

REGULATION OF THE COUNCIL OF MINISTERS

of 3 December 2002

on documents required upon the submission of an application for the licence to carry out practices under exposure to ionising radiation or when such practices are to be reported.

(Journal of Laws no. 220, item 1851)

Pursuant to the provisions of art. 6 point 2 of the Atomic Energy Law of 29 November 2000 (Journal of Laws of 2001, no. 3, item 18, no. 100, item 1085, no. 154, item 1800, of 2002, no. 74, item 676 and no. 135, item 1145), the following is ordained:

§ 1. This regulation defines:

- 1) documents required upon the submission of an application for a licence to carry out practices under exposure to ionising radiation, hereinafter referred to as "exposure", in which the applicant confirms that nuclear safety and radiation protection requirements have been met;
- 2) documents required to report the practices as set forth in point 1 above, in which the applicant confirms that nuclear safety and radiation protection requirements have been met;
- 3) actions of the authority competent for the issue of licences or acceptance of reports if the content of the submitted documentation is not sufficient to substantiate that nuclear safety and radiation protection requirements have been met.

§ 2. The following terms shall be assigned the following meanings under this regulation:

- 1) "licence" – shall mean the permit to carry out practices under exposure;
- 2) "report" – shall mean the act of notifying on practices carried out under exposure;
- 3) "applicant" – shall mean a manager of an organisational entity applying for the issue of a licence or notifying on practices.

§ 3. The applicant shall attach the following documents to the licence request:

- 1) document containing:
 - a) justification for practices carried out under exposure;
 - b) description of the organisational entity's division which shall directly carry out the licensed practices, including its seat and address,
 - c) proposed dose constraints related to the practices indicated in the application,
 - d) anticipated date of commencing and period of carrying out practices indicated in the application;
- 2) document containing the applicant's commitment to notify the licensing authority of any plans to transform or close down the organisational entity or its division directly carrying out the licensed practices, including the commitment to find an agreement regarding the methods of handling ionising radiation sources, nuclear materials or radioactive waste, as well as the obligation to perform dosimetry control and, possibly, to decontaminate the work place and its surroundings at own expense after the licensed practices are terminated;
- 3) documents set forth in Annex no. 1 hereto – if the application is submitted solely in respect of practices carried out under exposure, excluding practices carried out in nuclear facilities, spent nuclear fuel storage locations, radioactive waste repositories and spent nuclear fuel repositories;
- 4) documents set forth in Annex no. 2 hereto – if the application is submitted in respect of practices carried out under exposure in nuclear facilities, spent nuclear fuel storage locations, radioactive waste repositories and spent nuclear fuel repositories.

§ 4. The applicant shall attach the following documents to the report:

- 1) document containing:
 - a) justification for the commencement of practices under exposure,
 - b) description of the type and scope of planned practices under exposure, including maximum activity or concentration of radionuclides which are the object of practices set forth in the report,
 - c) description of the organisational entity's division which shall directly carry out practices indicated in the report, including its seat and address,
 - d) anticipated date of commencing and period of carrying out practices indicated in the report;
- 2) document containing the applicant's commitment to notify the President of the National Atomic Energy Agency of any plans to transform or end the operation of the organisational entity or a division thereof directly carrying out practices set forth in the report, the commitment to find an agreement regarding the methods of handling ionising radiation sources, nuclear materials or radioactive waste, the obligation to perform dosimetry control and, possibly, to decontaminate the work place and its surroundings at own expense after the practices indicated in the report are terminated.

§ 5. If the content of the documents submitted by the applicant does not substantiate enough that nuclear safety and radiation protection requirements have been met, the licensing authority or the authority accepting the report may:

- 1) check the fulfilment of nuclear safety and radiation protection requirements on applicant's site, or
- 2) request that the applicant conducts investigation or provides experts' opinion at own expense to ascertain that nuclear safety and radiation protection requirements are being met,.

§ 6. Previous regulations shall apply to applications and reports submitted prior to the enforcement of this regulation.

§ 7. This regulation becomes effective on 1 January 2003 1)

President of the Council of Ministers: *L. Miller*

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- 1) 1) This regulation was preceded by a regulation of the Council of Ministers of 21 November 1995 on the terms of licensing practices involving atomic energy (Journal of Laws of 1996, no. 3, item 16) which shall expire on 1 January 2003 pursuant to art. 137 of the Atomic Energy Law of 29 November 2000 (Journal of Laws of 2001, no. 3, item 18, no. 100, item 1085, no. 154, item 1800, of 2002, no. 74, item 676, no. 135, item 1145).

Annexes to the Regulation of the Council of Ministers of
3 December 2002 (item 1851)

Annex no. 1

DOCUMENTS TO BE ATTACHED TO THE APPLICATION FOR A LICENCE TO CARRY OUT PRACTICES UNDER EXPOSURE, EXCLUDING PRACTICES CARRIED OUT IN NUCLEAR FACILITIES, SPENT NUCLEAR FUEL STORAGE LOCATIONS, RADIOACTIVE WASTE REPOSITORIES AND SPENT NUCLEAR FUEL REPOSITORIES

1. The following documents shall be attached to the application, regardless of the type of practices under exposure submitted for licensing:

- 1) information on radioactive sources, radioactive waste, nuclear materials, ionising radiation emitted by devices containing radioactive sources or generating ionising radiation;

- 2) information on the qualifications of persons occupying work posts which require special authorisation and the qualifications of the radiation protection inspector;
- 3) definition of the type and scope of control conducted to assess the employees' exposure to ionising radiation, control of the work environment and the surroundings of the organisational entity, including information on the used dosimetry equipment and its calibration;
- 4) quality assurance programme for practices set forth in the application.

2. The following documents shall be attached to the application, subject to the type of practices under exposure submitted for licensing:

1) in relation to practices involving the application of radioactive sources, nuclear materials, devices containing radioactive sources or generating ionising radiation in a laboratory, with a reservation for point 10, the following shall be attached to the application:

- a) instructions manual for practices involving radioactive sources or nuclear materials, technical description of the design, operation and use of devices containing radioactive sources or generating ionising radiation,
- b) procedures for handling radioactive waste,
- c) utility emergency procedure plan,
- d) information on the facility or premises where a laboratory or workshop for carrying out practices set forth in the application shall be situated,
- e) information on the storage of radioactive sources, radioactive waste, nuclear materials and devices containing radioactive sources, if designed for storage outside of laboratory or workshop,
- f) information on the physical protection of nuclear materials,
- g) information on an organisational entity which installs devices containing radioactive sources or generating ionising radiation, and institutions foreseen for the maintenance and control of the said devices;

2) in relation to practices involving deliberate administration of radioactive substances to the persons or animals for the purpose of medical or veterinary diagnosis, treatment or scientific research, the following shall be attached to the application:

- a) documents set forth in point 1 letters a-e,
- b) for medical applications – instructions for patients who are administered radioactive substances for the purpose of medical diagnosis or treatment;

3) in relation to practices involving the use of radioactive sources, nuclear materials, devices containing radioactive sources or generating ionising radiation outside the laboratory or workshop, with a reservation for point 11, the following shall be attached to the application:

- a) documents set forth in point 1 letters a-c,
- b) information on the storage of radioactive sources, radioactive waste, nuclear materials and devices containing radioactive sources,
- c) information on the physical protection of nuclear materials,
- d) information on transporting of radioactive sources, radioactive waste, nuclear materials and devices containing radioactive sources,
- e) in the case of field works conducted with the application of open radioactive sources outside the premises of the organisational entity – the consent of the owner or administrator of the premises in which the above works shall be conducted, and the positive opinion of a respective voivodship sanitary inspector in question of the radiation hygiene;

4) in relation to practices involving the commissioning of laboratories where ionising radiation sources shall be applied or nuclear materials, radioactive sources and radioactive waste shall be stored, the following shall be attached to the application:

- a) parts of the technical documentation of the facility or premises where the said practices shall be carried out, which substantiate that nuclear safety and radiation protection requirements shall be met,
- b) utility emergency procedures plan,
- c) information on works to be conducted in the laboratory or workshop, including a specification of the type and maximum activity of simultaneously applied radioactive sources, and in respect of facilities and premises for the storage of nuclear materials, radioactive sources and radioactive waste – data on materials, sources and waste foreseen for storage,
- d) information on physical protection of nuclear materials;

5) in relation to practices involving the production or processing of nuclear materials, radioactive sources or radioactive waste, manufacture of devices containing radioactive sources or devices generating ionising radiation and intended addition of radioactive substances in the manufacture of mass consumption products or medical products, with a reservation for point 9, the following shall be attached to the application:

- a) technical documentation of the facility or premises where the proposed practices shall be carried out and where nuclear materials, radioactive sources and radioactive waste or finished products and devices shall be stored, to confirm that nuclear safety and radiation protection requirements have been met,
- b) technical description of the design, operation and handling of the manufactured devices and products,
- c) utility emergency procedure plan,
- d) information on the physical protection of nuclear materials;

6) in relation to practices involving the installation or operation of devices containing radioactive sources and the commissioning of devices generating ionising radiation, the following shall be attached to the application:

- a) technical description of the design, operation and use of devices applied in the practices,
- b) utility emergency procedure plan,
- c) information on the storage of radioactive sources, radioactive waste and devices containing radioactive sources,
- d) information on transporting of radioactive sources, radioactive waste and devices containing radioactive sources;

7) in relation to practices involving the acquisition of devices generating ionising radiation and the turnover of nuclear materials, radioactive sources, devices containing such sources, mass consumption products and medical products containing radioactive substances, with a reservation for point 9, the following shall be attached to the application:

- a) technical description concerning the design, operation and use of the acquired device which generates ionising radiation, device introduced for turnover or product containing radioactive substances,
- b) utility emergency procedure plan,
- c) information on the storage of devices, products and items introduced for turnover,
- d) information on the physical protection of nuclear materials;

8) in relation to practices involving transporting of nuclear materials, radioactive sources and radioactive waste, the following shall be attached to the application:

- a) utility emergency procedure plan,
- b) information on the storage of cargo during transport,
- c) certificate of completion of supplementary training for drivers transporting hazardous cargo, entitling the driver to transport radioactive materials, certificate of qualifications of driver transporting hazardous cargo, certificate of the vehicle's compliance with technical requirements imposed on vehicles transporting radioactive materials, issued pursuant to regulations concerning road transport of hazardous cargo, and if the shipment involves nuclear materials or nuclear fuel - additionally:
- d) information on the route and schedule of transporting of nuclear fuel and nuclear materials classified as category I pursuant to the regulations on the physical protection of nuclear materials,
- e) information on the physical protection of nuclear materials and nuclear fuel,
- f) instructions for the reloading of nuclear fuel during transport and information on the manner of load distribution in the means of transport;

9) in relation to practices involving the manufacture or acquisition of X-ray units generating radiation with energy of up to 300 keV for medical purposes, the following shall be attached to the application:

- a) technical documentation of unit,
- b) instruction manual,
- c) approval of the General Sanitary Inspector or an indicated by him institution competent in radiation hygiene;

10) in relation to practices involving the putting in operation or application of X-ray units with radiation energy of up to 300 keV for medical and veterinary purposes in X-ray laboratories, the following shall be attached to the application:

- a) copy of permit for the acquisition of X-ray unit, and
 - in the case of X-ray units for medical purposes – documents as set forth in point 9,
 - in the case of X-ray units for veterinary purposes – documents as set forth in point 9 letters a and b,
- b) design technical documentation of X-ray laboratory,
- c) instructions for the operation of X-ray units, defining detailed radiation protection standards,
- d) utility emergency procedure plan;

11) in relation to practices involving the commissioning or application of X-ray units with radiation energy of up to 300 keV for medical and veterinary purposes during field operation, the following shall be attached to the application:

- a) copy of permit for the acquisition of X-ray unit, and
 - in the case of X-ray units for medical purposes – documents as set forth in point 9,
 - in the case of X-ray units for veterinary purposes – documents as set forth in point 9 letters a and b,
- b) instructions for the operation of X-ray units, defining detailed radiation protection procedures,

c) utility emergency procedure plan;

Annex no. 2

DOCUMENTS TO BE ATTACHED TO THE APPLICATION FOR THE LICENCE TO CARRY OUT PRACTICES UNDER EXPOSURE IN NUCLEAR FACILITIES, SPENT NUCLEAR FUEL REPOSITORIES, RADIOACTIVE WASTE REPOSITORIES AND SPENT NUCLEAR FUEL STORAGE LOCATIONS

1. In relation to practices involving the construction of nuclear facilities, radioactive waste repositories, spent nuclear fuel repositories and spent nuclear fuel storage locations, the following documents shall be attached to the application:

- 1) safety report containing a detailed specification of the nuclear facility, repository or storage location and including an analysis of nuclear safety and radiation protection under standard operating conditions and in a case of radiological emergencies which can be anticipated ;
- 2) quality assurance programme applicable to all stages of the construction process, including design, construction, supply of structural elements and devices which guarantee nuclear safety and radiation protection of the nuclear facility, repository or storage location;
- 3) description of the terms of physical protection of the nuclear facility, repository or storage location;
- 4) description of the terms of quality assurance at the phase of start-up and commissioning of a nuclear facility or commissioning of a storage location.

Explanations to section 1:

- a) detailed specification of a nuclear facility or spent nuclear fuel storage location, as set forth in section 1 point 1 above, shall be inclusive of:
 - basic parameters and technical and organisational solutions,
 - description of safety means applied to prevent the leakage of radioactive substances to the environment during standard operation and in an emergency, including assessment of the type and activity of such substances,
 - description of functional and technological connections between installations on the premises of the nuclear facility or storage location and between the nuclear facility or storage location and the environment,
 - information on the type and quantity of radioactive waste and description of the handling procedure,
 - description of the procedure of handling spent nuclear fuel,
 - description of the programme for controlling the work environment and surroundings of the facility or storage location,
 - description of the physical protection of facility or storage location,
 - detailed site description,
 - data on population density in the area surrounding the facility or storage location and on location of population centres, traffic routes and industrial plants with regard to the facility or storage location ,
 - description of natural environment features which could affect the safety of the facility or storage location and the way the radioactive substances may be dispersed in the environment,
 - description of land development elements which could affect the safety of facility or storage location,
- b) a detailed specification of radioactive waste or spent nuclear fuel repository, as set forth in section 1 point 1, shall be inclusive of:

- data on radioactive waste or spent nuclear fuel intended for storage (type, volume, activity) and anticipated life cycle of repository,
 - basic parameters and technical and organisational solutions to be applied in repository,
 - description of the radioactive waste or spent nuclear fuel handling technology in repository,
 - description of the programme for the control of the work environment and the repository surroundings,
 - hydrogeological documentation in view of the geological stability of the repository and the possibility of leakage of radioactive substances to the environment,
 - description of site and its development elements in view of the safety of repository and its impact on the environment,
 - description of the physical protection of repository,
- c) the analysis of nuclear safety, as set forth in section 1 point above, shall be inclusive of:
- assessment of human and environmental exposure during the operation of the nuclear facility, radioactive waste repository, spent fuel storage location or spent fuel repository, including emergency situations, in relation to repositories – assessment of exposure hazard also after decommissioning,
 - justification of the adopted measures preventing the leakage of radioactive substances to the environment during standard operation of the nuclear facility, repository or storage location, and in emergency situations, the adopted operating conditions and limitations,
 - specification of external events which could occur in the area of the nuclear facility, repository or storage location in consequence of natural phenomena and human activity, including an assessment of their possible impact on the nuclear facility, repository or storage, as well as design solutions addressing the above,
 - specification of neighbouring industrial plants, traffic routes and other sites which could exert an adverse impact on the safety of the nuclear facility, repository or storage location at present and in the future,
 - current and anticipated demographic data, land development plans,
 - information on the storage and transport of fresh and spent nuclear fuel and on the handling of radioactive waste,
 - data on possible interactions between nuclear phenomena and non-nuclear phenomena, including radiobiological, thermal and chemical.

2. In relation to practices involving the commissioning or trial operation of a nuclear facility, the following shall be attached to the application:

- 1) safety report containing data and information as set forth in section 1 point 1 above;
- 2) start-up programme in view of the following start-up stages:
 - a) test of process installations and systems preceding their normal operation,
 - b) fuel loading into core and physical start-up of reactor,
 - c) productive start-up and trial operation of facility;
- 3) instructions for facility operation, including basic methods and procedures for the operation of installations and systems to ensure nuclear safety and radiation protection;
- 4) description of proposed operating conditions and limitations;

- 5) declaration of facility investor which confirms implementation of the required acceptance procedures and conducting required trials and technological tests in relation to installations and systems which influence nuclear safety and radiation protection, and indicating the facility's readiness for start-up;
- 6) declaration of facility investor that adequately qualified personnel shall be involved in every stage of facility start-up and operation, including copies of documents certifying such qualifications;
- 7) emergency procedure plans in and outside the facility for a case of a radiological emergency;
- 8) organisation of overhaul works;
- 9) declaration of facility investor confirming the availability of as-built documentation in relation to installations, systems and construction structures;
- 10) procedure of handling radioactive waste;
- 11) procedures of management of fresh and spent nuclear fuel;
- 12) terms and procedures related to the control of employee exposure to ionising radiation, control of the work environment and the facility surroundings;
- 13) terms and procedures of radioactive substance release to the environment;
- 14) results of radiation measurements in the environment;
- 15) programme for quality assurance during facility commissioning;
- 16) description of physical protection of nuclear facility.

3. In relation to practices involving continuous monitoring of the nuclear site or repository, the following shall be attached to the application:

- 1) documents required upon the commissioning of the nuclear site, updated in view of start-up results;
- 2) report on site commissioning, including testing report, prepared by the site's investor;
- 3) suggested operating conditions and limitations for repository;
- 4) operating programme for site or repository, including maintenance, periodic inspections, tests and control;
- 5) programme for monitoring employee exposure to ionising radiation, control of the work environment, the area of the site or repository;
- 6) programme for operating quality assurance;
- 7) description of physical protection of repository.

4. In relation to practices involving the operation of a radioactive waste or spent nuclear fuel repository, the following shall be attached to the application:

- 1) safety report containing data and information as set forth in section 1 point 1 above;
- 2) repository start-up programme;
- 3) instructions for repository operation, including basic methods and procedures for the operation of installations and systems to ensure nuclear safety and radiation protection;
- 4) description of proposed operating conditions and limitations;
- 5) declaration of facility investor which confirms implementation of the required acceptance procedures and conducting required trials and technological tests in relation to installations and systems which influence nuclear safety and radiation protection, and indicating the facility's readiness for start-up
- 6) applicant's declaration that adequately qualified personnel shall be involved in every stage of repository operation, including copies of documents certifying such qualifications;

- 7) emergency procedure plans in and outside the repository for a case of a radiological emergency;
- 8) organisation of overhaul works;
- 9) applicant's declaration confirming the availability of as-built documentation in relation to installations, systems and construction structures;
- 10) terms and procedures related to the control of employee exposure to ionising radiation, control of the work environment and the repository surroundings;
- 11) results of radiation measurements in the environment;
- 12) programme for quality assurance during repository operation.

5. In relation to practices involving the closure of radioactive waste and spent nuclear fuel repositories, the following shall be attached to the application:

- 1) justification of closure;
- 2) list of radioactive waste items in repository (type, volume, activity);
- 3) closure plan, including:
 - a) technical solutions for filling out empty spaces between waste packaging and, subject to the type of repository, also spaces between repository construction elements,
 - b) counteraction plan, if movements of radionuclides indicate that radiation protection objectives may not be met,
 - c) indication of inspection period, during which the repository's impact on the environment is monitored and safety devices are serviced,
 - d) environmental monitoring programme in the repository and the surrounding area,
 - e) description of sign posts identifying the localization of repository, boundaries of repository construction elements and three permanent control points of reference to the national geodesic network;
- 4) analysis of exposure to ionising radiation of employees participating in the closing process;
- 5) emergency plan if a radiological emergency occurs during repository closing;
- 6) evaluation of exposure of residents in the vicinity of the repository, conducted for a time period corresponding to the given type of disposed waste;
- 7) programme for quality assurance during repository closure.

6. In relation to practices involving the decommissioning of a nuclear facility, radioactive waste repository or spent nuclear fuel depository, the following shall be attached to the application:

- 1) justification of decommissioning;
- 2) scope of decommissioning;
- 3) programme for inventorying radionuclide activity in nuclear facility or repository;
- 4) decommissioning programme, including work schedule, decommissioning techniques, tools and procedures, handling radioactive waste evacuated from the site;
- 5) analysis of employees' exposure to ionising radiation;
- 6) evaluation of the facility's or repository's impact on the environment during decommissioning and after its completion;
- 7) programme for ionising radiation and radioactive contamination measurement in facility or repository and the surrounding area after the completion of the decommissioning process;

- 8) emergency plan if a radiological emergency occurs during the decommissioning of a nuclear site or radioactive waste repository;
- 9) programme for quality assurance during decommissioning.