

ACT OF PARLIAMENT  
of 29 November 2000

**Atomic Law**<sup>A, 1[1]</sup>

**Chapter 1**  
**General provisions**

**Article 1**

1. The Act defines the following:
  - 1) activities related to peaceful uses of atomic energy, involving actual and potential exposures to ionizing radiation emitted by artificial radioactive sources, nuclear materials, ionizing radiation generating devices, radioactive waste and spent nuclear fuel;
  - 2) duties of the head of organizational entity conducting these activities;
  - 3) authorities competent in the area of nuclear safety and radiological protection;
  - 4) principles of liability for nuclear damage,
  - 5)<sup>2[2]</sup> principles of the fulfillment of international obligations, including those within the European Union framework, involving nuclear safety, protection against ionizing radiation, nuclear material safeguards and the control of nuclear technologies.
2. The Act also establishes financial penalties for the violation of nuclear safety and radiological protection regulations, and the rules for imposing such penalties.

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<sup>A</sup> Ref. No 1 added to the title by the Art. 40 of the act of Parliament of 20 April 2004 on the amending and repealing some laws as the consequence of Poland's membership in European Union (Polish O.J. no 96, Item 959) which entered into force on 1 May 2004.

<sup>1[1]</sup> The provisions of this act implement the following European Union directives:

- 1) 96/29/Euratom of 13 May 1996 establishing basic safety standards for health protection of workers and general public against the dangers of ionizing radiation,
- 2) 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.

Data related to the publication of European Union laws given in this act – from the day of acquiring European Union membership by Poland – refer to the publication of these acts in the (European) Official Journal – special edition.

<sup>2[2]</sup> Added by Art. 1(1)(a) of the act of Parliament of 12 March 2004 amending the Atomic Law act and the financial charge law (Polish O.J. no 70 Item 632), which entered into force the day of acquiring European Union membership by Poland.

3. The Act shall also apply to the practices conducted in conditions of exposure to natural ionizing radiation enhanced by human activity.
- 4.<sup>3[3]</sup> Moreover, the Act defines the principles of radioactive contamination monitoring and establishes the rules governing the activities undertaken in the event of a radiological emergency as well as in chronic exposure conditions in the aftermath of the radiation emergency or some past practice.
- 5.<sup>4[4]</sup> The Act defines also special principles for the protection of people against the threats resulting from the ionizing radiation applications for medical purposes.

#### **Article 2.**

Activities and practices referred to in Article 1(1)(1) and Article 1(3) shall be permitted after undertaking the measures defined in appropriate regulations, aimed at ensuring safety and protection of human life and health, as well as protection of the property and environment.

#### **Article 3.** <sup>5[5]</sup>

For the purposes of this Act, the following terms have the meaning hereby assigned to them:

- 1) clinical audit – systematic control or review of radiological medical procedures, aimed at the improvement of the quality of health services rendered to the patient through systematized analysis within which the radiological practice, procedures and results are compared to the recognized standards and – if necessary – through the modification of existing procedure or the introduction of new standards;
- 2) nuclear safety - conditions reached through all organizational and technical measures undertaken to prevent the occurrence of uncontrolled and self-sustaining nuclear fission reaction related to activities involving nuclear materials, and to mitigate its consequences;
- 3) dose limit - value for ionizing radiation dose expressed in terms of effective dose or equivalent dose, established for specified groups of persons, and involving controlled occupational exposure, which shall not be exceeded, except under circumstances provided for in this Act;
- 4) absorbed dose – absorbed dose as defined in the Annex to this Act;
- 5) equivalent dose – equivalent dose as defined in the Annex to this Act;
- 6) effective dose – effective dose as defined in the Annex to this Act;
- 7) intervention measures – activities undertaken to prevent or to mitigate human exposure resulting from radiological emergency, consisting in acting upon the ionizing radiation source, radioactive contamination source, contamination pathways and upon people;

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<sup>3[3]</sup> As written down in Art. 1(1)(b) of the act referred to in ref. 2).

<sup>4[4]</sup> Added by Art. 1(1)(c) of the act referred to in ref. 2).

<sup>5[5]</sup> As written down in Art. 1(2) of the act referred to in ref. 2).

- 8) organizational entity – each entity engaged in activities involving exposure;
- 9) decommissioning of a nuclear facility – bringing a nuclear facility or device to the status which allows the conduct of any activity with no limitations from the nuclear safety and radiological protection viewpoint;
- 10) decommissioning of radioactive waste or spent nuclear fuel repository – bringing the site of a radioactive waste or spent nuclear fuel repository to a status which allows the conduct of any activity with no limitations from the viewpoint of nuclear safety and radiological protection;
- 11) nuclear material – ores, source materials or special fissile materials, referred to in Article 197 of the Treaty establishing the European Atomic Energy Community, hereafter referred to as “Euratom Treaty”;
- 12) nuclear medicine – all diagnostic procedures involving the radiopharmaceuticals administered to the patients, and also therapeutic procedures involving radiopharmaceutical products;
- 13) medical radiological procedure – the description of the activities necessary for performing an examination or treatment with the application of ionizing radiation, for diagnostic or therapeutic purposes;
- 14) medical radiological emergency – unintended event, such as the error in radiological device operation, radiological device failure or interrupted operation, and also other unfortunate event, with consequences that may not be disregarded from the viewpoint of radiological protection of the patient;
- 15) exposure – a process of exposing human body to ionizing radiation;
- 16) emergency exposure – exposure of the individual participating in clearing out the radiation emergency consequences or in the intervention activities, during which he / she may obtain a dose exceeding the annual dose limit for occupational exposure;
- 17) nuclear facility – a facility or an installation designed for manufacturing, use, processing, isotopic enrichment, storage and disposal of nuclear material in quantities allowing a self-sustained nuclear fission chain reaction, in particular: power plants, thermal-electric power plants and heating plants with power nuclear reactors, and also research, experimental and other nuclear reactors – from the start of construction until the end of decommissioning;
- 18) target volume – the volume of the tumor or other tissues, which is irradiated to obtain a planned therapeutic effect;
- 19) physical protection – all organizational and technical measures aimed at ensuring effective protection of nuclear materials against theft or acts of terrorism, diversion and sabotage;

- 20) radiological protection – prevention of human exposure and environmental contamination, and if such prevention is not possible – limitation of their consequences to the lowest reasonably achievable level, taking into account economic, social and health factors;
- 21) radiological protection of the patient – a set of actions and limitations aimed at the minimization of the patient’s exposure to the ionizing radiation, which will not excessively hamper or prevent obtaining the desired and valid diagnostic information or therapeutic effects;
- 22) radioactive waste – solid, liquid or gaseous waste containing radioactive substances or contaminated by such materials, further use of which has no purpose or is impossible, assigned to waste categories referred to in Article 47; this definition is not applicable to Article 62;
- 23) dose constraint – limiting value for expected individual doses, which may result from a specific ionizing radiation source, used in radiological protection planning for optimization purposes;
- 24) radioactive waste management - all practices involving processing, handling, storage or disposal of radioactive waste, including facility decommissioning;
- 25) spent nuclear fuel management – all practices involving reprocessing, handling, storage or disposal of spent nuclear fuel, including facility decommissioning;
- 26) intervention level – numerical value of avertable effective dose or equivalent dose, or the level of radioactive isotope content in foodstuffs and drinking water intended for people, and feeds for animals, which necessitates the consideration of specific remedial action if there is a possibility of exceeding this value;
- 27) reference levels – ionizing radiation doses to the skin surface in medical X-ray diagnostic practices, or in case of administering radiopharmaceuticals to the patients - levels of activity, related to the examination of standard-sized patients, for individual categories of radiological devices. These levels shall not be exceeded for standard radiological procedures when using appropriate practices and technical equipment. These levels may be exceeded in the case of important clinical considerations;
- 28) external employer – employer who employs the workers referred to in Article 17(1)(1), who conduct any activity on the another employer’s controlled area;
- 29) worker – worker as defined in the provisions of the Labor Law, an individual performing work on the basis other than employment contract, and also self-employed individual, who in the occupational exposure conditions may obtain doses exceeding the dose limit values for the members of public;
- 30) external worker – worker referred to in Article 17(1)(1), employed by an external employer or self-employed, conducting any activity in a controlled area for which neither he /she, nor his /her employer is responsible;

- 31) apprentice – an individual undergoing a training or practice in the organizational entity, to acquire specific skills;
- 32) nuclear safety and radiological protection program – a system of actions, which ensures the fulfillment of specified nuclear safety and radiological protection requirements, depending on conducted activity;
- 33) ionizing radiation – radiation composed of directly or indirectly ionizing particles, or of both those types of particles, or electromagnetic radiation of wavelength of 100 nm (nano-meter) or less;
- 34) natural radiation – ionizing radiation emitted from natural sources of terrestrial and cosmic origin;
- 35) spent nuclear fuel storage facility – nuclear facility intended for safe, secure, stable and protected storage of spent nuclear fuel, after its unloading from the nuclear reactor or from the reactor pool and before its handing over for reprocessing, or for disposal as radioactive waste;
- 36) storage of radioactive waste or spent nuclear fuel – holding of radioactive waste or spent fuel with the intention of retrieval for processing, reprocessing or disposal;
- 37) spent nuclear fuel reprocessing - process or operation aimed at partial or total extraction of radioactive isotopes from spent nuclear fuel for their further use;
- 38) nuclear material processing – process or operation aimed at changing the nuclear material's physical or chemical (conversion) form, from the conversion of uranium or thorium ore up to obtaining the material in the form of nuclear fuel or any other form allowing other applications of these materials, including spent nuclear fuel reprocessing and processing radioactive waste containing nuclear materials;
- 39) radioactive waste processing – process or operation to minimize the volume of waste, waste segregation according to waste category and waste preparation for transport or disposal;
- 40) interventional radiology – all therapeutic and diagnostic procedures, performed through the patient's skin or otherwise, performed under local or general anesthesia and using fluoroscopic imaging to localize pathologic changes and for the purposes of radiological medical procedure monitoring, and also for the purposes of therapy control and documentation;
- 41) radiotherapy – all therapeutic activities involving the use of radiological equipment, including:
  - a. surface therapy for treatment of tumors localized in human skin, and deep therapy for treatment of tumors and possibly some other pathologies in organs and tissues in other locations (tele-radiotherapy),
  - b. insertion of an isotopic source directly into the internal organs, into the tissues or body cavities, or its placement on the patient's body surface (brachytherapy),

- c. intended introduction of therapeutic quantities of radiopharmaceutical products into the organism;
- 42) X-ray diagnostics – all diagnostic activities involving the use of X-ray devices;
- 43) radioactive contamination – the contamination of objects, premises, environment or individuals by an undesirable presence of radioactive substance. In the special case of human body this includes both external and internal contamination, regardless of the radioactive substance intake pathway;
- 44) radioactive waste or spent nuclear fuel disposal – the emplacement of radioactive waste or spent nuclear fuel in an appropriate facility with no intention of retrieval;
- 45) radioactive substance – material containing one or more radioactive isotopes, with activity or radioactive concentration that may not be disregarded from the radiological protection viewpoint;
- 46) quality management system – a set of systematically planned and implemented activities, necessary for ensuring adequately that a given structure, system or their components, or the procedures will perform in an adequate way, fulfilling the requirements established in the regulations issued under Article 33c(9)(2);
- 47) human health detriment – evaluated risk of shortening of human life and impairment of its quality, resulting from ionizing radiation exposure. Includes the losses resulting from somatic consequences, tumors and serious genetic disorders;
- 48) controlled area – area with controlled access, covered by special regulations designed for the protection against ionizing radiation or radioactive contamination spreading;
- 49) supervised area – area under special supervision for the purposes of protection against ionizing radiation;
- 50) radiological equipment – ionizing radiation sources or equipment for the detection of ionizing radiation, used for therapeutic or diagnostic purposes;
- 51) spent nuclear fuel – nuclear fuel that has been irradiated in and permanently removed from a nuclear reactor core;
- 52) isotopic enrichment – process consisting in the separation of uranium isotopes for the purpose of increasing uranium-235 content in the output product;
- 53) hazard (potential exposure) – exposure which is possible and for which the probability and magnitude may be estimated beforehand;
- 54) closure of radioactive waste or spent nuclear fuel repository – discontinuation of further shipments of radioactive waste or spent nuclear fuel to the repository, decided upon by an appropriate authority, and accomplishment of all works necessary to ensure the safety and

- security of the repository;
- 55) radiological emergency – hazardous situation which requires urgent remedial actions for protection of the workers or general public;
- 56) radioactive source – radioactive substance made ready for the use of its ionizing radiation;
- 57) ionizing radiation source – radioactive source, device containing such source, device generating ionizing radiation or installation emitting radioactive substances.

## **Chapter 2**

### **Licences addressing nuclear safety and radiological protection issues**

#### **Article 4.** <sup>6[6]</sup>

1. Any practice involving exposures and concerning:
  - 1) manufacturing, processing, storage, disposal, transport or use of nuclear materials, radioactive sources, radioactive waste and spent nuclear fuel, as well as the trade in these materials, and also isotopic enrichment;
  - 2) construction, commissioning, experimental and normal operation, and decommissioning of nuclear facilities;
  - 3) construction, operation, closure and decommissioning of radioactive waste repositories and spent nuclear fuel repositories, and construction and operation of storage facilities for spent nuclear fuel;
  - 4) manufacture, installation, use and maintenance of the devices containing radioactive sources and trade in such devices;
  - 5) commissioning and application of the devices generating ionizing radiation;
  - 6) commissioning of laboratories and workrooms using ionizing radiation sources, including X-ray laboratories;
  - 7) deliberate addition of radioactive substances in the processes of manufacturing consumer and medical products and trade in such products, and also the import into the Republic of Poland's territory, and export from this territory, of consumer and medical products to which radioactive substances have been added;
  - 8) deliberate administration of radioactive substances to humans and animals, for the purposes of medical or veterinary diagnostics, therapy or research;

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<sup>6[6]</sup> As written down in Art. 1(3) of the act referred to in ref. 2).

- shall require a licence or a notification from the viewpoint of nuclear safety and radiological protection, subject to Article 6(1).

2. Practices involving addition of radioactive substances to foodstuffs, toys, personal jewelry or cosmetic products, as well as the import of such products into the Republic of Poland's territory, and their export from this territory, shall be prohibited.

#### **Article 5<sup>6</sup>**

1. Application to issue a licence for practices referred to in Article 4(1) shall include:
  - 1) designation of the organizational entity applying for the licence, indicating its localization and address,
  - 2) in case of entrepreneurs – the number in the entrepreneurs' register,
  - 3) description of the type, scope and place of conduct of the practice involving the exposure.
2. Application to issue a licence for practices referred to in Article 4(1), or the notification of such practice, shall be submitted by the head of the organizational entity.
3. Licence shall be issued by or the notification shall be made to the President of National Atomic Energy Agency, hereinafter referred to as "the Agency's President", subject to paragraph 4.
4. Licence for commissioning and operation of X-ray devices for the purposes of medical diagnostics, interventional radiology, surface radiotherapy and non-cancerous disease therapy, and for commissioning of the laboratories using such equipment, shall be issued by the regional sanitary inspector, while for the organizational entities:
  - 1) subjected or subordinated to the Minister of National Defense, or supervised or established by this Minister – shall be issued by the commander of the military center for preventive medicine,
  - 2) subjected or subordinated to the minister competent for home affairs, or supervised or established by this minister – shall be issued by the sanitary inspector of the Ministry of Home Affairs and Administration.
5. Licence shall be issued, or the notification shall be accepted, after establishing that the conditions required by law for performing practices involving radiation exposure and requiring a licence or notification have been fulfilled.
6. Issuing the licence, refusal to issue the licence and licence revocation, and also the acceptance and refusal of acceptance of the notification, shall have the form of an administrative decision.
7. The licence shall be issued for indefinite period, unless the organizational entity applying for the licence applies for the licence for a definite period.

8. The authorities referred to in paragraphs 3 and 4 shall establish and maintain the register of those organizational entities, whose activities require at least a notification.
9. The head of organizational entity shall report to the licensing body all changes concerning the data specified in the licence.
10. The provision of paragraph 9 shall apply accordingly to the notification.
11. The licensing body shall revoke the licence in the event when:
  - 1) a valid ruling has been passed, which prohibits the organizational entity to conduct practices involving exposure and covered by the licence,
  - 2) organizational entity ceased to fulfill the conditions required by law and necessary for the conduct of practices specified in the licence,
  - 3) organizational entity failed to eliminate, within the time specified by the licensing body, the factual or legal status, which does not comply with the conditions specified in the licence or with the legal provisions for licensed activities.
12. The decision to revoke the licence shall establish the method for managing the nuclear materials, ionizing radiation sources, radioactive waste or spent nuclear fuel held by the organizational entity.
13. The costs of proceedings referred to in paragraph 12 shall be borne by the organizational entity, whose licence has been revoked.
14. The charge for issuing the licence shall be paid in the amount established in the regulations for financial charges and duties.

## **Article 6**

The Council of Ministers shall establish by regulations:

- 1) cases where practices referred to in Article 4(1) shall be exempted from obtaining a licence or from issuing a notification, and the cases where such practices may be performed on the basis of a notification, by defining appropriate exemption criteria in the form of limiting values for radioactive isotopes total activity and radioactivity concentration;
- 2) documents required together with a licence application submitted for practices referred to in Article 4(1), or with the notification of such practice, which are necessary to confirm that the applicant fulfils the conditions satisfying nuclear safety and radiological protection requirements, taking into account specific characteristics of various practices, as well as the actions of the authority issuing the licence or receiving the notification in the event that the content of such documents is not sufficient to prove that these conditions have been fulfilled;

- 3) requirements concerning natural radioactive isotope content in raw materials and in construction materials used in the buildings intended for humans and livestock, and also in industrial waste used in construction industry, as well as the control over the content of such isotopes.

### **Chapter 3**

#### **Nuclear safety, radiological protection and health protection of the workers**

##### **Article 7**

1. Responsibility for compliance with the requirements for nuclear safety and radiological protection shall rest with the head of the organizational entity conducting the activities involving exposure.
- 2.<sup>7[7]</sup> Organizational entity conducting practices for which a licence is required, shall establish and implement a nuclear safety and radiological protection program, which includes at least the description of the equipment and procedures designed for protection against hazard of the worker, of general public and of the environment.
- 3.<sup>7</sup> In organizational entity conducting practices for which a licence is required, internal supervision over the fulfillment of nuclear safety and radiological protection requirements shall be executed by an authorized radiological protection inspector, subject to paragraph 3(a).
- 3a.<sup>8[8]</sup> Requirement referred to in paragraph 3 shall not be applicable to the organizational entity conducting practices involving X-ray devices used for veterinary purposes, operated in picture mode, and to the organizational entity conducting practices involving X-ray equipment designed for the control of people, shipments and luggage.
4. Application to be authorized to become a radiological protection inspector may be filed by the interested party or by the head of appropriate organizational entity.
5. Authorization to become a radiological protection inspector shall be granted to an individual who:
  - 1) is fully qualified from the legal point of view;
  - 2) is at least a secondary school graduate;
  - 3)<sup>9[9]</sup> passed an exam in the field of training referred to in the regulations issued under Article 12(2) or 12(3);
  - 4) possesses a medical certificate declaring the absence of contraindications for work in occupational exposure conditions;

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<sup>7[7]</sup> As written down in Art. 1(4)(a) of the act referred to in ref. 2).

<sup>8[8]</sup> Added by Art. 1(4)(b) of the act referred to in ref. 2).

<sup>9[9]</sup> As written down in Art. 1(4)(c) of the act referred to in ref. 2).

- 5)<sup>10[10]</sup> has worked in conditions of occupational exposure to ionizing radiation for the period established in the regulations issued under Article 12(2) or 12(3).
6. Authorization to be a radiological protection inspector shall be issued by the Agency's President, subject to paragraph 7.
- 6a.<sup>11[11]</sup> Training of the candidates for the authorization to become a radiological protection inspector, with the exception of the authorization for radiological protection inspector in X-ray laboratories using X-ray devices for the purposes of medical diagnosis, interventional radiology, surface radiotherapy and radiotherapy of non-cancerous diseases, shall be conducted by the entities which have been entered into the register of the Agency's President.
- 6b.<sup>11</sup> Training of the candidates for the authorization to become a radiological protection inspector in X-ray laboratories using X-ray devices for the purposes of medical diagnosis, interventional radiology, surface radiotherapy and radiotherapy of non-cancerous diseases, shall be conducted by the entities which have been entered into the register of the Chief Sanitary Inspector.
- 7.<sup>12[12]</sup> Authorization to become a radiological protection inspector in laboratories using the X-ray devices for the purposes of medical diagnosis, interventional radiology, surface radiotherapy and radiotherapy of non-cancerous diseases, shall be issued by the Chief Sanitary Inspector.
8. Costs associated with obtaining such authorization shall be borne by the applicant.

#### **Article 7a** <sup>13[13]</sup>

Head of the organizational entity shall ask for the radiological protection inspector's opinion on the issues related to the tests and checks of protective equipment and measuring instruments, including in particular:

- 1) assessment of the equipment relevant for radiological protection – prior to its admission for use,
- 2) admission for use of new or modified ionizing radiation sources, from the radiological protection viewpoint,
- 3) frequency of checking the effectiveness of the measures and techniques of radiological protection,
- 4) frequency of the calibration of measuring instruments, verification of their operability and proper usage.

#### **Article 8** <sup>14[14]</sup>

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<sup>10[10]</sup> Added by Art. 1(4)(c) sub. 2 of the act referred to in ref. 2).

<sup>11[11]</sup> Added by Art. 1(4)(d) of the act referred to in ref. 2).

<sup>12[12]</sup> As written down in Art. 1(4)(e) of the act referred to in ref. 2).

<sup>13[13]</sup> Added by Art. 1(5) of the act referred to in ref. 2).

<sup>14[14]</sup> Added by Art. 1(6) of the act referred to in ref. 2).

1. Prior to the start of practices involving exposure, the head of organizational entity shall prepare a justification for the practice, which should demonstrate that the scientific, economic, social and other benefits expected from this practice will prevail over possible human health detriment and damage to the state of environment resulting from this practice.
2. If some new and important circumstances concerning the effects of a given practice arise, the head of organizational entity shall verify the justification of this practice, taking into account the same factors, as those required for the justification itself.

**Article 8a** <sup>15[15]</sup>

Head of organizational entity shall inform in writing the body, which has issued the licence or accepted the notification, of the anticipated organizational entity transformation or discontinuation of its operation, and shall clear with this body in writing the rules for the management of held radioactive sources, nuclear materials or radioactive waste, and also, at the expense of organizational entity, following the termination of the practice, shall perform a dosimetric inspection and decontamination of the site where practice has been conducted and of its surroundings.

**Article 9** <sup>16[16]</sup>

1. Head of organizational entity shall ensure that the activities are conducted according to the optimization principle, which requires that – after accounting in a reasonable way for economic and social factors - the number of exposed workers and members of the public shall be as low as reasonably achievable and the doses received by them shall be as low as possible, subject to Article 33.c.
2. Head of organizational entity shall perform the assessment of the exposure of workers, and if the optimization analysis indicates such necessity – shall establish for them further limitations of exposure in such manner, that the doses received would not exceed the established dose constraints.
3. If dose constraints are established in the licence, than any possible case of exceeding these values shall be reported by the head of organizational entity to the licensing authority.

**Article 9a** <sup>17[17]</sup>

1. The Agency's President may include in the licence the obligation of the organizational entity to create a specialized, organizationally separated radiological protection service, to assist the radiological protection inspector in performing his tasks in the area of radiological protection.

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<sup>15[15]</sup> Added by Art. 1(7) of the act referred to in ref. 2).

<sup>16[16]</sup> As written down in Art. 1(8) of the act referred to in ref. 2).

<sup>17[17]</sup> Added by Art. 1(9) of the act referred to in ref. 2).

2. Specialized radiological protection service referred to in paragraph 1 may be shared by a number of organizational entities, if their heads so decide in a concluded agreement.

#### **Article 10**

1. A worker may be employed in exposure conditions after an appropriately qualified medical practitioner, hereinafter referred to as an “authorized medical practitioner”, issues a certificate stating that there are no contraindications for such employment.
2. Qualifications of authorized medical practitioner, procedures for issuing and preserving such certificates and the type and frequency of medical examinations for workers employed in exposure conditions, shall be established in the provisions of Labor Law, unless otherwise provided for in this Act.

#### **Article 11**

1. Work involving nuclear material, ionizing radiation source, radioactive waste or spent nuclear fuel, shall be performed by a worker possessing the knowledge of nuclear safety and radiological protection regulations appropriate for this position, as well as appropriate skills and qualifications.
- 2.<sup>18[18]</sup> Head of organizational entity shall be responsible for conducting preliminary and periodic (at least every 5 years) training for workers, apprentices and students on the nuclear safety and radiological protection issues, according to a training program developed by him. Appropriate training shall be also given to workers participating in the transport of nuclear materials, radioactive sources, radioactive waste and spent nuclear fuel.
  - 2a.<sup>19[19]</sup> Training referred to in paragraph 2 shall include in particular:
    - 1) general radiological protection procedures and preventive measures undertaken, as related to the activities conducted by organizational entity,
    - 2) radiological protection procedures and preventive measures undertaken, as related to the specific workplace,
    - 3) in case of female workers – also the information on the necessity to notify immediately the head of organizational entity of the pregnancy, and the information on the risk of radioactive contamination of a breast-fed child when there is a possibility of radioactive contamination of mother’s body.
- 3.<sup>20[20]</sup> Training programs developed by the head of organizational entity operated on the basis of a licence shall be approved by the licensing authority.

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<sup>18[18]</sup> As written down in Art. 1(10)(a) of the act referred to in ref. 2).

<sup>19[19]</sup> Added by Art. 1(10)(b) of the act referred to in ref. 2).

## Article 12

1. In an organizational entity, a position important for ensuring nuclear safety and radiological protection may be occupied only by an individual possessing an appropriate authorization issued by the Agency's President.
  - 1a.<sup>21[21]</sup> Application for granting the authorization referred to in paragraph 1 may be submitted by the head of organizational entity that plans to employ the individual on the position requiring such authorization, or by the head of a superior entity.
  - 1b.<sup>21</sup> Costs involved in obtaining the authorization shall be borne by the applicant.
  - 1c.<sup>21</sup> Training of the individuals applying for the authorization referred to in paragraph 1 shall be conducted by the entities, which have been entered into the register of the Agency's President.
- 2.<sup>22[22]</sup> The Council of Ministers shall establish by regulation:
  - 1) types of the positions referred to in paragraph 1,
  - 2) detailed conditions and procedures for the issuance by the Agency's President of authorizations for radiological protection inspectors and individuals occupying positions referred to in paragraph 1, procedures for establishing the examination board, its working procedures, procedures for conducting the exams, standard form of authorization certificate, procedure for payment of exam charge, the amount of such charge and the remuneration for the examination board members,
  - 3) required scope of training, requirements for the entities conducting the training, training curriculum and organizational forms, and also the procedure for obtaining the entry into the register referred to in Art. 7(6a) and into the register referred to in paragraph 1c,
  - 4) overall scope of duties and powers of a radiological protection inspector, whose authorization is issued by the Agency's President,
    - for the purpose of ensuring the compliance with the requirements of nuclear safety and radiological protection in the organizational entity, and also for appropriate exercising of internal supervision over the compliance with these requirements.
- 3.<sup>22</sup> Minister competent for health issues shall establish by regulation:
  - 1) detailed conditions and procedures for the Chief Sanitary Inspector for issuing authorizations to radiological protection inspectors in laboratories using X-ray devices for the purposes of medical diagnostics, interventional radiology, surface radiotherapy and non-oncological diseases radiotherapy, including the procedures for establishing the examination board, its

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<sup>20[20]</sup> As written down in Art. 1(10)(e) of the act referred to in ref. 2).

<sup>21[21]</sup> As written down in Art. 1(11)(a) of the act referred to in ref. 2).

<sup>22[22]</sup> As written down in Art. 1(11)(b) of the act referred to in ref. 2).

working procedures, procedures for conducting the exams, standard form of authorization certificate, procedure for the payment of exam charge, the amount of such charge and the remuneration for the examination board members,

- 2) required scope of training, requirements for the entities conducting the training, including training curriculum and organizational forms, and also the procedure for obtaining the entry into the register referred to in Art. 7(6b),
- 3) overall scope of duties and powers of a radiological protection inspector, whose authorization is issued by the Chief Sanitary Inspector,

- for the purpose of ensuring the compliance with the requirements of nuclear safety and radiological protection in the organizational entity.

### **Article 13**

1. Dose limits shall include the sum total of the doses from external and internal exposures.
2. Dose limits shall not include the exposures to natural radiation, provided that such exposures have not been enhanced by human activity; in particular they shall not include the exposures resulting from radon in homes, natural radioisotopes incorporated in human bodies, cosmic radiation on ground level and above-ground exposures to radioisotopes present in the undisturbed earth's crust.

### **Article 14**

1. Sum of all ionizing radiation doses to the workers and general public, incurred jointly from all kinds of practices, shall not exceed, subject to Articles 19(1), 20(2) and 20(3), the dose limits established in the regulations issued under Article 25(1).
- 2.<sup>23[23]</sup> Dose limits shall not apply to the individuals exposed to ionizing radiation for medical purposes, referred to in Article 33a(1).

### **Article 15 (repealed)<sup>24[24]</sup>**

### **Article 16**

1. In the case of accidental exposure, the assessment shall include the ionizing radiation dose received by exposed individual. Such exposure shall not include the situation referred to in Article 20(1).

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<sup>23[23]</sup> As written down in Art. 1(12) of the act referred to in ref. 2).

<sup>24[24]</sup> By Art. 1(13) of the act referred to in ref. 2).

2. Assessment of the exposure referred to in paragraph 1 shall be performed by the head of organizational entity on whose site the exposure has occurred, or by the Agency's President if the identification of such organizational entity is not possible.

### **Article 17**

1. To match the methods of exposure assessment to the expected exposure level for workers employed in organizational entities, two categories of workers shall be established, depending on the magnitude of exposure:
  - 1)<sup>25[25]</sup> category A, for workers who may be exposed to an effective dose exceeding 6 mSv (mili-sievert) in one year or to an equivalent dose exceeding one-third of the dose limits for eye lens, skin and limbs, established in the regulations issued under Article 25(1);
  - 2)<sup>25</sup> category B, for workers who may be exposed to an effective dose exceeding 1 mSv in one year or to an equivalent dose exceeding one-twentieth of the dose limits for eye lens, skin and limbs, established in the regulations issued under Article 25(1), and who are not included in category A.
2. Occupational exposure assessment shall be based on control measurements of individual doses, or on dosimetric measurements in the workplace.
3. Exposure assessments for category A workers shall be based on systematic individual dose measurements, and if such workers may be exposed to internal contamination having impact on the effective dose level for this category, such workers shall be subject also to internal contamination measurements.
- 4.<sup>26[26]</sup> Exposure assessment for category B worker shall be based on dosimetric measurements in the workplace, performed in a manner which allows the verification of their assignment to this category, unless the head of organizational entity decides to subject them to systematic individual dose measurements. Licence conditions may include the requirement to perform exposure assessment for category B workers employed at tasks covered by this licence, based on individual dose measurements.
- 5.<sup>26</sup> If individual dose measurement is impossible or inappropriate, the assessment of individual dose received by category A worker may be made on the basis of individual dose measurement results for other exposed workers belonging to this category, or on the basis of dosimetric measurements in the workplace.
6. Classification of occupationally exposed workers into category A or B shall be done by the head of organizational entity, according to the expected level of exposure of these workers.

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<sup>25[25]</sup> As written down in Art. 1(14)(a) of the act referred to in ref. 2).

<sup>26[26]</sup> As written down in Art. 1(14)(b) of the act referred to in ref. 2).

7. As regards the ability to perform the tasks in the category A worker's group, the following medical classification shall be established: able, able under certain conditions, unable.
- 7a.<sup>27[27]</sup> Medical classification of the category A worker shall be done by an authorized medical practitioner, who exercises medical supervision over this worker.
8. Worker shall not be employed in a specified position within category A if an authorized medical practitioner issues a certificate stating that this worker is unable to perform such job.

#### **Article 18** <sup>28[28]</sup>

1. To adapt the actions and measures used for radiological protection of workers to the magnitude and type of potential exposure, the head of organizational entity shall introduce the following classification of workplace sites:
  - 1) controlled areas, in which there is a possibility of receiving doses established for category A workers or of radioactive contamination spreading, or a possibility of occurrence of large variations in ionizing radiation dose rates,
  - 2) supervised areas, in which there is a possibility of receiving doses established for category B workers and which have not been classified as controlled areas.
2. The responsibility for the compliance with requirements established in the regulations for controlled and supervised areas, issued under Article 25(2), shall rest with the head of organizational entity, who shall undertake appropriate actions to fulfill these requirements after consulting the radiological protection inspector and the occupational medicine practitioner.

#### **Article 19**

- 1.<sup>29[29]</sup> In special cases, excluding radiological emergencies, category A workers, willingly and with the Agency's President consent, may receive the doses established by the Agency's President, which exceed the dose limit values, if this is necessary to perform a specified task, in a specified workplace and in a specified time.
- 2.<sup>29</sup> Exposure referred to in paragraph 1 shall be prohibited for apprentices, students and pregnant females, and if the exposure involves a probability of radioactive contamination of their bodies - also breast-feeding female workers.
- 3.<sup>29</sup> Head of organizational entity shall justify the necessity of exposure referred to in paragraph 1 and shall discuss the situation in advance with interested volunteer workers or their representatives, as well as with authorized medical practitioner and radiological protection inspector. Head of

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<sup>27[27]</sup> Added by Art. 1(14)(c) of the act referred to in ref. 2).

<sup>28[28]</sup> As written down in Art. 1(15) of the act referred to in ref. 2).

<sup>29[29]</sup> As written down in Art. 1(16) of the act referred to in ref. 2).

organizational entity shall also inform the interested volunteer workers of the risks involved in the exposure referred to in paragraph 1, and of necessary precautionary measures.

4. Proceedings referred to in paragraphs 1 and 3 shall be documented in a written form.
5. Doses received by the worker, referred to in paragraph 1, shall be registered separately in the records referred to in Article 30(3). Such exposures shall not result in the worker's withdrawal from normal tasks or in his transfer to another position against his will, subject to Article 31(2) and 31(3).

## **Article 20**

- 1.<sup>30[30]</sup> The individual participating in the elimination of radiological emergency consequences and in intervention actions, during such activities shall not receive a dose exceeding the annual dose limit for occupational exposure, with the exception of the situation of emergency exposure situation, referred to in paragraphs 2 and 3.
- 2.<sup>30</sup> In the situation of emergency exposure, resulting from the actions aimed to prevent:
  - 1) serious health detriment,
  - 2) major irradiation of a significant number of people,
  - 3) large-scale disaster,- all possible efforts should be taken to protect the individual participating in such actions against receiving an effective dose exceeding 100 mSv.
- 3.<sup>30</sup> Individual participating in saving of human life may receive an effective dose exceeding 100 mSv, but all possible efforts should be taken to protect this individual against receiving an effective dose exceeding 500 mSv.
4. Actions referred to in paragraphs 2 and 3 shall be undertaken exclusively by volunteers, who have been informed in advance of the health risks involved, and who subsequently voluntarily undertook the decision to participate in such actions. Resignation from participation in such activity shall not constitute the grounds for the termination of employment contract.
5. During the actions referred to in paragraphs 1-3, all possible means shall be undertaken to ensure proper protection of the individuals participating in these actions, as well as the assessment and recording of the doses received by them. After completion of these actions, the individuals involved shall obtain the information on doses received and on the resulting health risks.
6. Individuals who have received the doses referred to in paragraphs 1 and 2, shall not be withdrawn from further employment in exposure conditions nor transferred to other positions against their will, subject to Art. 31(2) and 31(3).

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<sup>30[30]</sup> As written down in Art. 1(17) of the act referred to in ref. 2).

7. Individual who has received the dose referred to in paragraph 3 shall be referred by the head of organizational entity for medical examinations. The provisions of Article 31(2) and 31(3) shall apply accordingly.

#### **Article 21**

1. Head of organizational entity shall keep the register of individual doses received by category A workers, based on the results of measurements and assessments referred to in paragraph 2.
- 2.<sup>31[31]</sup> Individual dose measurements and the assessment of doses resulting from internal contamination shall be performed by the entities possessing appropriate accreditation obtained on the basis of separate regulations, subject to paragraphs 4 and 5.
3. Central register of the doses referred to in paragraph 1 shall be kept by the Agency's President, based on measurement results referred to in paragraph 2, obtained from the head of organizational entity.
- 4.<sup>32[32]</sup> Until individual dose measurements and the measurements for the assessment of internal contamination doses have been performed by an accredited entity, radiological protection inspector shall perform a provisional operational assessment of individual doses received by external workers, who conduct activities on the controlled area in the organizational entity.
- 5.<sup>32</sup> Until individual dose measurements and the measurements for the assessment of internal contamination doses have been performed by an accredited entity, radiological protection inspector may perform a provisional operational assessment of individual doses received by the workers working in the organizational entity, other than external workers.

#### **Article 22<sup>33[33]</sup>**

Head of organizational entity, prior to employing a worker in radiation exposure conditions, shall apply to the Agency's President for the information from the central dose register on the doses received by this worker in the calendar year in which the application is submitted, and also in the period of the four preceding calendar years.

#### **Article 23**

1. Occupational activities involving the presence of natural radiation leading to an increase of the exposure of workers or the population, which is significant from radiological protection viewpoint, shall require an assessment of this exposure.
2. Exposure assessment shall be based on dosimetric measurements in the workplace.

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<sup>31[31]</sup> As written down in Art. 1(18)(a) of the act referred to in ref. 2).

<sup>32[32]</sup> As written down in Art. 1(18)(b) of the act referred to in ref. 2).

<sup>33[33]</sup> As written down in Art. 1(19) of the act referred to in ref. 2).

3. The activities referred to in paragraph 1 shall include in particular the work performed in:
  - 1)<sup>34[34]</sup> mines, caves and other underground sites, and also in health resorts and spas;
  - 2) aviation, excluding the tasks performed by the ground personnel.
- 4.<sup>35[35]</sup> The Council of Ministers may establish by regulation:
  - 1) types of occupational activities involving the presence of natural radiation leading to the increase of the exposure of workers or population, which is significant from radiological protection viewpoint, other than those referred to in paragraph 3,
  - 2) methods of assessment of the exposure resulting from occupational activities referred to in paragraph 1, procedures for reducing this exposure and other measures aimed at radiological protection of exposed workers and of population,

- taking into account the recommendations of the European Union, regulations issued under Art. 25(1), the characteristic features of the occupational activity and those of the exposed worker's tasks.

#### **Article 23a**<sup>36[36]</sup>

If past activities, in particular those consisting of mining and processing uranium ores and of the accumulation of radioactive sediments from mining waters, result in a subsisting radioactive contamination of the environment which is significant from the viewpoint of nuclear safety and radiological protection, the user of such contaminated site shall establish the borders of this site, shall perform test measurements of the exposure and, if necessary, shall control the access to this site, and also the use of soil and buildings on this site.

#### **Article 24**

Exposure of the population as a whole, due to the activities involving ionizing radiation, shall be regularly assessed by the Agency's President and shall be described in the report referred to in Article 110(13).

#### **Article 25**

The Council of Ministers shall establish by regulations:

- 1)<sup>37[37]</sup> ionizing radiation dose limits and indicators allowing the determination of those doses, used in exposure assessment, and the method and frequency of the assessment of exposure of workers and of general public, taking into account – while defining dose limits for the

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<sup>34[34]</sup> As written down in Art. 1(20)(a) of the act referred to in ref. 2).

<sup>35[35]</sup> As written down in Art. 1(20)(b) of the act referred to in ref. 2).

<sup>36[36]</sup> Added by Art. 1(21) of the act referred to in ref. 2).

<sup>37[37]</sup> As written down in Art. 1(22) of the act referred to in ref. 2).

workers – the doses for apprentices, students and female breast-feeding workers, and in case of pregnant females – restrictions resulting from the potential exposure of the fetus;

- 2) basic requirements for controlled and supervised areas, including the means for their designation, conditions for access and leaving these areas by workers and other persons, and conditions which must be fulfilled for dosimetric measurements in the workplaces within these areas, in particular the scope of measurement program and criteria for choosing the persons who conduct such measurements.

#### **Article 26**

Head of organizational entity employing the workers for tasks involving exposure, shall:

- 1) provide such workers with medical care, necessary means of individual protection and dosimetric equipment, as appropriate for the exposure conditions;
- 2) ensure that individual dose measurements or dosimetric measurements in the workplace are performed according to Article 17(3) and 17(4), and the records of pertinent data are maintained.

#### **Article 27**

1. Dosimetric equipment used for exposure control and assessment, which is not covered by obligatory metrological inspection established in the regulations on standards and measurements, should possess a calibration certificate.
2. Calibration certificate referred to in paragraph 1 shall be issued by the measurement laboratory, which possesses an accreditation issued on the basis of separate regulations.

#### **Article 28**

The Council of Ministers shall establish by regulations the requirements for:

- 1) individual dose records, taking into account the exposures referred to in Articles 19(1) and 20(1), the results of dosimetric measurements, the period during which measurement results shall be preserved, and organizational means for data collection, transfer and availability,
- 2) dosimetric equipment, taking into account technical requirements for its use in normal circumstances and during radiological emergencies.

#### **Article 29** <sup>38[38]</sup>

1. Head of organizational entity shall ensure that the external workers shall have protection equivalent to the protection provided to workers employed by this organizational entity.

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<sup>38[38]</sup> As written down in Art. 1(23) of the act referred to in ref. 2).

2. To each external worker the Agency's President shall issue an individual document of external worker's exposure (dosimetric passport), in which the external employer and the head of organizational entity shall enter the information established in the regulations issued under paragraph 3(2).
3. The Council of Ministers shall establish by regulations:
  - 1) detailed description of the duties of the head of organizational entity, external employer and external worker from the viewpoint of ionizing radiation protection of external workers exposed during work in controlled area, taking into account protection measures used for the workers of the organizational entity,
  - 2) information entered in the dosimetric passport by the head of organizational entity, external employer and authorized medical practitioner, with a view to protect the worker against radiation,
  - 3) procedure for issuing the dosimetric passport and its standard form, taking into account the necessity of giving an individual number to each passport, and ensuring the entry of information referred to in paragraph 2.

### **Article 30**

1. Responsibility for medical surveillance of category A workers shall lie with the head of organizational entity and with the authorized medical practitioner, who shall have access to the information necessary to issue a certificate on the workers' ability to perform specified tasks, including the information on environmental conditions in the workplace.
2. Medical surveillance referred to in paragraph 1 shall include a preliminary examination prior to the employment to ascertain whether the individual may be employed as category A worker, and periodic medical examinations, performed at least once a year, to verify whether the worker may continue to perform his duties.
3. For each category A worker the authorized medical practitioner shall set up a medical record, which shall be maintained and updated thorough the whole period of employment as a worker in this category. This record shall be preserved until the worker attains the age of 75 years, but at least for 30 years after the termination of work in occupational exposure conditions.
4. Medical record shall include the information on the type of work performed, the results of medical examinations performed prior to employment as category A worker, the results of periodic examinations, and the dose records referred to in Article 21(1).
5. Following the termination of work in occupational exposure conditions, authorized medical practitioner may order further health surveillance, if this shall be deemed necessary for the worker's health protection.

### **Article 31**

1. In the proven case of exceeding of any of the dose limits established in the regulations issued under Article 25(1), head of organizational entity shall refer the worker for an obligatory medical examination.
2. Further work in occupational exposure conditions shall require the consent of an authorized medical practitioner.
3. In the event that the authorized medical practitioner refuses to allow further employment in occupational exposure conditions, the provisions of Labor Law relevant for workers with recognized symptoms of an occupational disease shall apply accordingly.

### **Article 32** <sup>39[39]</sup>

Worker shall have the right to appeal to the court of law for labor against the medical decisions referred to in Articles 17(7a), 17(8) and 31(2).

### **Article 32a** <sup>40[40]</sup>

Provisions of Articles 10, 11, 14, 17, 21, 22, 26 and 29-32 shall apply accordingly to the students and apprentices.

### **Article 33**

1. To ensure national nuclear safety and radiological protection in ionizing radiation applications in normal circumstances and in radiological emergency situations, the costs of activities referred to in paragraph 2 may be partially reimbursed from national budget in the form of a special purpose subsidy, hereinafter referred to as “the subsidy.”
2. <sup>41[43]</sup> The subsidy may be used for:
  - 1) operating nuclear research reactors,
  - 2) decommissioning nuclear research reactors,
  - 3) operating storage facilities for spent nuclear fuel from nuclear research reactors,
  - 4) maintaining and developing the nuclear safety and radiological protection programs, related to the use of ionizing radiation beams for medical purposes other than programs of diagnostics and radiotherapy by the scientific and R&D entities,

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<sup>39[39]</sup> As written down in Art. 1(24) of the act referred to in ref. 2).

<sup>40[40]</sup> Added by Art. 1(25) of the act referred to in ref. 2).

<sup>41[43]</sup> As written down in Art. 1(26)(a) of the act referred to in ref. 2); shall enter into force on 1 January 2005.

- 5) conducting radiological protection, nuclear safety and physical protection activities, to ensure the safety and security of nuclear facilities and physical protection of nuclear materials in organizational entities located in Otwock-Świerk, and also radiological protection and security of the National Radioactive Waste Storage facility,
  - 6) assessing the impact of nuclear facilities, sites of uranium and thorium mining, and radioactive waste storage facilities on environment, and conducting the tests and analyses necessary for these assessments,
  - 7) performing measurements of ionizing radiation dose rates or of radioactive contamination thorough the country,
  - 8) maintaining ionizing radiation standards and maintaining and developing quality assurance systems for the calibration of dosimetric instruments,
  - 9) developing and applying analytical models for the radiation situation assessment, necessary for undertaking appropriate measures in case of radiological emergency, and developing the models necessary for the analyses underlying the justification of intervention measures,
  - 10) accrediting the laboratories which conduct the activities referred to in Articles 21(2) and 27(2),
  - 11) investments supporting the activities referred to in paragraphs 1-10.
3. The subsidy shall be granted by the Agency's President, from financial resources provided for this purpose in the Appropriation Act.
  - 4.<sup>42[45]</sup> The subsidy amount shall not be greater than the costs incurred while pursuing pertinent activities, reduced by the proceeds from these activities and means obtained from other sources, and moreover, in case of activities referred to in paragraph 2 subparagraphs 1, 4, 5, 8 and 10, shall not exceed 85% of overall costs of conducted activities.
  5. The Council of Ministers shall establish by regulation detailed rules and procedures for allocation, accounting and return of subsidies, including a standard application form for the allocation of subsidy and necessary enclosures, and the method of documenting the implementation of the task and of expenditures covered by the subsidy.

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<sup>42[45]</sup> As written down in Art. 1(26)(b) of the act referred to in ref. 2); shall enter into force on 1 January 2005.

## Chapter 3 a <sup>43[46]</sup>

### Ionizing radiation used for medical purposes

#### Article 33 a

1. Ionizing radiation used for medical purposes includes the exposures of:
  - 1) the patients, resulting from medical examinations and therapy, including preliminary and periodic medical examinations of the workers,
  - 2) the individuals undergoing screening examinations using ionizing radiation,
  - 3) healthy individuals or patients participating in medical research experiments,
  - 4) the individuals undergoing examinations using ionizing radiation for medico-legal purposes, when not necessitated by health reasons,
  - 5) the individuals who, outside their professional duty, knowingly and willingly support and comfort the patients.
2. Exposures referred to in paragraph 1 shall require justification. Justification shall be based on the expected net health benefit to an individual or the society, outweighing the health detriment that might result from the exposure.
3. Proper justification shall require the use of diagnostic or therapeutic radiological procedure of a proven or generally recognized effectiveness in the specified clinical circumstances. Justification process shall also involve the assessment of the benefits and risks related to alternative procedures serving the same purposes and leading to a smaller, or none, ionizing radiation exposure.
4. Patient's referral for a specific examination involving ionizing radiation exposure shall result from a justified conviction of the medical practitioner or other person authorized to issue such referral, that this examination shall furnish information enabling a correct diagnosis or exclusion of the disease, evaluation of its course and of the therapy's progress, as well as from the conviction that these benefits shall outweigh potential health detriments, which may result from ionizing radiation exposure.
5. Referral referred to in paragraph 4 may be given after ascertaining that equivalent information may not be obtained by other alternative methods, non-invasive and not involving ionizing radiation exposure, as well as from previous examinations using ionizing radiation.
6. Examination involving ionizing radiation exposure, which has not been justified as provided for in paragraphs 3 - 5, may be performed in special cases, to be evaluated on a case-by-case basis.

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<sup>43[46]</sup> Added by Art. 1(27) of the act referred to in ref. 2).

7. Examination involving ionizing radiation exposure, performed and justified as provided for in paragraph 6, shall be recorded in the patient's medical records. This shall apply in particular to the exposure for medico-legal purposes.
8. In the event of circumstances precluding or restricting the extent of the possible use of radiological procedure for the patient, although the procedure itself is generally justified, the decision to desist from the implementation of the procedure or on the scope of this implementation shall be taken by the referring physician (prescriber) or the practitioner performing the procedure.
9. Medical ionizing radiation exposures resulting from the procedure which has not been justified as provided for in paragraphs 3 - 5, shall be prohibited, subject to paragraph 6.

#### **Article 33 b**

1. Referral for the therapy involving ionizing radiation shall be issued by the oncologist or medical specialist in the field appropriate for the type of the disease, after considering the justification of other therapeutic methods, resulting from the nature of the disease, patient's condition and possible contraindications for radiotherapy.
2. Decision to implement the therapy and on its extent, or to waive such therapy, shall be taken by the specialist in oncological radiotherapy, basing on:
  - 1) prognosis for the success of therapy;
  - 2) disease nature and advancement;
  - 3) necessity for another treatment, either simultaneous or substitute;
  - 4) health status of patient;
  - 5) possible contraindications for radiotherapy.
3. Prescriber referring the patient for the examination or therapy involving ionizing radiation exposure shall justify his /her decision in the referral. Practitioner performing the examination or therapy shall evaluate this justification and shall be responsible for the choice of appropriate procedure and its correct implementation.

#### **Article 33 c**

1. Appropriate examination or therapy involving ionizing radiation exposure shall require the optimization of the patient's radiological protection against undesirable effects of the exposure.
2. In X-ray diagnostics and in nuclear medicine procedures, taking into account economic and social factors, the effective doses shall be kept at the lowest possible level, which ensures that the result will have a presumed diagnostic value. Optimization of the patient's radiological protection shall

be implemented also by reducing to the minimum the procedures, which would be unnecessarily repeated and incorrectly performed.

3. In interventional radiology, in addition to the provisions in paragraph 2, all necessary measures shall be taken to prevent skin and underlying tissue radio-damage resulting from long-term localized exposure, in particular - to high dose-rate X-ray beam.
4. In radiotherapy the optimization of patient's radiological protection shall require a maximal possible protection of healthy organs and tissues against the radiation in target volume for irradiation with prescribed therapeutic dose, applied according to the timetable which ensures maximal effectiveness of the therapy (ability to cure the disease).
5. Individuals, who perform and supervise medical examination and treatment procedures, shall enhance their qualifications in accordance with the provisions in Art. 33.i (2).
6. Children and females of childbearing age, pregnant and breastfeeding females, as well as the family members and individuals surrounding the patients who undergo a therapy involving radiopharmaceuticals, shall be subject to special protection related to the exposure in diagnostic and therapeutic procedures.
7. Health care entities, which perform procedures or therapy involving radiotherapy, nuclear medicine, interventional radiology and X-ray diagnostics, shall take appropriate measures to prevent medical radiological accidents. For this purpose the control of physical parameters of radiological equipment, and of internal and external clinical audits shall be performed, and quality management system shall be implemented.
8. Health care entities shall bear the costs of performing internal and external audits referred to in paragraph 7.
9. Minister competent for health issues shall establish by regulation the conditions for safe use of ionizing radiation for all types of medical exposure referred to in Article 33a(1), with the aim to ensure high quality of medical services and taking into account the standards valid in the European Union. These conditions shall include:
  - 1) principles and methods for good medical practices, aimed at restricting the doses received by the patients in X-ray diagnostics, radioisotope diagnostics, and interventional radiology, including the reference levels and physical parameters for X-ray examinations prerequisite for the conformance with good medical practices;
  - 2) requirements and detailed rules for the implementation of quality management system in X-ray diagnostics, interventional radiology, nuclear medicine and radiotherapy;
  - 3) requirements for special training for the individuals who perform and supervise medical examination and therapeutic procedures;

- 4) special rules for ionizing radiation exposures in diagnostics and therapy involving children, females in childbearing age, and pregnant and breastfeeding females;
- 5) rules for protection against excessive exposure of family members and people in the vicinity of the patients, following the therapy involving the use of radiopharmaceuticals;
- 6) detailed requirements for screening tests and medical research experiments resulting from the nature of medical exposures;
- 7) detailed rules for prevention of radiological accidents in radiotherapy, interventional radiology and X-ray diagnostics, and also the ways and procedures applied after the occurrence of such accidents;
- 7) dose limits for the individuals referred to in Article 33a (1) (3) and 33a (1)(5);
- 8) rules for controlling physical parameters of the equipment, and internal and external clinical audits to verify the compliance with the requirements for radiological protection of the patient.

#### **Article 33d.**

1. Activities involving medical exposure to ionizing radiation, consisting of oncological radiotherapy services, including cancer treatments using radiopharmaceuticals, shall require the consent of the minister competent for health issues.
2. The consent referred to in paragraph 1 may be granted to the entity, which:
  - 1) has an appropriate number of suitably qualified personnel,
  - 2) has radiological equipment necessary for performing diagnostic and therapeutic procedures,
  - 3) applies appropriate medical treatment procedures,
  - 4) has a quality management system for medical services involving ionizing radiation.
3. The consent referred to in paragraph 1 shall be granted after obtaining:
  - 1) positive opinion of the national consultant for oncological radiotherapy or national consultant for nuclear medicine,
  - 2) positive opinion of the regional sanitary inspector.
4. The consent may be revoked permanently or temporarily, on the request of the commission referred to in Article 33g(1)(1) or 33g(1)(2), if the health care entity does not fulfill the requirements established in the regulations issued under paragraph 5.
5. Minister competent for health issues shall establish by regulation the minimal requirements for the entities seeking the consent referred to in paragraph 1, concerning the diagnostic and therapeutic radiological equipment, supplementary equipment, number of personnel and their qualifications. The requirements shall also include the scope of documentation required for

granting the consent referred to in paragraph 1, from the viewpoint of safety of the personnel and the patients.

### **Article 33e**

1. Activities involving medical exposure to ionizing radiation within the procedures for X-ray diagnostics, non-cancerous diseases diagnostics and treatment, and palliative treatments using radiopharmaceuticals and interventional radiology procedures, shall require the consent of the regional sanitary inspector, subject to paragraph 2.
2. In the case of health care entities subjected or subordinated to, or supervised or established by the Minister of National Defense, the consent referred to in paragraph 1 shall be granted by the commander of military preventive medicine center, and in case of medical entities subjected, subordinated to, or supervised or established by the minister competent for home affairs – by the sanitary inspector of the Ministry for Home Affairs and Administration.
3. Consent referred to in paragraphs 1 and 2 may be granted to the entity, which:
  - 1) has an appropriate number of appropriately qualified personnel,
  - 2) holds radiological equipment necessary for the performance of diagnostic and therapeutic procedures,
  - 3) applies appropriate medical procedures,
  - 4) has a quality management system for medical services within the scope referred to in paragraph 1.
4. Consent referred to in paragraphs 1 and 2 shall be granted after obtaining the opinion of appropriate regional consultant for radiology – imaging diagnostics or nuclear medicine.
5. Regional consultant shall grant the opinion referred to in paragraph 4 not later than 14 days after receiving the request for the opinion from the consent-granting authority.
6. For health care entities performing procedures for X-ray diagnostics, interventional radiology, non-oncological diseases diagnostics and therapy, minister competent for the health issues shall establish by regulation the minimal requirements concerning the radiological equipment, supplementary equipment, number of personnel and their qualifications, and also the scope of documentation required for granting the consent referred to in paragraphs 1 and 2, from the viewpoint of the safety of the personnel and the patients.
7. Paragraphs 1 - 5 shall not apply to the stomatologic X-ray devices, nor to the equipment used solely for bone densitometry.

### **Article 33f**

The authority granting the licenses and consents referred to in Article 5(4), Article 33d(1) and Article 33e (1) and 33e(2) shall dispatch them immediately to the Chief Sanitary Inspector, who keeps central records of such documents.

### **Article 33g**

The commissions for procedures and external clinical audits (further called “the commissions”) shall be established for the following areas:

- 1) oncological radiotherapy,
  - 2) nuclear medicine,
  - 3) radiology - imaging diagnostics and interventional radiology.
2. The commissions shall consist, as appropriate, of:
- 1) national consultants for oncological radiotherapy, nuclear medicine and radiology – imaging diagnostics,
  - 2) experts proposed by Polish Medical Association for Radiology, Polish Association for Nuclear Medicine, and Polish Association for Medical Physics,
  - 3) representatives of the minister competent for health issues, Minister of National Defense, and minister competent for home affairs.
3. Commissions shall be chaired by appropriate national consultants referred to in paragraph 2(1), and the commission members shall be nominated and recalled by the minister competent for health issues.
4. Commissions shall establish their working rules, to be approved by the minister competent for health issues.
5. Commissions shall develop, in a written form, standard radiological procedures for justified medical exposures recognized as standard exposures.
6. On the basis of procedures referred to in paragraph 5, health care entity shall develop documented working procedures, required by the quality management system.
7. List of standard procedures shall be published in the Official Journal of the Ministry of Health.
8. Standard procedures shall be evaluated in the case of the appearance of new data related to their effectiveness or impacts.
9. Procedures, deemed to be insufficiently effective on the basis of evaluation referred to in paragraph 8, shall be removed from the list referred to in paragraph 7.

10. Commissions shall evaluate the new types of ionizing radiation's medical applications, which, subsequent to their justification, may be introduced into the list referred to in paragraph 7.
11. Commissions may request a temporary or permanent revocation of the consent for rendering by the health care entity the services of oncological radiotherapy, nuclear medicine and radiology – imaging diagnostics, and interventional radiology, in the case when the entity does not fulfill basic quality requirements for the services and patients' safety, which are consistent with the regulations issued under Articles 33c(9), 33d(5) and 33e(6).
12. In the case of request for temporary revocation of the consent, appropriate commission shall establish the scope of the activities, which the health care entity is obliged to undertake for the renewal of the consent.
13. Failure to implement the activities referred to in paragraph 12 shall result in the request for permanent revocation of the consent.
14. At least once in every 4 years the commissions shall perform an external clinical audit, including the review of the correctness of the procedures applied within rendered services, and the personnel's qualifications, concerning also the area referred to in Art.33i, and also the issues related to the equipment, the premises and the quality management system.
15. Minister competent for health issues shall establish by regulation the detailed requirements for the form and content of the standard and working procedures referred to in paragraphs 5 and 6, taking into account the European Union's recommendations.

#### **Article 33h**

Medical experiments involving ionizing radiation may be performed exclusively within the framework of scientific research or controlled clinical research performed by medical research institutions.

#### **Article 33i**

1. National consultants in the field of oncological radiotherapy, nuclear medicine, radiology – imaging diagnostics, medical physics, medical engineering, and in these medical areas where interventional radiology procedures are performed, while developing the specialized training programs shall include the training in the issues of patient's radiological protection, in the scope consistent with European Union's recommendations, and shall consult its curriculum with the Center referred to in Article 33j(1).
2. Experts in the fields of medicine referred to in paragraph 1, and auxiliary medical personnel, shall be required to undergo permanent training in the radiological protection of the patient, in the form of participation in post-degree training and in the forms established by appropriate national

consultants, according to the principles established in the regulations for professional advancement in medical professions.

### **Article 33j**

1. Minister competent for health issues shall establish the National Center for Radiological Protection in Medicine, hereinafter referred to as “the Center”, to be operated in the form of a budgetary institution.
2. Organizational form, mode of operation and detailed tasks of the Center shall be established by regulation by the minister competent for health issues, taking into account the monitoring of radiological protection status, which is necessary for medical applications of ionizing radiation.
3. The tasks of the Center shall include:
  - 1) monitoring of the radiological protection status which results from medical applications of ionizing radiation, based on:
    - a. control activities of the National Sanitary Inspection,
    - b. reports of the commissions,
    - c. information gained from individual dose control, assessments of the population’s exposure to radiation sources used in medicine,
    - d. scientific research,
  - 2) submitting annual reports to the minister competent for health issues, on the assessment of the implementation of the requirements for safety in medical applications of ionizing radiation,
  - 3) ensuring topical assistance and expert consulting for the organizational units for radiation hygiene in regional sanitary-epidemiological stations, in the area of medical applications of ionizing radiation,
  - 4) developing the methods and procedures for the tests of the technical parameters of the radiological equipment,
  - 5) issuing the opinions on the draft regulations in the area of the radiological protection of the patient,
  - 6) participation in investigative commissions to investigate the causes of accidents resulting from the medical applications of ionizing radiation,
  - 7) consultations in the area of training programs in radiological protection, addressed to medical practitioners and specialists in various fields,
  - 8) cooperation with the Agency’s President, Chief Sanitary Inspector, Chief Sanitary Inspector for Polish Military Forces, and Chief Sanitary Inspector for the Ministry for Home Affairs and Administration,

- 9) conducting every 5 years periodical assessments of the population dose, resulting from the medical applications of ionizing radiation.
4. The Center may conduct payable activities, consisting of:
  - 1) conducting training activities in the area of radiological protection,
  - 2) drawing up, translating and publishing the training materials,
  - 3) certification of laboratories, which perform the assessments of technical parameters of X-ray diagnostic devices, aimed at the radiological protection of the patients,
  - 4) calibration of the control and measurement instruments used for ionizing radiation measurements for radiological protection purposes.

### **Article 33k**

1. Chief Sanitary Inspector shall maintain a national radiological equipment database.
2. Regional sanitary inspectors, the commanders of military centers for preventive medicine, sanitary inspectors for Ministry for Home Affairs and Administration, and the Agency's President shall deliver to the Chief Sanitary Inspector, at least once a year, the information on the licensed radiological equipment.
3. Minister competent for health issues shall establish by regulation the organizational framework for radiological equipment database, and also the scope of information referred to in paragraph 2 and the procedure for its delivery, taking into account the implementation of appropriate policy to ensure the accessibility of diagnostic and therapeutic services, and also for the management and replacement of radiological equipment.

## **Chapter 4**

### **Nuclear facilities**

#### **Article 34** <sup>44[47]</sup>

1. Nuclear facilities and related buildings and equipment, whose failure or malfunctioning could result in impacts significant from the viewpoint of nuclear safety and radiological protection, shall be subject to obligatory physical protection, as provided in the regulations on the protection of people and property.

#### **Article 35** <sup>45[48]</sup>

1. Obligation to fulfill the requirements of nuclear safety, radiological protection and physical

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<sup>44[47]</sup> As written down in Art. 1(28) of the act referred to in ref. 2).

<sup>45[48]</sup> As written down in Art. 1(29) of the act referred to in ref. 2).

protection of nuclear facility, and also of the buildings and equipment referred to in Article 34, during the stages of siting, design, construction, commissioning and test operation shall lie with the investor, whereas during the stages of regular operation or decommissioning – with the head of operating entity.

- 2.<sup>48</sup> Independently from the investor's duties, the obligation to fulfill the requirements of nuclear safety and radiological protection shall be borne by the other participants in the investment process, according to the scope of their tasks.
3. During nuclear facility design, construction, commissioning and operation, all necessary technical and organizational measures should be applied that, in view of current scientific and technological developments, are necessary to ensure that at all stages of the facility lifetime the exposure of all persons on the site or of other people, and the contamination of the environment, will be as small as reasonably achievable when taking into account economic and social factors, and will not exceed the dose limit values established in the regulations issued under Article 25(1).

### **Article 36**

- 1.<sup>46[49]</sup> Authority competent to issue the decision on construction and development conditions for the site of a future nuclear facility, under the act of Parliament of 7 July 1994 on Land Use Planning (O.J. No 80, Item 717, and of 2004 No 6, Item 41 and No 141 Item 1492) shall issue this decision after obtaining a positive opinion of the Agency's President on nuclear safety and radiological protection matters.
- 2.<sup>47[50]</sup> In the event that a proposed local land-use plan includes a nuclear facility, this plan shall be cleared with the Agency's President, according to the procedure established in the act referred to in paragraph 1.

### **Article 37**

The Agency's President shall issue a licence for construction, commissioning and test operation of a nuclear facility at the investor's request, whereas the licence for regular operation and decommissioning shall be issued at the request of the head of operating entity. The licence shall be a prerequisite for obtaining the permit for nuclear facility construction, operation and dismantling, referred to in the act of Parliament of 7 July 1994 - Construction Law (O.J. of 2003 No 207 Item 2016, with subsequent amendments)<sup>48[51]</sup>.

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<sup>46[49]</sup> As written down in Art. 80 of the act of Parliament of 27 March 2003 on regional planning and development (O.J. no 80, Item 717) which entered into force on 1 July 2003; designation established in Article 1(3) of the act referred to in ref. 2).

<sup>47[50]</sup> Added by Art. 1(30) of the act referred to in ref. 2).

<sup>48[51]</sup> The amendments to this act have been published in O.J. of 2004 No 6 Item 41, No 92 Item 881, No 93 Item 888 and No 96 Item 959.

### **Article 38**

- 1.<sup>49[52]</sup> Regional governor shall establish a restricted use area surrounding the nuclear facility, referred to in the Act of Parliament of 27 April 2001 - Environmental Protection Law (O.J. No 62 Item 627, with subsequent amendments).<sup>50[53]</sup>
2. After consultation with the Agency's President, the minister competent for environmental matters shall establish by regulations detailed rules for the creation of a restricted use area surrounding nuclear facility, indicating relevant restrictions concerning its uses and in particular taking into account the site characteristics and conditions, possible emergency situations and the distribution of ionizing radiation doses at various distances from the facility.
3. The provisions of the act referred to in paragraph 1 shall be applicable to the cases concerning the damage caused by the establishment of restricted use area.

### **Article 39**

The Agency's President shall issue an order to decrease the power output or to stop the operation of a nuclear facility if, in his assessment, further operation of this facility shall endanger nuclear safety. Subsequent increase of power output or start-up of the facility shall require the consent of the Agency's President.

## **Chapter 5**<sup>51[54]</sup>

### **Nuclear materials and technologies**

#### **Article 40**

1. For the purpose of this Chapter, the following terms have the meaning hereby assigned them:
  - 1) nuclear documentation:
    - a. documents related to the origin, status or movement of nuclear materials,
    - b. declarations, notifications and reports submitted to the European Commission, concerning nuclear materials and installations in which nuclear materials have been, are, or will be, used, processed, stored or transported,
    - c. documents concerning the performance of installations referred to in subparagraph b,

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<sup>49[52]</sup> As written down in Art. 58(2) of the act referred to in ref. 42).

<sup>50[53]</sup> The amendments to this act have been published in O.J. of 2001 No 115 Item 1229, of 2002, No 74 Item 676, No 113 Item 984, No 153 Item 1271 and No 233 Item 1957; of 2003 No 46 Item 392, No 80 Items 717 and 721, No 162 Item 1568, No 175 Item 1693, No 190 Item 1865 and No 217 Item 2124; and of 2004 No 19 Item 177, No 49 Item 464, No 70 Item 631, No 91 Item 875, No 92 Item 880, No 96 Item 959 and No 121 Item 1263.

<sup>51[54]</sup> As written down in Art. 1(31) of the act referred to in ref. 2).

- d. design and operational documentation containing basic technical characteristics of the facility, indicated in European Union's regulations related to the nuclear material safeguards,
  - e. declarations and action plans concerning the use of nuclear materials,
  - f. assessments, recommendations, orders and decisions of the European Commission concerning the issues of nuclear material safeguards,
- 2) nuclear materials accountancy – recording, in a way compliant with the requirements for nuclear material safeguards and separately for each material balance area, on the basis of material accounting records, the information on the inventory of source materials and special fissionable materials, in particular on the quantity, type, location, inventory changes and the origin and intended use of these materials;
  - 3) Euratom – European Atomic Energy Community;
  - 4) control of nuclear technologies – measures undertaken to ascertain whether the research and development activities as defined in Article 18(a) of the Additional Protocol, manufacturing activities referred to in Annex I to the Additional Protocol, and the equipment, parts of equipment and materials referred to in Annex II to the Additional Protocol, and also imported or exported nuclear technologies, concern the applications in which nuclear materials are used in a way which does not infringe on the Non-proliferation Treaty;
  - 5) facility – facility as defined in Article 98 (l) of the Agreement;
  - 6) Agreement – Agreement between the Government of the Polish People's Republic and the International Atomic Energy Agency for the application of safeguards in connection with the Treaty on the Non-proliferation of Nuclear Weapons, signed in Vienna on 8 March 1972;
  - 7) Additional Protocol – Protocol additional between the Government of the Republic of Poland and International Atomic Energy Agency to the Agreement between the Government of the Polish People's Republic and the International Atomic Energy Agency for the application of safeguards in connection with the Non-proliferation Treaty, done in Vienna on 30 September 1997 (O.J. of 2003, No 15 Item 145);
  - 8) material balance area – an area within a facility or elsewhere, as defined in Article 98 (m) of the Agreement;
  - 9) nuclear technologies – technologies related to the nuclear fuel cycle, in particular those:
    - a. designed for manufacturing, processing, isotopic enrichment or use of source materials or special fissionable materials in nuclear installations,
    - b. used in the management of high- and medium-activity radioactive waste, which contains special fissile materials,

- c. designed for manufacturing of the equipment or its parts necessary for manufacturing, processing, irradiating or use of source materials, special fissile materials, heavy water, deuterium, tritium or graphite of nuclear purity;
- 10) site – the site as defined in Article 18(b) of the Additional Protocol;
  - 11) Treaty – Treaty on the Non-proliferation of Nuclear Weapons, done in Moscow, Washington and London on 1 July 1968 (O.J. of 1970, No 8 Item 60);
  - 12) nuclear material safeguards – a set of legal and organizational measures and practical arrangements, established in the framework of the Treaty, Agreement, Additional Protocol and Euratom Treaty and in the regulations issued under this treaty, for the purpose of preventing the diversion of nuclear materials intended for peaceful uses to the manufacture of nuclear weapons, other nuclear explosive devices or to unknown purposes.

#### **Article 41**

1. Nuclear materials, with the exception of uranium and thorium ores, shall be subject to physical protection.
2. Head of organizational entity engaged in activities involving nuclear materials shall establish a physical protection system, approved by the Agency's President.
3. The Agency's President shall conduct periodical control of the system referred to in paragraph 2.

#### **Article 41a**

1. The Agency's President shall fulfill the obligations of the Republic of Poland in the area of nuclear materials safeguards and control of nuclear technologies.
2. The Agency's President shall keep a national system for gathering and storage of data related to the execution of tasks referred to in paragraph 1, and shall determine, on a national scale, quantitative inventory of source materials and special fissile materials.
3. For the purpose of executing the tasks referred to in paragraph 1, the Agency's President shall conduct control activities, which cover:
  - 1) source materials and special fissile materials subject to nuclear material accountancy, manufactured, processed, stored or transported on the Republic of Poland's territory, with the exception of materials in transit, which are subject to the safeguards,
  - 2) nuclear documentation,
  - 3) premises and facilities located on the site,
  - 4) locations off the site, in particular the locations of past mining and refinement of uranium and thorium ores, and locations unconnected with the site but used for the disposal of radioactive waste which may contain special fissile materials,

- 5) plans and programs for research and development activities in the area of nuclear technologies,
  - 6) manufacturing of the parts of equipment and of equipment and materials referred to in Annex I to the Additional Protocol,
  - 7) import and export of equipment, parts of equipment and materials referred to in Annex II to the Additional Protocol.
4. Control of materials referred to in paragraph 3(1) shall be terminated upon their usage in final products designed for non-nuclear purposes, in the form preventing their retrieval, and also upon their consumption or dilution in a way which from the viewpoint of safeguards is sufficient to consider these materials to be practically irretrievable.
  5. Control referred to in paragraph 3(1-4) shall have the form of an inspection performed by regulatory inspectors and also of the examination of the copies of nuclear documentation and reports submitted to the Agency's President by the head of organizational entity.
  6. Control referred to in paragraph 3(5-7) shall have the form of examination of the information obtained by the Agency's President in accordance with the regulations issued under Article 42(1).
  7. Provisions of paragraphs 1 and 3(7) shall not infringe on the provisions for the foreign trade in goods, technologies and services of strategic importance for national security, and also for the preservation of international peace and safety.
  8. In matters concerning the control of research and development activities in the area of nuclear technologies, and in particular the long-term plans for such activities, the Agency's President shall cooperate with the minister competent for science and research issues.

#### **Article 41b**

1. Undertaking and conducting the activities consisting in the use of nuclear materials, or nuclear technologies, to build nuclear weapons or nuclear explosive devices, shall be prohibited.
2. Head of the entity shall inform the Agency's President of the intention to conduct research and development activities related to the nuclear fuel cycle, as defined in Article 18(a) of the Additional Protocol, and to manufacture the equipment, parts of equipment and materials related to nuclear technologies referred to in Annex I of the Additional Protocol, and also of their use, even when these activities are not subject to the obligation to obtain a licence nor to notification, referred to in Article 4(1).
3. The Agency's President shall be informed of the import and export of the equipment, parts of equipment and materials referred to in Annex II to the Additional Protocol.

4. In case of a legitimate suspicion, that the activity referred to in paragraph 2 may violate the prohibition referred to in paragraph 1, the Agency's President may request additional information or the *in situ* verification of this activity.

#### **Article 41.c**

1. Head of organizational entity which conducts the activities involving nuclear materials, shall make possible the control of these activities by regulatory inspectors, Euratom inspectors and International Atomic Energy Agency inspectors, in the scope established in the requirements for nuclear material safeguards, in particular by ensuring the access to the nuclear documentation, nuclear materials and the facility's buildings and equipment, and also to other buildings belonging to this entity.
2. Head of the organizational entity, which conducts the activities involving nuclear materials, shall convey to the Agency's President the copies of nuclear documentation submitted to, and obtained from, the European Commission.
3. Head of the organizational entity, which does not conduct the activities involving nuclear materials, shall grant the regulatory inspectors, Euratom inspectors and International Atomic Energy Agency inspectors the access to the buildings and equipment located on the site, for the purpose of verification that such activities are not conducted.
4. In case of a legitimate suspicion that the land or buildings located on the area, which at present does not consist a site, were used in the past for conducting activities involving nuclear materials, their user shall grant the access to these buildings and land by the regulatory inspectors and International Atomic Energy Agency inspectors, for the purpose of obtaining information to determine whether and what activity involving nuclear materials has been, or is conducted, including the environmental sampling.
5. Head of organizational entity, which conducts activities consisting of the disposal of radioactive waste that may contain special fissile materials, shall grant the regulatory inspectors, Euratom inspectors and International Atomic Energy Agency inspectors the access to these premises, for the purpose of obtaining information on the waste disposal, and collecting the environmental samples.
6. With the consent of the Agency's President, also Euratom inspectors may participate in the control referred to in paragraph 4.

#### **Article 42**

The Council of Ministers shall establish by regulations:

- 1) detailed obligations and duties concerning nuclear material safeguards, including the obligations and duties of:
  - a. heads of the entities conducting activities on the sites,
  - b. users of the buildings and land in locations outside the sites,
  - c. nuclear material carriers and intermediaries engaged in the trade in nuclear materials,
  - d. heads of radioactive waste repositories,
  - e. heads of the entities undertaking or conducting research and development activities related to the nuclear fuel cycle, in the area of nuclear technologies,
  - f. heads of the entities conducting activities in the area of manufacturing or using the equipment, parts of equipment and materials relevant for nuclear technologies,
  - g. heads of the entities using nuclear materials for non-nuclear purposes,
- taking into account the necessity to fulfil the international obligations of the Republic of Poland under the Treaty, the Agreement, Additional Protocol and Euratom Treaty;
- 2) nuclear materials subject to physical protection and the types of organizational and technical undertakings in the area of physical protection, establishing nuclear material categories and the procedures for control referred to in Article 41(3), taking into account the necessity to ensure appropriate physical protection level for various nuclear material categories and the assessment of the physical protection system's effectiveness.

## **Chapter 6**

### **Ionizing radiation sources**

#### **Article 43**

1. Ionizing radiation sources shall be subject to control and radioactive sources shall be also subject to registration.
2. Responsibility for control of ionizing sources and for maintaining the registers of radioactive sources status and movements shall lie with the head of organizational entity engaged in activities involving such sources.
- 3.<sup>52[55]</sup> Head of the organizational entity engaged in activities involving radioactive sources shall be responsible for securing them against damage, theft or unauthorized interception.

#### **Article 44**

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<sup>52[55]</sup> Added by Art. 1(32) of the act referred to in ref. 2).

1. Devices that contain radioactive sources or generate ionizing radiation, prior to their introduction into service, shall be subject to control from the radiological protection viewpoint. This control shall not cover the devices that may be used in the activities, which do not require a licence.
- 2.<sup>53[56]</sup> Devices containing radioactive sources shall be controlled by an organizational entity, which possesses a licence for the installation or trade in such devices. Devices generating ionizing radiation shall be controlled by an organizational entity, which possesses a licence for their commissioning.

#### **Article 45**

The Council of Ministers shall establish by regulations detailed conditions for safe work involving ionizing radiation sources, taking into account:

- 1) technological and radiological protection requirements for laboratories using radioactive sources or devices containing such sources, and the requirements for devices generating ionizing radiation and for the laboratories operating such equipment,
- 2) rules for work involving radioactive sources, devices containing such sources and devices generating ionizing radiation, which are used in places other than the laboratories referred to in paragraph 1,
- 3) rules and procedures for control and registration referred to in Article 43(1), including a standard form for radioactive sources inventory and registration.

#### **Article 46** <sup>54[57]</sup>

Minister competent for health matters shall establish by regulations detailed conditions for safe work involving radiological equipment, taking into account:

- 1) additional technological requirements for such equipment and for the laboratories using such equipment, not established in the regulations issued under Article 45,
- 2) rules and procedures for the supervision in the area of the radiological protection of the patient.

### **Chapter 7**

#### **Radioactive waste and spent nuclear fuel**

#### **Article 47**

- 1.<sup>55[58]</sup> Radioactive waste shall be classified into three categories according to its activity level or surface dose rate: low, medium and high-level radioactive waste. These categories may be further

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<sup>53[56]</sup> As written down in Art. 1(33) of the act referred to in ref. 2).

<sup>54[57]</sup> As written down in Art. 1(34) of the act referred to in ref. 2).

subdivided into sub-categories according to the half-lives of radioactive isotopes contained in the waste or to the thermal power of the waste.

2. Disused (spent) sealed radioactive sources shall constitute an additional radioactive waste category.
3. Spent sealed radioactive sources shall be classified, according to the level of their activity, into the following sub-categories of spent sealed radioactive sources: low, medium and high activity, which shall be further subdivided according to the half-lives of contained radioactive isotopes into short-lived and long-lived sub-categories.

#### **Article 48**

1. Radioactive waste classification shall be performed by the head of the organizational entity, on whose site the waste is present.
2. Radioactive waste classification may be performed by the Agency's President in the cases of:
  - 1) discrepancies in waste classification performed by the head of the organizational entity on whose site the waste is present, and the classification performed by the head of the organizational entity receiving the waste;
  - 2) evidence of irregularities in waste classification by the head of the organizational entity on whose site the waste is present.

#### **Article 49**

1. Head of the organizational entity, on whose site the radioactive waste or spent nuclear fuel is present, shall be responsible for keeping inventory registers. Inventory registers shall be kept for each type of activity involving radioactive waste management or spent nuclear fuel management.
2. Radioactive waste containing nuclear materials and spent nuclear fuel shall be subject to physical protection.

#### **Article 50**

Radioactive waste and spent nuclear fuel shall be stored in conditions allowing their segregation and in a manner that ensures adequate protection of humans and environment.

#### **Article 51**

The Council of Ministers shall establish by regulations:

- 1) method for radioactive waste classification into categories and sub-categories, taking into account the criteria referred to in Article 47(1) and 47(3);

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<sup>55[58]</sup> As written down in Art. 1(35) of the act referred to in ref. 2).

- 2) procedures for maintaining inventory registers and for the control of radioactive waste, and a standard inventory form, taking into account the procedures for maintaining common inventory registers for various activities involved in radioactive waste management, and the types of control activities,
- 3) conditions for storage of radioactive waste or spent nuclear fuel and the requirements for the facilities, rooms and packaging designed for the storage of radioactive waste belonging to various categories, taking into account the state of aggregation and other physicochemical properties of the waste, as well as the requirements for storage facilities for spent nuclear fuel.

#### **Article 52**

1. Liquid or gaseous radioactive waste, generated as a result of activities referred to in Article 4(1), may be discharged into the environment provided that its radioactive concentration in the environment may be disregarded from the radiological protection point of view. The method for waste discharge and its permissible activity shall be specified in the licence.
2. Radioactive waste that has been treated or which does not require treatment, and spent nuclear fuel that will not be reprocessed, shall be disposed of in repositories.
3. Spent nuclear fuel intended for disposal shall be dealt with as high-level radioactive waste.
4. Radioactive waste shall be disposed of exclusively in solid form and packaged in a manner which ensures radiological safety of humans and environment, ensuring heat removal and prevention of critical mass formation, and continuous control of these factors during the disposal and after repository closure.

#### **Article 53**

1. Radioactive waste repositories are divided into near-surface and deep repositories.
2. By the decision of the Agency's President, a radioactive waste repository may be declared as the National Radioactive Waste Repository.

#### **Article 54**

The authority which according to the act referred to in Article 36 is competent to issue the decisions on the conditions for construction and development of the site intended for construction of a repository, shall issue such decision after obtaining positive opinion from the Agency's President from the viewpoint of nuclear safety, radiological protection and physical protection.

#### **Article 55**

The Council of Ministers shall establish by regulations:

- 1) categories and sub-categories of radioactive waste which may be disposed of in specified types of repositories, taking into account the state of aggregation and physicochemical properties of the waste intended for disposal,
- 2) detailed requirements for various types of disposal facilities, concerning siting, construction, operation and closure, taking into account natural phenomena, geological conditions and systems of control,
- 3) conditions to be fulfilled by a repository in order to be granted the status of National Radioactive Waste Repository, taking into account the type of repository, categories of radioactive waste and the time during which the waste may be admitted into the repository,
- 4) detailed requirements for radioactive waste preparation for disposal, including the types of packaging of the waste placed for disposal.

#### **Article 56**

1. Activities involving the management of radioactive waste and spent nuclear fuel shall be conducted by the public utility referred to in Chapter 14.
2. Activities referred to in paragraph 1, with the exclusion of radioactive waste and spent nuclear fuel disposal and transport to the repository, may be conducted by some other organizational entity, provided that this organizational entity shall fulfill the requirements for nuclear safety and radiological protection and shall obtain appropriate licence. In particular, the organizational entity, in which the radioactive waste or spent nuclear fuel have been generated, may process and store them for the time specified in the licence.

#### **Article 57**

- 1.<sup>56[61]</sup> The commune (“gmina”), on whose territory the National Radioactive Waste Repository is sited, shall be eligible for an annual payment from the national budget:
  - 1) from the date on which the first shipment of waste is accepted for disposal until the date on which the decision to close the repository is made – in the amount of 400% of the previous year’s income from local real estate tax, but not exceeding 8 550 thousand PLN,
  - 2) after the decision to close the disposal facility has been taken – in the amount of 50% of the income from local real estate tax in the year of the closure of repository, for the period corresponding to the duration of operation of the repository.
2. Payment referred to in paragraph 1 shall be transferred from the national budget to the commune in equal quarterly installments, not later than 14 days after the last month of a given quarter.

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<sup>56[61]</sup> As written down in Art. 1(36) of the act referred to in ref. 2); shall enter into force on 1 January 2005.

3. Commune shall not be entitled to such quarterly installment if, due to the decisions of appropriate authorities of the commune or county (“powiat”) where the commune is located, during any period of the given quarter the admission of radioactive waste shipments into the repository was not possible.

## **Chapter 8**

### **Transport of nuclear materials, ionizing radiation sources, and radioactive waste and spent nuclear fuel**

#### **Article 58**

Nuclear materials shall be prepared for transport and transported in a manner which prevents the occurrence of a self-sustaining chain nuclear fission reaction and which complies with physical protection principles.

#### **Article 59** <sup>57[62]</sup>

In preparation for transport and during the transport of nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel, the risks that may result from their physico-chemical properties should be taken into account, and the conditions and requirements imposed on hazardous materials transport, established in other regulations, should be fulfilled.

#### **Article 60** <sup>62</sup>

Exposure of individuals participating in the transport, including the people engaged in loading and unloading of transported nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel, shall be subject to control, and the doses received by these individuals shall not exceed the dose limits for occupationally exposed workers, established in the regulations issued under Article 25(1).

#### **Article 61**

Conditions and requirements for the on-site transport, within the sites of organizational entities engaged in manufacturing, processing, use, storage and disposal of nuclear materials, ionizing radiation sources with the exception of the devices generating ionizing radiation, and also radioactive waste and spent nuclear fuel, shall be established by the Agency’s President in the licence.

#### **Article 61a** <sup>58[63]</sup>

1. Head of the organizational entity conducting the activities which require a licence, consisting of the transport of nuclear materials, radioactive sources, radioactive waste or spent nuclear fuel,

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<sup>57[62]</sup> As written down in Art. 1(37) of the act referred to in ref. 2).

<sup>58[63]</sup> Added by Art. 1(38) of the act referred to in ref. 2).

shall submit to the Agency's President an annual report on the carried-out transports of nuclear materials, radioactive sources, radioactive waste or spent nuclear fuel. The requirements concerning such reports shall be established by the Agency's President in the licence.

2. Provisions of paragraph 1 shall not be applied to the on-site transport, referred to in Article 61.

#### **Article 62** <sup>59[64]</sup>

1. Import into and export from the territory of the Republic of Poland of nuclear materials, radioactive sources, and equipment containing such sources, as well as import and export of radioactive waste and spent nuclear fuel, shall be conducted on the basis of an appropriate licence for, or notification of, the activity referred to in Article 4(1) and in the scope established in this licence, subject to paragraph 2.

1a.<sup>60[65]</sup> For the purpose of this Article, the term "radioactive waste" means the material, in which radioactive substances exceed the values for total activity and radioactive concentration established in the regulation issued under Article 6(1).

2.<sup>61[66]</sup> Import into the Republic of Poland's territory<sup>62[67]</sup>, export from the territory of the Republic of Poland<sup>67</sup>, and transit through this territory, of radioactive waste and spent nuclear fuel shall require the consent of the Agency's President.

3. Export from the territory of the Republic of Poland<sup>67</sup> and transit through this territory of radioactive waste and spent nuclear fuel shall be prohibited, if the destination of such shipment would lie to the south of 60° southern latitude.

4. The Council of Ministers shall establish by regulations:

- 1) conditions for the import into, export from, and transit through the territory of the Republic of Poland<sup>67</sup> of nuclear materials, radioactive sources and equipment containing such sources,
- 2)<sup>63[68]</sup> premises for the Agency's President for granting the consent for radioactive waste import into, export from, and transit through the Republic of Poland's territory<sup>67</sup>, the procedure for applying for the consent and the standard document for such procedure, taking into account the arrangement accepted in European Union,
- 3)<sup>64[69]</sup> premises for the Agency's President for granting the consent for spent nuclear fuel import into, export from, and transit through the territory of the Republic of Poland<sup>67</sup>, the

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<sup>59[64]</sup> As written down in Art. 1(39)(a) of the act referred to in ref. 2).

<sup>60[65]</sup> As written down in Art. 1(39)(b) of the act referred to in ref. 2).

<sup>61[66]</sup> As written down in Art. 1(39)(c) of the act referred to in ref. 2).

<sup>62[67]</sup> As amended by Art. 1(68) of the act referred to in ref. 2).

<sup>63[68]</sup> As written down in Art. 1(39)(d) first subparagraph of the act referred to in ref. 2).

<sup>64[69]</sup> Added by Art. 1(39)(d) second subparagraph of the act referred to in ref. 2).

procedure for applying for the consent and the standard document for such procedure, considering the necessity for ensuring safety in spent nuclear fuel management.

## **Chapter 9**

### **Supervision and control of compliance with the conditions for nuclear safety and radiological protection**

#### **Article 63**

1. Activities, which cause, or may cause, the exposure of humans and environment to ionizing radiation shall be subject to supervision and control from the viewpoint of nuclear safety and radiological protection.
2. Supervision and control referred to in paragraph 1 shall be executed by the:
  - 1) nuclear regulatory bodies – in case of activities for which the licence is issued, or notification is received, by the Agency’s President,
  - 2)<sup>65[70]</sup> regional sanitary inspector, commander of military preventive medicine center or sanitary inspector for the Ministry for Home Affairs and Administration – in case of activities licensed by those bodies.
- 3.<sup>66[71]</sup> Minister competent for health issues shall establish by regulations the rules and procedures for supervision and control of the compliance with radiological protection conditions in organizational entities using X-ray devices for the purposes of medical diagnostics, interventional radiology, surface radiotherapy and non-oncological diseases radiotherapy.
- 4.<sup>67[72]</sup> Prime Minister shall establish by regulation the procedures for the supervision and control of the Home Security Agency and Intelligence Agency, taking into account the procedures for preparation of the control, documentation of control activities, the preparation of control report, post-control statement and information on the results of the control.

#### **Article 64**

1. Nuclear regulatory bodies referred to in Article 63(2)(1) shall be the following:
  - 1) the Agency’s President, as the supreme nuclear regulatory body,
  - 2) Chief Nuclear Regulatory Inspector, as the organ superior in the chain of command to the regulatory inspectors,

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<sup>65[70]</sup> As written down in Art. 1(40)(a) of the act referred to in ref. 2).

<sup>66[71]</sup> As written down in Art. 1(40)(b) of the act referred to in ref. 2).

<sup>67[72]</sup> As amended by Art. 213 of the act of 24 May 2002 on the Home security Agency and Intelligence Agency (O.J. No 74 Item 676), which entered into force on 29 June 2002.

- 3) regulatory inspectors.
2. Chief Nuclear Regulatory Inspector shall be nominated from among regulatory inspectors, and recalled by the Agency's President.
3. Regulatory inspectors shall be nominated and recalled by the Agency's President at the request of the Chief Nuclear Regulatory Inspector.
4. Responsibilities of the nuclear regulatory body shall include in particular:
  - 1) issuing the licences and other decisions in the matters involving nuclear safety and radiological protection, according to the principles and procedures established by this Act,
  - 2) conducting inspections in nuclear facilities and in organizational entities which possess nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel,
  - 3) issuing summary orders referred to in Article 68,
  - 4)<sup>68[73]</sup> approving training programs referred to in Article 11(3), with the exclusion of training programs prepared by the heads of organizational entities which operate X-ray equipment for the purposes of medical diagnostics, interventional radiotherapy, surface radiotherapy and non-oncological diseases radiotherapy.
- 5.<sup>69[74]</sup> Regulatory inspectors shall conduct the inspection under the authorization issued by the Agency's President or Chief Nuclear Regulatory Inspector, subject to paragraph 6.
- 6.<sup>70[75]</sup> In the situation of a threat to human life or health, or to the environment, the regulatory inspectors may conduct the inspection on the ground of an official identity document. In such case the authorization for conducting the inspection shall be delivered to the head of the controlled organizational entity within 3 days from the start of the inspection.

#### **Article 65**

1. To be eligible for the nomination for regulatory inspector, the individual must:
  - 1) possess a certificate of higher education in physics, chemistry, technology or other specialization useful in nuclear regulatory body tasks,
  - 2) have no record for intentional offenses,
  - 3) have completed practical training and passed qualifying exam for the position of regulatory inspector in the area of nuclear safety and radiological protection, conducted by the commission established by the Agency's President,

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<sup>68[73]</sup> As written down in Art. 1(41)(a) of the act referred to in ref. 2).

<sup>69[74]</sup> As written down in Art. 1(41)(b) of the act referred to in ref. 2).

<sup>70[75]</sup> Added by Art. 1(41)(c) of the act referred to in ref. 2).

- 4) possess a medical certificate stating that there are no contraindications for employment in occupational exposure conditions.
3. Costs related to the activities of the commission referred to in paragraph 1(3) shall be covered from the National Atomic Energy Agency budget.

#### **Article 66**

1. In the context of regulatory control, nuclear regulatory bodies shall be entitled to:
  - 1) around-the-clock access to transport vehicles and the sites of organizational entities, where nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel are manufactured, used, stored, disposed of or transported,
  - 2) review the documentation concerning nuclear safety and radiological protection in inspected organizational entity,
  - 3) verify whether the activities referred to in Article 4(1) are conducted in compliance with nuclear safety and radiological protection regulations and with the requirements and conditions established in the licences,
  - 4) conduct independent technical and dosimetric measurements, whenever needed,
  - 5) request written or oral information, if this is necessary to clear up some issue.
2. In performing their inspection and control duties, nuclear regulatory bodies shall enjoy the protection provided for public officials in the Penal Code.

#### **Article 67**

1. Head of inspected organizational entity shall ensure the conditions necessary for the conduct of inspection and shall make available the documents referred to in Article 66(1)(2).
2. Workers of inspected organizational entity shall provide the regulatory body with all relevant written or oral explanations on the issues involved in the inspection objectives.
3. Individual conducting the regulatory inspection shall draw up a written report, which shall be signed by this person and by the head of inspected organizational entity.
4. Basing on the report identifying a non-compliance with nuclear safety and radiological protection regulations, in particular in the form of lack of licence or departure from requirements and conditions established in the licence, Chief Nuclear Regulatory Inspector shall issue a directive to correct the non-compliance within a specified time.

#### **Article 68**

1. If a threat to nuclear safety and radiological protection has been identified during the inspection, to remove that threat, nuclear regulatory body shall issue summary orders containing an

injunction or interdiction related to specified activities.

2. Summary orders aimed at the removal of direct threat to nuclear safety and radiological protection shall be executed immediately. Such orders shall be issued in writing; in exceptional circumstances they shall be issued in oral form and should be confirmed immediately in writing.
3. Summary orders addressing threats other than those referred to in paragraph 2 shall be executed within the time specified in these orders.
4. Head of inspected organizational entity may appeal to the Chief Nuclear Regulatory Inspector to overrule or modify the order referred to in paragraph 3, if the order has been issued by a regulatory inspector, or to the Agency's President if the order has been issued by the Chief Nuclear Regulatory Inspector.
5. Appeal referred to in paragraph 4 shall not suspend the execution of the summary order.

#### **Article 69** <sup>71[76]</sup>

1. If a non-compliance with a potential impact on nuclear safety and radiological protection has been detected during the inspection, the Agency's President may issue a post-inspection decision to the head of inspected organizational entity or to the head of the supervising entity, requesting appropriate corrective actions.
2. Head of the entity to which such post-inspection decision is addressed shall notify the Agency's President, within 30 days of receiving the decision, of the time and method of implementation of corrective actions.

#### **Article 70**

Proceedings concerning the surveillance and control issues shall be based on the provisions of the Administrative Code.

#### **Article 71**

The Council of Ministers, by regulations:

- 1) may establish detailed tasks and procedures for surveillance and control activities, including the tasks of Chief Nuclear Regulatory Inspector,
- 2) shall establish detailed requirements for practical training and qualifying exam for the position of regulatory inspector, taking into account the differences stemming from the regulatory needs for control of specific practices involving exposure, and shall establish a standard certificate to attest the acquisition of this authorization.

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<sup>71[76]</sup> As written down in Art. 1(42) of the act referred to in ref. 2).

## **Chapter 10**

### **Assessment of national radiological situation**

#### **Article 72**

1. The Agency's President shall conduct systematic assessments of the national radiological situation.
2. For the assessments referred to in paragraph 1, the Agency's President shall:
  - 1) collect, verify and analyze information obtained from the stations for early detection of radioactive contamination, hereinafter referred to as "the stations," and from the units performing radioactive contamination measurements, hereinafter referred to as "the units," and from the services possessing the data needed for the assessment of national radiological situation, including meteorological services,
  - 2) verify and analyze information obtained from other sources,
  - 3) create databases and information systems essential for the assessment of national radiological situation,
  - 4) analyze and forecast the development of national radiological situation and estimate the hazards for the population and environment, on the basis of the information referred to in paragraphs 1 and 2, and of the data contained in databases referred to in paragraph 3.
3. The Agency's President shall perform the tasks referred to in paragraph 2 with the support of the Center for Radiological Emergencies, established within the National Atomic Energy Agency.
- 4.<sup>72[77]</sup> Working time for the workers performing the tasks of the Center for Radiological Emergencies shall be determined by the Agency's President, under the principles established in the Labor Law. This shall not infringe on the other provisions for working time, as established in the Civil Service Act.

#### **Article 73**

- 1.<sup>73[78]</sup> Stations and units referred to in Article 72(2)(1) shall operate in the National Atomic Energy Agency, in the entities subordinated to the Polish Academy of Sciences and in the entities subordinated to the ministers competent for the areas of home affairs, environment, economy, higher education, agriculture, health and to the Minister of Defense.
2. Stations shall perform the following tasks:
  - 1) continuous measurements of gamma dose rate,

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<sup>72[77]</sup> Added by Art. 1(43) of the act referred to in ref. 2).

<sup>73[78]</sup> As written down in Art. 1(44) of the act referred to in ref. 2).

- 2) automatic detection and signaling any 15% excess in the dose rate value, caused by the presence of artificial radioactive substances,
  - 3) immediate and automatic transmission of measurement data to the Center for Radiological Emergencies,
  - 4) ensuring that the data shall be transmitted in the way compatible with calculation models used in the assessments of radiological situation.
3. Units shall perform the following tasks:
- 1) detection, identification and measurements of radioactive contamination in the environment, agricultural products and foodstuffs,
  - 2) preliminary evaluation of measurement results and their transmission to the Agency's President.

#### **Article 74**

The Agency's President shall coordinate the operation of stations and units, and in particular shall:

- 1)<sup>74[79]</sup> cooperate with appropriate ministers competent for the matters of home affairs, environment, economy, higher education, agriculture and health and with the Minister of Defense and the President of Polish Academy of Sciences,
- 2) approve measurement technologies, measurement programs and measurement organization,
- 3) cooperate with appropriate foreign agencies on matters of radioactive contamination detection and measurements.

#### **Article 75**

The Council of Ministers shall establish by regulation the list of stations and units and their detailed tasks and functions, as well as the ways of performing those tasks, taking as the criterion the feasibility of obtaining the data necessary for the assessment of national radiological situation.

#### **Article 76**

The Agency's President shall receive the information on domestic radiological emergencies, in particular those obtained on the basis of Articles 83 and 85(1), and, if necessary, on the basis of information obtained, shall lend immediate assistance in the assessment of the radiation hazard magnitude.

#### **Article 77** <sup>75[80]</sup>

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<sup>74[79]</sup> As written down in Art. 1(45) of the act referred to in ref. 2).

<sup>75[80]</sup> As written down in Art. 1(46) of the act referred to in ref. 2).

1. The Agency's President, in performing the tasks arising from the international system of the notification of radiological events in the areas of early notification of a nuclear accident, assistance in the event of a nuclear accident or radiological emergency, physical protection of nuclear materials and illicit trade in such materials, as well as carrying out the obligations of the Republic of Poland under bilateral international agreements, shall establish national contact points.
2. The tasks of national contact points shall include in particular:
  - 1) receiving the notifications from International Atomic Energy Agency (IAEA) and from contact points of foreign countries and international organizations, of nuclear accidents, illegal use, displacement or processing of nuclear materials, or of a real threat of any such deed, as well as receiving from these countries the requests for assistance in the event of radiological emergency and imparting the information on the possibility of lending such assistance and on its conditions and scope,
  - 2) notifying the IAEA and contact points referred to in paragraph 1 of radiological emergencies occurring on the territory of the Republic of Poland and of illegal use, displacement or processing of nuclear materials, or of a real threat of any such deed on the territory of the Republic of Poland or that of other country, as well as transmitting requests by the Republic of Poland for assistance in the event of radiological emergency,
  - 3) supplying the contact points referred to in paragraph 1 with other information, according to the obligations of the Republic of Poland under concluded international agreements.

#### **Article 78**

The Agency's President may entrust the tasks referred to in Articles 74, 76 and 77 to an institution specialized in radiological protection matters.

#### **Article 79**

Upon the Agency's President request, the institutions, organizations and individuals possessing the data and information essential for analyses and assessments of national radiological situation, shall make them available free of charge.

#### **Article 80**

The Agency's President, on the basis of the assessment of national radiological situation, shall:

- 1) issue the messages addressed to the general public on national radiation situation, including the information on radioactive contamination levels under normal conditions and in radiological emergency situations,

- 2) inform appropriate regional governor or the Council of Ministers of an emergency on regional or national scale,
- 3)<sup>76[81]</sup> deliver the information on radiological emergency and on the foreseen development of national radiological situation to the Chairman of appropriate governmental emergency management committee.

### **Article 81**

The Agency's President shall issue quarterly messages to the general public concerning national radiological situation, published in the Official Journal of the Republic of Poland "Monitor Polski (Polish Monitor)". In the event of radiological emergency, the public shall be informed according to the procedures specified in the Article 92(3) and 92(4).

## **Chapter 11**

### **Radiological emergency management**

#### **Article 82**

1. The following types of radiological emergencies shall be distinguished, according to the extent of their impact:
  - 1) on-site emergency – radiological emergency occurring on the site of organizational entity, with the impact limited to the area within the site boundaries of the organizational entity,
  - 2) public emergency on a regional scale – radiological emergency occurring on the site of organizational entity, or off-site during field works or during the transport of nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel, with the impact limited to the territory of a single region,
  - 3) public emergency on a national scale – radiological emergency referred to in paragraph 2, if its impact extends, or may extend, over the territory larger than that of a single region.
2. Each radiological emergency, which occurs within national borders or beyond them, with the impact reaching beyond the borders of the Republic of Poland, shall constitute a public emergency on a national scale.

#### **Article 83**

In the event of radiological emergency, the head of the organizational entity conducting activities referred to in Article 4(1) shall secure the emergency site and shall notify immediately the Agency's President and additionally, where the circumstances so justify, shall notify also other organizations and services, in accordance with the on-site emergency plan.

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<sup>76[81]</sup> As written down in Art. 1(47) of the act referred to in ref. 2).

#### **Article 84**

- 1.<sup>77[82]</sup> Radiological emergency, which constitutes an on-site emergency or an emergency on regional or national scale, shall require the implementation of appropriate intervention measures, as defined respectively in the on-site, regional or national emergency plan.
2. During an on-site radiological emergency, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the head of the organizational entity on whose site the emergency has occurred.
3. During radiological emergency on a regional scale, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the region's governor, subject to paragraph 4.
4. If a radiological emergency occurs during the transport, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the person responsible for the shipment security in transport, in arrangement with the regional governor appropriate for the emergency site.
5. During radiological emergency on a national scale, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the minister competent for home affairs, with the assistance of the Agency's President.

#### **Article 85**

1. In the event of radiological emergency caused by an unknown perpetrator, the service which first has obtained the information on the event shall secure the emergency site and notify the Agency's President and the regional governor appropriate for the emergency site.
- 2.<sup>78[83]</sup> In the case referred to in paragraph 1, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the regional governor appropriate for the emergency site, who shall implement appropriate intervention measures established in the regional emergency plan, subject to Article 84(5).

#### **Article 86**<sup>79[84]</sup>

If an increased level of ionizing radiation dose rate or a radioactive contamination has been detected, which is of unknown origin or results from an act of terror, with the exception of radiological emergencies referred to in Article 82, and also if abandoned radioactive substance has been found, the actions aimed at the elimination of the hazard and of the consequences of the emergency shall be directed by the governor of the region where such increased level of ionizing radiation dose rate or

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<sup>77[82]</sup> As written down in Art. 1(48) of the act referred to in ref. 2).

<sup>78[83]</sup> As written down in Art. 1(49) of the act referred to in ref. 2).

<sup>79[84]</sup> As written down in Art. 1(50) of the act referred to in ref. 2).

radioactive contamination has been detected, or abandoned radioactive substance has been found, subject to Article 84(5).

#### **Article 87**

The Council of Ministers shall establish by regulation:

- 1) national emergency plan, including the procedures for cooperation of various authorities and services participating in the elimination of radiological emergencies and of their consequences,
- 2) generic on-site and regional emergency plan, indicating the elements essential for prompt response by appropriate services,
- 3)<sup>80[85]</sup> intervention level values for various types of intervention measures referred to in Article 90, and also the criteria for revoking such measures, taking into account the recommendations of appropriate international organizations.

#### **Article 88**

1.<sup>81[86]</sup> Decision to implement the intervention measures referred to in Article 90, may be taken following:

- 1) the message by the Agency's President stating that the radiological emergency with consequences referred to in Article 82(1)(2) and 82(1)(3), may result in exceeding the intervention level values,
  - 2) demonstration, on the basis of advisability evaluation of intervention measures, that the mitigation of radiation-caused damage justifies the damage and costs caused by these measures, including the social costs.
2. During the advisability evaluation of intervention measures referred to in Article 90, the following should be taken into account:
- 1) present and predicted emergency scenario and scope,
  - 2) actual or potential values for ionizing radiation doses,
  - 3) number of threatened people,
  - 4) health impact of these intervention measures,
  - 5) foreseen costs and the extent of economic and social impact of these intervention measures.

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<sup>80[85]</sup> As written down in Art. 1(51) of the act referred to in ref. 2).

<sup>81[86]</sup> As written down in Art. 1(52) of the act referred to in ref. 2).

3. Intervention measures type, scale and time of duration shall be selected in such manner, that the benefits resulting from the mitigation of health detriments, after the deduction of intervention-related damage, are as large as possible.

#### **Article 89** <sup>86</sup>

1. Intervention measures referred to in Article 90, related to a radiological emergency with impact limited to the territory of a single region, shall be implemented in the form of a local regulation issued by the regional governor appropriate for the emergency site.
2. Intervention measures referred to in Article 90, related to a radiological emergency with impact extending beyond the territory of a single region, shall be implemented in the form of a regulation issued by the Council of Ministers.
3. Regulation referred to in paragraph 2, apart from its publication in the Official Journal of the Republic of Poland, shall be announced to the general public in the form of posters hanged out in public places in the area of the intervention measures implementation, and also in the form of announcement in mass media in this area.
4. Regulations referred to in paragraphs 1 and 2 shall state the cause, date of implementation, area and foreseen duration time, and also the type of necessary intervention measures.
5. Publication of the regulations referred to in paragraphs 1 and 2 shall be regulated by the provisions of the Act of Parliament of 26 January 1984 – Press Law (O.J. No 5 Item 24 with subsequent amendments<sup>82[87]</sup>).
6. Revocation of intervention measures referred to in Article 90, on the whole area of their implementation or on some part of this area, shall proceed according to the procedures foreseen for their publication.

#### **Article 90** <sup>86</sup>

Intervention measures, implemented in the event of the possibility that the intervention levels may be exceeded, shall have the following form:

- 1) evacuation,
- 2) sheltering,
- 3) administration of stable iodine,

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<sup>82[87]</sup> Amendments to this act have been published in O.J. of 1988 No 41, Item 324, of 1989 No 34 Item 187, of 1990 No 29 Item 173, of 2001 No 100 Item 442, of 1996 No 114 Item 542, of 1997 No 88 Item 554 and No 121 Item 770, of 1999 No 90 Item 999, of 2001 No 112 Item 1198 and of 2002 No 153 Item 1271.

- 4) ban or restrictions on the consumption of contaminated food and water by people, on feeding contaminated feeding stuffs and contaminated water to the animals and on cattle grazing on contaminated pastures,
- 5) temporary relocation of the population,
- 6) permanent relocation of the population.

**Article 91** <sup>86</sup>

Intervention measures referred to in Article 90 shall be directed by the:

- 1) regional governor appropriate for the radiological emergency site - in the event of public emergency on a regional scale,
- 2) minister competent for home affairs – in the event of radiological emergency causing:
  - a) public emergency on a national scale,
  - b) public emergency on a regional scale, if the implementation of intervention measures is beyond the capabilities of services subordinated to the regional governor.

**Article 92** <sup>86</sup>

1. Population, which in the event of radiological emergency could receive the dose exceeding the population dose limit, shall be periodically informed by the Agency's President of the feasible health protection measures and of the measures which should be taken by the population in the event of radiological emergency (preventive information).
2. Following the radiological emergency, the population which may receive ionizing radiation dose exceeding the limiting dose for the members of the public, shall be immediately informed of the emergency and on the undertaken measures, and, if necessary, also of the appropriate health protection measures.
3. Entities competent for developing and transmitting the information referred to in paragraph 2, and also the scope and mode of the transmission of this information, shall be established, as appropriate, in the regional and national emergency plan.
4. Council of Ministers shall establish by regulation the population groups to receive preventive information, competent bodies for the development and transmission of preventive information, the scope of this information and also the manner and frequency of its transmission, taking into account the need to prepare the population for radiological emergency, and also the types of activities which – in the event of radiological emergency – may lead to the population receiving ionizing radiation dose in excess of the limiting dose.

**Article 93** <sup>86</sup>

1. Costs of intervention measures and of the elimination of radiological emergency consequences shall be borne by the organizational entity, which caused the emergency.
2. In the event of radiological emergency which has not been caused by an organizational entity, the costs referred to in paragraph 1 shall be borne by the perpetrator, whereas in the event of emergency caused by an unknown perpetrator or when such costs may not be exacted from the perpetrator, and also in the event of emergency which has occurred outside the borders of the Republic of Poland - such costs shall be borne by the national budget.

#### **Article 94** <sup>86</sup>

Report on radiological emergency, after the deactivation of intervention measures referred to in Article 90, shall be delivered:

- 1) by regional governor to the minister competent for home affairs – in the case referred to in Article 91(1),
- 2) by the minister competent for home affairs and the Agency's President to the Prime Minister - in the cases referred to in Article 91(2).

#### **Article 95**

1. If the means at the disposal of the authority directing the actions aimed at the elimination of the emergency and its consequences are inadequate, this authority may impose the obligation to render personal and material services.
2. Issues involving the obligations referred to in paragraph 1 shall be governed by relevant regulations concerning the services rendered in natural disaster situations.

#### **Article 96**

1. Head of organizational entity and the regional governor, each within his respective scope of responsibilities, shall conduct periodic exercises aimed at emergency plan testing and updating. In case of nuclear facility, the exercise shall be conducted by the head of organizational entity, starting from the activities included in emergency plan for the commissioning stage. The exercise costs shall be borne respectively by the organizational entity or by the regional governor.
2. Minister competent for home affairs shall conduct periodic exercises to test the national emergency plan, at least once every three years. The costs involved in the preparation and conduct of such exercises shall be borne by the budget of the minister competent for home affairs.

#### **Article 97** <sup>83[88]</sup>

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<sup>83[88]</sup> As written down in Art. 1(53) of the act referred to in ref. 2).

1. Following a radiological emergency, the food and animal feeding stuff shall be subject to the control of compliance with the maximal permissible levels for radioactive contamination, as established in the European Union regulations.
  2. Food and animal feeding stuff, in which the radioactive contamination content exceeds the levels referred to in paragraph 1, shall not be introduced into trade, and also shall not be exported to the countries which are not Member States of the European Union.
  3. European Commission shall be informed of each and every case of exceeding the radioactive contamination levels referred to in paragraph 1.
  4. Council of Ministers shall establish by regulation the entities authorized to:
    - 1) exercise control referred to in paragraph 1,
    - 2) issue the decisions on non-admittance to trade, or on the ban on export to the countries which are not Member States of the European Union, of the food and animal feed referred to in paragraph 2,
    - 3) inform the European Commission on the issues referred to in paragraph 3,
- guided by the need to ensure the implementation of the European Union regulations concerning maximum permissible levels for radioactive contamination in food and animal feed following the accident in Chernobyl, and also in the aftermath of future radiation emergency.

**Article 98** (repealed) <sup>84[89]</sup>

**Article 99** <sup>85[90]</sup>

The Council of Ministers, by regulation, may establish the level of radioactive substance content in raw materials and products imported into the Republic of Poland following the radiological emergencies, taking into account the ionizing radiation dose limits and the manner of handling such products.

## **Chapter 12**

### **Civil liability for nuclear damage**

#### **Article 100**

For the purposes of this Chapter, the terms listed below shall have the following meaning:

- 1) nuclear installation:

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<sup>84[89]</sup> By Art. 1(54) of the act referred to in ref. 2).

<sup>85[90]</sup> As written down in Art. 1(55) of the act referred to in ref. 2).

- a) nuclear reactor, with the exception of a reactor installed in a vehicle of sea or air transport, as a source of power, for propulsion, or for other purposes,
  - b) plant using nuclear fuel for nuclear material manufacturing or facility for processing nuclear materials, including the facility for spent nuclear fuel reprocessing,
  - c)<sup>86[91]</sup> installation in which nuclear material is stored or disposed of, with the exception of the storage incidental to nuclear material transport,
- 2) nuclear reactor – device containing nuclear fuel in such an arrangement that a self-sustaining chain nuclear fission reaction can occur without an additional neutron source,
  - 3) nuclear fuel – material which is capable of producing energy through a self-sustaining chain nuclear fission reaction,
  - 4) nuclear material:
    - a) nuclear fuel, other than natural uranium or depleted uranium, capable of producing energy through a self-sustaining chain nuclear fission reaction outside a nuclear reactor, either by itself or in combination with other materials,
    - b) radioactive products or waste – radioactive substance generated in the processes of nuclear fuel production or use, or material which became radioactive after irradiation during such processes, but excluding radioactive isotopes which have reached the final stage of their production so that they could be used for applications in research, medicine, agriculture, trade or industry,
  - 5)<sup>87[92]</sup> nuclear damage:
    - a) personal injury,
    - b) damage to property,
    - c) damage to the environment – the costs of recovery measures implemented to restore the environment viewed as common property to its unimpaired status, unless the impairment is insignificant,
    - to the extent that the damage is caused by, or related to, the ionizing radiation emitted by any radiation source inside a nuclear installation, or emitted from nuclear fuel, radioactive substances and radioactive waste, or by nuclear materials originating in or introduced into a nuclear installation, when such damage results from the radioactive properties of such materials or from the combination of radioactive properties with toxic, explosive or other dangerous properties of such materials,

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<sup>86[91]</sup> As written down in Art. 1(56)(a) of the act referred to in ref. 2).

<sup>87[92]</sup> As written down in Art. 1(56)(b) of the act referred to in ref. 2).

- 6) recovery measures (undertaken to restore the environment to its unimpaired status) – all appropriate and properly applied measures to reinstate or repair all damaged or destroyed components of the environment or – whenever justified – to introduce equivalent substitutes,
- 7)<sup>88[93]</sup> countermeasures – all appropriate measures undertaken in the aftermath of nuclear accident to prevent or mitigate the nuclear damage referred to in paragraph 5,
- 8)<sup>93</sup> nuclear incident – any occurrence or a series of occurrences having the same origin, resulting in nuclear damage or a grave and imminent threat of causing such damage,
- 9) operator – entity which operates a nuclear installation,
- 10) SDR – accounting unit within the meaning of *the act of Parliament of 18 December 1998 – Foreign Currency Law (O.J. No 160, Item 1063, of 1999 No 83, Item 931, and of 2000 No 103 Item 1099)*<sup>89[94]</sup>.

#### **Article 100a**<sup>90[95]</sup>

1. Nuclear damage shall be compensated according to the principles established in the provisions in the Civil Code, subject to the exceptions provided for in this Act.
2. Nuclear damage to the environment, viewed as common property, shall be compensated in the form of reimbursement of the cost of recovery measures implemented by properly authorized bodies or by other entities on the basis of the decision by these properly authorized bodies.
3. Compensation of nuclear damage shall include also the reimbursement of the costs of countermeasures.
4. If the implementation of countermeasures resulted in the personal injury, or damage to property or environment viewed as common property, such damage shall be treated as nuclear damage referred to in Article 100(5).

#### **Article 101**

1. Exclusive liability for nuclear damage caused by a nuclear incident in nuclear installation or related to this installation, shall be borne by the operator, with the exception of damage caused directly by acts of war or armed conflict.
2. In the course of nuclear materials transport the liability shall lie with the operator of nuclear installation from which such materials have been dispatched, unless otherwise stipulated in the contract with the consignee.

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<sup>88[93]</sup> As written down in Art. 1(56)(c) of the act referred to in ref. 2).

<sup>89[94]</sup> Repealed under Article 61 of the act of 27 July 2002 – Foreign Currency Law (O.J. No 141 Item 1178), which entered into force on 1 October 2002.

<sup>90[95]</sup> Added by Art. 1(57) of the act referred to in ref. 2).

3. If the individual, who incurred the damage, has caused or aggravated this damage by intentional behavior, the court of justice may exempt the operator, wholly or partially, from the obligation to compensate the damage incurred by this individual.

#### **Article 102**

- 1.<sup>91[96]</sup> Operator's liability for nuclear damage shall be limited to the amount equivalent to 150 million SDR.
- 2.<sup>96</sup> In the event when the claims for nuclear damage exceed the amount referred to in paragraph 1, the operator shall establish a limited liability fund. The procedures for the establishment and distribution of this fund shall be regulated, as appropriate, by the provisions of the Sea Code on the limited liability for sea claims, subject to paragraphs 3-5.
3. Jurisdiction in matters related to the establishment of the fund and to its distribution shall lie with the District Court in Warsaw.
4. Petition to start the proceedings related to the establishment and distribution of the fund should conform to general conditions for petitions to start legal proceedings and additionally should include:
  - 1) name of the nuclear installation,
  - 2) identification of the nuclear incident that constitutes the basis for claims and the information on the activities aimed at the determination of this accident's scenario,
  - 3) description of the type of claims to be settled and creditors to be satisfied from the fund, as well as information on the claims, which already - according to the applicant's knowledge - have been brought to the court,
  - 4) statement of the intention to establish the fund, the justification of its magnitude and the description of the method of its establishment.
5. Documents containing the data relevant to the fund's magnitude should be submitted together with the petition.

#### **Article 103**

- 1.<sup>92[97]</sup> Operator shall be obliged to conclude a contract for insurance against civil liability for nuclear damage. If, apart from the damage to the property or environment, nuclear incident caused also personal injury, 10% of the insurance guaranty sum shall be earmarked for settling the claims

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<sup>91[96]</sup> As written down in Art. 1(58) of the act referred to in ref. 2).

<sup>92[97]</sup> As written down in Art. 153(1)(b) of the act of Parliament of 22 May 2003 on obligatory insurance, Insurance Guaranty Fund and Polish Office of Communication Insurance Agencies (O.J. No 124 Item 1152), which entered into force on 1 January 2004.

involving nuclear damage resulting in personal injury.

- 2.<sup>93[98]</sup> If within 5 years from the date of nuclear incident the claims against the operator involving nuclear damage resulting in personal injury do not exceed the total amount of the guaranty intended exclusively for settling such claims, the remainder of this guaranty shall be used for settling the claims involving damage to the property or environment, and also the claims for personal injury brought up not later than within 10 years from the date of the nuclear incident.
- 3.<sup>94[99]</sup> National Treasury shall guarantee the payment of compensation for nuclear damage incurred by an individual in the amount which could not be settled by the insurer from the insurance contract referred to in paragraph 1.
- 4.<sup>95[100]</sup> Minister competent for the matters of financial institutions, after consulting the Agency's President and Polish Chamber of Insurance, shall establish by regulation the detailed scope of the obligatory insurance referred to in paragraph 1, and minimal value for the guaranty, taking into account various types of nuclear installations referred to in Article 100(1).
- 5.<sup>96[101]</sup> Nuclear regulatory body shall be authorized to control and verify the compliance with the obligation to conclude insurance contract referred to in paragraph 1.
- 6.<sup>101</sup> Compliance with the obligation to conclude insurance contract referred to in paragraph 1 shall be verified on the basis of an insurance policy or other insurance document, drawn up for the operator by the insurer, which confirms that such insurance contract has been concluded.
- 7.<sup>101</sup> Operator who did not comply with the obligation to conclude insurance contract referred to in paragraph 1 shall make a payment to the national budget in the amount of 20% of minimal guaranty sum established in the regulations issued under paragraph 4. Such payment shall not exempt the operator from the obligation to conclude insurance contract referred to in paragraph 1.
- 8.<sup>101</sup> If the operator does not produce a document confirming the conclusion of insurance contract referred to in paragraph 1, or the proof of insurance payment, nuclear regulatory body shall call on the operator with the demand that within 30 days the operator will:
  - 1) produce the documents confirming that the insurance contract has been concluded at the time established in the regulations issued under paragraph 4, or
  - 2) in the event of lack of the documents confirming the conclusion of insurance contract - make the payment referred to in paragraph 7 and produce the documents confirming the conclusion of insurance contract at a later time.

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<sup>93[98]</sup> As amended by Art. 153(1)(b) subparagraph one and two of the act referred to in ref. 97).

<sup>94[99]</sup> As amended by Art. 153(1)(c) of the act referred to in ref. 97).

<sup>95[100]</sup> As written down in Art. 1(59)(a) of the act referred to in ref. 2).

<sup>96[101]</sup> Added by Art. 1(59)(b) of the act referred to in ref. 2).

9.<sup>101</sup> Payment referred to in paragraph 7 shall be collected under the regulations for enforcement proceedings in administration.

#### **Article 104** <sup>97[102]</sup>

1. Claims for nuclear damage may be filed directly against the insurer.
- 2.<sup>98[103]</sup> In the case referred to in paragraph 1, the insurer may benefit from the limitation of liability and of other defensive measures, to which the operator is entitled.

#### **Article 105**

1. Claim for compensation for nuclear damage resulting in personal injury shall not be subject to prescription.
2. Claim for compensation for nuclear damage to the property or environment shall be prescribed after 3 years from the date when the party incurring the damage had knowledge, or should have had knowledge, of the damage and of the identity of liable party. However such claims shall expire after 10 years from the date of nuclear incident.
3. Right to claim the compensation for nuclear damage to the environment shall be vested in the minister competent for environmental matters.

#### **Article 106**

1. In the event of nuclear damage, which has been caused by nuclear incident occurring within the territory of the Republic of Poland, the claims shall be filed with the district courts of law.
2. Cases related to damage claims shall be regulated by the provisions of the code of civil procedure.
3. In the event of nuclear damage, which has been caused by nuclear incident occurring outside the territory of the Republic of Poland, jurisdiction for damage claims shall lie with the courts as determined by the Vienna Convention on Civil Liability for Nuclear Damage, adopted in Vienna on 21 May 1963 (O.J. of 1990 No 63, Item 370 and 371).

#### **Article 107**

1. On the issues not covered by this Chapter, nuclear installations shall be regulated by relevant regulations for nuclear facilities.
2. Claims for damage, to the extent not covered by this Chapter, shall be regulated by the provisions of the Civil Code.

#### **Article 108**

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<sup>97[102]</sup> As amended by Art. 153(2)(a) of the act referred to in ref. 97).

<sup>98[103]</sup> As amended by Art. 153(2)(b) of the act referred to in ref. 97).

The provisions of this Chapter shall not infringe upon the regulations on the payment of benefits for industrial injuries and occupational illnesses.

## **Chapter 13**

### **The President of the National Atomic Energy Agency**

#### **Article 109**

1. The President of the National Atomic Energy Agency constitutes the central organ of the governmental administration, competent for nuclear safety and radiological protection matters to the extent specified in this Act.
- 2.<sup>99[104]</sup> The Agency's President shall be nominated by the Prime Minister, on the request of the minister competent for environmental matters. The Agency's President shall be recalled by the Prime Minister.
- 3.<sup>100[105]</sup> The Agency's deputy presidents shall be nominated and recalled by the minister competent for environmental matters, on the Agency's President request.
- 4.<sup>101[106]</sup> The Agency's President shall be supervised by the minister competent for environmental matters.

#### **Article 110**

Scope of activities of the Agency's President shall include the tasks involving national nuclear safety and radiological protection, in particular:

- 1) preparation of draft documents related to national policies involving nuclear safety and radiological protection, taking into account the development of nuclear power program and both internal and external threats,
- 2) exercising regulatory control and supervision over the activities leading to actual or potential ionizing radiation exposure of humans and environment, including the issuance of decisions on licences and authorizations and other decisions, as provided in this Act,
- 3) publication of technical and organizational recommendations concerning nuclear safety and radiological protection,

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<sup>99[104]</sup> As written down in Art. 35(1)(a) of the act of 21 December 2001 amending the act on the work organization and procedures for the Council of Ministers and the scope of work for ministers, act on governmental administration departments and amending other acts (O.J. No 154 Item 1800), which entered into force on 1 January 2002.

<sup>100[105]</sup> As amended by Art. 35(1)(b) of the act referred to in ref. 104).

<sup>101[106]</sup> As amended by Art. 35(1)(c) of the act referred to in ref. 104).

- 4) performing the tasks concerning the assessment of national radiological situation in normal conditions and in radiological emergency situations, and the transmission of relevant information to appropriate authorities and to the general public,
- 5) performing the tasks resulting from the obligations of the Republic of Poland concerning accountancy and control of nuclear materials, physical protection of nuclear materials and facilities, special control measures for foreign trade in nuclear materials and technologies, and from other obligations resulting from international agreements on nuclear safety and radiological protection,
- 6) activities involving public communication, education and popularization, as well as the scientific, technical and legal information concerning nuclear science and atomic issues, including the information on ionizing radiation and its impact on human health and environment, and on feasible measures to be activated in the event of radiological emergency,
- 7) cooperation with governmental and local administration authorities on matters involving nuclear safety and radiological protection, and in nuclear research issues,
- 8) performing the tasks involving national and civil defense and the protection of classified information, resulting from other legislation,
- 9) preparation of the opinions on proposed technical activities involving peaceful uses of atomic energy, on behalf of governmental and local administration authorities,
- 10)<sup>102[107]</sup> cooperation with appropriate foreign national bodies and international organizations on the issues covered by this Act, and facilitating the contacts of Polish scientific and industrial entities with these organizations,
- 11) preparation of drafts of legislation and regulations on the issues covered by this Act and conducting the process of establishing their final form, according to the procedures established in the Council of Ministers working rules,
- 12) issuing opinions on the draft legislation developed by authorized bodies,
- 13) submitting to the Prime Minister annual reports on the activities of the Agency's President and the assessments of national nuclear safety and radiological protection status.

#### **Article 111**

Prime Minister may establish by regulations the detailed range of activities for the Agency's President.

#### **Article 112**

1. The Agency's President shall execute his tasks through the National Atomic Energy Agency, hereinafter referred to as "the Agency."

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<sup>102[107]</sup> As written down in Art. 1(60) of the act referred to in ref. 2).

2. The Council for Atomic Affairs at the Agency, hereinafter referred to as “the Council”, shall act as the Agency’s President consulting and opinion-giving body.
3. Prime Minister shall establish by regulation the structure of the Council and the scope and working procedures for its activities, defining its working rules and the number of its members.
4. The Council’s Chairman shall be nominated and recalled by the Prime Minister, on the request of the Agency’s President.
5. Members of the Council shall be nominated and recalled by the Agency’s President.

#### **Article 113**

- 1.<sup>103[108]</sup> Minister competent for environmental matters, in the form of regulation, shall invest the Agency with the statute establishing its internal organization.
2. The Agency’s detailed organizational scheme, its working rules and the tasks of its organizational sub-units shall be established in organizational rules by the Agency’s President in form of an order.

### **Chapter 14**

#### **State-owned public utility “Radioactive Waste Management Plant”**

#### **Article 114**

1. State-owned public utility named “Radioactive Waste Management Plant” located in Otwock-Świerk, hereinafter referred to as “the Plant”, shall be established for conducting the activities involving radioactive waste management and spent nuclear fuel management, and - above all – with the aim to ensure permanent feasibility of radioactive waste and spent nuclear fuel disposal.
2. The Plant also may perform activities in the field of hazardous waste management referred to in the regulations on waste, and other activities specified in the statute referred to in Article 121.

#### **Article 115**

1. The Plant shall be invested with legal personality.
2. Governmental bodies may undertake the decisions concerning the Plant’s activity only in the cases covered by this Act.

#### **Article 116** <sup>104[109]</sup>

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<sup>103[108]</sup> As written down in Art. 35(2) of the act referred to in ref. 104).

<sup>104[109]</sup> Valid in this form until the entry into force of the amendment referred to in ref. 110).

1. Supervision over the Plant and the founder's functions shall be executed by the minister competent for economic affairs.
2. Minister competent for economic affairs shall control the Plant's activities and perform annual evaluation of these activities, and shall submit the results of this evaluation to the Prime Minister not later than on 30 March of the following year.
3. Minister competent for economic affairs may establish a commission to evaluate the administration of the Plant and to prepare the conclusions resulting from this evaluation.
4. On the basis of the commission's conclusions, the minister competent for economic affairs may oblige the Plant's director to improve the Plant's administration, or to submit and implement a corrective action program. Such program shall be approved by the minister competent for economic affairs.
5. Minister competent for economic affairs, upon finding that the Plant's director decision violates some law or regulation, shall order the suspension of the execution of this decision and shall oblige the Plant's director to modify or cancel this decision.
6. The Plant's director shall be entitled to appeal against the decisions taken by the minister competent for economic affairs, according to the rules and procedures established in the regulations for state-owned enterprises.

**Article 116** <sup>105[110]</sup>

- 1. Supervision over the Plant and the founder's functions shall be executed by the minister competent for National Treasury matters.**
- 2. Minister competent for National Treasury matters shall control the Plant's activities and perform annual evaluation of these activities, and shall submit the results of this evaluation to the Prime Minister not later than on 30 March of the following year.**
- 3. Minister competent for National Treasury matters may establish a commission to evaluate the management of the Plant and to prepare the conclusions resulting from this evaluation.**
- 4. On the basis of the commission's conclusions, the minister competent for National Treasury matters may oblige the Plant's director to improve the Plant's administration or to submit and implement a corrective action program. Such program shall be approved by the minister competent for National Treasury matters.**

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<sup>105[110]</sup> As amended by Art. 1(61) of the act referred to in ref. 2), which shall enter into force on 1 January 2006.

5. **Minister competent for National Treasury matters, upon finding that the Plant's director decision violates some law or regulation, shall order the suspension of the execution of this decision and shall oblige the Plant's director to modify or cancel this decision.**
6. **The Plant's director shall be entitled to appeal against the decisions taken by the minister competent for National Treasury matters, according to the rules and procedures established in the regulations for state-owned enterprises.**

#### **Article 117**

1. The Plant shall be managed and externally represented by the director, who shall constitute the Plant's official organ.
- 2.<sup>106[111]</sup>The Plant's director shall be nominated and recalled by the minister competent for economic affairs.
- 2.<sup>107[112]</sup>**The Plant's director shall be nominated and recalled by the minister competent for National Treasury matters, who with regard to the director shall discharge the functions provided for in the Labor Law.**
3. Director may nominate and recall the Plant's deputy directors and its plenipotentiary agents, who shall act independently within their scope of competence.
4. Agents shall be granted their plenipotentiary power in a written form, otherwise it shall be considered null and void.
5. Granting and revocation of plenipotentiary power shall be entered into the register of state-owned enterprises, with the exception of plenipotentiary power for performance of specific activities and for powers of attorney in legal proceedings.
6. Worker self-governing bodies shall not be active in the Plant.

#### **Article 118**

1. In business transactions the Plant shall act in its own name and on its own account.
2. The Plant shall collect payments for performed activities.
3. Sale and management of tangible fixed assets, or of organized parts of the property, shall be regulated by the regulations for state-owned enterprises.
4. Tangible fixed assets shall not be used for settlement of the Plant's monetary obligations.

#### **Article 119**

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<sup>106[111]</sup> Valid in this form until the entry into force of the amendment referred to in ref. 112).

<sup>107[112]</sup> As written down in Art. 1(62) of the act referred to in ref. 2), which shall enter into force on 1 January 2006.

1. The Plant shall receive from the national budget an allocated subsidy for radioactive waste management and spent nuclear fuel management.
- 2.<sup>109</sup> Amount of this subsidy shall be established in budgetary legislation, on the request of the minister competent for economical affairs.
- 2.<sup>110</sup> Amount of this subsidy shall be established in budgetary legislation, on the request of the minister competent for National Treasury matters.**
- 3.<sup>109</sup> The Plant's director shall submit to the minister competent for economic affairs the accounting for the disposal of the subsidy, in accordance with the regulations issued under Article 120(2).
- 3.<sup>110</sup> The Plant's director shall submit to the minister competent for National Treasury matters the accounting for the disposal of the subsidy, in accordance with the regulations issued under Article 120(2).**

#### **Article 119a** <sup>108[113]</sup>

In the event that the Plant has to perform an unplanned receipt, transport and treatment of radioactive waste from illegal trade or of unknown origin, the costs of such services shall be covered from the national budget.

#### **Article 120**

1. The Plant's finances shall be managed according to the rules for finance management in state-owned enterprises, except as otherwise provided in this Act.
2. The Council of Ministers shall establish by regulations accountability procedures for the subsidy referred to in Article 119(1), including the type of documentation and the data required for such accounting procedures; the method for fixing the payments referred to in Article 118(2) together with the factors which should be taken into account while fixing the payments; the procedures and timing for issuing public announcements on such payments; and rules for the Plant's finances management, including rules for the control of financial reports and for choosing the experts for performing audits; and also the competent authority for final approval of the Plant's annual financial reports, procedures for disposal of property, financing of salaries and investments, and also the procedures for decision making on financial issues.

#### **Article 121**

1. The Plant's detailed tasks, organizational scheme, procedures for creating outer branch offices and their powers, internal control system and operating rules shall be established in the Plant's statute. Additional tasks shall be specified taking into account the necessity for ensuring the implementation of the tasks for which the Plant has been created, the division of the Plant into the

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<sup>108[113]</sup> Added by Art. 1(63) of the act referred to in ref. 2).

task and service departments, the scope of issues, which shall not be delegated to outer branch offices.

2. Statute may provide for the establishment of advisory and opinion-making bodies for the Plant's director.
- 3.<sup>109</sup> The Plant shall receive its statute in the form of regulation issued by the minister competent for economic affairs.
- 3.<sup>110</sup> The Plant shall receive its statute in the form of regulation issued by the minister competent for National Treasury matters.**

#### Article 122

The provisions of the act of Parliament of 30 August 1996 on the commercialization and privatization of state-owned enterprises<sup>109[114]</sup> (O.J. of 2002 No 171 Item 1397 with subsequent amendments<sup>110[115]</sup>) shall not be applicable to the Plant.

### Chapter 15

#### Administrative fines and penal regulations <sup>111[116]</sup>

#### Article 123 <sup>112[117]</sup>

1. A fine in the amount not exceeding the fivefold average monthly pay in the national economy in the calendar year prior to the commitment of the offense, published by the President of the Central Statistical Office under the Article 20(1)(a) of the act of Parliament of 26 July 1991 on retirement and disability payments from Social Security fund (O.J. of 2004, No 39 Item 356 with subsequent amendments<sup>113[118]</sup>), shall be imposed on the head of organizational entity, who:
  - 1) without a required licence or in violation of such licence conditions, or without a required notification, engages in the activities referred to in Article 4(1) or in the import or export referred to in Article 62(1); or without a required permit engages in the import, export of transit referred to in Article 62(2); fails to fulfill the obligation referred to in Article 8a; or

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<sup>109[114]</sup> The title of the act as amended by Article 2(1) of the act of 5 December 2002 amending the act on the principles of the execution of National Treasury powers, the act on the commercialization and privatization of state-owned enterprises and some other acts (O.J. No 240 Item 2055), which entered into force on 15 January 2003.

<sup>110[115]</sup> Amendments to this act have been published in O.J. of 2002 No 240 Item 2055, of 2003 No 60 Item 535 and No 90 Item 844, and of 2004 No 6 Item 39, No 116 Item 1207 and No 123 Item 1291.

<sup>111[116]</sup> As written down in Art. 1(64) of the act referred to in ref. 2).

<sup>112[117]</sup> As written down in Art. 1(65) of the act referred to in ref. 2).

<sup>113[118]</sup> Amendments to this act have been published in O.J. of 2004 No 64 Item 593, No 99 Item 1001 No 120 Item 1252, and No 121 Item 1264.

employs the workers who do not possess the authorizations, qualifications or skills established in this Act,

- 2) bearing the responsibility for nuclear safety and radiological protection, allows the exposure of a worker or some other individual in violation of the provisions of Article 14(1) concerning the provisions of Article 25(1), Article 19(1) and Article 20(1-3),
  - 3) does not fulfil his responsibilities concerning nuclear safety and radiological protection for work involving nuclear materials, ionizing radiation sources, radioactive waste and spent nuclear fuel, or during the preparation of these materials for transport and in their disposal,
  - 4) loses or leaves without proper protection nuclear material, ionizing radiation source, radioactive waste or spent nuclear fuel consigned to his care,
  - 5) does not fulfil the requirements concerning dosimetric control or the accountancy of nuclear materials, ionizing radioactive sources, radioactive waste and spent nuclear fuel,
  - 6) prevents or impedes the conduct of regulatory inspection concerning nuclear safety or radiological protection, or refuses to give information or gives false information or conceals the truth in matters concerning nuclear safety and radiological protection
2. A fine in the amount not exceeding the twofold average monthly pay referred to in paragraph 1 shall be imposed on the worker of a nuclear facility, who does not notify the head of organizational entity or the nuclear regulatory body of the occurrence or condition, which may cause a threat to nuclear safety or radiological protection.

#### **Article 124**

1. Fines referred to in Article 123, in the form of an administrative decision, shall be imposed by:
  - 1) Chief Nuclear Regulatory Inspector – in the cases when the licence is issued, or notification is received, by the Agency's President,
  - 2)<sup>114[119]</sup> regional sanitary inspector, commander of the military center of preventive medicine, or sanitary inspector of the Ministry of Home Affairs – in the cases when the licence is issued by these bodies.
2. Decision referred to in paragraph 1 shall be executed immediately.

#### **Article 125**

1. Fines shall not be imposed after a lapse of 5 years from the date when the offense has been committed.

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<sup>114[119]</sup> As written down in Art. 1(66) of the act referred to in ref. 2).

2. Fines shall not be collected after a lapse of 5 years from the date of the final decision to impose this penalty.

#### **Article 126**

1. Penalties imposed on the basis of Article 123, together with the default interest, shall be collected according to the procedure established in the regulations for administrative execution proceedings.
2. Revenue obtained from the fines shall constitute the income for the national budget.

#### **Article 127** <sup>115[120]</sup>

Persons, who do not respect the ban on cattle grazing on contaminated area, or the ban on feeding contaminated feeding stuffs and water to the animals, shall be subject to fine or arrest.

### **Chapter 16**

#### **Transitional, adaptive and final provisions**

#### **Article 128**

Property of the “Experimental Plant for Radioactive Waste Management”, legally and organizationally portioned out from the property of the research and development entity named “Atomic Energy Institute” located in Otwock-Świerk, shall become the property of the Plant referred to in Article 114(1).

#### **Article 129** <sup>109</sup>

Minister competent for economic affairs, by arrangement with the minister competent for public finance matters, may endow the Plant with property other than that referred to in Article 128.

#### **Article 129** <sup>110</sup>

**Minister competent for National Treasury matters, by arrangement with the minister competent for public finance matters, may endow the Plant with property other than that referred to in Article 128.**

#### **Article 130 (omitted)**<sup>116[121]</sup>

#### **Article 131**

Workers of the Experimental Plant for Radioactive Waste Management of the Atomic Energy Institute shall become the workers of the Plant in accordance with Article 23<sup>1</sup> of the Labor Code.

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<sup>115[120]</sup> As written down in Art. 1(67) of the act referred to in ref. 2).

<sup>116[121]</sup> Included in the announcement.

### **Article 132**

Minister of National Defense with regard to the organizational entities under his authority, and the minister competent for home affairs with regard to the Police, National Fire Service, National Border Guard and the organizational entities under his authority, after consulting the Agency' President, shall establish by regulations the implementation procedures for this Act.

### **Article 133**

1. Chief Nuclear Regulatory Inspector and regulatory inspectors who have been appointed or authorized before the date of entry into force of this Act, shall become respectively the Chief Nuclear Regulatory Inspector and regulatory inspectors within the meaning of this Act.
2. Licences issued according to the act referred to in Article 138 shall be valid for the time established in the licence.
3. Authorizations obtained according to the provisions of Article 33(3)(1) and 33(4) of the act referred to in Article 138 shall be valid for the time established in the authorization.
4. Licences concerning radioactive substances purchase and use, issued under the regulations valid before the act referred to in Article 138 has entered into force, and in particular those issued under the:
  - 1) Council of Ministers regulation of 18 June 1968 on safety and hygiene in work involving ionizing radiation applications (Official Journal No 20, Item 122);
  - 2) Council of Ministers resolution No 166/64 of 29 August 1964 on the use of radioactive substances;
  - 3) regulation No 23/70 of 21 July 1970 of the Government Plenipotentiary for Nuclear Energy Uses on radioactive substances purchase and applications- shall be valid until their replacement by the licences issued under this Act, but not longer than for 24 months as from the date of entry into force of this Act.
5. National Radioactive Waste Repository in Rózan, established according to the regulations issued under the act referred to in Article 138, shall be recognized as the National Radioactive Waste Repository within the meaning of this Act.
6. Proceedings, which have been initiated before the date of the entry into force of this Act, shall be continued and concluded in accordance with previous regulations.

**Article 134 – 137 (omitted)** <sup>121</sup>

### **Article 138**

The Act of Parliament of 10 April 1986 – Atomic Law (O. J. No 12 Item 70; of 1987 No 33 Item 180;

of 1991 No 8 Item 28; of 1994 No 90 Item 418; of 1995 No 104 Item 515; of 1996 No 24 Item 110 and No 106 Item 496) is hereby repealed.

### **Article 139**

This Act shall enter into force on 1 January 2002, with the exception of:

- 1) Chapter 13 and Article 136, which shall enter into force 14 days after the date of publication<sup>117[122]</sup>,
- 2) Article 21(2) and Article 27(2), which shall enter into force 24 months after the date of publication<sup>122</sup>.

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<sup>117[122]</sup> The act has been published on 18 January 2001.

DEFINITION OF THE TERMS: ABSORBED DOSE, EQUIVALENT DOSE, AND EFFECTIVE DOSE.

**Absorbed dose D:** ionizing radiation energy imparted to the matter contained in a volume element, divided by the mass of this element, expressed by the formula:

$$D = \overline{d\varepsilon} / dm$$

where

- $\overline{d\varepsilon}$  is the mean value of imparted energy
- $dm$  is the mass contained in the volume element.

Absorbed dose means the dose averaged over the tissue or organ. Legal unit of absorbed dose is gray (Gy).

**Equivalent dose H<sub>T</sub>:** dose absorbed in the tissue or organ T, weighted for the type and energy of the ionizing radiation R, expressed by the formula:

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

where

- $D_{T,R}$  means the absorbed dose from ionizing radiation R, averaged over the tissue or organ T,
- $w_R$  means the weighting factor representing radiation R.

Legal unit of equivalent dose is sievert (Sv).

**Effective dose E:** sum of weighted equivalent doses from external and internal irradiation of tissues and organs, expressed by the formula:

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

where

- $D_{T,R}$  means the absorbed dose from radiation R, averaged over the tissue or organ T,
- $w_R$  means the weighting factor representing radiation R,
- $w_T$  means the weighting factor representing tissue or organ T.

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<sup>118[123]</sup> As written down in the annex to the act referred to in ref. 2)