



**HEAD
OF THE STATE NUCLEAR POWER SAFETY INSPECTORATE**

**ORDER
ON THE APPROVAL OF NUCLEAR SAFETY REQUIREMENTS BSR-1.8.7-2020
"SAFETY OF LICENSED ACTIVITIES WITH NUCLEAR AND FISSILE MATERIALS
REGULATED BY THE STATE NUCLEAR POWER SAFETY INSPECTORATE"**

17 January 2020 No. 22.3-15
Vilnius

Pursuant to Article 22(1)(3) of the Republic of Lithuania Law on Nuclear Energy and Articles 4(4), (6) to (9), 11(1), 30(3) and 33 of the Republic of Lithuania Law on Nuclear Safety, I hereby:

1. Approve the Nuclear Safety Requirements BSR-1.8.7-2020 "Safety of licensed activities with nuclear and fissile materials regulated by the State Nuclear Power Safety Inspectorate" (attached).
2. Establish that this Order shall enter into force on 1 May 2023.

Head

Michail Demčenko

APPROVED by
Order No. 22.3-15 of the Head of the State
Nuclear Power Safety Inspectorate of
17 January 2020

NUCLEAR SAFETY REQUIREMENTS
BSR-1.8.7-2020
"SAFETY OF LICENSED ACTIVITIES WITH NUCLEAR AND FISSILE MATERIALS
REGULATED BY THE STATE NUCLEAR POWER SAFETY INSPECTORATE"

CHAPTER I
GENERAL PROVISIONS

1. The Nuclear Safety Requirements BSR-1.8.7-2020 "Safety of licensed activities with nuclear and fissile materials regulated by the State Nuclear Power Safety Inspectorate" (hereinafter referred to as the "Requirements") shall establish:

1.1. criticality safety assurance requirements;

1.2. the emergency preparedness requirements for activities involving the use of nuclear and fissile materials in the quantities specified in Annex 1 to the legal act referred to in subparagraph 9.2 of the Requirements;

1.3. the requirements for the preparation of the safety assessment report referred to in Article 33 of the legal act referred to in subparagraph 9.2 of the Requirements in the case of a licence referred to in Article 22(1)(7) of the legal act referred to in subparagraph 9.2 of the Requirements;

1.4. the requirements for the criticality safety analysis referred to in subparagraph 5.3 of the legal act referred to in subparagraph 9.14 of the Requirements in the case of a licence referred to in Article 22(1)(6) of the legal act referred to in subparagraph 9.2 of the Requirements.

2. The requirements shall be mandatory:

2.1. for the holders of the licences referred to in Article 22(1)(1) to (5) of the legal act referred to in subparagraph 9.2 of the Requirements, if they carry out activities with nuclear and fissile materials referred to in Annex 1 of the legal act referred to in subparagraph 9.2 of the Requirements, in the quantities set out in that Annex;

2.2. for the holders of the licences referred to in Article 22(1)(1) to (5) of the legal act referred to in subparagraph 9.2 of the Requirements, if they carry out activities involving more than 450 grams of 233-U, 235-U or isotopes of plutonium, or a mixture of all of these substances, if the activities involve the use of depleted and/or natural uranium;

2.3. for the holders of the licences referred to in Article 22(7) of the legal act referred to in subparagraph 9.2 of the Requirements;

2.4. for the holders of the licences referred to in Article 22(6) of the legal act referred to in subparagraph 9.2 of the Requirements, if they carry out the activities involving cargo which is marked "FISSILE" in accordance with subsection 2.2.7.2.3.5 of the legal act referred to in subparagraph 9.12 of the Requirements and/or subsection 2.2.7.2.3.5 of the legal act referred to in subparagraph 9.13.

2¹. Holders of the licences referred to in Article 22(6) of the legal act referred to in subparagraph 9.2 of the Requirements shall be bound by the provisions of Chapters V, VII and IX of the Requirements for the regulated activities.

3. The Requirements shall not apply to nuclear reactors, critical and non-critical test facilities and research experiments designed to induce a self-sustaining fission chain reaction.

4. The designer or organisation of installations used in regulated activities may apply additional measures to improve the criticality safety of the regulated activity, take into account additional factors affecting criticality safety, and use additional criteria for criticality safety than those set out in the Requirements, but these additional measures and criteria shall not be in contradiction with the Requirements.

5. The holder of safety-critical small quantities of nuclear and fissile materials may, at its discretion, apply the provisions of the Requirements to the holder of safety-critical medium or large quantities of nuclear and fissile materials.

6. The holder of a safety-critical medium quantity of nuclear and fissile materials may, at its discretion, apply the provisions of the Requirements to the holder of a safety-critical large quantity of nuclear and fissile materials.

7. If an organisation carries out several activities involving nuclear and fissile materials, it may apply the provisions of the Requirements, which are different for holders of small, medium or large quantities of nuclear and fissile materials, respectively, in terms of criticality safety, to each activity separately, if it is not feasible to use the fissile materials together because of technical and organisational arrangements (e.g. fissile materials are stored in different buildings and it is not feasible to relocate them in a single location because of technical or organisational arrangements).

8. The Requirements shall apply to the management of spent fuel to the extent that the management of spent fuel is not regulated by the legal acts referred to in subparagraphs 9.8 and 9.9 of the Requirements.

CHAPTER II REFERENCES

9. The Requirements contain references to the following legislation and international treaties:

9.1. Republic of Lithuania Law on Nuclear Energy;

9.2. Republic of Lithuania Law on Nuclear Safety;

9.3. Republic of Lithuania Law on the Management of Radioactive Waste;

9.4. Republic of Lithuania Law on Radiation Protection;

9.5. Republic of Lithuania Law on Civil Protection;

9.6. Republic of Lithuania Law on Standardisation;

9.7. Nuclear Safety Requirements BSR-1.4.1-2016 "Management System", approved by Order No. 22.3-56 of the Head of the State Nuclear Power Safety Inspectorate (hereinafter referred to as "VATESI") of 21 June 2010 approving the Nuclear Safety Requirements BSR-1.4.1-2016 "Management System";

9.8. Nuclear Safety Requirements BSR-2.1.2-2010 "General requirements for safety assurance of nuclear power plants with RBMK-1500 type reactors", approved by the Order No. 22.3-16 of the Head of VATESI of 5 February 2010 approving the Nuclear Safety Requirements BSR-2.1.2-2010 "General requirements for safety assurance of nuclear power plants with RBMK-1500 type reactors";

9.9. Nuclear Safety Requirements BSR-3.1.1-2016 "Management of spent fuel in a dry cask storage facility", approved by Order No. 22.3-59 of the Head of VATESI of 21 July 2010 approving the Nuclear Safety Requirements BSR-3.1.1-2016 "Management of spent fuel in a dry cask storage facility";

9.10. Lithuanian Hygiene Standard HN 73:2018 "Basic radiation protection standards", approved by Order No. 663 of the Minister of Health of the Republic of Lithuania of 21 December 2001 approving Lithuanian Hygiene Standard HN 73:2018 "Basic radiation protection standards";

9.11. Lithuanian Hygiene Standard HN 99:2019 "Protection of the population in the event of a nuclear or radiological accident", approved by Order No. V-1040 of the Minister of Health of the Republic of Lithuania of 7 December 2011 approving Lithuanian Hygiene Standard HN 99:2019 "Protection of the population in the event of a nuclear or radiological accident";

9.12. Technical Annexes A and B to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);

9.13. Appendix C of the Convention concerning International Carriage by Rail (COTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);

9.14. Nuclear Safety Requirements BSR-4.1.2-2019 "Requirements for documents to be submitted with the application for a licence for the transport of nuclear fuel cycle, nuclear and fissile materials", approved by Order No. 22.3-169 of the Head of VATESI on 19 July 2019 approving the

Nuclear Safety Requirements BSR-4.1.2-2019 "Requirements for documents to be submitted with the application for a licence for the transport of nuclear fuel cycle, nuclear and fissile materials".

CHAPTER III DEFINITIONS

10. For the purposes of the Requirements:

10.1. **Double contingency** shall mean a principle of fissile material process organisation and fissile material process equipment design that ensures that a self-sustained fission chain reaction can only occur in the event of two unlikely independent simultaneous fissile material process changes.

10.2. **Effective multiplication factor** (hereinafter referred to as " k_{eff} ") shall mean the ratio of the number of neutrons produced by nuclear fission in a physical system with fissile materials during a time interval to the number of neutrons lost to leakage and absorption in the system during the same time interval.

10.3. **Fissile material physical system** (hereinafter referred to as the "physical system") shall mean a model of a device or process used for processes with fissile materials, the structural elements of which are fissile materials, a neutron moderator, a neutron absorber and/or a neutron reflector, used to estimate the effective multiplication factor.

10.4. **Nuclear fission chain reaction** shall mean a sequence of nuclear fission events caused by neutrons produced in a physical system by previous nuclear fission.

10.5. **Sub-critical state** shall mean the state of a physical system where the effective multiplication factor of this system is less than 1.

10.6. **External hazards in terms of criticality safety** (hereinafter referred to as "external hazards") shall mean natural events that may occur within or outside the territory controlled by the regulated economic entity, or human events that may occur outside the territory controlled by the economic entity, that may be unrelated to the activities of the entity, and that may have an impact on the criticality safety of processes involving fissile materials.

10.7. **Inherent features of an installation** shall mean the geometric properties of an installation or parts thereof and/or the physical and/or chemical properties of the materials used in the installation or of the physical processes occurring in the installation or other properties resulting from natural phenomena, which ensure that the functions of the installation can be carried out independently of the supply of electric power, an external activation signal, and/or any other external influences.

10.8. **Critical state or criticality** shall mean the state of a physical system where the effective multiplication factor of that system is 1.

10.9. **Critical mass** shall mean the smallest mass of a fissile material at which, under certain conditions of a physical system, a self-sustained nuclear fission chain reaction can occur.

10.10. **Criticality** shall mean the ability of a physical system to reach a critical state, whether planned or unplanned.

10.11. **Criticality accident** shall mean a nuclear accident in which the fissile material has unintentionally reached a critical or supercritical state, i.e. the effective multiplication factor of the physical system associated with the material is equal to or greater than 1.

10.12. **Criticality incident** shall mean a nuclear incident in which the effective multiplication factor of a physical system exceeds 0.95, but criticality accident conditions are not reached.

10.13. **Criticality event** shall mean a criticality incident, a criticality accident or a situation that could develop into a criticality incident or a criticality accident (e.g. an identified event that, if it continues to develop, could lead to a criticality accident).

10.14. **Criticality safety** shall mean a set of legal, organisational and technical measures applied in the context of a regulated activity to prevent, mitigate and eliminate the consequences of an unplanned spontaneous fission chain reaction.

10.15. **Critical value of criticality parameter or critical value of control parameter** shall mean the threshold value of criticality safety parameters at which the state of a physical system is critical or it is not known whether the state of the system is subcritical.

10.16. **Unsafe equipment** shall mean equipment for fissile material processes that does not meet the requirements for criticality safety equipment.

10.17. **Safe equipment** shall mean equipment for fissile material processes that is incapable of generating a self-sustained fission chain reaction due to the intrinsic properties of the equipment or parts thereof.

10.18. **Criticality parameter or control parameter** shall mean the value of a physical system that changes the effective multiplication factor of that system.

10.19. **Neutron moderator** shall mean a material in which the neutron energy is effectively reduced by efficient neutron scattering and low absorption.

10.20. **Neutron reflector** shall mean a low-absorbing material in a physical system close to a neutron source that can efficiently reflect neutrons back towards the source that would leave the system if not reflected.

10.21. **Neutron absorber** shall mean a material in which neutrons are effectively absorbed without causing a fission reaction.

10.22. **Organisation** shall mean a license holder specified in subparagraphs 2.1 to 2.3 of the Requirements, carrying out the activities specified in these subparagraphs.

10.23. **Passive features** shall mean equipment based on intrinsic properties or other technical means based on gravity, natural circulation and/or other physical phenomena, as well as energy stored in rotating bodies, compressed gases and/or other means, and which are independent of the power supply, an external activation signal and/or other external influences due to these features, and whose operation or inactivity does not depend on these characteristics.

10.24. **Regulated activities** shall mean the activities involving fissile or nuclear materials carried out by the licence holders referred to in subparagraphs 2.1 to 2.4 of the Requirements, as specified in those subparagraphs or in the legal acts governing their activities.

10.25. **Principle of fail-safe** shall mean a design principle for equipment, including its software, allowing the equipment to be designed so that, in the event of a failure of the equipment, the equipment automatically transitions to a fail-safe state in response to that failure.

10.26. **Self-sustained fission reaction** shall mean a fission chain reaction in which the number of free neutrons in the physical system at any instant is equal, i.e. the effective multiplication factor is 1.

10.27. **Validation** shall mean the provision of objective evidence confirming that a product, article or other object is suitable for use as specified.

10.28. **Verification** shall mean the provision of objective evidence confirming that the requirements set for a facility have been met.

10.29. **Internal hazards** shall mean fires, floods, explosions and other events that may occur on the premises of the regulated economic entity or within the area under its control that could affect the criticality safety of processes involving fissile materials.

10.30. **Supercritical or super-critical state** shall mean the state of a physical system where its effective multiplication factor is greater than 1.

10.31. **Human error** shall mean an accidental (unintentional) incorrect operation of equipment and/or technological process and/or failure to comply with established procedures.

10.32. The terms "emergency preparedness", "nuclear facility", "physical security of a nuclear facility, a nuclear facility site, nuclear and nuclear fuel cycle materials" (hereinafter referred to as "physical security"), "nuclear accident", "nuclear incident", "nuclear fuel" and "nuclear reactor" shall have the meanings defined in the legal act referred to in subparagraph 9.1 of the Requirements.

10.33. The terms "nuclear safety", "nuclear material", "fissile material" and "nuclear facility safety analysis report" shall have the meanings defined in the legal act referred to in subparagraph 9.2 of the Requirements.

10.34. The terms "management of radioactive waste" and "radioactive waste" shall have the meanings defined in the legal act referred to in subparagraph 9.3 of the Requirements.

10.35. The terms "ionising radiation", "radiation protection", "radiological accident" and "radiological incident" shall have the meanings defined in the legal act referred to in subparagraph 9.4 of the Requirements.

10.36. The term "emergency" shall have the meaning defined in the legal act referred to in subparagraph 9.5 of the Requirements.

10.37. The terms "standard" and "practice regulations" shall have the meanings defined in the legal act referred to in subparagraph 9.6 of the Requirements.

10.38. The term "management of the organisation" shall have the meaning defined in the legal act referred to in subparagraph 9.7 of the Requirements.

10.39. The term "severe ionising radiation-related effects" shall have the meaning defined in the legal act referred to in subparagraph 9.10 of the Requirements.

10.40. The term "urgent protective action" shall have the meaning defined in the legal act referred to in subparagraph 9.11 of the Requirements.

CHAPTER IV CLASSIFICATION OF ORGANISATIONS ACCORDING TO THE QUANTITY OF NUCLEAR AND FISSILE MATERIAL HELD

11. A holder of criticality safety small quantities of nuclear and fissile materials (hereinafter referred to as the "holder of small quantities") shall be an organisation having:

11.1. not more than 100 grams of isotopes of 233-U, 235-U or plutonium, or a mixture of all of these materials;

11.2. any quantity of natural or depleted uranium or natural thorium, provided that the regulated activity does not involve the use of other fissile materials and such quantities of graphite, heavy water, beryllium and/or any other neutron moderator more effective than light water as would affect neutron moderation;

11.3. not more than 200 kilograms of natural or depleted uranium, or natural thorium if the regulated activity also involves the use of isotopes of 233-U, 235-U or plutonium, provided that the total mass of these materials does not exceed 100 grams;

11.4. any amount of fissile materials, if the activity is carried out with homogeneous materials (for example, homogeneous radioactive waste) and the safety analysis report for the nuclear facility provides evidence that a critical mass cannot be generated during the activity.

12. A holder of criticality safety medium quantities of nuclear and fissile materials (hereinafter referred to as the "holder of medium quantities") shall be an organisation that does not meet the requirements for a holder of small quantities of nuclear materials and:

12.1. has no more than 450 grams of isotopes of 233-U, 235-U or plutonium, or a mixture of all of these materials, and, in the course of its regulated activities, does not use other fissile materials and quantities of graphite, heavy water, beryllium and/or any other neutron moderator more effective than light water that would affect neutron moderation;

12.2. whose available fissile materials do not exceed 80% of the critical mass of all fissile materials in the most efficient neutron moderator, neutron reflector and maximum k_{eff} physical system geometry.

13. A holder of criticality safety large quantities of nuclear and fissile materials (hereafter referred to as the "holder of large quantities") shall be an organisation that does not meet the criteria set forth in paragraphs 11 and 12 of the Requirements.

CHAPTER V MAIN MEASURES TAKEN TO ENSURE CRITICALITY SAFETY

14. To ensure criticality safety in regulated activities, the following shall be in place:

14.1. the limit values for criticality safety parameters and the conditions for the safe regulated activity (hereinafter referred to as the "limits and conditions for the regulated activity") under which the regulated activity is controlled;

14.2. technical and organisational measures implemented to prevent criticality events, including measures:

14.2.1. to prevent the neutron moderator and neutron reflector from reaching fissile materials;

14.2.2. to prevent the uncontrolled generation, accumulation, transfer, transport, entry into the neutron moderator or the neutron reflector of fissile materials;

14.2.3. ensuring the effectiveness of neutron absorbers if these absorbers are used to ensure the criticality safety of the regulated activity;

14.3. providing for technical and organisational measures to mitigate and eliminate the consequences of criticality accidents.

CHAPTER VI MANAGEMENT OF CRITICALITY SAFETY

15. The management of criticality safety shall be part of an organisation's management system.

16. Management of the organisation shall establish and document procedures governing the use of nuclear and fissile materials in regulated activities. The documents provided for in Chapter X shall form part of the implementation of these procedures.

17. Management of the holder of large quantities shall establish and document the procedures under which employees and other persons are permitted to carry out work related to regulated activities.

18. Management of the organisation shall ensure that employees and other persons carrying out work related to the regulated activity are familiar with the documents governing the procedures referred to in paragraphs 16 and 17 of the Requirements and any amendments hereto.

19. Management of the organisation shall designate an employee responsible for criticality safety within the organisation (hereinafter referred to as the "responsible employee").

20. Management of the organisation shall ensure that the responsible employee is familiar with the Requirements and has scientific and engineering knowledge of criticality safety (e.g. acquired through self-study or refresher training), and that they update this knowledge at the intervals specified in the organisation's management system documents.

21. Management of holders of medium and large quantities shall ensure that management personnel whose work is related to regulated activities, and personnel performing work related to those activities and whose errors could lead to criticality incidents or criticality accidents, are familiar with the Requirements, have scientific and engineering knowledge of criticality safety (e.g. acquired through self-learning or refresher training), and keep it up to date with the periodicity specified in the organisation's management system documents.

22. Management of the organisation shall assign responsibility and authority to the responsible employee to:

22.1. control compliance with the procedures set out in paragraphs 16 and 17 of the Requirements;

22.2. control that the personnel referred to in paragraph 21 of the Requirements are provided with the knowledge referred to in paragraph 21 of the Requirements;

22.3. inspect the condition of equipment, laboratory instruments and/or materials used in processes involving fissile materials in regulated activities;

22.4. assess and provide conclusions on changes to the regulated activities, including changes to equipment, laboratory instruments and/or materials used in the regulated activities, from the point of view of criticality safety;

22.5. check the status of emergency preparedness measures, including the criticality event detection system, related to regulated activities;

22.6. organise a periodic review of the criticality safety analysis in accordance with paragraph 75 or 76 of the Requirements, as appropriate;

22.7. report to management of the organisation deviations from the normal regulated activities;

22.8. make proposals to management of the organisation for improving criticality safety.

23. A responsible employee or a substitute employee complying with the provisions of paragraph 21 of the Requirements shall be present at all times during working hours in the organisation of the holder of large quantities, unless the regulated activity is not being carried out and physical barriers and/or physical security measures prevent it from being carried out (e.g. equipment, laboratory instruments and/or materials required for the regulated activity are locked, or the operation of the equipment is inhibited).

24. Management of the organisation shall ensure that changes to the regulated activities, including changes to equipment, laboratory instruments and/or materials and procedures, are subject to a criticality safety assessment and are only implemented after such assessment.

25. Holders of large quantities shall ensure that sufficient human and technical resources are available to deal with criticality incidents and criticality accidents.

26. Criticality safety training shall be included in the training programmes of holders of licences referred to in Article 22(1)(1) to (5) of the legal act referred to in subparagraph 9.2 of the Requirements and of holders of licences referred to in Article 22(1)(7) of the legal act referred to in subparagraph 9.2 of the Requirements who are holders of large quantities.

CHAPTER VII ASSURANCE OF SUB-CRITICAL STATE

27. The regulated activity shall be organised and conducted in such a way that the k_{eff} of the physical systems involved in the regulated activity, under normal conditions of operation of the regulated activity, and in the event of radiological incidents and accidents, equipment failures and human error, other than criticality incidents and criticality accidents, which are analysed in the criticality safety case, is not greater than 0.95, after taking into account tolerances and uncertainties.

28. Regulated activities shall be carried out in compliance with the principle of double contingency.

29. Technical and/or organisational preventive measures shall be in place to prevent criticality incidents and criticality accidents in the course of regulated activities.

30. The sub-critical state of the physical system shall be achieved by the following means (one or a combination of these):

30.1. by limiting the mass of fissile materials in the physical system;

30.2. by setting limits on the isotopic composition (enrichment) of fissile materials;

30.3. by determining the geometrical characteristics of the physical system and/or its structural elements;

30.4. by using neutron absorbers;

30.5. by avoiding neutron moderator;

30.6. by avoiding neutron reflector.

31. In order to ensure the sub-critical state of the physical system, priority shall be given to the means referred to in subparagraphs 30.1 and 30.2 of the Requirements. If it is not possible or appropriate to implement such means, priority shall be given to the means referred to in paragraph 30.3 of the Requirements.

32. The criticality safety assurance of the regulated activity shall be validated by a criticality safety analysis, which is regulated in Chapter IX of the Requirements.

**CHAPTER VIII
NUCLEAR SAFETY REQUIREMENTS FOR EQUIPMENT USED IN OR RELATED TO
REGULATED ACTIVITIES**

**SECTION ONE
CRITICALITY SAFETY REQUIREMENTS FOR EQUIPMENT USED IN OR RELATED
TO REGULATED ACTIVITIES**

33. When designing or acquiring equipment and parts thereof, used in processes involving fissile materials, the design of the arrangement of such equipment shall aim at:

33.1. giving priority to safe equipment;

33.2. prohibiting or restricting the presence of persons in places where a self-sustaining fission chain reaction may occur and where they may be exposed to ionising radiation during the reaction.

34. In order to achieve criticality safety aims during the normal course of a regulated activity and in the event of a deviation from the normal course of the regulated activity, criticality safety hazardous equipment (hereafter referred to as "hazardous equipment") shall be designed and operated using the principle of defence in depth.

35. Where the use of hazardous equipment is foreseen, priority shall be given to equipment that complies with the principle of fail-safe.

36. Regulated activities involving hazardous equipment may only be carried out in compliance with criticality safety parameter limits based on a criticality safety analysis.

37. Criticality safety parameters in hazardous equipment shall be maintained within specified limits by implementing the following measures:

37.1. passive measures;

37.2. automatically activated technical criticality safety measures, including human error blocking equipment;

37.3. the measures specified in the organisation's management system documents (e.g. manual activation of active technical criticality safety measures based on readings from measuring instruments or audible or visual signals).

38. The measures referred to in subparagraphs 37.1 to 37.3 of the Requirements are listed in the order of higher to lower priority. If the sub-critical state cannot be achieved by implementing higher priority measures, subsequent measures shall be applied.

39. Where a criticality incident or criticality accident requires immediate and/or reliable response action to prevent it, and manual action is not feasible given human capability and capacity, equipment shall provide for automatic activation of technical criticality safety measures. In other cases, automatic activation can be not foreseen, but in this case the management system documents shall specify the implementation of the response action, taking into account the maximum time that may elapse between the onset of an event that could lead to a criticality incident or a criticality accident and the identification of the event and the implementation of the response action, taking into account the human capability of the person, the conditions of the working environment resulting from such an incident and the possible incorrect actions of the personnel due to a possible misjudgement of the situation.

40. Criticality safety in hazardous equipment shall be ensured by automated technical criticality safety measures, using the reservation principle and by organisational measures.

41. The technical and organisational measures of controlling the physical system k_{eff} associated with the equipment shall take into account the errors due to the measuring instruments and the control methodology.

42. The entry into or near the equipment of a neutron moderator and/or neutron reflector that could affect the physical system k_{eff} associated with the equipment shall be prevented.

43. The regulated activity shall aim at being carried out in equipment that is not capable of forming accumulations of fissile materials, including accumulations resulting from chemical phenomena (such as deposition) that could lead to criticality incidents or criticality accidents. If there is a possibility for fissile materials to form such accumulations, technical and/or organisational

measures shall be provided for their detection in the equipment and the actions and measures to be taken to prevent a criticality accident or incident should such accumulations be detected.

44. The regulated activity shall aim at being carried out with equipment that cannot release fissile materials into the environment where their accumulation could lead to criticality incidents or criticality accidents. Where there is a possibility of fissile materials spreading outside the equipment, technical and/or organisational measures shall be provided for detecting such accumulations outside the equipment and for the corrective actions and measures to be taken to prevent a criticality accident or incident should such accumulations be detected.

45. Holders of medium and large quantities shall assess the impact of these measures on criticality safety before installing fire safety engineering measures on the site of the regulated activity and establishing fire safety organisational measures. The use of fire safety equipment, the use or incorrect operation of which would increase the likelihood of criticality incidents or criticality accidents, shall be prohibited.

SECTION TWO OTHER NUCLEAR SAFETY REQUIREMENTS FOR EQUIPMENT USED IN OR RELATED TO REGULATED ACTIVITIES

46. Equipment where gases may accumulate (e.g. fissile material containers) shall be provided with an automatic pressure relief system. Ventilation of the pressure relief system shall be provided to prevent the release of radionuclides or toxic substances into the environment.

47. Equipment where an explosive gas mixture may occur shall be ventilated to prevent the formation of such a mixture.

48. If the regulated activity involves the use or generation of radioactive materials in such quantities that the heat release may cause the disintegration of physical barriers that contain the radionuclides, or the release of radionuclides into the environment, provision shall be made for the cooling of such material.

CHAPTER IX CRITICALITY SAFETY ANALYSIS

49. Holders of small quantities shall not be required to carry out a criticality safety analysis for regulated activities. For holders of licences referred to in Article 22(6) of the legal act referred to in subparagraph 9.2 of the Requirements, a criticality safety analysis shall only be mandatory for regulated activities in the case referred to in subparagraph 5.3 of the legal act referred to in subparagraph 9.14 of the Requirements.

SECTION ONE OBJECTIVES OF THE CRITICALITY SAFETY ANALYSIS

50. The criticality safety analysis shall involve:

50.1. identification of potential scenarios for criticality incidents and criticality accidents;

50.2. establishment of the physical system k_{eff} during normal operation of the regulated activity and in the event of criticality incidents;

50.3. establishment and justification of contingency of criticality safety parameters up to critical values of criticality safety parameters under normal operation of the regulated activity and in the event of criticality incidents, and justified limits and conditions for operation;

50.4. establishment of conditions under which criticality accidents may occur, and their nature and course;

50.5. demonstration that all measures are in place to ensure that the likelihood of criticality incidents and criticality accidents is as low as possible;

50.6. justification of measures ensuring sub-critical state and demonstrated that such measures remain effective at all times in the regulated activity, including changes in the characteristics of measures ensuring sub-critical state due to ageing;

50.7. identification and justification of the effectiveness of the technical and organisational measures for the prevention of criticality incidents and criticality accidents.

SECTION TWO

IDENTIFICATION OF POSSIBLE SCENARIOS FOR CRITICALITY INCIDENTS AND CRITICALITY ACCIDENTS

Identification of potential scenarios for criticality incidents and criticality accidents in the case of the licences referred to in Article 22(1)(1)(1) to (5) and (7) of the legal act referred to in subparagraph 9.2 of the Requirements

51. Potential scenarios for criticality incidents and criticality accidents shall be identified by assessing the possible failures of equipment and parts thereof, human error, internal and external hazards that may lead to an increase in k_{eff} of the physical system due to:

51.1. a change in the physical and/or chemical properties of the materials used in the regulated activity, including changes in the isotopic composition and concentration of fissile materials;

51.2. changes in the geometry of the equipment and laboratory instruments used in the regulated activity (e.g. a solution with fissile materials leaking into a container with an unfavourable shape (increasing k_{eff}));

51.3. a change in the properties of the neutron moderator;

51.4. a change in the properties of the neutron absorber (e.g. geometric displacement of the neutron absorber, transfer, changes in isotopic composition);

51.5. a change in the properties of the neutron reflector.

52. Experience from the same or similar regulated activities shall be used to identify potential scenarios for criticality incidents and criticality accidents.

53. All events referred to in paragraph 51 of the Requirements shall be detected by:

53.1. an assessment of potential faults in the equipment used in the regulated activity;

53.2. an assessment of human error (e.g. in the operation of equipment, in the performance of the steps set out in the procedures) that may occur in the course of the regulated activity;

53.3. an assessment of internal and external hazards;

53.4. an assessment of the potential for two or more than two simultaneous equipment failures arising from the same single event or cause, together with an assessment of the potential for human error.

54. Spills of fissile materials, and errors in the transfer/transport of fissile materials and their consequences, shall be assessed as potential events that could lead to criticality incidents and criticality accidents.

55. In identifying potential criticality incidents and criticality accidents, the following internal hazards shall be assessed:

55.1. internal fires and fire fighting;

55.2. internal explosions;

55.3. internal flooding;

55.4. internal missiles;

55.5. structural collapse;

55.6. falling objects;

55.7. liquid and gas leaks;

55.8. electromagnetic interference.

56. In identifying potential criticality incidents and criticality accidents, the following external hazards shall be considered:

56.1. seismic events and other geological phenomena;

- 56.2. meteorological phenomena;
- 56.3. external flooding (e.g. floods or flooding due to extreme precipitation);
- 56.4. external fires;
- 56.5. explosions caused by the activities of surrounding civil installations;
- 56.6. traffic accidents.

57. The assessments referred to in paragraphs 53 to 56 of the Requirements may be carried out by expert judgment. If the expert judgment does not provide objective evidence that the hazard in question will not lead to an increase in k_{eff} , its impact shall be analysed using deterministic methods (e.g. structural analysis), and in addition probabilistic methods may be used.

58. Equipment and component failures, human error, internal and external hazards with a frequency of less than 1 event per 10000000 years may be not taken into account.

Identification of possible scenarios for criticality incidents and criticality accidents in the case of the licence referred to in Article 22(1)(6) of the legal act referred to in subparagraph 9.2 of the Requirements

58¹. Potential criticality incident and criticality accident scenarios shall be identified by assessing potential failures of equipment and parts thereof used for the transport of fissile materials, human error, traffic accidents or extreme transport conditions that could lead to an increase in k_{eff} of the physical system, in accordance with subsection 6.4.11.1 of the legal act referred to in subparagraph 9.12 of the Requirements, or subsection 6.4.11.1 of the legal act referred to in subparagraph 9.13 of the Requirements, depending on the mode of transport.

SECTION THREE ASSESSMENT OF k_{eff} OF THE PHYSICAL SYSTEM

59. The assessment of k_{eff} of the physical system shall be carried out under normal conditions of operation of the regulated activity, including intermediate processes (e.g. transfer of fissile materials between installations) and in the case of events determined in accordance with Chapter IX, Section Two.

60. The criticality safety analysis shall be carried out using a verified and validated methodology.

61. Criticality safety analysis shall be carried out with conservative assumptions regarding:

- 61.1. the isotopic composition and concentration of fissile materials;
- 61.2. the properties of the neutron moderators in the physical system;
- 61.3. the properties of the neutron absorber in the physical system;
- 61.4. the properties of the neutron reflector.

62. The criticality safety analysis under the normal operating conditions of the regulated activity shall analyse the physical states of the system with the highest k_{eff} . For this purpose, the states, chemical and isotopic compositions of the materials in the physical system shall be chosen to ensure maximum k_{eff} while meeting the aims of the regulated activity and the specifications of the equipment and materials used in the regulated activity.

63. Neutron absorbers that can be removed may be considered as passive criticality safety measures in the criticality safety analysis.

64. For the purpose of the criticality safety analysis of unused nuclear fuel, all nuclear fuel, including tolerances, shall be assumed to be at the maximum enrichment specified in the manufacturer's documentation, without burnable neutron absorbers.

64¹. For the purpose of the criticality safety analysis of spent fuel, all nuclear fuel, including tolerances, shall be considered as existing spent fuel at burnup and enrichment that would meet the maximum k_{eff} conditions. In the case of spent fuel from a light water nuclear reactor, the maximum k_{eff} conditions shall be assumed to be met by zero burnup nuclear fuel, i.e. the criticality safety analysis shall be carried out in accordance with paragraph 64 of the Requirements. The reduction of the quantity of fissile materials and/or burnable neutron absorber or the increased intensity of neutron

absorption due to nuclear fuel burnup shall only be included in the criticality safety analysis after the data on the validation of the nuclear fuel burnup assessment method using experimental data have been provided.

65. If the criticality safety of a regulated activity is based on data from other studies, the applicability of these data shall be demonstrated.

66. The criticality safety analysis shall take into account changes in k_{eff} due to temperature.

67. The criticality safety analysis shall consider errors and uncertainties.

68. All assumptions used in the criticality safety analysis that may affect the results of this analysis shall be justified.

69. When performing k_{eff} calculations of a physical system using a computer programme, quality control of the input data and the results of the calculations shall be assured (e.g. it shall be shown that the results of the Monte Carlo calculations converged).

70. The justification of the limits and conditions for the performance of the activity shall take into account the human capability and/or the capability of the equipment to perform the actions that would have prevented the criticality incident and the criticality accident.

71. In accordance with Article 30(3) of the legal act referred to in subparagraph 9.2 of the Requirements, in the context of the independent verification of the results of the nuclear safety analysis and justification, holders of large quantities and holders of nuclear safety certificates referred to Article 22(1)(6) of the legal act referred to in subparagraph 9.2 of the Requirements shall be required to carry out an independent nuclear safety assessment of k_{eff} the physical system using a different criticality safety analysis methodology (e.g. different software and nuclear data libraries) from that used for the criticality safety analysis of the regulated activity.

SECTION FOUR DOCUMENTATION OF CRITICALITY SAFETY ANALYSIS

72. The criticality safety analysis shall be documented in such a way that it can be independently assessed. Documentation of the criticality safety analysis shall include:

72.1. an introduction, which shall contain brief information on the activities of the economic entity for which the criticality safety analysis is being carried out;

72.2. the documentation and acceptance criteria used in the analysis:

72.2.1. a list of legal acts governing criticality safety;

72.2.2. a list of standards and practices that the organisation plans to apply in the area of criticality safety;

72.2.3. the acceptability criteria, principles of criticality safety and other requirements applied by the organisation to demonstrate the acceptability of the planned regulated activity, which are not set out in the documents referred to in subparagraphs 72.2.1 and 72.2.2 of the Requirements;

72.2.4. documents providing information or describing the scientific research work on which the criticality safety of the regulated activity is based, if the criticality safety is based on data from other studies;

72.2.5. documents describing the scientific and research work on which the verification and validation of the criticality safety analysis method is based, if the criticality safety analysis method is verified and validated using data from other studies;

72.3. input data, including the chemical and isotopic composition and physical state of the materials used in the regulated activity and of the materials that make up the equipment and/or laboratory instruments used in the regulated activity;

72.4. a description of the compliance of the conduct of the regulated activity with the principle of double contingency and the other principles of prevention of criticality incidents and criticality accidents set out in the Requirements, the purpose of which is to demonstrate that all the measures are in place to ensure that the likelihood of a criticality incident or a criticality accident is kept as low as possible;

72.5. a methodology for identifying potential criticality incident and criticality accident scenarios;

72.6. a list of conditions for the normal operation of the regulated activity for which criticality safety must be examined;

72.7. a description and list of potential criticality incidents and criticality accidents;

72.8. if the criticality safety analysis is carried out by means of calculations using computer programmes:

72.8.1. a description of the nuclear data libraries;

72.8.2. a description of the physical system (model);

72.8.3. a description of the method of criticality safety analysis, including the computer programmes used for the analysis. It shall also specify the software, hardware and operating system used;

72.8.4. data on the verification and validation of the criticality safety analysis method, including the computer programmes used for the analysis;

72.9. if the criticality safety analysis is based on data from other studies (e.g. scientific articles or manuals), a justification of the applicability of the criticality safety analysis method;

72.10. an assessment of the potential consequences of criticality incidents and criticality accidents;

72.11. evidence of quality assurance through criticality safety analysis;

72.12. the results of the criticality safety analysis;

72.13. conclusions on the compliance of the criticality safety of the regulated activity with the provisions of the documents referred to in subparagraph 72.2 of the Requirements and the acceptability criteria.

73. Criticality safety analysis shall be documented in:

73.1. the safety analysis report for the nuclear facility, if the organisation is the holder of, or applicant for, a licence referred to in Article 22(1)(1) to (4) of the legal act referred to in subparagraph 9.2 of the Requirements;

73.2. the operational safety assessment report if the organisation is the holder of, or applicant for, a licence referred to in Article 22(1)(5) and (7) of the legal act referred to in subparagraph 9.2 of the Requirements;

73.3. the operational safety assessment report if the organisation is the holder of, or applicant for, a licence referred to in Article 22(1)(6) of the legal act referred to in subparagraph 9.2 of the Requirements, in accordance with the legal acts referred to in subparagraph 9.14 of the Requirements.

SECTION FIVE UPDATING OF THE CRITICALITY ANALYSIS

74. The criticality safety analysis shall be updated when changes are made to the processes of the regulated activity or to the equipment, laboratory instruments or materials used in the regulated activity. In the case of a licence referred to in Article 22(1)(5) and (7) of the legal act referred to in subparagraph 9.2 of the Requirements, the criticality safety analysis shall be updated if, in accordance with paragraph 24 of the Requirements, the assessment of these changes would indicate that the regulated activity is not in conformity with the existing analysis.

75. The holder of a licence referred to in Article 22(1)(1) to (5) of the legal act referred to in subparagraph 9.2 of the Requirements shall carry out a periodic review of the criticality safety of the regulated activity by means of the periodic safety analysis and justification referred to in Article 32(7) of the legal act referred to in subparagraph 9.2 of the Requirements.

76. Holders of the licences referred to in Article 22(1)(6) and (7) of the legal act referred to in subparagraph 9.2 of the Requirements shall review the criticality safety analysis contained in the operational safety assessment report at least every 10 years, and if they identify any non-compliances of the regulated activities with that analysis, including any non-compliances that may arise in the future, the operational safety assessment report shall be updated. If this license holder has reviewed

the criticality safety analysis presented in the operational safety assessment report and has not identified the need to update the criticality safety analysis, such review shall be documented and the conclusion that no update of the criticality safety analysis is required, together with the documented information supporting this conclusion, shall be agreed with VATESI. The Head of VATESI shall take a decision on the admissibility of this conclusion in accordance with the deadlines set out in Article 34(2) of the legal act referred to in subparagraph 9.2 of the Requirements. This analysis shall be considered acceptable if the information contained therein is consistent with nuclear safety and radiation protection legislation, nuclear safety normative technical documents and the facts.

CHAPTER X CARRYING OUT REGULATED ACTIVITIES

SECTION ONE LIMITS AND CONDITIONS FOR CARRYING OUT ACTIVITIES

77. Holders of medium and large quantities shall establish and document the limits and conditions for the performance of their regulated activities, based on the designs of the installations used for the regulated activities, the documents of the manufacturers of those installations and the safety assessment report, in order to ensure criticality safety. Operational limits and conditions shall be set in direct accordance with k_{eff} of the physical system and/or by setting limit values for criticality safety parameters, with a contingency up to their critical value.

78. The criticality safety parameters used to define the limits and conditions for the performance of an activity shall be selected taking into account the nature of the regulated activity. These parameters shall be, for example:

78.1. the geometric shapes and geometric dimensions of the physical system and/or its structural elements (for example, the shape and dimensions of the lattice arrangement of elements containing fissile materials);

78.2. the mass of fissile materials;

78.3. the concentration of fissile materials (for example, in a homogeneous solution);

78.4. the amount of neutron moderator;

78.5. the isotopic composition of the fissile material;

78.6. the chemical composition of the fissile material;

78.7. the density of the fissile material;

78.8. the position, geometric shapes and geometric sizes of the neutron reflector;

78.9. the position, geometric shapes and geometric sizes of the neutron absorber;

78.10. parameters describing the integrity of the neutron absorber;

78.11. the distance between individual containers of fissile materials.

SECTION TWO PROCEDURES FOR CARRYING OUT REGULATED ACTIVITIES

79. Procedures for regulated activities and amendments thereto shall be implemented in the organisation in accordance with the procedures established by the organisation, through the preparation of procedure descriptions or amendments thereto, their verification and validation, and the organisation of induction, briefings, training, drills for employees and other persons planning to carry out the regulated activity.

80. Regulated activities shall be carried out in accordance with the approved descriptions of procedures of the organisation. These descriptions shall be part of the organisation's management system documents.

81. The descriptions of procedures referred to in paragraph 79 of the Requirements shall be drawn up in accordance with the normative technical documents on nuclear safety, the designs of the installations used for the regulated activity, the documents of the manufacturers of those installations,

the specifications of the laboratory instruments and materials used for the regulated activity, the safety assessment report for the activity, and the limits and conditions of the activity.

82. The procedure descriptions shall be designed to enable a qualified staff member to carry out the actions specified therein without direct supervision.

83. The descriptions of procedures referred to in paragraph 79 of the Requirements shall include:

83.1. a description of the fissile materials used, including the quantity, isotopic composition and physico-chemical properties the fissile materials;

83.2. rules for the marking of fissile materials, neutron moderators, neutron reflectors and laboratory materials used in the regulated activities;

83.3. rules on the marking of premises where the regulated activities are carried out;

83.4. a definition and description of the normal process for carrying out the regulated activity, including instructions for the use of the equipment employed in the regulated activity, laboratory instruments and materials;

83.5. an indication of the links between the procedure descriptions and which procedure description is to be applied and under what conditions in carrying out the regulated activity;

83.6. a description of the guidelines for the detection and identification of faults in regulated activity processes and criticality safety equipment;

83.7. a description of the actions to be taken in deviation from the normal performance of the regulated activity;

83.8. a description of the actions to be taken in case of a criticality event;

83.9. a description of the measures and actions to return the regulated activity to a known safe state without delay if the regulated activity results in a state not foreseen in the safety assessment report;

83.10. a description of the procedure for inspecting the equipment and measures used for the regulated activities, for the prevention of criticality incidents and criticality accidents and for emergency preparedness, and the documentation of the results of these inspections.

84. The descriptions of the procedures referred to in paragraph 79 of the Requirements shall be drawn up in accordance with the principle of proportionality in such a way as to ensure:

84.1. fissile material accounting for criticality safety assurance purposes;

84.2. compliance of the performance of the regulated activity with the principle double contingency principle;

84.3. the prevention of human error in the regulated activities;

84.4. the prevention of the dispersion of fissile materials to locations not foreseen by the regulated activity under normal conditions of its operation;

84.5. the prevention of improper handling, transport and storage of fissile materials.

85. The descriptions of procedures referred to in paragraph 79 of the Requirements shall include a requirement to report deviations from the normal performance of the regulated activity to the responsible person referred to in paragraph 19 of the Requirements and to management of the organisation.

86. The procedure descriptions referred to in paragraph 79 of the Requirements shall be verified and validated in accordance with procedures established by the organisation. Validation of procedures should be carried out to be as close as possible to the actual conditions for which the procedures are intended, without having a significant adverse effect on the assurance of criticality and radiation protection (e.g. by analysing draft procedure descriptions for several staff members, by checking the adequacy of the procedure descriptions using simulants, by conducting training, equipment tests and exercises, and by evaluating the experience of the regulated activity).

87. Changes to the descriptions of procedures shall be approved by the organisation and verified and validated in accordance with paragraph 86 of the Requirements.

SECTION THREE OTHER PROVISIONS FOR CARRYING OUT REGULATED ACTIVITIES

88. Processes involving fissile materials may only be carried out using equipment specified in the criticality safety analysis documents.

89. For processes involving fissile materials, only laboratory instruments and materials that are specified in the criticality safety analysis documents may be used, or the specifications of those instruments and materials may not conflict with the information provided in the criticality safety analysis documents.

90. Measuring instruments related to the control of criticality safety parameters shall be calibrated, verified and periodically checked (calibrated) in accordance with the procedures established by the organisation according to the documents of the manufacturer of these instruments.

91. Where computer programmes are used for criticality safety control, they shall be verified and validated and the correctness of the calculation results shall be periodically verified in the course of the regulated activity. The period for verifying the correctness of the calculation results shall be determined by the organisation, based on assumptions about the conditions under which the calculations are likely to produce incorrect results. Changes to these computer programmes shall be verified and validated.

92. Before transferring fissile materials from one installation to another, it shall be ensured that the transfer is within the limits and conditions of the activity (for example, if the regulated activity involves transferring fissile materials from an installation to an empty container, it shall be ensured that the container does not contain fissile materials or a neutron moderator).

93. Access to premises where fissile materials are handled shall be restricted for radiation protection and emergency preparedness purposes.

94. After changes have been made to the processes of the regulated activity and/or to the equipment used in the regulated activity, the regulated activity may only be continued after it has been ascertained, in accordance with the procedures established by the organisation (e.g. after testing), that the regulated activity can be carried out in accordance with the aim of the regulated activity and the design and/or manufacturer's documents for the equipment used in the regulated activity, within the limits of the provisions of the nuclear safety and radiation protection normative technical documents, and in accordance with the criticality safety analysis and the limits and conditions for carrying out the regulated activity.

95. The organisation shall conduct periodic inspections of the performance of regulated activities, including inspections of passive measures, to demonstrate that all equipment, laboratory instruments and materials used in the regulated activities are in compliance with the criticality safety analysis, and that measures to prevent criticality incidents and criticality accidents are effective. The frequency of inspections shall be determined by the organisation on the basis of information provided by the manufacturers of the equipment used for the regulated activity, laboratory instruments and materials, and the experience of the regulated activity. Inspections shall also check for changes in equipment, laboratory instruments and materials due to ageing and assess their impact on criticality safety (e.g. whether outdated chemical substances may lead to unacceptable fissile material accumulations due to deposition). The results of inspections shall be reviewed by the organisation and corrective measures shall be applied if non-conformities are found with the legal acts governing the regulated activity, the nuclear safety normative technical documents, the design documents of the equipment, the limits and conditions of the regulated activity, the manufacturer's documents for the laboratory instruments and materials, the criticality safety analysis documents, and the management system documents. Inspections, their results and the corrective measures implemented shall be documented.

CHAPTER XI CRITICALITY EVENT DETECTION AND PREVENTION SYSTEMS

96. Holders of large quantities shall install a critical event detection system (hereinafter referred to as the "CES") at the sites of regulated activities. The CES shall not be required for storage facilities for fresh uranium nuclear fuel, provided that the nuclear fuel is handled only in connection with the storage of the fuel and that the enrichment of the fuel does not exceed 5 per cent.

97. The CES shall be designed to generate an audible warning signal upon the occurrence of the least significant criticality event. A visual warning signal shall also be provided in premises where the noise level is, or is likely to be, such that occupants may not hear the audible warning. It is recommended that the least significant criticality event is a criticality event with an absorbed dose of 0.2 Gy within two metres of the event within 60 seconds.

98. The audible and visual warning signals of the CES shall be generated in such a way that all persons to be evacuated are alerted (e.g. the audible warning signal shall be audible in all rooms from which persons are to be evacuated).

99. The audio and visual warning signals generated by the CES shall be different from other signals used in emergency management (e.g. fires).

100. The audio and visual warning signals generated by CES shall be such that they can be used in emergency preparedness measures.

101. Visual warning signals (signs) shall be provided at the entrances to premises where a criticality event is likely to occur to warn of the fact and location of a criticality event in case the CES has been activated.

102. Visual warning signals (signs) shall be provided on the building where a criticality event may occur to warn of the location of the criticality event in case the CES has been activated.

103. The CES shall be designed in such a way that the warning signals it generates can only be deactivated manually.

104. Provision shall be made for manual activation of the warning signals of the CES.

105. Means shall be provided, as a separate measure or as part of the CES, to measure the radiation dose rate in evacuated spaces after the CES has been triggered.

106. The CES shall have at least two independent sensors. Sensors shall be placed in rooms to avoid shielding (obstructions between the area of a potential event and the sensor).

107. The sensors of the CES shall be calibrated.

108. The CES shall have a back-up power source to ensure the operation of the CES in the event of loss of the main power supply.

109. The CES shall be seismically qualified.

110. The CES shall be designed to indicate by audible and/or visual signals if the system is inoperative.

111. The storage facility for spent fuel shall be equipped with drainage systems to ensure that the storage area is not flooded with water or shall be equipped with a storage water flood detection alarm and organisational measures to be implemented in the event of the alarm being triggered.

112. The operation of the water flood detection alarms for the CES and the unused nuclear fuel storage facility shall be subject to periodic testing in accordance with procedures established by the organisation and drawn up in accordance with the manufacturer's documentation.

113. The drainage systems of the unused fuel storage facility, if installed for the purpose of preventing criticality events, shall be subject to periodic inspections in accordance with procedures established by the organisation, based on assumptions as to when the systems may fail.

CHAPTER XII COMMENCEMENT OF REGULATED ACTIVITIES

114. In the case of licence holders and applicants referred to in Article 22(1)(1) to (3) of the legal act referred to in subparagraph 9.2 of the Requirements, the regulated activities shall be commenced in accordance with the procedures set out in the programme of commissioning of the nuclear installation.

115. In the case of licence holders and applicants referred to in Article 22(1)(5) of the legal act referred to in subparagraph 9.2 of the Requirements, the regulated activities shall commence in accordance with the procedures laid down in the disposal facility closure plan.

116. In the case of licence holders and applicants referred to in Article 22(1)(7) of the legal act referred to in subparagraph 9.2 of the Requirements, the organisation shall establish, in accordance with this paragraph and paragraphs 117 to 118 of the Requirements, the procedures for the

commencement of the regulated activity. The purpose of this procedure shall be to ensure that the regulated activity can be carried out in accordance with its purpose and with the design and/or manufacturer's documents for the equipment used in the regulated activity, without prejudice to the provisions of the normative technical documents on nuclear safety, and in accordance with the safety assessment report and the limits and conditions for carrying out the regulated activity.

117. The procedure specified in paragraph 116 of the Requirements shall include:

117.1. inspection of equipment used in regulated activities, including radiation control and criticality safety parameter measurement instruments;

117.2. verification (e.g. inspection of documents used in the activity, inspection of workplaces) and validation (e.g. tests without fissile material, with fissile materials, exercises, control measurements of radiation dose rate and criticality safety parameters) of the processes of the regulated activity;

117.3. verification and testing of the adequacy of emergency preparedness measures, including the adequacy of the CES related to the regulated activities.

118. The regulated activity may only commence if the results of the actions referred to in subparagraphs 117.1 to 117.3 of the Requirements are satisfactory. These results shall be considered acceptable when it is ascertained that the regulated activity can be carried out in accordance with its aim and with the design and/or manufacturer's documents for the equipment used in the regulated activity, without prejudice to the provisions of the normative technical documents on nuclear safety, in accordance with the information provided in the safety assessment report, and in accordance with the limits and conditions for carrying out the regulated activity.

119. The holder of large quantities, if it is the holder of a licence referred to in Article 22(1)(7) of the legal act referred to in subparagraph 9.2 of the Requirements, shall, before commencing the regulated activity, coordinate with VATESI the documents describing the procedure referred to in paragraph 116 of the Requirements. The Head of VATESI shall take a decision on the acceptability of these documents in accordance with the deadlines referred to in Article 34(2) of the legal act referred to in subparagraph 9.2 of the Requirements. These documents shall be considered acceptable if the information contained therein is consistent with the legal acts governing nuclear safety and radiation protection, the normative technical documents on nuclear safety and the objective data (facts) relating to the regulated activity.

CHAPTER XIII EMERGENCY PREPAREDNESS

SECTION ONE GENERAL PROVISIONS

120. The organisation shall develop technical and organisational emergency preparedness measures and emergency preparedness documents that comply with the provisions of the legal act referred to in subparagraph 9.10 of the Requirements for emergency preparedness and the provisions of this Chapter for the management and elimination of emergencies related to regulated activities.

121. The use of emergency preparedness measures shall be documented in accordance with procedures established by management of the organisation.

122. The adequacy of technical and organisational emergency preparedness measures, including escape routes and their markings, shall be checked at a frequency specified in the organisation's management system documents, including during drills, in accordance with the procedures established by management of the organisation.

SECTION TWO EMERGENCY PREPAREDNESS CATEGORY

123. The organisation carrying out a regulated activity other than spent fuel storage shall determine the emergency preparedness category of that activity in accordance with the following criteria:

123.1. the regulated activity shall be classified as Emergency Preparedness Category II if it meets at least one of the following criteria:

123.1.1. the regulated activity is likely to result in a spontaneous fission chain reaction and the distance from the area of the criticality event to the boundary of the organisation's controlled area is less than 0.5 kilometre;

123.1.2. the amount of radionuclides used in the regulated activity, the physical and chemical state of the radionuclides and/or the energy generated by the regulated activity mean that in the event of a criticality accident or radiological incident or radiological accident, emergency protective action may need to be taken outside the organisation's area of control;

123.1.3. the regulated activity uses radionuclides such that the A/D_2 ratio, calculated in accordance with the legal act referred to in subparagraph 9.11 of the Requirements, is ≥ 100 , assuming that in the event of a criticality accident or a radiological incident or radiological accident 10 per cent of the amount of radionuclides used in the regulated activity will be released into the environment;

123.2. the regulated activity shall be classified as Emergency Preparedness Category III if it meets at least one of the following criteria:

123.2.1. the regulated activity is likely to result in a spontaneous fission chain reaction and the distance from the area of the criticality event to the boundary of the organisation's controlled area is greater than 0.5 kilometres;

123.2.2. the failure of radiation suppression in the course of a regulated activity may result in an external dose rate greater than 100 mGy/hr at a distance of 1 m from the source of ionising radiation;

123.2.3. the amount of radionuclides used in the regulated activity, the physical and chemical state of the radionuclides and/or the energy generated by the regulated activity mean that in the event of a criticality accident or radiological incident or radiological accident, emergency protective action may need to be taken in the area under the control of the organisation;

123.2.4. the regulated activity uses radionuclides such that the A/D_2 ratio, calculated in accordance with the legal act referred to in subparagraph 9.11 of the Requirements, is ≥ 0.01 , assuming that in the event of a criticality accident or a radiological incident or a radiological accident 10 per cent of the amount of radionuclides used in the regulated activity would be released into the environment.

124. If the regulated activities carried out by the organisation do not comply with the provisions of paragraph 123 of the Requirements, these activities shall not be classified as emergency preparedness.

SECTION THREE EMERGENCY PREPAREDNESS FOR CRITICALITY EVENTS

125. Holders of small and medium quantities shall not be required to establish and implement the emergency preparedness measures referred to in this Section.

126. The organisation shall develop technical and organisational emergency preparedness measures such that, in the event of a criticality accident during the performance of a regulated activity, the application of these measures will, as far as reasonably practicable, prevent the exposure of persons within and outside the organisation's territory to doses that could lead to severe radiation-induced radiation-related effects and reduce as far as reasonably practicable the occurrence of potential accidental radiation-induced radiation-related effects.

127. Emergency preparedness measures shall be in place to ensure that persons who are alerted to a criticality event withdraw as soon as possible from areas where they may be exposed to ionising radiation resulting from that event.

128. The design of emergency preparedness measures shall provide for the use of audio and visual signals generated by the CES in case of a criticality event.

129. Evacuation routes to be used in case of a criticality event shall be marked in such a way as to direct evacuees away from the area of the criticality event.

130. The organisation shall have the resources, means and plans to respond criticality accidents.

SECTION FOUR EMERGENCY PREPAREDNESS DOCUMENTS

131. Holders of the licences referred to in Article 22(1)(1) to (5) of the legal act referred to in subparagraph 9.2 of the Requirements shall specify the emergency preparedness measures to be used in case of a criticality event in the course of the regulated activity in emergency preparedness plans drawn up in accordance with Article 38(5) of the legal act referred to in subparagraph 9.2 of the Requirements, and the legislation implementing it.

132. Holders of the licence referred to in Article 22(1)(7) of the legal act referred to in subparagraph 9.2 of the Requirements shall specify the emergency preparedness measures related to the regulated activity in case of a criticality accident in the description of actions to be taken in case of an extraordinary event.

CHAPTER XIV PREPARATION OF THE OPERATIONAL SAFETY ASSESSMENT REPORT

133. This Chapter of the Requirements shall regulate the preparation of the safety assessment report referred to in Article 33 of the Law on Nuclear Safety for the purpose of obtaining the licence referred to in Article 22(1)(7) of the Law on Nuclear Safety (hereinafter referred to as the "Safety Assessment report").

134. The content of the Safety Assessment report shall include the following sections:

134.1. Introduction;

134.2. Norms and requirements;

134.3. Description of activities;

134.4. Equipment, laboratory instruments and materials used in the activity;

134.5. Internal and external hazards;

134.6. List of accidents and incidents;

134.7. Criticality safety analysis;

134.8. Ensuring radiation protection;

134.9. Emergency preparedness;

134.10. Radioactive waste management;

134.11. Decommissioning;

134.12. Summary and conclusions;

134.13. References.

135. The following information shall be included in the "Introduction" section of the Safety Assessment report:

135.1. the purpose of the regulated activity to be regulated;

135.2. information about the organisation, including its address and bank details;

135.3. the type of organisation in accordance with Chapter IV of the Requirements;

135.4. the purpose of the safety justification.

136. The Safety Assessment report shall specify, in the "Standards and requirements" section, the normative documents and regulatory requirements applicable to:

136.1. ensure nuclear safety and radiation protection and emergency preparedness of the activity;

136.2. demonstrate the proper management of radioactive waste to be generated by the activity;

136.3. demonstrate the feasibility of an orderly decommissioning.

137. The following information shall be provided in the "Standards and requirements" section of the Safety Assessment report:

137.1. a list of the legal acts which regulate the preparation of this Safety Assessment report and which lay down the requirements for nuclear safety, radiation protection, emergency preparedness in

the context of regulated activities, radioactive waste management in the context of regulated activities, and the decommissioning of regulated activities;

137.2. a list of standards and codes of practice that the organisation plans to apply;

137.3. the acceptability criteria, safety principles and other requirements that the organisation will apply to demonstrate the acceptability of the regulated activity, which are not set out in the documents referred to in subparagraphs 137.1 and 137.2 of the Requirements.

138. The following information shall be provided in the "Description of activities" section of the Safety Assessment report:

138.1. a brief description and characteristics of the regulated activity in terms of nuclear safety and radiation protection and emergency preparedness. Holders of small quantities, if they do not carry out a criticality safety analysis in accordance with paragraph 49 of the Requirements, shall indicate that this analysis is not necessary and the reason for this;

138.2. a description of the geographical location, buildings and premises where the regulated activity will be carried out;

138.3. the conformity of the regulated activity with the established practice, that is, the conformity of the equipment used for the regulated activity and the processes of the regulated activity with practices that have already been used in a similar field for an analogous purpose, and which have been proven to work;

138.4. the composition, physical and chemical state and quantity (total or over a period of time) of the radioactive waste expected to be generated in the course of the activity.

139. The following information shall be provided in the "Equipment, laboratory instruments and materials used in the activity" section of the Safety Assessment report for holders of small quantities:

139.1. the equipment planned for use in the regulated activity, an assessment of its potential malfunctions, including human error, and an initial assessment of potential malfunctions in terms of radiological consequences;

139.2. a description of the laboratory instruments to be used for the regulated activity, including their limitations (e.g. for laboratory glassware capacity);

139.3. an assessment of the materials (e.g. solutions) to be used for the regulated activity in terms of dispersion and transfer of radionuclides.

140. The following information shall be provided in the "Equipment, laboratory instruments and materials used in the activity" section of the Safety Assessment report for holders of medium and large quantities:

140.1. the equipment planned for use in the regulated activity, information on its design necessary for building of a physical system model, an assessment of its potential malfunctions, including human error, and an initial assessment of potential malfunctions from the point of view of criticality safety and radiological consequences;

140.2. a description of the laboratory instruments to be used for the regulated activity, including their limitations (e.g. capacity, shape of laboratory flasks), information on their design, and information on their construction, as necessary for building a model of the physical system;

140.3. an assessment of the materials (e.g. solutions) to be used for the regulated activity in terms of dispersion and transport of radionuclides, and the information needed to build a model of the physical system (e.g. chemical composition, density).

141. The following information shall be provided in the "Internal and external hazards" section of the Safety Assessment report:

141.1. an assessment of internal hazards (e.g. fires, falling objects, electromagnetic compatibility) and the potential impact on nuclear safety and radiation protection and emergency preparedness of equipment planned for use in the regulated activities;

141.2. an assessment of external hazards (e.g. meteorological phenomena, seismic events) and their potential impact on the equipment, planned activities, nuclear safety and radiation protection and emergency preparedness.

142. Holders of medium and large quantities shall, in addition to the information referred to in paragraph 141 of the Requirements, provide information in accordance with Section 2 of Chapter IX in the "Internal and external hazards" section of the Safety Assessment report.

143. The "List of accidents and incidents" section of the Safety Assessment report shall contain a list of criticality and radiological accidents and criticality and radiological incidents identified on the basis of the results of the assessments referred to in paragraphs 139, 141 and 142 of the Requirements.

144. In addition to the information referred to in paragraph 143 of the Requirements, holders of medium and large quantities shall also provide information in accordance with Chapter IX, Section Two, in the "List of accidents and incidents" section of the Safety Assessment report.

145. Holders of medium and large quantities shall have demonstrated compliance with the Requirements and other standards and requirements governing criticality safety set out in the "Standards and requirements" section of the Safety Assessment report under the heading "Criticality Safety Analysis". This section shall contain the information specified in subparagraphs 72.2.5, 72.3 to 72.13 of the Requirements.

146. The Safety Assessment report shall demonstrate compliance of the regulated activity with the standards and requirements for radiation protection set out in the "Standards and requirements" section of the Safety Assessment report in the normal course of operations and in the event of accidents and incidents referred to in the "Accidents and incidents" section.

147. The "Emergency preparedness" section of the Safety Assessment report shall demonstrate the feasibility of emergency preparedness measures in the event of criticality or radiological accidents, criticality or radiological incidents occurring during the regulated activity, in order to prevent their effects on human health. Emergency preparedness shall comply with the standards and requirements for emergency preparedness set out in the section "Standards and requirements". This section shall also include the emergency preparedness category of the regulated activity and the justification for it.

148. The "Radioactive waste management" section of the Safety Assessment report shall demonstrate the feasibility of safe management of radioactive waste generated by the regulated activity. The management of radioactive waste shall comply with the standards and requirements set out in the section "Standards and requirements" governing the management of radioactive waste.

149. The "Decommissioning" section of the Safety Assessment report shall demonstrate the possibility of decommissioning without violating the normative technical documents governing nuclear safety and radiation protection.

150. The "Summary and conclusions" section of the Safety Assessment report shall include:

150.1. a summary of the results of the analyses carried out;

150.2. the restrictions imposed on the performance of the regulated activity (for example, conditions for the performance of the regulated activity, parameter limit values);

150.3. a conclusion on the compliance of the activity with nuclear safety and radiation protection requirements, on the application of emergency preparedness measures, on the management of radioactive waste and on the possibility of decommissioning the regulated activity.

151. The Safety Assessment report shall be approved by management of the organisation.

152. The Safety Assessment report shall be considered acceptable if it complies with the legal acts governing nuclear safety and radiation protection, the normative technical documents on nuclear safety, the standards and requirements set out in the report, and the objective data (facts).

CHAPTER XV FINAL PROVISIONS

153. A person who violates the Requirements shall be liable in accordance with the procedure established by the Republic of Lithuania Law on Nuclear Safety and/or the Republic of Lithuania Code of Administrative Offences.