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

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Chapter One

GENERAL RULES FOR ISSUING LICENCES AND PERMITS

Section I

General provisions

Article 1.

This Regulation establishes the procedure for:

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

Article 2.

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

Article 3.

(1) Licences 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 licence or permit referred to in Paragraph 1 when:

1. all necessary documentation is submitted;
2. the instructions of the NRA Chairman for providing additional documents are complied with;
3. all the conditions specified in preceding licences, permits and other documents issued under the ASUNE and connected with issuing the respective licence 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 licences, permits and other administrative acts specified by the ASUNE as prerequisites for issuing the respective licence or permit have been issued to the applicant by the competent administrative authorities.

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

Section II
Procedure for issuing licences and permits

Article 4.

(1) In order to obtain a licence 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 licence or permit and general description of the activity to be performed;

3. the term of validity for which the licence or permit is required;

4. general description of the basic characteristics and location of the nuclear facility or a source of ionising radiation to be utilised 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 up-to-date court registration if the applicant is a legal entity or sole trader.

(3) The application could be signed by an authorised person if the authorisation is granted in a written form and certified by a notary. 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 related 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 licence or permit and the attached documents shall be submitted in Bulgarian language.

(3) Official documents in a foreign language shall be submitted together with a legalised 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 only be submitted in paper.

(6) Documents required according to this Regulation and enclosed to preceding applications on the basis of which a licence 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 licences 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 the registration at the NRA. In the case of application for issuing a licence or permit for a nuclear facility, the review shall be performed within 45-days.

(2) (Amended, SG No 76/2012) 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 an appropriate time limit, but not less than 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 licence or permit by a reasoned order.

Article 7.

(1) The NRA Chairman shall have the discretion to check the declared data and circumstances ex officio 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 SG 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 organisations 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 frame, 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 licence 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 licence 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 licence conditions, the NRA Chairman shall have discretion to make the amendment of the licence ex officio, following the procedure under Section IV of this chapter.

(3) The licences, 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) (Amended, SG No 76/2012) Any licence shall be issued for a term of validity not exceeding ten 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 licences, permits and denial orders shall be served to the applicant, to a legal or explicitly authorised representative, or shall be sent by mail with registered letter with acknowledgement of receipt. The type and the registration number of the issued document shall be indicated on the registered letter.

(2) Any licence 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 SG 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. ex officio amendment of the respective licence by a permit issued by the NRA Chairman under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE;

2. (Supplemented, SG No 76/2012) amendment of the respective licence or permit in order to meet the conditions stipulated in the same or in another licence or permit issued by the NRA Chairman to the same applicant, or in respect of the fulfilment of the instructions given in the course of the implementation of control under Chapter Five of the ASUNE and in the case of undertaking organisational changes in line with the legislation, or in line with a decision of the Council of Ministers.

Section III
Licences and permits scope and contents

Article 12.

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

(2) (Amended, SG No 76/2012) Unless otherwise stipulated by law, separate operating and decommissioning licences as well as separate permits for designing, construction and commissioning shall be issued for any unit or any other nuclear facility located at a nuclear power plant site.

(3) (Amended, SG No 76/2012) Permits under Paragraph 2 and orders for the approval of the selected site and the technical design may be issued for a particular stage of the activity if such necessity has been justified by the applicant through the documentation provided in respect of the issuance of the permit or order.

(4) Where a person performs activities with more than one source of ionising radiation subject to the same type of licenses and permits, a single license or permit may be issued for all these activities.

(5) (Amended, SG No 76/2012) In the cases where the same nuclear facility is involved, a succeeding permit under Article 33, Paragraph 1, or a licence under Article 35, Paragraph 1 of the ASUNE, shall be issued to the holder of a preceding permit or licence, to it's successor in case of transfer of the undertaking as well as to the legal entity exercising real right over the assets used to perform the activity. This provision shall be also applied in the cases where the procedure for issuing the permit or licence has been initiated by the holder of the preceding permit or licence if a prior consent in writing has been given.

(6) (New, SG No 76/2012) In the case of replacement of the permit or licence holder, the rights and obligations arising from the authorisations issued to holders of preceding permits and licences shall be binding upon the new holder.

Article 13.

(1) Any licence and permit shall contain:

1. the name of the issuing authority;

2. the type of the respective licence or permit;

3. the registration number of the licence or permit;

4. the legal grounds for issuing the act;

5. (Amended, SG No 76/2012) business registration data and unified identification number of the licensee or permit holder – legal person or sole trader; 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, and the same data for a natural person – foreign citizen.

6. the activity for which the licence or permit is issued;

7. the nuclear facility or entity with a source of ionising radiation to be utilised if operation of such an entity is foreseen;

8. the term of validity for which the licence 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 licence 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 licence or permit is issued;

2. detailed description of the nuclear facility or entity with a source of ionising radiation for which the licence 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. (Amended, SG No 76/2012) requirements related to the management system for the activity;

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 ensuring physical protection;

14. obligations related to submission information about the fulfilment of the licence or permit conditions;

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

16. obligations related to termination of the activity.

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

1. requirements related to organisation 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 licence or permit may comprise one or more enclosures.

(5) A list of the internal rules for carrying out the activity, including instructions, programmes, 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 licence 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 frame shall be considered to be a tacit consent for undertaking the modifications.

Article 14.

(1) (Supplemented, SG No 76/2012) In the cases covered under Article 21, Paragraph 1 and Article 21a of the ASUNE, the licensee or permit holder shall notify the NRA Chairman within one month following the occurrence of any circumstances requiring licence or permit amendment and shall request the respective amendment.

(2) (Amended, SG No 76/2012) Any commercial company - a holder of a permit under Article 33, Paragraph 1 of the ASUNE or of a licence under Article 35, Paragraph 1 of the ASUNE which intends to perform reorganisation through acquisition, merger, , division, splitting, splitting of a single member limited company, change in the legal form, transfer of commercial enterprise, or non-monetary contribution to the capital of another company of assets – subject to licences or permits, 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 or Article 21a 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 licences or permits issued.

Article 15.

Obtaining all the necessary licences, 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 licences and permits issued under this Regulation.

Section IV
Licences and permits amendment

Article 16.

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

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

Article 17.

(Amended, SG No 76/2012)

(1) Any licence or permit may be amended by the NRA Chairman ex officio for the cases covered under Article 21, Paragraph 4 of the ASUNE.

(2) Outside the cases referred to in Paragraph 1, any licence for the operation of a nuclear facility shall be amended ex officio in the cases where the issuance of a permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE leads to the necessity for amendment of the respective licence conditions.

(3) The NRA Chairman shall notify in writing the licensee or permit holder of the opening the licence or permit ex officio amendment procedure. Within 14-days, the licensee or permit holder may express a written opinion about the amendment indispensability.

(4) The licence or permit shall be amended after the expiration of the time limit under Paragraph 3.

(5) For the cases covered under Paragraph 2, the licence shall be amended by the permit issued under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE in order to be brought in line with the permit conditions. The permit shall specify the amended provisions of the licence and their content.

(6) In case of unconformity between the conditions of the permit issued under Paragraph 2 and the amended conditions of the licence, the conditions of the permit shall be applied.

Article 18.

(1) (Supplemented, SG No 76/2012) In the cases covered by Article 21, Paragraph 1 and Article 21a, Paragraph 1 of the ASUNE, the respective licence or permit shall be amended at request of the licensee or permit holder by an order issued by 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 licence or permit amendment shall contain:

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

(3) The following documents 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 licence amendment:

1. (Supplemented, SG No 76/2012) within six months – with regard to amendment of a licence under Article 15, Paragraph 3, Subparagraphs 1 and 8 of the ASUNE;

2. (Amended, SG No 76/2012) within one month – with regard to amendment of a licence under Article 15, Paragraph 3, Subparagraphs 2-5 of the ASUNE.

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

1. (Repealed, SG No 76/2012);

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 licence 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) (Supplemented, SG No 76/2012) Should the licensee or permit holder fail to request an amendment within 14-days, the NRA Chairman may revoke the licence or permit following the procedure under Section VII of this chapter, or amend the licence or permit ex officio.

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

Licences and permits renewal

Article 22.

Licences 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 licence or permit renewal shall contain:

1. the applicant's identification data;

2. the licence or permit registration number;

3. request for the licence 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 licence or permit conditions shall also be submitted.

(2) (Amended, SG No 76/2012) For the case where nuclear facilities are involved, a justification for the new term of validity shall be attached to the application under Paragraph 1. In case of renewal of a licence, the following documents shall also be attached:

1. (Amended, SG No 76/2012) updated safety assessment report of the nuclear facility which shall take account of:

a) the legislative requirements in force;

b) (Amended, SG No 76/2012) the actual status of the nuclear facility;

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.

(3) (New, SG No 76/2012) In the case of practices with sources of ionising radiation, a justification for the new term of validity shall be attached to the application under Paragraph 1. In case of renewal of licence, the following shall also be attached:

1. up-to-date checklist in a standard form approved by the NRA Chairman, containing information for:

a) used and stored sources of ionising radiation and the activities with them;

b) the personnel and the organisation of the work with the sources of ionising radiation within the site;

c) radiological surveillance of the working environment and individual monitoring devices;

d) organisation and measures for ensuring radiation protection and physical protection;

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.

(4) (New, SG No 76/2012) Up-to-date instructions, programmes, orders and other internal documents shall be attached to the current questionnaire under Paragraph 3, Subparagraph 1;

(5) (New, SG No 76/2012) In the case of sites with radioactive substances, the current questionnaire under Paragraph 3, Subparagraph 1 shall be coordinated with the competent authorities of the Ministry of the Interior in respect of the physical protection if required by the law.

Article 24.

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

1. (Supplemented, SG No 76/2012) not earlier than eighteen months and not later than twelve months before the expiration of the licence term of validity – in case of licences under Article 15, Paragraph 3, Subparagraphs 1 and 8 of the ASUNE;

2. (Amended, SG No 76/2012) not earlier than one month before the expiration of the current licence term of validity – in case of licences under Article 15, Paragraph 3, Subparagraphs 2-5 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) If the application has been submitted within the time limits under Paragraphs 1 and 2, the applicant shall have the right to perform the activity under the conditions of the initially issued licence or permit until the issuance of a new license or permit.

(4) Paragraph 3 shall also be applied to all the cases where an objective inability prevents the applicant from observing 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 for non-compliance under Paragraph 4, the provisions under Section II of this chapter for licence or permit issuing shall be applied.

Article 25.

(1) The NRA Chairman shall take a decision on an application for licence 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 licence or permit renewal shall include an assessment of the conformity with the requirements under Article 3. The review of the application for licence renewal shall also include an assessment of the fulfilment of the conditions of the initially issued licence.

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

(3) (Amended, SG No 76/2012) Any licence shall be renewed for a term of validity not exceeding 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
Licences and permits suspension

Article 28.

(1) Any licence or permit shall be suspended:

1. by the 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. (Amended, SG No 76/2012) on the basis of an application for suspension of the licence or permit submitted by the licensee or permit holder;

4. by reason of revocation of the licence or permit;

5. (Amended, SG No 76/2012) upon adjudication in bankruptcy or dissolution through liquidation of the legal entity - licensee or permit holder;

6. upon the death of the natural person - licensee or permit holder;

7. (Amended, SG No 76/2012) upon transformation of the legal entity – a licence or permit holder, where the licence or permit is not amended under Article 21a, Paragraph 1 of the ASUNE at the time of the registration in the Commercial Register.

8. (New, SG No 76/2012) upon the issuance of a new licence for the same activity to the same or a new licence holder.

(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 licence or permit for the next stage of the activity.

(3) (Amended, SG No 76/2012) The NRA Chairman shall suspend the licence or permit by issuing an order, except for the cases under Paragraph 1, Subparagraphs 1 and 5-8, where the licence or permit shall be suspended automatically.

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

(5) (Repealed, SG No 76/2012).

Article 29.

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

1. the applicant's identification data;

2. the licence or permit registration number;

3. measures taken and measures 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 licence or permit;

2. justified denial to suspend the licence or permit if the precautionary measures necessary for ensuring nuclear safety, radiation protection and physical protection have not been taken.

(2) (Amended SG No. 93/2009, SG No 76/2012) The NRA Chairman may ask the State Energy and Water Regulatory Commission, the Minister of Economy, Energy and Tourism, the Minister of Defence, the Minister of Interior, the Minister of Environment and Waters, 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 licence or permit.

(3) The NRA Chairman shall decide on the application for licence 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.

(Amended, SG No 76/2012) Any licence or permit shall be revoked in the cases provided for in Article 23, Paragraph 1 Subparagraph 1 "a" and "b" and Subparagraphs 2 and 4 of the ASUNE.

Article 32.

(1) Upon existence of any facts which constitute grounds for the revocation of a licence 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 licence or permit.

(2) Within the time frame 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 licence 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 licence or permit conditions within the determined time limit and after evaluating the circumstances and submitted explanations and objections, the NRA Chairman shall issue an order to revoke the licence or permit.

(2) The licence 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 licence 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 licence 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 licence 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 authorised representative.

Chapter Two

LICENCES AND PERMITS FOR ACTIVITIES AT NUCLEAR FACILITIES AND FOR COMMERCIAL TRANSACTIONS INVOLVING NUCLEAR FACILITIES AND NUCLEAR MATERIAL

Section I

General provisions

Article 34.

(1) (Amended, SG No 76/2012) The licences and permits under Article 15, Paragraph 3, Subparagraphs 1 and 8 and Paragraph 4, Subparagraphs 1-5, 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 licence 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 the issuance of 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.

(8) (New, SG No 76/2012) A permit under Paragraph 1 and orders under Paragraphs 3 and 4 may be issued for each separate stage of the activity if such necessity has been substantiated by the applicant through the documentation provided in respect of the issuance of the permit or order.

Article 35.

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

1. (Amended, SG No 76/2012) a copy of the document certifying the business registration of the applicant;

2. (Amended, SG No 76/2012) document certifying that the applicant is not subject to bankruptcy proceedings;

3. (Amended, SG No 76/2012) document declaring lack of previous convictions for crimes of general nature - for 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 organisational 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 SG No. 51/2001);

3. (Amended, SG No 76/2012) description of the management system for the activity;

(2) (Repealed, SG No 76/2012);

(3) (Amended, SG No 76/2012) In the case of a national repository for 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 characteristics of the selected site, 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 literature references, containing data and information used for justification of the selected site;

g) list of the specialists contributed to the preparation of the documentation and to site investigation, as well as data for their qualification;

2. on-site monitoring programmes, including seismic monitoring, groundwater 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. programme 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) In the case the planned location of a new nuclear facility is on the site of another constructed and commissioned nuclear facility, 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.

(Amended, SG No 76/2012) Before issuance an 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 and the decision under Article 37, Paragraph 1, Subparagraph 3 has entered into force.

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. technical specification or a contract for designing;

2. (Amended, SG No 76/2012) description of the management system for the activity;

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) (Amended, SG No 76/2012) intermediate safety analysis report prepared on the basis of the preliminary safety analysis report and the technical design; the minimum content of the Safety Analysis Report shall comprise the topics stipulated in Enclosure No 1;

b) the results of the verification of the design compatibility with the 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) (Repealed, SG No 76/2012);

(3) (Repealed, SG No 76/2012);

(4) (Repealed, SG No 76/2012);

(5) (Repealed, SG No 76/2012).

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 general schedule for implementation the construction and assembling works;

2. technical design and/or work design for nuclear facility construction;

3. (Amended, SG No 76/2012) description of the management system for the activity;

(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, Energy and Tourism 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) (Repealed, SG No 76/2012);

(5) (Repealed, SG No 76/2012);

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

Article 42.

(Repealed, SG No 76/2012);

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 programme for the nuclear facility determining the commissioning stages, activities to be performed during each stage and planned duration of each stage; the commissioning programme 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. (Repealed, SG No 76/2012);

6. (Amended, SG No 76/2012) description of the management system for the activity;

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. (Amended, SG No 76/2012) the technical specification for nuclear facility operation shall contain 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 authorised 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. (Amended, SG No 76/2012) list of the positions in the organisational 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” and “b” of the ASUNE;

12. programme for on-site radiation monitoring and for monitoring of the special statute areas during the operation of the nuclear faculty;

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 programmes 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’s 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. (Repealed, SG No 76/2012);

28. documents arranging the special-statute areas and controlled access areas;

29. programme for radiation monitoring of the environment;

30. (Repealed, SG No 76/2012).

(2) An amendment of the commissioning programme 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.

(3) (New, SG No 76/2012) The documents under Paragraph 1, Subparagraphs 12, 17 and 29 shall be submitted to the National Centre for Radiobiology and Radiation Protection.

Article 44.

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

(2) In the case of issuing 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 related to the actual preparedness of the facility for accomplishment the respective stage in accordance with the commissioning programme;

2. approved programmes 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 sub-critical 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 it's conformity with data and circumstances declared and preparedness for carrying out the respective stage. With regard to the stage specificity, representatives of other authorities exercising specialised control may be included 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 authorised 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 specialised 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
Licence for operation of a nuclear facility

Article 47.

(1) An application for a licence 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 licence 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. (Amended, SG No 76/2012) the documents under Article 43, Paragraph 1, Subparagraphs 7, 9, 10, 13, 16, 17, 22, 24, 28 and 29 updated on the basis of the results of the commissioning stage;

3. (Repealed, SG No 76/2012);

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. programmes and plans for spent nuclear fuel management for the nuclear facility lifetime and following final shut down of the facility;

7. RAW management programme for the requested term of validity of the licence and for the nuclear facility operating lifetime;

8. rules, procedures and programmes 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 organisational structure of the applicant to manage and control these activities and the minimum number and qualification of the staff to occupy them;

10. (Amended, SG No 76/2012) description of the management system for the activity;

11. (Repealed, SG No 76/2012);

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. programme and a time-schedule for personnel training and exercise related to the activation of the on-site emergency plan of the nuclear facility;

15. programme for equipment lifetime management for the requested term of validity of the licence and for the nuclear facility lifetime, including for monitoring the status of important to safety components;

16. (Repealed, SG No 76/2012).

Article 49.

In the case of issuing an operating licence 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. licence 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 coordination of the activities of the personnel within the framework of each unit and for the nuclear power plant as a whole;

4. (New, SG No 76/2012) instruction for the operation of the structures, systems and components important to the safety (SSC);

5. (Renumbered, SG No 76/2012) operating instructions for the reactor installation;

6. (Renumbered, SG No 76/2012) instruction for in-service inspection of the base and weld metal of the equipment and pipelines.

Article 50.

(Amended, SG No 76/2012) In the case of issuing an operating licence for a research reactor or critical stand, the documents under Article 48 and Article 49, Subparagraphs 5 and emergency operating instructions specifying the activities to be performed in case of an accident shall be attached.

Article 51.

In the case of issuing an operating licence 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. physicochemical and radiochemical properties of the nuclear material, which is extracted, produced, processed, stored or handled at the facility;

2. (Amended, SG No 76/2012) neutron-physical characteristics, isotope composition and enrichment with fissile isotope of the nuclear material 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 licence 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 completion of closure operations, institutional on-site control shall be exercised, which shall be:

1. active - monitoring of the site, and if necessary – remedial and restoration work; or

2. passive – land use control.

Article 53.

(Amended, SG No 76/2012) In the case of issuing an operating licence for RAW processing and/or storage 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 for processing and/or storage;

2. technical specification of the nuclear waste packages for conditioned RAW;

3. description of RAW management activities in their technological sequence;

4. list of the internal rules, instructions and procedures for performing the facility intended purpose.

Article 54.

(Amended, SG No 76/2012)

(1) In the case of issuing an operating licence for RAW disposal facility, 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. criteria for acceptance of RAW for disposal;

2. procedures for delivery and acceptance of RAW for disposal;

3. inspection programme for accepting nuclear waste packages for disposal;

4. plan for the facility closure including the control performed in the post-closure period.

(2) The plan under Paragraph 1, Subparagraph 4 shall take into account the results of the safety assessment of the facility for the post-closure period.

(3) The Safety Analysis Report for RAW disposal facility under Article 48, Subparagraph 1 shall include assessment of the safety of the facility for the operating period and for the post closure period.

Article 55.

(Repealed, SG No 76/2012)

Section VII
Permits for activities leading to modifications

Article 56.

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

(2) (New, SG No 76/2012) The applicant shall cover by one application for issuing modification permit all mutually inter-connected issues.

Article 57.

(1) The application for permit modification shall also contain the registration number of the operating licence 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. (Amended, SG No 76/2012) document describing the specific measures to be applied toward management system for the activity, including entrusting the responsibility for exercising control over the activities performed by contractors and acceptance the results as well as a mechanism to manage the non-conformities and undertaking corrective actions if necessary.

Section VIII
Permit for nuclear material import and export

Article 58.

(1) (Amended, SG No 76/2012) The application for a permit for import or export of nuclear material shall be accompanied by the respective documents confirming the compliance of the activity with import and export regime stipulated in the Defence related products and Dual-Use Items and Technologies Export Control Act.

(2) In the cases 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 future use of the nuclear material 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 demonstrating 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 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 transport of the respective nuclear material through the territory of the Republic of Bulgaria will be performed by a holder of a licence or permit issued under this Regulation;

7. document certifying that the consignee possesses the necessary licence 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 licence.

(5) (New, SG No 76/2012) In case of import into the Republic of Bulgaria or export from the Republic of Bulgaria from or into a Member State of the European Union, respectively, issuance of a permit for import or export of nuclear material shall not be required.

Section IX
Licence for decommissioning of a nuclear facility
(Title amended, SG No 76/2012)

Article 59

(Amended, SG No 76/2012)

(1) The whole process of decommissioning of a nuclear facility shall be organised, analysed, planned and justified in a decommissioning plan, which shall have the following minimum content:

1. description of the facility, its site, the special-statute areas, SSC and radioactive contamination of SSC and the environment components;

2. the nuclear facility operating history – authorised activities, description of significant operating events, including those related to the decommissioning stage; the reasons for decommissioning;

3. list of the standards applied to decommissioning planning;

4. assessment of the amount, type and location of the radioactive or other hazardous materials stored at the facility;

5. decommissioning strategy – description of the analysed decommissioning options and a justification for the selected option;

6. time-schedule for the decommissioning stages and the decommissioning activities;

7. description of the decommissioning activities related to the radioactively contaminated structures, components, soil and groundwater;

8. classification of the SSC in terms of their significance with respect to different stages of the decommissioning plan implementation;

9. description of the required basic modifications to the existing SSC, including the introduction of new SSC necessary especially for the decommissioning stage;

10. programme and time-schedules for monitoring and maintenance of the SSC, which shall be used during the decommissioning stage;

11. description of the analysed possible decontamination options and justification for the selected option;

12. description of the available and planned technologies and technical means for dismantling and decontamination;

13. programme for RAW management containing:

a) inventory of RAW stored on site in terms of the sources, streams, types and quantities;

b) criteria for sorting the radioactive materials;

c) the organisation of the activities associated with RAW management before disposal, including justification of methods of treatment necessary for the disposal stage;

d) criteria and possibilities for second use and recycling;

e) expected liquid and gaseous releases into the environment;

14. safety assessment programme, including justification of the options connected with clearance of regulatory control, which shall be submitted to the National Centre for Radiobiology and Radiation Protection;

15. description of the management system for the activity, including personnel management;

16. programme for radiation protection of the personnel, public and environment;

17. description of the organisation and the responsibilities associated with the emergency planning and readiness;

18. obligations and responsibilities for ensuring the physical protection of the facility and, if necessary, measures for physical separation of the decommissioned facility from the facilities in operation;

19. up-to-date assessment of the financial resources necessary for the decommissioning stage, financing mechanisms, and financing sources available;

20. description of the monitoring programmes, 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;

21. time-schedule for reporting intermediate and final results connected with decommissioning process to the NRA.

Article 60.

(Amended, SG No 76/2012) In the case of issuing a licence 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; 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. (New, SG No 76/2012) description of the management system for the activity;

5. (Renumbered, SG No 76/2012) operating instructions for the SSC remaining in operation during the decommissioning stage;

6. (Renumbered, SG No 76/2012) decision on EIA according to the Environmental Protection Act.

Article 61.

(1) (Supplemented, SG No 76/2012) If the decommissioning plan provides for that the nuclear facility decommissioning is a multistage process, a separate permit shall be issued for each stage within the frames of the decommissioning licence in force.

(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. (Repealed, SG No 76/2012);

3. (Amended, SG No 76/2012) actual technical specification for nuclear facility operation including limits and conditions for operation specific for the decommissioning stage;

4. (Amended, SG No 76/2012) list of the operating instructions for the SSC remaining in operation during the respective stage;

5. (Repealed, SG No 76/2012).

(3) (Repealed, SG No 76/2012).

Article 62.

(1) (Amended, SG No 76/2012) 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 and the actual state of the facility. Such plan shall be submitted only in case of envisaged modifications to the initially planned volumes, technologies and time limits for implementation of each stage activities due to new circumstances or technological improvement.

(2) (Repealed, SG No 76/2012).

Section X
Permit for commercial transactions involving nuclear facility

Article 63.

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

(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 licence for other nuclear facility.

Article 64.

(1) The application for a commercial transaction permit involving transfer of property or the right to use 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 licence or permit in force, which is related to the nuclear facility. In the cases under Article 63, Paragraph 2, the registration number of the licence shall also be indicated.

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

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

2. application for issuing a licence 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. programme 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 licence under Subparagraph 2.

(4) If 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.

If at the moment of submission of the application under Article 64 the licence or permit issued to the existing proprietor is suspended under the procedure prescribed by the ASUNE, the application under Article 64, Paragraph 3, Subparagraph 1 shall not be submitted. For such cases, the registration number of the suspended licence or permit shall be indicated.

Article 66.

(1) The NRA Chairman shall review the applications under Article 64 within nine months in order to verify the correspondence with 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 licence or permit issuance;

2. the plan and the programme under Article 64, Paragraph 3, Subparagraphs 3 and 4 provides for appropriate measures to ensure nuclear safety, radiation protection and physical protection for the period 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) Any 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 licence or permit issued to the existing proprietor, except for the cases under Article 65;

2. issue the same type licence 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 applied correspondingly.

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 licences 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 demonstrating that fact.

Chapter three

(Amended, SG No 76/2012)

LICENCES AND PERMITS FOR ACTIVITIES WITH SOURCES OF IONISING RADIATION

Section I

General provisions

Article 73.

(1) Activities involving sources of ionising radiation shall be performed on the basis of the licences and permits provided for in Article 15, Paragraph 3, Subparagraphs 2-4 and Paragraph 4, Subparagraphs 9-11 and 13 of the ASUNE.

(2) No licences and permits for activities with sources of ionising radiation shall be required where on the basis of the criteria defined by the Regulation under Article 26, Paragraph 3 of the ASUNE it has been proved that the probability of occurrence of harmful health effects is negligible. Such activities are not subject to regulation under the ASUNE as the radiation risk is negligible.

(3) No licences and permits for activities with sources of ionising radiation shall also be required in the cases where it has been proven that the probability of occurrence of harmful health effects is insignificant, according to the criteria defined by the regulation under Article 26, Paragraph 3 of the ASUNE. Any such practices shall be subject to control under the ASUNE with the aim of ensuring compliance with the radiation protection requirements as the radiation risk is insignificant, but the exposure should not be neglected from radiation protection point of view.

(4) A list of the activities under Paragraph 3 is given in the Enclosure No. 2.

(5) No licences and permits for activities with sources of ionising radiation shall also be required in the cases where activities not included in the list under Paragraph 4 fulfil the criteria

stipulated in the Regulation under Article 26, Paragraph 3 of the ASUNE.

(6) For the activities covered under Paragraphs 3 and 5, a questionnaire in a form approved by the NRA Chairman shall be applied. The Chairman of the Agency shall express a written statement on the application within 30 days.

(7) Any application under Paragraphs 5 involving activities related to use of sources of ionising radiation for medical purposes shall be coordinated with the National Centre of Radiobiology and Radiation Protection.

(8) The activities under Paragraphs 3 and 5 shall be recorded into the register maintained according to the provisions of Article 111, Paragraph 1, Subparagraph 1 as activities subject to control.

Article 74.

A permit shall not be required for temporary storage of sources of ionising radiation if such activity has been included into the scope of a licence for use and manufacture of sources of ionising radiation.

Article 75.

(1) Any application for issuing a licence or permit authorising activities with sources of ionising radiation shall meet the requirements under Article 4, Paragraph 1.

(2) For issuing licences authorising activities with sources of ionising radiation, following documents demonstrating fulfilment of the requirements of Article 60 of the ASUNE shall be attached to the application under Paragraph 1:

1. documents related to the management and organisational structure;

2. written declaration or other documents confirming that the applicant possesses sufficient financial resources for performing the activity in a safe manner;

3. applicant's statement determining the personnel performing activities with sources of ionising radiation and specifying the persons in charge of the activities related to radiation protection;

4. indicating the sources of ionising radiation and the activities performed through their use, including the technical documentation (explanatory notes, sketches, schemes, images) and certificates for the respective sources of ionising radiation necessary for the radiation protection assessment;

5. assessments for the expected exposure doses of the personnel both under normal conditions and in case of accident;

6. description of the envisaged means for ensuring protection of every member of the personnel, as well as the devices and equipment used for the fulfilment of the work in a safe manner and protection of the personnel against ionising radiation;

7. instruction for ensuring radiation protection;

8. on-site emergency plan;

9. expert medical opinion, containing a conclusion about the suitability of the members of the personnel to be engaged in performing activities associated with ionising radiation, issued following the procedure stipulated in the regulation adopted under Article 65, Paragraph 1, Subparagraph 4 of the Health Act;

10. individual licences for employment in work with sources of ionising radiation issued according to the procedure stipulated in the regulation under Article 65, Paragraph 3 of the ASUNE;

11. internal rules and procedures defining the responsibilities and obligations for ensuring radiation protection, including work organisation;

12. programme for monitoring the radiation parameters of the working premises as well as for occupational exposure monitoring, including description of the technical devices in use;

13. document indicating the results of the metrological control of the technical devices used for monitoring the radiation parameters of the working premises;

14. document confirming that occupational exposure monitoring has been ensured according

to the requirements of Article 30 of the Regulation on Basic Norms of Radiation Protection;

15. questionnaire in a form approved by the NRA Chairman;

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

(3) In the cases where an entity with radioactive substances is involved, the following documents shall be also attached:

1. in the cases provided by the law – a document confirming that the physical protection of the entity with radioactive substances has been ensured, issued by the competent authorities of the Ministry of Interior.

2. assessment of the types and quantities of RAW expected to be generated for the licence or permit term of validity and the measures to be carried out for their safe storage and delivery for management to persons possessing licences issued under the procedure of Articles 53 and 54;

(4) Any new activity for which it has not been proven that the expected benefits of the activity outweighs the possible adverse effects on human health shall be grounded.

(5) If the applicant is a natural person to perform the activity personally, the documents under Paragraph 2, Subparagraphs 1 and 2 shall not be required.

Article 76.

(1) A licence for manufacturing and use of sources of ionising radiation in the respective facilities shall be issued on the condition that those facilities have been already commissioned.

(2) The applicant shall notify the NRA Chairman of the entity with sources of ionising radiation readiness for commissioning.

(3) The NRA Chairman shall appoint by an order a commission for performing an inspection to confirm correspondence with the stated data and circumstances and the readiness of the entity for commissioning. The composition of the commission and the time limit for performing the activity shall also be specified in the same order.

(4) Members of the commission under Article 3 shall be the NRA inspectors and representatives of the National Centre of Radiobiology and Radiation Protection, or of the respective Regional Health Inspection having a section related to radiation control. Representatives of other authorities exercising specialised control may also be included in the composition of the commission.

(5) The applicant under Paragraph 2 shall submit to the commission:

1. the documents under Article 75, Paragraphs 2 and 3;

2. register of the accounting and control of the respective sources of ionising radiation;

3. register of the initial and regular safety briefing of the personnel;

4. registers for monitoring of all radiation related parameters at the working premises as well as for occupational exposure monitoring, individual dosimetric cards and radiation passports for every member of the personnel;

5. documents containing the results of the initial testing of the systems and equipment;

6. documents certifying the entity commissioning according to the provisions of the Act on the Territorial Structure and the secondary legislation for its application if such activity is envisaged by the Act.

(6) The commission shall prepare a protocol of the inspection findings. The protocol shall be approved by the Chairman of the commission. After measurement of the radiation factors of the environment in running and shutdown state of the source of ionising radiation, the representative of the National Centre of Radiobiology and Radiation Protection, or of the respective Regional Health Inspection under Paragraph 4, shall give a statement on the readiness of the facility for commissioning and for the correspondence with the radiation protection requirements. The statement shall be an integral part of the commission's protocol.

(7) The protocol under Paragraph 6 shall be served to the applicant or to authorised representative within 5 days after the end of the inspection. The causes that have led to the remarks, included in the protocol under Paragraph 2, shall be eliminated within a time limit indicated at the protocol. The applicant shall notify in writing the NRA and the National Centre of Radiobiology and

Radiation Protection, or of the respective Regional Health Inspection having a section related to radiation control, about the measures taken to eliminate the remarks of the commission.

(8) The positive conclusion of the commission, included in the protocol under Paragraph 6, serve as a basis for issuing the licences under Paragraph 1.

Article 77.

The provision under article 76 shall not be applied for:

1. sealed radioactive sources installed in process monitoring devices, excluding those representing neutron sources;

2. devices containing open sources designed for activities covered by class III according to the Regulation on Radiation Protection during Activities with Sources of Ionising Radiation (Promulgated, SG, No. 74/2004, amended and supplemented SG No. 74/2006, amended SG No. 46/2007, SG No. 5/2010 and SG No. 7/2011);

3. portable x-ray equipment designed for industrial use.

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

Article 78.

(1) For issuing permits authorising activities associated with construction of an entity with a source of ionising radiation, assembly and initial testing the following documents shall be attached:

1. the documents under Article 75, Paragraph 2, Subparagraphs 3, 9, 10 and 14 if necessary;

2. technical design and radiation protection measures concerning the respective entity;

3. documents expressing statements of the respective competent authority of the Ministry of Health confirming the correspondence of the site and the technical design whit the statutory requirements connected with ensuring public health;

4. document demonstrating the ownership or the right of use of the applicant over the site, respectively, a document certifying the consent of the site proprietor or property rights holder for performing the construction and assembly activities by the applicant;

5. documents related to the organisation of the activities executed by contractors hired for performing assembly works and initial testing of the sources of ionising radiation. The contractors must obtain a licence, issued under Article 15, Paragraph 3, Subparagraph 4 of the ASUNE.

(2) The applicant should hire contractors to perform construction of an entity with sources of ionising radiation, assembly works and initial testing on the condition that those contractors obtain licences for handling of sources of ionising radiation, issued under Article 15, Paragraph 3, Subparagraph 4 of the ASUNE. The documents under Article 75, Paragraph 2, Subparagraphs 3, 9, 10 and 14 shall not be required in such cases.

Section III

Permit for decommissioning of an entity with radioactive substances

Article 79.

(1) The following documents shall be attached to the application for issuing permits authorising activities associated with decommissioning of an entity with open sources and sealed sources category 1:

1. the documents under Article 75, Paragraph 2, Subparagraphs 3, 9, 10 and 14;

2. decommissioning plan, approved by the applicant, which shall include:

a) description of all the stages and the respective activities related to decommissioning;

b) assessment of the nature of each exposure and the probability of its occurrence, radiation protection measures connected with the separate decommissioning stages, including decontamination methods and means, measures for ensuring safety during dismantling of radioactive sources and in case of performing activities with components and materials containing radioactive substances;

c) inventory of the sealed and open sources, other radioactive substances, and RAW;

d) assessment of the expected amounts of RAW to be generated during dismantling, information about the radionuclide composition and activity;

3. documents related to the investigation of the radiation condition of the entity (land and corresponding buildings, premises, technological facilities, systems and equipment used for handling of radioactive substances);

4. description of the provided measures for safe storage of RAW under Article 16, Subparagraph 7 of the ASUNE.

Article 80.

(1) Issuing of a decommissioning permit shall not be required for any equipment containing sealed sources, category 2 – 5.

(2) For the cases covered under Paragraph 1, a document confirming the delivery of the sealed sources to the Radioactive Waste State-Owned Company shall be required.

Article 81.

(1) A permit for decommissioning of an entity with radioactive substances shall be issued to persons entitled to use and store the respective radioactive substances, to their successors, or to persons authorised to perform such activities by virtue of a statutory instrument.

(2) The applicant should hire contractors for performing decommissioning activities on the condition that those contractors obtain a licence for handling of sources of ionising radiation, issued under Article 15, Paragraph 3, Subparagraph 4 of the ASUNE.

(3) For the cases covered under Paragraph 2, the documents under Article 75, Paragraph 2, Subparagraphs 3, 9, 10 and 14 shall not be required.

Article 82.

The NRA Chairman shall notify the state bodies exercising health control for the completion of decommissioning work.

Section IV

Permit for temporary storage of radioactive substances

Article 83.

(1) The documents under Article 75, Paragraph 2, Subparagraphs 2, 3, 8, 9, 10, 12, 14, and a questionnaire in a form approved by the NRA Chairman shall be attached to the application for issuing permits authorising activities associated with temporary storage of radioactive substances. The questionnaire shall contain the following information:

1. inventory of the stored radioactive substances (sealed and open sources, other radioactive materials and RAW) as well as information concerning the nuclear waste packages, technical characteristics, quantity and activity, including information on the expected dose rate inside the facility and on its external surface;

2. scheme for facility location and for the position of the radioactive substances inside the facility.

(2) In the cases provided by the law, the questionnaire under Paragraph 1 shall be coordinated with the competent authorities of the Ministry of Interior in terms of physical protection.

Section V

Permit for import or export of sources of ionising radiation

Article 84.

(1) The following documents shall be attached to the application for issuing permits authorising activities associated with export or import of sources of ionising radiation, respectively to or from Non-Member-State:

1. documents containing identification data related to the consignee of the imported or exported sources of ionising radiation;

2. inventory and identification data of the imported or exported sources of ionising radiation (type, model, manufacturer, manufacturing serial number, total number, radionuclide activities and other technical characteristics for the respective type source of ionising radiation), including data for the packages of the radioactive sources during transportation;

3. filled in and signed by the applicant documents authorising the import or export of goods, required by the customs offices according to the common procedure for registration and permitting of foreign trade transactions, including documents certifying the correctness of data introduced into the import/export certificates;

4. documents certifying the compliance with certain standards related to import/export of sources of ionising radiation (technical documentation for the respective type of source of ionising radiation, certificates, photographs, schemes);

5. document certifying that the transport is performed by a holder of a permit or licence for transport of radioactive substances, issued under the procedure stipulated in Chapter Four, Section III.

(2) Together with the documents under Paragraph 1, the following documents shall also be attached to the application for issuing a permit for import or radioactive sources:

1. documents certifying that the person entitled to receive the respective commodities is a holder of a licence for use of sources of ionising radiation, or has ensured their safe storage;

2. documents certifying ensured return of imported sealed sources, category 1, 2 or 3, having radioactive half-life exceeding five years, to the manufacturer according to § 1, Subparagraph 9 of the Supplementary provisions of the ASUNE, after the termination of the utilisation.

(3) In the case of export of sources of ionising radiation, a document issued by the competent body of the state of the importer registration, certifying authorisation for performing the respective activity, shall also be attached to the application.

Article 85.

In the cases of shipment of sources of ionising radiation from or into a Member State of the European Union, respectively, the issuance of a permit under Article 15, Paragraph 4, Subparagraph 13 and Article 59 of the ASUNE shall not be required. In such cases the persons to perform the shipment shall:

1. ensure the transport of the radioactive sources to be performed by a holder of a permit or licence for transport of radioactive substances issued under the procedure of Chapter Four, Section III;

2. notify in writing the NRA Chairman immediately after the delivery of the consignment to the persons entitled to receive it;

3. in the case of import of sealed sources, to submit for confirmation by the NRA a declaration, filled in according to the form stipulated under Article 4 and Annex I to the Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between

Member States.

4. in the case of export of sealed sources, to submit to the NRA a declaration, confirmed by the competent authority of the respective state and filled in according to the form stipulated under Article 4 and Annex I to the Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

5. in the case of import of sealed sources, category 1, 2 or 3 having radioactive half-life exceeding five years, to notify in writing the NRA Chairman and to submit documents certifying ensured return of imported sealed sources to the manufacturer after the termination of the utilisation.

Section VI

Licence for use, manufacturing or handling of sources of ionising radiation

Article 86.

(1) The documents under Article 75 along with documents which confirm the availability of support technical services and maintenance for the technical devices in use shall be attached to the application for issuing licences authorising activities associated with use of sources of ionising radiation for industrial, scientific or process control purposes.

(2) The application for granting a licence for medical use of sources of ionising radiation shall be accompanied by the documents under Article 75 and a description of the envisaged means for radiation protection of every member of the personnel in case of medical exposure as well as by documents confirming the fulfilment the legal requirements in respect of health protection.

(3) As long as such a provision has been envisaged in the licence conditions, the licence for use of sources of ionising radiation shall give the licensee the right to perform maintenance, assembly, dismantling, measurement and repair work on the respective sources of ionising radiation.

Article 87.

(1) Any licence for use of sources of ionising radiation for medical purposes shall be issued after official agreement with the Minister of Health through the National Centre for Radiobiology and Radiation Protection.

(2) The official agreement under Paragraph 1 shall also be part of the procedure in case of amendment or renewal of any licence for use of sources of ionising radiation for medical purposes, which is connected with the commissioning of new sources of ionising radiation or with introducing changes in the construction and the position of the respective sources inside the facility.

(3) Within the coordination process under Paragraphs 1 and 2, the NRA Chairman shall send the questionnaire under Article 75, Paragraph 2, Subparagraph 15, the documents under Article 86, Paragraph 2, and an inventory of the documents submitted by the applicant, to the National Centre for Radiobiology and Radiation Protection.

(4) The National Centre for Radiobiology and Radiation Protection shall issue a agreement document (consent), or a justified denial. The agreement or the justified denial shall be sent to the NRA Chairman and to the applicant within 10 days after the receipt of the documents under Paragraph 3.

Article 88.

(1) In the case of adding new sources of ionising radiation or performing changes in the construction and the position of the existing sources in the entity, a new licence shall be issued or already issued licence for use of sources of ionising radiation shall be amended.

(2) In the cases under Paragraph 1, where a change of the design is envisaged, the amendment of the licence for use of sources of ionising radiation shall be performed after receiving a permit for construction, assembly and commissioning under Article 76 if the introducing of the changes require

reconsidering of the radiation protection measures.

Article 89.

The documents under Article 75 shall be also attached to the application for issuing a licence for manufacturing of sources of ionising radiation.

Article 90.

The documents under Article 75, Paragraph 2, Subparagraphs 1-4, 6, 7, 9-16 shall be also attached to the application for issuing a licence for handling of sources of ionising radiation for the purpose of maintenance, assembly, dismantling, measurement, construction, repair work and services.

Articles 91 - 98 (Repealed, SG No 76/2012).

Chapter four

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

Section I

General provisions

Article 99.

(1) The licences 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) (Repealed, SG No 76/2012);

(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 licence and/or permit issued under this Regulation procedure;

2. they are mounted in a 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.

(4) (New, SG No 76/2012) Transboundary shipments of spent nuclear fuel or radioactive waste shall be performed on the basis of a licence or permit issued under Paragraph 1 and a document confirming the transboundary shipment according to § 1b of the Supplementary provisions of the ASUNE if the Republic of Bulgaria is:

1. State of origin – in the case of shipment between Member States and in the case of export to countries outside the European Union;

2. State of destination – in the case of implementing import within the European Union;

3. the first Member State to receive the consignment - in the case of transit within the

European Union territory.

(5) (New, SG No 76/2012) The applicant for issuing a document confirming the transboundary shipment shall be:

1. the consignor – for the cases covered by Paragraph 4, Subparagraph 1;

2. the consignee - for the cases covered by Paragraph 4, Subparagraph 2;

3. the person to take the responsibility for undertaking the shipment within state territory - for the cases covered by Paragraph 4, Subparagraph 3.

(6) (New, SG No 76/2012) The application under Paragraph 4 shall be filled in according to a standard form approved by an order of the NRA Chairman, according to § 1b of the Supplementary provisions of the ASUNE.

(7) (New, SG No 76/2012) A document confirming the transboundary shipment under Paragraph 4 shall not be required:

1. if the activity and the specific activity of the consignment does not exceed the clearance levels stipulated by the regulation under Article 26, Paragraph 3 of the ASUNE;

2. in the case of shipment of used sealed radioactive sources to their supplier, manufacturer, or to any licensed facility for RAW management;

3. in the case of shipment of radioactive materials generated as a result of spent fuel treatment and intended for further use;

4. in the case of shipment of RAW containing only natural radionuclides.

Article 100.

The application for issuing a licence 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. (Amended, SG No 76/2012) a copy of the document confirming the business registration of the applicant – legal person or sole trader;

2. (Amended, SG No 76/2012) a certificate confirming that the applicant – trader is not subject to bankruptcy proceedings;

3. (Amended, SG No 76/2012) document declaring lack of previous convictions for crimes of general nature - for the members of the management and supervisory bodies of the applicant - legal person or sole trader, or natural person – applicant;

4. (Amended, SG No 76/2012) a documents confirming that the applicant possesses sufficient financial, technical and material resources for performing the activity in conformity with nuclear safety and radiation protection requirements, standards and rules;

5. (Repealed, SG No 76/2012);

6. (Repealed, SG No 76/2012);

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 licence, 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 contractors 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 demonstrating that the chosen conveyances correspond to the transport safety standards and to the safety standards for protection against ionising radiation;

8. documents demonstrating 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 licences 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 demonstrating 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 programme;

15. emergency plan;

16. document confirming that the physical protection is ensured, coordinated 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. (Amended, SG No 76/2012) document describing the management system for the activity through a range of processes and actions, including built up organisational structure, measures for exercising control, and the mechanism to undertake corrective actions.

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

Licence for transport of radioactive substances other than nuclear material
(Title supplemented, SG No 76/2012)

Article 102.

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

1. (Amended, SG No 76/2012) a questionnaire in a form approved by the NRA Chairman containing information about:

a) 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.);

b) transport packages – type, category, transport index;

c) the maximal stated and maximal admissible total transport index for any conveyance;

d) the chosen transport mode - 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 authorised by the carrier;

e) transportation safety consultants, members of the personnel responsible for notifying the NRA and dosimetrists;

f) performed individual monitoring and dose rate monitoring, the monitoring devices in use;

2. (Amended, SG No 76/2012) documents regulating the relations between the applicant and the contractors to participate in the shipment;

3. documents confirming the correspondence of any conveyance with the requirements and norms for safe shipment and radiation protection;

4. (Amended, SG No 76/2012) document, adopted by the management body of the applicant, defining:

a) transportation safety consultants, members of the personnel responsible for notifying the NRA and dosimetrists;

b) the persons in charge of the transportation activities;

c) the vehicle drivers engaged in road transport;

5. (Amended, SG No 76/2012) health certificate of compliance with the medical requirements - for every member of the personnel;

6. (Amended, SG No 76/2012) individual licences issued according to the procedure under Article 65, Paragraph 3 of the ASUNE and according to the ratified by the Republic of Bulgaria international agreements for shipment of dangerous goods;

7. (Amended, SG No 76/2012) documents to confirm conducting individual dosimetric control over the members of personnel;

8. (Amended, SG No 76/2012) radiation protection instruction, emergency plan related to the shipment, and radiation monitoring programme;

9. (Amended, SG No 76/2012) internal rules and procedures determining the responsibilities and the obligations in the case of periodic testing and maintenance of the transport packages, preparation of the radioactive material shipment, transport documentation, shipment operations, and the storage in transit;

10. (Amended, SG No 76/2012) 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.

11. (Repealed, SG No 76/2012);

12. (Repealed, SG No 76/2012).

Section IV

Permit for single transport of radioactive substances

Article 103.

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

1. (Amended, SG No 76/2012) documents containing information on:

a) the permit, licence or other administrative act authorising the consignee to store or use radioactive substances;

b) the expected date of departure and arrival of the shipment, the departure point, the transport route within the state, including the scheduled transit stops and radioactive substances delivery point;

c) the state of origin of the consignment, the state of destination and the states of transit.

2. (Amended, SG No 76/2012) documents regulating the relations between the consignor and consignee and between the applicant and the contractors to participate in the shipment;

3. (Amended, SG No 76/2012) the administrative acts, issued by the respective competent authorities, for approval of the transport packages and other structures according to the requirements of the regulation under Article 26, Paragraph 4 of the ASUNE;

4. (Amended, SG No 76/2012) transport permits or corresponding administrative acts, issued by the competent authorities of the state of destination and the states of transit after departure from Bulgarian territory – in the case of export or transit of radioactive materials;

5. (Repealed, SG No 76/2012);

(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, coordinated 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;

3. (New, SG No 76/2012) document certifying that the consignor/consignee is authorised to perform activities with goods and technologies determined to be of potential "dual-use" according to the Defence related products and Dual-Use Items and Technologies Export Control Act.

Section V

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

Article 104.

(1) (Supplemented, SG No 76/2012) 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 other than nuclear material. The following documents shall also be attached:

1. document containing information on:

a) (Repealed, SG No 76/2012);

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. (Amended, SG No 76/2012) 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 Defence related Products and Dual-Use Items and Technologies Export Control Act;

3. document confirming that the physical protection is ensured, coordinated 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) (Amended, SG No 76/2012) The documents under Article 101 shall be attached to the application for issuing a permit for transit of nuclear material or spent fuel along with a document giving information on:

1. the state of origin, the state of destination and the states of transit shipment;

2. the border crossing points to be used for entry and exit from the state and the expected dates of crossing them;

Chapter Five

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

Article 105.

(1) The NRA Chairman shall exercise regulatory control over the fulfilment of the conditions of the issued licences 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 subsequent 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 specialised 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, intervals, method for performing the inspections, procedure for objectifying the inspection results, coordination, and other measures ensuring that the inspections are conducted by lawful means and in an adequate manner.

Article 108.

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

Article 109.

(1) The inspectors shall present the results of their inspections in a statement of findings , attaching the evidence collected, the explanations and the measurement and/or test results.

(2) (Amended, SG No 76/2012) Any statement of findings shall be served to the inspected person.

(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 of administrative offence;

3. propose to the NRA Chairman imposition of administrative enforcement measures.

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

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

Article 110. (Repealed, SG No 76/2012).

Chapter Six

REGISTERS

Article 111.

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

1. (Supplemented, SG No 76/2012) licences and permits as well as their amendment, renewal, suspension and revocation including the entities subject to control under Article 73, Paragraphs 3 and 5;

2. individual licences for employment at nuclear facilities or with sources of ionising radiation.

(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 licence 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 licence, permit or individual licence, 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 licence 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 licences, permits and individual licences shall be kept in a separate archive.

SUPPLEMENTARY PROVISIONS

§ 1. Within the meaning of this Act:

1. "applicant" means any 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 licence 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. (Repealed, SG No 76/2012);

3. (Repealed, SG No 76/2012);

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

5. "permit holder" means any 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 over pack;

8. (Repealed, SG No 76/2012);

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, form 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);

13a. (New, SG No 76/2012) "management system for the activity" means a set of interrelated elements for establishing policies and objectives of the organisation and enabling the objectives to be achieved in an efficient and effective manner. The component parts of the management system include: structure, resources (personnel, equipment, financial resources); processes (working practices); organisational culture. The management system integrates all safety requirements taking into consideration their relation with all other requirements associated with health, environment, security, quality and economy in such a way to guarantee observance of the principle of priority of safety, including through giving possibility for maintenance and development of safety culture.

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 licence and/or permit under this Regulation procedure may ask the NRA Chairman beforehand to express a statement on certain procedural issues.

(2) (Repealed, SG No 76/2012).

§ 3. In the cases under Articles 17 and 18, an original document of the licence or permit where the amendments are incorporated into the initial contents may be served to the licensee or permit holder. In this case the licence 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 licence issued for nuclear facility operation.

§ 5. (Repealed, SG No 76/2012).

§ 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

(Connected with the promulgation of the Regulation, SG No. 41/2004)

§ 8. Where this Regulation provides for application of statutory instruments 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 licence 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 sources of ionising radiation 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 sources of ionising radiation 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 licence 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 licence 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.

TRANSITIONAL AND FINAL PROVISIONS

(Connected with the amendment of the Regulation by SG № 76/2012)

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§ 3. (1) Any initiated but not finalised proceedings related to issuing licences and permits for activities included into the scope of Enclosure 2 to Article 73, Paragraph 4 of the Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy shall be terminated.

(2) The termination of the proceedings under Paragraph 1 shall be done by the NRA Chairman

on the basis of an application filed under Article 73, Paragraph 6.

§ 4. (1) Any issued and entered into force licences and permits for activities included into the scope of Enclosure 2 to Article 73, Paragraph 4 of the Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy shall be terminated.

(2) The termination of the licences and permits under Paragraph 1 shall be done by the NRA Chairman order on the basis of an application filed under Article 73, Paragraph 6.

ENCLOSURE № 1
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 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 on the environment and the population;
3.6. Programmes 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 fundaments;
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, localisation, 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, and 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. Programme 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 ensuring and maintaining safety culture;
9.6. Operational experience feedback system;
9.7. Management of the equipment ageing;
9.8. Physical protection;
9.9. (Supplemented, SG No 76/2012) Emergency planning and preparedness for response in case of accident, including interrelation and coordination with the respective bodies of executive power to undertake actions in case of accident.

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 authorised 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.

ENCLOSURE № 2
to Article 73, Paragraph 4

(New, SG No 76/2012)

A list of the activities with sources of ionising radiation not subject to authorisation regime but subject to control under the ASUNE with the aim of ensuring compliance with the radiation protection requirements

1. Use of dental x-ray devices for sectional radiography.
2. Use of osteo-densitometers in diagnosing limb-bone density.
3. Use of x-ray devices for element and micro-structural analysis of materials:
3.1. x-ray analysers for chemical analysis;
3.2. devises for x-ray fluorescence and x-ray structural analysis.
4. Use of x-ray devices for control of hand baggage and packages.
5. Use of gas chromatographs and electron microscopes.
6. Use of sealed sources, category 5.