

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

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Chapter One GENERAL RULES FOR REGISTRATION AND ISSUING LICENCES AND PERMITS

(title amended, SG No. 37/ 2018)

Section I General provisions

Article 1. This Regulation establishes the procedure for:

1. issuing licences and permits to natural and legal persons for activities regulated under the Act on the Safe Use of Nuclear Energy (ASUNE);
2. amendment, renewal, suspension and revocation of issued licences and permits;
3. exercising control for compliance with the conditions set out in the licences and permits;
4. (Amended and supplemented, SG No. 37/2018, amended, SG No. 53/2019) maintaining the public registers under Article 27, Paragraph 1 and 2 of the ASUNE;
5. (New, SG No. 37/2018) registration of activities under the ASUNE as well as issuing, termination and revocation of registration certificates;
6. (New, SG No. 37/2018) notification for activities under the ASUNE.
7. (New, SG No. 36/2025) issuing an order for approval of the selected site and an order for approval of the prepared technical design of a nuclear facility under Article 33, Paragraph 4 of the ASUNE, as well as an order for approval of the results of a periodic safety review under Article 37c, Paragraph 2 of the ASUNE.

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. (Amended, SG No. 37/2018, No. 36/2025) The Chairperson of the Nuclear Regulatory Agency (NRA) shall issue a licence, permit or order, as well as perform registration for activities carried out under the ASUNE, when the following general requirements are met:

1. the applicant has submitted all necessary documents and provided the requested additional information and documents;
2. the applicant has fulfilled the conditions of the previous licences, permits and other authorisations issued according to the ASUNE, connected with ensuring the safety in carrying out the activity;
3. the review and assessment of the documents submitted by the applicant confirm compliance with the requirements under the ASUNE, this Regulation as well as other applicable regulations adopted to implement the ASUNE.
4. the applicant holds the necessary licences, permits and other authorisations which are also required under the ASUNE for the respective activity.

(2) (Amended, SG No. 36/2025) Paragraph 1 shall be applied correspondingly to the amendment and renewal of licences, permits or orders.

Section II

Licences and permits issuance procedure

Article 4. (1) (Supplemented, SG No. 4/2016, Amended SG No. 36/2025) In order to obtain a licence, permit or order, the applicant shall submit to the NRA Chairperson a written application, on paper or electronically in accordance with the procedure set out in Article 20 of the Electronic Government Act, which shall contain:

1. the applicant's identification data;
2. (Amended, SG No. 36/2025) the type of the licence, permit or order required and general description of the activity to be performed;
3. the period of time for which the licence or permit is required;
4. (Amended, SG No. 36/2025) general description of the main characteristics of the facility or entity where the activity will be carried out and its location, if operation of such a facility or entity is foreseen;
5. information on the authorisations issued by other state authorities, related to declared activity;
6. list of the documents attached to the application.

(2) The application shall be signed:

1. by the applicant if the applicant is acting in person;
2. (Amended and supplemented, SG No. 4/2016) by the person(s) appointed to represent the applicant if the applicant is a legal entity (company).

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

(4) (New, SG No. 4/2016, amended SG No. 36/2025) Where the application is submitted electronically, it shall be signed by qualified electronic signature, except in the cases under Article 22, Paragraph 6 of the Electronic Government Act.

Article 5. (1) (Amended, SG No. 36/2025) Depending on the type of activity carried out, all documents corresponding to the activity carried out under chapters Two, Three and Four of the regulation, as well as a payment document of the application review fee, if such a fee is due, shall be attached to the application. When the fee is paid electronically, no document is required to be submitted.

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

(3) (Amended, SG No. 36/2025) Official documents issued by another country and drawn up in a foreign language must be accompanied by a translation into Bulgarian, carried out in accordance with the Rules for Legalizations, Certifications and Translations of Documents and Other Papers (promulgated, SG, No. 73/1958), and must bear the relevant requisites in accordance with the bilateral agreements or be certified with an apostille, respectively legalized in accordance with the procedure provided for in the same rules. Other documents presented in a foreign language must be accompanied by a translation into Bulgarian, carried out in accordance with the procedure provided for in the same Rules.

(4) (Amended, SG No. 4/2016) The documents required by this Regulation shall be attached in original, or as certified copies, on paper and in electronic form. Where the application is submitted electronically, the documents shall be attached as scanned copies.

(5) (Repealed, SG No. 4/2016)

(6) Documents required according to this Regulation, which are already attached to previous applications, on the basis of which a licence or permit has been issued, need not be

attached again if the 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) (Amended, SG No. 4/2016) The applicant is not required to prove facts which are established by documentary evidence and confirmed by other competent authority, by persons carrying out public duties, or by organisations providing public services in the Republic of Bulgaria, notwithstanding if the data is kept in electronic form or on paper.

Article 6. (1) (Amended, SG No. 36/2025) The application and the attached documentation shall be reviewed for formal compliance with the established requirements within 14 days after the registration at the NRA. In case of an application for a licence, permit or order 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 Article 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) (Amended, SG No. 36/2025) Should the applicant fail to eliminate the deficiencies within the time limit under Paragraph 2, the NRA Chairperson shall refuse to issue the licence, permit or order stating the reasons for this decision.

(4) (New, SG No. 37/2018) A written statement objectifying the results of the review for formal compliance under Paragraph 1 is not required if no deficiencies have been found (tacit approval).

Article 7. (1) The NRA Chairperson shall have the discretion to check the declared data and circumstances ex officio and the respective competent governmental and municipal authorities, as well as the applicants, shall be obliged to provide necessary assistance.

(2) (Amended, SG No. 36/2025) In order to take a decision on the issuance of the license, permit or order, the NRA Chairperson may request the opinion of the competent governmental and municipal authorities.

Article 8. (1) (Amended, SG No. 4/2016, No. 37/2018) In order to verify the compliance with the requirements under Article 3, the NRA Chairperson shall assign the NRA units to perform a review and assessment of the application and the attached documents as well as an assessment of the circumstances of the case, including through on-site inspections.

(1) (Amended, SG No. 36/2025) In connection with the issuance of licenses, permits and orders, the NRA Chairperson may assign the Advisory Council on Nuclear Safety and the Advisory Council on Radiation Protection to provide opinions on the scientific aspects of nuclear safety and radiation protection.

(3) Where appropriate, the NRA Chairperson may assign external organisations or specialists to carry out research, studies and expertise connected with nuclear safety and radiation protection.

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

(5) (Amended, SG No. 36/2025) The time limit for the issuance of the respective licence, permit or order shall start to run from the receipt of the application under Article 4, Paragraph 1, respectively from the implementation of the instructions under Article 6, Paragraph 2 and 4 of this Article.

(6) (New, SG No. 4/2016, Amended, SG No. 36/2025) In cases other than those provided

for in Paragraph 5, connected with ex-officio collection of documentary evidence produced by another administrative authority, the time limit for issuance of a licence, permit or order shall start to run from the receipt of the relevant documents by the NRA.

Article 9. (1) (Amended, SG No. 36/2025) The NRA Chairperson shall issue the license, permit or order, if the requirements of Article 3 are met, or shall deny to issue the requested license, permit or order, stating the reasons for this decision.

(2) Upon issuing a permit which implies a consequential amendment to the licence conditions, the NRA Chairperson shall have the discretion to make the amendment to the licence ex officio following the procedure under Section IV of this Chapter.

(3) (Amended, SG No. 36/2025) The licences, permits and the reasoned denial referred to in Paragraph 1 shall be issued within the time limits specified in Article 18, Paragraph 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, Supplemented, SG No. 36/2025) Licences shall be issued for a term of validity not exceeding ten years, except in the cases of licences under Article 20, Paragraph 4 of the ASUNE which are not limited by time.

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

Article 11. (1) (Amended, SG No. 36/2025) The issued licenses, permits and orders, as well as the reasoned denial to issue a license, permit or order shall be delivered to the applicant, to his legal or explicitly authorized representative or shall be sent by post with registered letter with acknowledgment of receipt, in which the type and registration number of the issued document shall be indicated.

(2) (New, SG No. 4/2016) In case of an explicit request on behalf of the applicant, expressed by the application, the respective document may be sent at the indicated address through a licenced post operator or electronically, on the condition that there are technical, programme, and technological means for this.

(3) (Former 2, supplemented, SG No. 4/2016) The licences and permits shall be served or sent to the applicant following the procedure under Paragraph 1 and 2 after submission of a document demonstrating proof of payment of the initial licencing 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 Regulatory Agency under the ASUNE, approved by the Council of Ministers Decree No. 206/2003 (SG No. 85/2003).

(4) (Former 3, SG No. 4/2016) 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. A fee shall not be charged for:

1. (Supplemented, SG No. 36/2025) ex officio amendment of the respective licence by a permit issued under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE, of an order under Article 37c, Paragraph 2 of ASUNE, as well as on the basis of a statutory instrument or a decision of the Council of Ministers;

2. (Supplemented, SG No. 76/2012) licences and permits amendment in order to be brought in line with the conditions specified in the same or another licence or permit issued by the NRA Chairperson to the same applicant, or connected with the fulfilment of the instructions given in the course of the implementation of the control and supervision under Chapter Five of the ASUNE, as well as in case of undertaking organisational changes based on updated legislation or a decision of the Council of Ministers.

Section III

Licences and permits scope and contents

Article 12. (1) The NRA Chairperson shall issue a licence or a permit for carrying out the activities provided for in Article 15, Paragraph 3 and 4 of the ASUNE.

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

(3) (Amended, SG No. 76/2012) The permits under Paragraph 2 and the orders for the approval of the selected site and the technical design may be issued in stages - for clearly defined part of the activity if such necessity has been substantiated by the application for a permit or order.

(4) (Supplemented, SG No. 36/2025) In cases where one person carries out activities in several sites with sources of ionizing radiation (SIR), for which issuance of the same type of licences and permits is envisaged, a general license or permit may be issued for these activities.

(5) (Amended, SG No. 76/2012) For one and the same nuclear facility, a succeeding permit under Article 33, Paragraph 1 or a licence under Article 35, Paragraph 1 of the ASUNE shall be issued to the legal entity, which is a holder of preceding permit or licence, to the successor in case of performed transformation, as well as to the legal entity having a real right over the assets used to perform the activity. This provision shall be also applied where the procedure for issuing the permit or licence has been initiated by the holder of the preceding permit or licence if the latter has given prior consent in writing.

(6) (New, SG No. 76/2012) In 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, No. 4/2016) relevant identification data about the licensee or permit holder, observing the requirements of the Personal Data Protection Act;
6. the activity for which the licence or permit is issued;
7. (Supplemented, SG No. 36/2025) the facility or entity for which the licence or permit is issued, if operation of such a facility or 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 comprise:

1. detailed description of the activities for which the licence or permit is issued;
2. (Supplemented, SG No. 36/2025) detailed description of the facility or entity for which the license or permit is issued, if operation of such a facility or entity is foreseen;
3. basic requirements for carrying out the activity;
4. obligations related to maintaining financial and material resources;
5. requirements related to the personnel;
6. requirements related to the provision of the radiation protection;
7. (Amended, SG No. 76/2012) requirements related to the management system for the activity;

8. requirements related to emergency preparedness and response;
9. obligations related to notification in case of deviations from normal operation, incidents and 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 the provision of the physical protection;
14. obligations related to provision of information on the fulfilment of the licence or permit conditions;
15. obligations related to the control exercised to verify the compliance with the respective requirements;
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 carried out by contractors, as well as requirements connected with the possibility for exercising control over the fulfilment of these activities;
2. requirements related to document retention and management;
3. requirements related to periodical submission of information regarding the fulfilment of the licence or permit conditions;
4. requirements related to subsequent stages of the activity, where the permit has been issued for a separate stage of the activity;
5. requirements related to the fulfilment of the obligations under Article 16 of the ASUNE;
6. requirements related to public order and national security;
7. other conditions related to the commencement of the activity and its implementation.

(4) The licences and permits may also contain appendices.

(5) A list of the internal rules for carrying out the activity, including procedures, instructions, programmes, technical specifications, etc., whose substantial modification may have an impact on nuclear safety, radiation protection, physical protection, or emergency preparedness and for this reason have to be performed on the basis of a permit issued under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE shall be attached as an appendix to a licence for operation of a nuclear facility.

(6) Before modifying a document covered by an appendix under Paragraph 5, the licensee shall notify the NRA Chairperson for the envisaged modification. The NRA Chairperson may, within 30 days of receipt of the notification, deliver a formal response on the need for performing the modification on the basis of a permit, issued under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE. The absence of such a response within this time frame shall be considered to be a tacit consent for undertaking the modifications.

Article 13a. (New, SG No. 36/2025) The licenses, permits and orders issued under the ASUNE and this Regulation do not affect the acquisition and exercise of the right of ownership and the powers arising from this right with respect to the designated sites for location of nuclear facilities, as well as the sites designated for the use of SIR, as well as with respect to the facilities and entities themselves.

Article 14. (1) (Supplemented, SG No. 76/2012) Where there are grounds for introducing amendments of the licence or permit covered by Article 21, Paragraph 1 and Article 21a of the

ASUNE, the licensee or permit holder shall notify the NRA Chairperson within one month of the occurrence of such grounds and shall request the respective amendment.

(2) (Amended, SG No. 76/2012) A trading company - holder of a permit under Article 33, Paragraph 1 of the ASUNE or of a licence under Article 35, Paragraph 1 of the ASUNE, intending to perform a transformation through merging, consolidation, splitting, spinning off, spinning off of a sole-owner 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 Chairperson in advance and shall submit an assessment of the impact of these actions on nuclear safety and radiation protection in view of subsequent application of Article 21, Paragraph 1 or Article 21a of the ASUNE.

(3) In the cases under Paragraph 2, the NRA Chairperson shall, within 30 days after the notification, deliver a formal response on the existence of circumstances having substantial impact 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 Chairperson of any changes in the declared data and circumstances within 7-days after their occurrence, except where such changes serve as a basis for the issuance of a permit for modifications or for the amendment of issued licence or permit.

Article 15. (Amended, SG No. 36/2025) The licenses, permits and orders issued pursuant to this Regulation shall enter into force after the issuance of all licenses, permits or other administrative enactments required by law for the performance of the relevant activity.

Section IV

Amendment of licences and permits

Article 16. (1) The NRA Chairperson shall have the discretion to amend a licence or permit upon request or ex officio.

(2) The requirements regarding the amendment of licences and permits shall also apply in case of the supplement of these documents.

Article 17. (Amended, SG No. 76/2012) (1) A licence or permit shall be amended ex officio by the NRA Chairperson in the cases covered by Article 21, Paragraph 4 of the ASUNE.

(2) (Supplemented, SG No. 36/2025) Outside the cases referred to in Paragraph 1, an operating licence for a nuclear facility shall be amended ex officio if the issuance of a permit under Article 15, Paragraph 4, Subparagraph 5 of the ASUNE implies a consequential amendment to the licence conditions, as well as when the provision of Article 37c, Paragraph 6 of the ASUNE is applied.

(3) (Amended, SG No. 36/2025) In the cases under Article 21, Paragraph 3 of the ASUNE, the NRA Chairperson shall notify in writing the licensee or permit holder of the opening of the ex officio amendment procedure. In this case the licensee or permit holder is entitled to give an explanation about the grounds for the amendment of the licence or permit within 14-days.

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

(5) In the cases covered by Paragraph 2, the licence shall be amended through a 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 obligatory indicate the conditions of the licence, which are subject to amendment and their new content.

(5) (Amended and supplemented, SG No. 36/2025) In the cases under Paragraph 2, the licence shall be amended by the permit under Article 15, Paragraph 4, Subparagraph 5 or by the order under Article 37c, Paragraph 2 of the ASUNE, bringing it into compliance with the conditions provided for therein. The permit or order shall obligatory indicate the conditions of the licence, which are subject to amendment and their updated content.

(6) (Amended, SG No. 36/2025) In case of unconformity between the conditions of the permit issued under Paragraph 2 or of the order under Article 37c, Paragraph 2 of the ASUNE and the licence conditions as amended, the content of the permit, respectively of the order, shall have priority.

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 Chairperson.

(2) (Supplemented, SG No. 4/2016, amended SG No. 36/2025) The licensee or permit holder shall be obligated to request the amendment within one month following occurrence of any circumstance necessitating the amendment by an application submitted on paper or electronically according to the requirements of the Act on the Electronic Document and Electronic Trust Services in accordance with the procedure set out in Article 20 of the Electronic Government Act, containing:

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

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

1. documents proving the facts and circumstances justifying the amendment;
2. document demonstrating proof of payment of the respective fee.

Article 19. (1) The NRA Chairperson shall take a decision on the application for a licence amendment:

1. (Supplemented, SG No. 76/2012, No. 37/2018) within six months – with regard to amendment of a licence under Article 15, Paragraph 3, Subparagraph 1, 8 and 9 of the ASUNE;
2. (Amended, SG No. 76/2012, No. 37/2018) within two months – with regard to amendment of a licence under Article 15, Paragraph 3, Subparagraphs 2-5 of the ASUNE.

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

1. (Repealed, SG No. 76/2012);
2. (Amended - SG 37/2018) within three months – with regard to amendment of a permit under Article 15, Paragraph 4, Subparagraphs 1-4, 15 and 18 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 Chairperson 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 Chairperson 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

Renewal of licences and permits

Article 22. (Supplemented, SG No. 36/2025) The licences which are limited by time 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 carrying out the activity.

Article 23. (1) (Supplemented, SG No. 4/2016, amended SG No. 36/2025) In case of renewal of a license or permit, the applicant shall submit an application on paper or electronically in accordance with the procedure set out in Article 20 of the Electronic Government Act, containing:

1. the applicant's identification data;
2. the licence or permit registration number;
3. a request for the licence or permit renewal;
4. a proposal for the new term of validity; in 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, SG No. 37/2018, SG No. 36/2025) For nuclear facilities, a justification of the new time limit and payment document of the application review fee shall be attached to the application under Paragraph 1. In cases of renewal of a licence, a Periodic Safety Review Report and a draft integrated program for implementation of safety improvement measures shall also be attached. When the fee is paid electronically, no document proving the payment is required.

(3) (New, SG No. 76/2012, amended SG No. 37/2018, SG No. 36/2025) For activities with SIR, a justification for the new term of validity shall be attached to the application under Paragraph 1, and in cases of license renewal, the following shall also be attached:

1. updated check list in a standard form approved by the NRA Chairperson, containing information on:

- a) the radiation sources used and stored and the activities performed with them;
- b) the personnel and the organisation of the work with SIR within the site;
- c) the radiation monitoring instrumentation and individual dosimetric devices;
- d) the arrangements for the provision of the radiation protection and the physical protection;

2. (Amended, SG No. 36/2025) payment document of the application review fee under Chapter Four of the Tariff for the Fees Charged by the Nuclear Regulatory Agency under the ASUNE. When the fee is paid electronically, no document proving the payment is required.

(4) (New, SG No. 76/2012) Current procedures, instructions, programmes, orders and other internal documents applied by the applicant shall be attached to the updated check list referred to in Paragraph 3, Subparagraph 1.

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

Article 24. (1) Applications for renewal of licences shall be submitted within the following time frames:

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

2. (Amended, SG No. 76/2012, amended and supplemented, SG 37/2018) not earlier than one month before the expiration of the term of the current licence – in case of licences under Article 15, Paragraph 3, Subparagraphs 2-5 and 9 of the ASUNE.

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

(3) If the application has been submitted within the time limits under Paragraph 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 licence or permit.

(4) Paragraph 3 shall also apply in the event of non-compliance with the time limits under Paragraph 1 and 2 due to objective reasons.

(5) In case of non-compliance with the time limits under Paragraph 1 and 2 as well as where there are not objective reasons for non-compliance under Paragraph 4, the provisions under Section II of this Chapter shall apply.

Article 25. (1) The NRA Chairperson shall take a decision on an application for licence renewal within the time frames under Article 18, Paragraph 1 of the ASUNE.

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

1. within 20-days after the 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 compliance with the requirements under Article 3. The review of the application for a 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 Chairperson shall renew the licence or permit by reissuing them with the contents defined in Article 13.

(3) (Amended, SG No. 76/2012, SG No. 36/2025) Any licence shall be renewed for a period not exceeding the period stated in Article 20, Paragraph 1 of the ASUNE.

(4) Any permit shall be renewed for a term not exceeding the term of validity of the initially issued permit.

Article 27. Issues not explicitly covered by this section shall correspondingly be regulated under the procedure provided for in Section II of this Chapter.

Section VI

Suspension of licences and permits

Article 28. (1) A licence or permit shall be suspended:

1. (Supplemented, SG No. 36/2025) upon the expiration of its term, if the license is limited by time, provided that an application for a renewal under Section V of this Chapter has not been submitted;

2. before the expiration of its term – upon 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) in case of announced insolvency or in case of 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 licensee 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 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 Chairperson 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, supplemented No. 4/2016) The NRA Chairperson shall suspend the licence or permit by an order, except for the cases under Paragraph 1, Subparagraphs 1 and 5-8, where the licence or permit shall be suspended automatically. In relation to serving of the suspension order, the requirements of Article 11, Paragraph 1 and 2 shall apply.

(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 entry into force of the NRA Chairperson order.

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

Article 29. (Supplemented, SG, 4/2016, Amended, SG No. 36/2025) An application for licence or permit suspension under Article 28, Paragraph 1, Subparagraph 2 and 3 shall be submitted on paper or electronically in accordance with the procedure set out in Article 20 of the Electronic Government Act and shall contain::

1. the applicant's identification data;

2. licence or permit registration number;

3. the actions to be taken for the provision of nuclear safety, radiation protection and physical protection.

Article 30. (1) In case of an application submitted under Article 29, the NRA Chairperson 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 the provision of nuclear safety, radiation protection and physical protection have not been taken.

(2) (Amended, SG No. 93/2009; supplemented SG No. 76/2012, amended, SG No. 4/2018) The NRA Chairperson may request the Minister of Energy, the Minister of Defence, the Minister of Interior, the Minister of Environment and Waters, the Minister of Regional Development and Public Works and the Minister of Health to express their position on issues connected with the suspension of the licence or permit in question.

(3) The NRA Chairperson shall decide on the application for a licence or permit suspension:

1. within two months after the submission of an application for a licence suspension. In case of an application for suspension of operating licence for a nuclear facility, the time limit shall be nine months;

2. within one month after the submission of an application for suspension of a permit.

Section VII

Revocation of licences and permits

Article 31. (Amended, SG No. 76/2012, SG No. 36/2025) A licence or permit shall be revoked in the cases provided for in Article 23, Paragraph 1, Subparagraph 1 “a” and “b” and Subparagraph 2 - 4 of the ASUNE.

Article 32. (1) After the discovery of facts that constitute grounds for revocation of a licence or permit under Article 31, the NRA Chairperson shall inform in writing the licensee or permit holder and shall determine an appropriate time period for bringing the activity in line with the legislative requirements and licence or permit conditions.

(2) Within the time frame under Paragraph 1, the licensee or permit holder may submit explanations and objections, as well as may ask for a prolongation of the specified time limit.

(3) Where, on the basis of the explanations and the objections given, it has been established that the initially determined time frame for bringing the activity in line with the respective requirements is insufficient, or if there are other objective reasons, the NRA Chairperson may extend the time limit given to the licensee or permit holder. The latter have to be notified under the procedure of Paragraph 1.

Article 33. (1) Where the licensee or permit holder fails to fulfil the obligation for bringing the activity in compliance with the legislative requirements and with the licence or permit conditions within the determined time limit and after an analysis of the case and submitted explanations and objections, the NRA Chairperson shall revoke the licence or permit by an order.

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

1. the legal grounds for issuing the order;
2. the factual grounds 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. formal response 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) (Supplemented - SG No. 4/2016) The order under Paragraph 1 shall be made available to the licensee or permit holder, respectively to an authorised representative, according to the procedure under Article 11, Paragraph 1 and 2.

Chapter Two

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

Section I

General provisions

Article 34. (1) (Amended and supplemented, SG No. 76/2012, amended SG No. 37/2018) The licences and permits under Article 15, Paragraph 3, Subparagraph 1 and 8 and Paragraph 4, Subparagraphs 1-5, 15 and 16 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 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 the 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 might be issued within the time period for issuing the design permit;

2. the selected site and technical design might 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 construction permit for 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 Paragraph 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 Paragraph 3 and 4 may be issued for a specific 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.

Art. 34a. (New, SG No. 36/2025) (1) The licence holders under Article 20, Paragraph 4 of the ASUNE shall carry out periodic safety reviews of the nuclear facilities at least once every 10 years as required in Article 37a of the ASUNE. For these cases, the requirements of Chapter Five, Section V of the Regulation on the Safety of Nuclear Power Plants shall apply.

(2) The licence holders under Paragraph 1 shall submit an application for issuance of an order under Article 37c, Paragraph 2 of the ASUNE and shall attach to it the Periodic Safety Review results in the form of a report and an integrated programme for implementation of safety improvement measures.

(3) The Chairperson of the Agency shall assign the NRA units to review and assess the compliance of the documents submitted under Paragraph 2 with the requirements for nuclear safety and radiation protection. The time limit for the review shall be 9 months from the date of receipt of the documents referred to in Paragraph 2 by the NRA, taking into account the requirements of Article 8, Paragraph 5.

(4) In cases where compliance with the requirements for nuclear safety and radiation protection has been established, the Chairperson of the NRA shall approve by an order the Periodic Safety Review results, which shall be reflected in the licence for operation of the nuclear facility.

(5) The order under Paragraph 4 shall determine a deadline for submission of the subsequent Periodic Safety Review results to the NRA. The deadline shall be determined taking into account the results of the review and assessment performed by the NRA units, including the assessment of the actual state of the nuclear facility.

(6) The deadline for submitting the first Periodic Safety Review results shall be specified in the conditions of the licence for operation of the nuclear facility.

(7) The deadlines determined by the Chairperson of the NRA in accordance with paragraphs 5 and 6 related to the performance of a Periodic Safety Review and submitting its

results shall not exceed 10 years. In the cases referred to in Paragraph 5, the deadline shall start to run from the date of issue of the order under Article 37c, Paragraph 2 of the ASUNE. In the cases referred to in Paragraph 6, the deadline shall start to run from the date of issue of the respective licence.

(8) In cases where, as a result of the review and assessment carried out under Paragraph 3, compliance with the requirements for nuclear safety and radiation protection has not been established, the Chairperson of the NRA shall refuse to issue an order approving the Periodic Safety Review results, stating the reasons for this decision. The refusal to issue the approving order shall constitute grounds for revocation of the licence in accordance with Chapter One, Section VII.

(9) Upon issuance of the order under Paragraph 4, the conditions of the current operating license shall be amended ex officio by the Chairperson of the NRA in accordance with the procedure under Article 17, Paragraph 2.

(10) With regard to the procedure for issuing the order under Paragraph 4, the requirements of Chapter One, Sections I to IV of this Regulation shall apply accordingly.

Article 35. (1) (Supplemented, SG No. 4/2016) The application for a licence or permit under this Chapter shall contain the data under Article 4 while observing the requirements of Article 5, Paragraph 7. The following documents shall be attached to the application:

1. (Amended, SG No. 76/2012, repealed, No. 37/2018);
2. (Amended, SG No. 76/2012, repealed, No. 37/2018);
3. (Amended, SG No. 76/2012, repealed, No. 53/2019);
4. documents confirming that the applicant possesses sufficient financial resources for carrying out the activity in compliance with nuclear safety and radiation protection requirements, standards and rules;
5. documents confirming that the applicant possesses sufficient technical resources for performing the activity in compliance with nuclear safety and radiation protection requirements, standards and rules;
6. documents confirming that the applicant possesses sufficient material resources for performing the activity in compliance with 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 time period for which the licence or permit is required;
10. list of the standards applicable to the activity, as well as other documents verifying compliance with the requirements under this Chapter.

(2) The documents under Paragraph 1 shall not be attached to the application for a permit for introducing amendments 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-assignment for preliminary investigations containing information on the scope of the activities within the framework of the pre-investment studies according to Regulation No. 4 for the Scope and Contents of the Investment Projects (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) For 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 facility;
- b) basic safety principles, objectives and criteria related to safety justification;
- c) types and quantities of RAW expected to be generated as a result of facility operation and their management until final disposal or exemption;
- d) (Amended, SG No. 36/2025) comparison and ranking of the candidate sites from nuclear safety and radiation protection point of view and selection of an option, taking into account: the impact of natural and technogenic origin factors on facility safety; the radiological impact of the nuclear facility over the population and environment; the specific characteristics of the site having an impact on migration and accumulation of radioactive substances; potential for undertaking population protection measures in case of an accident; emergency planning areas;
- e) the results of the investigation of the characteristics of the selected site, including: geographic, topographic and demographic conditions; factors of technogenic origin; hydro-meteorological conditions; geological, hydrological, seismological and engineer-geological conditions; the specific characteristics of the region and site for the purposes of the emergency planning, accident management and physical protection;
- f) list of literary sources, containing data and information used for justification of the selected site;
- g) list of the specialists contributed to the preparation of the documentation and to site investigation, as well as data on their qualification;

2. on-site monitoring programmes, including seismic monitoring, groundwater and surface waters monitoring and monitoring of other natural phenomena;

3. (Repealed, SG No. 37/2018);

4. programme for implementation of additional investigations connected with the selected site if so provided in the Preliminary Safety Analysis Report;

5. other documents verifying compliance with the requirements of the regulations under Article 26, Paragraph 2 of the ASUNE and with site selection permit conditions.

(2) In case of envisaged location of a new nuclear facility at 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, No. 37/2018) The applicant may submit an application for a design permit before the issuance of the order for the approval of the selected site, provided that all necessary activities under Article 37, Paragraph 1, Subparagraph 1, letter “d” and “e” have been completed.

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. (Amended, SG No. 36/2025) terms of reference for design or a contract for design, which include the requirements for ensuring nuclear safety and radiation protection to be taken into account in the design project, as well as the main technological, functional and planning-compositional requirements and parameters;

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

3. list of the standards to be applied in the design stage.

(2) In the cases under Article 38, the time limit for taking a decision on the application for a design permit shall start 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 developed on the basis of the Preliminary Safety Analysis Report and Technical design of the facility; the minimum content of the Safety Analysis Report shall contain the information set out in Appendix No. 1;

b) the results of the review of the design for compliance with the requirements, standards and rules for nuclear safety and radiation protection, including those connected with effective safety management, as well as the results of an independent review (verification) of the safety analysis;

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 shall also be attached to the application:

1. preliminary general time-table for the implementation of the construction and assembling works;

2. technical design and/or detailed design for construction of the nuclear facility;

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

(2) In case of an application for a construction permit for 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, No. 93/2009, No. 4/2018) The decision under Paragraph 2 shall be taken on the basis of a proposal submitted by the Minister of Energy, and shall contain an assessment of:

1. the nuclear safety, radiation protection and physical protection;
2. the impact on the environment;
3. the social and economic significance of the construction of the nuclear power plant for the country or certain areas;
4. the radioactive waste 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 environmental impact assessment 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 shall also 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 establishing the existence of a financial guarantee covering the civil liability for nuclear damage according to Article 132 of the ASUNE;
3. (Amended SG No. 37/2018) protocol for establishing the fitness of the construction for use (or a part/ stage of it) according to Template 16 of Regulation No. 3/2003 on Producing Acts and Protocols in the Construction Process (SG 72/2003).
4. commissioning programme for the nuclear facility determining the commissioning stages, the activities to be performed during each stage and their planned duration; the commissioning programme shall contain information confirming:
 - a) planning of all the tests that are identified in the Intermediate Safety Assessment Report as necessary for confirmation of the design characteristics;
 - b) that the tests are planned in stages in order the load to be increased gradually;
 - c) determination of periods of hold-up during the process of commissioning, in which the facility has to be operated according to predetermined parameters;
 - d) specification of the systems and equipment needed for each commissioning stage;
5. (Repealed, SG No. 76/2012);
6. (Amended, SG No. 76/2012) description of the management system for the activity;
7. information on approved modifications in the technical design of the nuclear facility;
8. information on the results of the pre-operational tests of the structures, systems and equipment;
9. (Amended, SG No. 76/2012) Technical Specifications for Operation of the nuclear facility, which shall contain operational limits and conditions, including: safety limits; the values of the parameters for actuation of the safety systems; operational limits and conditions; tests, inspections, surveillance and in-service inspections on the systems important to safety; minimum number of operating personnel to carry out activities in different 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 to be applied to nuclear facility operation;

11. (Amended, SG No. 76/2012) list of the positions in the organisational structure authorised to carry out activities 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, letters “a” and “b” of the ASUNE;

12. (Amended, SG No.36/2025) programme for radiation monitoring of the site and the emergency planning areas during the operational stage of the nuclear facility;

13. list of the structures, systems and components important to safety;

14. list of the systems and equipment needed for each commissioning stage;

15. methodologies and programmes for carrying out tests and experiments during each individual commissioning stage;

16. instruction for ensuring nuclear safety during commissioning and operational stage;

17. instruction for the provision of the radiation protection during commissioning and operational stage;

18. instruction for ensuring nuclear safety during transportation and storage of nuclear material on-site;

19. procedure for the provision of the physical protection of the facility and the nuclear material;

20. instruction for the admission regime;

21. accident management procedure to be applied at the operational stage;

22. instruction for accounting and control of nuclear material;

23. document confirming that the applicant has ensured sufficient number of personnel possessing required level of qualification and competence for employment at nuclear facilities in order to perform 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 actions of the personnel in case of radiological emergency at the nuclear facility;

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

28. (Amended, SG No. 36/2025) documents demonstrating determination of emergency planning areas and controlled access areas;

29. programme for radiation monitoring of the environment;

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

(2) Amendment of the commissioning programme for the nuclear facility shall be performed through 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, Subparagraph 12, 17 and 29 shall be submitted to the National Centre for Radiobiology and Radiation Protection.

Article 44. (1) If the commissioning of the nuclear facility is a multistage process, a separate permit shall be issued for each stage.

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

1. documents to confirm the readiness of the facility for carrying out the activities associated with the respective stage in accordance with the commissioning programme;

2. approved programmes, procedures and instructions applied to the respective stage;

3. documents confirming the presence of sufficient personnel possessing required level of qualification and competence 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 fuel loading and subcritical tests;
3. initial criticality and low power tests;
4. power start-up of the unit at stage-by-stage power increase;
5. trial-testing operation – in case of evolutionary NPP units.

Article 45. (1) Until the beginning of each commissioning stage, a commission of NRA inspectors appointed by the NRA Chairperson shall inspect the site for confirming correspondence with stated data and circumstances and preparedness for carrying out the respective stage. Depending on the specificity of each stage, representatives of other authorities exercising specialised control may be included in the commission.

(2) The commission under Paragraph 1 shall prepare a report on the inspection results, which have to be signed by the commission members and made available to the applicant or to an authorised representative.

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

1. the report under Paragraph 2;
2. the administrative actions of the state authorities to exercise specialised control functions in the construction process;
3. the document confirming the elimination of the causes for the observations and remarks included in the report under Paragraph 2.

Article 46. (1) The results of the tests and experiments for each stage of the nuclear facility commissioning process shall be included in a report, which shall contain:

1. list of the work activities performed during the respective stage;
2. analysis of the correspondence between the design features and the performance of the equipment as shown by the tests and experiments results;
3. description of detected defects and failures;
4. determination of the causes of the nonconformities regarding the actual state and the design characteristics and an analysis of their significance, as well as planned corrective actions.

(2) The reports under Paragraph 1 shall be signed by the experts involved in carrying out the tests and shall be approved by the management body of the applicant.

(3) A permit for a subsequent commissioning stage shall be issued upon submission of the reports on the results obtained from the preceding commissioning stages together with an 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 conditions of the commissioning permit shall be verified by a commission of NRA inspectors, appointed by the NRA Chairperson. The Commission shall examine 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, developed on the basis of the report under Article 40, Paragraph 1, Subparagraph 1, taking into account the results from the commissioning of the nuclear facility;

2. (Amended, SG No. 76/2012) the documents under Article 43, Paragraph 1, Subparagraph 7, 9, 10, 13, 16, 17, 22, 24, 28 and 29 updated on the basis of the results from the commissioning of the nuclear facility;
3. (Repealed, SG No. 76/2012);
4. time-tables, procedures and instructions for testing and control of the systems important to safety;
5. time-schedule for maintenance and repair of the main equipment;
6. programmes and plans for spent nuclear fuel management through the operational lifetime and after final shut down of the facility;
7. RAW management programme including the requested term of the licence as well as the entire operational lifetime of the nuclear facility;
8. rules, procedures and programmes for training of the employees and for continuous improvement and control of their qualification;
9. analysis of the activities to be carried out by contractors, as well as the positions in the organisational structure of the applicant having responsibilities for management and control of these activities, their minimum number and qualification;
10. (Amended, SG No. 76/2012) description of the management system for the activity involving the operational phase of the facility;
11. (Repealed, SG No. 76/2012);
12. documents, approved by the management body of the applicant, defining the safety policy, including establishing and maintaining a high level of safety culture;
13. instruction associated with the reporting order and methods for analysis of operational events;
14. programme and a time-table for training and exercise related to the activation of the on-site emergency plan of the nuclear facility;
15. ageing management programme for the requested term of the licence and throughout the service life of the equipment including monitoring the status of components important to safety;
16. (Repealed, SG No. 76/2012).

Article 49. For the purposes of issuing an operating licence for a nuclear power plant unit, the documents under Article 48 shall be attached to the application. The following shall also be attached:

1. electricity and/or heat generation licence issued under the provisions of the Energy Sector Act;
2. symptom-based emergency procedure specifying the activities to be performed in case of an accident;
3. instruction on the cooperation between the operating personnel of the unit and of the nuclear power plant as a whole;
4. (New, SG No. 76/2012) procedure for operation of the structures, systems and components (SSC) important to safety;
5. (Former 4, SG No. 76/2012) procedure for operation of the reactor installation;
6. (Former 5, SG No. 76/2012) procedure for in-service inspection of the base and weld metal behaviour and of the pipelines.

Article 50. (Amended, SG No. 76/2012) For the purposes of the issuing a licence for operation of a research reactor or a critical stand, the documents under Article 48 and Article 49, Subparagraph 5 and the instructions specifying the activities to be performed in case of an accident shall be attached.

Article 51. For the purposes 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. the physico-chemical and radiochemical properties of the nuclear material to be extracted, produced, processed, stored or handled at the facility;
2. (Amended, SG No. 76/2012) neutron-physical characteristics, isotope composition and enrichment with a fissile isotope of the nuclear material at the facility if the latter represents a special nuclear material within the meaning of § 1, Subparagraph 36 of the Supplementary provisions of the ASUNE;
3. where nuclear material is produced or processed at the nuclear facility – the characteristics of the end-product;
4. description of the operations in their technological sequence;
5. list of the instructions and procedures regulating the activities related to nuclear safety and radiation protection;
6. procedures for operation of the systems designed to achieve the intended purpose of the facility;
7. waste package specifications corresponding to the acceptance criteria for storage or disposal of nuclear material.

Article 52. (1) For the purposes of issuing a licence for operation of a facility for disposal of nuclear material, the documents under Article 48 shall be attached to the application. The following shall also be attached:

1. technical specification of the packages;
2. procedure for acceptance of the material;
3. instruction for ensuring nuclear safety to be applied for the facility and the activity;
4. instruction for ensuring nuclear safety to be applied to transportation activities, interim storage and other on-site activities;
5. description of the activities in their technological sequence;
6. procedures for operation of the systems designed to achieve the intended purpose of the facility;
7. plan for facility closure and for exercising institutional control.

(2) After the completion of closure activities, institutional control shall be exercised over the site, which shall be:

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

Article 53. (Amended, SG No. 76/2012) For the purposes 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, demonstrating compliance with the requirements of the Regulation under Article 77, Paragraph 3 of the ASUNE, shall also be attached:

1. waste acceptance criteria for processing and/or storage;
2. technical specification of the packages of conditioned waste;
3. description of the activities in their technological sequence;
4. procedures for operation of the systems designed to achieve the intended purpose of the facility;

Article 54. (Amended, SG No. 76/2012) (1) For the purposes of issuing an operating licence for RAW disposal facility, the documents under Article 48 shall be attached. The

following documents demonstrating compliance with the requirements of the Regulation under Article 77, Paragraph 3 of the ASUNE shall also be attached:

1. waste acceptance criteria for disposal;
 2. procedures for delivery and acceptance of RAW for disposal;
 3. programme for inspection of nuclear waste packages intended for disposal;
 4. plan for closure of the facility, 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 performed for the purposes of the post-closure period.
- (3) The Safety Assessment Report for RAW disposal facility under Article 48, Subparagraph 1 shall include an assessment of the facility safety for the period of operation and for the post-closure period.

Article 55. (Repealed, SG No. 76/2012)

Section VII

Modification permits

Article 56. (1) This section provisions shall be applied to the procedure for issuing 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 a modification permit all mutually interconnected issues.

Article 57. (1) (Supplemented, SG No. 37/2018) The application for a modification permit shall contain the registration number of the operating licence for the nuclear facility, respectively the decommissioning licence.

- (2) The following shall be attached to the application under Paragraph 1:
1. justification for the envisaged modification; reasons for undertaking the modification;
 2. justification for the envisaged time period for carrying out the modification;
 3. (Supplemented, SG No. 37/2018) assessment of the impact of the envisaged modification on the limits and conditions for safe operation and decommissioning;
 4. list of the standards to be applied for the activity;
 5. the amended parts or sections of the Safety Assessment Report;
 6. analysis and assessment of the impact of unfavourable external events or of the operating conditions, including those connected with increase in the volume and activity of generated RAW, increase in the radioactive contamination as well as with additional occupational exposure;
 7. description of the modifications in the maintenance works.

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

1. proposed design modifications;
2. as-built drawings and schemes reflecting the state before and after modification;
3. technical specification of the equipment and components to be used;
4. description of the assembly mode or proof for certification of the equipment and components;
5. description of planned factory tests, assembly and functional tests to verify conformity with the acceptance criteria, methods for verification and validation of the computer codes;
6. description of the operational state of the nuclear facility, or the respective part of it, at which the modification would occur;

7. (Amended, SG No. 76/2012) document describing the specific management system components connected with the activity, including the responsibility for exercising control over the activities carried out by contractors, as well as the mechanism to manage the non-compliance and undertaking corrective actions.

Section VIII

Permit for import and export of nuclear material

Article 58. (1) (Amended, SG No. 76/2012) The documents demonstrating compliance with the import and export regime under the Defence related products and Dual-Use Items and Technologies Export Control Act shall be attached to the application for a permit for import or export of nuclear material.

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

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

(3) Where the applicant is a sole trader or a legal entity not having a valid licence or permit issued under this Regulation, the documents under Article 35, Paragraph 1 shall be attached to the application under Paragraph 1 as well as the following documents:

1. contract between the applicant and the consignee of the material;
2. specification of the type, form and quantity of the nuclear material, including enrichment with a fissile isotope and radioisotope composition;
3. document containing information on the purpose for which the nuclear material is intended;
4. document containing information on the transport mode to be used – by river, sea, air, rail, road, or combined transport;
5. document indicating the border crossing points and the customs post through which the nuclear material will be imported or exported and the expected date of import or export;
6. documents demonstrating that the transport of the 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 demonstrating that the consignee of the material holds 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 respectively from or into a Member State of the European Union, issuance of a permit for import or export of nuclear material shall not be required.

Section IX
Decommissioning licence for a nuclear facility
 (Title amended, SG No. 76/2012)

Article 59 (Amended, SG No. 76/2012) (1) The overall commissioning process of a nuclear facility shall be organised, analysed, planned and justified in a decommissioning plan, which shall have the following minimum content:

1. (Amended, SG No. 36/2025) description of the facility, its site, the emergency planning areas, the SSC, including information regarding contaminated SSC and environmental components;
2. information on the operational history of the facility – authorised activities, significant operational events relevant to the decommissioning stage, reasons for decommissioning;
3. list of the standards used in the planning of the decommissioning process;
4. assessment of the amount, type and location of the radioactive or other hazardous materials contained in the facility;
5. decommissioning strategy – description of the analysed decommissioning options and justification for the selected one;
6. time-table for the duration of any of the decommissioning stages and the activities to be carried out;
7. description of the decommissioning activities related to contaminated structures, equipment, soil and groundwater;
8. classification of the SSC on the basis of their safety significance taking into account the stages specified in the decommissioning plan;
9. description of required basic modifications to the existing SSC and newly designed SSC to be used especially for decommissioning purposes;
10. programme and time-schedules for monitoring and maintenance of the SSC to be used during the decommissioning process;
11. description of compared decontamination approaches and a justification for the selected option;
12. description of the available and planned technologies and technical means for dismantling and decontamination;
13. RAW management programme, which shall contain:
 - a) the radiation sources stored on site, the radioactive waste streams, types and quantities of RAW;
 - b) criteria for sorting of radioactive material;
 - c) organisation of the activities associated with the management of RAW before their disposal, including a justification for the methods of treatment, taking into account envisaged disposal option;
 - d) criteria and possibilities for second use and recyclability;
 - e) expected liquid and gaseous releases into the environment;
14. safety assessment programme, which shall include inter alia a justification for the possibilities of clearance from regulatory control, which shall be submitted to the National Centre for Radiobiology and Radiation Protection by the NRA;
15. description of the management system for the activity, including employee management system;
16. radiation protection programme, which shall take into account occupational, public and environmental exposure;
17. description of the organisation and the responsibilities associated with the emergency planning and readiness;

18. responsibilities for the provision of the physical protection of the facility and, if necessary, measures to ensure physical separation of the facility to be decommissioned from the facilities which are in operation;

19. current assessment of the financial resources necessary for the decommissioning of the facility, financing mechanisms, available financing resources;

20. description of the monitoring programmes, methods and techniques for carrying out a survey of the site after completion of the decommissioning activities, in order to demonstrate compliance with the criteria for release from regulatory control under the ASUNE;

21. time-schedule for reporting interim and final results connected with the decommissioning process.

Article 60. (Amended, SG No. 76/2012) For the purposes of issuing a licence for decommissioning of a nuclear facility, the documents under Article 35, Paragraph 1 shall be attached to the application. The following shall also be attached:

1. Safety Assessment Report for the period of the implementation of the decommissioning plan including a review of all aspects of the decommissioning plan related to occupational and public exposure and an independent review (verification) of the safety analysis;

2. (Amended, SG No. 37/2018) decommissioning plan under Article 59;

3. Technical Specifications for Operation containing limits and conditions for operation to be observed during the decommissioning stage;

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

5. (Previous 4, renumbered, SG No. 76/2012) procedures for operation of the SSC remaining in operation during the decommissioning stage;

6. (Previous 5, renumbered, SG No. 76/2012) decision on EIA according to the Environment 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 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 Specifications for Operation including limits and conditions for operation specific for the respective decommissioning stage;

4. (Amended, SG No. 76/2012) list of the procedures for operation of 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 be required only in case of envisaged changes in initially planned volumes, technologies and time limits for implementation of the activities due to new circumstances or technological improvement. The updated plan shall include information on the activities performed during the previous stages of the decommissioning process and the actual state of the facility.

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

Article 62a (New, SG No. 4/2016) (1) The site of a nuclear facility shall be released from regulatory control by an order issued by the NRA Chairperson under Article 28, Paragraph 1, Subparagraph 2, on the condition that it has been proven to comply with established dose criteria and upon fulfilment of the conditions of the decommissioning licence for the nuclear facility.

(2) With the issuance of the order under Paragraph 1 the activities under the decommissioning licence shall be deemed to be completely fulfilled, the licence shall be terminated and the licensee shall be released from further responsibility under the ASUNE in respect of the nuclear facility.

Section X

Permit for commercial transactions involving a nuclear facility

Article 63. (1) The NRA Chairperson shall issue permits for commercial transactions involving nuclear facilities according to the procedure under this section as long as they are under commissioning or are already commissioned and/or operated.

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

Article 64. (1) The application for a permit for commercial transaction involving transfer of property or the right of use over the nuclear facility shall be signed and submitted by both parties to the transaction – the proprietor of the facility (licensee or permit holder) and the transferee under the transaction.

(2) The application shall contain the information provided for in Article 4 concerning the 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 actions 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 transaction involving the 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, ensuring 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 complete 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 proprietor has been 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 Chairperson 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 the respective 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, Subparagraph 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 case of non-compliance with the conditions under Paragraph 1, the NRA Chairperson shall deny the application by a reasoned order.

Article 67. (1) A permit for a commercial transaction involving a 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 guarantee against nuclear damage.

(3) A permit for commercial transaction involving nuclear facility shall be issued for a term of validity not exceeding 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 guarantee on the basis of a Council of Ministers decision under Article 129, Paragraph 1 of the ASUNE.

(2) Within 14-days after the submission of the documents under Paragraph 1, the NRA Chairperson 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. The NRA Chairperson shall issue permits for commercial transactions other than those envisaged under Article 64, Paragraph 1 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) (Amended, SG No. 36/2025) The NRA Chairperson shall issue a permit for each individual transaction involving nuclear material following the procedure under this section on the condition that the parties to the transaction are holders of licences for operation of nuclear facilities in which nuclear material is used, handled or stored, issued on the basis of

the requirements of the ASUNE, and also on the condition that the nuclear safety and radiation protection requirements, standards and rules are fulfilled.

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

Article 71. (1) (Amended, SG No. 36/2025) The application for a permit for a transaction involving nuclear material shall be submitted by one of the contracting parties and shall contain the registration numbers of the licences issued to them.

(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 and quantity of the nuclear material, including its chemical and physical composition, enrichment with fissile isotope and radioisotope composition.

(3) Depending on the subject matter, place of delivery and other characteristics of the transaction, 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 demonstrating that the transport of the 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 type and characteristics of the nuclear material, other necessary documents could be also submitted.

Article 72. Within 14-days after the completion of the transaction, the permit holder shall submit to the NRA the respective documents demonstrating this fact.

Chapter Three

(Amended, SG No. 76/2012)

ISSUING OF LICENCES AND PERMITS, REGISTRATION AND NOTIFICATION FOR ACTIVITIES INVOLVING SOURCES OF IONISING RADIATION

(Title amended, SG 37/2018)

Section I

General Provisions

Article 73. (Amended, SG No. 76/2012, No. SG 37/2018) (1) According to the requirements of the ASUNE, the activities involving SIR shall be performed on the basis of a licence, permit, registration or notification.

(2) No licence or permit, registration or notification shall be required for activities involving SIR if they are associated with negligible radiation risk, and if it has been proved that they correspond to the dose criteria and/or exemption levels defined by the Regulation under Article 26, Paragraph 3 of the ASUNE.

(3) Activities under Article 56, Paragraph 2 of the ASUNE shall be subject to notification in accordance with Section VIII.

(4) Activities under Article 56, Paragraph 3 of the ASUNE shall be subject to registration in accordance with Section VII.

Article 74. (Amended, SG No. 76/2012, No. 4/2016, No. 37/2018) A permit shall not be required for temporary storage of radiation sources if such activity has been included in the scope of a licence for use of SIR, manufacture of SIR, or manufacture of consumer products, including medical devices within the meaning of the Medical Devices Act, by adding radioactive substances.

Article 75. (Amended, SG No. 76/2012) (1) (Amended, SG No. 4/2016) Licences and permit for activities involving SIR shall be issued upon submission of an application under Article 4.

(2) In issuing a licence for activities involving SIR, the following documents demonstrating compliance with the requirements of Article 60 of the ASUNE shall be attached to the application under Paragraph 1:

1. the management and organisational structure;
2. (Amended, SG No. 53/2019) a document confirming that the applicant possesses sufficient financial resources required for carrying out the activity in a safe manner;
3. document determining the personnel to perform activities involving SIR and specifying the employees in charge of radiation protection;
4. the radiation sources and the activities performed by their use, including technical documentation (explanatory notes, drawings, schemes, images) and certificates of SIR necessary for radiation protection assessment;
5. expected occupational radiation exposures in normal and emergency situations;
6. description of the personal protection devices, as well as the devices and equipment used for performance of the work in a safe manner and for protection against occupational exposures;
7. procedure for ensuring radiation protection in the performance of the work;
8. on-site emergency plan;
9. expert medical opinion on fitness for duty of the employees to carry out activities involving work with ionising radiation, issued following the procedure stipulated in the Regulation referred to in Article 65, Paragraph 1, Subparagraph 4 of the Health Act;
10. employees' individual licences for work with SIR issued according to the procedure stipulated in the Regulation referred to in Article 65, Paragraph 3 of the ASUNE;
11. internal rules and procedures defining the responsibilities for provision of radiation protection, including organisation of the work activities;
12. programme for monitoring the radiation parameters of the working premises as well as for monitoring of the occupational exposure, including description of the technical devices in use;
13. (Repealed, SG No. 53/2019);
14. (Amended, SG No. 37/2018) document demonstrating availability of occupational exposure monitoring according to the requirements of the Regulation on Radiation Protection;
15. questionnaire in a standard form endorsed by the NRA Chairperson;
16. other documents demonstrating compliance with the requirements for carrying out the respective activity.

(3) If a site with radioactive substances is involved, the following documents shall also be attached:

1. in the cases provided by the law, a document confirming that the physical protection of the respective entity has been provided, issued by the competent authorities of the Ministry of Interior;
2. assessment of the types and quantities of RAW expected to be generated during the licence or permit term of validity, and the organisation of its management in a safe manner and

delivery for management to legal persons holding a licence issued under the procedure of Article 53 and 54.

(4) (Supplemented, SG No. 37/2018) New activities for which it has not been proven that the expected benefits of the activity exceed the possible health damage shall be justified. The rationale for existing activities shall be reviewed on the basis of new data and circumstances that require a reassessment of the benefit and the detriment of an action.

(5) (Amended, SG No. 37/2018) If the applicant is a natural person to perform the activity personally, the documents under Paragraph 2, Subparagraph 1 and 3 shall not be required.

Article 76. (Amended, SG No. 76/2012) (1) (Supplemented, SG No. 4/2016, amended, SG No. 37/2018) Licences for the use of high-activity sources, unsealed sources, or charged particle accelerators as well as licences for production of SIR shall be issued on the condition that the respective facility has been commissioned.

(2) (Amended, SG No. 37/2018) The applicant shall notify the NRA Chairperson of readiness of the facility under Paragraph 1 for commissioning.

(3) The NRA Chairperson shall appoint by an order an inspection commission to evaluate the completeness of presented data and information as well as the readiness of the facility for commissioning and shall set a deadline for this to be achieved.

(4) (Amended, SG No. 4/2016) Representatives of other authorities exercising specialised control may also be included in the composition of the commission mentioned above.

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

1. the documents under Article 75, Paragraph 2 and 3;
2. register intended to provide information on accounting and control of SIR;
3. register intended to provide information on initial and regular radiation protection briefing of the personnel;
4. registers intended to provide information on the monitoring of the environmental conditions in the working premises as well as on individual dosimetric control results, individual dosimetric cards and radiation passports of the personnel;
5. documents containing the results of the initial testing of the systems and equipment;
6. (Amended SG No. 37/2018) protocol confirming the readiness of the construction for use (or a part/stage of it) according to Template 16 of Regulation No. 3 of 2003 for Producing Certificates of Completion and Protocols in the Construction.

(6) (Amended, SG No. 4/2016) The commission shall prepare a protocol regarding the readiness of the facility for commissioning.

(7) (Amended, SG No. 4/2016) The protocol under Paragraph 6 shall be served to the applicant or to an authorised representative within 5 days after the inspection. The applicant is obliged to eliminate the deficiencies observed by the commission and to notify the NRA about this in writing.

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

Article 77. (Amended, SG No. 76/2012, repealed, SG No. 37/2018)

Section II

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

Article 78. (Amended, SG No. 76/2012) (1) In issuing a permit for construction of an entity with SIR, assembly and initial testing, the following documents shall be attached to the application:

1. the documents under Article 75, Paragraph 2, Subparagraph 3, 9, 10 and 14 if appropriate;
 2. (Amended, SG No. 4/2016) Technical design and envisaged radiation protection-related measures;
 3. (Amended, SG No. 4/2016) a copy of a medical report, prepared by the competent authorities of the Ministry of Health, demonstrating the compliance of the site with the regulatory requirements connected with health protection;
 - 4 (Repealed, SG No. 4/2016);
 5. (Amended, SG No. 37/2018) documents regulating the relationship between the applicant and the contractors to perform assembly operations and initial testing of SIR, which must be registered under Article 56, Paragraph 3 of the ASUNE.
- (2) (Repealed, SG No. 4/2016).

Section II "a". Permit to modify structures, systems and components related to radiation protection included in the design of entities involving SIR (New - SG No. 37/2018)

Article 78a. (New, SG No. 37/2018) The following shall be applied to the application for a permit to modify structures, systems and components related to radiation protection included in the design of entities involving SIR:

1. rationale for the necessity to introduce the modifications in the existing structures, systems and components related to radiation protection and an assessment of the impact of the envisaged changes;
2. technical design for the modifications under Subparagraph 1;
3. documents regulating the relationship between the applicant and the contractors to carry out the activities associated with the modifications under Subparagraph 2, which must be registered under Article 56, Paragraph 3 of the ASUNE.

Section III

Permit for decommissioning of a site with radioactive substances

Article 79. (Amended, SG No. 76/2012) (1) The following documents shall be attached to the application for a permit authorising decommissioning activities related to a facility with unsealed sources of ionising radiation or with sealed sources, Category 1:

1. the documents under Article 75, Paragraph 2, Subparagraph 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 process;
 - b) assessment of expected exposure doses and radiation protection measures associated with each decommissioning stage, including decontamination methods and means, provision of safety during dismantling of radioactive sources and in case of activities involving equipment and materials containing radioactive substances;
 - c) inventory of the sealed and unsealed sources, radioactive substances and RAW;
 - d) assessment of the expected amounts of RAW to be generated during the decommissioning process, information on their activity and radionuclide composition;

3. documents related to the evaluation of the radiation status of the site (the land and corresponding buildings, premises, installations, systems and equipment used for handling of radioactive substances);

4. description of the measures for provision of safe storage of RAW in accordance of Article 16, Subparagraph 7 of the ASUNE.

Article 80. (Amended, SG No. 76/2012) (1) A decommissioning permit is not required for 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. (Amended, SG No. 76/2012) (1) A permit for decommissioning of a site with radioactive substances shall be issued to persons having used and stored the respective radioactive substances, to their successors, or to persons authorised to perform such activities by virtue of a statutory instrument.

(2) (Repealed, SG No. 37/2018)

(3) (Repealed, SG No. 37/2018)

Article 82. (Amended, SG No. 76/2012) The NRA Chairperson shall notify the state bodies exercising health control of the completion of the decommissioning activities.

Section IV

Permit for temporary storage of radioactive substances

Article 83. (Amended, SG No. 76/2012) (1) The documents under Article 75, Paragraph 2, Subparagraph 2, 3, 8, 9, 10, 12, 14, and a questionnaire in a form approved by the NRA Chairperson shall be attached to the application for issuing permits authorising activities associated with temporary storage of radioactive substances. The following topics should be covered in the questionnaire:

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

2. scheme of the location of the facility itself and the location 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 the physical protection.

Section V

Permit for import or export of sources of ionising radiation

Article 84. (Amended, SG No. 76/2012) (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-EU-Member-State:

1. documents containing identification data related to the consignee of the imported or exported SIR;

2. inventory and identification data of the imported or exported SIR (type, model, manufacturer, manufacturing serial number, total number, the activity of the radionuclides and other technical characteristics for the respective SIR type), including information on the packaging of the 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 general procedure for registration and permitting of foreign trade transactions, including documents demonstrating correctness of data which is introduced in the import/export certificates;

4. documents demonstrating conformity with certain standards related to import/export of SIR (technical documentation for the respective type of SIR, certificates, images, schemes);

5. document demonstrating that the transport of the imported or exported radioactive sources will be 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) The documents under Paragraph 1 and the following documents shall also be attached to the application for issuing a permit for import or radioactive sources:

1. documents demonstrating 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 guaranteeing the return after the termination of the utilisation of the respective sealed sources, Category 1, 2 or 3, which have radioactive half-life exceeding five years, back to the respective producer/supplier, according to § 1, Subparagraph 9 of the Supplementary provisions of the ASUNE.

(3) In issuing a permit for export of sources of ionising radiation, a document issued by the competent authority of the state where the importer is registered authorising the respective activity shall also be attached to the application.

Article 85. (Amended, SG No. 76/2012, No. 37/2018) In case 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 14 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 radiation 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 Chairperson immediately after the delivery of the consignment to the persons entitled to receive it;

3. submit for validation 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 (+OJ, L 148, 19.6.1993) - in case of import of sealed sources;

4. submit to the NRA a declaration validated 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 - in case of export of sealed sources.

5. notify in writing the NRA Chairperson and submit documents guaranteeing the return of imported sealed sources to the producer/supplier after termination of the utilisation - in case of import of sealed sources, Category 1, 2 or 3 having radioactive half-life exceeding five years.

Section V "a". Permit for reclamation of sites contaminated with radioactive substances (New, SG No. 37/2018)

Article 85a. (New, SG 37/2018)

(1) The following documents shall be attached to the application for a permit for reclamation of sites contaminated with radioactive substances:

1. scheme of the location and the boundaries of the site, data on the terrain and planned restoration activities, defined end state prior to finalising the reclamation activities;
2. the management and organizational structure and internal rules (instructions, procedures, orders) defining the organisation of the work and the responsibilities for the safe conduct of the activity;
3. preliminary analysis and assessment of the contamination level of the site taking into account the radionuclides having natural and/or artificial origin, an analysis of the possible risks and exposure pathways and spread of radioactive contamination during the execution of planned reclamation activities;
4. assessment of the occupational exposure doses expected to be received during the execution of the activities;
5. soil reclamation design for the site contaminated with radioactive substances, a plan-schedule for the execution of the activities and acceptance criteria;
6. radiation protection programme for implementation of the activities and for radiation monitoring of the working environment, including procedures and measures for control and prevention of radioactive contamination of waters, air and soil, as well as measures to respond to emergency situations;
7. plan for management of the industrial waste and contaminated earth masses generated during the terrain recovery process, including preliminary assessment of their quantity and activity;
8. documents demonstrating that the employees engaged to perform reclamation activities possess required qualifications, knowledge, experience and competence, as well as documents demonstrating that the applicant possesses sufficient financial, technical and material resources for the safe conduct of the activity.

Section VI

Licence for use of SIR, manufacture of SIR and consumer products, including medical devices by adding radioactive substances

(Title amended, SG No. 37/2018)

Article 86. (Amended, SG No. 76/2012) (1) (Amended, SG No. 37/2018) The documents under Article 75, Paragraph 2 and documents to confirm the availability of technical support services and maintenance for the technical devices in use shall be attached to the application for issuing licences authorising activities associated with use of SIR for industrial, veterinary, scientific or process control purposes.

(2) (Supplemented, SG No. 37/2018) The documents under Article 75, Paragraph 2 and a description of the envisaged individual means of radiation protection in case of medical exposure as well as documents demonstrating compliance with the statutory requirements connected with the protection of health.

(3) (Supplemented, SG No. 37/2018) As specified in the licence conditions, the licence for use of SIR gives to the licensee a right to perform maintenance, assembly, dismantling, measurements and repair works involving the respective SIR, as well as transport of radioactive substances.

Article 87. (Amended, SG No.76/2012, No. 4/2016, repealed, No. 37/2018)

Article 88. (Amended, SG No. 76/2012) (1) In case of adding new sources or in case of modification in the construction and the position of the sources, which have already exist within a particular entity, depending on the specific circumstances, a new licence shall be issued or already issued licence for use of SIR shall be amended.

(2) (Amended, SG No. 4/2016) In the cases under Paragraph 1, the radiation protection measures shall be reviewed and an amendment of the licence for use of SIR shall be performed after obtaining a permit for construction of an entity with SIR, assembly, preliminary testing and commissioning under the procedure according to Article 76.

Article 89. (Amended, SG No. 76/2012, No. 37/2018) The applicant shall attach the documents under Article 75, Paragraph 2 to the application under Article 4 for issuance of a licence for manufacture of SIR or for manufacture of consumer products, including medical devices (within the meaning of the Medical Devices Act) by adding radioactive substances.

Article 90. (Amended, SG No. 76/2012, repealed, SG No. 37/2018)

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

Section VI "a". Licences for operation and technical liquidation of sites for extraction and processing of ore containing natural uranium or thorium

(New, SG No. 37/2018)

Article 98a. (New, SG No. 37/2018) (1) The following documents shall be attached to the application for a licence for operation and technical liquidation of sites for extraction and processing of ore containing natural uranium or thorium:

1. rationale for the activity to be performed, taking into account the economic, social and other benefits compared to possible harmful effect of expected occupational and public exposure as a result of the activity;
2. management and organisational structure, internal rules and procedures defining the organisation of work, distribution of the responsibilities related to performance of the activity and the implementation of envisaged radiation protection measures and radiation monitoring;
3. document demonstrating that the applicant holds a concession for the extraction of ore containing natural uranium or thorium;
4. plan for management of the mining waste associated with extraction and processing of ore which contain natural uranium or thorium (description of the activity generating mining waste; characterisation of the waste and estimation of its quantity; possible environmental risks - water, air and soil pollution, and measures to minimise them; control and monitoring procedures; measures to prevent accidents);
5. comprehensive detailed design for extraction and processing of ore containing natural uranium or thorium;
6. radiation protection program for the site for extraction and processing ore containing natural uranium or thorium and radiation monitoring program involving operational and natural environment;
7. documents proving the qualification, knowledge, experience and competence of the personnel to perform the activity;
8. documents proving that the applicant possesses sufficient financial, technical and material resources for safe conduct of the activity;
9. technical liquidation plan defining the end state of the site prior to finalising the activities.

Section VII Registration of activities

(New, SG No. 37/2018)

Article 98b. (New, SG No. 37/2018, Amended, SG No. 36/2025) (1) For registration of an activity under Article 56, Paragraph 3 of the ASUNE, the applicant shall submit an

application on paper or electronically in accordance with the procedure set out in Article 20 of the Electronic Government Act, which shall contain:

1. the applicant's identification data;
2. the purpose, scope, type and general description of the activity;
3. information on the regulatory decisions and other documents issued by other state authorities, which are related to that activity and demonstrate compliance with the statutory and regulatory requirements as a whole;
4. the period of time for which the registration of the activity is requested;
5. list of the documents attached to the application.

(2) In order to receive registration for handling of SIR for the purpose of maintenance, assembly, dismantling, measurement, construction and repair work or other services for the benefit of persons using or manufacturing SIR, the applicant shall attach to the application under Paragraph 1 the following documents:

1. management and organizational structure and internal rules defining the responsibilities of the employees to carry out the activity;
2. orders to designate a radiation protection officer and occupationally exposed employees to carry out the activity;
3. description of the kind, type and radiation characteristics of the radiation sources to be utilised, including a description of the radiation impact factors and the envisaged means of individual protection and radiation monitoring during work activities involving SIR;
4. description of the envisaged technical means, devices and auxiliary equipment necessary for performance of the activity in a safe manner and for radiation protection;
5. procedures for radiation protection in the performance of the work;
6. document demonstrating provision of individual dosimetric control of the employees to carry out the activity;
7. expert medical opinion on fitness for duty of the employees associated with work with ionising radiation and individual licences issued according to the procedure under Article 65, Paragraph 3 of the ASUNE;
8. (Amended, SG No. 53/2019) document demonstrating that the applicant possesses sufficient financial resources for carrying out the activity in a safe manner;
9. other documents demonstrating compliance with the applicable statutory requirements.

(3) In order to receive registration for use of SIR for non-medical imaging, the applicant shall attach to the application under Paragraph 1:

1. rationale for the activity to be performed, taking into account the economic, social and other benefits compared to possible harmful effect of expected exposure;
2. management and organisational structure and internal rules defining the responsibilities of the employees to carry out the activity;
3. description of the kind, type and radiation characteristics of the radiation sources to be utilised, including a description of radiation impact factors and envisaged means of individual protection and radiation monitoring during work activities involving SIR;
4. description of envisaged measures and means for radiation protection and for radiation monitoring in carrying out the activity;
5. orders to designate a radiation protection officer and the employees to perform non-medical imaging;
6. assessment of the expected external exposure dose for the employees to carry out the activity and to the individuals subjected to non-medical imaging;
7. procedures for radiation protection in carrying out the activity;
8. document to demonstrate provision of individual dosimetric control of the personnel;

9. expert medical opinion on fitness for duty of the employees to be engaged in work with ionising radiation and individual licences issued according to the procedure under Article 65, Paragraph 3 of the ASUNE;

10. (Amended, SG No. 53/2019) document demonstrating that the applicant possesses sufficient financial resources for carrying out of the activity in a safe manner;

11. other documents demonstrating compliance with the applicable regulatory requirements.

(4) The documents required according to Paragraphs 1-3 shall be attached in original, or as certified copies, on paper and in electronic form. Where the application is submitted electronically, the documents shall be attached as scanned copies.

(5) The Chairperson of the NRA shall take a written decision on the application under Paragraph 1 and on the documents under Paragraph 2 and 3 within one month after their submission.

Article 98c. (New, SG No. 37/2018) (1) The Chairperson of the NRA shall issue a registration certificate for the activities under Article 56, Paragraph 3 of the ASUNE and shall order its entry into the public register under Article 27, Paragraph 1, Subparagraph 2 of the ASUNE on the condition that the requirements under Article 3 are met.

(2) The registration certificate under Paragraph 1 shall contain:

1. the name of the issuing authority;
2. the registration number of the certificate;
3. the legal grounds for issuing the certificate;
4. the applicant's identification data, taking into account the requirements of the Personal Data Protection Act;
5. the activity for which the certificate is issued and the place of its carrying out (including radiation sources to be utilised);
6. the term of the registration;
7. requirements related to provision of information on carrying out the activity and for the radiation sources.

(3) The term of validity of the registration certificate shall not exceed 5 years.

(4) In case of non-compliance with the requirements under Article 3, the Chairperson of the NRA shall refuse to register the respective activity under Article 56, Paragraph 3 of the ASUNE by a reasoned order.

Article 98d. (New, SG No. 37/2018) (1) The persons to carry out activities on the basis of issued registration certificate shall notify annually the Chairperson of the NRA about the activities performed in the respective sites and for the fulfilment of the requirements under Article 98c, Paragraph 2, Subparagraph 7.

(2) The persons under Paragraph 1 shall be obliged to carry out new measurements, analyses and assessments in case of change in the circumstances under which the registration has been made and shall inform the Chairperson of the NRA about obtained results.

(3) The control over the observance of the statutory requirements for providing radiation protection in carrying out the activities under Article 56, Paragraph 3 of the ASUNE shall be performed according to Article 100 of the ASUNE. In case of violations, the relevant administrative penalty provisions of the ASUNE shall be applied.

(4) The persons under Paragraph 1 shall comply with all statutory requirements for provision of the radiation protection during the implementation of the activity.

Article 98e. (New, SG No. 37/2018) A registration certificate for activities under Article 56, Paragraph 3 of the ASUNE shall be terminated:

1. upon completion of the activity;
2. upon expiration of the term of validity;
3. upon submitting of an application for termination of the registration;
4. in case of revocation under Article 98f.

Article 98f. (New, SG No. 37/2018) The Chairperson of the NRA shall, after a written warning determining a deadline for remedial measures, revoke a registration certificate by a reasoned order in the cases where:

1. the person registered for an activity under Article 56, Paragraph 3 of the ASUNE does not fulfil or violates:
 - a) obligations under Article 16 of the ASUNE applicable to the activity;
 - b) the prohibitions under Article 17 of the ASUNE;
 - c) prescriptions or imposed coercive administrative measures under the ASUNE;
2. A person registered for an activity under Article 56, Paragraph 3 of the ASUNE has provided untrue information which served as a basis for the registration;
3. there are reasons related to national security and public order - on the basis of a reasoned request by the competent state authority.

Article 98g. (New, SG No. 37/2018) The termination or revocation of the respective certificate of registration shall be entered in the respective register under Article 27, Paragraph 1, Subparagraph 2 of the ASUNE.

Article 98h. (New, SG No. 37/2018)

(1) The Chairperson of the NRA is entitled to require the opinion of the specialised control bodies in respect of the registration of any activity under Article 56, Paragraph 3 of the ASUNE.

(2) The provisions of Sections II and VI shall apply accordingly for procedural issues that are not explicitly regulated in this section.

Section VIII. Notification of activities

(New, SG No. 37/2018)

Article 98i. (New, SG No. 37/2018, amended, SG No. 36/2025) (1) A person carrying out activities under Article 56, Paragraph 2 of the ASUNE shall submit a notification on paper or electronically in accordance with the procedure set out in Article 20 of the Electronic Government Act.

(2) A document demonstrating compliance of the activity with the requirements and criteria specified in the Regulation under Article 26, Paragraph 3 of the ASUNE shall be attached to the notification under Paragraph 1.

Article 98j. (New, SG No. 37/2018) (1) A list of the activities under Article 56, Paragraph 2, Subparagraph 4 of the ASUNE subject to notification according to this Regulation, is given in Annex 2.

(2) Notification of activities under Paragraph 1 shall also be required for activities with SIR not included in the list under Paragraph 1 where it is proven that the radiation risk is negligible.

Article 98k. (New, SG No. 37/2018) (1) The persons to carry out activities subject to notification are required:

1. to comply with the radiation protection requirements applicable to the activity;

2. to carry out analyses, assessments and/or measurements in case of change in the circumstances under which the notification has been made and to inform the NRA Chairperson about obtained results;

3. (Amended, SG No. 53/2019) to notify in writing the NRA Chairperson upon termination of the activity entered in the register under Article 27, Paragraph 2 of the ASUNE.

Chapter Four

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

Section I

General provisions

Article 99. (1) (Amended, SG No. 37/2018) The licences and permits under Article 15, Paragraph 3, Subparagraph 5 and Paragraph 4, Subparagraph 7, 13 and 17 of the ASUNE shall be issued under the procedure prescribed for in this Chapter.

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

(3) The provisions of this Chapter shall not apply to nuclear material, RAW and/or other radioactive substances if:

1. they are transported within the boundaries of the site in order to be managed on the basis of a licence and/or permit issued under this Regulation;

2. they are an integral part of 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 specific activity and total activity in the consignment do not exceed 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 specified in 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 together with 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 case of shipment between Member States and in case of export to countries outside the European Union;

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

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

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

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

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

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

(6) (New, SG No. 76/2012) The application under Paragraph 4 shall be filled in a standard form approved by an order of the NRA Chairperson, 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 specific activity of the consignment does not exceed the clearance levels defined by the Regulation under Article 26, Paragraph 3 of the ASUNE;
2. in case of shipment of used sealed radioactive sources back to the supplier/manufacturer, or to licenced facility for RAW management;
3. in case of shipment of radioactive materials generated as a result of treatment of spent fuel and intended for further use;
4. in case of shipment of RAW containing only natural radionuclides.

Article 100. (Supplemented, SG No. 4/2016) The application for a licence or permit under Article 99, Paragraph 1 shall contain the data under Article 4 while observing the requirements of Article 5, Paragraph 7. The following documents shall also be attached to the application:

1. (Amended, SG No. 76/2012, repealed, SG No. 37/2018);
2. (Amended, SG No. 76/2012, repealed, SG No. 37/2018);
3. (Amended, SG No. 76/2012, repealed, SG No. 53/2019);
4. (Supplemented, SG No. 76/2012) documents confirming that the applicant possesses sufficient financial, technical and material resources for performing the activity in compliance 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 time period for carrying out the activity;
8. other documents demonstrating compliance with the requirements for carrying out the activity.

Section II

Permit for transport of nuclear material

Article 101 (1) The documents under Article 100 shall be attached to the application for a permit for transport of nuclear material. 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, 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 scheduled transit stops and nuclear material delivery point;
 - d) chosen mode of transport within the territory of the state - road, rail, river, sea, air, or combined transport; in the case of combined transport - the intermediate points between the departure and arrival and identification data for the contact persons authorized by the carrier;

5. documents regulating the relationship between the consignor and consignee and between the applicant and the contractors to be engaged in transport activities 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 conveyances comply with the transport safety standards and with the standards for protection against ionising radiation;

8. documents demonstrating that the cargo loading and unloading devices correspond to the requirements for carrying out the activity in a safe manner;

9. written document, approved by the management body of the applicant, determining:

a) the individuals in charge of transport safety;

b) the employees to take part in the transport operations;

c) the vehicle drivers engaged in road transport;

10. the individual licences issued according to the procedure under Article 65, Paragraph 3 of the ASUNE to the individuals included in the document under Subparagraph 9;

11. expert medical opinion on fitness for duty of the individuals to carry out the activity;

12. (Amended, SG No. 53/2019) document demonstrating that the licensee has examined the actual condition of the roads to be used as well as a positive conclusion that the shipment could be performed in a safe manner;

13. documents containing the results of radiometric measurements performed in accordance with the requirements of the Regulation under Article 26, Paragraph 4 of the ASUNE;

14. nuclear safety and radiation protection programme;

15. emergency plan;

16. document demonstrating the provision of the physical protection, coordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure under Article 113, Paragraph 4 of the ASUNE;

17. procedure for the provision of the physical protection;

18. (Amended, SG No. 76/2012) document describing the management system for the activity, including the organisational structure, control measures 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 demonstrating the readiness of the waste packages for transport of the spent fuel according to the operating procedures;

2. protocol demonstrating that the spent fuel 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 loading the container with spent 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 a licence for transport of radioactive substances. The following documents shall also be attached:

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

a) the radioactive substances to be transported in any conveyance – type, physical and chemical characteristics, quantity, activity, numbers according to uniform classification adopted by United Nations (UN No.);

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

c) declared total transport index for any conveyance as compared to the admissible value;

d) chosen mode of transport - road, rail, river, sea, air, or combined transport; in case of combined transport - the intermediate points between the departure and arrival and identification data for the contact persons authorised by the carrier;

e) the transportation safety consultants, employees responsible for notifying the NRA, dosimetrists;

f) performed individual and total radiometric measurement, measuring devices in use;

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

3. (Amended, SG No. 76/2012) documents demonstrating compliance of the vehicles 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) the transportation safety consultants, employees responsible for notifying the NRA, dosimetrists;

b) the employees 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 the members 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 international agreements for shipment of dangerous goods ratified by the Republic of Bulgaria;

7. (Amended, SG No. 76/2012) documents to demonstrate ensuring individual dosimetric control of the personnel;

8. (Amended, SG No. 76/2012) instructions for radiation protection, emergency plan related to shipment activities, radiation monitoring programme;

9. (Amended, SG No. 76/2012) internal rules and procedures determining the responsibilities in case of periodic testing and maintenance of the transport packages, preparation of the shipment, transport documentation, shipment operations and storage during 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 non-reoccurring transport of radioactive substances

Article 103. (1) The documents under Article 102 shall be attached to the application for a permit for non-reoccurring transport of radioactive substances. The following shall also be attached:

1. (Amended, SG No. 76/2012) documents containing information on:
 - a) the respective permit, licence or other document authorising the consignee to store or use the radioactive substances in question;
 - b) the expected date of departure and arrival of the shipment, the departure point, the transport route within the state, including scheduled transit stops and 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 relationship between the consignor and consignee and between the applicant and the contractors to be engaged in the shipment;
 3. (Amended, SG No. 76/2012) the administrative acts issued by the 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) the 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 case of export or transit of radioactive materials;
 5. (Repealed, SG No. 76/2012);
- (2) Depending on the type and characteristics of the radioactive substances, the NRA Chairperson may request the applicant to submit:
1. document demonstrating the provision of the physical protection, coordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure under Article 113, Paragraph 4 of the ASUNE;
 2. procedure for the provision of the physical protection;
 3. (New, SG No. 76/2012) document demonstrating that the consignor/consignee is authorised to perform activities involving 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 a permit for transit of RAW or 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 passing across them;
2. (Amended, SG No. 76/2012) document demonstrating 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 demonstrating the provision of the physical protection, coordinated with the competent authorities of the Ministry of Interior under the conditions and according to the procedure under Article 113, Paragraph 4 of the ASUNE;
4. procedure for the provision of the physical protection.

(2) (Amended, SG No. 76/2012) The documents under Article 101 shall be attached to the application for a permit for transit of nuclear material or spent fuel along with a document to contain information on:

1. the State of origin, State of destination and States of transit;
2. the border crossing points to be used and the expected date of passing across them;

Chapter Five

REGULATORY CONTROL OVER THE ACTIVITIES PERFORMED UNDER THE ASUNE AND OVER THE FULFILMENT OF LICENCES AND PERMITS CONDITIONS

(Title amended, SG No. 37/2018)

Article 105. (Amended, SG No. 37/2018) (1) The Chairperson of the NRA shall perform control over the compliance with the statutory requirements associated with safe conduct of the activities under Article 15, Paragraph 3 and 4 and Article 56, Paragraph 2 and 3 of the ASUNE as well as control over the compliance with the conditions of the licences and permits in force.

(2) The Chairperson of the NRA shall perform preventive, current and confirmatory control over the compliance with the statutory requirements in terms of carrying out the activities under the ASUNE, the Rules of Procedure of the NRA and this Regulation.

(3) The control under Paragraph 2 shall be carried out by documentary checks and/or on-site inspections by inspectors who are officials from the NRA staff and are determined by an order of the Chairperson of the NRA under the ASUNE and the Rules of Procedure of the NRA.

(4) The Chairperson of the NRA shall implement the control activities while observing the graded approach principle, shall approve programs for the inspection activities of the NRA and shall include annually a summary of the implemented activities in the report under Article 5, Subparagraph 10 of the ASUNE.

Article 106. (Amended, SG No. 37/2018) The NRA inspectors shall conduct on-site inspections separately or together with representatives of other competent authorities authorised by law to exercise specialised control.

Article 107. The NRA Chairperson shall direct the NRA inspection activities and shall approve a procedure for performing the inspections, defining the inspections type, the frequency of the inspections, the methods for their performance, procedure for objectifying the inspection results, the coordination, as well as other specific issues to ensure that the inspections are conducted according to the statutory requirements and standards.

Article 108. (Supplemented, SG No. 37/2018) The inspectors of the NRA are entitled to inspect the suppliers or providers of services to persons authorised to carry out activities under this Regulation in order to establish facts and circumstances related to the fulfilment of the conditions of the licences or permits in force, as well the fulfilment of the regulatory requirements for carrying out activities on the basis of registration or notification.

Article 109. (Supplemented, SG No. 37/2018) (1) The inspectors shall prepare a protocol of findings encompassing the results of the on-site inspections performed at the start of the regulated activity under the ASUNE as well as during its carrying out and shall enclose the evidence gathered during the inspections, the explanations and the results from performed monitoring, measurements and/or testing.

(2) (Amended, SG No. 76/2012) The protocols of findings shall be served to the inspected persons.

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

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

(4) The persons to receive mandatory directives shall report to the respective inspector on the implementation of the directives within the prescribed time period.

(5) (Supplemented, SG No. 37/2018) The NRA inspectors shall exercise confirmatory control by means of documentary and/or on-site inspections to verify the implementation of the recommendations and prescriptions given.

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

Chapter Six REGISTERS

Article 111. (Amended, SG No. 4/2016, No. 37/2018) (1) The NRA shall maintain public registers in which the following shall be recorded:

1. the licences and permits which have been issued, as well as their amendment, renewal, suspension and revocation;
2. (Supplemented, SG No. 53/2019) the registration certificates and individual licences issued by the NRA Chairperson, as well as their termination and revocation;
3. the notifications for activities to be performed under Article 56, Paragraph 2 of the ASUNE.

(2) The following information shall be entered into the registers under Paragraph 1, Subparagraph 1 and 2:

1. the registration number of the respective authorisation;
2. the day of issue;
3. the term of validity;
4. the type of the issued authorisation;
5. the applicant's identification data, while observing the requirements of the Personal Data Protection Act;
6. imposed restrictive conditions – in respect of authorisations involving separate stages of the activity, using parts of the facility or entity, or other specific conditions connected with the scope of the activity;
7. data on subsequent amendments to the authorisations as well as on their suspension;
8. the activity within the scope of respective authorisation;

(3) In case of notification under Paragraph 1, Subparagraph 3, the information under Paragraph 2, Subparagraph 5 shall be entered in the register as well as the activity for which the notification has been made.

(4) Where the NRA Chairperson refuses to issue a licence, permit, registration certificate or individual licence, the following data shall also be entered in the register under Paragraph 1:

1. the registration number and the date of issue of the refusal order;
2. the type of the authorisation to be requested;
3. the applicant's identification data;

(5) Kept with each register under Paragraph 1 shall be an archive storing the documents for all issued permits, licences, registration certificates or individual licences as well as for entry in the register of activities under Article 56, Paragraph 2 of the ASUNE.

SUPPLEMENTARY PROVISIONS

§ 1. Within the meaning of this Act:

1. (Supplemented, SG No. 37/2018) "applicant" shall mean any person to submit or on behalf of which an application has been submitted under the procedure according to this Regulation regarding issuing, amendment, renewal or suspension of a licence or permit under the ASUNE as well as:

a) the transaction parties, in case of application for issuing a permit for commercial transactions involving a 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 in case of a sole trader or a legal entity intending to perform import or export on the basis of Article 40, Paragraph 2 of the ASUNE;

1a. (New, SG No. 37/2018) "applicant's identification data" shall mean the full name, unique citizenship number (UCN), place of birth, permanent and current address in the Republic of Bulgaria – for natural persons, and the full name, head office and management address, data of the registration document and the UIC or BULSTAT code, as well as the full name of the persons authorised to represent the applicant according to current registration – for legal persons and sole traders;

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

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

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

5. "permit holder" shall mean 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" shall mean the final stage of the operation of the nuclear facility during which the spent fuel have to be removed from the site or emplaced in a facility located at the same site and designed for safe long-term storage of the spent fuel;

7. "conditioning of RAW" shall include the activities leading to the production of a waste package suitable for handling, transport, storage and/or disposal; the conditioning shall include the conversion of the waste to a solid waste form and producing packages;

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

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

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

11. (Amended, SG No. 36/2025) "transport" shall mean changing the location of the load from the place of origin to the place of destination. The transport activities comprise all the operations associated with the preparation for shipment, the activities related to loading, carriage, unloading and receipt at the final destination; if necessary, it might include in-transit stops and temporary storage.

12. (Amended, SG No. 36/2025) "carrier" shall mean any person undertaking the carriage of radioactive substances by any means of transport.

13. "conveyance" shall be:

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" shall mean 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. (Amended, SG No. 36/2025) "consignment" shall mean any package or packages, or load of radioactive substances that have been prepared for transport in accordance with the legislative requirements for safety;

15. "consignor" shall mean any person to prepare a consignment and the transport documents in order to be transported on a specified route.

16. "consignee" shall mean any person entitled to receive a consignment.

§ 1a. (New, SG No. 4/2016) The Chairperson of NRA and authorised by him/her officials shall have the right to access to National data base "Population" maintained by the Ministry of Regional Development and Public Works.

(2) The Ministry of Regional Development and Public Works, through General Directorate Civil Registration and Administrative Service, shall provide to the persons under Paragraph 1 the following information from National data base "Population":

1. UCN;
 2. full name;
 3. changes in the names;
 4. place of birth;
 5. permanent address;
 6. present address;
 7. identity document;
 8. data on death registration (date of death, number of the document, date and place of issuance).
- (3) The information under Paragraph 2 shall be provided to the NRA free of charge and only for official purposes while observing the requirements of the Personal Data Protection Act.

§ 1b. (New, SG No. 53/2019) The documents required under Article 98a, Subparagraph 3, as well as the individual licences under Article 75, Paragraph 2, Subparagraph 10, Article 98b, Paragraph 2, Subparagraph 7 and Paragraph 3, Subparagraph 9, Article 101, Paragraph 1, Subparagraph 10 and Article 102, Subparagraph 6 of this Regulation shall be provided ex officio.

§ 2. (1) Persons intending to submit an application for a licence and/or permit following the procedure under this Regulation may request the NRA Chairperson to express a position on certain procedural issues beforehand.

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

§ 3. In the cases referred to in Articles 17 and 18, an original of the licence or permit with incorporated amendments 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 start-up of a power plant unit after reloading of the nuclear fuel shall be determined by the conditions of the licence issued for nuclear facility operation.

§ 5. (Repealed, SG No. 76/2012).

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

§ 7. The NRA Chairperson shall issue instructions for the implementation of this Regulation as well as guidance documents, 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 regulations for the implementation of the ASUNE, which are not adopted at the moment of entering into force of this Regulation, the respective regulations 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 (SG No.13/1989, amended and supplemented with SG No. 37/1993 and No.12/2001), reissuing of this acts according to the procedure under this Regulation shall not be required.

§ 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 holding a permit under the Regulation No.5 of 1988 for Issuing Permits for Nuclear Energy Use but exercising factual control over sources of ionising radiation at the moment of entering into force of this Regulation, are obliged to request a permit for temporal storage within three months after entering into force of the Regulation. In case of non-compliance, the sanctions under Article 138, Paragraph 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 in a safe way until delivery for management as RAW.

§ 12. If at the moment of entering into force of this Regulation the time limits for submission of an application for a renewal of a licence or permits defined in Article 24, Paragraph 1 and 2 have been expired, the licensee or permit holder still may submit an application for a renewal until the 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, SG No. 76/2012)

....

§ 3. (1) Any initiated but not finalised proceedings related to issuing licences and permits for activities included into the scope of Appendix 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 made by the NRA Chairperson 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 Appendix 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 made by an order issued by the NRA Chairperson on the basis of an application filed under Article 73, Paragraph 6.

APPENDIX № 1

to Article 40, Paragraph 1, Subparagraph 1, "a"
(Amended and supplemented, SG No. 76/2012)

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.

APPENDIX № 2
to Article 98j, Paragraph 1

(New, SG No. 76/2012, amended, SG No. 37/2018)

A list of the activities involving 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 intraoral radiography;
2. Use of osteodensitometers in diagnosing limb-bone density;
3. Use of x-ray devices for element and microstructural analysis of materials:
 - 3.1. x-ray analysers for chemical analysis;
 - 3.2. devices 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 gaschromatographs and electron microscopes;
6. Use of sealed sources, Category 5.