ACT No. 18/1997 Coll.

of 24 January 1997

on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Alterations to Some Acts

As amended by:

- Act No. 83/1998 Coll.
- Act No. 71/2000 Coll.
- Act No. 132/2000 Coll.
- Act No. 13/2002 Coll.
- Act No. 310/2002 Coll.

Act No. 320/2002 Coll.

Act No. 13/2002 Coll.

- Act No. 1/2005 Coll.
- Act No. 253/2005 Coll.

Act No. 413/2005 Coll.

- Act No. 342/2006 Coll.
- Act No. 186/2006 Coll.
- Act No. 296/2007 Coll.
- Act No. 124/2008 Coll.
- Act No. 274/2008 Coll.
- Act No. 158/2009 Coll.
- Act No. 223/2009 Coll.
- Act No. 227/2009 Coll.
- Act No. 249/2011 Coll.

Act No. 250/2011 Coll.

Act No. 375/2011 Coll.

Act No. 350/2012 Coll.

The Parliament has passed this Act of the Czech Republic:

PART I

PEACEFUL UTILISATION OF NUCLEAR ENERGY AND IONISING RADIATION

CHAPTER ONE

INTRODUCTORY PROVISIONS

Section 1

Scope

This Act regulates

- a) the method of utilising nuclear energy and ionising radiation, and conditions for the performance of practices related to nuclear energy utilisation and radiation activities;
- b) the system for protection of people and the environment from undesirable effects of ionising radiation;
- c) obligations during preparation for and implementation of intervention intended to reduce exposures to natural sources and exposures due to radiation accidents;
- d) specific requirements for civil liability in the case of nuclear damage;
- e) conditions for safe management of radioactive waste;
- f) performance of State administration and supervision within nuclear energy utilisation, within radiation activities and over nuclear items.

Section 2

Basic Terms

For the purposes of this Act

a) activity related to nuclear energy utilisation means

- 1. the siting, construction, commissioning, operation, reconstruction and decommissioning of nuclear installations;
- 2. designing nuclear installations;
- 3. designing, manufacturing, repairs and verification of nuclear installation systems or their components, including materials used for their production;
- 4. designing, manufacturing, repairs and verification of packaging assemblies for the transport, storage or disposal of nuclear materials;
- 5. handling of nuclear materials and of selected items and, in the case of their use in the nuclear field, also of items of dual use;
- 6. research and development into the activities mentioned in points 1 to 5;
- 7. professional training of personnel, specialised from the nuclear safety viewpoint for the activities stated under point 1;
- 8. transport of nuclear materials;
- b) radiation activity means
 - 1. radiation practice which involves
 - aa) an activity that may increase the exposure of individuals to radiation from an artificial sources of ionising radiation, except activity in the case of radiological emergency, or
 - bb) an activity in which natural radionuclides are used for their radioactive, fissile or fertile properties;
 - 2. a work activity associated with the increased presence of natural radionuclides or increased influence of cosmic radiation and lead or may lead to a significant increase in exposure of individuals;
- c) ionising radiation source means a substance, equipment or installation capable of emitting ionising radiation or releasing radioactive substances;
- d) nuclear safety means the condition and ability of a nuclear installation and its servicing personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionising radiation into the environment, and to reduce the consequences of accidents;
- e) radiation protection means a system of technical and organisational measures to reduce exposure of individuals and to protect the environment;
- f) physical protection means a system of technical and organisational measures preventing unauthorised activities with nuclear installations, nuclear materials and selected items;
- g) emergency preparedness means an ability to recognise the occurrence of a radiological emergency and, upon its occurrence, to carry out measures specified in emergency plans;
- h) nuclear installation means
 - 1. constructions and operating units containing a nuclear reactor utilising a fission chain reaction;
 - 2. facilities for the production, processing, storage and disposal of nuclear materials, except uranium ore treatment plants and storages of uranium concentrate;
 - 3. repositories of radioactive waste, with the exception of repositories containing only natural radionuclides;

- 4. facilities for the storage of radioactive waste with an activity exceeding the values set out in an implementing legal regulation;
- i) classified equipment means nuclear and technical safety-related components or systems of nuclear installations assigned to safety classes according to their significance for nuclear installation operation safety, according to the safety function of the system to which they belong, or according to the relevance of their possible breakdown. The criteria for classified equipment to be assigned and categorised into safety classes shall be set out in an implementing legal regulation;
- j) nuclear item means

1. nuclear materials which are

- aa) source materials represented by uranium containing a mixture of isotopes occurring in nature, uranium depleted in the 235U isotope or thorium and each of these items in the form of metal, alloy, chemical compound or concentrate, as well as materials containing one or more of these items in a concentration or amount exceeding values set out in an implementing legal regulation;
- bb) special fission materials represented by 239Pu, 233U, uranium enriched in the isotope 235U or 233U and materials containing one or more of these radionuclides, except initial materials exceeding in concentration or amount values set out in an implementing legal regulation;
- cc) other materials, should implementing legal regulation so determine;
 - 2. selected items which are materials, equipment or technologies designed and manufactured to be used in the nuclear field, a list of which shall be provided in an implementing legal regulation;
 - 3. dual-use items, which are materials, equipment and technologies not designed and manufactured to be used in the nuclear field but which may be utilised there, a list of which shall be provided in an implementing legal regulation;
- k) radiation incident means an event resulting in an inadmissible release of radioactive substances or ionising radiation, or an inadmissible exposure of individuals;
- 1) radiation accident means radiation incident requiring urgent measures in order to protect the population and environment;
- m) radiological emergency means a situation following the radiation accident or such radiation incident or such increase in level of radioactivity or exposure which require urgent action in order to protect individuals;
- n) emergency plan means a set of planned measures to deal with a radiation incident or radiation accident and to limit their consequences which is elaborated for:
 - 1. nuclear installation premises or workplaces in which radiation practicies are performed (on-site emergency plan);
 - 2. transport of nuclear materials or ionising radiation sources (emergency rule);
 - the region in the vicinity of the nuclear installation or the workplace with a source of ionizing radiation where, based on results of analyses of potential radiation accident consequences, emergency planning requirements are in force and which is called emergency planning zone (offsite emergency plan);
- o) decommissioning means activities aimed at releasing nuclear installations or workplaces where radiation practices were performed, for their utilisation for other purposes;
- p) radioactive substance means any substance that contains one or more radionuclides and whose activity or concentration cannot be disregarded as far as radiation protection is concerned;
- r) radioactive waste means substances, objects or equipment containing or contaminated by radionuclides for which no further use is foreseen;

- s) radioactive waste and spent fuel storage means a temporary emplacement of radioactive waste or spent or irradiated nuclear fuel for a period restricted in advance into areas, facilities or installations designed for this purpose;
- t) radioactive waste disposal means a permanent emplacement of radioactive waste in an areas, facilities or installations without the intention of its further retrieval;
- u) radioactive waste repository means an area, facility or installations at the surface or underground used for the disposal of radioactive waste;
- v) limits and conditions for the safe operation of a nuclear installation means a set of unambiguously defined conditions for which it is proven that operation of a nuclear installation is safe and which is comprised of data on admissible parameters, requirements for the operability of the installation, protective system settings, requirements for personnel activity and organisational measures to meet all the defined conditions for design operational modes;
- w) ionising radiation means transfer of energy in the form of particles or electromagnetic waves of the wavelength equal to 100 nanometers or less, or frequency of 3×10^{15} Hertz or more, capable of producing ions directly or indirectly;
- x) exposure means an exposure of individuals and the environment to ionising radiation; it is namely
 - 1. occupational exposure of workers performing radiation practices;
 - 2. medical exposure as a part of
 - aa) medical examination or treatment;
 - bb) occupational health services and preventive health services;
 - cc) voluntary participation of the healthy persons or patients in medical, biomedical, diagnostic or therapeutic research programme within the process of verification of new methods which have not yet been introduced into clinical practice;
 - dd) medico-legal procedures¹;
 - 3. emergency exposure of individuals due to a radiation incident or a radiation accident, with the exception of an emergency exposure of intervening individuals;
 - 4. emergency exposure of intervening individuals voluntarily involved in intervention, during which some of dose limits laid down for exposed workers may be exceeded;
 - 5. lasting exposure resulting from long-term after-effects of a radiological emergency or radiation activities performed in the past;
 - 6. potential exposure which cannot be surely foreseen, however the probability of its occurrence may be estimated in advance;
- y) exposed worker means any person subject to an occupational exposure; meanwhile it is not essential whether the individual is an employee, or person in a different labour-legal position;
- z) members of the public means any person, with the exception of exposed workers while performing their work, apprentices and students during their working hours, individuals exposed due to their own medical diagnosis or treatment, individuals knowingly and willingly beyond their working obligations help to persons undergoing medical exposure as part of their medical diagnosis or treatment and volunteers participating in application of methods which have not yet been introduced in the clinical practice;
- aa) critical group of the population means a model group comprising these individuals from the population whose exposure relating to a given source of ionising radiation and a given way of exposure is the highest;
- bb) supervised area means an area subject to systematic supervision for the purposes of radiation protection;

¹⁾ Act No 372/2011 Coll., On healthcare services and conditions for their provision (the Healthcare Services Act).

- cc) controlled area means an area to which access is controlled and which are subject to special rules for the purpose of radiation protection or of preventing the spread of radiation contamination;
- dd) optimisation of radiation protection means procedures for achieving and maintaining such levels of radiation protection by which the risks to life, human health and environment are as low as reasonably achievable, considering the existing economic and social circumstances;
- ee) dose constraint means an upper limit of prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved;
- ff) guidance level means an index or a criterion used for the evaluation of the radiation protection level in the case where details on radiation activities or interventions enabling to evaluate the optimisation of radiation protection in particular given case are not available;
- gg) reference level means an index or a criterion whose exceeding or non-meeting leads to adoption of measures in radiation protection; an implementing legal regulation shall lay down details for determination of reference levels and measures adopted as a result of their exceeding;
- hh) diagnostic reference level means a guidance level for exposure in medical radiodiagnostics;
- ii) clearance level means a level of specific activity or total activity at or below which radioactive waste, radioactive substances and materials or equipment containing radionuclides or contaminated by them may be released into environment without an approval of the State Office for Nuclear Safety;
- jj) exemption level means level of specific activity or total activity at or below which the contamination by radionuclides is usually considered to be insignificant;
- kk) maximum permitted level means an index or a criterion for regulation of inadmissible exposure to a natural radionuclides;
- intervention means activities aimed at averting or reducing the exposure to radiation from ionising radiation sources which are not part of radiation activities or which are out of control, by acting on sources, transmission pathways or exposed individuals;
- mm) health detriment which is made by estimation of the risk of reduction in length and quality of life means probability of the harm to the health arising from somatic effects of ionising radiation, including cancer, and severe genetic disorders occurring in individuals following exposure to ionising radiation;
- nn) technical safety means the ability of classified equipment during activities related to nuclear energy utilisation not to endanger under the defined conditions of its operation human health and property throughout its lifetime and to ensure permanent conformity to the technical requirements, which are included in the implementing legal regulation or another binding technical specification for the classified equipment.

Section 2a

Sensitive activities

Pursuant to the special legal regulation^{1c)}, sensitive activities shall mean

- a) in the field of organisation and management in a nuclear installation
 - 1. organisation and management of the operation of a nuclear installation,
 - 2. organisation or management of the activities according to on-site emergency plan or emergency rules,
 - 3. organisation or management of the activities of radioactive waste repositories,
 - 4. shift management of a nuclear power plant including individual power units,
 - 5. shift management of a nuclear research reactor,
- b) in the field of management of nuclear materials of category I or II from the perspective of physical protection
 - 1. accounting for and control of nuclear materials,
 - 2. management or control of the handling of nuclear materials,
 - 3. management or control of the storage of nuclear materials,
 - 4. organisation of the transports of nuclear materials,
 - 5. organisation of the transports of ionising radiation sources requiring a licence of the Office,
- c) in the field of the assurance of physical protection of nuclear materials or nuclear installations
 - 1. management or control of the physical security of nuclear materials or nuclear installations,
 - 2. management or control of the service and operation of the control centre and the service of the control centre of the technical physical protection system,
 - 3. management or control of the maintenance and repairs of the technical physical protection system and its components.

Section 3

Competence of the State Office for Nuclear Safety

(1) State administration and supervision of the utilisation of nuclear energy and ionising radiation and in the field of radiation protection shall be performed by the State Office for Nuclear Safety^{1a)} (hereinafter ,,the Office").

- (2) The Office
- a) shall carry out State supervision of nuclear safety, nuclear items, physical protection, radiation protection, emergency preparedness and technical safety of classified equipment and shall inspect the adherence to the fulfilment of the obligations arising out of this Act;
- b) shall monitor non-proliferation of nuclear weapons and carry out state supervision of nuclear items and physical protection of nuclear materials and nuclear installations;
- c) shall issue licences to perform practices governed by this Act and shall issue typeapprovals for packaging assemblies for transport and storage of nuclear materials and

^{1c)} Act No. 412/2005 Coll., On the Protection of Classified Information.

^{1a)} Section 1 para 4 of Act of the Czech National Council No. 21/1993 Coll., amending Act of the Czech National Council No. 2/1969 Coll., on the Establishment of Ministries and Other Central Authorities of State Administration of the Czech Socialist Republic, as amanded, and by which further measures in the system of central authorities of State administration of the Czech Republic are executed.

radioactive substances given in an implementing legal regulation, ionising radiation sources and other products;

- d) shall issue authorisations for activities performed by selected personnel;
- e) shall approve documentation, programmes, lists, limits, conditions, methods of physical protection assurance, emergency rules and, subject to discussion with the relevant Regional Authorities and relevant Municipal Authorities of Municipalities with extended competence of compatibility with offsite emergency plans, on-site emergency plans and their modifications;
- f) shall establish conditions, requirements, limits, maximum permitted levels, maximum permitted levels of radioactive contamination of foodstuffs, guidance levels, dose constraint, reference levels, diagnostic reference levels, exemption levels and clearance levels;
- g) shall establish the emergency planning zone and, if applicable, its further structuring, and shall approve delineation of the controlled area;
- h) in accordance with an implementing legal regulation, shall establish requirements on emergency preparedness of licensees, and shall inspect their fulfilment;
- i) shall monitor and assess the exposure status and regulate exposure of individuals;
- j) shall issue, register and verify personal radiation passport; related details shall be set out in an implementing legal regulation;
- k) shall provide information to municipalities and Regional Authorities concerning radioactive waste management within their territory of administration;
- shall control the activity of the National Radiation Monitoring Network, the functions and organisation of which shall be set out in an implementing legal regulation, shall provide for the functioning of its head-office, and shall provide for the activities of an Emergency Response Centre and for an international exchange of information on the radiation situation;
- m) shall establish State and Professional examination commissions for verification of special professional competence of selected personnel or other individuals, and shall issue statutes for these commissions and specify activities directly affecting nuclear safety and activities especially important from the radiation protection viewpoint;
- n) shall maintain a State system of accounting for and control of nuclear materials and data and information in accordance with international agreements binding on the Czech Republic, and shall set out requirements for accounting methods and inspection thereof in an implementing legal regulation;
- o) shall maintain a national system for registration of licensees, registrants, imported and exported selected items, ionising radiation sources, and a record of exposure of individuals;
- p) shall ensure, by means of the National Radiation Monitoring Network and based on assessment of a radiation situation, the availability of background information necessary to take decisions aimed at reducing or averting exposure in the case of a radiation accident;
- r) shall approve a classification of nuclear installation or its components and nuclear materials into appropriate categories, from the physical protection viewpoint;
- s) shall perform the function of the national authority for an international verification of a comprehensive ban of nuclear tests;
- t) shall ensure international co-operation within its sphere of competence and, in particular, shall be an intermediary of technical co-operation with the International Atomic Energy Agency, and within its sphere of competence shall communicate information to the European Commission or, if applicable, to other bodies of the European Union and shall ensure implementation of other obligations arising out of the regulations of the European

Union⁴¹⁾ related in particular to a natioanl and international evaluation of the state supervision of nuclear safety of the nuclear facilities;

- u) shall decide on assurance of handling nuclear items, ionising radiation sources or radioactive wastes having been treated inconsistently with rules of law, or where the detrimental condition is not being removed;
- v) shall be obliged to give out information according to special legal provisions^{1b)} and once a year to publish a report on its activities and submit it to the Government and to the public;
- w) shall set the technical requirements for the technical safety of classified equipment;
- x) upon agreement with the administrative authority, shall inspect the activities of persons authorised under the special legal regulation^{2a};
- y) shall make known its view on the spatial development policy and spatial planning documentation from the perspective of safety and radiation protection in practices related to nuclear energy utilisation and radiation activities.

Section 3a

Expertise Fees

The expertise fees shall be a) the fee for the application for a licence (hereinafter ,,the application fee"), b) the maintenance fee.

Section 3b

Persons Liable to Expertise Fees

- (1) The applicant for a licence shall be the payer of the application fee.
- (2) The licensee shall be the payer of the maintenance fee.

Section 3c

⁴¹⁾ Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.

^{1b)} Act No 123/1998 Coll., On the right on information about the environment, as amended by Act No 132/2000 Coll.

Act No 106/1999 Coll., On free access to information, as subsequently amended.

^{2a)} Act No. 22/1997 Coll., On Technical Requirements for Products and on Amendments to some Acts, as amended.

Object of Expertise Fees

(1) The application fees shall apply to the activities of the Office relating to issuing

a) a licence for siting of a nuclear installation,

b) a licence for the construction of

1. a nuclear installation, or

2. category IV workplace having unsealed ionising radiation sources,

c) the first licence for the operation of

1. a nuclear installation,

2. category III workplace comprising mining and processing of uranium ore, or

3. category IV workplace having unsealed ionising radiation sources, or

d) a licence for individual stages of decommissioning of

1. a nuclear installation

2. category III workplace comprising mining and processing of uranium ore, or

3. category IV workplace having unsealed ionising radiation sources.

(2) The maintenance fee shall apply to the activities of the Office relating to the performance of State supervision over licensee's activities in regard to licences for

a) the operation of

1. a nuclear installation

2. category III workplace comprising mining and processing of uranium ore, or

3. category IV workplace having unsealed ionising radiation sources, or

b) individual stages of decommissioning of

1. a nuclear installation,

2. category III workplace comprising mining and processing of uranium ore, or

3. category IV workplace having unsealed ionising radiation sources.

Section 3d

Expertise Fees Exemptions

(1) Exemptions from the expertise fees shall apply to

a) public universities and healthcare institutions, provided their activities governed by this Act are financed by the public health insurance,

b) persons whose activities governed by this Act are financed solely by public science and research funds including funds of the European Union.

(2) The payer shall provide documentary evidence of the facts relevant for the exemptions from the expertise fees when an application for the licence is submitted or upon the demand of the Office.

(3) Should a change in facts relevant for the exemptions from the expertise fees occur, the payer shall notify the Office thereof no later than 15 days after the date on which this change has occurred.

Section 3e

Expertise Fees Rates

(1) The application fees rates shall be, in the case of an application for a licence under

a) section 3c para 1 a) not more than CZK 30 000 000,

b) section 3c para 1 b) not more than CZK 150 000 000,

c) section 3c para 1 c) not more than CZK 60 000 000,

d) section 3c para 1 d) not more than CZK 60 000 000.

(2) The maintenance fees rates shall be not more than CZK 4 000 000 per each calendar month to which expertise fees liability applies.

(3) The Government shall issue a Decree stipulating expertise fees rates for individual activities of the Office under section 3c.

Section 3f

Maintenance Fee Liability

(1) The maintenance fees liability arises as of the first day of the calendar month in which the decision on issuing the licence comes into legal effect.

(2) The maintenance fees liability terminates on the last day of the calendar month in which the decision on issuing the licence has terminated.

Section 3g

Administration and Budgetary Determination of Expertise Fees

(1) The application fee is payable within 30 days of the day of submitting the application for a licence.

(2) The maintenance fee is payable within 30 days of the expiry of the charging period, which is a calendar year.

- (3) The Office shall be the administrator of the expertise fees.
- (4) The expertise fees shall be the revenue of the State budget.

CHAPTER TWO

GENERAL CONDITIONS FOR PERFORMANCE OF PRACTICES RELATED TO NUCLEAR ENERGY UTILISATION, RADIATION ACTIVITIES AND INTERVENTIONS TO REDUCE EXPOSURE

Section 4

(1) Nuclear energy and nuclear items may be utilised in accordance with international commitments of the Czech Republic²⁾ solely for peaceful purposes.

(2) Whoever utilises nuclear energy or performs radiation activities or interventions to reduce natural exposure or exposure due to radiation incidents must ensure that his or her action is justified by the benefits outweighing the risks arising or liable to arise from these activities.

(3) Whoever performs practices related to nuclear energy utilisation or radiation practices shall proceed in such a manner that nuclear safety and radiation protection are ensured as a matter of priority.

(4) Whoever utilises nuclear energy or performs radiation activities, prepares or performs interventions to reduce emergency, lasting or natural exposure must maintain a level of nuclear safety, radiation protection, physical protection and emergency preparedness such that the risk to human life health and to the environment shall be kept as low as reasonably achievable, economic and social factors being taken into account. Implementing regulation shall establish the technical and organisational requirements and guidance levels of exposure, which are considered to be sufficient to demonstrate a reasonably achievable level or an alternative procedure to demonstrate this level.

(5) Intervention aimed at averting or reducing an exposure shall always be performed if the exposure

²⁾ Decree No. 61/1974 Coll. of the Foreign Minister, On the Non-Proliferation Treaty.

Decree of the Foreign Minister No. 62/1974 Coll., On the Treaty on Prohibition of Siting of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and the Ocean Floor and the Subsoil thereof.

- a) approaches or without the intervention could approach levels at which acute damage to health is caused, or
- b) exceeds or without the intervention could exceed guidance levels set out in the implementing legal regulation and if expected reduction in health detriment due to intervention is sufficient to justify harm and costs related to the intervention. Implementing legal regulation shall establish guidance levels and details on rules for preparation and undertaking of intervention.

(6) Whoever performs radiation activities shall reduce exposure of persons so that the total exposure caused by a possible combination of exposure from all radiation activities does not exceed as a total the specified exposure limits. The Office shall establish the exposure limits in an implementing legal regulation. The Office is authorised to establish dose constraint as upper limits for optimisation of radiation protection and in its approval to establish lower limits, specific for a given activity (hereinafter "authorised limits").

(7) The following shall not be subject to the exposure limits

- a) medical exposure; the implementing legal regulation shall establish diagnostic reference levels for medical exposure;
- b) exposure from natural sources, with the exception of the exposure to those natural sources that are utilised intentionally and consciously and, with the exception of the cases specified in an implementing legal regulation, where exposure to such sources is significantly increased;
- c) emergency exposure of intervening individuals; the exposure shall not exceed ten times the limits laid down for exposed workers, unless it is a matter of saving human lives or preventing the development of radiological emergency, potentially causing extensive social and economic consequences. Intervening persons shall be demonstrably informed about the risks relating to such intervention and shall participate in the intervention on voluntary basis only;
- d) emergency exposure.

(8) Any person performing or providing for practices related to nuclear energy utilisation or radiation practices, with the exception to practices as in Section 2 a) items 5 and 6, must have implemented a quality assurance system to the extent and in the manner set out in an implementing regulation, aimed at achieving the required quality of a relevant item, including tangible or intangible products, processes or organisational arrangements, with respect to the importance of this item from the aspect of nuclear safety and radiation protection. The implementing regulation shall establish basic requirements for quality assurance of classified equipment with respect to their safety classification.

(9) For the purpose of physical protection, nuclear installations or their parts shall be placed in category I, II or III. From the aspect of physical protection assurance, guarded, protected and internal areas in nuclear installations must be specified. The classification and the specification are to be carried out from the aspect of the relevance of possible effects on nuclear safety in the event of unauthorised activities. Details concerning the classification and specification, together with the manner and scope of physical protection shall be laid down in an implementing regulation.

(10) For the purpose of physical protection, nuclear materials shall be placed in category I, II or III. Classification of nuclear materials is performed in terms of its type, weight, enrichment and with regard to the consequences of its misuse. Details concerning the classification of nuclear materials into appropriate categories, together with the manner and scope of physical protection, shall be laid down in an implementing regulation.

(11) At workplaces where radiation practices are performed, supervised and control areas shall be delineated. Activities performed in such areas shall be, from the radiation protection viewpoint, subject to permanent surveillance, recording and regulation. Signs indicating supervised and control areas, details for their delineation, details of manners and scope of radiation protection during activities performed there, details for the restriction of access into them and details for reporting of supervised areas and approval of controlled areas shall be laid down in an implementing legal regulation.

(12) Depending on the size of risk to health and the environment caused by ionising radiation, ionising radiation sources shall be classified as insignificant, minor, simple, significant and very significant ones and workplaces where radiation practices are performed, shall be placed into categories I, II, III or IV and exposed workers shall be placed into categories A or B (hereinafter "A category workers" and "B category workers"). Details for classification of ionising radiation sources, including exemption levels, categorisation of exposed workers and classification of workplaces shall be laid down in an implementing legal regulation.

(13) Each A category worker issued with a personal radiation passport shall be obliged to protect it against loss, theft, destroying and misappropriation, and upon a request to present it to the Office or a respective licensee.

(14) Whoever has found a source of ionising radiation or nuclear materials or has such a suspicion shall report without any delay such a finding to the Police of the Czech Republic or to the Office.

(15) Whoever that has determined a loss or a theft of and damage to ionising radiation source, nuclear material or any package thereof shall be obliged to report without any delay such event to the Police of the Czech Republic or to the Office.

(16) Whoever handles the selected items, manufactures package assemblies for exposed or spent nuclear fuel or performs construction of hot chambers or performs research and development activities relating to the nuclear fuel cycle shall report the beginning and scope of such activities to the Office. The scope and the method of such reporting shall be laid down in an implementing legal regulation.

(17) Whoever mines or processes uranium or thorium ores on the Czech Republic's territory shall keep and submit to the Office a record thereon. The details on keeping and submitting of the records and sample forms shall be laid down in an implementing legal regulation.

Section 4a

Technical safety of classified equipment

(1) Whoever produces classified equipment specifically designed for a nuclear installation shall ensure a conformity assessment of such equipment in the manner and in the scope as defined in an implementing legal regulation; the implementing legal regulation shall define the method of specifying such equipment and the associated technical requirements.

(2) The obligations referred to in para 1 apply to the importers of classified equipment specifically designed for nuclear installations, except when the classified equipment in the state where it was produced conforms to

- a) the technical regulations for nuclear installations, which are binding for the production of such equipment,
- b) the technical standards or rules for good practice intended for nuclear installations, issued by the national standardisation body or any entity at the same level,
- c) the international technical standards for nuclear installations lawfully used in that state, or
- d) the production methods used in compliance with their legal regulations for nuclear installations for which there is available a sufficiently detailed technical documentation ensuring that such equipment may be assessed for the given purpose of use if necessary also on the basis of complementary equipment testing, provided the said technical regulations, technical standards, rules for good practice or procedures guarantee such a level of protection of the legitimate interest corresponding to the level of this protection in the Czech Republic.

Section 4b

Conformity assessment

(1) Classified equipment specifically designed for a nuclear installation may be used in the nuclear energy sector after they have been assessed by a legal person who shall be authorised for this purpose in the manner according to the special legal regulation^{2a)} (hereinafter ",authorised person"). Authorised person shall assess conformity of such equipment to the technical requirements using the procedures provided for in an implementing legal regulation.

(2) Costs in connection with the activity of an authorised person in assessing conformity are borne by those requesting this activity.

(3) If the activities in assessing conformity of classified equipment to the technical requirements are not provided by an authorised person, the Office shall ensure the accomplishment of the person's tasks.

Section 5

(1) International transfers of nuclear items into states not owning nuclear weapons and into states owning nuclear weapons but which are not parties to the Non-Proliferation Treaty that would be in breach of commitment of the Czech Republic under international agreements²⁾ is prohibited.

(2) Carrying out of any nuclear weapon test explosion or any other nuclear explosion, encouraging or participating in carrying out of any nuclear weapon test explosion or other nuclear explosion is prohibited.

(3) An import of radioactive waste into the territory of the Czech Republic, with the exception of the re-import of ionising radiation sources produced in the Czech Republic or radioactive waste originated from materials exported from the Czech Republic for the purpose of their processing or reprocessing having been approved by the Office, is prohibited.

(4) It is prohibited for persons other than persons authorised so to do under Sections 26 and 48 para 1 to dispose of radioactive waste on the territory of the Czech Republic.

(5) It is prohibited to add radioactive substances into foodstuffs, toys, jewellery or cosmetic products, as well as to import or export products treated in this manner.

(6) It is prohibited to transport radioactive waste to

a) a destination south of latitude 60° south;

- b) a state party to the Forth ACP-EEC Convention which is not a member state of the European Union unless the transport is a re-export of ionising radiation sources manufactured in such a state or of radioactive waste from materials exported from such a state in order to process or reprocess them in the Czech Republic;
- c) a state which, in the option of the competent authority of the country of radioactive waste origin, does not have special legal or, according to accessible information, technical or administrative resources to manage the radioactive waste safely.

Section 6

Exposure to natural sources

(1) If natural radionuclides are used knowingly and intentionally owing to their radioactive, fissile or fertile properties, their handling shall be subject to the provisions of this act in the same scope as a handling of artificial ionising radiation sources. Mining, treatment and processing of radioactive minerals³⁾ shall be considered the radiation practices.

(2) An implementing legal regulation shall define workplaces where exposure of workers to natural ionising radiation sources or exposure of individuals living within the vicinity of such a defined workplace may increase significantly.

(3) At workplaces specified by an implementing legal regulation referred to in para 2, legal or natural person being in possession of a real estate in which such workplace is situated or owners of such workplace shall be obliged

- a) to inform workers concerned about a potential increase in exposure due to natural ionising radiation sources and about the health risks associated therewith and about an excess of guidance levels and about remedies carried out;
- b) to assure measurements allowing to determine annual effective dose to the persons specified in an implementing legal regulation, and record and regularly submit to the Office data, in the scope and the form specified in an implementing legal regulation;

³⁾ Act No. 61/1988 Coll., On Mining, Explosive Substances and the State Mining Authority, as amended. Act No 44/1988 Coll., On Protection and Use of Mineral Resources (the Mining Act), as amended.

- c) to permit release of natural radionuclides into the environment only in the scope not exceeding clearance levels laid down in an implementing legal regulation or in the scope and under the terms specified in a licence issued by the Office under Section 9 para 1 h);
- d) to take remedial actions aimed at reducing exposure in those cases when guidance levels laid down in an implementing legal regulation are exceeded and when an expected reduction of health detriment due to such remedy is sufficient to substantiate damage and related costs;
- e) to report to the Office the cases where the exposure of workers due to natural ionising radiation sources may exceed three tenths of any exposure limits for exposed workers; and the same scope of requirements as for A category workers, including preventive healthcare and personal monitoring, is applied to such workers concerned.

(4) Whoever proposes siting of construction with living or accommodation rooms^{3a)} or applies for a construction permit for such a construction, shall ensure the determination of radon-related index of the site and submit the results to the construction office. Whoever notifies of or applies for a permit to perform refurbishment work for change in the use of any part of the building, which shall newly contain dwelling or residential rooms, or notifies of change in the use of the building, which shall newly contain dwelling or residential rooms, shall ensure the measurement of radon concentration and present the results to the construction office or to the authorised inspector. If such construction is placed on or constructed a site with a radon-related index higher than low, the construction shall be protected preventively against radon penetration from the subsoil. Determination of radon-related index of a site need not be performed on condition that the construction will have such a location in a terrain that all its circumferential structures are separated from the subsoil with an air layer allowing free circulation of air. An implementing legal regulation shall establish criteria for determination of radon-related index of a site.

(5) For constructions with living or accommodation rooms where level of exposure to natural radionuclides in the inside atmosphere exceeds the guidance levels specified in an implementing legal regulation and the exposure may be reduced by remedial actions resulting in such reduction in health detriment which is sufficient to substantiate damage and costs associated therewith, the owner of the building shall seek the reduction to a level reasonably achievable, taking into account the given economic and social circumstances. Provided the exposure level exceeds maximum permitted levels specified in an implementing legal regulation the construction office shall, due to serious health risks and pertinently in public interest, that necessary adjustments be performed in the building. Any exceeding of guidance or maximum permitted levels and remedies performed shall be reported by the owner to the tenant.

(6) Manufacturers and importers of building materials, manufacturers and importers of bottled water and suppliers of drinking water for general public shall provide for systematic measurements and evaluation of natural radionuclides concentration, and in the scope specified by an implementing legal regulation shall record and file the results and report them to the Office. Neither building materials, nor bottled water, with the exception of water designated as a natural healing source^{3b}, shall be put into circulation, nor drinking water shall be supplied if

1. the natural radionuclides concentration exceeds maximum permitted levels laid down by an implementing legal regulation, or

^{3a)} Decree No. 268/2009 Coll., On Technical Requirements for Construction.

^{3b)} Act No. 164/2001 Coll., On Natural Healing Sources, Natural Mineral Water Sources, Natural Health Spas and Places and on Amendment to Some Related Acts.

2. the natural radionuclides concentration exceeds guidance levels laid down in an implementing legal regulation, with exception of cases when costs of remedial actions aimed at reduction of radionuclides concentration were provably higher than risks of health detriment.

Section 6a

Lasting Exposure

Owner of a real estate where source of lasting exposure has been identified is responsible for preparation and undertaking of intervention. Provided identified lasting exposure exceeds established guidance levels the owner of such real estate shall promptly report the identified situation to the Office and inform persons using this estate, fence the area concerned and ensure appropriate regulation of access to the area and in the buildings including their uses.

Section 7

Medical exposure

(1) The medical exposure may be applied only if justified by a benefit ballancing a detriment that the exposure causes or might cause.

(3) Conditions of medical exposure and rules for exposure of individuals knowingly and voluntarily helping to individuals subject to medical exposure, including their provable instructing and written approval of such individuals shall be established in an implementing legal regulation.

Section 8

Discharge of Radionuclides into the Environment

(1) Provided the clearance levels laid down in an implementing legal regulation or in a decision of the Office are not exceeded then radioactive wastes, radioactive substances, objects or equipment containing radionuclides or contaminated by them may be discharged into the environment without a prior approval of the Office; they are not subsequently monitored from the viewpoint of radiation protection and they are treated as if they were not radioactive. In case the content or the contamination by radionuclides exceed the clearance

levels, the radioactive wastes and other substances, objects or equipment containing radionuclides or contaminated by them may be discharged into the environment only based on an approval of the Office under Section 9 para 1 h).

(2) Provided an approval to discharge substances into the environment is issued by a ministry or other administrative body under specific regulations⁵⁾, and the content of radionuclides is one of the aspects under consideration for issue of the approval, an approval of the Office is an obligatory basis for issue of such ministerial approval.

CHAPTER THREE

CONDITIONS FOR NUCLEAR ENERGY AND IONISING RADIATION UTILISATION

Section 9

Licences for Particular Practices

(1) A licence issued by the Office is required for

- a) siting of a nuclear installation or radioactive waste repository,
- b) construction of a nuclear installation or category IV workplace,
- c) particular stages, laid down in an implementing legal regulation, of nuclear installation commissioning,
- d) operation of a nuclear installation or category III or IV workplace,
- e) restart of a nuclear reactor to criticality following a fuel reload,
- f) reconstruction or other changes affecting nuclear safety, radiation protection, physical protection and emergency preparedness of a nuclear installation or category III or IV workplace,
- g) particular stages of decommissioning of a nuclear installation or category III or IV workplace to the extent and in the manner established in an implementing legal regulation;
- h) discharge of radionuclides into the environment to the extent and in the manner established in an implementing legal regulation;
- i) ionising radiation sources management to the extent and in the manner established in an implementing regulation;
- j) radioactive waste management to the extent and in the manner established in an implementing legal regulation;
- k) import or export of nuclear items or transit of nuclear materials and selected items;

⁵⁾ E.g. Act No. 138/1973 Coll., On water, as amended, Act No. 309/1991Coll., On air protection, as amended.

l) nuclear materials management;

- m) transport of nuclear materials and radioactive substances laid down in an implementing legal regulation; this licence does not relate to the person performing the transport, or to the carrier, unless he is simultaneously the shipper, or consignor or consignee;
- n) professional training of selected personnel (Section 18 para 5);
- o) re-import of radioactive waste originated in the processing of materials exported from the Czech Republic;
- p) international transport of radioactive wastes to the extent and in the manner established in an implementing regulation;
- r) performance of personal dosimetry and other services significant from the viewpoint of radiation protection to the extent and in the manner established in an implementing regulation;
- s) adding of radioactive substances into consumer products during their manufacturing or preparation or import or export of such products.

(2) Licences issued by the Office under para (1) do not substitute licences or authorisations issued by other administrative bodies under specific regulations⁶.

(3) The activities referred to in para 1, except for activities according to para 1 i), n) and r), are not services according to the Act on Free Movement of Services. A licence under para 1 is required also for the activities carried out by persons whose registered office or residence is located on the territory of another EU Member State and who hold a licence to carry out such activities in that state.

Section 10

(1) A licence shall be issued on condition that

- a) the natural person to whom the licence is to be issued, and his responsible representative, if any, are competent to perform legal acts, are persons of probity and are professionally competent; the requirement for the applicant to be professionally competent is waived if it is met by his responsible representative;
- b) persons who are in position of a statutory body or are member of a statutory body of a legal person to whom a licence is to be issued, are competent to perform legal acts, are persons of probity, and at least one of members of the statutory body must be professionally competent.

(2) The evidence that the applicant has designated a physical person performing systematic surveillance over the fulfilment of radiation protection requirements and meeting requirements on special professional competence under Section 18 para 2 b) and according to the extent and in the manner of ionising radiation sources management (hereinafter "the supervising person") or that the applicant possesses such a special professional competence himself shall be the precondition to issue the licence under Section 9 para 1 i).

⁶⁾ E.g. Act No. 455/1991 Coll., On Trade Enterprises (the Trade Act), as amended, Act No. 222/1994 Coll., On Conditions for Enterprise and the Performance of State Administration in Power Generation Industries and on State Inspection for Power Generation, Act No. 50/1976 Coll., On Land Planning and Construction Regulations (the Construction Act), as amended, Act No. 21/1997 Coll., On Control of Importation and Exportation of Goods and Technologies Subject to International Control Regimes, Act No. 44/1988 Coll., On Protection and Use of Mineral Resources (the Mining Act), as amended, Act of the Czech National Council No. 61/1988 Coll., as amended.

(3) A person to whom a licence has been issued (hereinafter ,,the licensee") shall communicate to the Office without delay any change that may occur in facts specified in para 1 or 2.

(4) Performance of practices under Section 9 para 1 or their stages shall not commence before the licence issued by the Office enters into legal force.

Section 11

Probity

(1) For the purposes of this Act, a person is considered to be of probity if he has not been legally sentenced for a criminal offence involving negligence, where this offence is associated with licensed activities, or for a criminal offence committed with intent.

(2) For the purpose of demonstrating the probity, the Office shall request the excerpt from the Criminal Record according to the special legal regulation^{6a)}. The requests for issue of the excerpt from the Criminal Record and the excerpt from the Criminal Record shall be handed over electronically and in the manner allowing remote access.

Section 12

Professional Competence

(1) Under Section 10 para 1 the professional competence means

- a) for activities related to nuclear energy utilisation a duly completed university degree in the respective field of specialisation and three years of on-job experience in the field;
- b) for radiation activities related to a medical radiodiagnostic which is part of the health care provided by the dentists a basic qualification required for performing the profession of the dentist by the Act concerning the conditions for receiving and recognition of basic qualification and specialist qualification for performing the medical profession of physician, dentist and pharmacist;
- c) for other radiation activities a duly completed university degree in the respective field of specialisation and three years on-job experience in the field, or graduate from a relevant secondary technical school having GCE and six years of on-job experience in the field.

(2) In recognising professional qualification obtained in another EU Member State to carry out the activities referred to in para 1 a) and c), the Office shall follow the Act on

^{6a)} Act No. 269/1994 Coll., On Criminal Record.

Recognition of Professional Qualification^{6a)}. The Office's decision on the recognition of professional qualification serves as a document demonstrating professional competence pursuant to this Act.

Section 13

Licence Application

- (1) A licence application shall contain
- a) for a natural person its name, or names, and surname, birth registration number, if assigned, address of permanent residence or domicile; or name, or names, and surname, birth registration number, if assigned, and address of permanent residence or domicile of his/her responsible representative, if one is appointed; for a legal person its name and legal form, registered office or address of organizational unit in the Czech republic, if established, registration number in the Companies Register, if assigned; name and surname, address of permanent residence or domicile of the person or persons who constitute its statutory body (hereinafter "identification") and the registration number if already assigned by the Office;
- b) the subject and scope of practice for which the licence is requested, the location where the practice is to be performed and the manner in which it will be carried out, the period of its existence and the manner of its termination.

(2) A licence application shall be signed by the applying natural person or by the statutory body of the applying legal person or by another representative of the statutory body, authorised in a Power of Attorney.

(3) The following documents shall be attached to a licence application

a) Certificate of Incorporation in the case of legal person entering on the Companies Register,

- b) a document proving professional competence of a natural person for the performance of the practice being licensed, or a document proving professional competence of a responsible representative, if appointed, in the event that a natural person submits the application, or a document proving professional competence for the performance of the practice being licensed of at least one of the members of the statutory body or authorised agent in the event that a legal person submits the application; provided a supervising person is appointed his/her approval with the appointment and a document proving his/her special professional competence;
- c) the documentation required for the particular practices being licensed. The content of this documentation is listed in an Appendix to this Act. The scope and form of the documentation to be approved by the Office concerning the activities subject to licence, shall be laid down in an implementing regulations;

^{6a)} Act No. 18/2004 Coll., On the recognition of professional qualifications and other competencies of nationals of Member States of the European Union and on the amendment of some Acts (Act on recognition of professional qualifications), as amended.

- d) a certificate of land ownership in the case of application for a nuclear installation construction licence and a written consent of the real estate owner with a workplace of category III or IV establishment, provided such a workplace is to be established;
- e) an insurance certificate covering nuclear damage liability insurance or a certificate of other financial security as in Section 36;
- f) in the event that radioactive waste is to be generated as a part of activities being licensed, a document demonstrating safe management of radioactive waste, including associated funding of this management;
- g) in the event of a transit of nuclear materials or radioactive substances a document demonstrating that they will be taken back if the transit is not completed.

(4) An environmental impact assessment, if laid down in a special Act⁷, is a prerequisite for the issue of a licence under Section 9 para 1 a), b) and g). An environmental impact assessment under the special Act⁷, is a prerequisite for a licence issue under Section 9 para 1 f) in case a reconstruction or other change influencing nuclear safety, radiation protection, physical protection or emergency preparedness of nuclear installation or category III or IV workplaces is connected with an increase of authorised limits for discharges established by the Office under Section 4 para 6.

(5) An approval issued by the Office of a quality assurance programme for the practice being licensed is a prerequisite for the issue of a licence under Section 9 para 1 a) to g) and i), j), l), n) and r). An approval of a quality assurance programme for the design phase in advance of the commencement of design activities affecting nuclear safety or radiation protection and an approval of the quality assurance programme for construction activities are a prerequisite for a licence granted under Section 9 para 1 b). Requirements for the content of quality assurance programme and quality system shall be laid down in an implementing regulation.

(6) An approval issued by the Office of the method used to ensure physical protection of nuclear installations and nuclear materials is a prerequisite to the issue of a licence under Section 9 para 1 c), d), e), f), g), k), l), and m). Requirements for the method used to ensure physical protection shall be laid down in an implementing regulation.

(7) An approval issued by the Office of the on-site emergency plan or emergency rules is a prerequisite to the issue of a licence under Section 9 para 1 c), d), e), f), g), i), j), m) and o). Requirements for their content, including details on how to ensure emergency preparedness, shall be laid down in an implementing regulation.

(8) The Office may require supplementary documentation. The documents under para 3 a) and b) do not need to be submitted if the applicant has received a registration number under a previous licensing procedure and there have been no changes to the information provided in the documentation. In such case the applicant shall provide an affidavit only, stating that no changes have occurred in documents required under para 3 a) and b).

Section 14

(1) In administrative proceedings, the Office shall conduct independently of the proceedings of any other administrative body. The applicant shall be the only participant in the proceedings.

⁷⁾ Act No. 100/2001 Coll., On Environmental Impact Assessment, and on Alteration of Some Related Acts.

(2) The Office shall take a decision on the issue of a licence having verified that the applicant has fulfilled all the conditions established in this Act and in implementing regulations.

(3) From commencement of licence proceedings for a particular practice, the Office shall take a decision within the following time period

- a) four months, in the case of a licence for siting of a nuclear installation or very significant ionising radiation source;
- b) one year, in the case of a licence for construction of a nuclear installation or very significant ionising radiation source;
- c) six months, in the case of a licence for the first fuel load into a reactor, under Section 9 para 1 c), and 10 days in the case of other stages of commissioning;
- d) 24 hours, in the case of a licence under Section 9 para 1 e); the procedure for submission and assessment of required documentation shall be laid down in an implementing regulation;
- e) 90 days, in the case of other licences for particular practices.

(4) A licence represents at the same time an approval as required by a specific Act^{8} .

(5) A licence for the activities referred to in Section 9 para 1 i), n) and r) shall also arise by the expiry of the time period and in the manner according to Sections 28 to 30 of the Act on Free Movement of Services.

Section 15

Requisites of Licence

(1) In decision on the issue of a licence, the Office

- a) shall specify identification of the applicant and the assigned registration number;
- b) shall define the subject and scope of the practice being licensed;
- c) shall set conditions for performance and termination of the practice being licensed, as required from the aspect of nuclear safety, radiation protection and physical protection and, subject to discussion with the relevant Regional Authority and relevant Municipal Authorities of Municipalities with extended competence, conditions for emergency preparedness;
- d) shall specify the period for which the licence is issued; the Office shall issue a licence under Section 9 para 1 b), e), f), h), i), n), r) and s) for an indefinite period of time.

(2) An integral part of the licence Statement shall be an approval of documentation, if this is required in the Appendix to this Act. A single decision may cover several repeated or interrelated activities.

Section 16

⁸⁾ E.g. Act No. 50/1976 Coll., as amended.

Alteration, Cancellation and Cessation of Licence

(1) Without a previous licence provided by the Office, no installation modifications nor other technical or organisational changes with an impact on nuclear safety, radiation protection, physical protection or emergency preparedness may be performed. Changes influencing the off-site emergency plan may only be performed subject to an agreement with the relevant Regional Authority and relevant Municipal Authorities of Municipalities with extended competence,.

(2) A licence is not required to take urgent interventions aimed at averting a radiation incident or dealing with its consequences. Such intervention shall be taken without delay and shall be demonstrably communicated to the Office.

(3) The Office may modify conditions set out in the licence in the event of a change in the circumstances impacting on nuclear safety, radiation protection, physical protection or emergency preparedness under which the licence is issued, or as a response to an application by the licensee. The conditions of a licence impacting on off-site emergency plan may be established and altered only subject to agreement with the relevant Regional Authority and relevant Municipal Authorities of Municipalities with extended competence.

(4) In the event of a licensee violating his obligations as established in this Act or by other regulations or conditions laid down in the licence issued by the Office, the Office may restrict or suspend performance of the licensed practice.

(5) The Office shall withdraw the licence if the licensee

- a) ceases to fulfil the obligations on which the issue of licence is based or does not fulfil his obligations as established in this Act or does not remove, within a specified period, deficiencies identified by the Office;
- b) applies in writing for a withdrawal, and proves that he has ensured nuclear safety and radiation protection.
 - (6) A licence shall become extinct
- a) in the case of natural persons, in the event that the person dies or is declared to be dead;
- b) on the date a legal person which is a licensee ceases to exist;
- c) on expiry of the period for which it was issued in case of the licence under Section 9 para 1
 a), c), d), g), j) to m), o) and p);
- d) by decision of the Office to cancel the licence.

(7) Before a licence become extinct, the licensee shall, with the approval of the Office, provide on a contractual basis a legal successor or ensure safe termination of activities related to nuclear energy utilisation or radiation activities.

Section 17

General Obligations of Licensees

(1) A licensee under Section 9 para 1 shall, besides other obligations established in law

- a) ensure nuclear safety, and the responsibility for nuclear safety of a nuclear installation cannot be delegated to another person, radiation protection, physical protection and emergency preparedness, including its verification, in the scope appropriate to the particular licences;
- b) assess in a systematic and comprehensive manner the fulfilment of conditions set in Section 4, from the aspect of the current level of science and technology, and ensure that the assessment results are put into practice;
- c) comply with the conditions of the licence issued by the Office, proceed in accordance with approved documentation and investigate, without delay, any breach of such conditions or procedures and take remedial measures and measures to prevent repetition of such situations. Any case when exposure limits or limits for safe operation of a nuclear installation have been exceeded or violated shall be reported to the Office without delay;
- d) comply with technical and organisational conditions for safe operation of nuclear installations, ionising radiation sources and workplaces with ionising radiation source as laid down in an implementing regulations, comply with the approved quality assurance programme and adhere to specific requirements for uniformity and correctness of measurements and measuring devices to the extent laid down in an implementing regulation;
- e) provide co-operation as required for performance of inspection activities by the Office under Section 39 and provide co-operation for persons called upon by the Office in order to assess expert issues related to the performance of an inspection;
- f) participate in the operation of the National Radiation Monitoring Network to the extent established in government order under Section 19 para 3;
- g) introduce into circulation only ionising radiation sources that bear the specified labels and are accompanied by appropriate documentation and are in type-approved transport packaging;
- h) allow authorised persons only to handle nuclear materials, radioactive waste and ionising radiation sources and to handle them in accordance with this Act;
- i) entrust performance of the specified activities only to such persons who fulfill conditions of special professional competence and are physically and mentally sound, and entrust performance of the sensitive activity under Section 2a only to such persons who is eligible in terms of security in accordance with a specific legal regulation^{1c};
- j) report to the Office without delay any change or event impacting on nuclear safety, radiation protection, physical protection, nuclear materials management or emergency preparedness, and changes in any circumstances on which issue of the licence was based;
- k) provide the public with information on maintenance of nuclear safety and radiation protection which is not subject to State, professional or commercial secrecy;
- 1) inform without any delay the Office about an initiation of the insolvency proceedings;
- m) ensure technical safety of the operated classified equipment in accordance with an implementing legal regulation.
 - (2) A licensee shall submit to the Office for approval
- a) documentation mentioned in the Appendix to this Act and quality assurance programmes as in Section 4 para 7;
- b) commissioning and decommissioning programmes and non-standard programmes or tests affecting nuclear safety as specified in the licence;

- c) transport, storage, loading and reloading of nuclear fuel and related activities programmes as specified in the licence;
- d) a list of important working activities impacting on nuclear safety, competence requirements, professional training and method of its verification;
- e) assignment of nuclear installations and nuclear materials to categories appropriate from the aspect of physical protection;
- f) the on-site emergency plan and the emergency rules;
- g) changes to the documentation specified in a) to f) above.

(3) A licensee shall submit to the Office a proposal for designation of an emergency planning zone and for delineation of a controlled area.

Section 18

Obligations from the Aspect of Nuclear Safety, Radiation Protection, Physical Protection and Emergency Preparedness

(1) A licensee shall also

- a) monitor, measure, evaluate, verify and record values, parameters and facts impacting on nuclear safety, radiation protection, physical protection and emergency preparedness, to the extent laid down in an implementing regulations;
- b) account for and control of nuclear materials, archive associated records and report to the Office, as laid down in an implementing regulation, results of physical inventory taking and material balance of nuclear materials and any changes in nuclear materials inventory;
- c) keep and archive records of ionising radiation sources, facilities, materials, activities, quantities and parameters and other facts impacting on nuclear safety, radiation protection, physical protection and emergency preparedness, and submit the recorded information to the Office in the manner set out in an implementing regulation;
- d) keep production of radioactive waste and spent nuclear fuel to the minimum necessary level;
- e) prepare and submit to the legal person authorised to dispose of radioactive waste under Section 26 data on short-term and long-term production of radioactive waste and spent nuclear fuel together with other background information to determine the amount and method of transfer of payments to the nuclear account;
- f) keep records of radioactive waste by type of waste in such a manner that all characteristics affecting its safe management are apparent;
- g) allow access and provide necessary co-operation for performance of inspection activities to International Atomic Energy Agency inspectors, as in Section 39 para 5, and to persons called upon by the Office to assess expert aspects of inspected activities;
- h) in case an estimate of total costs of decommissioning verified by the Radioactive Waste Repository Authority (hereinafter "the Authority") exceeds 300 000 CZK, steadily make provision¹⁰ for decommissioning of nuclear installation or category III or IV workplace, so that financial resources deposited on a blocked account will be available for preparation and performing of decommissioning, at the required time and in the required

¹⁰⁾ Act No. 593/1992 Coll., On Reserves for Calculation of the Income Tax Base, as amended.

amount, in line with the programme of decommissioning approved by the Office. Provided the estimate of total costs exceeds 1 billion CZK the licensee shall deposit financial means at the amount of this provision on a blocked account with a bank in the Czech Republic. Yields from means on the blocked account shall be income to this blocked account. The provision shall be expenditure for generating, ensuring and maintaining revenues. Details for making provision shall be established in an implementing regulation. Financial means on the blocked account may be utilised solely for the preparation and an implementation of decommissioning and any drawing on such funds shall be approved by the Authority. The obligation to make provision for the decommissioning shall not apply to organisational units of the state¹¹, and state-subsidised organisation^{11a}, public universities^{11b} and organisational bodies and subsidised organisations established by territorial self-governing units^{11c};

- i) ensure systematic supervision of observance of nuclear safety, radiation protection, physical protection and emergency preparedness, including verification of emergency preparedness;
- j) ensure medical examination prior to employment or classification as category A workers and at least once a year periodic reviews of health and in cases where, according to the Office evaluation exposure limits have been exceeded to ensure extraordinary and subsequent reviews of health^{11d)} and for the employees performing activities with direct impact on nuclear safety assure verification of their mental competence. The costs of the medical examinations shall be paid by the employer unless a specific regulation shall set out otherwise. The licensee shall also on regular basis inform provider of occupational health services providing medical surveillance of exposed workers about personal doses of the workers;
- k) ensure conditions for pregnant and breastfeeding women working within a controlled area such that a foetus or a breastfed infant receives the same level of radiation protection as any member of the public;
- verify security eligibility in a manner laid down in a specific legal regulation^{1c)} for persons performing sensitive activities under Section 2a and verify probity of personnel and persons handling category I and II nuclear materials, providing physical protection of nuclear installations and nuclear materials, having unsupervised access to internal premises of nuclear installations and ensure that only such persons perform, control and inspect the mentioned activities and have access to the internal and protected areas of a nuclear installation;
- m) verify probity of a part of personnel and persons handling category III nuclear materials or having unsupervised access to guarded and protected areas of a nuclear installation and ensure that only such persons perform the activities in question and have an access to guarded and protected areas of a nuclear installation;
- n) suspend the validity of an approval to handle nuclear materials or enter nuclear installations for an employee, in a case where and at the moment when a licensee learns that legal proceedings have commenced with such an employee for a criminal offence perpetrated

¹¹⁾ Section 3 of Act No. 219/2000 Coll., On the State Property of Czech Republic and its Behavior in Legal Relations.

^{11a)} Act No. 218/2000 Coll. On Budgetary Rules and Alteration of Some Related Acts (Budgetary Rules), as amended.

^{11b)} Act No. 111/1998 Coll., On Universities and Amendment to and Alteration of Some Related Acts (Universities Act), as amended.

^{11c)} Act No. 250/2000 Coll., On Budgetary Regulations for Regional Budgets, as amended by Act No. 320/2001 Coll.

^{11d)} Section 84 para 1 v) of Act No. 258/2000 Coll., On Public Health Protection and on Alteration of Some Related Acts, as amended.

through negligence, where the offence is related to activity performed, or for a criminal offence committed with intent;

- o) provide a system of training and verification of competence of personnel in accordance with the importance of the work they perform;
- p) present to the Office and to the European Commission data required by this Act and by the EC legislation; the scope of data, the form and the manner of the presentation shall be set out in an implementing legal regulation;
- r) provide A category exposed workers working in the controlled area of another licensee with personal radiation passports issued by the Office and regularly update the data therein to the extent and in the manner laid down in an implementing regulation;
- s) provide for and maintain adequate financial and human resources required to fulfil their obligations with respect to nuclear safety of a nuclear installation.
 - (2) A special professional competence, within the meaning of this Act, means
- a) skills and expertise of natural persons, as verified by a State Examination Commission and required for activities directly affecting nuclear safety of nuclear installations. The State Examination Commission shall be established and its Chairman and members appointed by the Chairman of the Office;
- b) skills and expertise of natural persons, as verified by an Expert Examination Commission of the Office and required to perform activities especially important from the radiation protection viewpoint, set in an implementing regulation.

(3) Activities directly affecting nuclear safety may only be performed by natural persons who are physically and mentally competent, with professional competence and to whom the Office has granted an authorisation for the activities in question, subject to an application by the licensee.

(4) Only natural persons with knowledge of the principles and procedures of radiation protection, as verified by the Expert Examination Commission of the Office, and holding an authorisation to perform the working activity in question granted by the Office may perform activities especially important from the radiation protection viewpoint specified by an implementing legal regulation.

(5) Activities directly affecting nuclear safety and activities especially important from the radiation protection viewpoint, qualification and professional training requirements, the method to be used for their verification and the issue of authorisations for persons authorised to perform activities as in para 3 and 4 (hereinafter "selected personnel") shall be laid down in an implementing regulation.

(6) A licensee who operates a controlled area in which A category workers of another licensee (outside workers) perform activities shall check their personal radiation passports before beginning of the activities and shall make entries into them to the extent and in the manner laid down in an implementing legal regulation.

(7) In recognising professional qualification to carry out the activities for which special professional competence is required by this Act, the Office shall follow the Act on Recognition of Professional Qualifications^{6a)}. The Office's decision on the recognition of professional qualification serves as a certificate of special professional competence pursuant to this Act.

Obligations in case of Radiation Incident Occurrence

(1) A licensee shall, to the extent and in the manner determined by the on-site emergency plan approved by the Office

- a) in accordance with a special legal regulation^{11e)} immediately notify the relevant Municipal Authority of Municipality with extended competence, the Office and other relevant bodies specified in the on-site emergency plan of the occurrence or suspected occurrence of a radiation accident;
- b) in the event of a radiation accident, ensure that a warning is issued to the public within the emergency planning zone;
- c) ensure that the consequences of the radiation incident are dealt with in premises where his activities are performed and take steps to protect employees and other persons from the effects of ionising radiation;
- d) ensure monitoring of exposures of employees and other persons and prevent any escape of radionuclides or ionising radiation into the environment;
- e) inform relevant bodies, especially of monitoring results, factual and anticipated development of the situation, interventions taken to protect employees and the public, and interventions taken to deal with the radiation incident, and also of factual and anticipated exposure of people;
- f) control and regulate exposure of employees and persons participating in the radiation incident mitigation within the premises where he performs his activities;
- g) co-operate in dealing with the consequences of the radiation incident that occurred on his premises;
- h) in the event of a radiation accident, participate in the activities of the National Radiation Monitoring Network.

(2) A licensee for transport as in Section 9 para 1 m) shall also, to the extent and in the manner established in the emergency rules approved by the Office

- a) in accordance with a special legal regulation^{11e)} immediately inform the relevant Municipal Authority of Municipality with extended competence, the Office and other relevant bodies specified in the emergency rules of the occurrence or suspected occurrence of a radiation accident;
- b) in the event of a radiation incident, take immediate steps to protect persons involved in transport from the effects of ionising radiation;
- c) immediately inform relevant bodies of, in particular, his monitoring results, factual and anticipated development of the situation, interventions taken to protect persons involved in transport and interventions taken to deal with the radiation accident, and also of factual and anticipated exposure of people;
- d) control and participate in regulation of exposure of people involved in transport and participating in the radiation incident clean-up process;
- e) co-operate in dealing with the consequences of a radiation accident that has occurred on his equipment.

^{11e)} Section 5 of Act No. 239/2000 Coll., On the Integrated Rescue System and Amendments to Some Related Acts.

(3) A licensee shall also submit to the relevant Regional Authority and relevant Municipal Authorities of Municipalities with extended competence background documents to prepare the off-site emergency plan, co-operate with it to ensure emergency preparedness within the emergency planning zone, to the extent established in a government order concerning the emergency planning zone, and participate financially, at his own cost¹²⁾ in enabling the activities of the National Radiation Monitoring Network, providing the public in the emergency planning zone of relevant installations or workplaces with antidotes, running a press and information campaign aimed at ensuring that the public is prepared for radiation accidents, providing a system for notification of relevant bodies to the extent and in the manner established in the on-site emergency plan, and providing a warning system to inform the public living in the vicinity of the nuclear installation, and shall participate in radiation accident clean-up operations within the emergency planning zone.

Section 20

Obligations in Transport and Shipment of Nuclear Item and Radioactive Substances

(1) A licensee under Section 9 para 1 m) or a person who arrange for such a shipment of radioactive substances to be carried out specified as a sender in the shipping documents (hereinafter ,,carrier") is obliged to

- a) make sure that a consignee is authorised to handle nuclear materials or radioactive substances in accordance with this Act;
- b) ensure that the transport and shipment of nuclear materials and radioactive substances specified in an implementing regulation is performed as specified in an implementing regulation and in accordance with the requirements established in special legal regulations¹³;
- c) supply nuclear materials and radioactive substances specified in an implementing regulation solely in packaging assemblies which have been type-approved by the Office in accordance with this Act;
- d) ensure that during transport and shipment neither radionuclide escape nor exposure of people exceeds limits and guidance levels laid down in an implementing regulation, and ensure physical protection of nuclear material shipments in accordance with the implementing regulation.

(2) A carrier or a licensee under Section 9 para 1 i), j), k), l), o) or p) shall ensure that the person performing the transport presents to the Customs Office in carrying out supervision^{13a)} or carrying out inspection activities during transport of

¹²⁾ Section 24 para 2 p) of Act No. 586/1992 Coll., On Income Taxes, as amended.

¹³⁾ E.g. Act No. 111/1994 Coll., On Road Transport, Decree of the Ministry of Transport No. 187/1994 Coll., Which implements the Road Transport Act, Act No. 266/1994 Coll., On Railways, Appendix 1 to Decree of the Minister of Foreign Affairs No. 8/1985 Coll., On the Convention on International Rail Transport (COTIF), Act No. 114/1995 Coll., On Inland Navigation, Decree of the Ministry of Transport No. 17/1966 Coll., On Air Transport Rules, as amended by Decree No. 15/1971 Coll.

^{13a)} Art. 4/13 of the Council Regulation (EEC) No. 2913/92 of 12 October 1992 establishing the Community Customs Code.

- a) nuclear items, radioactive substances or radioactive waste, an authorised copy of a relevant licence issued by the Office, if required, and reports their entry to or exit from the territory of the Czech Republic to the Customs Office,
- b) radioactive substances or radioactive waste within the European Union, besides the documents referred to in a), a written declaration of the consignee of radioactive substances or radioactive waste^{13b}, acknowledged by the competent body of the consignee's state,
- c) nuclear materials, classified items and radioactive substances exported across the territory of the Czech Republic from the territory of the European Union, besides the documents referred to in a) and b), an authorised copy of a valid licence of the country to which the nuclear materials, classified items or radioactive substances are being shipped,
- d) during international transports of radioactive waste pursuant to Section 9 para 1 p), besides the documents referred to in a), b) and c), forms required by special legal regulation^{13c)}.

In the case of nuclear items, the Customs Office shall immediately communicate data referred to in such documents to the Office; in the case of radioactive substances or radioactive waste, the Customs Office shall communicate the required data to the Office in summary on a monthly basis.

(3) If radioactive substances or radioactive waste, whose consignee or consignor has registered office or residence in the Czech Republic, are imported to the territory of EU Member State or exported from the territory of EU Member State, a customs declaration shall be submitted to the Customs Office with its registered office in the Czech Republic to let them into the relevant regime^{13d)}.

(4) Should the Customs Office find any deficiency in the activity of the persons inspected according to para 2, it shall detain the transported nuclear items, radioactive substances or radioactive waste and immediately notify the Office thereof.

Section 21

Use of Insignificant and Minor Ionising Radiation Sources

(1) A licence for ionising radiation sources management under Section 9 para 1 i), is not required for the use of insignificant or type-approved minor ionising radiation sources, if used in accordance with user manuals provided for the sources which have been approved by the Office as part of their type-approval.

(2) A minor source user (hereinafter "registrant") is required to notify the Office not later than one day before commencement of this activity of the following

^{13b)} Art. 4 of the Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

^{13c)} Section 10 of the Decree No. 317/2002 Coll., On Type-Approval of Packaging Assemblies for Transport, Storage and Disposal of Nuclear Materials and Radioactive Substances, on Type-Approval of Ionizing Radiation Sources and on Transport of Nuclear Materials and Specified Radioactive Substances (On Type-Approval and Transport).

^{13d)} Art. 4 p) of the Council Regulation (EEC) No. 2913/92 of 12 October 1992 establishing the Community Customs Code.

a) the identification of the registrant;

b) the specification of the ionising radiation sources to be utilised and their quantity;

c) the facility where the sources will be located;

d) the proposed method of disposal of the ionising radiation sources;

(3) A licence for ionising radiation sources management under Section 9 para 1 i) and notification under para 2 are not required if they concern individual working operations and work with sources, within an approved or notified process of handling of ionising radiation sources.

Section 22

Obligations of the Registrant

A registrant shall

- a) use ionising radiation sources only in accordance with user manuals approved by the Office as part of their type approval under Section 23;
- b) notify the Office of any change in information provided under Section 21;
- c) check on any breach of this Act or of implementing regulations and take remedial measures;
- d) ensure safe termination of activities;
- e) maintain and keep records of ionising radiation sources and communicate the recorded information to the Office, as laid down in an implementing regulation;
- f) provide the necessary co-operation for performance of inspection activities by the Office.

Section 23

Type-Approval

(1) Packaging assemblies for transport, storage or disposal of nuclear materials and radioactive substances specified in an implementing regulation may only be used if type-approved by the Office. Ionising radiation sources specified in an implementing regulation may be placed on a market only if typeapproved by the Office. Conformity assessment of products carried out in accordance with procedures laid down in special legal regulation^{13e)} shall replace type-approval of the Office, and products assessed in this way shall be considered type-approved hereunder unless provided otherwise by a special legal regulation^{13e)}; this shall not apply to packaging assemblies for transport, storage or disposal of nuclear material and radioactive substances specified in an implementing legal regulation.

^{13e)} Sections 12 and 13 of Act No. 22/1997 Coll., On Technical Requirements for Products and Alterations and Amendments to Some Related Acts, as amended by Act No. 71/2000 Coll.

(2) The Office shall open type-approval proceedings under para 1 on application by a manufacturer or, in the case of imported equipment, on application by the importer, on the day the application is received. The Office shall make a decision in respect of a type-approval application for a packaging assembly for transport or storage of nuclear materials or radioactive substances specified in an implementing regulation within 12 months of commencement of the proceedings. In other cases within 90 days since the commencement of the application, documents to be attached to the application and the method of approval shall be laid down in an implementing regulation.

(3) In the case of products defined in an implementing regulation, documentation of tests performed at the applicant's cost at legal entities designated by the Office shall become part of the background documents required by the Office to issue a type-approval decision.

(4) A manufacturer of equipment under para 1 that is manufactured for the purposes of introduction into circulation shall manufacture such equipment in conformity with the type-approved by the Office, verify the identity of characteristics and parameters of particular products with the approved-type and demonstrate this identity, to the extent and in the manner established by the Office in the equipment typeapproval decision or in an implementing regulation.

(5) An equipment importer under para 1 shall import types approved by the Office only. The importer or a person introducing this equipment into circulation shall ensure conformity assessment of characteristics and parameters of particular products with the approved type and demonstrate this conformity, to the extent and in the manner established by the Office in the equipment type-approval decision or in an implementing regulation.

(6) Insignificant and minor ionising radiation sources and B(U)-type^{13f)} package assemblies for transport of radioactive substances approved in a similar manner in the EU Member States shall be considered type-approved hereunder.

CHAPTER FOUR

RADIOACTIVE WASTE MANAGEMENT

Section 24

(1) Any person who manages radioactive waste shall take into consideration all its physical, chemical and biological properties that might have a bearing on its safe management.

(2) An owner of radioactive waste or other natural person or legal person managing the assets of an owner in such a manner that radioactive waste is generated (hereinafter "generator") shall bear all costs associated with its management, from its time of origin to its

^{13f)} Decree No. 142/1997 Coll., On Type-Approval of Assemblies for Transport, Storage or Disposal of Radionuclide Sources and Nuclear Materials, Type-Approval of Protective Aids for Works with Ionising Radiation Sources and Other Equipment for the Work therewith (On Type–Approval).

disposal, including monitoring of radioactive waste repositories after their closure, and including the necessary research and development activities. A contractual transfer of rights to manage radioactive waste or of its ownership must be stipulated in writing.

(3) Until a generator or the Office declares spent or irradiated fuel to be radioactive waste, its management, apart from the requirements arising out of other provisions of this Act, is subject to the same requirements as apply to radioactive waste. An owner of spent or irradiated fuel shall manage it in such a way as not to encumber the potential for subsequent conditioning.

(4) Radioactive waste management shall not be subject to the Act on Waste¹⁴⁾. Details concerning radioactive waste management shall be laid down in an implementing regulation.

(5) A person who apply the Office for a licence for the activity under Section 9 para 1, during which radioactive waste shall be produced, shall register with the Authority as a future producer of radioactive waste; this person shall indicate data needed for his/her unique identification, if a legal person is concerned, also data needed for the identification of the members of the statutory body as well as data concerning the activity to be licensed and the expected type and amount of radioactive waste to be produced. Data from the registration records is retained for the period of 5 years after the termination of payments under Section 27.

Section 25

Under the terms of this Act, the State guarantees safe disposal of all radioactive waste, including monitoring and supervision of repositories after their closure.

Section 26

(1) To provide for activities associated with radioactive waste disposal, the Ministry of Industry and Trade shall set up the Authority as a state organisational unit. The Authority shall carry out relevant activities based on a licence under Section 9 para 1, of this Act. In case of the Authority ceasing to exist, its rights and obligations shall be transferred to its founder.

(2) The activities of the Authority shall be financed from an interest-bearing account opened with the Czech National Bank (hereinafter "the nuclear account"). The Ministry of Finance shall manage the nuclear account, which shall be included among the accounts of State financial assets and liabilities, the utilisation of which is decided by the Government¹⁵. Resources in the nuclear account may only be used for purposes within the provisions of this Act.

(3) The Authority shall engage in the following activities

¹⁴⁾ Act No. 238/1991 Coll., On Waste, as amended by Act No. 300/1995 Coll.

¹⁵⁾ Act No. 576/1990 Coll. On Budgetary Rules of the Czech Republic, as amended.

- a) preparation, construction, commissioning, operation and closure of radioactive waste repositories and monitoring of their impact on the environment;
- b) radioactive waste management;
- c) conditioning of spent or irradiated nuclear fuel into a form suitable for its disposal or further utilisation;
- d) keeping records of radioactive waste receipts and their generators;
- e) administration of payments under Section 27;
- f) drafting of proposals for determination of payments to the nuclear account;
- g) provision for and co-ordination of research and development in the field of radioactive waste management;
- h) monitoring of reserves of licensees for decommissioning of their installations and approval of drawing on funds in the reserves;
- i) provision of services in the field of radioactive waste management;
- j) management of radioactive waste transported to the territory of the Czech Republic from abroad when it is not possible to return it;
- k) provision of temporary administration¹⁶ in the case of radioactive waste that, under a specific Act¹⁷, has become State property; if these are items that were found, left or hidden¹⁸, the Authority is entitled also to accept them, instead of a State body determined by a specific Act¹⁹;
- 1) administration of radioactive substances seized pursuant to special Act^{19a};
- m) provision of contributions to municipalities according to Section 27.

(4) The Authority shall operate on the bases of a statute approved by the Government, a budget, and oneyear, two-year and long-term plans for its activities. The Authority shall provide for the activities referred to in para 3 a), b) and c), chiefly by selecting suppliers on the basis of an assessment of nuclear safety, radiation protection and economic benefit. The Authority shall perform activities under para 3 i) of this Act solely in connection with its other activities.

(5) The Ministry of Finance shall transfer financial resources from the nuclear account to a special account of the Authority according to the plan of activities and budget for the Authority approved by the Government.

(6) The Authority shall exercise the right to manage State property, maintaining an appropriate accounting system²⁰⁾. The Authority shall not have its own property. The Authority shall not depreciate fixed assets, and shall not create provisions or correction items.

(7) The Authority shall observe a specific Act^{21} in placing orders.

(8) The resources of the Authority shall be subject to annual clearing with the nuclear account. The Authority shall transfer income from its own activities to the nuclear account and is authorised to mediate payments to this account.

¹⁶⁾ Section 761 para 1 of Act No. 513/1991 Coll., the Commercial Code, as amended.

¹⁷⁾ E.g. Section 135 of Act No. 40/1964 Coll., the Civil Code, as amended.

¹⁸⁾ Section 135 para 1 and 3 of Act No. 40/1964 Coll., as amended.

¹⁹⁾ Section 13 of Act No. 102/1992 Coll., Amending certain matters relating to the promulgation of Act No. 509/1991 Coll., Which amends and supplements the Civil Code.

^{19a)} Act No. 279/2003 Coll., Concerning the management of seized assets to all assets seized on the basis of the Code of Criminal Procedure and on amendments of other acts.

²⁰⁾ Act No. 563/1991 Coll., On Accountancy, as amended by Act No. 117/1994 Coll.

²¹⁾ Act No. 199/1994 Coll., On Public Procurement, as amended by Act No. 148/1996 Coll.

(9) Under Section 27, the Authority statute establishes the method of financial clearing to the nuclear account and other management details, and defines which property the Authority has the right to manage at the time of its establishment.

(10) The Authority shall create a cultural and social needs fund under a specific regulation²².

Section 27

(1) The income to the nuclear account shall specifically comprise

a) payments from radioactive waste generators;

b) interest from the nuclear account;

c) revenues from operations with nuclear account resources on the financial market;

d) income received and payments mediated by the Authority;

e) subsidies, gifts, grants and other income.

(2) Generators shall allocate to their own debit¹²⁾ financial provisions to cover expenses for disposal of radioactive waste which have been arising or will arise and for associated activities of the Authority. These financial resources shall be accumulated in the nuclear account in the form of payments. Unless otherwise specified in this Act, the payments shall be administered subject to Tax code.

(3) The amount of payments shall be determined on the basis of the estimated costs of activities provided by the Authority and of the proportion of the total amount of waste attributable to the individual radioactive waste generators in respect of specific activities of the Authority three years in advance and related to the one-year plan, three-year plan and long-term plan of activity of the Authority.

(4) The contributions under para 2 and 3 shall be paid

- a) monthly in advance from the base of the payment, which is for producers operating nuclear power plants the annual electricity generation measured at generator terminals and for producers operating nuclear research reactors with heat removal greater than 0.1 megawatt hour the annual generation of thermal energy; the amount of the advance payment shall be derived from the generation in the respective month and the rate of contribution set out by the government decree;
- b) on a lump-sum basis by producers not referred to in a) (hereinafter "producers of small amount of radioactive waste"), namely in the amount set by the government decree under the conditions for the acceptance of radioactive waste for disposal or storage (Section 31); the amount of the contributions increases on an annual basis, however maximum by 7% against the immediately preceding year; the producers of small amount of radioactive waste shall pay the contribution on acceptance of radioactive waste by the Authority, the Authority shall appropriately set the contribution for radioactive waste failing to comply with the conditions for disposal or storage.

(5) A contribution return under para 4 a) shall be filed with the Authority using its form until 31 January of the next year.

²²⁾ Decree of the Ministry of Finance No. 310/1995 Coll., On the Cultural and Social Needs Fund.

(6) The balance of the nuclear account run as State financial assets may be invested on the financial market, but only in liquid government bonds, bonds of the Czech National Bank, State guaranteed bonds, or in securities of issuers whose rating level granted by a rating agency selected by the Ministry of Finance is at least as good as that of the Czech Republic. The Ministry of Finance may carry out financial investment through the intermediary of other persons. The manner of investment and its profitability shall be subject to supervision by the Ministry of Finance.

(7) The amount and method of payments to the nuclear account, especially the payment basis, payment rate, payment period, payment due, submission of a payment return form and payment advances, together with the manner of their administration, including the way payer records are kept, principles enabling generators of a small amount of radioactive waste to pay payments by means of refunding the costs of its disposal credited to the nuclear account through the medium of the Authority shall be established in a governmental order.

(8) In the event that radioactive waste is safely disposed of so that the costs of the Authority for activities relating to waste from the generator in question do not reach the expected amount, and the generator has terminated his activities associated with radioactive waste generation, the Government, as part of the Authority budget approval process, shall decide on reimbursement of unused resources to this generator.

(9) A contribution from the nuclear account shall be paid to the municipality in the cadastral area of which

- a) a survey area is defined for special intervention in the Earth's crust for underground disposal of radioactive waste⁴¹⁾,
- b) a protected area is defined for special intervention in the Earth's crust for underground disposal of radioactive waste³⁾, or

c) the operation of radioactive waste repository is licensed.

(10) Municipalities entitled in a calendar year to receive the contribution under para 9 a) or c), are not entitled to receive the contribution under para 9 b). The contribution is provided ex officio after the expiry of the time limit for bringing an action against administrative body's decision within the meaning of para 9.

(11) The contribution from the nuclear account amounts to maximum of CZK 4,000,000 per year. The Government shall set out in its decree the rules for providing the contribution and its amount under para 9 b) and c), as well as the method of calculation of the contribution under para 9 a), namely taking into account the size of survey area for special intervention in the Earth's crust for underground disposal of radioactive waste.

Section 28

(1) The State shall provide financial resources to the Authority for activities performed under Section 26 para 3 j) and k) and to manage radioactive waste disposed of subject to regulations effective prior to this Act coming into force.

(2) The State may provide a subsidy to eliminate old radiation burdens, namely for

a) disposal of radioactive waste which arose prior to privatisation²⁴⁾ of its generators;

⁴¹⁾ Act No. 62/1988 Coll., On geological work, as amended.

- b) elimination of radioactive environmental contamination that occurred before privatisation²⁴⁾ of its generators;
- c) elimination of radioactive waste which arose from substances or items contaminated by radionuclides before the time of privatisation²⁴⁾ of its generators to the extent of a proportional share of the costs;
- d) decommissioning of installations commissioned before their privatisation²⁴⁾, including the cost of necessary research and development work to the extent of a proportional share of the costs;
- e) identification of risks arising from the presence of indoor radon and products of its transformation, taking intervention measures demonstrably justified under Section 6 para 5 and measures to lower a level of the natural radionuclides in a drinking water for supplying to the public.
- A subsidy may be provided on the basis of an application reporting circumstances as specified in a) to e).

Section 29

(1) The bodies of the Authority shall be the Board and the Director. The Director shall be a statutory body of the Authority. The Director shall be a person of probity under Section 11 and fulfil requirements verified as established in a specific Act⁹, shall be competent to perform legal acts, university graduate and at least 6 years of expert experience.

(2) The Board members and the Director shall be appointed and dismissed by the Minister of Industry and Trade (hereinafter ,,the Minister").

(3) The Board shall comprise 11 members. The Board shall comprise representatives of State administration bodies, generators of radioactive waste and the public. Four persons shall be representatives of radioactive waste generators and four persons shall represent the public. Membership of the Board membership shall be a public function²⁵⁾.

(4) A Board member may only be a person of probity under Section 11, and competent to perform legal acts. A Board member may not be in an employer-employee or similar relation to the Authority. The period for Board membership shall be 5 years.

(5) The Board shall

- a) supervise the management and efficiency of use of resources spent on activities provided for and performed by the Authority, notify the Authority Director and the Minister of identified discrepancies and propose remedial measures;
- b) recommend to the Minister the one-year, three-year and long-term plans of activity and the budget of the Authority for submission to the Government;
- c) assess implementation of the one-year plan of activity and spending of the budget and arrange an audit of the annual financial Statement of the Authority;
- d) recommend to the Minister the dismissal or appointment of the Authority Director and, if need be, organisational changes to the Authority or changes to its statute;
- e) recommend to the Minister proposals for determination of payments to the nuclear account.

²⁴⁾ Act No. 92/1991 Coll., On Conditions of Transfer of State-Owned Property to Other Persons, as amended.

⁹⁾ Act No. 148/1998 Coll., On Protection of Classified Information and Amendments to Related Acts, as amended.

²⁵⁾ Section 124 para 1 and 2 of Act No. 65/1965 Coll., the Labour Code, as amended.

(6) The Director shall be entitled to participate at Board meetings on a non-voting basis.

Section 30

(1) On the basis of a proposal from the Authority, the Minister shall submit the following issues for approval to the Government

a) the one-year plan of activity of the Authority, including the annual budget;

- b) the three-year plan of activity of the Authority, including expected income and expenditure, together with the long-term plan of activity of the Authority and with an estimate of forecast income and expenditure;
- c) the annual report of the Authority, including the annual financial Statement verified by the auditor and an analysis of the effectiveness of utilisation of resources;
- d) the Authority statute;
- e) a draft government ordinance concerning determination of payments to the nuclear account on the basis of a proposal under Section 26 para 3 f).

(2) In the event of a hazard arising from delay in approving the Authority's one-year plan of activity and its budget, the Minister shall be entitled to approve a provisional one-year plan and budget for the Authority on the basis of which, the Authority shall perform its activities until the plan and budget are approved by the Government.

Section 31

(1) The Authority shall accept radioactive waste from a generator in the event that the waste meets acceptance criteria for waste disposal (hereinafter "acceptance criteria").

(2) The criteria for take over of the waste for disposal and criteria for payments to the nuclear account, including penalties, shall be regulated by an agreement concluded between the generator and the Authority.

(3) The acceptance criteria shall be established by the Office in the operating licence for particular repositories, subject to an assessment performed by the Authority of submitted safety analyses from the aspect of nuclear safety, radiation protection, physical protection and emergency preparedness.

(4) The Authority shall accept radioactive waste or handle radioactive waste subject to a decision of the Office under Section 3 para 2 u), even in case where the waste does not meet the acceptance criteria. In such cases, the Authority shall make provision, at the expense of the generator, to have the waste conditioned into a form meeting the acceptance criteria for a repository or for safe storage of such waste until conditions are created for a final solution to the problem.

(5) Compensation claims for radioactive waste management costs shall lapse three years from the date of identification of the radioactive waste generator, but not later than twenty years from the date on which the Authority accepted the radioactive waste for disposal.

(6) On the date the Authority accepts radioactive waste from its generator, the waste shall pass into the ownership of the State. The Authority and the generator shall confirm acceptance of the radioactive waste in writing.

CHAPTER FIVE

CIVIL LIABILITY FOR NUCLEAR DAMAGE

Section 32

(1) The provisions of the international agreement²⁶, which is legally binding on the Czech Republic, shall be applied for the purposes of civil liability for nuclear damage.

(2) The provisions of general legal regulations²⁷,²⁸⁾ concerning liability for nuclear damage shall be applied only unless otherwise provided for by the international agreement²⁶⁾ or this Act.

Section 33

(1) The licensee licensed for operation of nuclear installation²⁹⁾ or performing any practice related to nuclear installation utilisation, or licensed for nuclear material transport³⁰⁾ shall be the operator³¹⁾ liable for nuclear damage³²⁾ under the international agreement²⁶⁾ which is legally binding on the Czech Republic.

(2) In the event that a single person has been licensed for a number of nuclear installations located within an area, and for which a joint on-site emergency plan has been approved, these installations shall be considered, for the purposes of liability for nuclear damage, as a single nuclear installation. However, a number of nuclear installations for which different persons have been licensed cannot be considered as a single nuclear installation, from the aspect of liability for nuclear damage, even if such installations are directly linked.

²⁶⁾ The Vienna Convention on Civil Liability for Nuclear Damage and the Joint Protocol Relating to the Application of the Vienna and Paris Conventions, published under No. 133/1994 Coll. $^{27)}$ A $^{(10)}$ Coll. $^{(27)}$ A $^{(27)}$ Coll. $^{(27)}$

 $^{^{27)}}$ Act No. 40/1964 Coll., as amended.

 ²⁸⁾ Section 5 para 2 of Act of the Czech National Council No. 425/1990 Coll., On Local Authorities, their Competence and Some Other Related Measures, as amended by Act No. 254/1994 Coll.

²⁹⁾ Vienna Convention on Civil Liability for Nuclear damage, Art. I para 1 j).

³⁰⁾ Vienna Convention on Civil Liability for Nuclear Damage, Art. I para 1 h).

³¹⁾ Vienna Convention on Civil Liability for Nuclear Damage, Art. I para 1 c).

³²⁾ Vienna Convention on Civil Liability for Nuclear damage, Art. I para 1 k).

Section 34

(1) In determining the extent and manner of compensation for nuclear damage, provisions of general legal regulations on liability for damage²⁷⁾ shall be applied. To determine the amount of damage, legal regulations effective at the time of occurrence of the nuclear event³³⁾ that caused the nuclear damage shall be applied.

(2) Nuclear damage shall also be damage arising in the form of costs of interventions necessary to prevent or reduce exposure or restore the original or equivalent State of the environment, if these interventions were made necessary by a nuclear event and the nature of the damage thus permits.

(3) An implementing regulation shall set limits for concentrations and quantities of nuclear materials to which, under the international agreement³⁴⁾, the provisions on nuclear damage do not apply.

Section 35

The liability of a licensee for nuclear damage caused by each single nuclear event shall be limited in the case of

a) nuclear installations used for power generation purposes³⁵⁾, storage facilities and repositories of spent nuclear fuel assigned to these installations, or nuclear materials generated by processing of this fuel, to the sum of CZK 8,000 million;

b) other nuclear installations and shipments, to the sum of CZK 2,000 million.

Section 36

(1) A licensee under Section 33 shall arrange insurance covering his liability for nuclear damage with an insurer suitably authorised by a specific Act^{36} , if no other financial security is stipulated to cover the nuclear damage liability.

(2) The Ministry of Finance, by agreement with the Office and with the Ministry of Industry and Trade, shall determine, by way of a decision granting an exception from the provision of par. 1, in the interest of efficient employment of State funds, which licensee shall be required to have alternative type of financial cover of liability for nuclear damage instead of insurance covering his liability for nuclear damage.

(3) The insured sum in cases under Section 35 a), shall not be less than CZK 2,000 million, and in cases under Section 35 b), shall not be less than CZK 300 million.

³³⁾ Vienna Convention on Civil Liability for Nuclear Damage, Art. I para 1 l).

³⁴⁾ Vienna Convention on Civil Liability for Nuclear Damage, Art. I para 2.

³⁵⁾ Act No. 222/1994 Coll.

³⁶⁾ Act of the Czech National Council No. 185/1991 Coll., On Insurance, as amended.

(4) Insurance shall be arranged or other financial security established separately for each nuclear installation or nuclear material transport within the meaning of Section 33 para 2.

(5) Detailed insurance policy conditions shall be established in the general insurance conditions of the insurer, as approved by the State insurance supervisory authority. Detailed conditions of other financial security shall be established by the Ministry of Finance.

Section 37

(1) The State undertakes to settle acknowledged claims for compensation of nuclear damage, if they are not reimbursed from the mandatory insurance or financial security otherwise established, up to a sum of

- a) CZK 8,000 million over and above the sum paid by the insurer in the sum of CZK 2,000 million, in cases of installations under Section 35 a);
- b) CZK 2,000 million over and above the sum paid by the insurer in the sum of CZK 300 million, in cases of installations under Section 35 b).

(2) The right of recourse of the State as guarantor for settlement of acknowledged claims for compensation of nuclear damage against the licensee is not affected.

Section 38

(1) The right to indemnification for nuclear damage shall expire if a claim for compensation is not made within three years of the date on which the person suffering nuclear damage had knowledge or should have had knowledge of the event that caused the nuclear damage and of who was liable, but not later than ten years after the occurrence of this event, or after expiry of the insurance, if the validity of the insurance was longer.

(2) In case of a nuclear event occurring, a licensee shall issue written notification, in the region affected by the event as identified by the Office on the basis of National Radiation Monitoring Network activities under Section 3 para 2 j), stating his liability for nuclear damage caused by this event. This written notification shall be accessible to the public at the premises of the licensee and at the Regional Authority and all Municipal Authorities within this region.

CHAPTER SIX

STATE SUPERVISION AND PENALTIES

Supervising Activities

(1) The Office shall check compliance with this Act and subsequent regulations issued pursuant to it. The Office shall carry out inspections at the premises of persons granted a licence under Section 9 para 1, or registered under Section 21 para 2, at the premises of persons performing activities related to nuclear energy utilisation and radiation activities not requiring either a licence or a registration, at the premises of persons responsible for preparation or implementation of remedial actions to reduce exposure to natural radioactive sources or exposure due to radiation incidents, and at the premises of persons where there is a reason to believe that they utilise nuclear energy or perform radiation activities without authorisation, and at the premises of persons who are justifiably suspicious that they breach of obligations from international treaties binding on the Czech Republic, and at premises of manufacturers and suppliers of building materials and water.

(2) The Office's staff responsible for the inspection shall be inspectors of nuclear safety and inspectors of radiation protection (hereinafter "inspector"). Inspector shall be only person competent to perform legal acts, who are university graduates in a relevant field and have three years of professional experience. An inspector shall be professionally competent in matters under his supervision, shall be a person of probity under Section 11 and eligible in terms of security in accordance with a specific legal regulation^{1c)} in case of performing sensitive activities under Section 2a. The inspectors shall be appointed by the Chairman of the Office.

(3) Inspectors shall check whether the persons referred to in para 1 are observing provisions of this Act and implementing regulations, and whether they are keeping to the subject and scope of the issued licence, including specified conditions.

(4) Within the framework of their inspection activities, inspectors, and also the Chairman of the Office, are authorised, in addition to the rights arising from specific regulations³⁷, to

- a) enter at any time facilities, installations, operational areas, territories and other workplaces of inspected persons where activities related to nuclear energy utilisation or practices resulting in exposure are being carried out;
- b) check the compliance with requirements and conditions of nuclear safety, radiation protection, physical protection and emergency preparedness and inspect the nuclear installation conditions, adherence to limits and conditions and service regulations and to technical requirements on technical safety of the classified equipment;
- c) demand evidence of fulfilment of all set of obligations for the provision of nuclear safety, radiation protection, physical protection, emergency preparedness of nuclear installations and technical safety of the classified equipment;
- d) take measurements and collect samples at the premises of inspected persons such as are necessary for checking the compliance with this Act and other regulations issued on its basis;

³⁷⁾ Act of the Czech National Council No. 552/1991 Coll., On the State Inspection and Monitoring, as amended by Act No. 166/1993 Coll.

- e) perform a physical inspection of nuclear items or ionising radiation sources, including the checking of their records;
- f) verify professional competence and special professional competence under this Act;
- g) participate in investigations and clean-up of events with an impact on nuclear safety, radiation protection, physical protection and emergency preparedness, including unauthorised handling of nuclear items or ionising radiation sources.

(5) According to the international treaty²⁾ which is legally binding on the Czech Republic, inspectors of the International Atomic Energy Agency are also authorised to perform a physical inspection of nuclear items and an inspection of their accountancy for, provided they are accompanied by inspectors of the Office. Verification of fulfilment of the obligations under the Comprehensive Test Ban Treaty shall be performed by the inspectors appointed hereunder. The manner of inspection shall be governed by the provisions hereof.

(6) Unless otherwise stated in this Act, the procedure for inspection activities shall be governed by a specific Act^{37} .

Section 40

Remedial Measures

(1) Should an inspector identifies deficiencies at the premises of an inspected person, he is authorised, depending on the nature of the identified discrepancy, to

a) require the inspected person to remedy the situation, within a set time period;

- b) charge the inspected person to perform technical inspections, reviews or testing of operating condition of the installations, their parts, system or their assemblies, if necessary for verification of nuclear safety, radiation protection, and further to monitor and implement remedial actions for reducing or mitigation of lasting exposures;
- c) withdraw the special professional competence authorisation issued to an employee of the inspected person, in the event of a serious violation of his obligations or his not fulfilling requirements of professional competence and physical and mental capability;

d) propose the imposition of a penalty.

(2) The Office is authorised, in the event of a hazard arising from delay or an occurrence of undesirable situations with an impact on nuclear safety, radiation protection, physical protection and emergency preparedness, to issue a provisional measure³⁸⁾ imposing on the inspected person the obligation to reduce the power output or suspend operation of the nuclear installation, suspend an installation of components or systems of nuclear installations. Further it is authorised to prohibit the handling of nuclear items, ionising radiation sources or radioactive waste, or impose on the inspected person to suffer the imposition of management by another person, at the expense of the inspected person.

Section 41

³⁸⁾ Section 43 of Act No. 71/1967 Coll., On Administrative Proceedings (the Administrative Code).

Penalties

For violation of a legal obligation established in this Act, the Office shall impose a penalty, up to the sum of

- a) CZK 100 million on those who violate the prohibition on nuclear energy utilisation for other than peaceful purposes under Section 4, or the prohibition under Section 5 para 1;
- b) CZK 50 million on a person performing activities under Section 9 para 1, without a licence;
- c) CZK 10 million on a licensee violating an obligation under Sections 17 to 20;
- d) CZK 10 million on a person violating the prohibition on importation of radioactive waste for disposal under Section 5 para 2 and not fulfilling the obligation of providing payments to the nuclear account under Section 27, or the obligation of disposal of radioactive waste by an authorised person only, under Section 26 and Section 48 para 1;
- e) CZK 200,000 on natural persons of statutory bodies and CZK 100,000 on employees of an inspected person for distortion or concealment of facts important for performance of an inspection or for non-cooperation during an inspection;
- f) CZK 1 million for failure to fulfil other obligations imposed by this Act.

Section 42

(1) A penalty under Section 41 may be imposed within three years of the date on which the Office identified the violation of an obligation, but no later then 10 years after the occurrence of the violation.

(2) The amount of the penalty shall reflect the seriousness, significance and time period of the illegal activity and the extent of consequences that were caused, and early and efficient co-operation in removing the deficiencies. In the event that the deficiencies are removed immediately following the identification of the breach of the obligations and the Office has been provided with efficient co-operation, and neither persons nor the environment have suffered any damage, the Office may decide to refrain from imposing a penalty.

(3) The Office shall not instigate an administrative proceedings or stay an initiated proceedings concerning an imposing a penalty with natural person if the administrative offence was committed concurrently with its criminal activity and legitimate decision has been made a body active in criminal proceedings. In case a criminal proceeding has been only initiated, the Office shall stay administrative proceedings. For a term of criminal proceeding the term pursuant to Section 42 shall not run.

(4) The Office shall collect penalties imposed under Section 41. Penalties shall constitute an income to the State budget.

PART II

Repealed

Section 43

Repealed

PART III

Repealed

Section 44

Repealed

PART IV

AMENDMENT TO ACT NO. 586/1992 COLL. OF THE CZECH NATIONAL COUNCIL, ON INCOME TAXES, IN THE WORDING OF SUBSEQUENT REGULATIONS

Section 45

Act No 586/1992 Coll. of the Czech National Council, on income taxes, as amended by Act No 35/1993 Coll. of the Czech National Council, Act No 96/1993 Coll., Act No 157/1993 Coll., Act No 196/1993 Coll., Act No 323/1993 Coll., Act No 42/1994 Coll., Act No 85/1994 Coll., Act No 114/1994 Coll., Act No 259/1994 Coll., Act No 32/1995 Coll., Act No 87/1995 Coll., Act No 118/1995 Coll., Act No 149/1995 Coll., Act No 248/1995 Coll. and Act No 316/1996 Coll., is amended as follows:

In Section 18 para 2 b), the full stop is replaced by a colon and a new letter c) including note 19e) is inserted, in the following wording:

"c) income from own activities of the Radioactive Waste Repository Authority^{19e)}, excluding income subject to a special tax rate under Section 36 of this Act.

19e) Act No. 18/1997 Coll. on peaceful utilisation of nuclear energy and ionising radiation (the Atomic Act), and on alterations and amendments to related legislation.".

PART V

GENERAL, TEMPORARY AND FINAL PROVISIONS

Section 46

Tasks and Obligations of Central State Administrative Bodies in Emergency Preparedness

(1) For the requisite of the Radiation Monitoring Network on the Czech Republic territory

- a) the Ministry of Finance shall ensure operation of specified parts of monitoring points at border crossings and participate in operation of mobile monitoring groups;
- b) the Ministry of Defence shall participate in operation of Early Warning Network, monitoring points at roadblocks and border crossings, operation of mobile monitoring groups and aircraft monitoring groups and shall ensure means of aerial survey;
- c) the Ministry of Interior shall participate in operation of mobile groups;
- d) the Ministry of Agricultural shall participate in operation of water contamination monitoring points and foodstuffs contamination monitoring points;
- e) the Ministry of Environment shall ensure meteorological support and shall participate in operation of the Early Warning Network, air contamination monitoring points and water contamination monitoring points.

Implementing legal regulation shall establish a system of data transfer.

(2) For purposes of emergency preparedness support the Ministry of Interior shall provide for a system of notification and warning.

(3) The Ministry of Health shall create a system of special medical care provided by selected clinics to persons irradiated in the course of radiation accidents.

Section 46a

(1) As part of the protection of the population against exposure to natural sources, the Regional Authority shall

- a) distribute and collect detectors for searching buildings with higher level of exposure to natural radionuclides in their internal atmosphere in the manner set by an implementing legal regulation;
- b) hand over to the owners of buildings the measurement results and inform them on the conditions for obtaining a subsidy from the state budget pursuant to Section 28 para 2 e);
- c) receive applications for the provision of a subsidy from the state budget pursuant to Section 28 para 2 e) and together with its opinion and the Office's opinion requested by it, submit them to the Ministry of Finance;
- d) control, in cooperation with the Office and the competent construction office, the efficiency of implemented measures to protect health of the population against exposure to natural radionuclides.

(2) The subsidy from the state budget under Section 28 para 2 e) shall be provided by the Ministry of Finance. The procedure for receiving the applications for the provision of the subsidy, the particulars of the application as well as the procedure for submitting the applications by the Regional Authority to the Ministry of Finance shall be governed by an implementing legal regulation.

(3) The Office shall

- a) coordinate and manage in terms of methodology the distribution and collection of detectors for searching buildings with higher level of exposure to natural radionuclides in their internal atmosphere;
- b) set out in an implementing legal regulation the conditions for the provision of a subsidy from the state budget pursuant to Section 28 para 2 e) and, in cooperation with the Regional Authorities, keep records of searched objects meeting such conditions;
- c) issue an opinion on the application for the provision of a subsidy from the state budget pursuant to Section 28 para 2 e) and an opinion on the assessment of the efficiency of the radon reducing measure.

Section 46b

Competencies assigned to Regional Authority, Municipal Authority of Municipality with extended competence or Municipal Authority hereunder represent execution of delegated competencies.

Section 46c

(1) The Ministry of the Interior or the Police of the Czech Republic shall provide to the Office for the performance of the competence pursuant to Section 3 para 2 i) and o) of the Act

a) reference data from the basic civil register;

b) data from the agenda information system of civil registration;

c) data from the agenda information system of foreigners.

(2) The data provided under para 1 a) shall be as follows

a) surname;

- b) name or, if appropriate, names;
- c) date, place and district of birth; for an entity born abroad, date, place and state of birth;
- d) address of the place of residence;
- e) date, place and district of death; if this concerns death of an entity outside the territory of the Czech Republic, date of death, place and state on the territory of which the death occurred; if a court decision declaring the death was issued, day stated in the decision as the day of death or day which the entity declared dead did not outlive, and date on which this decision became effective;

f) nationality or, if appropriate, more nationalities.

(3) The data provided under para 1 b) shall be as follows

a) given name or, if appropriate, names, surname, maiden name;

b) date of birth;

c) sex;

- d) place and district of birth; for a citizen born abroad, state of birth;
- e) national register number;
- f) nationality or, if appropriate, nationalities;
- g) date, place and district of death; if this concerns death of a citizen outside the territory of the Czech Republic, date, place and state on the territory of which the death occurred.

(4) The data provided under para 1 c) shall be as follows

a) given name or, if appropriate, names, surname, maiden name;

b) date of birth;

- c) sex;
- d) place and state of foreigner's birth;
- e) national register number;
- f) nationality or, if appropriate, nationalities;
- g) type and address of the place of residence;
- h) date, place and district of death; if this concerns death outside the territory of the Czech Republic, state on the territory of which the death occurred, and date of death.

(5) Data kept as reference data in the basic civil register shall be used from the agenda information system of civil registration or the agenda information system of foreigners only if it is in the state preceding its current state.

(6) In a certain case, only such data may be used from the provided data which may be considered necessary for the performance of the task concerned.

Section 47

General and Temporary Provisions

(1) Proceedings under this Act shall be governed by general legal regulations^{37),39)}, unless otherwise specified by this Act.

(2) Persons disposing of radioactive waste on the basis of licences granted under Act No. 28/1984 Coll., on State Nuclear Safety Supervision for Nuclear Installations, or under Decree No. 59/1972 Coll. of the Health Ministry of the Czech Socialist Republic, on Health Protection from Ionising Radiation, shall be authorised to perform this activity until such time as the radioactive waste repositories are transferred to the Authority under Section 48 para 1.

(3) Persons performing activities regulated by this Act on the basis of a licence or approval granted under Act No. 28/1984 Coll., on State Nuclear Safety Supervision of Nuclear Installations, shall, within 1 year of this Act entering into force, accommodate their legal relations to the requirements Stated under Section 18 para 1 e) and Section 36, and within 2 years of this Act entering into force, to the requirements Stated under Section 17 para 1 i) and under Section 18 para 1 m) and n), and to other requirements of this Act within 5 years of this Act entering into force, with the exception of Section 48, where the obligation enters into effect on the date of opening of the nuclear account. On expiry of the time periods mentioned above, the original licence or approval ceases to be valid.

(4) The validity of an authorisation to manage ionising radiation sources granted under Decree No. 59/1972 Coll. of the Health Ministry of the Czech Socialist Republic, on Health Protection from Ionising Radiation, shall terminate on expiry of the period for which it was issued, but no later than five years from the date that this Act enters into force.

(5) Proceedings not completed prior to this Act entering into force shall be completed under the legal regulations effective at the time of their commencement.

(6) Emergency planning zones established before this Act entered into force shall be considered as emergency planning zones established in this Act.

(7) The Office shall issue regulations to implement Sections 2, 3, 4, 4a, 4b, 6, 7, 8, 9, 13, 14, 17, 18, with the exception of para 1 h), Sections 20, 22, 23, 24, 34, 46 and points A.I.1, A.I.2, B.I.1, D. b) 4, I.6, I.7, I.8, I.12, I.13 and P. of the Appendix.

(8) The Ministry of Industry and Trade, by agreement with the Office, shall establish by legal regulation specific requirements to ensure uniformity and correctness of measuring devices and measurements performed as part of activities related to nuclear energy utilisation, and practices resulting in irradiation.

(9) The Ministry of Industry and Trade, by agreement with the Office and the Ministry of Finance shall issue an implementing legal regulation to Section 18 para 1 h).

(10) The Office shall issue regulation to implement Section 46a para 1 a) and Section 46a para 3 b). The Ministry of Finance shall issue implementing legal regulation to Section 46a para 2.

(11) The Ministry of Defence shall, within the framework of its scope of power to perform a state supervision over the radiation protection in military premises, adopt measures to remove found shortcomings and provide the Office with information important from radiation protection viewpoint.

(12) For the purposes of a special legal regulation39a the exposure to ionising radiation, including significantly increased exposure to natural sources, shall be considered a risk factor in working conditions at workplaces and requirements of the special legal regulation^{39a)} shall

³⁹⁾ Act No. 71/1967 Coll.

^{39a)} Section 134c of Act No. 65/1997 Coll., Labour Code, as amended.

apply to work in controlled areas, unless provided otherwise herein. Activities with ionising radiation sources which may be performed only by A category workers and activities performed while supervising nuclear safety and radiation protection shall in agreement with a special legal regulation^{39b)} be considered the activities of the second category and risk activities. The other activities with ionising radiation sources shall be considered activities of the first category.

Section 48

(1) Radioactive waste repositories operated until the present time by other persons than the Authority shall be transferred within 3 years of this Act entering into force into the ownership of the State and entrusted to the Authority, with the exception of repositories in the form of dumps, tailings dumps or spoil heaps originating from mining, containing radioactive waste or created by mining operations with radioactive waste used as part of their filling,

- a) if operated by a State enterprise⁴⁰⁾, and within three years of the date that this Act enters into force a licence is granted to this enterprise by the Office under Section 9 j);
- b) if their owner, within three years of the date that this Act enters into force, concludes a contract with the Authority to ensure radiation protection; or
- c) where measures to reduce radioactive contamination are not justified by benefits as in Section 6 para 2.

(2) A State enterprise⁴⁰⁾, the founder of which has declared a attenuation programme, is not obliged to establish a decommissioning provision under Section 18 para 1 h).

Section 49

Final Provisions

The following are repealed:

1. Act No 287/1993 Coll. on Competence of the State Office for Nuclear Safety, as amanded by Act No. 85/1995 Coll.

2. Act No 28/1984 Coll. on State Supervision of Nuclear Safety at Nuclear Installations.

3. Decree No 59/1972 Coll. of the Health Ministry of the Czech Socialist Republic, on Protection of Health from Ionising Radiation.

4. Decree No 28/1977 Coll. of the Czechoslovak Atomic Energy Commission, on Accountancy for and Control of Nuclear Materials, as amanded by Decree No. 100/1989 Coll.

^{39b)} Act No. 258/2000 Coll., as amended.

⁴⁰⁾ Act No. 111/1990 Coll., On State Enterprises, as amended.

5. Decree No 67/1987 Coll. of the Czechoslovak Atomic Energy Commission, on Nuclear Safety Assurance in Radioactive Waste Management.

6. Decree No 100/1989 Coll. of the Czechoslovak Atomic Energy Commission, on Physical Protection of Nuclear Installations and of Nuclear Materials.

7. Decree No 191/1989 Coll. of the Czechoslovak Atomic Energy Commission, which establishes methods, terms and conditions for verification of special professional competence of selected personnel at nuclear installations.

8. Decree No 436/1990 Coll. of the Czechoslovak Atomic Energy Commission, on Quality Assurance at Selected Installations with Regard to Nuclear Safety of Nuclear Installations.

9. Decree No 76/1991 Coll. of the Health Ministry of the Czech Republic, on Reduction of Exposure from Radon and Other Natural Radionuclides.

10. Directive No 2/1978 of the Czechoslovak Atomic Energy Commission, on Nuclear Safety Assurance in the Process of Nuclear Power Installations Designing, Licensing and Construction (registered in Section 28/1987 Coll.).

11. Directive No 4/1979 of the Czechoslovak Atomic Energy Commission, on General Criteria for Nuclear Safety Assurance in the Process of Nuclear Power Installations Siting (registered in Section 9/1979 Coll.).

12. Directive No 6/1980 of the Czechoslovak Atomic Energy Commission, on Nuclear Safety Assurance in the Process of Nuclear Power Installation Commissioning and Operation (registered in Section 13/1980 Coll.).

13. Directive No 8/1981 of the Czechoslovak Atomic Energy Commission, on Testing of Equipment for Shipment and Storage of Radioactive Materials (registered in Section 20/1981 Coll.).

14. Directive No 9/1985 of the Czechoslovak Atomic Energy Commission, on Nuclear Safety Assurance for Nuclear Research Installations (registered in Section 11/1985 Coll.).

Section 50

This Act shall enter into force on 1 July 1997, except for parts Four and Five and Section 48, which come into force on the day of its promulgation.

Appendix

Content of the Documentation Required for Issue of a Licence for Individual Activities under Section 13 para 3 d) of this Act

А.

Documentation for the issue of a licence for siting of a nuclear installation or radioactive waste repository

I. Initial Safety Report which shall include

1. Description and evidence of suitability of the selected site from the aspect of siting criteria for nuclear installations or radioactive waste repositories as established in a legal implementing regulation;

2. Description and preliminary assessment of design conception from the aspect of requirements laid down in an implementing regulation for nuclear safety, radiation protection and emergency preparedness;

3. Preliminary assessment of impact of operation of proposed installation on personnel, the public and the environment;

4. Proposal of conception for safe termination of operation;

5. Assessment of quality assurance in process of selection of site, method of quality assurance for preparatory stage of construction and quality assurance principles for linking stages.

II. Analysis of needs and possibilities of physical protection.

В.

Documentation for the issue of a licence for construction of a nuclear installation or a category IV workplace

I. Preliminary Safety Report which shall include

1. Evidence that the proposed design meets all requirements for nuclear safety, radiation protection and emergency preparedness as laid down in an implementing regulations;

2. Safety analyses and analyses of the potential unauthorised handling of nuclear materials and ionising radiation sources, and an assessment of their consequences for personnel, public and environment; 3. Information on predicted lifetime of nuclear installation or very significant ionising radiation source;

4. Assessment of nuclear waste generation and management of it during commissioning and operation of the installation or workplace being licensed;

5. Conception of safe termination of operation and decommissioning of the installation or workplace being licensed, including disposal of nuclear waste;

6. Conception for spent nuclear fuel management;

7. Assessment of quality assurance during preparation for construction, method of quality assurance for the carrying out of construction work and principles of quality assurance for linking stages;

8. List of classified equipment.

II. Proposed method of providing physical protection.

The documentation specified under I.8 and II shall be subject to approval by the Office.

С.

Documentation for the issue of a licence for individual stages of nuclear installation commissioning

a) For stages prior to loading nuclear fuel into a reactor

- 1. Time schedule for work in a given stage;
- 2. Programme for the stage in question;
- 3. Evidence that installation and personnel are prepared for the stage in question;
- 4. Evaluation of results of the preceding stage;
- 5. Method by which physical protection is to be provided.
- b) For the first loading of nuclear fuel into a reactor
- I. Pre-operational Safety Report which shall include

1. Description of changes to original design assessed in the Preliminary Safety Report and evidence that there has been no decrease in the level of nuclear safety of the nuclear installation;

2. Supplementary and more precise evidence of nuclear safety and radiation protection provisions;

3. Limits and conditions for safe operation of the nuclear installation;

- 4. Neutron-physics characteristics of the nuclear reactor;
- 5. Method of radioactive waste management;
- 6. Quality assessment of classified equipment;
- II. Further documentation which shall include
- 1. Evidence that all prior decisions and conditions of the Office were fulfilled;
- 2. Time schedule for nuclear fuel loading;
- 3. Programme for nuclear fuel loading;
- 4. Evidence that installation and personnel are prepared for nuclear fuel loading;
- 5. Evaluation of the result of previous stages;
- 6. On-site emergency plan;
- 7. Changes in the provision of physical protection;
- 8. Programme of operational inspections;
- 9. Proposed decommissioning method;
- 10. Cost estimate for decommissioning as in II.9, verified by the Authority.
- c) For stages following the first nuclear fuel loading into the reactor
- 1. Time schedule for work in this stage;
- 2. Programme of this stage;
- 3. Evidence that installation and personnel are prepared for the stage in question;
- 4. Evaluation of results of the previous stage.
- d) For a trial operation stage of the radioactive waste repository
- I. Pre-operational Safety Report which shall include

1. Description of changes to the original design assessed in the Preliminary Safety Report and evidence that the level of nuclear safety of the nuclear installation has not been decreased;

2. Supplementary and more precise evidence of nuclear safety and radiation protection maintenance;

- 3. Limits and conditions for safe operation of the nuclear installation;
- 4. Method of radioactive waste management;
- 5. Quality assessment of selected equipment;

II. Further documentation which shall include

- 1. Time schedule of activities;
- 2. Programme of activities;
- 3. Evidence of implementation of previous decisions and conditions of the Office
- 4. Evidence that installation and personnel are prepared;
- 5. Methods of physical protection maintenance;
- 6. On-site emergency plan;
- 7. Programme of in-service inspections.

Documentation as specified under a), items 2 and 5, under b), items I.3, II.6 to II.9 and under c), item 2 and under d) items I.3, II.5 and II.6 shall be subject to approval by the Office. The Office may open proceedings even if documentation as in II.4 is not submitted.

D.

Documentation for the issue of a licence for nuclear installation or category III or IV workplace

a) For the issue of a licence for nuclear installation operation

1. Supplements to the Pre-operational Safety Report and further supplements to documentation required for the issue of a licence for the first nuclear fuel loading into the reactor, relating to changes carried out after the first nuclear fuel loading;

2. Evaluation of results of previous commissioning stages;

3. Evidence of implementation of previous decisions and conditions of the Office;

4. Evidence that installation and personnel are prepared for operation;

- 5. Operation time schedule;
- 6. Up-dated limits and conditions for safe operation.

b) For the issue of a licence for a category III or IV workplace

1. Expected extent and manner of activities with ionising radiation sources at the workplace, specification of radiation sources to be managed, their types and fixtures and fittings;

2. Description of status of building and installation activities, evidence of the effectiveness of shielding, insulation and protective equipment permitting to start radiation activities;

3. Evidence of radiation protection optimisation (Section 4 para 4 of this Act);

4. Programme of monitoring in the extent specified in an implementing legal regulation;

5. Proposal of controlled area delineation, assumed number of persons working in the area and a method of preventing unauthorised persons from entering the area;

6. On-site emergency plan;

7. Evidence of special professional competence of workers performing activities important from radiation protection viewpoint;

8. Assumed types and quantities of released radionuclides and assumed types and quantities of generated radioactive wastes and methods of their disposal;

9. Proposal of a decommissioning method and estimated costs of such decommissioning verified by the Administration;

Documentation as specified under a) item 6 and under b) items 4, 5 and 6 shall be subject to approval by the Office. The Office may open the proceedings even if documentation as in a) item 4 is not submitted.

E.

Documentation for the issue of a licence for restart of a nuclear reactor to criticality following a nuclear fuel reload

1. Neutron-physics characteristics of the reactor;

2. Evidence that installation and personnel are prepared for restart of the nuclear reactor to criticality, including preliminary evaluation of in-service inspections;

3. Time schedule for subsequent operation.

The Office may open proceedings even if documentation under item 2 is not submitted.

F.

Documentation for the issue of a licence for reconstruction or other changes impacting on nuclear safety, radiation protection, physical protection or emergency preparedness of nuclear installation or category III or IV workplace

1. Description and justification of prepared reconstruction or other changes;

2. Up-date of documentation approved for commissioning and operation of nuclear installation;

3. Anticipated time schedule for reconstruction or changes;

4. Evidence that the consequences of reconstruction or other changes will not adversely influence nuclear safety, radiation protection, physical protection or emergency preparedness.

Documentation specified under point 2 shall be subject to approval by the Office.

G.

Documentation for the issue of a licence for individual stages of decommissioning of a nuclear installation or category III or IV workplace

1. Evidence of availability of finance for decommissioning activities;

2. Description of changes to local area due to nuclear installation operation;

3. Description of technical procedures proposed for decommissioning;

4. Decommissioning time schedule;

5. Method of dismantling, decontamination, conditioning, transport, storage and elimination of parts of installation contaminated by radionuclides;

6. Assumed types and activities of radionuclides discharged into the environment and radioactive waste generated;

7. Method of radioactive waste management, including its disposal;

8. Limits and conditions for safe management of radioactive waste during decommissioning process;

9. Safety analyses;

10. Scope and method of measurement and evaluation of exposure of exposed workers and other persons and contamination of the workplace and its vicinity by radionuclides and ionising radiation;

11. On-site emergency plan;

12. Evidence of provision of physical protection of decommissioned nuclear installation. Documentation specified under items 8, 10 and 11 shall be subject to approval by the Office.

H.

Documentation for the issue of a licence to discharge radionuclides into the environment

1. Justification of discharge of radionuclides into the environment;

2. Types and activities of radionuclides discharged into the environment;

3. Evaluation of exposure of critical group of the population from discharged radionuclides;

4. Analysis of a possible accumulation of radionuclides in the environment in the case of long-term discharging.

I.

Documentation for the issue of a licence for ionising radiation source management

1. Justification of the radiation practice;

2. Specification of radiation sources which are to be managed, their types and fixtures and fittings;

3. Description of the supervised area (Section 4 para 4 of this Act) at a workplace where the sources will be handled (schematic plan), supplemented by information on shielding and protective facilities and equipment of workplaces;

4. evidence of radiation protection optimisation (Section 4 para 4 of this Act);

5. Document on special professional competence of workers performing activities important from radiation protection viewpoint;

6. Monitoring programme in the extent specified in an implementing regulation;

7. In cases specified by an implementing regulation proposal of controlled area delineation, assumed number of personnel working in this area and method of preventing entry of unauthorised persons into this area;

8. On-site emergency plan for management of sources specified in an implementing legal regulation;

9. If release of radionuclides into the environment or generation of radioactive waste is expected then assumed types and quantities of released radionuclides and assumed types and quantities of generated radioactive waste and methods of their disposal;

10. In case of manufacturing or import of sources, specification of types ionising radiation sources to be manufactured or imported, their assumed quantities and schedule of manufacturing or import and evidence of the capability to verify conformity assessment of individual products with a given type;

11. In case of ionising sources distribution or other placing on the market, specification of ionising sources types and expected quantities of individual products;

12. For the performance of tests specified in an implementing legal regulation to evaluate properties of artificial sources, evidence of the capability to measure and verify properties of ionising radiation sources, proposal of applicable methods and procedures, overview of

instrumentation and its availability for performance of the proposed services and a concept of metrological testing;

13. If exported, a specification of types of ionising radiation sources to be exported, their expected quantities and export schedule and, for sources specified in an implementing legal regulation, also a document confirmed by a competent authority of the country of the consignee proving that the consignee fulfils all conditions setting for ionising radiation sources management.

Documentation specified under items 6, 7 and 8 shall be subject to approval by the Office.

J.

Documentation for the issue of a licence for radioactive waste management

1. Description of equipment and technology used;

2. Information on origin, type, amount, radionuclide structure and activity of radioactive waste;

3. Method of collection, sorting, storage, processing, conditioning and disposal of radioactive waste;

4. Assumed amount of radionuclides released into the environment;

5. Scope and method of measurement (monitoring programme) and evaluation of exposure of exposed workers and other persons and contamination of workplace and its vicinity by radionuclides and ionising radiation;

6. Safety analyses;

7. On-site emergency plan;

8. Document on the special professional competence of personnel directly manage the working activities with ionising radiation sources and perform other activities especially important from the radiation protection viewpoint;

9. Limits and conditions for safe management of radioactive waste.

Documentation specified under items 5, 7 and 9 shall be subject to approval by the Office.

K.

Documentation for the issue of a licence for import or export of nuclear items or for transit of nuclear materials and selected items

a) Documentation required for nuclear materials and selected items

1. If imported, Statement of the user on the purpose of use thereof, including his commitment to enforce application of safeguards, provide physical protection, not to transfer and not to export these items without written agreement by the Office, under the terms arising out of international treaties, agreements and conventions by which the Czech Republic is bound;

2. If exported or during transit thereof, a guarantee from the State into which the nuclear materials or selected items are imported, under the terms arising out of international treaties, agreements and conventions by which the Czech Republic is bound.

b) Documentation required for items of dual use

1. If imported, Statement of the user on the purpose of use thereof and a his commitment not to export these items without written agreement by the Office, under the terms arising out of international treaties, agreements and conventions by which the Czech Republic is bound;

2. If exported, a guarantee by the end user or by the State to which items of dual use are imported, under the terms arising out of international treaties, agreements and conventions by which the Czech Republic is bound.

L.

Documentation for the issue of a licence for nuclear materials management

1. Purpose, justification and time interval for nuclear materials management;

2. Specification of type and amount of nuclear materials, including their chemical and physical form and enrichment;

3. Description of handling operations involving nuclear materials with respect to the possibility of their operational losses and/or their consumption;

4. Guidelines for accountancy for and control of nuclear materials;

5. Information necessary for fulfilment of conditions arising out of international treaties, agreements and conventions by which the Czech Republic is bound in the field of accountancy for and control of nuclear materials.

М.

Documentation for the issue of a licence for transport of nuclear materials and radioactive substances

1. Transport instructions containing specification of type of transport and proposed route, including an alternative route;

2. Assessment of risks arising from the nature of radioactive content, type of transport and selected route;

3. Emergency rules;

4. Method of radiation protection during transport;

5. Document proving the competence of crew of vehicles transporting hazardous goods, or evidence of this competence under a specific regulation¹⁴;

6. Document on capability of the means of transport, or evidence of this capability under a specific regulation¹⁴;

7. Proposal for classification of transported nuclear materials into relevant categories from the physical protection aspect;

8. Proposed physical protection arrangements during transport;

9. Evidence of conformity of packaging assemblies with type-approval.

Documentation specified under items 3, 7 and 8 shall be subject to approval by the Office.

N.

Documentation for the issue of a licence for expert training of selected personnel

1. Documents establishing the organisational and technical capability of an applicant for expert training of selected personnel;

2. Documents establishing the professional competence of the applicant personnel for expert training of selected personnel;

3. Documents establishing the method of expert training of selected personnel.

Documentation specified under item 3 shall be subject to approval by the Office.

О.

Documentation for the issue of a licence for re-importation of radioactive waste originating from material exported from the Czech Republic, for the purpose of its processing (reprocessing)

1. Document establishing origin, type, physical properties and chemical composition of material which was exported and processed outside the territory of the Czech Republic, together with a document stating the total mass of this material;

2. Document on the physical properties of imported radioactive waste and its chemical composition together with a document stating its total mass;

3. Document on the technical process by which the exported material was processed (reprocessed) together with the material balance, which will demonstrate the probable amount of radioactive waste that may arise from the given amount of material through the technological process specified.

P.

Documentation for the issue of licence for international transport of radioactive waste

Data about the applicant for transport licence, about the type and method of transport submitted in a form whose sample shall be specified in an implementing legal regulation.

R.

Documentation for the issue of the licence for performing personal dosimetry and other services important from radiation protection viewpoint

- 1. Description of services to be provided and their assumed scope;
- 2. Description of preparedness of the equipment and personnel;
- 3. Documents proving special professional competence to perform the services;
- 4. Specification of employed methods and procedures;
- 5. Overview of instrumentation and its availability to perform the proposed services;
- 6. Concept of metrological testing.

Documentation specified under items 4 through 6 is not submitted in the event that the services are not associated with measurement and evaluation of ionising radiation or radionuclides.

S.

Documentation for the issue of the licence for adding radioactive substances into consumer products in the process of their manufacture or preparation or for import or export of such products

1. Justification of benefits resulting from addition of radioactive substances into the products;

2. Radionuclide composition and activities of radionuclides added into the individual products;

- 3. Overall expected volume of the production or the import;
- 4. Draft of the instructions for use (instructions for safe utilisation of the products by users);
- 5. Concept of disposal of used products.