### **Particulars of a product type-approval decision**

- (1) The Office shall provide the following in a product type-approval decision
- a) in the case of type-approval of packaging assemblies
    1. identification of the packaging assembly within the scope of the information provided in the application,
    2. period of validity of the decision,
    3. restrictions relating to transportation of the packaging assembly,
    4. a list of legislation and international documents, according to which the type of the packaging assembly was approved,
    5. a description of the packaging assembly, including the total weight and total external dimensions, with references to technical drawings, material sheets or description of the product type,
    6. reproducible illustration of the packaging assembly, not larger than 21 cm × 29.7 cm,
    7. description of allowable radioactive contents,
    8. detailed technical specifications of the packaging assembly within the scope of the information provided in the documentation for the application,

9. a list of additional measures applicable to loading, carriage, handling and unloading of the packaging assembly, including special conditions for heat dissipation while loaded on the means of transport during carriage, if heat is generated,
  10. references provided by the applicant to information about any measures required when handling the packaging assembly or before transportation,
  11. a list of ambient conditions taken into account when designing the packaging assembly,
  12. radiation extraordinary event management measures and procedures and
  13. identification of the manufacturer within the scope of the information provided in the application,
- b) if the packaging assembly contains a fissile material, the following shall also be provided
1. description of the allowable content and form of the fissile material,
  2. the criticality safety index value,
  3. references to documentation providing evidence that the content is maintained subcritical,
  4. description of the device or equipment to prevent water penetration into the free space in the packaging assembly when evaluating criticality, if the packaging assembly contains them,
  5. information about the facts used in the evaluation of criticality, in the case of packaging assemblies for irradiated nuclear fuel and
  6. the ambient temperature range for which the design type of the packaging assembly has been approved,
- c) in the case of type B(M)<sup>17)</sup> packaging assemblies, a list of the requirements under the implementing legislation for type B(M)<sup>17)</sup> packaging assemblies that the shipping container does not satisfy shall also be provided,
- d) in the case of special form radioactive materials and low dispersible radioactive materials
1. identification of the product within the scope of the information provided in the application,
  2. period of validity of the decision,
  3. a list of legislation and international documents, according to which the design type of the product was approved,
  4. description of the product, with references to technical drawings, material sheets or descriptions of the design type of the product,
  5. description of the product's make-up, including weight and total external dimensions, and a reproducible illustration, not larger than 21 cm × 29.7 cm, showing the make-up,
  6. description of the allowable radioactive contents, including its physical state, chemical form, activity and quantity in grams,
  7. the conditions under which the type-approval of the product is being issued and
  8. identification of the manufacturer within the scope of the information provided in the application,
- e) in the case of sources of ionising radiation
1. identification of the product within the scope of the information provided in the application,
  2. period of validity of the decision,
  3. a list of legislation and international documents, according to which the design type of the product was approved,

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<sup>17)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods

4. description of the product, with references to technical drawings, material sheets or descriptions of the design type of the product,
5. the conditions under which the type-approval of the product is being issued,
6. identification of the manufacturer within the scope of the information provided in the application,
7. classification of the source of ionising radiation and
8. the frequency and minimum scope of acceptance testing, long-term stability testing and operational stability testing of the source of ionising radiation.

(2) The office shall issue a decision on the type-approval of a packaging assembly within a period of 12 months of commencement of the product type-approval procedure.

## § 140

### **Verification and documentation of conformity of a product's characteristics with the approved product type**

(1) Manufacturers, importers or distributors of products subject to product type-approval or other persons making such products available on the market shall ensure verification of the conformity of every product unit with the approved product type, document this verification by a declaration of conformity and report the serial number of every product unit to the office.

(2) The verification of conformity of a product or a packaging assembly intended for carriage, storage or disposal of radioactive or fissile materials specified in implementing legislation, special form radioactive materials and low dispersible radioactive materials shall be carried out by verifying conformity of the product with the documentation presented to the office for type-approval of the product, except packaging assemblies intended for carriage, storage and disposal of spent fuel, which is selected equipment, in which case the procedure under § 58 is followed.

(3) Manufacturers, importers or distributors of products subject to product type-approval or other persons making such products available on the market shall ensure new verification of compliance and issue a declaration of conformity, in case of a change in facts that may affect product characteristics relevant to nuclear safety and radiation protection.

(4) The declaration of conformity shall be in Czech and shall contain

- a) identification data of the person to whom it is issued,
- b) identification data of the product,
- c) a declaration that the product is safe and appropriate for the given purpose,
- d) the method of verification of conformity used and a list of legislation and technical standards, according to which the conformity was verified,
- e) references to documents issued in the course of verification of conformity,
- f) the name, address of registered office and identification number of the person who verified the conformity,
- g) the date of issue of the declaration of conformity and the name(s), surname and position of the natural person issuing the declaration of conformity.

## Part 3 Carriage

### Subpart 1

## Carriage of radioactive or fissile materials

### § 141

#### Obligations of carriers in respect of carriage of radioactive or fissile materials

(1) The carrier shall

- a) hand over radioactive or fissile materials only to persons authorised to manage them under this Act,
- b) ensure that the carriage and transport of the radioactive or fissile material complies with implementing legislation and other legislation<sup>8)</sup>, ensure security of the radioactive or fissile material, physical protection of nuclear materials, and radiation extraordinary event management, and prevent misuse of information about the carriage,
- c) determine the transport index, criticality safety index and category of the radioactive shipment, non-fixed contamination and equivalent dose rates,
- d) provide technical and organisational conditions for the carriage and transport of the radioactive or fissile material,
- e) ensure the documentation necessary for the carriage and transport of the radioactive or fissile material,
- f) draw up and make permanently available intervention instructions,
- g) inform the office, the administrative authorities concerned, the transporter and other persons concerned about the carriage,
- h) ensure identification of the radioactive shipment with the relevant information, including the UN number,
- i) affix hazard labels to the radioactive shipment and, where a container is used, mark it appropriately and affix large hazard labels and orange plates to it,
- j) affix large hazard labels and orange plates to the means of transport in accordance with other legislation<sup>8)</sup>,
- k) use only such types of packaging assemblies for the carriage of radioactive or fissile materials that comply with the technical requirements for the design, safety functions and marking of packaging assemblies and for the handling thereof depending on the radioactive contents,
- l) discuss the necessary radiation extraordinary event management measures with the Fire Rescue Service of the Czech Republic, unless otherwise provided in emergency regulations, and
- m) in the event of a radiation accident or suspected radiation accident, immediately inform the office, the relevant operations centre of the Police of the Czech Republic and the relevant operations and information centre of the Fire Rescue Service of the Czech Republic.

(2) When carrying radioactive or fissile materials to the Czech Republic or during their transit through the Czech Republic, the carrier shall carry a declaration of the consignor of the radioactive or fissile material who is established in a State that is not a member of the Euratom, approved by the competent authorities of that State, that the materials will be taken back if the shipment cannot be completed.

(3) Implementing legislation shall establish

- a) the method of determination and the highest permissible values of the transport index, the criticality safety index, non-fixed contamination and equivalent dose rate and the method of identifying the radioactive shipment category,
- b) the technical and organisational conditions for the carriage and transport of radioactive or fissile materials,



- c) the requirements on content, language version and availability of the documentation necessary for the carriage and transport of radioactive or fissile materials,
- d) the method and scope of notifying administrative authorities and persons concerned about shipments and terms for its performing,
- e) the method of marking, appearance and method of using the hazard labels for the labelling of radioactive shipments and the means of transport and containers used for carriage.

§ 142

**Obligations of carriers in respect of carriage of radioactive or fissile materials subject to authorisation**

When carrying radioactive or fissile materials, the carriage of which is subject to authorisation under this Act, the carrier shall

- a) notify the competent customs office of their entry into the territory of the Czech Republic from a State that is not a member of the Euratom or of their exit to a State that is not a member of the Euratom,
- b) in the case of transit through the Czech Republic, upon their entry into the territory of the Czech Republic present to the competent customs office the original or a certified copy of a valid authorisation from the State to which this material is to be released from a Member State of the Euratom.

Subpart 2

**Transboundary shipments of radioactive waste or spent fuel**

§ 143

**Authorisation of transboundary shipments of radioactive waste or spent fuel**

(1) Applications for authorisation of transboundary shipments of radioactive waste or spent fuel shall be filed using the standard document, in accordance with Euratom legislation<sup>18)</sup>.

(2) Combined authorisation for multiple shipments of radioactive waste or spent fuel may be granted, if it was applied for it by one application and

- a) the radioactive waste or spent fuel has the same physical, chemical and radioactive characteristics,
- b) the shipments are to be made only from the same holder of radioactive waste or spent fuel to the same consignee and always involve the same competent authorities and
- c) the shipments are to be made via the same border crossing point, if they concern a State that is not a member of the Euratom.

(3) The Office may, in agreement with the competent authorities of the Member States of the Euratom which the shipment concerns, authorise a shipment even in cases where the condition referred to in paragraph 2(c) is not satisfied.

(4) Implementing legislation shall establish forms of standard documents in the area of transboundary shipments of radioactive waste or spent fuel.

§ 144

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<sup>18)</sup> Commission Decision 2008/312/Euratom.

### **Shipments from the Czech Republic to another Member State of the Euratom**

(1) When shipping radioactive waste or spent fuel from the Czech Republic to another Member State of the Euratom, the holders thereof shall

- a) file an application for authorisation of the shipment in the manner referred to in § 143(1),
- b) ensure that the radioactive waste or spent fuel is taken back at their own cost, where the shipment cannot be completed or where the conditions for shipment do not comply with the provisions of this Act and other legislation<sup>8)</sup>, unless other safe arrangements can be made to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management, and security, and
- c) ensure that, if necessary, the transporter takes the necessary corrective measures to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management, and security.

(2) When shipping radioactive waste or spent fuel from the Czech Republic to another Member State of the Euratom, the Office shall

- a) send a copy of the application referred to in paragraph 1(a) to the competent authorities of the State of destination or the State of transit that is a Member State of the Euratom,
- b) take the necessary measures to ensure that all information regarding the shipment is protected against any misuse,
- c) ensure the immediate transmission of additional information to the competent Authority of the Member State concerned, if requested,
- d) issue authorisation for the transboundary shipment of radioactive waste or spent fuel
  1. after obtaining the acknowledgement of receipt of a duly completed application from the competent authorities of the State of destination,
  2. on the basis of receipt of consents to the shipment from the competent authorities of the States to which the application referred to in (a) was sent; the fruitless expiry of the period for granting consent under (e) shall be construed as an expression of the competent Authority's consent to the proposed shipment, and
  3. if the shipment complies with the relevant legislation of the Czech Republic, legislation of the Euratom and international legislation applicable to shipments of radioactive substances,
- e) issue, without undue delay, authorisation for the transboundary shipment referred to in (d) after
  1. the expiry of a period of two months from the acknowledgement of receipt of the application by the competent authorities of the State of destination, unless a State to which the application referred to in (a) was sent requested an additional period, or
  2. the expiry of the additional period of not more than one month, requested by a State to which the application referred to in (a) was sent,
- f) issue the authorisation referred to in (d) in the form laid down in legislation of the Euratom<sup>18)</sup>; the authorisation shall be valid for a period of not more than three years; when establishing this period of validity of the authorisation, the Office shall take into account the conditions set out in the consents to the shipment given by the competent authorities of all of the States to which the application referred to in (a) was sent,
- g) inform all competent authorities of the Member States of the Euratom or third countries concerned that the authorisation has been issued,
- h) send a copy of the acknowledgement of receipt of the radioactive waste or spent fuel, i.e. the relevant part of the standard document received from the competent Authority of the State of destination, to the original holder of the radioactive waste or spent fuel,
- i) report to the European Commission any cases of unjustified delays or lack of cooperation by the competent authorities of another Member State of the Euratom.

(3) The Office may decide that the shipment cannot be completed if the conditions for shipment do not comply with the provisions of this Act or other legislation<sup>8)</sup> or if these conditions are not in accordance with the authorisations or consents given by the Member State of the Euratom concerned, and immediately inform of this fact the competent authorities of the Member State or third countries concerned. Decision is the first administrative act in the proceedings.

## § 145

### **Shipments from the Czech Republic to a State that is not a member of the Euratom**

(1) When shipping radioactive waste or spent fuel from the Czech Republic to a State that is not a member of the Euratom, the holders thereof shall

- a) file an application for authorisation of the shipment in the manner referred to in § 143(1),
- b) ensure that the radioactive waste or spent fuel is taken back at their own cost, where the shipment cannot be completed or where the conditions for shipment do not comply with the provisions of this Act and other legislation<sup>8)</sup>, unless other safe arrangements can be made to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security,
- c) ensure that, if necessary, the transporter takes the necessary corrective measures to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management, and security,
- d) ensure that immediately after receiving the radioactive waste or spent fuel, the consignee sends them the acknowledgement of receipt of the radioactive waste or spent fuel using the relevant part of the standard document or a declaration with the same content and informs them of the last customs office in the Euratom, through which the shipment passed, and
- e) send to the Office within 15 days of handing over the radioactive waste or spent fuel, the acknowledgement of receipt of the radioactive waste or spent fuel completed by the consignee in the relevant part of the standard document, specifying the last customs office in the Euratom, through which the shipment passed; if the standard document is not completed by the consignee, it shall be completed by the holder of the radioactive waste or spent fuel and accompanied by the consignee's declaration referred to in (d).

(2) When radioactive waste or spent fuel is shipped from the Czech Republic to a State that is not a member of the Euratom, the Office shall

- a) inform the competent authorities of the State of destination of the planned shipment, ask their consent and send a copy of the application referred to in paragraph 1(a) to the competent authorities of the Member States of transit in the Euratom and
- b) proceed in accordance with § 144(2)(b) to (g) and paragraph 3.

## § 146

### **Shipments to the Czech Republic from a State that is not a member of the Euratom**

(1) When shipping radioactive waste or spent fuel from a State that is not a member of the Euratom to the Czech Republic, the consignees thereof shall

- a) ensure that the holders of the radioactive waste or spent fuel complete and confirm the application for authorisation of the shipment of radioactive waste or spent fuel using the standard document and present this application to the Office,
- b) provide evidence to the Office that they have made arrangements to ensure that the radioactive waste or spent fuel is taken back by the holders of the radioactive waste or spent

fuel at their own cost, where the shipment cannot be completed or where the conditions for shipment do not comply with the provisions of this Act and other legislation<sup>8)</sup>, unless other safe arrangements can be made to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security; such a contract shall be approved by the competent authorities of the third country, in which the holder is established,

- c) ensure that, if necessary, the transporter takes the necessary corrective measures to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management, and security, and
- d) send to the Office within 15 days of receiving the radioactive waste or spent fuel, the acknowledgement of receipt of the radioactive waste or spent fuel using the relevant part of the standard document.

(2) In the case of transboundary shipment of radioactive waste or spent fuel from a State that is not a member of the Euratom to the Czech Republic, including transit through Member States of the Euratom, the Office shall

- a) send a copy of the application referred to in paragraph 1(a) to the competent authorities of the State of transit in the Euratom,
- b) proceed in accordance with § 144(2)(b) to (g) and paragraph 3, and
- c) send a copy of the acknowledgement of receipt of the radioactive waste or spent fuel using the relevant part of the standard document to the competent authorities of all Member States of the Euratom or third countries concerned.

## § 147

### **Transit shipments**

(1) In the case of shipments of radioactive waste or spent fuel between States that are not members of the Euratom, which involve transit through Member States of the Euratom and where the Czech Republic is the first Member State of the Euratom which the radioactive waste or spent fuel is to enter, the persons who ensures carrying out the shipment in the territory of the Czech Republic shall

- a) ensure that the holders of the radioactive waste or spent fuel complete and confirm the application for authorisation of the shipment of radioactive waste or spent fuel using the standard document and present this application to the Office,
- b) provide evidence to the Office that they have made arrangements to ensure that the radioactive waste or spent fuel is taken back by the holders of the radioactive waste or spent fuel at their own cost, where the shipment cannot be completed or where the conditions for shipment do not comply with the provisions of this Act and other legislation<sup>8)</sup>, unless other safe arrangements can be made to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security; such a contract shall be approved by the competent authorities of the third country, in which the holder is established, and
- c) ensure that the holder of the radioactive waste and spent fuel ensures that, if necessary, the transporter takes the necessary corrective measures to ensure nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security.

(2) Holders of authorisation for transboundary shipment of radioactive waste or spent fuel shall

- a) make arrangements to ensure that immediately after receiving the radioactive waste or spent fuel, the consignee sends them a notification that the radioactive waste or spent fuel

has reached its destination, indicating the last customs office through which the shipment passed,

- b) inform the Office within 15 days of handing over the radioactive waste or spent fuel to the consignee that the radioactive waste or spent fuel has reached its destination and
- c) send to the Office the consignee's notification referred to in (a).

(3) In the case of transboundary shipments of radioactive waste or spent fuel between States that are not members of the Euratom, which involve transit through Member States of the Euratom and where the Czech Republic is the first Member State of the Euratom which the radioactive waste or spent fuel is to enter, the Office shall

- a) send a copy of the application referred to in paragraph 1(a) to the competent authorities of the State of transit in the Euratom and
- b) proceed in accordance with § 144(2)(b) to (g) and paragraph 3.

### § 148

#### **Shipments not subject to authorisation**

(1) In the case of shipments of radioactive waste or spent fuel that are not subject to authorisation under § 9(4), where the Czech Republic is a State of transit, but not the first Member State of the Euratom which the radioactive waste or spent fuel is to enter, the Office shall

- a) within 20 days of receipt of the request for consent to the shipment of radioactive waste or spent fuel from the competent authorities of a Member State of the Euratom, verify that the application is duly completed and, if necessary, request the competent authorities of the Member State of the Euratom to provide any missing information; it may be agreed with the competent authorities of the Member States concerned in the shipment to shorten the 20-day period, if these authorities have made sure that the application is duly completed,
- b) inform other competent authorities of the Member States concerned in the shipment that it has requested additional information,
- c) within two months of the date of issue of the acknowledgement of receipt of a duly completed application, notify the competent Authority of the Member State of the Euratom authorising the shipment of its consent to the shipment, consent to the shipment with conditions on which the intended shipment may be carried out, or refusal to consent to the shipment,
- d) provide reasons for attaching conditions to the consent granted or the refusal of consent; these reasons shall be in accordance with other legislation, legislation of the Euratom or international treaties binding on the Czech Republic, relating to shipments of radioactive substances,
- e) have the right to request the competent Authority of the Member State of the Euratom authorising the shipment to extend the time limit for notification referred to in (c), however, by no more than one month; if the Office gives no opinion within this time limit, this shall be deemed as consent to the shipment,
- f) give consent to reshipment of radioactive waste or spent fuel, if
  1. it has previously granted consent to the transit shipment for treatment or reprocessing purposes, it concerns reshipment of products equivalent to the original material after treatment or reprocessing and other legislation is respected, or
  2. the State of destination, origin or transit decides that a shipment cannot be completed and the reshipment is carried out under the same conditions and with the same specifications.

(2) When radioactive waste or spent fuel is shipped from a Member State of the Euratom to the Czech Republic

- a) within 15 days of receiving the radioactive waste or spent fuel, the consignee shall complete and send to the Office the acknowledgement of receipt of the radioactive waste or spent fuel using the relevant part of the standard document,
- b) after receiving the acknowledgement of receipt of the radioactive waste or spent fuel according to (a), the Office shall send a copy thereof to the competent authorities of the Member States of the Euratom or third countries concerned,
- c) The Office shall proceed in accordance with paragraph 1 and, in addition,
  1. send an acknowledgement of receipt of a duly completed application to the competent Authority of the Member State of the Euratom authorising the shipment, if the application is duly completed, no earlier than 20 days of receipt of the application, but not later than 10 days after the expiry of the period of 20 days; if any of these authorities or the office request that missing information be provided, it shall send an acknowledgement of receipt of a duly completed application no earlier than 20 days of receipt of the application, but not later than 10 days after the receipt of the missing information; it may be agreed with the competent authorities of the Member States concerned in the shipment to shorten these periods, and
  2. proceed in accordance with legislation governing the radioactive waste management or spent fuel if conditions are attached to the consent granted or consent is refused.

(3) The Office may decide that a shipment cannot be completed if the conditions for shipment do not comply with the provisions of this Act or other legislation<sup>8)</sup> or with the authorisations or consents to the shipment granted by the Member State of the Euratom concerned, and immediately inform of this fact the competent authorities of the Member State or third countries concerned. Decision is the first administrative act in the proceedings.

## Title VII **Radiation situation monitoring**

### § 149

(1) Radiation situation monitoring in the territory of the Czech Republic shall be carried out

- a) in the form of monitoring under normal radiation situation, including monitoring during emergency exercises, drills and comparative measurements, in planned and existing exposure situations or in the form of accidental monitoring in emergency exposure situations,
- b) by measuring and evaluating the physical quantities characterising the radiation field and the radionuclide content in monitored items at monitoring sites or in monitoring routes organised into monitoring networks for the purposes of evaluating external and internal public exposure,
- c) by using direct measurements and its evaluating at monitoring sites or in monitoring routes or using indirect measurements and its evaluating in a measurement laboratory of samples taken at monitoring sites or in monitoring routes,
- d) by transmitting monitoring data to the Office, which processes, evaluates and publishes the data.

(2) The radiation situation monitoring referred to in paragraph 1, except monitoring during emergency exercises, drills and comparative measurements, shall be ensured by

- a) the Office, throughout the territory of the Czech Republic, administrative authorities referred to in §§ 216 to 218 and §§ 220 to 223, persons who are holders of a tip, settling pond or other residue of b)e) activity related to acquiring of radioactive minerals or other mining activity accompanied by the occurrence of a radioactive mineral, or other persons referred to in the national monitoring programme for the territory of the Czech Republic (hereinafter the “national monitoring programme”) for selected parts of the territory of the Czech Republic,
- b) licence holders according to the monitoring programme applicable to the site for a nuclear installation or a workplace using sources of ionising radiation is sited or to the area of an emergency planning zone, if established.

(3) The office under the radiation situation monitoring management, when an emergency exposure situation occurs, initiates emergency monitoring and in the situation scope and in accordance with the monitoring programme may determine the extent and manner of participation of each of the persons referred to in paragraph 2(a) to the emergency monitoring.

(4) Radiation situation monitoring during emergency exercises, drills and comparative measurements shall follow the monitoring programme referred to in paragraph 2 and the instructions given for emergency exercises, drills and comparative measurements by their organisers.

(5) For the purposes of monitoring and evaluating the radiation situation, graded monitoring levels shall be set out in the monitoring programme.

(6) Implementing legislation shall establish

- a) the detailed requirements for the form and method of radiation situation monitoring,
- b) the criteria for selecting further persons to perform radiation situation monitoring,
- c) the content of the national monitoring programme,
- d) the requirements for establishing emergency planning zones.

## § 150

(1) Holders of a licence for the operation of a category III workplace, who are at the same time holders of a licence for the discharge of a radioactive substance from the workplace, and holders of a licence for the operation of a category IV workplace shall

- a) provide for the monitoring of discharges and the surrounding area in accordance with the monitoring programme, including accidental monitoring,
- b) provide for a measurement laboratory and its participation in comparative measurements organised by the Office and the European Commission,
- c) tolerate the monitoring of discharges by the Office at the nuclear installation grounds or in the workplace, in accordance with the national monitoring programme, and provide the necessary assistance,
- d) perform accidental monitoring drills as part of the emergency exercises referred to in § 156(1)(f),
- e) transmit data from the monitoring of discharges and their surrounding areas to the Office, and
- f) draw up an annual report on the monitoring of discharges and their surrounding areas and forward it to the Office by 15 February of the following calendar year.

(2) Holders of a licence for the siting of a nuclear installation, holders of a licence for the construction of a nuclear installation, holders of licence for the construction of a category IV workplace or holders of a licence for the closure of a radioactive waste disposal facility shall

- a) provide for the monitoring of the surrounding area in accordance with the monitoring programme, including accidental monitoring,
- b) provide for a measurement laboratory and its participation in comparative measurements organised by the Office and the European Commission,
- c) transmit data from the monitoring of the surrounding area to the Office, and
- d) draw up an annual report on the monitoring of the surrounding areas and forward it to the Office by 15 February of the following calendar year.

(3) Holders of a licence for the performance of services relevant to radiation protection under § 9(2)(h), Point 3, shall

- a) provide for a measurement laboratory and its participation in comparative measurements organised by the Office and the European Commission and
- b) transmit data from the monitoring of the surrounding area to the Office.

(4) Implementing legislation shall establish

- a) the requirements for the activities performed by measurement laboratories and for the equipment of measurement laboratories,
- b) the scope and method of comparative measurements,
- c) the content of the annual report on the monitoring of discharges and surrounding areas.

## Title VIII

### **Radiation extraordinary event management**

#### § 151

#### **Definition of certain terms in the area of radiation extraordinary event management**

For the purposes of this Act, the following definitions shall apply

- a) radiation extraordinary event response means the application of a set of measures to manage a situation related to the occurrence of a radiation extraordinary event, with the aim of regaining control over the situation and preventing and mitigating the consequences of the radiation extraordinary event that has arisen, including non-radiation consequences,
- b) radiation extraordinary event response preparedness means a set of organisational, technical, material and personnel measures prepared according to the likely course of a radiation extraordinary event in order to avert or mitigate its impacts; these measures may take the form of intervention instructions, on-site emergency plans, emergency regulations, off-site emergency plans and the national radiation extraordinary event plan.

#### § 152

When managing radiation extraordinary event in matters not regulated by this Act it shall be proceeded by the Act on Integrated Rescue System or the Act on Crisis Management.

#### § 153

#### **Categorisation in the area of radiation extraordinary event management**

(1) Depending on the magnitude of the potential impacts of a radiation incident or radiation accident in the territory of the Czech Republic, nuclear installations, workplaces using sources of ionising radiation and activities in exposure situations shall be classified in threat categories A to E.



(2) For the purposes of a graded approach to radiation extraordinary event response preparedness, radiation extraordinary events shall be categorised as first degree radiation extraordinary event, radiation incident or radiation accident.

(3) Implementing legislation shall establish the rules for classifying nuclear installations, workplaces using sources of ionising radiation and activities in exposure situations in threat categories.

#### § 154

##### **Radiation extraordinary event analysis and assessment**

(1) Applicants for licences referred to in § 9(1)(b) and (g), § 9(2)(a), (b), (d) and (f), § 9(3)(a) and (b), and § 9(4) shall

- a) draw up a radiation extraordinary event analysis and assessment,
- b) on the basis of the results of the radiation extraordinary event analysis and assessment, determine the category of the radiation extraordinary event that may arise while performing the licensed activity,
- c) on the basis of the results of the radiation extraordinary event analysis and assessment, determine the threat category,
- d) report the threat category to the person drawing up the off-site emergency plan and the national radiation extraordinary event plan, and
- e) take into account the results of the radiation extraordinary event analysis and assessment when drawing up the documentation for the licensed activity.

(2) Radiation extraordinary event analysis and assessment shall be conducted on the basis of a list of potential radiation extraordinary events, their causes and the extent of their impacts on the execution of activities in exposure situations, activities related to the use of nuclear energy, radioactive waste management and spent fuel, or carriage of radioactive or fissile materials.

(3) Implementing legislation shall establish the detailed rules for conducting radiation extraordinary event analysis and assessments.

#### § 155

##### **Radiation extraordinary event response preparedness**

(1) Radiation extraordinary event response preparedness shall include education and training for radiation extraordinary event response and preparation for

- a) the detection of radiation extraordinary events,
- b) the classification of radiation extraordinary events that have arisen in categories,
- c) the declaration of a radiation extraordinary event and notification of the authorities concerned,
- d) the management and implementation of response to radiation extraordinary events,
- e) the restriction of accidental exposure,
- f) health matters,
- g) the provision of preliminary information to the general public,
- h) the checking of radiation extraordinary event response preparedness,
- i) the receipt of external assistance, and

- j) the documentation of radiation extraordinary event response preparedness, including the drawing up of on-site emergency plans, off-site emergency plans and the national radiation extraordinary event plan, as well as emergency regulations.

(2) On-site emergency plan shall be drawn up for nuclear installation grounds or ionising radiation sources workplace. Off-site emergency plan shall be drawn up for emergency planning zone.

(3) Implementing legislation shall establish

- a) the requirements for the content of the national radiation extraordinary event plan and  
b) the procedure and measures for ensuring radiation extraordinary event response preparedness.

## § 156

### **Obligations of the holders of a licence for ensuring radiation extraordinary event response preparedness**

(1) The licence holders shall

- a) immediately familiarise all persons concerned with the approved on-site emergency plan, including persons operating a facility or installation that may be influenced or affected by a radiation extraordinary event arisen in the course of the activities for which the licence has been granted to the licence holder (hereinafter the “neighbouring person”) and persons designated in the on-site emergency plan to respond to radiation extraordinary events,  
b) immediately familiarise the natural persons concerned with the intervention instructions drawn up,  
c) immediately familiarise all persons designated in emergency regulations to ensure transportation and natural persons designated to perform response action with the approved emergency regulations,  
d) share information necessary for the management and implementation of response to a radiation extraordinary event arisen in the context of the licensed activity with neighbouring persons, if they are also holders of a licence under this Act,  
e) provide for a system of education on radiation extraordinary event management for the natural persons concerned with the intervention instructions, the on-site emergency plan or emergency regulations,  
f) regularly check radiation extraordinary event response preparedness by means of drills, emergency exercises and verification of the functionality of technical means in accordance with the on-site emergency plan, intervention instructions and emergency regulations; the checking of radiation extraordinary event response preparedness shall be conducted on the basis of an annual plan and evaluated, and  
g) ensure compliance of the quantities and parameters monitored under their programmes for the monitoring of discharges and programmes for the monitoring of the surrounding areas with the monitoring levels set out in the on-site emergency plan.

(2) Holders of a licence for the performance of activities related to the use of nuclear energy and for the performance of activities in exposure situations, for which an emergency planning zone has been established, shall

- a) cooperate with State and territorial authorities and with the intervention units of the integrated rescue system to ensure radiation extraordinary event response preparedness in the case of a radiation accident in the emergency planning zone,  
b) provide supporting documents for the drawing up of

1. the off-site emergency plan, to the Fire Rescue Service of the Czech Republic and regional authorities,
  2. the national radiation extraordinary event plan, to the office and the Ministry of the Interior,
- c) provide for radiation situation monitoring systems at the nuclear installation grounds and in the emergency planning zone and take part in radiation situation monitoring in the territory of the Czech Republic in accordance with § 149(2)(b),
  - d) in cooperation with the competent regional Authority or the Fire Rescue Service of the Czech Republic, ensure that the general public and the integrated rescue system units intervening to radiation accidents in the emergency planning zone are provided with iodine prophylaxis antidotes,
  - e) provide basic information to the general public in the emergency planning zone for the case of a radiation accident and update it regularly; basic information for the case of a radiation accident may only be provided or updated on the basis of an affirmative statement of the office, the Fire Rescue Service of the Czech Republic and the president of the region,
  - f) provide for a system of notification of the authorities concerned,
  - g) acquire, maintain and operate warning system terminals in the emergency planning zone<sup>20)</sup>,
  - h) verify, by means of exercises and tactical exercises<sup>21)</sup> in cooperation with the competent public administration authorities and integrated rescue system units, the accuracy, efficiency and mutual consistency between on-site and off-site emergency plans and their consistency with the national radiation extraordinary event plan,
  - i) participate in the evaluation of the exercises and tactical exercises referred to in (h) and, on the basis of the results of the evaluation, take measures to remedy the deficiencies found,
  - j) immediately inform the Office of the provision of supporting documents for the drawing up of the off-site emergency plan to regional authorities and the Fire Rescue Services of the Czech Republic and of their content, and
  - k) draw up an annual report on radiation extraordinary events response preparedness in the course of the activities performed by the licence holder and submit it to the office by 31 January of the following calendar year.

(3) The extent of participation by holders of a licence for the performance of activities related to the use of nuclear energy and for the performance of activities in exposure situations, for which an emergency planning zone has been established, in the activities referred to in paragraph 2(e) and (g), except maintenance and operation of the warning system terminals, shall be specified for the relevant calendar year in an agreement between the licence holder and the person drawing up the off-site emergency plan, after the draft agreement has been discussed by the regional security Council.

(4) Implementing legislation shall establish

- a) the method and frequency of verification of on-site emergency plans, the national radiation extraordinary event plan, intervention instructions, emergency regulations and functionality of technical means,
- b) the method and frequency of verification of the efficiency and mutual consistency between on-site emergency plans, off-site emergency plans and the national radiation extraordinary event plan,
- c) the requirements for ensuring radiation extraordinary event response preparedness in the emergency planning zone,

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<sup>20)</sup> § 9(7) of Decree No 380/2002 concerning the preparation and implementation of public protection measures.

<sup>21)</sup> § 17 of Act No 239/2000, as amended.

- d) the content, the form and the scope and method of updating basic information for the event of a radiation accident,
- e) the content of the annual report on preparedness for response to radiation extraordinary events.

§ 157

**Radiation extraordinary event response**

(1) A radiation extraordinary event response performed within a nuclear installation grounds or a workplace using sources of ionising radiation shall be part of the measures and procedures applicable to responding to emergencies or crisis situations in accordance with other legislation<sup>22)</sup>.

(2) Licence holders shall ensure a response to a radiation extraordinary event that has arisen in the course of the activities performed by them, in accordance with the relevant on-site emergency plan, emergency regulations or, if the on-site emergency plan is not drawn up, intervention instructions, specifically

- a) if the maximum monitoring level has been exceeded, immediately initiate a response to the radiation extraordinary event and record the course of the response to the radiation extraordinary event,
- b) immediately warn natural persons present at the nuclear installation grounds or in the premises of the workplace using a source of ionising radiation, take measures to protect them and inform the Office of these measures, and, in the case of a radiation incident involving a suspected release of radioactive substances or ionising radiation out of the nuclear installation grounds or premises of the workplace using a source of ionising radiation, or in the case of a radiation accident, also inform other authorities concerned and the persons specified in the on-site emergency plan or emergency regulations; in the case of a radiation accident, the warning shall include a proposal for taking urgent protective action,
- c) immediately notify the Office about the occurrence or suspected occurrence of a radiation extraordinary event and, in the case of a radiation incident involving a suspected release of radioactive substances or ionising radiation out of the nuclear installation grounds or premises of the workplace with ionising radiation sources, or in the case of a radiation accident, also immediately inform the locally competent mayors of municipalities with extended authorities and the locally competent president of region through the territorially competent operations centre of the Fire Rescue Service of the Czech Republic, other authorities concerned as specified in the on-site emergency plan or emergency regulations, and the neighbouring persons,
- d) in the case of the occurrence or suspected occurrence of a radiation accident, in cooperation with the Fire Rescue Service of the Czech Republic, immediately start warning the general public in the emergency planning zone and ensure the immediate broadcast of the emergency information<sup>23)</sup>; the information shall include the instruction to take urgent protective action in the form of sheltering and application of iodine prophylaxis,
- e) control, evaluate and regulate the exposure of natural persons participating in radiation extraordinary event response at the nuclear installation grounds or in the premises of the workplace using a source of ionising radiation,

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<sup>22)</sup> Act No 239/2000, as amended.

<sup>23)</sup> § 10 of Decree No 380/2002

- f) propose to the president of the region the taking of urgent measures to protect the general public in the emergency planning zone in the form of evacuation according to the actual or expected development of the radiation accident and according to the results of radiation situation monitoring performed in accordance with (j),
- g) transmit to the Office data to evaluate the radiation accident and forecast its development, including data on the meteorological situation in the site of the radiation accident,
- h) in the case of a radiation incident or radiation accident, inform the Office and, in the case of a radiation incident or radiation accident involving a suspected release of radioactive substances or ionising radiation out of the nuclear installation grounds or the premises of the workplace with ionising radiation sources, inform the Fire Rescue Service of the Czech Republic and other authorities and persons concerned as specified in the on-site emergency plan or emergency regulations about the actions taken by them in the course of responding to the radiation extraordinary event,
- i) in the case of a radiation accident, immediately inform the general public affected by this radiation accident about the facts and expected development of the radiation accident,
- j) if a radiation incident or radiation accident is suspected, ensure radiation situation monitoring in the emergency planning zone in accordance with the relevant monitoring programme and the relevant instructions from the Office given in response to the development of the exposure situation, and transmit the data obtained from the monitoring to the Office,
- k) ensure elimination of the consequences of a radiation incident at a nuclear installation grounds or in the premises of a workplace using a source of ionising radiation,
- l) compile the record of the course of the radiation extraordinary event response made in accordance with (a) into a report on the occurrence and development of the radiation extraordinary event and forward this report to the Office within
  1. three months of declaration in the case of radiation accidents or
  2. one month of declaration in the case of other radiation extraordinary events,
- m) keep and retain the record of the course of the radiation extraordinary event response and the report on the occurrence and development of the radiation extraordinary event for a period of at least five years from declaration in the case of radiation extraordinary events or for a period of 30 years from declaration in the case of radiation accidents, and
- n) cooperate in the preparation of remedial action after a radiation accident in the area affected by the radiation accident.

(3) Implementing legislation shall establish the rules for ensuring radiation extraordinary event response referred to in paragraph 2.

## § 158

### **Remedial action after a radiation accident**

(1) The office shall provide proposals for implementation, clarification or recall of remedial actions related to a contaminated area and member of the public within a management of a contaminated area under § 102(4) to ensure remedial action after a radiation accident in the area, or part of the area, affected by the radiation accident.

(2) Licence holders whose activities caused the radiation accident shall

- a) take remedial action after a radiation accident at a nuclear installation grounds or in a category IV workplace, in compliance with the optimised radiation protection strategy as set out in the on-site emergency plan,

- b) decommission the nuclear installation or category IV workplace if it cannot resume operation and
- c) provide assistance in the administration of the contaminated area outside the nuclear installation grounds or category IV workplace and participate in the compensation for damage to third parties under other legislation<sup>24)</sup>.

(3) Implementing legislation shall establish the scope and method of remedial action after a radiation accident.

## Title IX Security

### § 159

#### **Categorisation in the area of security**

(1) Anyone who ensures security shall classify selected nuclear materials in categories I, II or III. Nuclear materials shall be classified according to their type and enrichment, taking into account the risk of unauthorised diversion for the purposes of manufacturing a nuclear explosive device.

(2) Implementing legislation shall establish the method of classifying nuclear materials in categories for security purposes.

### § 160

#### **Physical protection**

(1) Nuclear installations and nuclear materials of categories I to III shall be secured by physical protection.

(2) Physical protection of nuclear installations shall be ensured

- a) at least three months prior to the commencement of loading of nuclear fuel into the nuclear reactor, in the case of nuclear installations with a nuclear reactor, or
- b) at least two months prior to delivery of nuclear material or radioactive waste to the nuclear installation, in the case of nuclear installations other than those referred to in (a).

(3) The method of ensuring physical protection of nuclear installations and nuclear material shall correspond to the hazards arising from the design basis threat.

(4) The design basis threat and rights and duties to ensure physical protection under paragraph (3) for a person ensuring physical protection shall be established by decision of the office.

(5) The design basis threat may only be established on the basis of a binding opinion of the Ministry of the Interior, the Ministry of Defence and the Ministry of Industry and Trade. The binding opinion on the design basis threat shall be issued within 30 days of receipt of the office's request for opinion.

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<sup>24)</sup> Act No 18/1997 on peaceful utilization of nuclear energy and ionising radiation (atomic act) and on changes and amendments of other acts, as amended.

§ 26 Act No 240/2000 on crisis management and on amendments to certain laws (Crisis Act), as amended.

(6) Implementing legislation shall establish the scope and method of ensuring physical protection of nuclear installations and nuclear materials of categories I to III during carriage, taking into account the design basis threat.

§ 161

**Areas within nuclear installations for the purposes of physical protection**

(1) For the purposes of physical protection and on the basis of an analysis of potential consequences of unauthorised activities for nuclear safety, areas shall be delineated and physically demarcated within nuclear installations with restricted and controlled entry on foot or by vehicle, specifically

- a) a guarded area,
- b) a protected area,
- c) an inner area and
- d) a vital area.

(2) Perimeter of a guarded area and a protected area shall be separated by mechanical barriers. Perimeter of an inner area and a vital shall be formed of mechanical barriers.

(3) Only natural persons of good repute may have entry into the guarded area of a nuclear installation and unrestricted access to nuclear material of categories I to III.

(4) Implementing legislation shall establish the rules for delineation, physical demarcation and detection of unauthorised intrusion into a guarded area, protected area, inner area or vital area and the scope of restrictions on entry into these areas on foot or by vehicles.

§ 162

**Security outside physically protected areas and sensitive activities**

(1) The security of nuclear material not classified in the categories referred to in § 159 shall be ensured by placing it in a locked, enclosed area and by keeping a record of any authorised access to it to ensure that it is protected against unauthorised access.

(2) Within the meaning of the act on the protection of classified information, the following shall be deemed to be sensitive activities

- a) the performance of duties as a member of a statutory body of a legal person that is a holder of a licence under § 9(1) and that performs activities for which a vital area or an inner area must be delineated,
- b) organisation and management of the operation of a nuclear installation,
- c) direct management of the operation of a nuclear reactor,
- d) management of radiation extraordinary event responses in accordance with an on-site emergency plan or emergency regulations,
- e) unaccompanied entry into a vital area,
- f) unaccompanied entry into an area where nuclear material of category I or II is located and management of this material.

§ 163

### **Obligations of licence holders in the area of security of nuclear installations and nuclear material**

(1) Holders of a licence under § 9(1)(b) to (h) and (5) shall

- a) secure the computer systems necessary for the management of nuclear safety, nuclear material accountancy, physical protection and radiation extraordinary event management against unauthorised use,
- b) adopt organisational and technical measures and maintain documentation concerning security of nuclear installations and nuclear materials,
- c) for nuclear installations and nuclear material of categories I to III, ensure
  1. entry and access control and monitoring,
  2. surveillance, evaluation, monitoring and signalling of intrusion or unauthorised access, and
  3. transmission of information about intrusion or unauthorised access to a nuclear installation or nuclear material of categories I to III,
- d) ensure that the construction site of a nuclear installation under construction is fenced and entry into the site on foot or by vehicle is controlled, and
- e) ensure physical surveillance of nuclear installations and nuclear materials located in a guarded area, protected area, inner area or vital area (hereinafter “physical surveillance”).

(2) Implementing legislation shall establish

- a) the organisational and technical measures to ensure security of nuclear installations and nuclear materials,
- b) the scope and method of ensuring physical surveillance.

### § 164

#### **Security of radionuclide sources**

(1) Licence holders performing activities in planned exposure situations and notifying persons using a type-approved minor source of ionising radiation shall

- a) secure the radionuclide source against unauthorised access, use or relocation by applying a graded approach, taking into account the security category and the method of management of the radionuclide source,
- b) instruct and verify the knowledge of workers with access to the radionuclide source of the security requirements and
- c) ensure security of radionuclide sources of security categories 1 to 3.

(2) Implementing legislation shall establish the method of ensuring security of radionuclide sources, including radionuclide sources of security categories 1 to 3.

### Title X

#### **Non-proliferation of nuclear weapons**

### § 165

#### **Definition of certain terms in the area of non-proliferation of nuclear weapons**

For the purposes of this Act, safeguarded installation means

- a) a nuclear reactor, a critical facility, a conversion plant, a plant for the fabrication of nuclear fuel, a reprocessing plant, an isotope separation plant, or a separate storage installation used for the storage of nuclear material,



- b) an installation, in which nuclear material in amounts greater than one effective kilogram is customarily used<sup>25)</sup>.

## § 166

### **Obligations of persons in the area of non-proliferation of nuclear weapons**

(1) Persons intending to operate a safeguarded installation shall notify the office of this fact at least 200 days before the expected commencement of construction.

(2) Persons operating a safeguarded installation shall notify the office of any changes in its basic technical characteristics<sup>26)</sup> within 30 days after the modification is complete.

(3) Persons intending to manufacture a selected nuclear item or operate a safeguarded installation and sites where nuclear material is used in quantities less than one effective kilogram, except safeguarded installations or sites where such nuclear material is used only for shielding purposes, shall present to the Office, prior to the commencement of manufacturing or operation, documentation for the delimitation of the site<sup>27)</sup>.

(4) Persons intending to close down a safeguarded installation shall notify the office of this fact immediately.

(5) Persons liable under Euratom legislation to transmit information to the European Commission concerning the fulfilment of commitments arising from the Treaty on the Non-Proliferation of Nuclear Weapons shall immediately send this information to the Office. These persons shall also immediately send to the office information concerning the fulfilment of commitments arising from the Treaty on the Non-Proliferation of Nuclear Weapons that they have received from the European Commission.

(6) Implementing legislation shall establish

- a) the concentration of isotopes of an element in a material making it a source material,
- b) the concentration of radionuclide in a material making it a special fissile material,
- c) list of other special fissile materials that are significant for non-proliferation of nuclear weapons,
- d) list of selected nuclear items, dual-use nuclear items and other nuclear items are significant for non-proliferation of nuclear weapons.

## § 167

### **Obligations of holders of a licence in the area of non-proliferation of nuclear weapons**

(1) Holders of a licence in the area of non-proliferation of nuclear weapons shall

- a) allow only authorised persons to manage nuclear items,
- b) perform nuclear material control in the manner laid down in Euratom legislation and implementing legislation,
- c) maintain a system of nuclear material accountancy and document and notify the Office and the European Commission of
  1. any changes in the inventory of nuclear materials and

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<sup>25)</sup> Article 2(13) of Commission Regulation (Euratom) No 302/2005.

<sup>26)</sup> Article 4 of Commission Regulation (Euratom) No 302/2005.

<sup>27)</sup> Article 2(21) of Commission Regulation (Euratom) No 302/2005.

2. the results of the physical inventory and material balance of nuclear materials,
- d) retain the documentation referred to in (c) for a period of five years,
- e) as soon as they learn that criminal proceedings have been brought against an employee for a crime or criminal offence committed in connection with the activities performed, prevent this employee from access to nuclear material or entry into a safeguarded installation, and
- f) transmit to the office information about the content of the documents required under Euratom legislation and the data required under Euratom legislation.

(2) Implementing legislation shall establish

- a) the scope and method of nuclear material control by holders of a licence in the area of non-proliferation of nuclear weapons,
- b) the information about the content of documents and the scope of data to be transmitted to the Office under paragraph 1(f), as well as the term and method of transmission,
- c) the scope and method of nuclear material accountancy,
- d) specimens of the forms for reporting data from the nuclear material accountancy system to the Office and the European Commission.

#### § 168

##### **Export and transit of nuclear materials and selected nuclear items**

(1) Persons intending to export nuclear material or a selected nuclear item shall ensure protection of information that could be misused for the production of a nuclear explosive device or for nuclear terrorism.

(2) A licence for the export or transit of nuclear material or a selected nuclear item may only be issued on the condition that the receiving State issues a guarantee covering the requirements arising from international treaties binding on the Czech Republic (hereinafter "State guarantee"). The State guarantee shall be requested from the receiving State by the office, which shall suspend the administrative procedure for the issue of the licence for this purpose.

(3) Holders of a licence for the export of nuclear material or a selected nuclear item shall, after realisation of the export, notify the Office of the date of export from the territory of the Czech Republic, the quantity, name and specifications of the nuclear material or selected nuclear item in accordance with implementing legislation and present a written confirmation of receipt from the end-user.

#### § 169

##### **Import of nuclear materials and selected nuclear items**

(1) A licence for the import of nuclear material or a selected nuclear item may only be issued on the condition that the end-user in the Czech Republic makes a declaration on the basis of which the office will issue a State guarantee to the exporter's State covering the requirements arising from international treaties binding on the Czech Republic.

(2) Holders of a licence for the import of nuclear materials or selected nuclear items shall, prior to realisation of the import, notify the Office of

- a) the date of import into the territory of the Czech Republic and
- b) the quantity, name and specifications of the nuclear material or selected nuclear item in accordance with implementing legislation.

(3) The end-user shall manage the nuclear material or selected nuclear item in compliance with the commitments set out in an international treaty binding on the Czech Republic.

(4) The end-user declaration form shall be provided in implementing legislation.

## § 170

### **Export of dual-use nuclear items**

(1) When authorising the export of a dual-use nuclear item, the Office shall take into account whether

- a) the receiving State is a signatory to the Treaty on the Non-Proliferation of Nuclear Weapons or other similar international treaty,
- b) a receiving State which is not a signatory to the treaty referred to in (a), owns a nuclear explosive device or a safeguarded installation not subject to the safeguards of the International Atomic Energy Agency,
- c) the dual-use nuclear item corresponds to the purposes provided in the end-user declaration referred to in paragraph 2,
- d) the dual-use nuclear item is intended for use in research and development, design, construction, operation or maintenance of a uranium reprocessing or enrichment plant,
- e) there is risk of subsequent export of the dual-use nuclear item due to ineffective export controls in the receiving State.

(2) A licence for the export of a dual-use nuclear item may only be issued on the condition that the end-user in the receiving State makes a declaration covering the requirements arising from international treaties binding on the Czech Republic.

(3) Holders of a licence for the export of a dual-use nuclear item shall, after realisation of the export, notify the office of the date of export from the territory of the Czech Republic, the quantity, name and specifications of the dual-use nuclear item in accordance with implementing legislation and present a written confirmation from the end-user of the receipt of the dual-use nuclear item.

(4) Implementing legislation shall establish the content of the end-user declaration.

## § 171

### **Import of dual-use nuclear items**

(1) A licence for the import of a dual-use nuclear item may only be issued on the condition that the end-user in the Czech Republic makes a declaration on the basis of which the office will issue a State guarantee to the State of establishment or residence of the person exporting the dual-use nuclear item to the Czech Republic covering the requirements arising from international treaties binding on the Czech Republic.

(2) Holders of a licence for the import of a dual-use nuclear item shall, prior to realisation of the import, notify the Office of

- a) the date of import into the territory of the Czech Republic and
- b) the quantity, name and specifications of the dual-use nuclear item in accordance with implementing legislation.

(3) The end-user in the Czech Republic shall manage the dual-use nuclear item in accordance with the declaration referred to in paragraph 1.

(4) When transferring a dual-use nuclear item to another user in the Czech Republic, the end-user in the Czech Republic shall alert the other user to the fact that it is a dual-use nuclear item and notify the office of the change of the end-user in the Czech Republic.

(5) The end-user declaration form shall be provided in implementing legislation.

## § 172

### **Obligations of holders of a licence for the export, import or transit of nuclear items**

Holders of a licence for the export, import or transit of nuclear items shall

- a) present the licence for the export or import of a nuclear item to the respective customs authority, if requested by them,
- b) in the case of import of nuclear material, provide the respective customs authority with evidence that the consignee is authorised to manage this material under this Act and
- c) maintain registers, business documents and records about executed exports, imports and transfers of a nuclear item since the end of a calendar year when they were done in the case of a nuclear item which is
  1. a nuclear material for a period of at least five years,
  2. a selected nuclear item or a dual-use nuclear item for a period of at least three years.

## § 173

### **Transfer of a nuclear item**

Notifying persons transferring a nuclear item shall

- a) maintain a register of their transfers of nuclear items within a scope that allows subsequent verification of the transfers of a nuclear item and verification of the actual use of the nuclear item,
- b) notify the Office after transferring a nuclear item of
  1. the date of entry of the nuclear item into the territory of the Czech Republic or exit of the nuclear item from the territory of the Czech Republic,
  2. the quantity, name and specifications of the nuclear item in accordance with implementing legislation,
- c) allow only persons authorised under the relevant legislation to manage nuclear items and
- d) retain the register, commercial documents and records of their transfers of nuclear items for the following periods counted from the end of the calendar year in which the transfer of the nuclear item took place
  1. in the case of a nuclear item which is nuclear material, for a period of at least five years,
  2. in the case of a nuclear item which is a selected nuclear item or a dual-use nuclear item, for a period of at least three years.

## § 174

### **Management of found nuclear materials**

(1) Owners or holders of found nuclear material shall dispose of it within the time limit and in the manner provided in a decision of the office.

(2) If the owner or holder of found nuclear material is unknown or fails to fulfil the obligation imposed by the office under paragraph 1, the office shall, by decision, impose the obligation to take over this material on a person authorised to manage nuclear material or on the Authority, or the office shall decide to return it to the State of origin.

(3) The Authority shall, on the basis of the office's decision, ensure the safe management of the found nuclear material until such time it is handed over to the owner or the holder or until such time as the procedure under paragraph 2 is applied.

(4) The costs associated with taking over or returning the material referred to in paragraph 2 shall be borne by the last known owner of the nuclear material. If this person is unknown or the claim for compensation of the costs cannot be enforced against this person or the compensation cannot be recovered, the costs shall be borne by the Czech Republic. If the owner of the found nuclear material is identified retrospectively, the owner shall reimburse the costs incurred by the State in ensuring the safe management of found nuclear material.

## PART THREE

### OFFENCES

#### Title I

#### Offences of licence holders

##### § 175

(1) Natural persons, legal persons or sole traders who are holders of a licence under this Act will commit an offence by

- a) failing to comply with the licence conditions under § 21(1)(c),
- b) failing, contrary to § 22(7), to discontinue a licensed activity safely,
- c) failing, contrary to § 24, to act in accordance with the documentation for the licensed activity, retain this documentation or keep it in compliance with the requirements under this Act, the principles of good practice and the actual status of the licensed activity,
- d) failing to comply with any of the obligations under § 25,
- e) breaching the obligation to keep or retain a register in accordance with this Act,
- f) failing to carry out categorisation in accordance with this Act,
- g) using, contrary to the act on metrology, a specified measuring instrument without valid verification for a purpose for which the given type of measuring instrument was declared as specified,
- h) failing to keep a register, including the last verification date, of the specified measuring instruments in use that are subject to new verification and failing to present these instruments for verification in accordance with the act on metrology.

(2) Fines of up to the following amounts may be imposed for an offence

- a) CZK 1 000 000, for the offences referred to in paragraph 1(e) through (h),
- b) CZK 2 000 000, for the offences referred to in paragraph 1(a), (c) or (d),
- c) CZK 10 000 000, for the offence referred to in paragraph 1(b).

##### § 176

(1) Legal persons or sole traders who are

- a) holders of any of licences referred to in § 9(1), (2)(a) to (d) and (f)(7), and operate a category III workplace, or
- b) holders of any of licences referred to in § 9(3), (4) and (6)(a) and provide training and further training to selected workers performing activities of particular relevance to nuclear safety,

will commit an offence by failing to comply with any of the obligations laid down for the management system under § 29 or 30.

(2) Fines of up to CZK 1 000 000 may be imposed for the offence referred to in paragraph 1.

### § 177

(1) Legal persons or sole traders who are holders of a licence referred to in § 9(1) will commit an offence by

- a) failing to ensure that, from the commencement of construction to decommissioning, the nuclear installation complies with the requirements for nuclear installation design under § 46,
- b) failing to conduct safety assessment under § 48,
- c) failing to comply with any of the obligations under § 49(1) in the context of activities related to the use of nuclear energy.

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(1) will commit an offence by

- a) failing to comply with any of the obligations under § 50(1),
- b) failing to act in compliance with § 50(2) in the context of ensuring the readiness of a nuclear installation with a nuclear reactor and its personnel for the first physical start-up of a nuclear installation with a nuclear reactor,
- c) failing to comply with any of the obligations under § 50(3) in the context of ensuring the readiness of a nuclear installation without a nuclear reactor and its personnel for active testing of the nuclear installation.

(3) Legal persons or sole traders who are holders of a licence referred to in § 9(1)(c) will commit an offence by

- a) failing to comply with any of the obligations under § 51(1)(a) after loading nuclear fuel into the nuclear reactor,
- b) failing to comply with any of the obligations under § 51(1)(b) in the context of ensuring the readiness of a nuclear installation and its personnel for the first power-generation start-up of a nuclear installation with a nuclear reactor.

(4) Legal persons or sole traders who are holders of a licence referred to in § 9(1)(d) will commit an offence by

- a) failing to verify or document any of the facts referred to in § 52(1)(a) or (b),
- b) failing to perform the activities referred to in § 52(1)(c) in the context of ensuring the operational readiness of the nuclear installation and its personnel.

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 10 000 000, for the offences referred to in paragraph 1(b), paragraph 2(b) or (c), paragraph 3, or paragraph 4,
- b) CZK 50 000 000, for the offences referred to in paragraph 1(a) or (c) or paragraph 2(a).

§ 178

(1) Legal persons or sole traders who are holders of a licence referred to in § 9(1)(e) will commit an offence by

- a) failing to act in compliance with § 53(1)(a) in the context of ensuring the operational readiness of a nuclear installation and its personnel prior to commencing active testing,
- b) failing to perform active testing in accordance with § 53(1)(b),
- c) failing to verify or demonstrate the design characteristics of the nuclear installation and its compliance with the nuclear installation design in trial operation under the actual future operational states in accordance with § 53(1)(c).

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(1)(f) will commit an offence by

- a) failing to comply with any of the obligations under § 54(1),
- b) failing to comply with any of the obligations under § 54(2) prior to bringing a nuclear reactor to criticality,
- c) failing to comply with any of the obligations under § 54(3) after replacement of the fuel in the nuclear reactor,
- d) using selected equipment before it has passed conformity assessment in accordance with § 58(5),
- e) failing to verify or document regularly the conformity of selected equipment with technical requirements contrary to § 59(1) or (3).

(3) Legal persons or sole traders who are holders of a licence referred to in § 9(1)(g) will commit an offence by failing to comply with any of the obligations under § 55(1).

(4) Legal persons or sole traders who are holders of any of licences referred to in § 9(1)(b) to (h) will commit an offence by

- a) failing to accumulate steadily reserves for the decommissioning of the nuclear installation, despite falling under the conditions referred to § 51(2) and (3), or using the reserves contrary to § 51(5),
- b) failing to ensure quality of selected equipment or to document how this quality is ensured in accordance with § 56(1),
- c) failing to ensure compliance of selected equipment or parts of selected equipment with technical requirements in accordance with § 57(1) to (2) or failing to document how this compliance is ensured.

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 10 000 000, for the offences referred to in paragraph 1, 3 or 4,
- b) CZK 50 000 000, for the offence referred to in paragraph 2.

§ 179

(1) Legal persons or sole traders who are holders of a licence referred to in § 9(2) will commit an offence by

- a) failing to restrict exposure in accordance with § 64,
- b) failing to comply with any of the obligations under § 65 in respect of exceptional exposure,
- c) failing to optimise radiation protection in accordance with § 66,
- d) failing to comply with any of the obligations under § 68(1) in a planned exposure situation,
- e) failing to comply with any of the special obligations under § 69(1)(a) to (d) or (f) in a planned exposure situation,

- f) failing to comply with the obligation under § 69(1)(e) during decommissioning of a category IV workplace with radioactive waste disposal facility,
- g) failing to delineate a supervised area or comply with any of the obligations under § 74(1) or (3),
- h) failing to comply with any of the obligations for the safe operation of a workplace under § 75(1) in a planned exposure situation,
- i) failing to comply with any of the obligations under § 78(1) in respect of an exposed worker,
- j) failing to comply with any of the obligations under § 79 in respect of an outside worker.

(2) Fines of up to the following amounts may be imposed for an offence

- a) CZK 1 000 000, for the offences referred to in (1)(a) through (e),(i) or (j),
- b) CZK 10 000 000, for the offences referred to in paragraph (1)(f) through (h).

### § 180

(1) Legal persons or sole traders who are holders of any of licences referred to in § 9(2)(b), (f), (g) or (i), or § 9(3)(a), will commit an offence by failing to ensure continuous surveillance of radiation protection under § 72(1) to (4).

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(2)(b) or (f) will commit an offence by failing to comply with any of the obligations under § 73(1) or (2).

(3) Legal persons or sole traders who are holders of a licence to the operation of category III workplace or category IV workplace will commit an offence by failing to comply with any of the obligations under § 75(2).

(4) Legal persons or sole traders who are holders of a licence to the individual phases of decommissioning of a category III workplace or a category IV workplace will commit an offence by failing to comply with any of the obligations under § 75(4).

(5) Legal persons or sole traders who are holders of a licence to the management of a source of ionising radiation will commit an offence by failing to comply with conditions of performing activities in a temporary workplace under § 77(1).

(6) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraph 1 or 2,
- b) CZK 1 000 000, for the offences referred to in paragraph 3 through 5.

### § 181

(1) Legal persons or sole traders who are holders of a licence referred to in § 9(2)(b), (d) or (e) will commit an offence by failing to comply with any of the obligations under § 81(2) in the context of radiation protection of the general public.

(2) Legal persons or sole traders who are licence holders performing non-medical exposure will commit an offence by failing to comply with any of the obligations under § 83.

(3) Legal persons or sole traders who are licence holders performing medical exposure will commit an offence by failing to comply with any of the obligations under §§ 84 to 87 in the context of radiation protection of patients.



(4) Legal persons or sole traders who are holders of a licence referred to in § 9(2)(f)(1) or (2), will commit an offence by failing to ensure identification and marking of a high-activity source or its accessories in accordance with § 89(1).

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraphs 1 or 4,
- b) CZK 1 000 000, for the offences referred to in paragraph 2 through 3.

#### § 182

(1) Legal persons or sole traders who are licence holders holding a radionuclide source for which they have no further use will commit an offence by failing to transfer it to an authorised user in accordance with § 90(1).

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(2)(f) will commit an offence by failing to generate funds for the safe discontinuation of management of a radionuclide source in accordance with § 90(2).

(3) Legal persons or sole traders who are licence holders holding a simple or significant radionuclide source which is expected to be not used for a period longer than 12 months will commit an offence by failing to transfer it, at their own cost, to a recognised storage facility for storage in accordance with § 90(3) or (4).

(4) Legal persons or sole traders who are holders of a licence referred to in § 9(2)(f)(3), and who are exporting a radionuclide source of security category 1 or 2 will commit an offence by exporting the radionuclide source in conflict with § 92(2) or (3).

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 100 000, for the offence referred to in paragraph (4),
- b) CZK 500 000, for the offences referred to in paragraph (1) through (3).

#### § 183

(1) Legal persons or sole traders who are holders of a licence referred to in § 9(3) will commit an offence by managing radioactive waste in conflict with § 111(1) or (2) .

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(3)(b) will commit an offence by failing to comply with any of the obligations under § 112(1) in the context of the closure of a radioactive waste disposal facility.

(3) Fines of up to the following amounts may be imposed for an offence

- a) CZK 1 000 000, for the offence referred to in paragraph 2,
- b) CZK 10 000 000, for the offence referred to in paragraph 1.

#### § 184

(1) Legal persons or sole traders who are holders of a licence referred to in § 150 will commit an offence in the area of radiation situation monitoring by failing to comply with any of the obligations under § 150.

(2) Legal persons or sole traders who are holders of a licence referred to in this Act will commit an offence in the area of radiation extraordinary event management by failing to comply with any of the obligations under § 156(1) or § 157(2).

(3) Legal persons or sole traders who are holders of a licence referred to in § 9(1) or (2) and who have an emergency planning zone established will commit an offence by failing to comply with any of the obligations under § 156(2) in the context of radiation extraordinary event response preparedness.

(4) Legal persons or sole traders who are holders of a licence and whose activity led to a radiation accident will commit an offence by failing to comply with any of the obligations under § 158(2) while taking remedial action after a radiation extraordinary event.

(5) Fines of up to CZK 10 000 000 may be imposed for the offences referred to in paragraphs 1 to 4.

#### § 185

(1) Legal persons or sole traders who are holders of any of licences referred to in § 9(1)(b) to (h) and (5) will commit an offence by

- a) failing to ensure physical protection of a nuclear installation or nuclear material in accordance with §§ 160 or 161,
- b) failing to ensure security of nuclear material not classified in a category referred to in § 162(1),
- c) failing to comply with any of the obligations under § 163(1) in the context of security of a nuclear installation or nuclear material.

(2) Legal persons or sole traders who are holders of a licence referred to in § 9(2) will commit an offence by failing to ensure security of a radionuclide source in accordance with § 164(1).

(3) Legal persons or sole traders who are holders of a licence referred to in § 9(5) will commit an offence by breaching any of the obligations under § 167(1).

(4) Fines of up to the following amounts may be imposed for an offence

- a) CZK 100 000, for the offence referred to in paragraph 1(b),
- b) CZK 1 000 000, for the offences referred to in paragraph 2 or 3,
- c) CZK 10 000 000, for the offences referred to in paragraph 1(a) or (c).

#### § 186

##### **Offences by registered persons**

(1) Legal persons or sole traders who are registered persons under this Act will commit an offence by

- a) failing, contrary to § 23(4), to discontinue a registered activity in accordance with this Act,
- b) failing to comply with any of the obligations under § 25,
- c) breaching the obligation to keep or retain a register in accordance with this Act,
- d) failing to carry out categorisation in accordance with this Act,
- e) failing to comply with any of the obligations under § 68(1) in a planned exposure situation,

- f) failing to comply with any of the special obligations under § 70(1) in a planned exposure situation,
- g) failing to delineate a supervised area or comply with any of the obligations under § 74(1) or (3),
- h) failing to comply with any of the obligations for the safe operation of a workplace under § 75(1) in a planned exposure situation,
- i) failing to comply with any of the obligations under § 78(1) in respect of an exposed worker.

(2) Legal persons or sole traders who are registered persons performing non-medical exposure will commit an offence by failing to comply with any of the obligations under § 83.

(3) Legal persons or sole traders who are registered persons performing medical exposure will commit an offence by failing to comply with any of the obligations under §§ 84 to 87 in the context of radiation protection of patients.

(4) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraph 1(c), (d) or (g),
- b) CZK 1 000 000, for the offences referred to in paragraph 1(a), (b), (e), (f), (h), or (i), or paragraph 2 or 3.

## § 187

### **Offences by notifying persons**

(1) Legal persons or sole traders who are notifying persons using a type-approved minor source of ionising radiation will commit an offence by failing to comply with any of the special obligations under § 71 while using it.

(2) Legal persons or sole traders who are notifying persons using a type-approved minor source of ionising radiation will commit an offence by failing to comply with any of the obligations for the safe operation of a workplace under § 75(1) in a planned exposure situation.

(3) Legal persons or sole traders who are notifying persons using a type-approved minor source of ionising radiation will commit an offence by failing to secure the radionuclide source in accordance with § 164(1).

(4) Legal persons or sole traders who are notifying persons making a transfer of a nuclear item will commit an offence by allowing a person other than that referred to in § 173(c) to manage the nuclear item.

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offence referred to in paragraph 1,
- b) CZK 1 000 000, for the offences referred to in paragraphs 2 through 4.

### **Other offences by natural persons, legal persons and sole traders**

## § 188

(1) Natural persons, legal persons or sole traders will commit an offence by

- a) failing to prevent radiation extraordinary event or minimise its consequences under § 5(1)(a) when using a nuclear energy or performing activities in exposure situations,

- b) failing to justify the activity under § 5(1)(b) or (e) when using a nuclear energy, managing a nuclear items or performing activities in exposure situations,
- c) failing to proceed according to § 5(1)(c) when using a nuclear energy or performing activities in exposure situations,
- d) failing to assess, to take measures or to ensure application of the assessment results according to § 5(5) when using a nuclear energy or performing activities in exposure situations,
- e) failing to apply a feedback system under § 5(7),
- f) failing to use a graded approach under § 5(8),
- g) acting contrary to § 6(1) and breaching the prohibition of the use of nuclear energy and nuclear items for other than peaceful purposes,
- h) failing to comply with any notification or information obligations under this Act,
- i) carrying out any of the prohibited activities under §§ 7 or 8,
- j) breaching the obligation of confidentiality under § 28(4).

(2) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offence referred to in paragraph 1(j),
- b) CZK 1 000 000, for the offence referred to in paragraph 1(h),
- c) CZK 10 000 000, for the offences referred to in paragraph 1(a) through (f),
- d) CZK 100 000 000, for the offences referred to in paragraph 1(g) or (i).

## § 189

(1) Natural persons, legal persons or sole traders will commit an offence by

- a) performing an activity subject to a licence under § 9 without a licence,
- b) performing an activity subject to registration under § 10 without registration,
- c) performing an activity subject to notification under § 11 without notification.

(2) Natural persons or sole traders will commit an offence by performing an activity of particular relevance to nuclear safety or radiation protection without authorisation under § 31.

(3) Natural persons, legal persons or sole traders who are legal successors of a licence holder whose licence has lapsed or legal persons whose licence has lapsed by transformation will commit an offence by failing to ensure the safe discontinuation of the licensed activity or compliance with the obligations laid down in this Act until the safe discontinuation of activities as referred to in § 22(8).

(4) Natural persons, legal persons or sole traders who are legal successors of a registered person whose registration has lapsed will commit an offence by failing to ensure compliance with the obligations laid down in this Act during the period for which these persons may continue the activity as referred to in § 23(5).

(5) Legal persons or sole traders referred to in § 29(1)(b) to (f) will commit an offence by failing to comply with any of the obligations laid down for the management system under §§ 29 or 30.

(6) Fines of up to the following amounts may be imposed for an offence

- a) CZK 1 000 000, for the offences referred to in paragraph 4 or 5,
- b) CZK 10 000 000, for the offences referred to in paragraph 1(b) or (c) or paragraph 2 or 3,
- c) CZK 100 000 000, for the offence referred to in paragraph 1(a).

§ 190

(1) Legal persons or sole traders who design, manufacture, assemble, repair or perform maintenance of selected equipment or parts of selected equipment will commit an offence by

- a) failing to ensure compliance of selected equipment or parts of selected equipment with technical requirements in accordance with § 58(1),
- b) failing to ensure that conformity of selected equipment or parts of selected equipment is assessed by a person referred to in § 58(2).

(2) Legal persons or sole traders importing selected equipment for the purposes of using it in the Czech Republic will commit an offence by failing to ensure that this equipment is assessed for conformity in accordance with § 58(4).

(3) Legal persons or sole traders who repair or perform maintenance of selected equipment will commit an offence by failing to ensure that the conformity of this selected equipment with technical requirements is assessed before reuse in accordance with § 59(2).

(4) Legal persons or sole traders will commit an offence by

- a) failing to restrict exposure in a planned exposure situation in accordance with § 62,
- b) failing to optimise radiation protection in accordance with § 66,
- c) failing to regulate, contrary to the general measure referred to in § 102(1), exposure in an existing exposure situation resulting from an emergency exposure situation.

(5) Legal persons or sole traders performing activities in exposure situations will commit an offence by failing to ensure radiation protection of the general public from the exposure in accordance with § 81(1).

(6) Legal persons or sole traders performing activity involving radiation will commit an offence by failing to ensure that the dose constraints referred to in § 82(1) are used.

(7) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraph 5 or 6,
- b) CZK 1 000 000, for the offences referred to in paragraphs 1 through 4.

§ 191

(1) Natural persons who are outside workers referred to § 79(2)(b) will commit an offence by failing to comply with any of the obligations under § 79.

(2) Legal persons or sole traders who are operators of a supervised or controlled area will commit an offence by failing to comply with any of the obligations under § 79 in respect of an outside worker.

(3) Legal persons or sole traders who are employers of exposed workers will commit an offence by failing to ensure occupational medicine services to these workers in accordance with § 80.

(4) Legal persons or sole traders who are holders of a tip, settling pond or other residue of activities related to acquiring of a radioactive mineral or other mining activity accompanied by the occurrence of a radioactive mineral will commit an offence by failing in the obligations under § 88(4).

(5) Natural persons, legal persons or sole traders who are owners of land referred to § 88(5) will commit an offence by failing to tolerate activities related to monitoring or remedial action.

(6) Legal persons or sole traders who are operators of an installation intended for melting, collecting or processing scrap metal will commit an offence by

- a) failing to take measures to detect orphan sources in accordance with § 91(1),
- b) failing to fulfill obligations in accordance with § 91(1)(a) through (d) towards a worker exposed to ionising radiation from an orphan source,
- c) failing to ensure radiation protection of natural persons in accordance with § 91(2)(a), Point 1, in the event an orphan source is detected.

(7) A fine of up to CZK 500 000 may be imposed for the offences referred to in paragraphs 1 through 6.

### § 192

(1) Legal persons or sole traders performing an activity involving the operation of a workplace with potentially increased exposure to a natural source of radiation will commit an offence by failing to comply with any of the obligations under § 93(2) or (3).

(2) Legal persons or sole traders performing an activity involving the operation of a workplace with increased exposure to a natural source of radiation will commit an offence by failing to comply with any of the obligations under § 94(2).

(3) Legal persons or sole traders discharging a radioactive substance from a workplace with potentially increased exposure to a natural source of radiation will commit an offence by failing to comply with any of the obligations under § 95(1).

(4) Legal persons or sole traders performing an activity involving the operation of a workplace with potentially increased exposure to radon will commit an offence by failing to comply with any of the obligations under § 96(2).

(5) Legal persons or sole traders performing an activity involving the operation of a workplace with increased exposure to radon will commit an offence by failing to comply with any of the obligations under § 97(2).

(6) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraph 3 or 4,
- b) CZK 1 000 000, for the offences referred to in paragraph 1, 2 or 5.

### § 193

(1) Legal persons or sole traders proposing the siting of a building with residential rooms or rooms intended to be occupied by persons will commit an offence by failing to ensure that the building site radon index is determined in accordance with § 98(1).

(2) Natural persons, legal persons or sole traders who are owners of a building with residential rooms or rooms intended to be occupied by persons, in which the reference level or the level of annual average radon activity concentration in the air has been found to be exceeded, will commit an offence by failing to comply with any of the obligations under § 99(1) or (4).

(3) Natural persons, legal persons or sole traders who are owners of a building used as a school or a school facility or building used for the provision of social or health services involving long-term residence of natural persons will commit an offence by failing to ensure measurement of the indoor air activity concentration of radon in accordance with § 99(2) or failing to take measures reducing the level of exposure in accordance with § 99(3).

(4) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offences referred to in paragraph 1 or 2,
- b) CZK 1 000 000, for the offence referred to in paragraph 3.

#### § 194

(1) Legal persons or sole traders who are water suppliers or producers or importers of bottled water will commit an offence by failing to comply with any of the obligations under § 100.

(2) Legal persons or sole traders who are suppliers, manufacturers or importers of building material will commit an offence by failing to comply with any of the obligations under § 101.

(3) Legal persons or sole traders sending an emergency worker to a response action will commit an offence by failing to ensure fulfilling of obligations referred to in § 104(5).

(4) Legal persons or sole traders sending an emergency worker to a response action will commit an offence by failing to ensure consent of an emergency worker referred to in § 104(6) or (8).

(5) Fines of up to the following amounts may be imposed for an offence

- a) CZK 500 000, for the offence referred to in paragraph 2,
- b) CZK 1 000 000, for the offences referred to in paragraph 1, 3 or 4.

#### § 195

(1) Legal persons or sole traders managing radioactive waste or spent fuel will commit an offence by managing it in conflict with § 108(2) or § 109(2).

(2) Natural persons, legal persons or sole traders will commit an offence by

- a) rendering the possibility of further transportation or further management of spent fuel that they have produced more difficult contrary to § 110(2),
- b) managing radioactive waste that they have produced in conflict with § 111(1),
- c) using, manufacturing, importing or distributing the products referred to in § 137(1) or (2) without their prior type-approval.

(3) Legal persons or sole traders who are manufacturers, importers or distributors of a product that is subject to type-approval by the Office or other persons placing such a product on the market will commit an offence by

- a) failing to verify the conformity of every product unit with the approved type in accordance with § 140(1) and (2),
- b) failing to ensure new verification of compliance or issue a declaration of conformity in case of a change in the facts referred to in § 140(3).

(4) A fine of up to CZK 1 000 000 may be imposed for the offences referred to in paragraphs 1 through 3.

#### § 196

(1) Legal persons or sole traders who are carriers referred to in this Act will commit an offence by

- a) failing to comply with any of the obligations under § 141(1) during carriage,
- b) failing to carry the declaration referred to in § 141(2) during carriage.

(2) Legal persons or sole traders who are holders of radioactive waste or spent fuel will commit an offence by breaching any of the obligations under § 144(1) or under § 145(1) when shipping it from the Czech Republic.

(3) Legal persons or sole traders who are consignees of radioactive waste or spent fuel will commit an offence by breaching any of the obligations under § 146(1) when shipping it to the Czech Republic from a State that is not a member of the Euratom.

(4) Legal persons or sole traders who ensures carrying out a shipment under § 147(1) will commit an offence by breaching any of the obligations under § 147(1)(a) to (c).

(5) A fine of up to CZK 100 000 may be imposed for the offences referred to in paragraphs 1 through 4.

#### § 197

(1) Legal persons or sole traders intending to export nuclear material or a selected nuclear item will commit an offence by failing to ensure protection of information in accordance with § 168(1).

(2) Natural persons, legal persons or sole traders who are end-users will commit an offence by failing to manage the item in accordance with the declaration referred to in § 171(1).

(3) Natural persons, legal persons or sole traders who are owners or holders of found nuclear material will commit an offence by failing to ensure management of the found nuclear material in accordance with § 174.

(4) Fines of up to the following amounts may be imposed for an offence

- a) CZK 100 000, for the offences referred to in paragraphs 1 or 3,
- b) CZK 500 000, for the offence referred to in paragraph 2.

### Title II

#### **Common provisions concerning offences**

#### § 198

The limitation period shall be 5 years. When the limitation period is suspended, liability for an offence shall lapse not later than 8 years after the date it was committed.

#### § 199



(1) Offences under this Act shall be dealt with by the Office.

(2) Fines shall be collected by the Office.

(3) The amounts of fines for offences under this Act shall be doubled, up to a limit of CZK 100 000 000, if the same offence has been committed repeatedly. An offence shall be deemed to have been committed repeatedly if less than one year has passed since the date on which the decision imposing a fine for the same offence became final.

## PART FOUR

### EXERCISE OF STATE AUTHORITY

#### Title I

#### Controls and corrective measures

#### § 200

##### Subject matter of controls

(1) The Office shall conduct controls of compliance with this Act, regulations issued to implement this Act, commitments arising from international treaties binding on the Czech Republic applicable to the peaceful use of nuclear energy and ionising radiation, and decisions issued on the basis of this Act, and controls of the performance of the obligations laid down in the metrology act as regards measuring instruments intended or used for measuring ionising radiation and radioactive substances.

(2) The Office shall control

- a) licence holders, registered persons and notifying persons,
- b) manufacturers, importers and distributors of products type-approved by the Office,
- c) persons performing activities in the context of the peaceful use of nuclear energy and ionising radiation not subject to authorisation under this Act,
- d) persons engaged in radiation situation monitoring,
- e) holders of authorisations for the performance of activities of particular relevance to nuclear safety and radiation protection,
- f) authorised and accredited persons performing assessment of conformity of selected equipment with technical requirements,
- g) persons in respect of whom there are reasonable grounds for believing that they are breaching obligations laid down in this Act, regulations issued to implement this Act and decisions issued on the basis of this Act, or commitments arising from international treaties binding on the Czech Republic applicable to the peaceful use of nuclear energy and ionising radiation.

#### § 201

##### Persons conducting controls

(1) The persons conducting controls shall be inspectors.

(2) The authorisation of an inspector to conduct controls shall have the form of an identity card issued by the Office. The identity card shall contain

- a) the name(s) and surname of the inspector,
- b) the date and place of birth of the inspector,
- c) a photograph or other form of visual identification of the inspector,
- d) the inspector's signature,
- e) the date of issue of the identity card and
- f) the name and address of the seat of the office.

(3) The conduct of controls by inspectors shall be second category work and risk-involving work within the meaning of act on protection of a public health.

## § 202

### **Special rules for the conduct of controls**

(1) The office's plan of controls shall take into account the potential extent and nature of the risk associated with the subject matter of the controls and a general assessment of radiation protection issues.

(2) The office shall make the plan of controls available to the public in a manner allowing remote access.

(3) If facts related to an outside worker are detected by the controls, the inspector shall inform of these facts the outside worker's employer or the outside worker him/herself, if ensuring his/her own radiation protection.

## § 203

### **Binding orders of the inspectors**

- (1) An inspector shall, based on the performed control, prohibit until a remedy is ensured
- a) nuclear material or other source of ionising radiation management,
  - b) discharge of radioactive substance from a workplace,
  - c) the addition of a radioactive substance to a consumer product when manufacturing or preparing it and for importing and exporting such a consumer product,
  - d) the performance of services relevant to radiation protection,
  - e) the provision of services in the controlled area to the operator of a category IV workplace,
  - f) the making available on the market of building materials, if license is required in accordance with this Act,
  - g) radioactive waste management,
  - h) the re-import of radioactive waste produced during the processing of a material exported from the Czech Republic or re-transfer thereof from a Member State of the Euratom,
  - i) the import or transfer of radioactive waste from a Member State of the European Union to the territory of the Czech Republic for the purposes of processing or reusing it,
  - j) carriage of radioactive and fissile materials,
  - k) the import or export of a nuclear item or transit of nuclear material and a selected nuclear item,
  - l) performing activities of particular relevance to nuclear safety and radiation protection, or
  - m) using, manufacturing, import or distribution of a product, which type was not approved by the office, even though it should be type approved according to this Act,
- if they are not performed in compliance with requirements of this Act and there is a risk of delay.

(2) An inspector has right to order seizure of radioactive waste or ionising radiation source if unauthorized radioactive waste management or nuclear material or other ionising radiation source is demonstrated.

(3) The office may store a seized object out of reach of the controlled person. The controlled person shall hand the seized object over to the inspector. The seized object shall be taken from the controlled person if he/she refuses to hand it over. The inspector shall make an official record on seizure or handing over of the object. Expenses of the storage bears the controlled person, if not demonstrated that radioactive waste management or nuclear material or other ionising radiation source is authorized.

(4) The inspector shall impose the binding order under paragraph (2) or (3) orally to the controlled person or to other person present at the site of the control with effects to the controlled person and make an official record on the binding order. If the binding order is notified to other person than the controlled person the inspector shall notify it to the controlled person subsequently.

(5) If the controlled person does not agree with the binding order under paragraph (2) or (3) he/she may submit written and justified objections against it in 3 days term after its delivery or notification, if done subsequently. The objections shall not have suspensory effect. The office shall decide on the objections. Written version of a decision on the objections shall be delivered to the controlled person and is final.

(6) Seizure of the radioactive waste or nuclear material or other ionising radiation source shall last until an effective decision on forfeiture or confiscation of it is issued, eventually until the management of the controlled person with it is demonstrated as authorized. The office shall revoke the binding order if demonstrated that the management of the controlled person with the object is authorized and inform the controlled person on this matter. If the binding order is revoked, the seized object shall be returned back to the controlled person in unharmed state without undue delay. The inspector shall make an official record on returning of the object.

#### § 204

##### **Corrective measures**

(1) If the Office finds a deficiency in the activities of persons performing activities related to the use of nuclear energy or activities in exposure situations, it may impose, by decision, depending on the nature of the deficiency found, corrective measures on the persons and set a time limit for the implementation of the measures to correct the deficiency found.

(2) The persons on whom corrective measures have been imposed shall immediately notify the Office of the method of implementation of the imposed measures.

(3) An appeal against the decision to impose corrective measures shall not have suspensory effect.

#### § 205

##### **International controls**

(1) International controls in the area of non-proliferation of nuclear weapons in accordance with an international treaty binding on the Czech Republic<sup>28)</sup> may be conducted by inspectors of the International Atomic Energy Agency in the scope and under conditions set by this treaty. International controls shall perform inspectors of the International Atomic Energy Agency accompanied by the inspectors of the office.

(2) International controls in the area of non-proliferation of nuclear weapons in accordance with Treaty establishing the European Atomic Energy Community may be conducted by inspectors of the European Commission in the scope and under conditions set by this treaty. International controls shall perform inspectors of the European Commission accompanied by inspectors of the Office.

(3) Radiation situation monitoring controls in respect of persons participating in this monitoring may be conducted by representatives of the European Commission in accordance with the Treaty establishing the European Atomic Energy Community.

(4) Controlled persons shall enable performance of controls under paragraph (1) through (3).

## Title II Exercise of State Authority

### § 206

#### **Authorities exercising State Authority in the area of the peaceful uses of nuclear energy and ionising radiation**

State Authority under this Act shall be exercised by

- a) the office,
- b) the government,
- c) the Ministry of Industry and Trade,
- d) the Ministry of the Interior,
- e) the Ministry of Health,
- f) the Ministry of Finance,
- g) the Ministry of Defence,
- h) the Ministry of Foreign Affairs,
- i) the Ministry of Agriculture,
- j) the Ministry of the Environment,
- k) the Ministry for Regional Development,
- l) the Fire Rescue Service of the Czech Republic,
- m) the Police of the Czech Republic,

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<sup>28)</sup> Agreement between the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the European Atomic Energy Community and the International Atomic Energy Agency in implementation of Article III(1) and (4) of the Treaty on the Non-Proliferation of Nuclear Weapons, promulgated under No 35/2010.

Additional Protocol to the Agreement between the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland, the Federal Republic of Germany, the Hellenic Republic, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of Netherlands, the Portuguese Republic, the Kingdom of Spain, the Kingdom of Sweden, the European Atomic Energy Community and the International Atomic Energy Agency, in implementation of Article III(1) and (4) of the Treaty on the Non-Proliferation of Nuclear Weapons, promulgated under No 36/2010.

- n) bodies of the Customs Administration of the Czech Republic,
- o) the Czech Agriculture and Food Inspection Authority,
- p) regional offices and presidents of regions, and
- q) municipal offices of municipalities with extended authorities.

### **Office**

#### § 207

(1) The Office is a central administrative Authority for the area of use of nuclear energy and ionising radiation.

(2) The Office is seated in Prague.

(3) The head of the Office is a chairperson, which is designated and recalled by the government; selection, designation and recalling of the chairperson is regulated by the act on state services.

#### § 208

The Office shall

- a) issue licences for the performance of activities and register and receive notifications of activities,
- b) type-approve packaging assemblies for the carriage, storage or disposal of radioactive or fissile materials, sources of ionising radiation and other products,
- c) grant authorisations for the performance of activities of particular relevance to nuclear safety and radiation protection,
- d) approve documentation for licensed activities,
- e) establish emergency planning zones,
- f) monitor and assess the exposure situation and regulate exposure of natural persons, including exposure from natural sources of radiation and draw up, in cooperation with the relevant administrative authorities, national plans to address and provide information about situations,
- g) issue, register and verify individual radiological monitoring documents,
- h) maintain lists and registers in the area of the peaceful uses of nuclear energy and ionising radiation, including lists and registers according to international treaties binding on the Czech Republic,
- i) establish the design basis threat,
- j) perform the role of the organisation for international verification of compliance with the comprehensive nuclear test ban,
- k) ensure international cooperation within the field of its competence, provide information from the field of its competence to the International Atomic Energy Agency, the Euratom and other authorities of the Euratom and ensure implementation of other obligations arising from Euratom legislation relating to, in particular, the national and international evaluation of the exercise of State Authority over nuclear safety of nuclear installations and management of nuclear materials and high-activity sources,
- l) decide on the management of nuclear items, sources of ionising radiation or radioactive waste in cases where they are managed in conflict with legislation or a situation that has arisen is not being rectified, including cases when these have been found, and, if necessary, organise a search for such sources of ionising radiation,

- m) once a year, present to the Government and to the public a report on its activities and an annual report on radiation situation monitoring in the territory of the Czech Republic,
- n) submit opinions on territorial development policies and territorial planning documentation in terms of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security of activities related to the use of nuclear energy and activities in exposure situations,
- o) provide information in the area of radioactive waste management and spent fuel,
- p) issue binding opinions on spatial planning decisions concerning construction on land where a closed radioactive waste disposal facility is sited; the binding opinions shall express if the intended plan is acceptable from a perspective of radiation protection and monitoring of radiation situation and set down conditions of radiation protection and monitoring of radiation situation ensurance relevant to this plan,
- q) issue binding opinions in proceedings and other actions relating to nuclear installations under the building act,
- r) provide information on important findings obtained in the context of its control activities and from reporting on radiation extraordinary events and radiological occurrences, including information relating to the justification of activities, regulation of sources of ionising radiation and radiation protection,
- s) draw up and update the national action plan for regulation of public exposure from radon and define the concept for the management of existing exposure situations,
- t) inform the general public about potential risks of exposure from a source of water for an individual supply providing on average less than 10 m<sup>3</sup> a day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial activity or public service.

#### § 209

The Office shall

- a) draw up the national monitoring programme and, after it has been approved, forward it to the persons referred to in § 149(2)(a),
- b) manage and carry out radiation situation monitoring in the territory of the Czech Republic in accordance with § 130, including the comparative measurements organised by the European Commission, evaluate its results and report radiation situation monitoring data to the European Commission<sup>29)</sup>,
- c) ensure and conduct drills and emergency exercises for radiation extraordinary event response,
- d) in cooperation with the Ministry of the Interior, draw up the national radiation extraordinary event plan for threat categories A, B, D and E in accordance with § 153(1),
- e) provide preliminary information to the general public for the event of a radiation accident, concerning protective measures and steps that need to be taken to ensure radiation protection; the preliminary information provided shall be up-to-date and constantly available and it shall be provided automatically and repeatedly, at regular intervals and whenever a significant change occurs,
- f) issue proposals for urgent protective action or follow-up protective action, in accordance with the national radiation extraordinary event plan and on the basis of the results of the radiation situation monitoring carried out, or to further specify or withdraw the action and to confirm or further specify proposals for the introduction of urgent protective action issued by licence holders,

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<sup>29)</sup> Commission Recommendation 2000/473/Euratom of 8 June 2000 on the application of Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole.

- g) ensure information of the general public about the occurrence and the course of a radiation accident which has an impact on the territory of the Czech Republic outside an emergency planning zone and about the steps and measures to be taken during the various stages of development of the radiation accident, unless this information is being provided by another administrative Authority,
- h) participate, within the scope of its competence, in the provision of information about the occurrence and the course of a radiation accident within an emergency planning zone,
- i) ensure that the competent regulatory authorities of neighbouring Member States of the Euratom are notified of the occurrence and the course of a radiation accident which has an impact on the territory of the Czech Republic and about the steps and measures to be taken during the various stages of development of the radiation extraordinary event,
- j) ensure that an international peer review is invited immediately in the case of a radiation accident that has occurred in the territory of the Czech Republic and led to the implementation of protective measures outside a nuclear installation grounds,
- k) provide information about the adoption of measures to protect the general public in the Czech Republic in the event of a radiation accident arisen in the territory of Member States of the Euratom to the European Commission and other Member States of the Euratom which may be affected by these measures and, in accordance with the Czech Republic's international commitments, provide public access to information thus obtained,
- l) ensure notification of regional authorities about the occurrence and the course of a radiation accident outside the territory of the Czech Republic and about the steps and measures to be taken in the course of the radiation extraordinary event.

## § 210

### **Government**

The Government shall approve

- a) the Authority's statute and annual, three-year and long-term plan of activities,
- b) the annual report on the Authority's activities,
- c) the national radiation extraordinary event plan,
- d) the report on the office's activities and the annual report on radiation situation monitoring in the territory of the Czech Republic.

## § 211

### **Ministries and other administrative authorities**

(1) In order to ensure protective measures within their fields of competence, ministries Fire Rescue Service of the Czech Republic, regional offices and presidents of regions and municipal offices of municipalities with extended authorities and other administrative authorities shall

- a) forward to the Office and to the Ministry of the Interior support documents for drawing up or updating the national radiation extraordinary event plan and, after it has been approved, conduct exercises and act in compliance with the plan,
- b) methodically direct and control their subordinate units and unify their approaches when drawing up partial plans for the specific activities under the off-site emergency plan that are attributed to them,
- c) participate in the regulation of public exposure from radon in the context of the national action plan for regulating public exposure from radon.

(2) Implementing legislation shall establish the scope and method of exercises under the national radiation extraordinary event plan.

§ 212

**Ministry of Industry and Trade**

The Ministry of Industry and Trade shall

- a) draw up the concept for radioactive waste and spent fuel management and amendments to the concept in accordance with § 108, present it to the government for approval and notify the European Commission of the concept,
- b) issue binding opinions on the office's decisions on the design basis threat,
- c) in the context of the national action plan for regulating public exposure from radon, participate in informing and educating the public and professional groups in the area of protection against exposure to radon and developing methods and technologies for reducing this exposure.

§ 213

**Ministry of the Interior**

The Ministry of the Interior shall

- a) issue binding opinions on the Office's decisions on the design basis threat,
- b) cooperate with the Office in drawing up the national radiation extraordinary event plan.

§ 214

**Ministry of Health**

The Ministry of Health shall

- a) create a system for the provision of special medical assistance to natural persons exposed to radiation in radiation extraordinary events by selected clinical workplaces,
- b) designate the providers of health services to provide care to natural persons exposed to radiation in radiation extraordinary events and publish a list of these providers of health services in the Bulletin of the Ministry of Health in a manner allowing remote access,
- c) in the context of the national action plan for regulating public exposure from radon, participate in informing and educating the public and professional groups in the area of protection against exposure to radon and developing methods and technologies for reducing this exposure.

§ 215

**Ministry of Finance**

The Ministry of Finance shall

- a) provide subsidies for the identification of the risks arising from the presence of radon and its conversion products in indoor air of buildings so that justified measures under § 103(1)(b) and measures reducing the natural radionuclide content of drinking water intended for public use can be adopted,
- b) administer the nuclear account.

§ 216

**Ministry of Defence**

(1) The Ministry of Defence shall



- a) participate in radiation situation monitoring in accordance with § 149 and perform this monitoring on monitoring routes and sites,
- b) in cooperation with the office, exercise State Authority over the use of ionising radiation by the armed forces of the Czech Republic and by organisational units of the State, budget-funded organisations and State enterprises established by the Ministry,
- c) provide the Office with information relevant to radiation protection acquired in the exercise of State Authority under (b),
- d) maintain a list of sources of ionising radiation and doses received by exposed workers of category A falling under its competence and, at request, provide information from the list to the Office,
- e) issue binding opinions on the office's decisions on the design basis threat.

(2) Selected workers may perform activities of particular relevance to radiation protection, the performance of which has been authorised by the Ministry of Defence, only in the armed forces of the Czech Republic and organisational units of the State, budget-funded organisations and State enterprises established by the Ministry.

#### § 217

##### **Ministry of Agriculture**

The Ministry of Agriculture shall participate in

- a) radiation situation monitoring in accordance with § 149, and perform monitoring on monitoring sites and ensure the operation of the measurement laboratory and its participation in comparative measurements,
- b) informing and educating the public and professional groups in the area of protection against exposure to radon and developing methods and technologies for reducing this exposure, in the context of the national action plan for regulating public exposure from radon.

#### § 218

##### **Ministry of the Environment**

The Ministry of the Environment shall participate in

- a) radiation situation monitoring in accordance with § 149, and perform monitoring on monitoring sites, including observation and forecasts of the development of the meteorological situation and distribution of released radionuclides as part of accidental monitoring, and ensure the operation of the measurement laboratory and its participation in comparative measurements,
- b) informing and educating the public and professional groups in the area of protection against exposure to radon and developing methods and technologies for reducing this exposure, in the context of the national action plan for regulating public exposure from radon.

#### § 219

##### **Ministry for Regional Development**

In the context of the national action plan for regulating public exposure from radon, the Ministry for Regional Development shall participate in informing and educating the public and professional groups in the area of protection against exposure to radon and in developing methods and technologies for reducing this exposure.

§ 220

**Fire Rescue Service of the Czech Republic**

(1) The Fire Rescue Service of the Czech Republic shall

- a) participate in radiation situation monitoring in accordance with § 149 and perform monitoring on monitoring routes and sites,
- b) lay down the requirements for fire protection of nuclear installations,
- c) within the scope of its competence defined in other legislation for the case of a radiation accident, provide preliminary information to the affected general public about the applicable measures for the protection of the general public and the steps that need to be taken if such a situation occurs; the preliminary information provided shall be up-to-date and constantly available and it shall be provided automatically and repeatedly, at regular intervals and whenever a significant change occurs,
- d) in the case of a radiation incident or radiation accident, immediately provide information, within the scope of its competence defined in other legislation, to the general public affected by this radiation extraordinary event about
  1. the facts of the radiation incident or radiation accident,
  2. the steps to be taken and
  3. where necessary, measures for the protection of the general public to be adopted,
- e) cooperate in the provision of information referred to in (d) with the president of the region and the municipal office of a municipality with extended authorities, in the case of a radiation incident where release of radioactive substances or ionising radiation outside the nuclear installation grounds or workplace using sources of ionising radiation is suspected or in the case of a radiation accident,
- f) draw up off-site emergency plans,
- g) cooperate with licence holders and the competent regional office in the provision of iodine prophylaxis antidotes to the general public in the emergency planning zone.

(2) Implementing legislation shall establish the rules for the provision of iodine prophylaxis antidotes to the general public.

§ 221

**Police of the Czech Republic**

The Police of the Czech Republic shall

- a) participate in radiation situation monitoring in accordance with § 149,
- b) perform monitoring on monitoring routes and sites,
- c) ensure emergency protection of nuclear installations,
- d) provide protection of nuclear materials of categories I and II during carriage outside the guarded area,
- e) allow use of the centralised protection systems of the Police of the Czech Republic.

§ 222

**Bodies of the Customs Administration of the Czech Republic**

Bodies of the Customs Administration of the Czech Republic shall participate in radiation situation monitoring in accordance with § 149 and perform monitoring on monitoring routes and sites.

§ 223

**Czech Agriculture and Food Inspection Authority**

The Czech Agriculture and Food Inspection Authority shall participate in radiation situation monitoring in accordance with § 149 and perform monitoring on monitoring routes and sites.

§ 224

**Regional offices and presidents of regions**

(1) Regional offices shall

- a) cooperate with licence holders and the Fire Rescue Service of the Czech Republic to provide the general public in the emergency planning zone with iodine prophylaxis antidotes,
- b) in the case of a radiation accident, provide preliminary information, within the scope of its competence defined in other legislation, to the general public in the emergency planning zone about the applicable measures for the protection of the general public and the steps that need to be taken if such a situation occurs; the preliminary information provided shall be up-to-date and constantly available and it shall be provided automatically and repeatedly, at regular intervals and whenever a significant change occurs,
- c) in the context of protecting the general public from exposure to natural sources of radiation
  1. participate in the detection of buildings with increased levels of exposure from natural sources of radiation in their indoor air and in informing the general public about the risks arising from increased concentrations of radon in homes,
  2. in cooperation with the office, check the efficiency of the measures taken to protect the health of the general public from exposure to natural radionuclides.

(2) The president of the region shall

- a) in the case of a radiation incident involving a suspected release of radioactive substances or ionising radiation outside the nuclear installation grounds or the premises of a workplace using sources of ionising radiation, or in the case of a radiation accident within the territory of the region, immediately provide information, within the scope of its competence defined in other legislation, to the general public affected by this radiation extraordinary event about
  1. the facts of the radiation incident or radiation accident,
  2. the steps to be taken and
  3. where necessary, measures for the protection of the general public to be adopted,
- b) cooperate with the Fire Rescue Service of the Czech Republic and municipal offices of municipalities with extended authorities to provide the information under (a),
- c) approve off-site emergency plans.

(3) The authorities delegated to regional offices and presidents of regions under this Act represent the exercise of delegate Authority.

§ 225

**Municipal offices of municipalities with extended authorities**

(1) Municipal offices of municipalities with extended authorities shall

- a) in the case of a radiation incident involving a suspected release of radioactive substances or ionising radiation outside the nuclear installation grounds or the premises of a workplace using sources of ionising radiation, or in the case of a radiation accident within the territory of the municipality, immediately provide information, within the scope of its competence defined in other legislation, to the general public affected by this radiation extraordinary event about
  - 1. the facts of the radiation incident or radiation accident,
  - 2. the steps to be taken and
  - 3. where necessary, measures for the protection of the general public to be adopted,
- b) cooperate with the Fire Rescue Service of the Czech Republic and presidents of regions to provide the information under (a).

(2) The authorities delegated to municipal offices of municipalities with extended authorities under this Act represent the exercise of delegate Authority.

§ 226

*repealed*

PART FIVE

**COMMON, TRANSITIONAL AND FINAL PROVISIONS**

**Common provisions**

§ 227

This Act was notified in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, as amended.

§ 228

(1) The office shall issue a binding opinion to decisions and other acts of construction office under the building act and their changes related to buildings

- a) situated in nuclear installation grounds and not being part of a nuclear installation or a nuclear installation itself, or
- b) traffic and technical infrastructure situated out of nuclear installation grounds with possible influence on nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security of a nuclear installation.

(2) A binding opinion shall not be issued in the case of buildings with a license issued according to this Act.

(3) The office shall express by the binding opinions if the intended plan is acceptable from a perspective of ensuring nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security of a nuclear installation and set down conditions of nuclear safety, radiation protection, technical safety, radiation extraordinary event management and security relevant to this plan.

(4) Buildings related to radioactive waste disposal facility containing exclusively natural radionuclides or buildings that are nuclear installations or belonging to structures that are nuclear installations and buildings according to paragraph (1)(a) and (b) are not suitable for being approved by an authorized inspector.

### **Transitional provisions**

#### **§ 229**

(1) Persons performing activities governed by this Act on the basis of a licence issued under Act No 18/1997 on the peaceful uses of nuclear energy and ionising radiation (the Atomic Act) and on amendments to certain acts, as in force prior to the date of entry into force of this Act, shall be deemed since the entry into force of this Act to be holders of a licence under this Act and shall be required to adapt their legal framework to this Act, unless otherwise provided in this Act, within two years of the entry into force of this Act or within one year of the entry into force of this Act in the case of the activities in exposure situations.

(2) If a holder of a licence for the operation of a nuclear installation or holder of a licence for the operation of a category IV workplace under Act No 18/1997, as in force prior to the date of entry into force of this Act, applies for a licence for continued operation of the same nuclear installation under § 9(1)(f) or a licence for continued operation of the same category IV workplace under § 9(2)(b) of this Act within three years of the entry into force of this Act, the procedure for the submission of licence applications under § 16 of this Act shall be followed, except paragraph 2(d). The licence applicant may attach to the application documentation within the scope and in the manner referred to in Act No 18/1997, as in force prior to the date of entry into force of this Act, except the on-site emergency plan, the programme for the monitoring of discharges and the programme for the monitoring of the surrounding area, which shall be submitted within the scope and in the manner laid down in this Act. The documentation for licensed activities referred to in the first sentence and for continued performance of licensed activities by holders of a licence for the operation of a nuclear installation or a category IV workplace shall be brought into compliance with this Act within three years of the entry into force of this Act.

(3) Where the licences referred to in paragraph 1 were issued for a definite period, they shall be valid for the period for which they were issued, but not longer than for a period of 10 years, including the conditions for the operation and discontinuation of the licensed activity necessary in terms of nuclear safety, radiation protection and physical protection, provided that they are not in conflict with the requirements under this Act. Where the licences referred to in paragraph 1 were issued for an indefinite period, they shall cease to be valid 10 years after the entry into force of this Act.

(4) The decision approving the documentation shall be valid for the period of validity of the licence referred to in paragraph 3, to which the documentation applies. Decisions approving amendments to documentation shall cease to be valid upon approval of the documentation that has been amended.

(5) Persons performing activities on the basis of a licence issued under Act No 18/1997, as in force prior to the date of entry into force of this Act, who are subject to registration under this Act shall be deemed to be registered persons upon entry into force of this Act and their registration shall cease to be valid five years after the entry into force of this Act.

§ 230

(1) Persons ensuring radiation protection of a registered person shall satisfy all the training requirements referred to in § 70(1)(a) within one year of the entry into force of this Act, unless they are holders of authorisation for the performance of continuous surveillance of compliance with radiation protection requirements in workplaces using sources of ionising radiation for medical exposure or in veterinary medicine.

(2) The use of type-approved minor sources of ionising radiation, for which notification is required under this Act and which has been notified to the office in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be notified under this Act.

(3) Type-approved minor sources of ionising radiation, for the use of which registration or a licence under this Act is required, the use of which has been notified to the office in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, may be used without registration or a licence for a period of one year from the date of entry into force of this Act.

(4) Type-approval decisions issued under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be decisions on product type-approval under this Act and shall cease to be valid upon expiry of the period for which they were issued.

§ 231

(1) The validity of authorisations for the performance of activities directly affecting nuclear safety and activities of particular relevance to radiation protection issued under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall lapse on expiry of the original period of validity, if these authorisations were issued for a definite period, or remain valid unchanged, if issued for an indefinite period.

(2) Holders of authorisations for the performance of activities directly affecting nuclear safety and activities of particular relevance to radiation protection issued for an indefinite period under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall undertake further training in accordance with this Act within five years of the entry into force of this Act.

(3) A response action to avert or reduce exposure which commenced prior to the entry into force of this Act shall be completed in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act.

(4) A management system introduced in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be a management system under this Act. Persons who have introduced a quality system and who are required to introduce a management system under this Act shall bring this system into compliance with the requirements for management systems set out in this Act within three years of the entry into force of this Act.

(5) Quality assurance programmes approved in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, for activities for which a management system programme is required under this Act shall be deemed to be management system programmes under this Act.

(6) A quality assurance system approved in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, for activities in exposure situations for which a radiation protection assurance programme is required under this Act shall be deemed to be a radiation protection assurance programme under this Act.

§ 232

(1) Supervised and controlled areas delineated in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be supervised and controlled areas under this Act. Persons delineating supervised or controlled areas shall bring them into compliance with the requirements under this Act within one year of the entry into force of this Act.

(2) Individual radiological monitoring documents of exposed workers of category A issued under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be individual radiological monitoring documents of exposed workers of category A under this Act and shall cease to be valid upon expiry of the period for which they were issued.

(3) Building site radon index determination started in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be completed in accordance with the legislation previously in force and its results shall be deemed to be results of building site radon index determination under this Act.

(4) Measurement of radon activity concentration started in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be completed in accordance with the legislation previously in force and its results shall be deemed to be the results of measurement of radon activity concentration under this Act.

(5) The reserves for decommissioning of a nuclear installation, category III workplace or category IV workplace accumulated prior to the entry into force of this Act shall become reserves for decommissioning of a nuclear installation, category III workplace or category IV workplace in accordance with § 51(2) to (4) and 6(c) of this Act.

(6) Proceedings initiated by the office or other administrative authorities under Act No 18/1997, as in force prior to the date of entry into force of this Act, which have not been completed as of this date shall be completed and the rights and obligations related to these proceedings shall be assessed in accordance with the legislation previously in force.

(7) Conformity assessment of selected equipment designed specifically for nuclear installations initiated prior to the entry into force of this Act under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be completed in accordance with the legislation previously in force and shall be regarded as conformity assessment of selected equipment under this Act.

(8) The Radioactive Waste Repository Authority established in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be the Authority under this Act.

§ 233

(1) Controls initiated by the office or other administrative authorities prior to the date of entry into force of this Act under Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be completed in accordance with the legislation previously in force.

(2) Proceedings on administrative offences or imposition of corrective measures under Act No 18/1997, as in force prior to the date of entry into force of this Act, which were initiated, but not completed, prior to the date of entry into force of this Act shall be completed by the office in accordance with the legislation previously in force.

(3) Fees obligations in the case of the fees for the office's expert activities under Act No 18/1997, as in force prior to the date of entry into force of this Act, which arised prior to the date of entry into force of this Act and for a fees period prior to the date of entry into force of this Act and the rights and obligations related to these fees shall be regulated by Act No 18/1997, as in force prior to the date of entry into force of this Act.

(4) Natural persons performing a sensitive activity referred to in § 162(2) after the entry into force of this Act, who do not satisfy the conditions for the performance of sensitive activities, shall present valid proof of safety competence of a natural person or a valid certificate of a natural person to the licence holder within three years of the date of entry into force of this Act. Until such time that the obligation under the first sentence is fulfilled, for the purposes of this Act, this natural person shall be deemed to be a natural person satisfying the conditions for the performance of sensitive activities, unless a decision not to issue proof of safety competence of a natural person has been issued in proceedings concerning this person during this period or during the period of the last five years prior to the date of entry into force of this Act. The provisions of the second sentence shall not apply if, prior to the date of entry into force of this Act, the natural person performed sensitive activities under the legislation previously in force without meeting the conditions for the performance of sensitive activities, or if a decision terminating the validity of proof of safety competence of a natural person or a decision terminating the validity of a certificate of a natural person was issued during the period of the last five years prior to the date of entry into force of this Act.

(5) Carriage and transport of nuclear items and radioactive substances started prior to the entry into force of this Act shall be completed in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act.

(6) Emergency planning zones established by the office for nuclear installations prior to the entry into force of this Act shall be deemed to be emergency planning zones established in accordance with this Act.

(7) Inspectors appointed in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be inspectors under this Act.

(8) Funds obligations in the case of the contributions to the nuclear account under Act No 18/1997, as in force prior to the date of entry into force of this Act, which arised prior to the date of entry into force of this Act and the rights and obligations related to these contributions shall be regulated by Act No 18/1997, as in force prior to the date of entry into force of this Act.



(1) The office shall issue the national monitoring programme within two years of the entry into force of this Act. Every person shall act in compliance with the first national monitoring programme after a period of two years from the issue thereof.

(2) The national radiation extraordinary event plan shall be drawn up by the office in cooperation with the Ministry of the Interior and approved by the government within four years of the entry into force of this Act. Every person shall act in compliance with the first national radiation extraordinary event plan within two years from the issue thereof.

(3) The Ministry of Industry and Trade shall draw up the concept for radioactive waste and spent fuel management and inform the European Commission about the concept within one year of the entry into force of this Act.

(4) Neighbouring persons shall be familiarised with on-site emergency plans, as referred to in § 156(1)(a), within three months of the entry into force of this Act.

### § 235

(1) The information about workplaces with potentially increased exposure from natural sources of radiation referred to in § 93(2)(b) and information about workplaces with potentially increased exposure to radon referred to in § 96(1)(a) and (b) shall be reported to the office within one year of the entry into force of this Act. Information about workplaces in which a significant increase in exposure from natural sources may occur, reported in accordance with Act No 18/1997, as in force prior to the date of entry into force of this Act, shall be deemed to be the information referred to in § 93(2)(b) and in § 96(2)(a) of this Act.

(2) Anyone who performs an activity involving the operation of a workplace referred to in § 96(1)(c) shall start performing the obligations laid down in § 96(2) in one year after the date of entry into force of this Act.

## Authorising provisions

### § 236

The office shall issue a decree to implement § 6(8)(a) and (b), § 9(2)(c) and (j), (4)(a) and (b), § 17(3)(a) and (b), § 18(5), § 24(7), § 25(2)(a) to (e), § 29(7)(a) to (g), § 30(9)(a) and (b), § 31(6)(a) to (e), § 32(10)(a) to (c), § 33(8)(a) to (c), § 44(4)(a) to (c), § 45(4), § 46(8), § 47(4)(a) to (c), § 48(6)(a) to (c), § 49(2)(a) to (h), § 50(4), § 51(6)(a) and (b), § 52(2)(a) and (b), § 53(2)(a) and (b), § 54(4)(a) to (d), § 55(2), § 56(2)(a) and (b), § 57(3)(a) to (c), § 58(7)(a) to (c), § 59(4)(a) and (b), § 60(4)(a) and (b), § 61(6)(a) to (d), § 63(6), § 66(6)(a) to (c), § 67(4), § 68(2)(a) to (j), § 69(2)(a) to (e), § 70(2)(a) to (c), § 71(2), § 72(5)(a) to (e), § 73(3)(a) to (e), § 74(4)(a) to (c), § 75(5)(a) to (c), § 76(6), § 77(2)(a) to (c), § 78(3)(a) to (f), § 79(9)(a) to (d), § 81(3)(a) to (d), § 82(4), § 83(7), § 84(6)(a) and (b), § 85(4), § 86(3)(a) to (d), § 87(5)(a) to (d), § 88(6), § 89(2), § 93(4)(a) to (d), § 95(6)(a) to (d), § 96(3)(a) to (d), § 98(4), § 99(5)(a) and (b), § 100(3)(a) to (d), § 101(4)(a) to (d), § 103(6)(a), § 104(9)(a) to (e), § 111(3)(a) to (d), § 112(2), § 137(6), § 138(6)(a) to (d), § 141(3)(a) to (e), § 143(4), § 149(6)(a) to (d), § 150(4)(a) to (c), § 153(3), § 154(3), § 155(3)(a) and (b), § 156(4)(a) to (e), § 157(3), § 158(3), § 159(2), § 160(6), § 161(4), § 162(2)(a) and (b), § 163(2)(a) and (b), § 164(2), § 166(6)(a) to (d), § 167(2)(a) to (d), § 169(4), § 170(4), § 171(5), § 211(2) and § 220(2).

### § 237

(1) The Ministry of Industry and Trade and the Office shall issue a decree in accordance with § 108(3)(a) to (c).

(2) The Ministry of Finance shall issue a decree in accordance with § 103(6)(b) to (d).

(3) The Ministry of Industry and Trade shall issue a decree in accordance with § 51(6)(c) and § 75(5)(d).

## § 238

### **Repealing provisions**

The following shall be repealed:

1. Government Regulation No 11/1999 concerning the emergency planning zone.
2. Government Regulation No 416/2002 laying down the amount and method of payment of contributions to the nuclear account by producers of radioactive waste and the amount and rules for granting the annual subsidies to municipalities.
3. Government Regulation No 73/2009 concerning the transmission of information related to international carriage of radioactive waste and spent fuel.
4. Government Regulation No 399/2011 concerning the fees for expert activities of the State Office for Nuclear Safety.
5. Government Regulation No 46/2005 amending government Regulation No 416/2002 laying down the amount and method of payment of contributions to the nuclear account by producers of radioactive waste and the amount and rules for granting the annual subsidies to municipalities.
6. Government Regulation No 341/2009 amending government Regulation No 416/2002 laying down the amount and method of payment of contributions to the nuclear account by producers of radioactive waste and the amount and rules for granting the annual subsidies to municipalities, as amended by government Regulation No 46/2005.
7. Government Regulation No 461/2011 amending government Regulation No 416/2002 laying down the amount and method of payment of contributions to the nuclear account by producers of radioactive waste and the amount and rules for granting the annual subsidies to municipalities, as amended.
8. Decree No 144/1997 concerning physical protection of nuclear materials and nuclear installations and their classification into individual categories.
9. Decree No 146/1997 laying down the activities directly affecting nuclear safety and activities of particular relevance to radiation protection, qualification and training requirements, method of verification of special professional competence and granting of authorisations to selected workers, and the form of the documentation to be approved for the granting of a licence for training selected workers.
10. Decree No 215/1997 concerning the criteria for the siting of nuclear installations and very significant sources of ionising radiation.

11. Decree No 106/1998 concerning nuclear safety and radiation protection assurance for nuclear installations during commissioning and operation.

12. Decree No 195/1999 concerning the requirements for nuclear installations in respect of nuclear safety, radiation protection and emergency preparedness assurance.

13. Decree No 307/2002 concerning radiation protection.

14. Decree No 317/2002 concerning type-approval of packaging assemblies for the carriage, storage and disposal of nuclear materials and radioactive substances, type-approval of sources of ionising radiation and carriage of nuclear materials and specified radioactive substances (type-approval and carriage decree).

15. Decree No 318/2002 concerning the details of emergency preparedness assurance for nuclear installations and workplaces using sources of ionising radiation and requirements for the content of on-site emergency plans and emergency regulations.

16. Decree No 319/2002 concerning the function and organisation of the national radiation monitoring network.

17. Decree No 360/2002 laying down the method of accumulating reserves for the decommissioning of nuclear installations or category III or category IV workplaces.

18. Decree No 419/2002 concerning individual radiological monitoring documents.

19. Decree No 185/2003 concerning the decommissioning of nuclear installations or category III or category IV workplaces.

20. Decree No 309/2005 concerning technical safety assurance for selected equipment.

21. Decree No 461/2005 concerning the procedure for the provision of subsidies for the adoption of measures to reduce exposure to natural radionuclides in indoor air of buildings and to reduce the natural radionuclide content of drinking water intended for public use.

22. Decree No 462/2005 concerning the distribution and collection of detectors for identification of buildings with higher levels of exposure to natural radionuclides and laying down the conditions for the granting of subsidies from the State budget.

23. Decree No 132/2008 concerning the quality system for carrying out and ensuring activities related to the use of nuclear energy and activities involving radiation and concerning quality assurance of selected equipment with regard to their safety classification.

24. Decree No 165/2009 laying down the list of selected nuclear items.

25. Decree No 166/2009 laying down the list of dual-use nuclear items.

26. Decree No 213/2010 concerning the accountancy and control of nuclear materials and reporting of information required by European Communities legislation.

27. Decree No 500/2005 amending State Office for Nuclear Safety Decree No 144/1997 concerning physical protection of nuclear materials and nuclear installations and their classification into individual categories.

28. Decree No 315/2002 amending State Office for Nuclear Safety Decree No 146/1997 laying down the activities directly affecting nuclear safety and activities of particular relevance to radiation protection, qualification and training requirements, method of verification of special professional competence and granting of authorisations to selected workers, and the form of the documentation to be approved for the granting of a licence for training selected workers.

29. Decree No 499/2005 amending State Office for Nuclear Safety Decree No 307/2002 concerning radiation protection.

30. Decree No 389/2012 amending State Office for Nuclear Safety Decree No 307/2002 concerning radiation protection, as amended by Decree No 499/2005.

31. Decree No 77/2009 amending State Office for Nuclear Safety Decree No 317/2002 concerning type-approval of packaging assemblies for the carriage, storage and disposal of nuclear materials and radioactive substances, type-approval of sources of ionising radiation and carriage of nuclear materials and specified radioactive substances (type-approval and carriage decree).

32. Decree No 2/2004 amending Decree No 318/2002 concerning the details of emergency preparedness assurance for nuclear installations and workplaces using sources of ionising radiation and requirements for the content of on-site emergency plans and emergency regulations.

33. Decree No 27/2006 amending State Office for Nuclear Safety Decree No 319/2002 concerning the function and organisation of the national radiation monitoring network.

#### § 239

#### **Entry into force**

This Act shall enter into force on 1st January 2017.

**Documentation for the activity to be licensed**

**1. Activities related to the use of nuclear energy**

- a) The documentation to be provided where the activity to be licensed is the siting of a nuclear installation is as follows:
1. management system programme,
  2. initial safety report,
  3. analysis of physical protection assurance needs and possibilities,
  4. intention to ensure the monitoring of discharges from the nuclear installation,
  5. monitoring programme,
  6. intention to ensure radiation extraordinary event management,
  7. draft concept for the safe decommissioning,
  8. description of the method of quality assurance for the preparation of construction project implementation,
  9. principles of quality assurance for the subsequent phases of the nuclear installation's life cycle.
- b) The documentation to be provided where the activity to be licensed is the construction of a nuclear installation is as follows:
1. management system programme,
  2. limits and conditions,
  3. programme of controls for the construction phase,
  4. preliminary safety report,
  5. list of selected equipment, including classification of selected equipment into safety classes,
  6. list of activities relevant to nuclear safety and description of the system of education, training and exercises for the personnel, including a description of the qualifications of the personnel,
  7. description of the system of training for selected workers,
  8. programme of construction of the nuclear installation, including the timetable,
  9. preliminary commissioning plan for the nuclear installation,
  10. preliminary probabilistic safety assessment,
  11. preliminary physical protection assurance plan,
  12. concept for the safe permanent shutdown of the installation to be licensed, including the method of the radioactive waste management produced,
  13. monitoring programme,
  14. radiation extraordinary event analysis and assessment for the period from the commencement of construction of the nuclear installation to the commencement of decommissioning,
  15. on-site emergency plan,
  16. establishment of the emergency planning zone,
  17. preliminary controlled ageing programme,
  18. proof that the financing of the radioactive waste management has been secured, if such waste is generated,
  19. evaluation of quality assurance for the preparation of the construction of the nuclear installation,
  20. description of the method of quality assurance for construction project implementation,

21. principles of quality assurance for the phases of the nuclear installation's life cycle following construction.

The documentation referred to in Points 2, 3, 5, 11, 13, 15 and 16 shall be subject to approval by the Office.

c) The documentation to be provided where the activity to be licensed is the first physical start-up of a nuclear installation with a nuclear reactor is as follows:

1. management system programme,
2. limits and conditions,
3. programme of operational controls,
4. operational safety report for the first physical start-up of a nuclear installation with a nuclear reactor,
5. list of selected equipment, including classification of selected equipment into safety classes,
6. list of activities relevant to nuclear safety and description of the system of education, training and exercises for the personnel, including a description of the qualifications of the personnel,
7. description of the system of training for selected workers,
8. neutron-physical characteristics of the nuclear reactor's active zone,
9. certificate of successful completion of construction and certificate of readiness of the installation, personnel and internal regulations for the next phase of the nuclear installation's life cycle,
10. physical start-up programme, including the timetable,
11. probabilistic safety assessment,
12. physical protection assurance plan,
13. statement that all checkings of radiation extraordinary event response preparedness in the emergency planning zone under § 156(2)(c) through (g) have been conducted,
14. pre-operational programme of controlled ageing,
15. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
16. assessment of the quality of selected equipment,
17. emergency operating rules,
18. severe accident management guidelines.

The documentation referred to in Points 2, 3, 5 and 12 shall be subject to approval by the Office.

d) The documentation to be provided where the activity to be licensed is the first power-generation start-up of a nuclear installation with a nuclear reactor is as follows:

1. management system programme,
2. limits and conditions,
3. programme of operational controls,
4. operating safety report,
5. list of selected equipment, including classification of selected equipment into safety classes,
6. list of activities relevant to nuclear safety and description of the system of education, training and exercises for the personnel, including a description of the qualifications of the personnel,
7. description of the system of training for selected workers,
8. neutron-physical characteristics of the nuclear reactor,
9. certificate of successful completion of the first physical start-up and certificate of readiness of the installation, personnel and internal regulations for the operation of the nuclear installation,

10. programme for the first power-generation start-up of a nuclear installation with a nuclear reactor and trial operation, including the timetable,
11. probabilistic safety assessment,
12. physical protection assurance plan,
13. operational controlled ageing programme for the first power-generation start-up and trial operation of a nuclear installation with a nuclear reactor,
14. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
15. statement on verification of the expiry date of iodine prophylaxis antidotes distributed in accordance with § 156(2)(d),
16. emergency operating rules,
17. severe accident management guidelines.

The documentation referred to in Points 2, 3, 5 and 12 shall be subject to approval by the Office.

- e) The documentation to be provided where the activity to be licensed is the commissioning of a nuclear installation without a nuclear reactor is as follows:

1. management system programme,
2. limits and conditions,
3. programme of operational controls,
4. operating safety report,
5. list of selected equipment, including classification of selected equipment into safety classes,
6. list of activities relevant to nuclear safety and description of the system of education, training and exercises for the personnel, including a description of the qualifications of the personnel,
7. certificate of successful completion of construction and certificate of readiness of the installation, personnel and internal regulations for the operation of the nuclear installation,
8. nuclear installation commissioning programme, including the timetable,
9. physical protection assurance plan,
10. decommissioning plan for a nuclear installation other than radioactive waste disposal facility,
11. decommissioning and closure plan for radioactive waste repositories,
12. estimation of decommissioning costs,
13. operational programme for a nuclear installation without a nuclear reactor,
14. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
15. description of the system of training for selected workers.

The documentation referred to in Points 2, 3, 5, 9, 10 and 11 shall be subject to approval by the Office.

- f) The documentation to be provided where the activity to be licensed is the operation of a nuclear installation is as follows:

1. management system programme,
2. limits and conditions,
3. programme of operational controls,
4. operating safety report,
5. list of selected equipment, including classification of selected equipment into safety classes,
6. neutron-physical characteristics of the nuclear reactor's active zone,

7. list of activities relevant to nuclear safety and description of the system of education, training and exercises for the personnel, including a description of the qualifications of the personnel,
8. description of the system of training for selected workers,
9. certificate of readiness of the installation, personnel and internal regulations for the operation of the nuclear installation,
10. evaluation of the results of the first power-generation start-up of a nuclear installation with a nuclear reactor,
11. evaluation of the results of trial operation if this is the first licence for the operation of a nuclear installation,
12. operational programme, including the timetable,
13. probabilistic safety assessment,
14. physical protection assurance plan,
15. decommissioning plan,
16. estimation of decommissioning costs,
17. operational controlled ageing programme,
18. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
19. emergency operating rules,
20. severe accident management guidelines.

The documentation referred to in Points 2, 3, 5, 14 and 15 shall be subject to approval by the Office.

g) The documentation to be provided where the activity to be licensed are the individual phases of decommissioning of a nuclear installation is as follows:

1. management system programme,
2. limits and conditions,
3. safety report on the decommissioning of the nuclear installation,
4. timetable for the decommissioning of the nuclear installation,
5. proposal for the organisational preparation and staffing for the decommissioning of the nuclear installation,
6. physical protection assurance plan,
7. radiation extraordinary event analysis and assessment for the decommissioning of the nuclear installation,
8. monitoring programme,
9. on-site emergency plan,
10. modification of the emergency planning zone,
11. decommissioning controlled ageing programme,
12. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
13. certificate of the availability of sufficient funding for decommissioning,
14. conditions for further use of the area and systems, structures or components, if complete decommissioning is not possible.

The documentation referred to in Points 2, 6, 8 and 10 shall be subject to approval by the Office.

h) The documentation to be provided where the activity to be licensed is the carrying out of modifications affecting nuclear safety, technical safety and physical protection of a nuclear installation is as follows:

1. management system programme,
2. description and justification of the modification,
3. timetable for the implementation of the modification,



4. draft update of the documentation for other licensed activities, if affected by the modification,
5. assessment of the effect of the modification on nuclear safety, technical safety and security,
6. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated.

## **2. Activities in exposure situations**

- a) The documentation to be provided where the activity to be licensed is the construction of a category IV workplace, except workplaces with a nuclear installation, is as follows:
1. certificate that the proposed design complies with the requirements for radiation protection, security, and radiation extraordinary event management laid down in legislation,
  2. security analyses and analyses of the possibilities for unauthorised management of sources of ionising radiation and assessment of the consequences thereof for the personnel, general public and the environment,
  3. assessment of the generation and radioactive waste management in the course of commissioning and operation of the workplace,
  4. concept for the safe permanent shutdown and decommissioning of the workplace, including the disposal of radioactive waste,
  5. evaluation of quality assurance for the preparation of the construction of the workplace,
  6. management system programme,
  7. intention to ensure the monitoring of discharges,
  8. programme for the monitoring of the surrounding area,
  9. intention to ensure radiation extraordinary event management,
  10. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
  11. method of quality assurance for the implementation of the workplace construction project,
  12. principles of quality assurance for the phases of the workplace's life cycle following construction.

The documentation referred to in Point 8 shall be subject to approval by the Office.

- b) The documentation to be provided where the activity to be licensed is the operation of a category III workplace or a category IV workplace is as follows:
1. the expected scope and method of work using the source of ionising radiation in the workplace and the specifications, type and accessories of the source of ionising radiation to be managed,
  2. description of progress of construction and assembly work, certificate of efficiency of shielding, insulation and protective equipment allowing the commencement of activities involving radiation,
  3. radiation protection optimisation procedures,
  4. monitoring programme,
  5. delineation of the controlled area,
  6. radiation extraordinary event analysis and assessment for the operation of a category III workplace or a category IV workplace which is not a workplace with a nuclear installation,
  7. on-site emergency plan,

8. establishment of the emergency planning zone for a category IV workplace, except workplaces with a nuclear installation,
9. list of workers who will perform activities of particular relevance to radiation protection,
10. the expected type and quantity of discharged radioactive substances and the expected type and quantity of radioactive waste produced, as well as the method of disposal,
11. decommissioning plan and estimation of decommissioning costs verified by the Authority,
12. management system programme,
13. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated.

The documentation referred to in Points 4 and 7, if category IV workplace is concerned, and Point 8 shall be subject to approval by the Office.

- c) The documentation to be provided where the activity to be licensed is the carrying out of reconstruction or other modifications affecting radiation protection, radiation situation monitoring and radiation extraordinary event management in a category III workplace or a category IV workplace is as follows:
1. description and justification of the planned reconstruction or other modifications,
  2. the expected timetable for the reconstruction or modifications,
  3. certificates that the consequences of the reconstruction or other modifications implemented will not adversely affect radiation protection, radiation situation monitoring, radiation extraordinary event management and security,
  4. management system programme,
  5. draft updates of the submitted and approved documentation, if affected by the changes,
  6. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated.
- d) The documentation to be provided where the activity to be licensed are the individual phases of decommissioning of a category III workplace or a category IV workplace is as follows:
1. certificate of availability of funds for the decommissioning,
  2. description of the technological procedures proposed for the decommissioning,
  3. decommissioning timetable,
  4. method of dismantling, decontamination, treatment, transportation, storage and disposal of parts of the equipment contaminated by a radioactive substance,
  5. the expected radionuclide composition and activity of radioactive substances discharged from the workplace and radioactive waste generated,
  6. method of management of radioactive waste, including disposal,
  7. safety report,
  8. monitoring programme,
  9. radiation extraordinary event analysis and assessment for the decommissioning,
  10. on-site emergency plan,
  11. modification of the emergency planning zone,
  12. management system programme,
  13. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
  14. conditions for further use of the area and systems, structures or components, if complete decommissioning is not possible.

The documentation referred to in Points 8 and 10, if category IV workplace is concerned, and Point 11 shall be subject to approval by the Office.

- e) The documentation to be provided where the activity to be licensed is the discharge of radioactive substances from the workplace is as follows:
  - 1. justification of the activity,
  - 2. radionuclide composition and activity of the radionuclides in the radioactive substances discharged from the workplace,
  - 3. evaluation of exposure of the representative person from the discharged radioactive substance,
  - 4. analysis of the potential for accumulation of the radioactive substance in the environment when discharged for a long period of time,
  - 5. radiation protection optimisation procedures.
- f) The documentation to be provided where the activity to be licensed is the management of a source of ionising radiation is as follows:
  - 1. for all methods of management
    - 1.1. justification of the activity,
    - 1.2. specifications, type and accessories of the source of ionising radiation to be managed,
    - 1.3. description of the delineation of the supervised area in the workplace where the source of ionising radiation will be managed, including a schematic plan and complete with information about shielding, protective devices and equipment of working posts,
    - 1.4. radiation protection optimisation procedures,
    - 1.5. list of workers who will perform activities of particular relevance to radiation protection,
    - 1.6. monitoring programme, unless the activity is the import, export or distribution of a source of ionising radiation, which does not involve use or storage of the source of ionising radiation,
    - 1.7. delineation of the controlled area, the anticipated number of natural persons working in the area and the method of preventing unauthorised natural persons from entering this area,
    - 1.8. radiation extraordinary event analysis and assessment for the management of the source of ionising radiation,
    - 1.9. on-site emergency plan for the management of sources of ionising radiation in a workplace of category II or higher,
    - 1.10. if it is planned that radioactive substances will be discharged from the workplace or radioactive waste will be generated, the expected type and quantity of the discharged radioactive substances and the expected type and quantity of radioactive waste generated, as well as a document about the method of disposal thereof,
    - 1.11. radiation protection assurance programme, if not used in a workplace of category III or a workplace of category IV
    - 1.12. security plan for the source of ionising radiation, in the case of a radionuclide source of security category 1. through 3.,
    - 1.13. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated,
      - 2. if used in a workplace of category III or a workplace of category IV, the management system programme shall also be provided,
      - 3. in the case of manufacture, import, distribution and export of a source of ionising radiation, the following shall also be provided
        - 3.1. specification of the type of source of ionising radiation,
        - 3.2. the expected number of sources of ionising radiation,
        - 3.3. in the case of import, the method of ensuring that the source of ionising radiation is returned to the country of origin, or the method of its future use,

- 3.4. in the case of re-import of a source of ionising radiation, evidence documenting the origin, type, physical properties and chemical composition of the source of ionising radiation exported outside the territory of the Czech Republic, together with evidence of its use and evidence of overall activity and weight of the source of ionising radiation,
4. in the case of import or manufacture of a source of ionising radiation, the following shall also be provided
  - 4.1. manufacturing or import timetable,
  - 4.2. proof of competence for the verification of conformity of the product's characteristics with the given product type,
5. in the case of export of a source of ionising radiation, the export timetable shall be included,
6. when evaluating the characteristics of a source of ionising radiation, the following shall also be provided
  - 6.1. proof of competence for the measurement and verification of the characteristics of the source of ionising radiation,
  - 6.2. methodologies, procedures and model measurement reports,
  - 6.3. overview of instrumentation and its availability for the performance of the proposed services,
  - 6.4. concept for ensuring the measurement of quantities.
- g) The documentation to be provided where the activity to be licensed is the addition of a radioactive substance to consumer products when manufacturing or preparing them and for importing and exporting such products is as follows:
  1. justification of the activity,
  2. radionuclide composition and activity of the radionuclide added to each product,
  3. instructions for use of the product,
  4. concept for the disposal of the used product,
  5. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated.
- h) The documentation to be provided where the activity to be licensed is the performance of services relevant to radiation protection is as follows:
  1. description and the expected scope of the services to be provided,
  2. description of readiness of equipment and the personnel,
  3. list of workers who will perform activities of particular relevance to radiation protection,
  4. radiation protection assurance programme,
  5. in the case of services involving measurement and evaluation of ionising radiation or radionuclide content, the following shall also be provided
    - 5.1. methodologies and procedures,
    - 5.2. overview of instrumentation and its availability for the performance of the proposed services,
    - 5.3. concept for ensuring the measurement of quantities,
    - 5.4. document demonstrating that safe radioactive waste management has been ensured, including the financing thereof, if radioactive waste is generated.
- i) The documentation to be provided where the activity to be licensed is the provision of services in a controlled area to an operator of a category IV workplace is as follows:
  1. description and the expected scope of the activities to be provided,
  2. description of readiness of equipment and the personnel,
  3. list of workers who will perform activities of particular relevance to radiation protection,
  4. radiation protection assurance programme.

- j) The documentation to be provided where the activity to be licensed is the making available of building materials on the market is as follows:
1. report containing the results of measurements of natural radionuclide content of building materials, information about the origin of the raw materials and manner of use of the building materials,
  2. estimation of the effective dose to the representative person from external exposure to gamma radiation as a result of the use of the building material for construction of a building with residential rooms or rooms intended to be occupied by persons,
  3. estimation of the effective dose to the representative person from radon emissions when the building material is used for construction of a building with residential rooms or rooms intended to be occupied by persons,
  4. set of measures reducing the level of exposure from building materials, including optimisation procedures,
  5. conditions for making the building material available on the market.
- k) The documentation to be provided where the activity to be licensed is the mixing of radioactive substances discharged from a workplace is as follows:
1. purpose and objective of mixing,
  2. justification of the activity,
  3. radionuclide composition and radionuclide activity of the radioactive substances before and after mixing,
  4. radiation protection optimisation procedures.

### **3. Activities in the area of radioactive waste management**

- a) The documentation to be provided where the activity to be licensed is radioactive waste management, except collection, segregation and storage of radioactive waste directly by the radioactive waste producer, who is authorised to manage the waste as an unsealed radionuclide source, is as follows:
1. description of the equipment and technology used,
  2. information about the origin, type, quantity, and radionuclide composition and activity of radioactive waste,
  3. method of collection, segregation, treatment, conditioning, storage and disposal of radioactive waste,
  4. expected quantity of radioactive substances discharged from the workplace,
  5. safety analyses,
  6. limits and conditions,
  7. radiation extraordinary event analysis and assessment,
  8. management system programme,
  9. on-site emergency plan.
- The documentation referred to in Point 6 shall be subject to approval by the Office.
- b) The documentation to be provided where the activity to be licensed is the closure of a radioactive waste disposal facility is as follows:
1. final safety report, which shall contain
    - 1.1. certificate of availability of funds for the closure of the radioactive waste disposal facility and institutional control of the radioactive waste disposal facility,
    - 1.2. description of the changes in the area due to the operation of the radioactive waste disposal facility,
    - 1.3. baseline situation in respect of the radioactive waste and radioactive waste disposal facility prior to carrying out the closure of the radioactive waste disposal facility,

- including description of the operation of and changes and modifications to the radioactive waste disposal facility,
- 1.4. overall inventory of radioactive waste present in the radioactive waste disposal facility prior to carrying out the closure of the radioactive waste disposal facility,
  - 1.5. timetable for the closure of the radioactive waste disposal facility and institutional control of the radioactive waste disposal facility,
  - 1.6. description of the technological procedures proposed for the closure of the radioactive waste disposal facility,
  - 1.7. safety analyses,
  2. limits and conditions,
  3. description of the method of ensuring institutional control, organisational preparation and personnel for the closure of the radioactive waste disposal facility,
  4. management system programme,
  5. physical protection assurance plan for the radioactive waste disposal facility,
  6. description of the method of monitoring the surrounding area after the closure of the radioactive waste disposal facility,
  7. delineation of the controlled area for the period of carrying out the closure of a radioactive waste disposal facility,
  8. radiation extraordinary event analysis and assessment after the closure of the radioactive waste disposal facility,
  9. on-site emergency plan,
  10. modification of the emergency planning zone.

The documentation referred to in Points 2, 5, 9 and 10 shall be subject to approval by the Office.

- c) The documentation to be provided where the activity to be licensed is the re-import or re-transfer from a Member State of the Euratom of radioactive waste produced during the processing of a material exported from the Czech Republic or import or transfer of radioactive waste from a Member State of the Euratom to the Czech Republic for the purposes of processing or reusing it is as follows:
1. evidence documenting the origin, type, physical properties and chemical composition of the radioactive waste to be imported or transferred to the Czech Republic for the purposes of processing or recycling, including documents stating its overall weight and radioactivity,
  2. evidence of the technological process to be used to process or recycle the imported or transferred radioactive waste, including the material balance report demonstrating the additional quantity of radioactive waste likely to be produced by the given technological process,
  3. declaration of the producer of the radioactive waste on the immediate take-back of the processed radioactive waste and additional radioactive waste likely to be produced in the course of processing or recycling.

#### **4. Carriage of radioactive or fissile materials**

The documentation to be provided where the activity to be licensed is the carriage of radioactive or fissile materials in accordance with § 9(4)(a) to (c) is as follows:

- a) shipping instructions, complete with carriage specifications and the proposed route, including backup route,
- b) radiation protection assurance programme, including the monitoring programme,
- c) physical protection assurance plan for the carriage of nuclear materials of categories I to III,

- d) radiation extraordinary event analysis and assessment for carriage,
- e) emergency regulations,
- f) certificates for the service personnel of the means of transport to be used for carriage of dangerous goods that they have undergone training and passed examination on the specific requirements for carriage of dangerous goods under an international treaty binding on the Czech Republic<sup>30)</sup> or an equivalent certificate of competence for carriage of dangerous goods,
- g) certificate for the vehicle to be used for carriage of dangerous goods under the international treaty binding on the Czech Republic<sup>30)</sup> or an equivalent approval certificate for the vehicle to be used for carriage of dangerous goods,
- h) declaration of conformity of the materials, manufacturing processes and parameters and technical requirements placed on each packaging assembly with the data in the documentation used as a basis for the type-approval of the packaging assembly,
- i) management system programme,
- j) in the case of carriage of radioactive or fissile materials under special conditions, a list of the requirements under this Act or other legislation which cannot be satisfied, including justification, and a description of the special conditions for carriage replacing the conditions that cannot be satisfied, including evidence that equal or higher level of nuclear safety, radiation protection and physical protection will be ensured during carriage under special conditions,
- k) in the case of carriage of a radioactive or fissile material whose activity value has been calculated in order to determine the activity limits, the calculation of the activity value of the radioactive substance to determine the activity limits shall also be provided, including justification for not using the values set out in implementing legislation,
- l) in the case of carriage of radioactive substances contained in instruments or articles containing radionuclides, for which the exempt consignment values set out in implementing legislation were replaced with calculated values, the calculation of the individual doses to transport workers and representative persons and collective doses arising from routine, normal and accident conditions of transport, based on representative transport scenarios the consignments are subject to, in accordance with the principles and methodologies established by the International Atomic Energy Agency,
- m) in the case of carriage of radioactive substances as excepted fissile materials
  1. detailed description of the substance, with special emphasis on its physical and chemical status,
  2. evidence that the radioactive substances transported meet the exemption requirements set out in implementing legislation,
  3. description of the management system used and, where appropriate, special measures to be taken prior to carriage.

The documentation referred to in Points (c) and (e) shall be subject to approval by the Office. The documentation referred to in Point (g) shall be provided only if the international treaty binding on the Czech Republic requires such documentation for the carriage of radioactive or fissile materials to be licensed.

## **5. Activities in the area of non-proliferation of nuclear weapons**

- a) The documentation to be provided where the activity to be licensed is the management of nuclear material is as follows:

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<sup>30)</sup> European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), promulgated under No 64/1987, as amended.

1. nuclear material accountancy and control guidelines,
2. description of handling of the nuclear materials, including categorisation, quantity and purpose of use of the nuclear materials,
3. data necessary for compliance with the requirements under international commitments.

The documentation referred to in Point 1 shall be subject to approval by the Office.

- b) The documentation to be provided where the activity to be licensed is the import or export of a nuclear item or transit of nuclear material or a selected nuclear item is as follows:
  1. the set of data needed to request the State guarantee or a copy of the State guarantee, in the case of nuclear materials and selected nuclear items,
  2. in the case of import of a nuclear item, the end-user declaration,
  3. in the case of export of a dual-use nuclear item, declaration of the end-user or the receiving State,
  4. the set of data needed to comply with the requirements under international commitments.

## **6. Training and further training of selected workers and training of persons ensuring radiation protection of a registered person**

The documentation to be provided where the activity to be licensed is training and further training of selected workers and training of persons ensuring radiation protection of a registered person is as follows:

- a) evidence documenting the applicant's organisational and technical competence,
- b) evidence documenting professional competence of the applicant's personnel,
- c) evidence documenting the method of training.

## **7. Complete decommissioning**

The documentation to be provided where the activity to be licensed is complete decommissioning is as follows:

- a) description of the area where the decommissioned nuclear installation or category III workplace or category IV workplace is sited and description of a description of the work implemented in the context of decommissioning,
- b) inventory of radioactive wastes, including the method of disposal or storage thereof, and inventory of remaining radioactive substances released into the environment,
- c) list of data to be retained after the completion of decommissioning, including the period for which they will be retained,
- d) the procedures used and the results of radiation situation monitoring in the area where the nuclear installation or category III workplace or category IV workplace is sited and their comparison with the results of the on-site baseline survey prior to the commencement of construction of this workplace.



**Annex 2 to Act No 263/2016**

**Documentation for product type-approval applications**

The documentation to be provided with product type-approval applications is as follows:

- a) for all packaging assemblies
  1. material specifications of radioactive or fissile materials for which the packaging assembly is designed, in particular a description of their physical and chemical states,
  2. detailed technical specifications of the packaging assembly, including a detailed description of the construction type of the packaging assembly, including design documentation, complete technical drawings, and a list of materials and technological methods employed in its manufacture; in the case of a packaging assembly that has obtained similar approval abroad, proof of its approval shall be provided,
  3. the manufacturer's management system programme,
  4. technological and manufacturing documentation with detailed schedules of materials and technological methods employed in the manufacture of the containment system,
  5. description of the samples to be taken and the tests to be made, if the packaging assembly is designed to have a maximum normal operating pressure in excess of 100 kPa gauge,
  6. documentation demonstrating that radiation protection has been ensured and, if the packaging assembly is designed for a fissile material, documentation demonstrating that it has been ensured that the content is maintained subcritical,
  7. statement and justification of assumptions relating to the characteristics of irradiated nuclear fuel used in safety analyses for criticality calculations, if the packaging assembly is designed for irradiated nuclear fuel,
  8. statement of specific requirements necessary for the dissipation of heat in relation to each particular type of carriage and means of transport, if the packaging assembly is designed for radioactive or fissile material producing heat,
  9. reproducible illustration, not larger than 21 cm × 29.7 cm, showing the make-up of the packaging assembly,
  10. documentation of tests or calculations and analyses, including their independent verification by an authorised person,
- b) the following shall also be provided for type B(M) packaging assemblies
  1. a list of requirements for type B(M) packaging assemblies with which the type B(M) packaging assembly does not conform and a list of supplementary technical, operational and organisational measures to ensure nuclear safety and radiation protection, and
  2. the highest and lowest values of ambient conditions (temperature, solar radiation) which are expected to be encountered during transport and which have been taken into account in the design,
- c) for packaging assemblies intended for the carriage of 0.1 kg or more of uranium hexafluoride, information about compliance with the special requirements due to the nature of uranium hexafluoride shall also be provided,
- d) for special form radioactive materials or low dispersible radioactive materials
  1. material specifications of the radioactive or fissile material contents, including a description of their physical and chemical states,
  2. description of the product's design type and manufacturing and technological documentation, including schedules of materials and technological methods of manufacture,
  3. documentation of tests or calculations and analyses, including their independent verification by an authorised person,

4. the manufacturer's management system programme,
5. description of the proposed instructions for the handling of the product necessary for carriage,
6. reproducible illustration, not larger than 21 cm × 29.7 cm, showing the make-up of the product.