

**Regulation on the Procedure for Issuing Licenses and Permits for Safe Use of
Nuclear Energy**

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Chapter One

GENERAL RULES FOR ISSUING LICENSES AND PERMITS

Section I

General provisions

Article 1.

This Regulation establishes the procedure for:

1. issuing licenses and permits to natural and legal persons for performing activities for which licenses and permits are required according to the Act on the Safe Use of Nuclear Energy (ASUNE);
2. amendment, renewal, suspension and revocation of the licenses and permits issued;
3. exercising control over the fulfilment of the conditions of the licenses and permits issued;
4. maintaining the public registers of the licenses, permits and individual licenses issued.

Article 2.

The procedure for issuing, amendment, renewal, suspension and revocation of licenses for specialized training and for issuing, suspension and revocation of individual licenses under Chapter Three, Section VII of the ASUNE shall be determined by a separate regulation.

Article 3.

(1) Licenses and permits shall be issued, amended, renewed, suspended and revoked by the Nuclear Regulation Agency (NRA) Chairman according to the principles and under the conditions specified by the ASUNE.

(2) The applicant shall comply with the conditions for issuing a license or permit referred to in Paragraph 1 when:

1. all necessary documentation is submitted;
2. the NRA Chairman's instructions for providing additional documents are complied with;
3. all the conditions specified in preceding licenses, permits and other documents issued under the ASUNE and connected with issuing the respective license or permit are fulfilled;
4. the review and assessment of the applicant's submissions confirm the compliance with the requirements of the ASUNE and this Regulation, as well as with all the other regulations for the application of the ASUNE;
5. all necessary licenses, permits and other administrative acts specified by the ASUNE as prerequisites for issuing the respective license or permit have been issued to the applicant by the competent administrative authorities.

(3) Paragraph 2 shall be applied correspondingly to amendment and renewal of a license or permit.

Section II

Procedure for issuing licenses and permits

Article 4.

(1) In order to obtain a license or permit, the applicant shall submit to the NRA Chairman a written application, which shall contain:

1. applicant's identification data;
2. the type of the required license or permit and general description of the activity to be performed;
3. the term of validity for which the license or permit is required;
4. general description of the basic characteristics and location of the nuclear facility or entity with a source of ionising radiation to be utilized if operation of such an entity is foreseen;
5. information on the administrative acts, issued by other state authorities, related to the stated activity;
6. list of the documents attached to the application.

(2) The application shall be signed:

1. by the applicant if the applicant is a natural person;
2. by the person who has the authority to represent the applicant according to current court registration if the applicant is a legal entity or sole trader.

(3) The application could be signed by an authorized person if the authorisation is granted in a written form with certified by a notary genuineness of the signature. The documents related to the authorisation shall be attached to the application.

Article 5.

(1) Depending on the type of the activity, all required documents under Chapters Two, Three and Four, or only those corresponding to the activity, as well as a payment document of the application review fee, if such a fee is due, shall be attached to the application.

(2) Any application for issuing a license or permit and the attached documents shall be submitted in the Bulgarian language.

(3) Official documents in a foreign language shall be submitted together with a legalized translation in Bulgarian. The rest of the documents in a foreign language shall be submitted together with a translation in Bulgarian prepared by a certified translator.

(4) An original document or officially certified copy of any document required according to this Regulation shall be submitted.

(5) Any document shall be submitted both in paper and in an electronic form, with the exception of the official documents issued by competent state authorities, which shall be submitted in paper only.

(6) Documents required according to this Regulation and enclosed to preceding applications on the basis of which a license or permit has been issued may not be attached to the application if the stated data and circumstances remain unchanged. Such documents shall be indicated in the application along with the registration numbers of the respective licenses and permits.

(7) Where certain facts are certified by other competent authority and are included in a public register in the Republic of Bulgaria, the applicant may not demonstrate their availability if a written declaration is submitted.

Article 6.

(1) The application and the enclosed documentation shall be reviewed for formal compliance with the established requirements within 14-days after registration at the

NRA. In the case of application for issuing a license or permit for a nuclear facility, the review shall be performed within 45-days.

(2) In case of non-compliance with the requirements as per Articles 4 and 5, the applicant shall be instructed in writing to eliminate the deficiencies within 14-days.

(3) Should the applicant fail to eliminate the deficiencies within the time limit under Paragraph 2, the NRA Chairman shall deny issuing the license or permit by a reasoned order.

Article 7.

(1) The NRA Chairman shall have the discretion to check the declared data and circumstances on his own volition and the respective competent governmental and local authorities and applicants shall provide necessary assistance.

(2) With regard to the licensing process, the NRA Chairman may request expert advice from the competent governmental and local authorities.

Article 8.

(1) In accordance with the Rules of Procedure of the Nuclear Regulatory Agency, approved by the Council of Ministers Decree No. 199/2002 (promulgated in the State Gazette No. 86/2002), the NRA Chairman shall assign review and assessment of the application and the attached documents to the NRA units. Where necessary, on-site inspections shall be performed for verifying compliance with the requirements under Article 3.

(2) With regard to the licensing process, the NRA Chairman may ask the Advisory Council on Nuclear Safety and the Advisory Council on Radiation Protection to give expert advice on the scientific aspects of nuclear safety and radiation protection.

(3) Where necessary, the NRA Chairman may assign research, studies and expertise connected with nuclear safety and radiation protection related issues to external organizations or specialists.

(4) Based on the results under Paragraphs 1-3, the NRA Chairman may instruct the applicant to submit supplementary information or additional documents, to perform additional calculations, or any other activity to justify conformity with the requirements under Article 3 within a reasonable time, but not longer than three months. In case of non-compliance with the instructions, Article 6, Paragraph 3 shall be applied.

(5) The time limit for the issuance of the respective license or permit shall begin to run with the receipt of the application under Article 4, Paragraph 1, respectively with the fulfilment of the instructions under Article 6, Paragraph 2 and Paragraph 4 of this Article.

Article 9.

(1) The NRA Chairman shall issue the requested license or permit upon fulfilment of the requirements specified in Article 3, or shall deny the application by issuing a reasoned order.

(2) Upon issuing a permit requiring changes in the license conditions, the NRA Chairman shall have discretion to make the amendment of the license ex officio – initiated on his own volition, following the procedure under Section IV of this chapter.

(3) The licenses, permits and orders referred to in Paragraph 1 shall be issued within the time limits specified in Article 18, Paragraphs 1 and 2 of the ASUNE. The rest of the orders under this Regulation shall be issued within the time limits specified in the Regulation.

Article 10.

(1) Any license for operation of a nuclear facility shall be issued for a term of validity not exceeding ten years; any license for practices with sources of ionising radiation (SIR) shall be issued for a term of validity not exceeding five years.

(2) Any permit shall be issued for a term of validity determined according to the type of the performed activity.

Article 11.

(1) All issued licenses, permits and denial orders shall be served to the applicant, to a legal or explicitly authorized representative, or shall be sent by mail with registered letter with acknowledgement of receipt. The type and the registration number of the issued act shall be indicated on the registered letter.

(2) Any license or permit shall be served or sent to the applicant following the procedure under Paragraph 1 after submission of a document demonstrating proof of payment of the initial licensing fee or the fee for issuing the permit. The fees shall be charged according to the rates determined in the Tariff for the Fees Charged by the Nuclear Regulation Agency under the ASUNE, approved by the Council of Ministers Decree No. 206/2003 (promulgated in the State Gazette No. 85/2003).

(3) Where more than one permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE is required for the completion of the same modification, the fee shall be charged for issuance of the first permit only. The fee shall not be charged for:

1. amendment of the respective license by a permit issued on the NRA Chairman own volition under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE;
2. amendment of the respective license or permit in order the conditions stipulated in the same or in another license or permit issued by the NRA Chairman to the same applicant to be met.

Section III

Licenses and permits scope and contents

Article 12.

(1) The NRA Chairman shall issue a license or permit for each of the activities provided for in Article 15, Paragraphs 3 and 4 of the ASUNE.

(2) A separate operating license and permits shall be issued for any unit or any other nuclear facility located at a nuclear power plant site if the licensed or permitted activities are connected with the respective unit or nuclear facility.

(3) Where commissioning or decommissioning is a multistage process, a separate permit for each stage of the commissioning or decommissioning may be issued. The requisite documents for issuing a permit for the next stage or stages may be specified in the conditions of the permit issued for the previous stage.

(4) Where one person intends to operate more than one entity with a source of ionising radiation to be covered by the same type licenses and permits, only one license or permit may be issued for all these activities.

(5) Unless otherwise provided for in this Regulation, if the ASUNE requires for issuing in consecutive order of several licenses and permits for one nuclear facility or entity with a source of ionising radiation, the subsequent acts shall be issued to the holder of the first permit or license.

Article 13.

(1) Any license and permit shall contain:

1. the name of the issuing authority;
2. the type of the respective license or permit;

3. the registration number of the license or permit;
4. the legal grounds for issuing the act;
5. the first name, second name and surname, personal identification number, permanent and present address in the Republic of Bulgaria of the licensee or permit holder – natural person; the name, head office, registered office, court registration, BULSTAT and tax number of the licensee or permit holder – legal person;
6. the activity for which the license or permit is issued;
7. the nuclear facility or entity with a source of ionising radiation to be utilized if operation of such an entity is foreseen;
8. the term of validity for which the license or permit is issued;
9. general and special conditions specifying the rights and obligations of the licensee or permit holder.

(2) The general conditions of the license or permit shall be determined in accordance with the type of the activity and may specify:

1. detailed description of the activities for which the license or permit is issued;
2. detailed description of the nuclear facility or entity with a source of ionising radiation for which the license or permit is issued if operation of such an entity is envisaged;
3. basic requirements for performing the activity;
4. obligations related to maintaining financial and material resources;
5. requirements related to the personnel;
6. requirements related to radiation protection;
7. requirements related to quality assurance;
8. requirements related to emergency preparedness;
9. obligations related to notification for deviation from normal operation and for accidents;
10. obligations related to accounting and control of nuclear material and radioactive waste (RAW);
11. obligations related to spent fuel and RAW management;
12. obligations related to the application of the safeguards for non-proliferation of nuclear weapons;
13. obligations related to physical protection assurance;
14. obligations related to submission information about the fulfilment of the license

or permit conditions;

15. obligations related to exercising control over the fulfilment of the license or permit conditions;

16. obligations related to termination of the activity.

(3) The special conditions of the license or permit may specify:

1. requirements related to organization of the activity of the licensee or permit holder if activities having substantial effect on nuclear safety, radiation protection, emergency preparedness and physical protection will be executed by contractors, as well as requirements connected with the possibility for exercising control over such activities;
2. requirements related to the documentation management;
3. requirements related to submission information on a periodic basis about the fulfilment of the licensed or permitted activity;
4. requirements related to the implementation of subsequent stages of the activity in the case of a permit issued for a separate stage of the activity;
5. requirements related to the fulfilment of the licensee or permit holder obligations under Article 16 of the ASUNE;
6. requirements related to public order and national security;
7. other conditions related to starting or implementation of the activity.

(4) Any license or permit may comprise one or more enclosures.

(5) A list of the internal rules for carrying out the activity, including instructions, programs, technical specifications and similar matters whose modification may have substantial effect on nuclear safety, radiation protection, physical protection or emergency preparedness and for this reason serves as a basis for issuing a permit under Art. 15, Paragraph 4, Subparagraph 5 of the ASUNE shall be attached as an appendix to an operating license for a nuclear facility.

(6) Before modifying any document covered by the appendix under Paragraph 5, the licensee shall notify the NRA Chairman of the modification subject matter. Within 30-days, the NRA Chairman shall express a written statement on the necessity of performing the modification on the basis of a permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE. The non-issuance within this time limit shall be considered to be an implicit consent for undertaking the modifications.

Article 14.

(1) Where grounds exist for amendment of a license or permit under Article 21, Paragraph 1 of the ASUNE, the licensee or permit holder shall notify the NRA Chairman within one month following the occurrence of any circumstances requiring license or permit amendment and shall request the respective amendment.

(2) Any company - a holder of a permit under Article 33, Paragraph 1 of the ASUNE or of an operating license for a nuclear facility, which intends to perform reorganization through merging, consolidation, splitting or splitting off, as well as decreasing or increasing the capital, shall notify the NRA Chairman in advance and shall submit an assessment of the effect of these activities on nuclear safety and radiation protection with regard to subsequent application of Article 21, Paragraph 1 of the ASUNE.

(3) In the cases under Paragraph 2, the NRA Chairman shall express a written statement on the existence of circumstances having substantial effect on nuclear safety and radiation protection, as well as on the existence of circumstances requiring suspension or amendment of the licence or permit issued.

(4) The applicants, licensees and permit holders shall notify the NRA Chairman of any changes in the declared data and circumstances within 7-days after their occurrence, except where such changes serve as a basis for issuing a modification permit or for amendment of a licenses or permits issued.

Article 15.

Obtaining all the necessary licenses, permits and other administrative acts stipulated by law as a prerequisite for performing the respective activity shall be prior condition for entering into force of the licenses and permits issued under this Regulation.

Section IV

Licenses and permits amendment

Article 16.

(1) The NRA Chairman shall have the discretion to amend an issued license or permit upon request or ex officio.

(2) The rules for licenses and permits amendment shall also be applied to supplementing those documents.

Article 17.

(1) An operating license for a nuclear facility shall be amended on the NRA Chairman own volition if the issuance of a permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE leads to the necessity the license conditions to be brought into compliance with the permit conditions.

(2) The NRA Chairman shall notify the licensee in writing of the opening of the license amendment procedure under Paragraph 1. Within 14-days, the licensee may express a written opinion about the amendment indispensability.

(3) Any permit under Paragraph 1 shall not be issued before the expiration of the time limit under Paragraph 2.

(4) Any permit under Paragraph 1 shall specify the conditions of the license, which have to be amended in order to be brought in compliance with the permit conditions.

(5) In case of unconformity between the conditions of the permit issued under Paragraph 1 and the amended conditions of the license, the conditions of the permit shall be applied.

(6) The provisions of Paragraphs 1–5 shall be applied accordingly to amendment of a permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE.

Article 18.

(1) In the cases covered by Article 21, Paragraph 1 of the ASUNE the respective license or permit shall be amended at request of the licensee or permit holder by an order of the NRA Chairman.

(2) The licensee or permit holder shall be obligated to request the amendment within one month following the occurrence of any circumstance necessitating the amendment. Any application for a license or permit amendment shall contain:

1. the applicant's identification data;
2. the license or permit registration number;
3. justification for the requested amendment;
4. proposal for the amendment;

(3) The following shall be attached to the application:

1. documents specifying the circumstances covered under the requested amendment;
2. document demonstrating proof of payment of the fee, if such a fee is due.

Article 19.

(1) The NRA Chairman shall take a decision on the application for a license amendment:

1. within six months – with regard to amendment of a license under Article 15, Paragraph 3, Subparagraph 1 of the ASUNE;
2. within one month – with regard to amendment of a license under Article 15, Paragraph 3, Subparagraphs 2-6 of the ASUNE.

(2) The NRA Chairman shall take a decision on the application for a permit amendment:

1. within six months – with regard to amendment of a permit under Article 15, Paragraph 4, Subparagraph 6 of the ASUNE;
2. within three months – with regard to amendment of a permit under Article 15, Paragraph 4, Subparagraphs 1-4 and 14 of the ASUNE;
3. within one month – for the rest of the cases.

Article 20.

(1) Should the licensee or permit holder fail to request a license or permit amendment within the time limit referred to in Article 21, Paragraph 2 of the ASUNE, the NRA Chairman shall notify in writing the licensee or permit holder of the existence of circumstances requiring amendment and of the consequences under Article 23, Paragraph 2 of the ASUNE in case of non-compliance.

(2) Should the licensee or permit holder fail to request an amendment within 14-days, the NRA Chairman may revoke the license or permit following the procedure under Section VII of this chapter.

Article 21.

Issues not explicitly covered by this section shall correspondingly be arranged under the procedure provided for in Section II of this chapter.

Section V

Licenses and permits renewal

Article 22.

Licenses and permits shall be renewed under the procedure provided for in this section at the licensee or permit holder request. The renewal may include:

1. extension of the term of validity;
2. extension of the term of validity together with an amendment of the conditions for performing the activity.

Article 23.

(1) Any application for a license or permit renewal shall contain:

1. the applicant's identification data;
2. the license or permit registration number;
3. request for the license or permit renewal;
4. proposal for the new term of validity; for the cases under Article 22, Subparagraph 2, a justification for the amendment of the license or permit conditions shall also be submitted.

(2) A justification for the new term of validity shall be attached to any application under Paragraph 1. In the case of renewal of a license, the following documents shall also be attached:

1. updated safety assessment report of the nuclear facility or entity with a source of ionising radiation, comprising an analysis of:
 - a) the legislative requirements in force;
 - b) the actual status of the nuclear facility or entity with a source of ionising radiation;
 - c) envisaged operating period;
 - d) contemporary analytical methods, national and international operating experience and scientific and technical achievements in the field;
2. payment document of the application review fee under Chapter Four of the Tariff for the Fees Charged by the Nuclear Regulation Agency under the ASUNE.

Article 24.

(1) An application for a license renewal shall be submitted within the following time limits:

1. not earlier than eighteen months and not later than twelve months before the expiration of the license term of validity – for the licenses under Article 15, Paragraph 3, Subparagraph 1 of the ASUNE;
2. not earlier than three months and not later than two months before the expiration of the license term of validity – for the licenses under Article 15, Paragraph 3, Subparagraphs 2-6 of the ASUNE.

(2) An application for a permit renewal shall be submitted not later than 30-days before the expiration of its term of validity.

(3) In case the application is submitted within the time limits under Paragraphs 1 and 2, the applicant shall perform the activity under the conditions of the initially issued license or permit until the issuance of a new license or permit.

(4) Paragraph 3 shall also be applied in those cases where an objective inability prevents the observance of the time limits under Paragraphs 1 and 2.

(5) In the case of non-observance of the time limits under Paragraphs 1 and 2, as well as if there are not valid reasons under Paragraph 4, the provisions under Section II of this chapter for license or permit issuing shall be applied.

Article 25

(1) The NRA Chairman shall take a decision on an application for license renewal within the time limits under Article 18, Paragraph 1 of the ASUNE.

(2) The NRA Chairman shall take a decision on an application for permit renewal:

1. within 20-days after submission – with regard to renewal of a permit under Article 22, Subparagraph 1;
2. within the time limits under Article 18, Paragraph 2 of the ASUNE – with regard to renewal of a permit under Article 22, Subparagraph 2.

Article 26.

(1) The review of the application for license or permit renewal shall include an assessment of the conformity with the requirements under Article 3. The review of the application for license renewal shall also include an assessment of the fulfilment of the conditions of the initially issued license.

(2) On the basis of the assessment under Paragraph 1, the NRA Chairman shall renew the license or permit by reissuing them with the contents defined in Article 13.

(3) Licenses shall be renewed for the requested term of validity, but not longer than the time limits under Article 35, Paragraph 3 and Article 58, Paragraph 3 of the ASUNE.

(4) Permits shall be renewed for a term of validity not longer than the term of validity of the initially issued permit.

Article 27.

Issues not explicitly covered by this section shall correspondingly be arranged under the procedure provided for in Section II of this chapter.

Section VI

Licenses and permits suspension

Article 28.

(1) Any license or permit shall be suspended:

1. by expiration of the term of validity if an application for renewal under Section V of this chapter has not been submitted;
2. before the expiration of the term of validity – with the completion of the activity for which the permit has been issued;
3. on the basis of an application for suspension of the license or permit submitted by the licensee or permit holder, including upon the occurrence of at least one condition under Article 56, Paragraphs 2 and 3 of the ASUNE;
4. by reason of revocation of the license or permit;
5. upon dissolution of the legal entity - licensee or permit holder;
6. upon the death of the natural person - licensee or permit holder;
7. upon suspension of the license for generating electrical and/or thermal power – in the cases under Article 47, Paragraph 1 of the ASUNE.

(2) In the cases under Paragraph 1, Subparagraph 2, the permit holder shall be obliged to notify in writing the NRA Chairman of the completion of the activity. The notification may be submitted together with the application for issuing a license or permit for the next stage of the activity.

(3) The NRA Chairman shall suspend the license or permit by issuing an order, except for the cases under Paragraph 1, Subparagraphs 1 and 5-7, where the license or permit shall be suspended automatically.

(4) The license or permit suspension shall take effect upon occurrence of the event, except the cases under Paragraph 1, Subparagraphs 2-4 where the license or permit suspension shall take effect upon entering into force of the NRA Chairman order.

(5) In case of suspension of an operating license for a nuclear facility for generation of electrical and/or thermal power on the grounds under Paragraph 1, Subparagraphs 1 and 3-5, the NRA Chairman shall officially notify the State Energy Regulatory Commission.

Article 29

Any application for license or permit suspension under Article 28, Paragraph 1, Subparagraphs 2 and 3 shall include:

1. the applicant's identification data;
2. the license or permit registration number;
3. actions taken and actions necessary for ensuring nuclear safety, radiation protection and physical protection.

Article 30

(1) In the case of an application submitted under Article 29, the NRA Chairman shall issue:

1. order for suspension of the license or permit;
2. justified denial to suspend the license or permit if the preliminary actions necessary for ensuring nuclear safety, radiation protection and physical protection have not been taken.

(2) (amended SG No. 78/2005) The NRA Chairman may ask the State Energy Regulatory Commission, the Minister of Economy and Energy, the Minister of Defence, the Minister of Interior, the Minister of Environment and Water, the Minister of Regional Development and Public Work and the Minister of Health to give an expert opinion on issues connected with the suspension of a license or permit.

(3) The NRA Chairman shall decide on the application for license or permit suspension:

1. within two months after submission of an application for a license suspension; in the case of an application for suspension of an operating license for a nuclear facility, the time limit shall be nine months;
2. within one month after submission of an application for a permit suspension.

Section VII**Licenses and permits revocation****Article 31.**

Licenses and permits shall be revoked under the conditions provided for in Article 23, Paragraph 1 Subparagraph 1 "a" and "b" and Subparagraphs 2-4 of the ASUNE, as

well as where, as a result of exercising regulatory control, it has been determined that the licensee violates the prohibitions under Article 17 of the ASUNE.

Article 32.

(1) Upon existence of any facts which constitute grounds for the revocation of a license or permit under Article 31, the NRA Chairman shall give to the licensee or permit holder a written notice containing the conclusions made and an appropriate time limit for bringing the activity to a condition that will conform to the legislative requirements and to the conditions of the issued license or permit.

(2) Within the time limit under paragraph 1, the licensee or permit holder may submit explanations, as well as may ask prolongation of the defined time limit.

(3) If on the basis of the submitted explanations and objections it has been determined that the initially defined time limit for bringing the activity in conformity with the legislative requirements and conditions of the license or permit is not enough, or if there are other valid reasons, the NRA Chairman may prolong the time limit. The licensee or permit holder shall be notified of these actions under the procedure of Paragraph 1.

Article 33.

(1) In case the licensee or permit holder fails to fulfil the obligation for bringing the activity in conformity with the legislative requirements and with the license or permit conditions within the determined time limit and after evaluating the circumstances and submitted explanations and objections, the NRA Chairman shall revoke the license or permit by issuing an order.

(2) The license or permit revocation order shall contain:

1. the legal grounds for issuing the order;
2. the factual reasons for issuing the order, except where the license or permit is revoked on the basis of Article 23, Paragraph 1, Subparagraph 4 of the ASUNE;
3. statement with regard to the licensee or permit holder explanations, except where the license or permit is revoked on the basis of Article 23, Paragraph 1, Subparagraph 4 of the ASUNE;
4. time limit, not longer than one year, during which the former licensee or permit holder may not apply for a new license or permit for the same activity.

(3) The order under Paragraph 1 shall be made available to the licensee or permit

holder, respectively to an authorized representative.

Chapter Two
LICENSES AND PERMITS FOR ACTIVITIES AT NUCLEAR
FACILITIES AND FOR COMMERCIAL TRANSACTIONS INVOLVING
NUCLEAR FACILITIES AND NUCLEAR MATERIAL

Section I
General provisions

Article 34.

(1) The licenses and permits under Article 15, Paragraph 3, Subparagraph 1 and Paragraph 4, Subparagraphs 1-6, 14 and 15 of the ASUNE shall be issued under the procedure provided for in this chapter.

(2) The permits under Article 15, Paragraph 4, Subparagraphs 1-4 of the ASUNE shall be issued before issuing of an operating license for the respective nuclear facility.

(3) Except as provided for in this Regulation, an application for issuing a design permit under Article 15, Paragraph 4, Subparagraph 2 of the ASUNE shall be submitted after issuing the order for approval of the selected site.

(4) Except as provided for in this Regulation, the selected site and technical design shall be approved by separate orders, issued under Article 33, Paragraph 4 of the ASUNE within nine months after submission of the documents under Article 37, respectively the documents under Article 40.

(5) Upon request of the site selection permit holder, made with the application for a design permit, and on the condition that the requirements provided for in this Regulation are fulfilled:

1. the order for approval of the selected site under Article 33, Paragraph 4 of the ASUNE shall be issued within the time limit for issuing the design permit;
2. the selected site and technical design shall be approved by a single order under Article 33, Paragraph 4 of the ASUNE, which shall be issued after issuing the design permit.

(6) An application for a permit for construction of a nuclear facility under Article 15, Paragraph 4, Subparagraph 3 of the ASUNE shall be submitted after the approval of the

selected site and technical design under the procedure of Article 33, Paragraph 4 of the ASUNE.

(7) The orders under Paragraphs 4 and 5 shall be made available to the applicant following the procedure under Article 11.

Article 35.

(1) The application for a license or permit under this chapter shall contain the data under Article 4. The following documents shall be attached to the application:

1. court decision for registration of the applicant in the commercial register and a certificate of current legal status;
2. certificate, issued by the respective court, certifying that the applicant - trader is not subject to bankruptcy proceedings;
3. certificate showing no previous conviction of the members of the management and supervisory bodies of the applicant - legal person or sole trader;
4. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with the nuclear safety and radiation protection requirements, standards and rules;
5. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the nuclear safety and radiation protection requirements, standards and rules;
6. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with the nuclear safety and radiation protection requirements, standards and rules;
7. documents related to the management and organizational structure of the applicant;
8. documents related to the actual number of personnel, specifying the level of education, qualification, and allocation of duties;
9. justification for the proposed term of validity;
10. list of the standards applied to this activity, as well as other documents confirming the compliance with the requirements for performing the activity envisaged in this chapter.

(2) The documents under Paragraph 1 shall not be attached to the application for a permit amendment under Section VII of this chapter.

Section II

Permit for siting of a nuclear facility (site selection)

Article 36.

(1) The application for a permit for site selection shall comply with the requirements under Article 35, Paragraph 1. The following documents shall also be attached to the application:

1. conceptual description of the nuclear facility, general characteristics and criteria for acceptability of the sites;
2. plan requirements for preliminary investigations containing information about the scope of the envisaged pre-investment investigations according to the Regulation No. 4 for the Scope and Contents of the Investment Projects (promulgated in the State Gazette No. 51/2001);
3. quality assurance program for performing the activity (quality guide) containing description of the main activities associated with site selection investigations, the methods for their execution and assessment, as well as description of the system for control and storage of documents.

(2) For a nuclear power plant, a decision of the Council of Ministers containing approval in principle for construction of a new capacity for generating electrical power – a nuclear power plant, according to Article 8, Paragraph 4 of the Energy Act shall be attached to the application under Paragraph 1.

(3) For a national repository for storage and/or RAW disposal, a decision of the Council of Ministers under Article 74, Paragraph 3 of the ASUNE shall be attached to the application under Paragraph 1.

Article 37.

(1) The following documents shall be attached to the application for an order for approval of the selected site under Article 33, Paragraph 4 of the ASUNE:

1. preliminary safety analysis report for the nuclear facility, which shall contain at least the following:
 - a) general description and characteristics of the nuclear facility;
 - b) basic goals, principals and criteria for safety applied to justification of safety;
 - c) the types and quantities of RAW expected to be generated as a result of

- the facility operation, the mode of management until their final disposal or exemption;
- d) comparison of the proposed sites from nuclear safety and radiation protection point of view and selection of an option, taking into account: the impact of natural and human origin factors on the facility safety; the radiological impact of the nuclear facility over the population and environment; the specific characteristics of the site having an impact on the migration and accumulation of radioactive substances; potential for undertaking population protection measures in case of accident; the size of the special-statute areas and emergency planning areas;
 - e) the results of the investigation of the selected site characteristics, including: geographic, topographic and demographic conditions; factors of human origin; hydro-meteorological conditions; geological, hydrological, seismological and engineer-geological conditions; the specific characteristics of the region and site for the purposes of emergency planning, accident management and physical protection;
 - f) list of literary sources, containing data and information used for justification of the selected site;
 - g) list of the persons contributed to the preparation of the documentation and to site investigation, as well as data for their qualification;
2. on-site monitoring programs, including seismic monitoring, underground and surface waters monitoring and monitoring of other natural phenomena;
 3. decision on the environmental impact assessment (EIA) or a decision of a competent authority under the Environment Protection Act confirming that EIA is not necessary;
 4. program for implementing additional investigations connected with the selected site if the prepared safety analysis report substantiates such necessity;
 5. other documents confirming the compliance with the requirements of the regulations under Article 26, Paragraph 2 of the ASUNE and with the conditions of the site selection permit.

(2) Where location of a new nuclear facility on the site of another constructed and commissioned nuclear facility is envisaged, the possible impact on the safety of the new nuclear facility and the other nuclear facilities located on-site shall be analysed in the

preliminary safety analysis report.

Article 38.

Before issuance the order for selected site approval, the applicant may submit an application for a design permit provided that all necessary investigations under Article 37, Paragraph 1, Subparagraph 1 “d” and “e” have been completed, the decision under Article 37, Paragraph 1, Subparagraph 3 has entered into force and the design basis for the facility has been determined.

Section III

Permit for design of a nuclear facility

Article 39.

(1) The application for a permit for design of a nuclear facility shall comply with the requirements under Article 35, Paragraph 1. The following documents shall also be attached to the application:

1. requirements specification or a contract for designing;
2. quality assurance program for the designing stage;
3. list of the standards applied to the designing stage.

(2) In the cases under Article 38, the time limit for taking a decision on the application for a design permit starts to run with the submission of the documents under Paragraph 1 of this article and of Article 37, except where Article 34, Paragraph 5, Subparagraph 2 is applied.

Article 40.

(1) The following documents shall be attached to the application for an order for technical design approval:

1. intermediate safety assessment report, which shall include:
 - a) intermediate safety analysis report prepared on the basis of the preliminary safety analysis report and the technical design; recommendable structure of the safety analysis report is enclosed as an appendix to this Regulation;
 - b) the results of the examination of the design in terms of verifying the fulfilment of nuclear safety and radiation protection requirements, standards and rules, including those connected with effectiveness of safety, as well as with the results of

an independent verification of the safety assessment;

2. technical design for the nuclear facility;
3. other documents confirming the fulfilment of the design permit conditions;

(2) Any order for approval of the selected site, design permit and order for approval of the prepared technical design of a nuclear power plant shall be issued upon fulfilment of this Regulation requirements to one of the following persons:

1. to the existing holder of permits and orders for the same facility if at the moment of submission of the application a license for generating electrical power under Article 39, Paragraph 3 of the Energy Act has not been issued;
2. to the holder of a license for generating electrical power if such a license is issued on the basis of a competition held under the procedure of Article 46-50 of the Energy Act.

(3) If Paragraph 2, Subparagraph 2 is applied, the following documents shall also be submitted:

1. application for issuing an order for technical design approval, submitted by the person under Paragraph 2, Subparagraph 2;
2. license under Article 39, Paragraph 3 of the Energy Act;
3. application for suspension of the permits in force, submitted by the existing holder of permits for the same facility.

(4) The conditions of the permit for site selection, order for approval of the selected site, design permit and order for approval of the selected technical design issued to the previous holder shall be deemed to be binding on the person under Paragraph 2, Subparagraph 2.

(5) The person under Paragraph 2, Subparagraph 2 may benefit from the legal statements for implementation of the procedure under Article 34, Paragraph 5 expressed by the previous holder.

Section IV

Permit for construction of a nuclear facility

Article 41.

(1) The application for a construction permit for a nuclear facility shall comply with the requirements under Article 35, Paragraph 1 and shall contain the registration numbers of the orders under Article 33, Paragraph 4 of the ASUNE. The following

documents shall also be attached to the application:

1. preliminary summarized schedule for implementation the construction and assembling works;
2. technical design and/or work design for nuclear facility construction;
3. quality assurance program for construction of the nuclear facility;

(2) In the case of an application for a construction permit of a nuclear power plant, a decision of the Council of Ministers for construction of a nuclear power plant under Article 45, Paragraph 1 of the ASUNE shall also be attached.

(3) (amended SG No. 78/2005) The decision under Paragraph 2 shall be taken on the basis of a proposal submitted by the Minister of Economy and Energy, containing an assessment of:

1. the nuclear safety, radiation protection and physical protection;
2. the environmental impact;
3. the social and economic significance of the construction of the nuclear power plant for the country or separated regions;
4. RAW and spent nuclear fuel to be generated, as well as the mode of their management.

(4) The investigations related to the assessment under Paragraph 3, Subparagraphs 1 and 4 shall be performed within the framework of the working out the safety analysis report under Article 37, Paragraph 1, Subparagraph 1, and Article 40, Paragraph 1, Subparagraph 1.

(5) The correspondence between the investigation results under Paragraph 4 and the requirements for nuclear safety and radiation protection provided for in the ASUNE and the regulations for its application, the permits issued under Article 15, Paragraph 4, Subparagraphs 1 and 2 and the orders under Article 33, Paragraph 4 of the ASUNE shall be analysed in the assessment under Paragraph 3, Subparagraphs 1 and 4.

(6) The EIA under Paragraph 3, Subparagraph 2 shall be performed according to the provisions of the Environment Protection Act.

Article 42.

(1) An application for a construction permit for nuclear power plant shall be submitted by one of the following persons:

1. the existing holder of permits and orders for the same facility if at the moment of

submission of the application a license for generating electrical power under Article 39, Paragraph 3 of the Energy Act has not been issued;

2. the holder of a license for generating electrical power if such a license is issued on the basis of a competition held under the procedure of Article 46-50 of the Energy Act;

(2) In the cases under Paragraph 1, Subparagraph 2, the following shall be attached to the application along with the documents under Article 41:

1. license under Article 39, Paragraph 3 of the Energy Act;
2. application for suspension of the permits in force, submitted by the existing holder of permits and orders for the same facility.

(3) A construction permit shall be issued upon fulfilment of the requirements of this Regulation only to a holder of a license for generating electrical power under Article 39, Paragraph 3 of the Energy Act determined on the bases of a competition held under the procedure of Article 46-50 of this act.

(4) The conditions of the permit for site selection, order for approval of the selected site, design permit and order for approval of the selected technical design issued to the previous holder shall be deemed to be binding on the person under Paragraph 2, Subparagraph 2.

Section V

Permit for commissioning of a nuclear facility

Article 43.

(1) The application for a permit for commissioning of a nuclear facility shall comply with the requirements under Article 35, Paragraph 1. The following documents shall be attached to the application:

1. decision of the Council of Ministers under Article 129, Paragraph 1 of the ASUNE if the nuclear facility is a nuclear installation within the meaning of the Vienna Convention on Civil Liability for Nuclear Damage;
2. document confirming the existence of financial security covering civil liability for nuclear damage according to Article 132 of the ASUNE;
3. utilisation facility permit issued under the procedure of the Act on the Territorial Structure;
4. commissioning program for the nuclear facility determining the

commissioning stages, activities to be performed during each stage and planned duration of each stage; the commissioning program contents shall confirm:

- a) that all tests determined by the intermediate safety assessment report as necessary for approval of the nuclear facility design characteristics are included;
 - b) that the tests are planned by stages in order the load to be increased gradually;
 - c) determination of time periods in which the facility will be operated according to previously set conditions;
 - d) the availability of a list of the systems and equipment intended to be used during each commissioning stage;
5. document certifying that the operating instructions have been approved by the management body of the applicant;
 6. quality assurance program for the commissioning period;
 7. description of the approved modifications in the nuclear facility technical design;
 8. description of the results of the pre-operation acceptance testing of the structures, systems and components;
 9. technical specification for nuclear facility operation, which shall contain at least the following:
 - a) the rules and basic modes of safe operation;
 - b) general procedure for carrying out the technological operations related to facility safety;
 - c) limits and conditions for operation, including: safety limits; values of the parameters for actuation of the safety systems; operational limits and conditions; tests, inspections, surveillance and in-service inspections over the systems important to safety; minimum number of operating personnel to carry out activities connected to the respective operational states, including qualified and authorized main control room staff; actions to be taken in case of deviations from the operational limits and conditions;
 10. list of the internal rules, instructions and procedures applied to nuclear facility operation;
 11. list of the positions in the organizational structure of the applicant exercising functions related to ensuring nuclear safety and radiation protection for which competence for employment at nuclear facilities is required under Article 64, Paragraph 2, Subparagraph 1 “a” of the ASUNE;

12. program for on-site radiation monitoring and for monitoring of the special-statute areas during the operation of the nuclear facility;
 13. list of the structures, systems and components important to safety;
 14. list of the systems and equipment related to different commissioning stages;
 15. methods and programs for performing tests and experiments during each commissioning stage;
 16. instructions for ensuring nuclear safety during commissioning and operation;
 17. instruction for ensuring radiation protection during commissioning and operation;
 18. instruction for ensuring nuclear safety during on-site transport and storage of nuclear material;
 19. instruction for physical protection of the nuclear facility and nuclear material;
 20. instruction for admission regime;
 21. instruction for prevention the progression of accidents during the operation of the nuclear facility;
 22. instruction for accounting and control of nuclear material;
 23. document confirming the presence of sufficient personnel possessing required level of qualification and competence for employment at nuclear facilities for performing commissioning and operating activities;
 24. description of the applicant system for providing personnel training and retraining, as well as for continuous improvement and control of the qualification;
 25. on-site emergency plan for the nuclear facility;
 26. instruction for the personnel actions in case of radiological accident at the nuclear facility;
 27. quality guide for performing the activity;
 28. documents arranging the special-statute areas and controlled access areas;
 29. program for radiation monitoring of the environment;
 30. program for monitoring the radiation parameters of the nuclear facility site.
- (2) An amendment of the commissioning program for the nuclear facility shall be performed only on the basis of an amendment of the permit issued under the procedure of Chapter One, Section IV.

Article 44.

(1) If the commissioning of the nuclear facility is a multistage process, a separate permit shall be issued for each stage.

(2) In the case of issuing of a permit under Paragraph 1, the documents under Article 43, Paragraph 1, updated for each stage, shall be attached. The following documents shall also be attached to the application:

1. documents confirming the actual preparedness of the facility for accomplishment the respective stage in accordance with the commissioning program;
2. approved programs and instructions applied to the respective stage;
3. documents confirming the presence of sufficient personnel possessing required level of qualification and competence for employment at nuclear facilities for performing the respective stage activities.

(3) A power plant unit shall be commissioned under the following stages:

1. initial on-site nuclear fuel storage;
2. initial loading of the reactor core and testing at a subcritical condition;
3. initial reactor criticality and low-power testing;
4. initial power start-up of the unit at stage-by-stage power increase;
5. trial-testing operation – for a new type nuclear reactor.

Article 45.

(1) Until the beginning of each commissioning stage, a commission of NRA inspectors appointed by the NRA Chairman shall inspect the site for confirming correspondence with stated data and circumstances and preparedness for carrying out the respective stage. With regard to the stage specificity, representatives of other authorities exercising specialized control may participate in the commission.

(2) The commission under Paragraph 1 shall issue a protocol, which shall be signed by the commission members and shall be made available to the applicant or to an authorized representative.

(3) The NRA Chairman shall issue a permit for each commissioning stage on the basis of:

1. the protocol under Paragraph 2;
2. the administrative acts issued by the respective authorities exercising specialized control;

3. document confirming the elimination of the causes that have led to the remarks included in the protocol under Paragraph 2.

Article 46.

(1) The results of the tests and experiments for each stage of the nuclear facility commissioning shall be included in protocols, which shall contain:

1. list of the work activities performed during the respective stage;
2. analysis of the correspondence between project characteristics and actual characteristics of the equipment obtained during testing and experiments;
3. description of the detected defects and failures;
4. analysis and conclusions about the reasons and admissibility of the actual characteristics deviation from the project characteristics and measures for their elimination.

(2) The protocols under Paragraph 1 shall be signed by the specialists involved in conducting the tests and shall be approved by the management body of the applicant.

(3) A permit for the next commissioning stage shall be issued upon submission a data report on the previous stage results, including analysis of these results.

Section VI

License for operation of a nuclear facility

Article 47.

(1) An application for a license for nuclear facility operation shall be submitted after fulfilment of the commissioning permit conditions.

(2) The fulfilment of the commissioning permit conditions shall be verified by a commission of NRA inspectors, appointed by the NRA Chairman, which shall review the documents submitted by the applicant and shall carry out an on-site inspection.

Article 48.

The application for a license for nuclear facility operation shall comply with the requirements under Article 35, Paragraph 1. The following shall also be attached to the application:

1. final safety analysis report, prepared on the basis of the report under Article 40, Paragraph 1, Subparagraph 1, taking into account the commissioning stage results;
2. the documents under Article 43, Paragraph 1, Subparagraphs 7, 14, 16, 17, 20, 22, 24, 27 and 28, updated on the basis of the results of the commissioning stage;
3. operating instructions for the structures, systems and components important to safety;
4. time-schedules and instructions for testing and control of the status of the systems important to safety;
5. time-schedule plan for maintenance and repair of the main equipment;
6. programs and plans for spent nuclear fuel management for the nuclear facility lifetime and following final shut down of the facility;
7. RAW management program for the requested term of validity of the license and for the nuclear facility operating lifetime;
8. rules, procedures and programs for personnel training and for continuous improvement and control of the qualification;
9. analysis of the activities executed by contractors, as well as the positions in the organizational structure of the applicant to manage and control these activities and the minimum number and qualification of the staff who occupy them;
10. quality assurance program applied to the operating stage;
11. list of the documents related to ensuring and maintaining the quality of the operational activities;
12. documents, approved by the management body of the applicant, defining the safety policy, including for establishing and maintaining a high level of safety culture;
13. instruction for the procedure for reporting and methods for analysis of the operational occurrences;
14. program and a time-schedule for personnel training and exercise related to the activation of the on-site emergency plan of the nuclear facility;
15. program for equipment lifetime management for the requested term of validity of the license and for the nuclear facility lifetime, including for monitoring the status of important to safety components;
16. updated decommissioning plan for the nuclear facility.

Article 49.

In the case of issuing an operating license for a nuclear power plant unit, the documents under Article 48 shall be attached to the application. The following documents shall also be attached:

1. license for generation of electric and/or heating energy issued under the provisions of the Energy Act;
2. symptom-based emergency operating instructions specifying the activities to be performed in case of an accident;
3. instruction for co-ordination of the activities of the personnel within the framework of each unit and for the nuclear power plant as a whole;
4. operating instructions for the reactor installation;
5. instruction for in-service inspection of the base and weld metal of the equipment and pipelines.

Article 50.

In the case of issuing an operating license for a research reactor or critical stand, the documents under Article 48 and Article 49, Paragraphs 2 and 4 shall be attached.

Article 51.

In the case of issuing an operating license for a facility for nuclear material extraction, producing, processing, storage or handling, the documents under Article 48 and the following shall be attached to the application:

1. physico-chemical and radiochemical properties of the nuclear material, which is extracted, produced, processed, stored or handled at the facility;
2. neutron-physical characteristics, isotope composition and enrichment with fissile isotope of the nuclear material produced at the facility if it is a special nuclear material within the meaning of § 1, Subparagraph 36 of the Final provisions of the ASUNE;
3. characteristics of the final product if nuclear material is produced or processed at the nuclear facility;
4. description of the operating activities in their technological sequence;
5. list of the instructions and procedures for performing main technological activities related to nuclear safety and radiation protection during operation;
6. operating instructions for technological systems connected with performing the facility intended purpose;

7. technical specification for nuclear material packages corresponding to the acceptance criteria for on-site storage or disposal of nuclear material.

Article 52.

(1) In the case of issuing an operating license for nuclear material disposal facility, the documents under Article 48 shall be attached to the application. The following documents shall also be attached:

1. technical specifications for the nuclear waste packages;
2. procedure for accepting nuclear material for disposal;
3. instruction for ensuring nuclear safety applied to disposal of nuclear material at the facility;
4. instruction for ensuring nuclear safety applied to transportation activities, interim storage and other on-site activities connected to the nuclear material handling before final disposal;
5. description of the operating activities in their technological sequence;
6. instructions for operation of the technological systems designed for performing the facility intended purpose;
7. plan for facility closure and for exercising institutional control.

(2) After the facility closure, institutional control shall be exercised at the site, which shall be:

1. active - monitoring of the site, and if necessary – remedial and restoration work;
- or
2. passive – land use control.

Article 53.

In the case of issuing an operating license for RAW management facility, the documents under Article 48 shall be attached to the application. The following documents, confirming conformity with the requirements of the regulation under Article 77, Paragraph 3 of the ASUNE, shall also be attached:

1. criteria for accepting RAW at the facility;
2. description of the sources and characteristics of RAW to be accepted at the facility;
3. technical specification of the nuclear waste packages for conditioned RAW;
4. description of RAW management activities in their technological sequence;

5. internal rules, instructions and procedures for performing the facility intended purpose.

Article 54.

In the case of issuing an operating license for RAW conditioning facility or for conditioned RAW disposal, the documents under Article 48 shall be attached. The following documents confirming conformity with the requirements of the regulation under Article 77, Paragraph 3 of the ASUNE shall also be attached:

1. technical specification of the nuclear waste packages for conditioned RAW;
2. procedures for delivery and acceptance of RAW for disposal or storage;
3. inspection program for accepting nuclear waste packages for disposal or storage;
4. program for the inspections to be exercised over the respective RAW conditioning facility by the holder of an operating license for conditioned RAW storage or disposal.

Article 55.

(1) In the case of issuing an operating license for RAW disposal facility, the documents under Article 48 and a plan for facility closure and for exercising institutional control shall be attached.

(2) The plan under Paragraph 1 shall analyse the results of the post- closure safety assessment.

(3) The safety assessment report of a RAW disposal facility under Article 48, Subparagraph 1 shall include an assessment of the facility safety for the operating and post-closure period.

Section VII

Permits for activities leading to modifications

Article 56.

This section provisions shall be applied to issuing the permits under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE.

Article 57.

(1) The application for permit modification shall also contain the registration number of the operating license for the nuclear facility.

(2) The following shall be attached to the application under Paragraph 1:

1. justification for the proposed modification; reasons for undertaking the modification;
2. justification for the proposed time limit for performing the modification;
3. assessment of the proposed modification impact on the limits and conditions for safe operation;
4. list of the standards applied to the activity;
5. the amended parts or sections of the safety assessment report;
6. analysis and assessment of the unfavourable external or operational conditions, including those connected with increase in the volume and activity of generated RAW, increase in the radioactive pollution, as well as with additional occupational radiation exposure;
7. description of the modifications in the maintenance activities.

(3) In the case of issuing a permit for structures, systems and components modification, the following shall be attached:

1. technical design for the modification;
2. schemes and drawings reflecting the state before and after modification;
3. technical specification of the necessary equipment and components to be used for the modification;
4. certificate for the modified structures, systems and components or description of the modes of production and assembling of the equipment and components;
5. description of the factory tests foreseen, the assembly and functional tests for confirming acceptance criteria, including the methods for verification and validation of computer codes related to operation;
6. description of the operational state of the nuclear facility or of the respective part of it at which the modification is to be performed;
7. quality assurance program applied to this activity and a plan for quality control.

Section VIII

Permit for nuclear material import and export

Article 58.

(1) The application for a permit for import or export of nuclear material shall also contain the registration number of the license for performing activities with goods and technologies determined to be of potential "dual-use" and the registration number of the permit authorising the import of nuclear material for this specific case, issued under the procedure of the Act on the Control of Foreign Trade in Arms and in Potential "Dual-Use" Goods and Technologies.

(2) Where the applicant is a licensee or holder of a permit issued according to this Regulation, the following documents shall be attached to the application under Paragraph 1:

1. contract between the applicant and the consignee;
2. specification of the type, condition and quantity of the nuclear material, including enrichment with fissile isotope and radioisotope composition;
3. document containing information on the purpose for which the nuclear material shall be used by the consignee;
4. document containing information about the selected transport mode – by river, sea, air, rail, road, or combined transport;
5. document indicating the border crossing points and the customs posts through which the nuclear material shall be imported or exported and the expected date of import or export;
6. documents certifying that the import or export is related to the applicant activity.

(3) If the applicant is a sole trader or legal entity which is not a licensee or holder of a permit issued under this Regulation, the documents under Article 35, Paragraph 1 shall be attached to the application. The following documents shall also be attached:

1. contract between the applicant and the consignee;
2. specification of the type, condition and quantity of the nuclear material, including enrichment with fissile isotope and radioisotope composition;
3. document containing information on the purpose for which the nuclear material shall be used by the consignee;
4. document containing information about the selected transport mode – by river, sea, air, rail, road, or combined transport;
5. document indicating the boarder crossing points and the customs posts through which the nuclear material shall be imported or exported and the expected date of import or export;

6. documents certifying that the transport of the respective nuclear material through the territory of the Republic of Bulgaria will be performed by a holder of a license or permit issued under this Regulation;

7. document certifying that the consignee possesses the necessary license or permit authorising the use or storage of the material.

(4) Any particular import or export of nuclear material shall be covered by a separate license.

Section IX

Permit for decommissioning of a nuclear facility

Article 59

(1) The whole process of decommissioning of a nuclear facility shall be organized, analyzed, planned and justified in a decommissioning plan, which shall contain:

1. short description of the basic elements of the plan;
2. description of the facility, its site, the special-statute areas and the emergency planning areas;
3. description of the circumstances and events related to decommissioning, which have occurred during the operation of the facility; the reasons for decommissioning;
4. list of the standards applied to decommissioning planning;
5. radiological criteria applied to decommissioning;
6. justification for the selected decommissioning option;
7. time-schedule and description of the decommissioning activities;
8. assessment of the amount, type and location of the radioactive or other hazardous materials generated within the facility, including a description of the assessment methods;
9. classification of the systems and structures in terms of their significance with respect to different stages of decommissioning plan implementation;
10. description of the planned modifications to the existing systems and the new systems to be needed for the decommissioning stage;
11. description of the decontamination activities, analyzed possible options and justification for the selected option;
12. description of the available and planned technologies and technical means for dismantling;

13. program for RAW management containing information on:
 - a) RAW sources, types and quantities;
 - b) criteria for sorting the materials;
 - c) the methods of RAW treatment, conditioning, transport, storage and disposal;
 - d) criteria and possibilities for second use and recycling;
 - e) expected releases of radioactive substances into the environment;
 14. safety assessment program for the decommissioning period;
 15. radiation protection concept, including description of the programs and procedures for radiation protection to be applied during decommissioning;
 16. programs for radiation monitoring of the nuclear facility site and the special-statute areas;
 17. description of the organization and responsibilities of the personnel engaged in decommissioning activities specifying the personnel necessary for each decommissioning stage, the level of qualification of the personnel, as well as the measures taken and measures foreseen for continuous improvement and control of the qualification;
 18. quality assurance program for the decommissioning stage;
 19. on-site emergency plan for the decommissioning stage;
 20. documents defining physical protection measures and, if necessary, measures for physical separation of the decommissioned facility from the facilities in operation;
 21. assessments of the financial resources necessary for the decommissioning stage and indication of the financing sources;
 22. description of the monitoring programs, methods and means for site investigation after completion of the decommissioning activities aiming at exemption from regulatory control under the ASUNE of the site and the facilities located on it;
 23. time-schedule for reporting intermediate and final results connected with decommissioning process to the NRA.
- (2) The decommissioning plan for a nuclear power plant, for a separate unit, or for another nuclear facility located on the same site shall be submitted to the NRA Chairman at least three years before the facility shut down for decommissioning.

Article 60.

In the case of issuing a permit for nuclear facility decommissioning, the documents under Article 35, Paragraph 1 shall be attached to the application. The following documents shall also be attached:

1. safety assessment report for the period of implementation of the decommissioning plan, which shall include the results of the analysis of all aspects of the decommissioning plan related to protection of the personnel and population, as well as an independent verification of the safety analysis.
2. decommissioning plan under Article 59, Paragraph 1;
3. technical specification for the nuclear facility operation containing limits and conditions for operation specific for the decommissioning stage;
4. operating instructions for the systems remaining in operation during the decommissioning stage;
5. decision on EIA according to the Environmental Protection Act.

Article 61.

(1) If the decommissioning plan provides for that the nuclear facility decommissioning is a multistage process, a separate permit shall be issued for each stage.

(2) In the cases under Paragraph 1, the documents under Article 35, Paragraph 1 shall be attached to the application. The following documents shall also be attached:

1. updated decommissioning plan covering the respective stage;
2. plan for organization and performing the activities within the respective stage;
3. technical specification for nuclear facility operation including limits and conditions for operation specific for the decommissioning stage;
4. operating instructions for the systems remaining in operation during the respective stage;
5. safety assessment report updated for the respective stage.

(3) A decision on EIA shall be submitted for each of the stages related to dismantling or shut down of a nuclear power plant or nuclear power plant unit within the meaning of the Environmental Protection Act.

Article 62.

(1) The updated plan under Article 61, Paragraph 2, Subparagraph 1 shall include a

description of the performed activities and the results of the previous nuclear facility decommissioning stages. Information on the actual state of the facility and possible modifications to the initially planned volumes, technologies and time limits for implementation of each stage activities due to new circumstances or technological improvement shall also be included.

(2) The plan under Article 61, Paragraph 2, Subparagraph 2 shall describe and justify the respective stage activities and the measures for their performing in a safe manner.

Section X

Permit for commercial transactions involving nuclear facility

Article 63.

(1) The NRA Chairman shall issue permits for commercial transactions involving nuclear facilities, which are under commissioning, are commissioned or operated following the procedure according to this section.

(2) The provisions under this section shall be correspondingly applied to issuing permits for commercial transactions involving nuclear facilities in a process of constructing under already issued construction permit if the transferee under the transaction holds an operating license for other nuclear facility.

Article 64.

(1) The application for a commercial transaction permit involving transfer of property or the right of use over the nuclear facility shall be signed and submitted by both parties to the transaction – the proprietor of the facility (licensee or permit holder) and the transferee under the transaction.

(2) The application shall contain the information provided for in Article 4 concerning parties to the transaction and the registration number of the license or permit in force, which is related to the nuclear facility. In the cases under Article 63, Paragraph 2, the registration number of the license shall also be indicated.

(3) The following documents shall be attached to the application:

1. application for suspension of the respective license or permit in accordance with the requirements under Article 29, signed by the licensee, respectively the permit holder;

2. application for issuing a license or permit of the same type in accordance with the requirements under Article 35, Paragraph 1, signed by the transferee under the transaction;
3. plan for the activities necessary with regard to transfer of property or establishing right of use, which shall specify the procedure for undertaking legal actions concerning the transaction and the conditions, stages and procedure for nuclear facility delivery for management to the transferee;
4. program containing measures for maintaining a high level of nuclear safety, radiation protection and physical protection, and for their continuous improvement; measures for maintaining sufficient number of well qualified personnel for whole period until the final delivery to the transferee under the transaction;
5. payment documents of the application review fees for issuing a permit for commercial transactions involving nuclear facility and for issuing a license under Subparagraph 2.

(4) Where the transaction involves a nuclear facility, which is a part of a nuclear power plant, the following shall also be attached to the application:

1. plan guaranteeing the use and functioning of any other facility located on the same site and necessary for the safe operation of the nuclear facility - subject of the transaction; or
2. plan for entire separation of the nuclear facility subject to the transaction.

Article 65.

Where at the moment of submission of the application under Article 64, the license or permit issued to the existing proprietor is suspended under the procedure of the ASUNE, the application under Article 64, Paragraph 3, Subparagraph 1 shall not be submitted. In this case, the registration number of the suspended license or permit shall be indicated.

Article 66.

(1) The NRA Chairman shall review the applications under Article 64 within nine months, observing the provisions under Chapter One, Sections II and VI of this Regulation and shall issue a permit for a commercial transaction involving nuclear facility on the condition that:

1. the transferee under the transition complies with the requirements under Article 3 for license or permit issuance;
 2. the plan and the program under Article 64, Paragraph 3, Subparagraphs 3 and 4 provides for appropriate measures to ensure nuclear safety, radiation protection and physical protection until the final actual delivery of the facility to the consignee under the contract.
- (2) In the case of non-compliance with the conditions under Paragraph 1, the NRA Chairman shall deny the application by issuing a reasoned order.

Article 67.

- (1) The permit for a commercial transaction involving nuclear facility shall be issued to the applicants under Article 64. The conditions of the permit shall be specified according to the requirements under Article 13.
- (2) The permit under Paragraph 1 shall serve as a basis for concluding the transaction, for taking a Council of Ministers decision under Article 129, Paragraph 1 of the ASUNE, and for furnishing a financial security against nuclear damage liability.
- (3) Any permit for commercial transaction involving nuclear facility shall be issued for a term of validity up to one year.

Article 68.

- (1) Within 14-days after completion of the activities under Article 67, Paragraph 2, the transaction permit holders shall submit to the NRA the documents confirming the conclusion of the transaction and availability of a financial security on the basis of a Council of Ministers decision under Article 129, Paragraph 1 of the ASUNE.
- (2) Within 14-days after submission of the documents under Paragraph 1, the NRA Chairman shall:
1. suspend the license or permit issued to the existing proprietor, except for the cases under Article 65;
 2. issue the same type license or permit to the transferee under the transaction.
- (3) The administrative acts under Paragraph 2 shall be delivered simultaneously to the transaction parties and shall enter into force simultaneously.

Article 69.

Except for the cases under Article 64, Paragraph 1, the NRA Chairman shall issue permits for commercial transactions involving nuclear facilities on the condition that the nuclear safety and radiation protection requirements, standards and rules are not violated. In this case the procedure under Articles 64-68 of this Regulation shall be correspondingly applied.

Section XI**Permit for transactions involving nuclear material****Article 70.**

(1) The NRA Chairman shall issue a permit for each specific transaction involving nuclear material following the procedure under this section on the condition that the nuclear safety and radiation protection requirements, standards and rules are fulfilled.

(2) This section provisions shall not be applied to issuing permits involving nuclear material transport, import or export.

Article 71.

(1) The application for a permit for transaction involving nuclear material shall be submitted by one of the contracting parties and shall contain the registration numbers of the licenses and permits for manufacturing, use, processing, reprocessing or storage of nuclear material issued to the contracting parties.

(2) The application under Paragraph 1 shall contain the information provided for in Article 4, Paragraph 1, Subparagraphs 1-3, 5 and 6 concerning both the contracting parties. The following documents shall be attached to the application:

1. draft contract between the contracting parties;
2. specification of the type, form and quantity of the nuclear material, including its chemical and physical form, enrichment with fissile isotope and radioisotope composition.

(3) Depending on the subject, place of delivery and other transaction characteristics, the following documents shall also be attached to the application:

1. document containing information on the purpose for which the nuclear

material will be used;

2. document containing information about the nuclear material packaging and for the transport mode;

3. documents certifying that the transport of the respective nuclear material through the territory of the Republic of Bulgaria will be performed by a holder of a permit for transport of nuclear material issued under this Regulation;

(4) Depending on the type of the transaction and the nuclear material type or characteristics, other necessary documents shall also be submitted.

Article 72.

Within 14-days after accomplishment of the transaction, the permit holder shall submit to the NRA the documents certifying this fact.

Chapter three

LICENSES AND PERMITS FOR ACTIVITIES WITH SOURCES OF IONISING RADIATION

Section I

General provisions

Article 73.

(1) Activities involving SIR shall be performed on the basis of the licenses and permits provided for in Article 15, Paragraph 3, Subparagraphs 2-6 and Paragraph 4, Subparagraphs 8-11 and 13 of the ASUNE.

(2) The application for issuing a license or permit under this chapter shall contain the data under Article 4. The following documents shall be attached to the application:

1. court decision for registration of the applicant in the commercial register and a certificate of current legal status of the applicant - legal entity or sole trader;

2. certificate, issued by the respective court, certifying that the applicant - trader is not subject to bankruptcy proceedings;

3. certificate showing no previous conviction of the applicant – natural person or sole trader, or of the members of the management and supervisory bodies of the applicant - legal person;

4. justification for the proposed term of validity;
5. justification for the necessity for performing activities with SIR and analysis of the advantages of using SIR compared to other methods of achieving the same goal, as well as of the benefit of the activity compared to possible harmful health effects;
6. planned measures for quality assurance of the stated activity:
 - a) quality assurance program specifying the organizational measures, conditions and mode of performing the activity with SIR; the methodology and standards used; the procedure for documenting the results of the activities and for implementing internal control over observing the program;
 - b) SIR characteristics and description of the activities performed with them;
 - c) assessment of the types and quantities of RAW expected to be generated for the license or permit term of validity, and the measures that will be carried out for their safe storage and delivery for management to persons possessing licenses issued under the procedure of Articles 53-55;
7. safety assessment, which shall include:
 - a) analysis and assessment of the nature of each exposure and the probability of its occurrence as a result of the activity, as well as the expected exposure dose;
 - b) analysis and assessment of the envisaged radiation protection measures for all categories exposed individuals, both under normal conditions and in case of incident or accident, including analysis and assessment of the means for ensuring protection of every member of the personnel, the devices used for protection against ionising radiation; means for monitoring the radiological characteristics of the working premises and the environment;
8. documents confirming that an inspection of the devices for measurement of the radiation parameters of the working premises and the environment is performed according to the requirements of the Measurements Act;
9. on-site emergency plan;
10. document confirming the presence of sufficient personnel possessing required level of qualification and competence:
 - a) document, adopted by the management body of the applicant, defining the personnel to perform activities with SIR, including its allocation in groups, in compliance with the requirements of the regulation under Article 26, Paragraph 3 of the ASUNE;
 - b) documents, issued under the procedure determined by law, containing a medical

conclusion about the suitability of every member of the personnel to be engaged in the respective activity;

c) individual licenses for employment in work with SIR issued under the procedure of the regulation under Article 65, Paragraph 3 of the ASUNE;

11. documents confirming that the applicant possesses internal rules, procedures and personnel job descriptions, including those connected with performing suitable monitoring and providing information to the exposed persons:

a) instruction for radiation protection during performing the activity;

b) program for monitoring the radiation parameters of the working premises and the environment within the special-statute areas during operation of an entity with a source of ionising radiation, as well as occupational exposure monitoring;

c) document confirming that monitoring of the exposure of every member of the personnel is ensured;

d) document, adopted by the management body of the applicant, defining activity director, radiation protection officer, health physicist, a person with control over receiving, storage and accounting for radioactive substances and a person in charge of notifying the NRA in case of an event, incident or accident involving SIR;

e) personnel job descriptions;

12. other documents confirming correspondence with the requirements for performing the respective activity.

(3) If the applicant is a natural person to perform the activity personally, the documents under Paragraph 2, Subparagraph 10, "a" and Subparagraph 11, "d" and "e" shall not be required.

Article 74.

(1) Any permit under Article 15, Paragraph 4, Subparagraph 10 of the ASUNE shall be issued to a person who have used or stored radioactive substances, to an assignee, or to a person upon whom it is imposed by a legislative enactment.

(2) Issuing of a permit for temporal storage shall not be necessary for SIR, which are included within the scope of a license or permit for use or manufacturing SIR.

(3) Where SIR or parts of them are not determined to be of potential "dual-use" within the meaning of the Act on the Control of Foreign Trade in Arms and in Potential "Dual-Use" Goods and Technologies, a permit under Article 15, Paragraph 4, Subparagraph 13 of the ASUNE shall be issued to:

1. person to perform import or export of SIR or parts of them without possessing a license issued under the procedure of Section X of this chapter;
2. person possessing a license issued under the procedure of Section X of this chapter - for each specific case of import or export.

Article 75.

A permit under Article 15, Paragraph 4, Subparagraph 9 of the ASUNE for SIR assembling and initial testing shall not be necessary if a licensee under Sections VII and VIII of this chapter has assigned carrying out the activity to a person possessing a license under Section IX of this chapter.

Article 76.

(1) Any license under Article 15, Paragraph 3, Subparagraphs 2-4 of the ASUNE shall be issued after the commissioning of the entity with a source of ionising radiation in which the activity will be performed if operation of such an entity is envisaged.

(2) An entity with a source of ionising radiation shall be commissioned under the procedure of Article 78 on the condition that the permits for location of this entity at a selected site and for constructing, assembling and initial testing are issued.

Article 77.

Any license under Article 15, Paragraph 3, Subparagraph 3 of the ASUNE for manufacturing SIR or parts of them shall be issued upon availability of conditions for determining correspondence between the properties and parameters of the manufactured SIR or parts of them and the applied standards, as well as upon furnishing evidence in support of such conclusion.

Article 78.

(1) The applicant shall notify the NRA Chairman of the entity with SIR readiness for commissioning.

(2) The NRA Chairman shall appoint a commission of NRA inspectors for performing an inspection to confirm correspondence with the stated data and circumstances and readiness for commissioning. With regard to the stage

specificity, representatives of other authorities exercising specialized control may also be included in the commission.

(3) The applicant under Paragraph 1 shall submit to the commission:

1. the documents required for issuing a license under Article 15, Paragraph 3, Subparagraphs 2-4 of the ASUNE under the procedure of Section VII- IX of this chapter;
2. the technical documentation for the apparatus, devices and entities containing radioactive substances, or for the generators of ionising radiation;
3. register of the initial and regular safety briefing of the personnel;
4. register of general and individual dosimetric control;
5. documents required according to the regulation under Article 26, Paragraph 2 of the ASUNE;
6. documents containing the results of the initial testing;
7. documents certifying the entity commissioning according to the provisions of the Act on the Territorial Structure and the secondary legislation for its application.

(4) Every member of the commission shall submit to the commission chairman a written opinion prepared on the basis of the performed inspection.

(5) The commission shall prepare a protocol, which shall include the results of the inspection. The protocol shall be served to the applicant, or to an authorized representative, together with the opinions of the commission members.

(6) The positive statement of the commission, included in the protocol under Paragraph 5, shall serve as a basis for issuing the licenses under Article 15, Paragraph 3, Subparagraphs 2-4 of the ASUNE.

Article 79.

Article 78 shall not be applied to commissioning of facilities with:

1. SIR installed in smoke detectors;
2. sealed radioactive SIR installed in devices constructed in a way that at a distance from the surface equal to 0, 1 m the equivalent dose rate does not exceed 1 $\mu\text{Sv/h}$;
3. radioactive markers and kits;
4. X-ray luggage inspection systems;
5. SIR installed in devices for process monitoring;

6. SIR installed in static electricity neutralizers.

Section II

Permit for location of an entity with a source of ionising radiation at a selected site

Article 80.

In the case of issuing a permit for location of an entity with a source of ionising radiation at a selected site, the documents under Article 73, Paragraph 2, Subparagraphs 1-5 shall be attached to the application. The following documents shall also be attached:

1. documents related to the management and organizational structure of the applicant;
2. document containing SIR characteristics and a description of the activities performed with them;
3. document containing the selected site characteristics and the boundaries of the special-statute areas, as well as justification for their determination;
4. assessment of the impact of the factors with natural and human origin on the SIR located on-site;
5. assessment of the impact of all SIR located on-site on the working premises and the environment.

Article 81.

(1) New entity with a source of ionising radiation shall be located on a site for which a permit has been issued under this section procedure in order licensed or permitted activity to be performed on the basis of an amendment of the respective permit or license under Chapter One, Section IV.

(2) In the cases under Paragraph 1, the applicant shall submit the documents under Article 80, Subparagraphs 2 and 5 to certify compliance with the requirements for radiation protection established with the regulations under Article 26, Paragraphs 2 and 3 of the ASUNE, which are applicable to the new circumstances.

Article 82.

The documents under Article 80, Subparagraphs 1, 4 and 5 shall not be required in case of issuing permits for location entities with following SIR:

1. SIR installed in smoke detectors;
2. sealed radioactive SIR installed in devices constructed in a way that at a distance from the surface equal to 0, 1 m the equivalent dose rate does not exceed 1 $\mu\text{Sv/h}$;
3. radioactive markers and kits;
4. X-ray installations;
5. SIR installed in devices for process monitoring;
6. SIR installed in static electricity neutralizers.

Section III

Permit for construction of an entity with a source of ionising radiation, assembly and initial testing

Article 83.

(1) Any permit for construction, assembly and initial testing shall be issued after issuing a permit for location of an entity with a source of ionising radiation at a selected site.

(2) In the case of issuing a permit under Paragraph 1, the documents under Article 73, Paragraph 2, Subparagraphs 1-4 and 7 shall be attached to the application. The following documents shall also be attached:

1. document certifying that the applicant possesses ownership rights or property rights over the site where the construction and assembling works will take place, respectively a document certifying the consent of the site proprietor or property rights holder for performing the respective activities;
2. technical design for construction containing "Radiation protection report" section;
3. document establishing the procedure for performing the activity, if assembling and initial testing works will be carried out by a contractor;
4. document confirming that the physical protection of the entity with radioactive substances has been ensured, co-ordinated with the Ministry of Interior competent bodies under the conditions and according to the procedure of Article 113, Paragraph 4 of the ASUNE.

Section IV

Permit for decommissioning of an entity with radioactive substances

Article 84.

(1) In the case of issuing a permit for decommissioning of an entity with radioactive substances, the documents under Article 73, Paragraph 2, Subparagraphs 1-4 and 7 of this Regulation shall be attached to the application. The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules;
2. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the radiation protection requirements, standards and rules;
3. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with radiation protection requirements, standards and rules;
4. documents related to the management and organizational structure of the applicant;
5. protocol for investigation the entity functional capability, prepared by a commission appointed by the applicant;
6. decommissioning plan, approved by the management body of the applicant, containing:
 - a) description of the stages and the respective activities with regard to decommissioning;
 - b) information on decommissioning works scope and the approach to carrying out these activities;
 - c) information on the organization of the activities for technical liquidation of the entity;
7. protocol containing radiation monitoring results and an assessment of the radiological consequences;
8. inventory of existing SIR and RAW, their specific and total activity and radioisotope composition;

9. assessment of RAW generated during the decommissioning process, including specific and total activity and radioisotope composition;

10. document confirming that delivery of RAW to a license holder under Article 53-55 is ensured;

11. document confirming that the physical protection of the entity with radioactive substances has been ensured, co-ordinated with the competent bodies of the Ministry of Interior in the cases provided by the law.

(2) In case of decommissioning of a facility for extracting and processing uranium, the documents under Paragraph 1 and a radio-ecological assessment shall be attached. The assessment shall include:

1. measurement results of the natural background gamma radiation of the area (in the form of a cartogram);

2. data on the radiological state of the soils, vegetation and waters in the area;

3. prognosis for radiological outcome;

4. proposal for undertaking measures for limitation of radiation risks to the population and the environment;

5. schemes for location of radioactive materials and contaminated equipment, co-ordinated with the Ministry of Environment and Water and the Ministry of Health.

Section V

Permit for temporary storage of radioactive substances

Article 85.

In the case of issuing a permit for temporary storage of radioactive substances, the documents under Article 73, Paragraph 2, Subparagraphs 1-5 and 7, “b”, Subparagraph 10, “b” and “c”, Subparagraph 11, “c” shall be attached to the application. The following documents shall also be attached:

1. documents related to the management and organizational structure of the applicant;

2. document certifying that all necessary actions have been taken for ensuring physical protection of the entity with radioactive substances, co-ordinated with the competent bodies of the Ministry of Interior in the cases provided by the law;

3. documents containing identification of the stored radioactive substances, their

characteristics and quantities.

Section VI

Permit for import or export of sources of ionising radiation or parts of them

Article 86.

In the case of issuing a permit for import or export of SIR or parts of them, the documents under Article 73, Paragraph 2, Subparagraphs 1-5 shall be attached to the application. The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules;
2. documents containing identification data related to the consignee of the imported or exported SIR or parts of them;
3. certificate for import or export of goods in the form according to Article 6 of the Regulation for the Conditions and Procedure for Registration and Permitting of Foreign Trade Transactions – Appendix No. 4 to Article 7 of the Council of Ministers Decree No. 233/2000 (promulgated in the State Gazette No. 93/2000, amended and supplemented by No. 112/ 2001 and No. 110/2002), filled in by the applicant in duplicate;
4. documents certifying the actuality of the data stated in the certificate for import or export of goods;
5. documents certifying compliance with the respective standards;
6. manufacturing serial numbers inventory of the imported or exported SIR or parts of them;
7. document certifying that the transport of the imported or exported radioactive sources will be performed by a holder of a permit or license for transport of radioactive substances issued under the procedure of Chapter Four, Section III.

Article 87.

In the case of issuing a permit for import of SIR or parts of them, a document certifying that the person entitled to receive the respective commodities is a holder of a license or permit issued by the NRA Chairman authorising their use or storage shall also be attached to the application along with the documents

under Article 86.

Article 88.

In the case of issuing a permit for export of SIR or parts of them, a document issued by a competent body of the state of the importer registration certifying authorisation for performing the respective activity shall also be attached to the application along with the documents under Article 86.

Section VII

License for use of sources of ionising radiation for economic, medical, scientific or process control purposes

Article 89.

In the case of issuing a license for use of SIR for economic, medical, scientific or process control purposes, the documents under Article 73, Paragraph 2 shall be attached to the application. The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules;
2. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the radiation protection requirements, standards and rules;
3. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with radiation protection requirements, standards and rules;
4. documents related to the management and organizational structure of the applicant;
5. certificate confirming compliance of SIR with the respective Bulgarian or foreign national standards, or with international or European standards;
6. document, in a prescribed by the NRA Chairman form, containing information on the respective SIR; personnel involved in the activity; work organization; radiation protection measures taken and the means for radiation monitoring and control;
7. document confirming that the physical protection of the entity with

radioactive substances has been ensured, co-ordinated with the competent bodies of the Ministry of Interior in the cases provided by the law.

Article 90

(1) In the case of issuing a license for use of x-ray installations, the documents under Article 73, Paragraph 2, Subparagraph 6 "c" and Subparagraph 9 shall not be attached to the application.

(2) The documents under Article 73, Paragraph 2, Subparagraphs 1-5, Subparagraph 6 "b" and "c", Subparagraph 7, "b", Subparagraphs 8-10 and Subparagraph 11, "a"- "d" shall be attached to the application for issuing a license for the use of:

1. SIR installed in smoke detectors;
2. sealed radioactive SIR installed in devices constructed in a way that at a distance from the surface equal to 0, 1 m the equivalent dose rate does not exceed 1 $\mu\text{Sv/h}$;
3. radioactive markers and kits;
4. SIR installed in devices for process monitoring;
5. SIR installed in static electricity neutralizers.

Article 91.

In the case of issuing a license for use of SIR for medical purposes, the documents under Article 89 shall be submitted, as well as a description of the individual radiation protection means and the devices for radiological protection of the patients and persons who voluntarily render assistance to them, as well as of the visitors of patients undergoing brachytherapy or treatment with radiopharmaceuticals.

Article 92.

A license for use of SIR for medical purposes shall be issued after official coordination with the Minister of Health through the National Centre for Radiobiology and Radiation Protection.

Article 93.

Within the co-ordination process, the documents under Article 89 and 91 shall be

sent by the NRA Chairman to the National Centre for Radiobiology and Radiation Protection.

Article 94.

(1) The National Centre for Radiobiology and Radiation Protection shall coordinate the issuance of the license for use of SIR if the applicant activity complies with the requirements under Article 61 of the ASUNE and with the respective applicable statutory instruments, or shall issue a justified denial.

(2) The coordinating decision of the National Centre for Radiobiology and Radiation Protection shall be taken and made available to the NRA Chairman and the applicant within 10-days after receiving the documents under Article 93.

(3) The non-issuance of the coordinating decision within the determined time limit shall be considered to be an implicit consent for issuing the license.

Section VIII

License for manufacturing sources of ionising radiation or parts of them

Article 95.

(1) In the case of issuing a license for manufacturing SIR or parts of them, the documents under Article 73, Paragraph 2 shall be attached to the application. The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules;
2. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the radiation protection requirements, standards and rules;
3. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with radiation protection requirements, standards and rules;
4. documents related to the management and organizational structure of the applicant;
5. documents confirming existence of conditions for verification the parameters and characteristics of the manufactured SIR and parts of them;

6. methodologies applied to manufacturing and quality control in manufacturing SIR and parts of them;

7. list of the standards to be used with regard to licensed activity;

8. document confirming that the physical protection of the entity with radioactive substances has been ensured, co-ordinated with the competent bodies of the Ministry of Interior in the cases provided by law.

(2) The documents under Article 73, Paragraph 2, Subparagraphs 1-5, Subparagraph 6 "a" and "b", Subparagraphs 7-11 and the documents under Paragraph 1, Subparagraphs 1- 7 shall be attached to the application for issuing a license for manufacturing x-ray installations.

Section IX

License for handling of SIR for the purpose of maintenance, assembly, dismantling, measurement, construction and repair work or other services to persons using or manufacturing SIR or parts of such sources

Article 96.

(1) In the case of issuing a license for handling of SIR for the purpose of maintenance, assembly, dismantling, measurement, construction and repair work or other services to persons using or manufacturing SIR or parts of such sources, the documents under Article 73, Paragraph 2 shall be attached to the application.

The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules;

2. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the radiation protection requirements, standards and rules;

3. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with radiation protection requirements, standards and rules;

4. documents related to the management and organizational structure of the applicant.

(2) The documents under Article 73, Paragraph 2, Subparagraphs 1-5 and 6 “a” and “b”, and Subparagraphs 7-11 shall be attached to the application for issuing a license for work with x-ray installations.

Section X

License for import or export of sources of ionising radiation or parts of them

Article 97.

In the case of issuing a license for import or export of SIR or parts of them, the documents under Article 73, Paragraph 2, Subparagraphs 1-5 shall be attached to the application. The following documents shall also be attached:

1. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with radiation protection requirements, standards and rules.
2. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the radiation protection requirements, standards and rules;
3. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with radiation protection requirements, standards and rules;
4. documents related to the management and organizational structure of the applicant.

Article 98.

Any particular import or export of SIR or parts of them shall be covered by a separate permit under Section VI of this chapter.

Chapter four

LICENSES AND PERMITS FOR TRANSPORT OF NUCLEAR MATERIAL, RADIOACTIVE WASTE AND OTHER RADIOACTIVE SUBSTANCES

Section I

General provisions

Article 99.

(1) The licenses and permits under Article 15, Paragraph 3, Subparagraph 5 and Paragraph 4, Subparagraphs 7, 12 and 16 of the ASUNE shall be issued under the procedure prescribed for in this chapter.

(2) The licenses under Article 15, Paragraph 3, Subparagraph 5 of the ASUNE and the permits under Article 15, Paragraph 4, Subparagraphs 12 and 16 of the ASUNE shall correspondingly be issued in case of transport of RAW or other SIR containing radioactive substances.

(3) This chapter provisions shall not be applied to nuclear material, RAW and/or other radioactive substances if:

1. they are transported within the site boundaries in order to be utilised or managed on the basis of a license and/or permit issued under this Regulation procedure;
2. they are mounted to a transport conveyance;
3. they are implanted or introduced into humans or animals for medical or scientific purposes;
4. they are added in consumer products lawfully offered for sale;
5. the values of their specific activity and the total activity in the consignment are not higher than the values defined in the regulation under Article 26, Paragraph 4 of the ASUNE;
6. they are natural radioactive materials or ores, which are not subject to treatment, if their specific activity does not exceed ten times the values indicated by the regulation under Article 26, Paragraph 4 of the ASUNE.

Article 100.

The application for issuing a license or permit under Article 99, Paragraph 1 shall contain the data under Article 4. The following documents shall also be attached to the application:

1. court decision for registration of the applicant – legal person in the commercial register and a certificate of current legal status;
2. certificate issued by the respective court certifying that the applicant – legal person or sole trader is not subject to bankruptcy proceedings;
3. certificate showing no previous conviction of the applicant – natural person or sole

trader, respectively of the members of the management and supervisory bodies of the applicant - legal person;

4. documents confirming that the applicant possesses sufficient financial resources for performing the activity in conformity with nuclear safety and radiation protection requirements, standards and rules;
5. documents confirming that the applicant possesses sufficient technical resources for performing the activity in conformity with the nuclear safety and radiation protection requirements, standards, and rules;
6. documents confirming that the applicant possesses sufficient material resources for performing the activity in conformity with the nuclear safety and radiation protection requirements, standards, and rules;
7. justification for the proposed term of validity;
8. other documents confirming compliance with the requirements for performing the respective activity.

Section II

Permit for nuclear material transport

Article 101

(1) The documents under Article 100 shall be attached to the application for issuing a permit for nuclear material transport. The following documents shall also be attached:

1. transport permits or corresponding administrative acts issued by the competent authorities of the state of destination and the states of transit – in case of export of nuclear material;
2. specification of the nuclear material type, form and quantity, including enrichment with fissile isotope and radioisotope composition;
3. specification of the transport packages: number, type, category, transport index and criticality safety index;
4. documents containing information on:
 - a) the registration number of the permit or license, issued under this Regulation procedure, stipulating the conditions according to which the consignee may store or use the respective nuclear material – in case of nuclear material import or transport within the territory of the state;

- b) the expected date of departure and arrival of the shipment;
 - c) the departure point, transport route within the state, including the scheduled transit stops, and nuclear material delivery point;
 - d) the chosen mode of transport within the state territory - road, rail, river, sea, air, or combined transport; in case of combined transport - the intermediate points between the departure and arrival points and identification data for the contact persons authorized by the carrier shall also be specified;
5. documents regulating the relations between the consignor and consignee and between the applicant and the subcontractors to participate in the shipment within the territory of the state;
 6. the administrative acts, issued by the respective administrative authorities, for approval of the transport packages according to the requirements of the regulation under Article 26, Paragraph 4 of the ASUNE;
 7. documents certifying that the chosen transport conveyances correspond to the transport safety standards and to the safety standards for protection against ionising radiation;
 8. documents certifying that the cargo loading and unloading devices correspond to the requirements for safe performance of these activities;
 9. written document, approved by the management body of the applicant, determining:
 - a) the persons in charge of transport safety;
 - b) the personnel to take part in the transport operations;
 - c) the vehicle drivers engaged in road transport;
 10. individual licenses issued according to the procedure under Article 65, Paragraph 3 of the ASUNE to the persons named in the document under Subparagraph 9;
 11. health certificate for compliance with the medical requirements - for every member of the personnel to be engaged in transport operations;
 12. documents certifying that the actual condition of the roads to be used corresponds to the requirements for safe transport;
 13. documents containing the results of the radiometric measurement performed in accordance with the requirements under Article 26, Paragraph 4 of the ASUNE;
 14. nuclear safety and radiation protection program;
 15. emergency plan;

16. document confirming that the physical protection is ensured, co-ordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure of Article 113, Paragraph 4 of the ASUNE;

17. instruction for physical protection;

18. quality assurance program;

19. documents demonstrating the applicant's obligation to return the consignment to the starting point and the consignor's obligation to accept the consignment back in case of non-delivery.

(2) The documents under Paragraph 1, Subparagraph 13 shall not be attached to the application for transport of fresh (non-irradiated) nuclear fuel.

(3) The documents under Paragraph 1 shall be attached to the application for issuing a permit for spent (irradiated) nuclear fuel transport. The following documents shall also be attached:

1. protocols for inspection of the respective waste packaging in order their readiness to meet the respective operating instructions requirements to be demonstrated;
2. protocol to verify that the waste material is hermetically sealed;
3. information, presented in a tabular form, on the packaging parameters according to the nuclear safety requirements for spent nuclear fuel transport determined in the regulation under Article 26, Paragraph 4, of the ASUNE;
4. cartogram for waste containers loading with spent nuclear fuel.

Section III

License for transport of radioactive substances

Article 102.

The documents under Article 100 shall be attached to the application for issuing a license for transport of radioactive substances. The following documents shall also be attached:

1. specification of the radioactive substances to be transported in any conveyance – type, physical and chemical characteristics, quantity, activity, numbers according to the unified classification of the UN (UN No.);
2. specification of the transport packages – type, category, transport index;
3. documents containing information on:

- a) the maximal stated and maximal admissible total transport index for any conveyance;
 - b) the chosen transport mode within the state territory - road, rail, river, sea, air, or combined transport; in the case of combined transport, the intermediate points between the departure and arrival points and identification data for the contact persons authorized by the carrier shall also be specified;
4. document regulating the relations between the applicant and the subcontractors to participate in the shipment;
 5. documents certifying that the chosen transport conveyances correspond to the transport safety standards and the safety standards for protection against ionising radiation;
 6. document, adopted by the management body of the applicant, defining:
 - a) the persons in charge of the transport safety;
 - b) the personnel to take part in the transport operations, including health physicists;
 - c) the vehicle drivers engaged in road transport;
 7. individual licenses issued according to the procedure under Article 65, Paragraph 3 of the ASUNE to the persons named in the document under Subparagraph 6;
 8. health certificate of compliance with the medical requirements - for every member of the personnel to be engaged in transport operations;
 9. radiation protection program;
 10. emergency plan;
 11. quality assurance program;
 12. documents demonstrating the applicant's obligation to return the consignment to the starting point and the consignor's obligation to accept the consignment back in case of non-delivery.

Section IV

Permit for non-reoccurring transport of radioactive substances

Article 103.

(1) The documents under Article 102 shall be attached to the application for issuing a permit for non-reoccurring transport of radioactive substances. The following documents shall also be attached:

1. documents containing information on:
 - a) the registration number of the permit or license, issued under this Regulation procedure, stipulating the conditions according to which the consignee may store or use the nuclear material – in case of nuclear material import or transport within the territory of the state;
 - b) the expected date of departure and arrival of the shipment;
 - c) the departure point, transport route within the state, including the scheduled transit stops and nuclear material delivery point;
 2. documents regulating the relations between the consignor and consignee and between the applicant and the contractors to participate in the shipment within the territory of the state;
 3. the administrative acts, issued by the respective administrative authorities, for approval of the transport packages or other structures according to the requirements of the regulation under Article 26, Paragraph 4 of the ASUNE;
 4. documents certifying that the cargo loading and unloading devices correspond to the requirements for safe performance of these activities;
 5. transport permits or corresponding administrative acts issued by the competent authorities of the state of destination and of the states of transit – in case of export of radioactive substances;
- (2) Depending on the radioactive substances type and characteristics, the NRA Chairman may request the applicant to submit:
1. document confirming that the physical protection is ensured, co-ordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure of Article 113, Paragraph 4 of the ASUNE;
 2. instruction for physical protection.

Section V

Permit for transit of nuclear material, radioactive waste, spent fuel or other radioactive substances

Article 104.

- (1) The documents under Article 102 and 103 shall be attached to the application for issuing a permit for transit of RAW or other radioactive substances. The following documents shall also be attached:

1. document containing information on:
 - a) the number and date of issuance of the Council of Ministers decision authorising the transit of the nuclear material, RAW and/or spent fuel through the territory of the state;
 - b) the state of origin, state of destination and states of transit;
 - c) the border crossing points to be used and the expected date of crossing them;
 2. document certifying that the consignor is authorised to perform activities with goods and technologies determined to be of potential "dual-use" issued by the respective competent body according to the Act on the Control of Foreign Trade in Arms and in Potential "Dual-Use" Goods and Technologies;
 3. document confirming that the physical protection is ensured, co-ordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure of Article 113, Paragraph 4 of the ASUNE;
 4. instruction for physical protection;
- (2) The documents under Paragraph 1 shall be attached to the application for issuing a permit for transit of nuclear material or spent fuel alongwith the following documents:
1. specification of the type, form and quantity of nuclear material, including enrichment with fissile isotope and radioisotope composition;
 2. specification of the transport packages: number, type, category, transport index, criticality safety index;
 3. nuclear safety and radiation protection program.

Chapter Five

REGULATORY CONTROL OVER COMPLIANCE WITH THE CONDITIONS OF THE ISSUED LICENSES AND PERMITS

Article 105.

(1) The NRA Chairman shall exercise regulatory control over the fulfilment of the conditions of the issued licenses and permits and the requirements and standards for safe use of nuclear energy and ionising radiation, RAW and spent fuel management according to the provisions of the ASUNE.

(2) The NRA Chairman shall execute preventive, current and confirmatory control according to the ASUNE, the NRA Rules of Procedure and this Regulation.

(3) The control under Paragraphs 1 and 2 shall be executed by inspectors, who are NRA officials, designated by an order issued by the NRA Chairman under the procedure of the ASUNE and the NRA Rules of Procedure.

Article 106.

The NRA inspectors shall conduct the inspections separately or together with representatives of other competent bodies, which are authorised by law to exercise specialized control over the persons involved in licensed or permitted activities covered by this Regulation.

Article 107.

The NRA Chairman shall direct the NRA inspectors activities and shall approve rules for performing the inspections, defining the inspections types, regularity, method for performing the inspections, procedure for objectifying the inspection results, co-ordination, and other measures ensuring that the inspections are conducted by lawful means and in an adequate manner.

Article 108.

The NRA inspectors shall be authorized to inspect activities assigned by a licensee or permit holder to contractors in order compliance with the license or permit conditions to be confirmed.

Article 109.

(1)The inspectors shall issue protocols of findings on the results of their inspections, attaching the evidence collected, the explanations and the measurement and/or test results.

(2) Any protocol of findings shall be served to the inspected person, who shall have the right to provide explanations and submit objections within 7-days after the service.

(3) On the basis of the results of the inspections performed, the inspectors may:

1. issue mandatory directives to the inspected persons;
2. issue written statements on administrative infractions;
3. propose to the NRA Chairman imposition of administrative enforcement measures.

(4) The persons who have received mandatory directives shall report to the inspector on implementation of the directives within the prescribed time limit.

(5) The NRA inspectors shall perform confirmatory control over the implementation of the directives given.

Article 110.

(1) In case of emergency or other extraordinary circumstances, when during on-site inspection the NRA inspector determines that nuclear safety and/or radiation protection requirements have been violated, a protocol of findings may be prepared without further delay and mandatory urgent actions directives may be given for prevention of possible incidents or accidents, or for mitigation of their consequences.

(2) In the cases under Paragraph 1, the protocol of findings and the mandatory directives shall be served to the inspected person simultaneously and the inspector shall notify immediately the NRA Chairman of the performed activities.

Chapter Six REGISTERS

Article 111.

(1) The NRA shall maintain public registers both in paper and in an electronic form, in which the following acts issued by the NRA Chairman shall be recorded:

1. licenses and permits, as well as their amendment, renewal, suspension and revocation;
2. individual licenses for employment at nuclear facilities or with SIR.

(2) The following information shall be recorded in the registers:

1. the registration number of the respective administrative act;
2. the date of issuing of the administrative act;
3. the term of validity of the act;
4. the type of the issued administrative act;
5. applicant's identification data;
6. restrictive conditions – in case of issuing a license for a separate stage of the activity or in other cases connected with performing the activity using parts of the facility or entity involved, or with the activity scope;
7. data related to subsequent amendments of the administrative act, as well as data related to its suspension if it is imposed by an order of the NRA Chairman;
8. identification data for the NRA official who entered the information into the register.

(3) Where the NRA Chairman refuses to issue a license, permit or individual license, the following shall also be included in the register under Paragraph 1:

1. the registration number and the date of issue of the NRA Chairman order of refusal for issuing the license or permit;
2. the type of the requested administrative act;
3. applicant's identification data;
4. identification data for the NRA official who entered the information in the register.

(4) The documentation related to registered under Paragraph 1 licenses, permits and individual licenses shall be kept in a separate archive.

SUPPLEMENTARY PROVISIONS

§ 1. Within the meaning of this Act:

1. "applicant" means a person who has submitted or on behalf of whom an application has been submitted under the procedure of this Regulation regarding issuing, amending, renewing or suspending of a license or permit under the ASUNE, as well as:

a) the transaction parties, in the case of application for issuing a permit for commercial transactions involving nuclear facility;

b) the licensee of the nuclear facility, in case of an application for import or export of nuclear material under Article 40, Paragraph 1 of the ASUNE, or sole trader, or legal

entity intending to perform import or export on the basis of Article 40, Paragraph 2 of the ASUNE;

2. "undertaker" means a construction contractor defined as assignor according to the Act on the Territorial Structure;

3. "applicant's identification data" are the first name, second name, surname, personal identification number, permanent and present address in the Republic of Bulgaria – for natural persons, and the entire name, registered office and main office, number of the court resolution for company registration, BULSTAT and tax number, as well as the first name, second name, surname of the persons who have a representative power according to the current court registration – for legal entities and sole trades;

4. "licensee" means holder of a license issued under the ASUNE, which is entered into force and has not been suspended;

5. "permit holder" means holder of a permit issued under the ASUNE, which is entered into force and has not been suspended;

6. "final shut down of a nuclear facility" means the final stage of the operation of the nuclear facility during which it is brought to a condition that the nuclear fuel is removed from the site or is emplaced in a special facility located at the same site and designed for long and safe storage of nuclear fuel;

7. "RAW conditioning" means the activities that produce a waste package suitable for handling, transport, storage and/or disposal. Conditioning shall include conversion of the waste to a solid waste form and providing an overpack;

8. "RAW disposal" means emplacement of waste in an appropriate facility without the intention for retrieval;

9. "packaging" means assembly of components necessary to enclose the radioactive contents completely;

10. "package" means the packaging with its radioactive contents as presented for transport;

11. "transport" means changing the location, a specific movement (carriage, convey) of a consignment, including, if necessary, a transit stay and temporary storage, from the place of origin to the place of its destination;

12. "carrier" means any person undertaking the carriage of radioactive material by any means of transport;

13. "conveyance" means:

a) for transport by road – a road vehicle or a tractor and semi-trailer combination;

- b) for railway transport – a railroad car or railway wagon;
- c) for transport by sea or inland waterway – any vessel, or any hold, compartment, or defined deck area of a vessel;
- d) for transport by air - any aircraft (cargo or passenger airplane);

14. "consignment" means any package or packages, or load of radioactive material, which is classified, packaged, marked, labelled and completely brought to a condition that will allow its lawful transport;

15. "consignor" means any person who prepares a consignment and the transport documents and submits them for transport on a specified route.

16. "consignee" means any person who is entitled to receive a consignment.

§ 2. (1) The persons who intend to submit an application for issuing a license and/or permit under this Regulation procedure may ask the NRA Chairman beforehand to express a statement on certain procedural questions.

(2) Before submission of an application for issuing a license or permit for activities involving SIR, the persons who intend to perform such activity are entitled to ask the NRA Chairman to assign an assessment on the availability of the conditions under Article 56, Paragraphs 2 and 3 of the ASUNE. The assessment shall be performed on the basis of the presented documents, containing radiation characteristics of the source.

§ 3. In the cases under Articles 17 and 18, an original document of the license or permit where the amendments are incorporated into the initial contents may be served to the licensee or permit holder. In this case the license or permit term of validity shall not be changed.

§ 4. The procedure for a power plant unit start up after nuclear fuel reloading shall be determined by the conditions of the license issued for nuclear facility operation.

§ 5. In the cases under Article 47, Paragraph 1 of the ASUNE, the State Energy Regulatory Commission shall send to the NRA Chairman a copy of the document by which the license is suspended. The Commission shall officially notify the NRA Chairman of the entering into force of this document.

§ 6. The NRA Chairman shall approve by an order the forms for the applications, which shall be published on the NRA official website.

§ 7. The NRA Chairman shall issue instructions for the implementation of the Regulation, as well as guidance, methodologies and other documents for its application.

TRANSITIONAL AND FINAL PROVISIONS

§ 8. Where this Regulation provides for application of the acts of secondary legislation for the ASUNE implementation, which are not adopted at the moment of entering into force of this Regulation, the respective secondary legislation acts issued on the basis of the Act on the Use of Atomic Energy for Peaceful Purposes shall be applied insofar as they do not contradict the ASUNE.

§ 9. If the ASUNE and this Regulation require issuing of more than one permit in a subsequent order and some of these acts have been issued under the Regulation No.5 of 1988 for Issuing Permits for Nuclear Energy Use (promulgated in SG No.13/1989, amended and supplemented with SG No. 37/1993 and No.12/2001), reissuing of this acts according to this Regulation procedure shall not be necessary.

§ 10. (1) The procedure for allocation items and real estate properties associated with existing state-owned facilities for RAW management to the Radioactive Waste State-Owned Company shall start within the time limits defined by the ASUNE.

(2) Until the issuance of a license or permit to the Radioactive Waste State-Owned Company for performing activity at the facilities under Paragraph 1, these facilities shall be operated by the existing permit holders under the conditions of the permits issued to them.

§ 11. (1) Persons not possessing a permit under the Regulation No.5 of 1988 for Issuing Permits for Nuclear Energy Use, who have at their actual disposal SIR upon entering into force of this Regulation, are obliged within three months after entering into force of the Regulation to request a permit for temporal storage. In case of non-compliance, the sanctions under Article 138, Paragraphs 2 and 3 of the ASUNE shall be applied.

(2) The persons under Paragraph 1 who are subject to bankruptcy or liquidation proceedings are obliged to store the respective SIR safely until delivery for management as RAW.

§ 12. If on the date of entering into force of this Regulation the time limits for submission of an application for renewal of a license or permits defined in Article 24, Paragraphs 1 and 2 have been expired, the licensee or permit holder may submit an application for renewal until the last moment before expiration of the license or permit term of validity.

§ 13. This Regulation is issued pursuant to Article 26, Paragraph 1 of the Act on the Safe Use of Nuclear Energy.

ENCLOSURE

to Article 40, Paragraph 1, Subparagraph 1, “a”

Structure of the Safety Analysis Report (SAR) of a Nuclear Facility

1. Chapter I. Introduction

- 1.1. Designation of the nuclear facility;
- 1.2. General characteristics of the nuclear facility;
- 1.3. Safety objectives and criteria;
- 1.4. SAR structure, purposes and scope of the chapters;
- 1.5. List of the statutory instruments and standards to be applied to performing the activity.

2. Chapter II. General characteristics of the nuclear facility

- 2.1. Layout of the nuclear facility;
- 2.2. Simplified diagram of the nuclear facility;
- 2.3. General and specific design criteria;
- 2.4. Basic technical characteristics;
- 2.5. Operating modes;
- 2.6. Concept for ensuring the safety;
- 2.7. Basic technical solutions of the systems and equipment;
- 2.8. Basic principles for organisation of the operations;
- 2.9. Quality assurance.

3. Chapter III. Site evaluation

- 3.1. Geographical, topographical and demographic conditions of the site location;
- 3.2. Human induced factors, specific to the site;
- 3.3. Hydrological and meteorological conditions;
- 3.4. Geology, hydro-geology, seismology and engineering geology;
- 3.5. Impact of the nuclear facility over the environment and the population;
- 3.6. Programs for monitoring and control of site related parameters;

3.7. Site related issues in emergency planning and accident management;

3.8. List of the external site specific hazards;

4. Chapter IV. Basic criteria and approaches to the design of building structures, systems and elements of the nuclear facility

4.1. Basic statutory criteria and requirements to the design of building structures, systems and elements;

4.2. Safety, quality and seismic classification of the systems and elements;

4.3. Description and justification of the nuclear facility layout;

4.4. Expected impacts originating during normal operation and transient conditions.

Impact characteristics;

4.5. Design load combinations of the equipment and building structures of the nuclear facility;

4.6. Site protection against hazardous geological processes and flooding;

4.7. Methods for justification and criteria for ensuring the resistance of buildings and equipment of the nuclear facility steadiness;

4.8. Determination of the loads from external and internal dynamic effects;

4.9. Building structures, equipment, constructions, bases and fundamentals;

4.10. Justification for the strength and operability of the systems and the elements of the nuclear facility;

4.11. Ergonomic and other requirements related to human factors and man-machine interface;

4.12. Basic criteria to the systems for physical, fire and emergency protection.

5. Chapter V. Description of the systems and elements of the nuclear facility and their conformance with the design requirements

5.1. Basic technical systems and elements, which ensure the normal operation of the nuclear facility (detailed description of each individual system and its elements);

5.2. Protection, localization, control and supporting safety systems;

5.3. Instrumentation and control systems and means;

5.4. Electrical power supply systems;

5.5. Auxiliary systems;

5.6. Systems for physical, fire and emergency protection.

6. Chapter VI. RAW management - for the nuclear facilities with RAW generation or intended for RAW management

- 6.1. RAW sources and characteristics;
- 6.2. Criteria for RAW acceptance at the facility and requirements to the packages;
- 6.3. System for management of gaseous RAW;
- 6.4. System for management of liquid RAW;
- 6.5. System for management of solid RAW;
- 6.6. Radiation control and sampling system.

7. Chapter VII. Management of nuclear fuel – for nuclear facilities where nuclear fuel is being used and/or stored

- 7.1. System for control and accounting of the nuclear material;
- 7.2. Incoming acceptance control of the fuel;
- 7.3. Criteria for defected fuel detection;
- 7.4. Fuel handling: equipment, elements, procedures;
- 7.5. Fuel treatment in case of damage or failure;
- 7.6. Radiation fields, control of the radiation contamination and anticipated release of radio-nuclides to the environment during normal operation;

8. Chapter VIII. Radiation protection

- 8.1. Objectives and criteria for radiation protection and strategy for their achievement and implementation;
- 8.2. Optimisation of the radiation protection;
- 8.3. Sources of ionising radiation;
- 8.4. Consideration of the layout of buildings, facilities and equipment and the design features of the radiation protection;
- 8.5. Assessment of the personnel exposure to ionising radiation during normal operation and during accidents;
- 8.6. Program for radiation monitoring;

9. Chapter IX. Operation

- 9.1. Organisational structure of the operator;
- 9.2. Personnel training and qualification;
- 9.3. Instructions and procedures;

- 9.4. Maintenance and repair;
- 9.5. Measures for assuring and maintaining the safety culture;
- 9.6. Operational experience feedback system;
- 9.7. Management of the equipment ageing;
- 9.8. Physical protection;
- 9.9. Emergency planning and preparedness for response in case of accidents;

10. Chapter X. Safety analysis of the facility, including accident analysis

- 10.1. Methods for safety analysis;
- 10.2. List and classification of the initiating events and design basis accidents;
- 10.3. Initial conditions, input data for the calculations; description and justification of the models; acceptance criteria;
- 10.4. Analysis of design basis accidents;
- 10.5. Analysis of beyond design basis accidents and accident management measures;
- 10.6. Demonstration of acceptability of the safety level of the nuclear facility and/or of the need for planning of safety upgrading measures.

11. Chapter XI. Limits and conditions for operation

- 11.1. Safety limits;
- 11.2. Limiting safety systems settings;
- 11.3. Operational limits and conditions;
- 11.4. Tests, inspections, surveillance and operational control of the systems important to safety;
- 11.5. Minimum number of operating personnel in the operational states, including qualified and authorized main control room staff;
- 11.6. Personnel actions in case of deviations.

12. Chapter XII. Quality management

- 12.1. Design and analysis;
- 12.2. Facility construction;
- 12.3. Operation;
- 12.4. Decommissioning.

13. Chapter XIII. Decommissioning - for nuclear facilities, which are to be decommissioned

13.1. Decommissioning concept;

13.2. Facility characteristics with regard to the decontamination and dismantling activities;

13.3. Anticipated inventory of radioactive and other dangerous materials in the facility;

13.4. RAW management during decommissioning;

13.5. Clearance – criteria, prognostic quantities, options for second use, recycling and/or management as conventional waste;

13.6. Measures, systems and equipment for facilities decontamination and dismantling.

14. Chapter XIV. Safety analysis after closure – for nuclear facilities for RAW disposal

14.1. RAW characteristics;

14.2. Protective engineering and natural barriers;

14.3. Release of radionuclides from the facility at normal conditions;

14.4. Release of radionuclides from the facility in case of failure of the protective barriers, including human activity on the site;

14.5. Transfer of radionuclides to the population and assessment of the exposure to ionising radiation;

14.6. Long-term stability of the facility;

14.7. Results analysis and conclusions.