

APPROVED

By Order No 22.3-56 of 21 June 2010 of the Head of the State Nuclear Power Safety Inspectorate (revised Order No 22.3-13 of 29 January 2016 of the Head of the State Nuclear Power Safety Inspectorate)

**NUCLEAR SAFETY REQUIREMENTS  
BSR-1.4.1-2016**

**MANAGEMENT SYSTEM**

**CHAPTER I  
GENERAL PROVISIONS, DEFINITIONS AND REFERENCES**

**SECTION ONE  
GENERAL PROVISIONS**

1. Nuclear Safety Requirements BSR-1.4.1-2016 “Management System” (hereinafter – the Requirements) set the requirements for establishment, implementation, , assessment and continual improvement of the management systems of the persons operating in the area of nuclear energy or other area related to nuclear and fissile materials, the quantities of which are set forth in Annex 1 to the legal acts referred to in subparagraph 4.2 of the Requirements, and/or area related to nuclear fuel cycle materials, which requires obtaining the licence from the State Nuclear Power Safety Inspectorate (hereinafter – the VATESI) as set forth in part 1 of Article 22 of the legal act referred to in subparagraph 4.2 of the Requirements, and of the persons applying for the issuance of the licence specified in part 1 of Article 22 of the legal act referred to in subparagraph 4.2 of the Requirements (hereinafter the activities – the licensed activities; the persons – the organisation), i.e. the requirements for actions aimed at improving nuclear safety, radiation protection, physical security and/or control over compliance with nuclear non-proliferation commitments, including accounting and control of nuclear materials (hereinafter – the safety), processes and management system used by the organisation.

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2. Additional special requirements for the management systems of the persons referred to in paragraph 1 of the Requirements can be set in other technical normative documents on nuclear safety.

**SECTION TWO  
DEFINITIONS**

3. The terms and concepts used in the Requirements shall bear the following meanings:

3.1. **Integrated management system** (hereinafter – the management system) – an integrated safety, environmental, quality, occupational safety and health management system combining all elements of the organisation management, including economic, and designating safety as a priority objective of the organisation.

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**3.2. Self-assessment** – review of the organisation’s activities by the management members, covering analysis of process effectiveness and efficiency in all the respective areas of their responsibility.

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**3.3. Senior management of the organisation** (hereinafter – the senior management) – a top-level manager or a group of top-level managers managing the licensed activities of the organisation, conducting their assessment, undertaking responsibility for their performance and controlling the organisation’s resources.

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**3.4. Organisational structure** – a whole of elements – requirements in respect of the number of units, job positions, employees, subordination, competence of employees and other requirements relating to the job position – ensuring proper fulfilment of the organisation’s functions.

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**3.5. Product important for safety** (hereinafter – the product) – an item of goods, services, software, documentation or work, non-conformity of which with the requirements of the procurement documentation, legal acts and/or nuclear safety technical normative documents may have impact on safety.

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**3.6. Supplier of product important for safety** (hereinafter – the supplier) – a person or a group of persons independent from and collaborating with the organisation, who supply or are capable of supplying products important to safety, including the suppliers–subcontractors who are involved in the fulfilment of commitments by collaborating with such a person or a group of persons.

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**3.7. Safety culture** – an assembly of characteristics, understanding of potential consequences of activities, safety-critical attitudes, values and practices demonstrated by the organisation and each of its employees, leading to exceptional focus on safety by all employees of the organisation.

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**3.8. Security culture** – a whole of characteristics, understanding of potential consequences of activities, safety-critical attitudes, values and practices demonstrated by the organisation and each of its employees, ensuring that safety-related issues are adequately addressed in view of the degree of relevance to safety.

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3.9. **Management system review** – actions taken by the senior management on a systematic basis to assess effectiveness, efficiency and suitability of the organisation’s management system for the fulfilment of the organisation’s policy and achievement of the organisation’s objectives and targets.

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3.10. Other terms and concepts used in the Requirements shall bear the meanings defined in the documents referred to in paragraph 4 herein.

### **SECTION THREE REFERENCES**

4. The Requirements contain references to the following documents:

4.1. The Republic of Lithuania Law on Nuclear Energy;

4.2. The Republic of Lithuania Law on Nuclear Safety;

4.3. The Republic of Lithuania Law on Public Procurement;

4.4. The Republic of Lithuania Law on Public Procurement in the Fields of Defence and Security;

4.4<sup>1</sup>. The Republic of Lithuania Law on Cyber Security;

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4.5. The Regulations for Issuing Licences and Permits to Engage in Activities in the Area of Nuclear Energy, as approved by Resolution No. 722 of 20 June 2012 of the Government of the Republic of Lithuania “Regarding Approval of Regulations for Issuing Licences and Permits to Engage in Activities in the Area of Nuclear Energy and Proclamation of Order No. 103 of 27 January 1998 of the Government of the Republic of Lithuania “Regarding Approval of Provisions for Licensing Activities in the Area of Nuclear Energy” to be Invalid”;

4.6. Lithuanian Standard LST EN ISO 9001:2008 “Quality Management Systems. Requirements”;

4.7. Lithuanian Standard LST EN ISO 9001:2015 “Quality Management Systems. Requirements”;

4.8. Lithuanian Standard LST EN ISO 14001:2015 “Environmental Management Systems. Requirements with Guidance for Use”;

4.9. Lithuanian Standard LST 1977:2008 (BS OHSAS 18001:2007) “Occupational Health and Safety Management Systems. Requirements”;

4.10. Lithuanian Standard LST EN ISO 9000:2015 “Quality Management Systems. Fundamentals and Vocabulary”;

4.11. The List of Measuring Instrument Groups Referred to Legal Metrology and Time Intervals Between Periodic Verifications, as approved by Order No. 4-523 of 1 August 2014 of the Minister of Economy of the Republic of Lithuania “Regarding Approval of the List of Measuring Instrument Groups Referred to Legal Metrology and Time Intervals Between Periodic Verifications”;

4.12. Nuclear Safety Requirements BSR-1.1.1-2014 “Description of Procedure for Drafting Nuclear Safety Requirements and Nuclear Safety Rules”, as approved by Order No. 22.3-58 of 15 June 2009 of the Head of VATESI “Regarding Approval of Nuclear Safety Requirements BSR-1.1.1-2014 “Description of Procedure for Drafting Nuclear Safety Requirements and Nuclear Safety Rules”;

4.13. Nuclear Safety Requirements BSR-1.8.2-2015 “Categories of Modifications of Nuclear Facility and Procedure of Performing the Modifications”, as approved by Order No. 22.3-99 of 7 October 2011 of the Head of VATESI “Regarding Approval of Nuclear Safety Requirements BSR-1.8.2-2015 “Categories of Modifications of Nuclear Facility and Procedure of Performing the Modifications”.

## **CHAPTER II ORGANISATION’S MANAGEMENT SYSTEM**

### **SECTION ONE GENERAL REQUIREMENTS FOR THE ORGANISATION’S MANAGEMENT SYSTEM**

5. The organisation shall establish, document and implement the management system that meets the objectives and nature of its licensed activities, and shall carry out its assessment and improvement on a regular basis in accordance with the Requirements. The main types of improvement actions are: continual improvement, preventive action, corrective action and correction.

6. The requirements established in the documentation of organisation`s management system are obligatory for the organisation

7. The organisation shall not transfer the responsibilities set forth in paragraph 51 herein to the suppliers involved in the development, documentation, implementation or assessment of the management system.

8. The objective of the organisation’s management system is to ensure and improve safety of the NF, other activities pursued by the organisation in the area of nuclear energy, and activities involving nuclear, nuclear fuel cycle and/or fissile materials, so that the needs of the organisation are not treated in isolation from the requirements of technical normative documents on nuclear safety and other legal acts applicable to the licensed activities of the organisation (hereinafter – the requirements applicable to the organisation’s licensed activities), and that the implementation of the organisation’s needs has no adverse effects on safety.

9. The highest priority in the organisation’s management system shall be given to safety.

10. Upon changes in or adoption of new requirements applicable to the organisation’s management system, the organisation shall elaborate and take measures implementing such changes and/or new requirements, make available and explain such changes and/or new requirements to related employees, communicate such changes and/or new requirements to other interested parties, and make changes to the related management system documents or adopt new ones.

11. The management system documentation shall specify in detail as to how the objectives of the organisation’s licensed activities will be achieved and how the requirements applicable to the organisation’s licensed activities will be met.

12. The management system shall specify the procedures designed to assess and manage the risks arising from the organisation’s licensed activities to people, their assets and environment.

13. The organisation shall ensure effective execution and control of all processes within the organisation in line with the requirements set forth in the management system documentation.

14. The organisation shall be capable of demonstrating effective and efficient implementation of the management system.

15. The organisation shall monitor compliance of the suppliers with the requirements applicable to their activities.

16. The management system documentation shall define the decision-making procedure within the organisation that ensures clarity at any moment as to who, when and how makes the decisions. The employees responsible for managing the NF's technological process shall be subordinate only to individuals responsible for the NF's safety.

17. As the organisation implements the requirements applicable to its licensed activities, it shall apply *the graded approach* in each of its processes, whereby it ensures that the management system documentation is drafted, the licensed activities are planned and carried out, and the employees, information, knowledge, infrastructure, work environment, suppliers and funds (hereinafter – the resources) are allocated in view of:

17.1. impact on safety;

17.2. relevance, complexity of the NF, licensed activities, performance, and risks imposed on people, their assets and environment;

17.3. type of the NF (nuclear power plant, unit of nuclear power plant, non-power reactor, nuclear material storage facility, radioactive waste management facility);

17.4. stage of a lifecycle of the NF;

17.5. characteristics of structures, systems and components important for safety (hereinafter – the SSCs important for safety) and/or characteristics of the NF;

17.6. potential consequences in case of inappropriate execution of a certain process, unusual event or non-conformity;

17.7. any other factors that can have impact on safety.

18. Before making safety-related decisions, the organisation shall analyse all safety aspects of such decisions and make decisions based on the graded approach.

19. The nuclear safety analysis and justification results, which are officially documented in nuclear safety supporting documents, and other related documents shall be subject to independent verification (hereinafter – the independent verification) by persons not involved in nuclear safety analysis and justification and documentation of the results. The organisation shall have a right to involve suppliers – scientific-technical support organisations and independent experts, specialists, consultants for the independent verification of the aforementioned documents. When the organisation relies on internal resources to conduct the independent verification, it shall ensure that the persons involved in the independent verification are not subordinate directly to the persons involved in nuclear safety analysis and justification and/or in documentation of the results at the time of the independent verification.

20. The safety justification documents shall contain a mark confirming completion of the independent verification, and a reference to the independent verification report.

21. The organisation' management system documentation shall specify the procedure to be followed during the arrangement of the independent verification.

22. The independent verification shall cover:

22.1. checking of whether all safety aspects in relation to the NF and/or planned activities have been considered, as prescribed by the requirements applicable to the organisation's licensed activities;

22.2. checking of whether it contains input data and assumptions, analysis methods applied, results obtained and their acceptance criteria;

22.3. review of compliance of input data and assumptions, analysis methods applied, reliability and acceptability of results obtained with the requirements applicable to the organisation's licensed activities;

22.4. conclusion on compliance of the results of nuclear safety analysis and justification and their documentation with the requirements applicable to the organisation's licensed activities.

23. The process and results of the independent verification shall be documented in the independent verification report. The independent verification report shall be submitted to the VATESI in cases set forth in the legal act referred to in subparagraph 4.5 herein and in the legal acts approved by the head of the VATESI.

24. The interested parties shall be identified and specified by the organisation in its management system documentation.

25. As the organisation implements and improves its management system, it should take into account the guidelines of the International Nuclear Energy Agency, the provisions of standards referred to in subparagraphs 4.6-4.10 herein, as well as the practice of other organisations operating in the same or similar area.

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## **SECTION TWO SAFETY CULTURE AND SECURITY CULTURE**

26. Management members at all levels shall foster individual and collective work values to be followed while ensuring safety and compliance with the provisions of the management system, establish and specify in the management system documentation the requirements for attitude to safety and behaviour of employees, including the suppliers, that would meet the aforementioned values.

27. Management members at all levels shall promote and encourage such behaviour and attitude towards safety that enhances safety culture and security culture, shall be role models for others in how to apply the organisation's management system and the values fostered therein, and shall demonstrate disapproval of actions and conditions that are not compatible with safety.

28. The management system documentation shall specify safety culture and security culture monitoring indicators, as well as safety culture and security culture assessment techniques.

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29. The management system documentation shall contain a description of safety culture and security culture development measures designed to promote and consolidate the expected attitude towards safety and the expected behaviour of employees, and to foster and develop safety culture and security culture of the organisation and the suppliers.

30. The implementation of measures set forth in the description of safety culture and security culture development measures referred to in paragraph 29 herein shall be planned, executed and documented in the plan for implementation of safety culture and security culture development measures.

31. Appropriateness and effectiveness of safety culture and security culture monitoring indicators, assessment techniques and development measures shall be regularly evaluated based on the procedure and at time intervals specified in the organisation's management system documentation. If the indicators, techniques or measures are found to be no longer appropriate or effective, the corrective actions shall be taken.

32. In order to maintain safety culture and security culture of the organisation and the suppliers at a high level, the organisation shall:

32.1. make sure that the main aspects of safety culture and security culture are familiar to and understood by the organisation's employees and suppliers;

32.2. provide resources and means necessary for safe and successful work of individual employees and teams, taking into account the interactions between the employees, the organisation and technologies;

32.3. promote the processes contributing to professional development of employees (hereinafter – the training), as well as questioning attitude at all management levels of the organisation;

32.4. undertake systematic assessment and consistent development of safety culture and security culture.

33. Safety culture and security culture shall be assessed on a systematic basis in accordance with the procedure and at time intervals set forth in the organisation's management system documentation. Such an assessment shall cover analysis of safety culture and security culture monitoring indicators, results of surveys of employees, monitoring and self-assessments and data on effectiveness and efficiency of the processes and management system, including other information about the level of safety culture and security culture.

34. The organisation shall provide its employees, including the supplier's employees, with opportunities to express their personal views and give suggestions about the safety matters, and inform the senior management about safety issues and process improvement possibilities. The organisation shall maintain such work environment where any employee is free to raise safety-related questions with no adverse consequences. In addition, the organisation's management system shall specify measures designed to ensure that all safety-related questions raised by employees are registered and the necessary improvement actions are taken, if necessary.

35. The survey of employees aimed at assessing the organisation's safety culture and security culture shall include interviewing the organisation's employees whose job function is to ensure and/or be involved in ensuring safety. Such surveys at the organisations operating a nuclear power plant shall be carried out at time intervals specified in the organisation's management system documentation, but not less than once every three years. The organisations engaged in licensed activities other than operation of a nuclear power plant shall conduct such surveys at time intervals specified in the organisation's management system documentation, but not less than once every five years.

36. The results of the surveys referred to in paragraph 35 herein, and analysis of the results shall be documented in the reports.

### **SECTION THREE REQUIREMENTS FOR THE DOCUMENTATION OF THE MANAGEMENT SYSTEM**

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37. The management system documentation shall describe the responsibilities of all employees of the organisation and the suppliers in relation to ensuring compliance with the requirements applicable to the organisation's licensed activities, the powers and functions assigned to them, their subordination and interrelationship. Each employee shall be familiarised with such a documentation.

38. The management system documentation shall be marked, accounted, updated and allocated in the event of changes in legal acts or actual circumstances or adoption of new legal acts in accordance with the procedure established within the organisation, and such documentation shall be clear, understandable and easily accessible to its users.

39. The organisation's management system documentation shall specify how and in what order the processes shall be executed, as well as the procedure for monitoring and evaluation of processes, indicating monitoring and evaluation criteria and designed to monitor, evaluate and control them to ensure that all processes are effective and meet the requirements applicable to the organisation's licensed activities.

40. The organisation's management system documentation shall be classified into different hierarchy levels. These hierarchy levels shall cover:

40.1. the first level management system documentation specifying:

40.1.1. the organisation's vision, mission and long-term objectives;

40.1.2. the organisation's policy or policies in the areas of safety, quality assurance and management of human resources (hereinafter the policies collectively referred to as "the policy");

40.1.3. description of the organisational structure, necessary to ensure safety of the licensed activities, including in case of unusual events, by indicating the names of, powers granted, functions assigned to and subordination of the basic structural units, all management members and other managerial bodies within the organisation and job positions independent from the structural units, as well as justification of such organisational structure;

40.1.4. description of the organisation's management system;

40.1.5. an overview of the organisation's processes and responsibilities of the owners of such processes;

40.1.6. description of the effectiveness assessment measures of the management system;

40.1.7. other information designated as the first level management system documentation at the discretion of the organisation;

40.2. the second level management system documentation – documents approved by senior management that describe the ways in which the processes are executed, the sequence of actions to be taken and other aspects related to execution of the processes (hereinafter – the procedure descriptions), defining the administration guidelines at all levels of management and specifying:

40.2.1. all processes in which the organisation's divisions, functional units or persons independent from the organisation are involved;

40.2.2. the responsibilities assigned to the organisation's divisions, functional units or persons independent from the organisation and involved in the process;

40.2.3. information about interrelations between different processes and references to relevant documents;

40.2.4. other information classified as the second level management system documentation at the discretion of the organisation;

40.3. the third level management system documentation shall cover information not included in the first and second level management system documentation, defining the individual or teamwork actions, including the job descriptions of all employees of the organisation, technical specification;

40.4. the organisation may develop the areas of activities encompassing policies other than those specified in paragraph 40.1.2 herein and introduce additional levels for the management system documentation to encompass documents not attributed to the levels of management system documentation referred to in subparagraphs 40.1-40.3 herein: records on compliance with the established requirements, including the forms of records, drawings, numerical models and computer databases.

41. Prior to their approval, any modifications to the organisation's first and second level management system documentation containing information specified in subparagraphs 40.1.2-40.2.4 herein, shall be agreed with the VATESI based on the procedure set forth in paragraph 150 herein.

42. The policy shall specify:

42.1. responsibilities of senior management in ensuring and continually improving safety, as well as the responsibilities in the areas of quality assurance and management of human resources;

42.2. the guidelines in the areas relevant for safety of the organisation's licensed activities, as well as the guidelines for policy execution and assessment;

42.3. the requirements for continual improvement of safety and for setting safety targets and corresponding indicators so that the management members are able to monitor easily their implementation.

43. The policy shall be compatible with the organisation's licensed activities and objectives, approved by the senior management, announced and explained to all employees, and practicable. The main provisions of the organisation's policy shall also be communicated to the suppliers so that the organisation's expectations and requirements are well understood and used in the activities of the suppliers.

44. The documents referred to in subparagraphs 40.1–40.2 shall be reviewed at least once over three years in accordance with the procedure set in the organisation's management system documentation, and shall be updated in case such review reveals non-conformity of the documents with the legal acts or actual circumstances, and/or modification of the documents leads to improvement of the safety level. The descriptions of maintenance of the SSCs important for safety shall be reviewed at least once over five years. Other management system documentation shall be reviewed and updated at least once over five years in accordance with the procedure and at time intervals set forth in the organisation's management system documentation.

45. Each description of the management system procedure shall contain:

45.1. the document identification data, information about its validity, approval, agreement with the units involved in the process described in the document and engaged in its supervision;

45.2. the objectives, scope of the procedure description, by whom and when it shall be executed;

45.3. the definitions of terms and explanations of acronyms;

45.4. the responsibilities of each process participant;

45.5. the process description, stages of execution, sequence of actions and requirements applicable;

45.6. the process inputs and outputs;

45.7. the process risks and risk management guidelines;

45.8. the process planning, supervision and assessment procedure, responsibility for the assessment of process effectiveness, assessment criteria, time intervals, procedure of documentation and use of assessment results;

45.9. the process improvement procedure;

45.10. the interaction with other processes and references to documents relevant to process execution and improvement, and information about who and how prepares, uses and handles it, also who, where and how long retains the corresponding process documents within the organisation.

45.11. the requirements for handling and use of process records and other process-relevant documents;

45.12. other information important for process execution.

46. The organisation shall develop, document and apply the procedure for management of documents **and records**, whereby it sets the requirements for:

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46.1. the drafting and modification of documentation, approval of acceptability, official documentation, marking, coordination, approval, control, traceability, retainment, declaration as invalid, destruction and deployment within the organisation and interested parties. Any modifications of documentation shall be handled in a manner similar to the documentation that is subject to modification;

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46.2. the acceptance, evaluation, approval of acceptability and marking of external origin documents received by the organisation from the suppliers, prior to bringing them into use;

46.3. the control, review and renewal of the validity of the approved documentation;

46.4. the protection of documentation and records, including those kept in electronic format, against accidental and deliberate events, including cyber incidents, imposing threats to confidentiality, integrity of and accessibility to records compiled, retained and transferred that are relevant for safety;

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46.5. the use of documents and access thereto at the points of use;

46.6. the protection of documents to ensure their eligibility and unsophisticated use throughout the entire period of use and expected retention;

46.7. the identification of the documents received;

46.8. the requirements preventing from the use of invalid documentation and marking of such documentation in case it is intended for retention.

47. All employees and other persons involved in drafting, review or approval of the organisation's management system documentation shall be duly assigned for such a function and shall have the required competence for that purpose.

48. The management system documentation shall define all types and forms of records used within the organisation and the procedure of their management.

49. The records specified in the procedure descriptions shall allow identifying the supplier of data, as well as the documented facts and date of record.

50. In respect of all records, including those kept in electronic format, the period of retention shall be indicated in view of the relevance of records for safety. As the records are retained, including those in electronic format, it is required to ensure their accessibility (findability, eligibility, recoverability, etc.) and protection against unauthorised modification or destruction throughout the entire period of their retention.

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### **CHAPTER III MANAGEMENT RESPONSIBILITY**

51. Senior management shall be responsible for establishment, implementation, assessment and continual improvement of the management system. The management members at all levels shall be involved in development, implementation, assessment and continual improvement of the management system. The senior management shall make sure that adequate resources are allocated for development, implementation, assessment and continual improvement of the management system.

52. Senior management shall ensure that measurable performance objectives are set for all the processes and structural and/or functional units of the organisation that are involved in such processes or for the persons that do not belong to the organisation. Such objectives shall be compatible with the policy, the organisation's strategies and plans.

53. Senior management shall ensure that the organisation's licensed activities are conducted in a safe manner and in compliance with the organisation's management system documentation and the requirements applicable to the organisation's licensed activities.

54. Senior management shall make sure that safety has been given the highest priority compared to other objectives and requirements of the interest parties.

55. Senior management shall ensure that the organisation has measures in place to allow for appropriate monitoring of the safety level, and that safety, safety culture and security culture are subject to continual improvement.

56. Senior management shall fulfil its commitments to ensure and continually improve safety and the management system as set forth in the organisation's policy by:

56.1. communicating to the organisation's employees, suppliers and other interested parties the requirements applicable to the organisation's licensed activities and the importance of their implementation;

56.2. drafting the activity plans with reference to the policy in agreement with the performance objectives, and monitoring their implementation;

56.3. allocating adequate resources necessary to ensure and continually improve safety;

56.4. leading the implementation of the management's commitments and the established performance objectives in a way that the impact on the pursued activities is clearly understandable and well managed;

56.5. ensuring that the level of safety condition of the licensed activities is continually monitored and improved.

57. Senior management shall appoint one management member as their representative and provide him/her with the powers and resources necessary to fulfil such a function. The management member appointed to represent the management shall be responsible for:

57.1. determining the organisation's processes, coordination of the management system improvements and ensuring compliance of the management system documentation with the requirements applicable to the organisation's licensed activities;

57.2. arranging the monitoring of effectiveness and efficiency of the management system and processes, assessment of compliance of the management system and processes with the requirements applicable to the organisation's licensed activities, audits and independent verifications;

57.3. monitoring the safety condition and reporting the safety condition, safety culture and security culture to the management;

57.4. reporting to the senior management the effectiveness and efficiency of the management system, compliance of the management system and processes with the requirements applicable to the organisation's licensed activities, the need for improvement of the management system determined in the course of assessments or analysis of operation (manufacturing) experiences, and the fulfilment of the requirements applicable to the organisation's licensed activities.

58. The management's representative shall be directly subordinate to the head of the organisation. If the NF is a nuclear power plant, the management's representative shall lead the structural unit that is responsible for arranging the development, implementation, application, assessment, monitoring and continual improvement of the management system, audits and independent verifications, as well as for arranging the assessment of the safety culture within the organisation.

59. In respect of each process, the senior management shall appoint one competent employee to fulfil the process owner's function by providing such an employee with the necessary powers, resources and assistance in relation to administration of process-related matters. The process owner shall:

59.1. lead the process and improvements thereof;

59.2. supervise the drafting, application and improvement of documentation;

59.3. ensure interaction with the related processes;

59.4. inform the senior management about the process execution, its effectiveness and efficiency, and need for further improvement;

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59.5. provide information about the process to auditors and independent verifiers.

60. The management shall encourage participation of each employee in the development, implementation, assessment and continual improvement of the management system.

61. The management members at all levels shall monitor and assess the safety condition of the licensed activities by means of process monitoring, visitations at work places of the subordinate employees, monitoring their performance and communicating with them.

## **CHAPTER IV RESOURCE MANAGEMENT**

### **SECTION ONE PROVISION OF RESOURCES**

62. The organisation shall establish the required resources, ensure their availability and utilisation while pursuing the licensed activities and while developing, implementing, applying, assessing and continually improving the management system.

63. The organisation's long-term and annual plans shall provide for availability of adequate resources for the fulfilment of all activities during every stage of the licensed activities. Resources on hand and in stock specified in the long-term plans for provision of resources shall be reviewed at least once per year and, in view of the results of the review, shall be updated in terms of the need for resources over the near future periods.

64. Information and safety-critical knowledge accumulated by the organisation's employees shall be managed as resources and updated constantly in view of the requirements applicable to the organisation's licensed activities, achievements in the area of applied science, operation (manufacturing) experiences and suggestions of employees.

65. As the organisation plans and carries out licensed activities, ensures safety and implements the performance objectives set by the organisation, it shall consider the resources necessary for its activities, and assess and manage the risks pertaining to availability of resources.

### **SECTION TWO HUMAN RESOURCE MANAGEMENT**

66. The procedure for human resource management shall be described in the organisation's management system documentation.

67. The organisation shall establish and document competence requirements for all employees and provide professional training in view of the functions assigned to each specific employee.

68. The organisation shall ensure that its employees are competent for the functions assigned to them and understand the consequences of their tasks on safety. The employees shall be duly qualified for the function assigned to them and shall have the skills, knowledge and/or experience, the minimum requirements for which shall specified in their job descriptions.

69. The organisation, on a systematic basis, shall analyse data relating to the number and competence of employees, document the results of such analysis and, in view of the results, establish and specify in the documents referred to in subparagraph 40.1.3 herein, the minimum required number of employees with functions important for safety.

70. The organisation shall make sure that at any time the number of competent employees is not less than the established and documented number of employees assigned with the function to ensure safety of the licensed activities. The organisation shall have:

70.1. employees who have knowledge and experience to define in a qualified manner the requirements for the suppliers, to monitor them and assess their performance;

70.2. employees who understand safety fundamentals in respect of activities involving nuclear, fissile and/or nuclear fuel cycle materials.

71. The number of employees and job positions assigned with the function important for safety within the organisation shall be supported by safety justification documents, and any changes therein shall be planned in advance and implemented in accordance with the provisions of Chapter VII.

### **SECTION THREE INFRASTRUCTURE AND WORK ENVIRONMENT MANAGEMENT**

72. The organisation shall create such infrastructure and work environment that are necessary to ensure safety and achieve the organisation's objectives. At the time intervals specified in the management system documentation, the organisation shall assess appropriateness of infrastructure and work environment for safe execution of tasks, and ensure that the tasks assigned to the employees are fulfilled in compliance with the requirements applicable to the organisation's licensed activities. The senior management shall make sure that the work environment has positive impact on motivation and performance of employees.

73. The organisation shall observe the environmental effects that may have impact on safe work, assess them in terms of safety and, in case of identification of any threats implying unsafe performance of the tasks, the organisation shall respond to such potential impacts of environmental effects by undertaking the improvement actions.

74. The work carried out at the NF site shall be supervised (monitored) by the organisation's employees responsible for work supervision to ensure quality and safety of work.

75. The management system shall define the work environment supervision measures designed to:

75.1. assess the impact of work environment on processes and/or effects on employees;

75.2. assess appropriateness of work environment, means and tools used at work;

75.3. assess other factors that may have impact on work environment.

76. To prevent the use of obsolete, damaged or otherwise inappropriate materials, tools, means, equipment and components, the organisation shall elaborate and implement the measures of their marking, accounting and control.

## **CHAPTER V PROCESS IMPLEMENTATION**

### **SECTION ONE PROCESS ESTABLISHMENT**

77. The organisation shall establish, implement, assess and continually improve its processes that are necessary for implementation of the organisation's policy, objectives, supply of the organisation's product and ensure compliance with the requirements applicable to the organisation's licensed activities.

78. In view of the licensed activities carried out by the organisation and based on the graded approach, the organisation's descriptions of management system procedures shall specify the processes and the order of their execution, which are designed to:

78.1. manage the drafting, use and handling of management system documentation;

78.2. manage the personnel, including personnel trainings;

78.3. manage the product supply and control;

- 78.4. manage the relationships within the organisation and exchange of information with the interest parties;
  - 78.5. manage the radioactive waste management;
  - 78.6. manage the financial resources;
  - 78.7. perform self-assessments and audits, and manage the non-conformities and improvement actions identified;
  - 78.8. perform the assessment and improvement of safety culture and security culture;
  - 78.9. perform the analysis and application of operational experience;
  - 78.10. perform the NF's modifications and changes in the organisational structure;
  - 78.11. carry out the activities specified in the licence issued by the VATESI;
  - 78.12. ensure nuclear safety and perform continual improvement thereof;
  - 78.13. ensure physical security and perform continual improvement thereof;
  - 78.14. ensure radiation protection and perform continual improvement thereof;
  - 78.15. ensure emergency preparedness;
  - 78.16. ensure occupational safety and health, and perform continual improvement thereof;
  - 78.17. ensure environmental protection and perform continual improvement thereof.
79. The organisation's descriptions of management system procedures may establish additional processes that are required to pursue the licensed activities, other than those specified in paragraph 78 herein, and shall indicate the procedure of their execution.

## **SECION TWO PROCESS MANAGEMENT**

80. Effectiveness of each process and control shall be assessed at time intervals and based on procedure established by the organisation.

81. The activities specified in the processes shall be carried out under controlled conditions – with reference to the approved procedure descriptions, instructions, schemes and other means (e.g., control of environmental conditions, including cleanliness, tools and equipment, software, chemical materials and chemical products) that shall be inspected for appropriateness at time intervals set by the organisation.

82. The organisation shall be responsible for all the processes, including those that involve or are executed by the suppliers. When the process is carried out in full or in part by the supplier, the organisation shall define the supplier's performance control criteria and measures designed to control compliance of the supplier's activities and performance with the requirements applicable by the organisation to the supplier's activities.

83. The management members at all levels shall promote involvement of employees in the improvement of processes and encourage them to report safety issues to the senior management.

84. The organisation shall ensure such internal and external communication with the interest parties where information about the process execution, results and other issues pertaining to effectiveness of management system and assurance of safety is exchanged accurately, timely and in line with the requirements applicable to the organisation's licensed activities.

85. Information related to safety, health protection, environmental protection, work quality and economic aspects of the assigned tasks, which is necessary to fulfil the functions assigned to the employees, shall be made available to the employees before commencement of such tasks. Such information shall also be made available to the suppliers involved in the activities and other interest parties relating to the activities performed, if such supply of information is not restricted by imperative provisions of legal acts.

## **CHAPTER VI**

### **PRODUCT SUPPLY AND MEASURING INSTRUMENT CONTROL**

*Section title amendment:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

#### **SECTION ONE**

##### **SUPPLY OF PRODUCTS IMPORTANT FOR SAFETY**

*Section title amendment:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

86. The organisation shall draft, approve and follow the procedure description, which in view of and without prejudice to the legal acts referred to in subparagraphs 4.3 and 4.4 herein, shall specify:

86.1. the criteria and procedure for supplier selection;

86.2. the procedure for drafting, approval and publication of procurement documentation;

86.3. the procedure for checking compliance of supplied or to be supplied products with the applicable requirements and procurement documentation;

86.4. the requirements for the supplier's management system;

86.5. the procedure for planning, execution, assessment and improvement of product procurement;

86.6. the procedure for the supplier's performance control and assessment;

86.7. the procedure for controls at the time of product acceptance;

86.8. the criteria and procedure for assessment of qualification of the supplier's employees. The qualification of the supplier's employees shall be assessed when the employees are required to have special skills and experience;

86.9. the requirements for the suppliers who will use the products of other persons for the product supply purposes, which are designed to control compliance of such products with the requirements laid down in the organisation's procurement documentation at all stages of the product supply;

86.10. the procedure for audit of the suppliers.

87. The organisation's supplier selection procedure shall ensure that the contracts are signed only with those suppliers who have adequate appropriate technical, financial and human resources and expertise to supply the product in accordance with the requirements specified in the procurement documentation.

88. Having signed the contract with the supplier, the organisation shall control its execution and accept the product only after having satisfied itself as to the compliance with the requirements of the procurement documentation.

89. In view of the legal acts referred to in subparagraphs 4.3 and 4.4. and without prejudice to the provisions thereof, in its procurement documentation the organisation shall specify the scope of work, technical requirements for the products purchased, verification and testing requirements, requirements for access to the supplier's manufacturing facilities, quality assurance requirements, documentation requirements, requirements for deadlines of submission of documents, requirements for reporting non-conformities, requirements for the supplier's capabilities, the qualification of the supplier's employees and the applicable management system.

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

90. The requirements for the suppliers and the products supplied by them in the procurement documentation shall be determined by the duly qualified employees of the organisation. Before entering into the supply contract, the requirements for procurement

documentation shall be assessed by the duly qualified employees who are not involved in drafting of documentation. The organisation shall ensure that at any time it has an adequate number of qualified employees who are competent to determine the requirements for the suppliers and the products supplied by them and who are competent to assess compliance of the supplied product with the requirements of nuclear safety technical normative documents and other requirements indicated in the procurement documentation.

91. The requirements set by the organisation shall ensure that the management system of the supplier complies with the requirements of the standard referred to in subparagraph 4.7 (before 30 September 2018, compliance of the supplier's management system with the requirements of the standard referred to in subparagraph 4.6 rather than those of the standard referred to in subparagraph 4.7 may be assessed, provided the supplier declares compliance of its management system with the requirements of the standard referred to in subparagraph 4.6) or any other equivalent quality management standard. The standard is considered to be equivalent, provided it complies with or sets more stringent requirements than the requirements of the standard referred to in subparagraph 4.7.

92. The organisation shall require that the supplier drafts its own description of quality assurance measures for its activities that covers the measures aimed at ensuring that the product supplied to the organisation complies with the requirements stipulated in safety technical normative documents and procurement documentation.

93. The organisation shall require that the supplier supplies its products in a way that allows checking whether the products are in conformity with the requirements stipulated in the procurement documentation.

94. The organisation shall require that prior to supply of the products, the supplier shall satisfy itself as to whether the product complies with all the requirements stipulated in safety technical normative documents and/or procurement documentation and shall confirm such compliance in accordance with the procedure set in the procurement documentation (by a separate compliance confirmation document, mark, record or otherwise).

95. Before bringing the product into use, the organisation shall ensure that the product verification and validation actions have been carried out in respect of the product.

96. The organisation shall satisfy itself and confirm that the product meets the requirements stipulated in the safety technical normative documents and/or other requirements set in the procurement documentation.

97. The actions referred to in paragraphs 95 and 96 shall be officially documented in accordance with the procedure set forth in the organisation's management system documentation, and such documents shall be retained throughout the entire period of the licensed activities.

98. In view of the degree of importance of the products for safety, the following actions shall be taken:

- 98.1. product acceptability verifications and pre-production and/or production tests;
- 98.2. product acceptance and testing at the premises of the supplier;
- 98.3. control at the time of product acceptance at the premises of the organisation;
- 98.4. control of mounting and other work and services;
- 98.5. acceptance testing after mounting of equipment;
- 98.6. other aspects of product quality assessment as set forth in the procurement documentation.

99. Having accepted the product from the supplier, the organisation shall confirm (by a separate compliance confirmation document, mark, record or otherwise) the product's compliance with the requirements set forth in the safety technical normative documents and or procurement documentation, and shall monitor its functioning during its use.

100. The marking of the products shall ensure appropriate use and traceability of the products. For this purpose, records shall be made about the use, storage, etc. of products. Interrelated or interacting products shall be identified and such interaction shall be monitored.

101. The products shall be handled, carried, stored, maintained and used in a way that prevents from damages to products, alternation of their properties or their unauthorised use.

102. The organisation's suppliers shall be responsible for meeting the contractual requirements, however, the organisation shall not transfer its responsibility for safety to the suppliers.

103. The organisation shall require that the suppliers indicate what and for which part of the procurement it intends to rely on the work of sub-contractors. Such requirement shall not affect the principal supplier's liability for the performance of the procurement contract.

104. The organisation shall evaluate the sub-contractors for appropriateness and make sure that the activities of the sub-contractors, the quality of products supplied by them, and compliance of the products with the requirements set forth in the procurement documentation in respect of the supplied products are monitored.

105. The organisation shall ensure that the supplier's employees working on the NF site are familiar with the requirements of the safety technical normative documents applicable in the area of their activities.

106. Upon occurrence of a dangerous situation at the time of work of the suppliers at the NI site (e.g., at the time of technical maintenance of the system, testing, repair, mounting and dismantling of safety-critical systems) or upon finding that the product supplied does not comply with the requirements of the procurement documentation, the organisation shall suspend the work in a safe manner and take measures necessary to ensure safety at the NF.

107. In its procurement documentation, the organisation shall indicate that the organisation's employees and authorised employees of the VATESI shall be provided with a possibility:

107.1. to make sure that the requirements of the procurement documentation, including the safety technical normative documents, are met at the place of manufacturing of the product;

107.2. to familiarise themselves with the documents pertaining to supply of the product;

107.3. to take part in product checking and testing carried out at the premises of the supplier;

*Paragraph amendments:*

No. [22.3-15](#), dated 31 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

107.4. to take part in acceptance of products by the organisation at the premises of the supplier.

108. The organisation shall make a list of suppliers by indicating all areas of competence of the suppliers verified by the organisation in accordance with the procedure set in the requirements of the head of the VATESI regulating the management systems, and the dates of such verifications, and shall update the list at time intervals and based on procedure set in the organisation's management system documentation.

109. The organisation shall develop the audit programme of the suppliers and describe in the management system documentation the procedure for its execution, which is intended to check compliance of the management systems of all suppliers with the requirements applicable to the management system of the suppliers at time intervals established by the organisation, and to check preparedness of the suppliers to fulfil the requirements of the procurement documentation and other contractual commitments that may have impact on safety.

## **SECTION TWO CONTROL OF MEASURING INSTRUMENT**

110. The organisation shall ensure that accounting records of measuring instruments are kept, and that the lists of measuring instruments intended for legal metrology are approved by the senior management.

111. The organisation shall use only those measuring instruments that are technically fit, and:

111.1. the measuring instruments intended for legal metrology shall be subject to verification at the accredited laboratories at time intervals indicated in the legal act referred to in subparagraph 4.11 herein;

111.2. the technological control measuring instruments designed to monitor the condition of equipment, its operating modes and technological processes shall be used and maintained in accordance with the procedure set by the senior management, taking into account the technical requirements of the manufacturers of such measuring instruments, by ensuring that they are linked to the corresponding physical unit of reference;

111.3. the reference measuring instruments for calibration and verification of technological control measuring instruments shall be linked to reference of higher accuracy by calibrating them at the accredited laboratories.

112. Compliance of the measuring instruments with the metrological requirements, international or national measurement standards shall be marked and monitored. In case of absence of such standards, the organisation's management system documentation shall describe other fundamentals for calibration and verification of measuring instruments.

113. The organisation shall ensure that the measuring instruments in use, as well as their accuracy within the entire variation range of the parametre measured, meet the requirements of the technical normative documents on nuclear safety.

114. If the measuring instruments are found to be non-conforming to the metrological requirements and/or requirements of technical normative documents on nuclear safety, the organisation shall:

114.1. assess the measurements made and make records as to the reasonableness of the measurement results;

114.2. perform re-measurement with measuring instruments that conform to the metrological requirements;

114.3. assess the need for additional improvement actions.

115. If specialised software is used for measurement, the organisation shall have the documents certifying compliance of such software with the applicable requirements, i.e. the organisation shall verify and validate such software by itself or outsource these tasks to the supplier. Validation and verification of such software shall be carried out before bringing software into use.

## **CHAPTER VII MANAGEMENT OF ORGANISATIONAL STRUCTURE CHANGES**

116. The organisation shall plan, control, monitor, document, keep the track of, and report the organisational structure changes to employees and other interested parties, and shall ensure that such organisational structure changes have no adverse effects on safety, safety culture and security culture.

117. Having implemented the organisational structure change, the organisation shall assess whether the such change allowed achieving the established goals, and shall document the results of such assessment.

118. The organisation shall document the procedure for classification, planning, execution, communication, supervision and assessment of organisational structure changes. The procedure and changes planned therein shall be agreed upon with the head of the VATESI in accordance with paragraph 150 herein. Each and every organisational structure change shall have the supporting documents.

119. Planning, execution, supervision and assessment of implementation of organisational structure changes shall be carried out in compliance with the requirements set in the legal act referred to in subparagraph 4.13 herein.

## **CHAPTER VIII ASSESSMENT AND IMPROVEMENT OF MANAGEMENT SYSTEM**

### **SECTION ONE MONITORING AND ASSESSMENT OF MANAGEMENT SYSTEM**

120. In order to confirm that the management system and individual processes thereof are appropriate for achieving the expected results and in order to find possibilities of their improvement, the organisation shall:

120.1. monitor effectiveness and efficiency of the management system and individual processes thereof;

120.2. undertake self-assessment;

120.3. assess compliance of the management system and individual process thereof with the requirements applicable to the organisation's licensed activities.

121. Monitoring effectiveness and efficiency of the management system and processes and assessment of compliance of the management system and processes with the requirements applicable to the organisation's licensed activities shall encompass all aspects of licensed activities pursued by the organisation.

122. As one of alternative management system assessment approaches, the organisation shall undertake monitoring of information relating to implementation of requirements set by the interested parties.

123. The results of monitoring effectiveness and efficiency of the management system and processes and assessment of compliance of the management system and processes with the requirements applicable to the organisation's licensed activities shall be documented.

124. Compliance of the management system and processes with the requirements applicable to the organisation's licensed activities shall be confirmed by the organisation. Such confirmation shall be carried out by the organisation through monitoring and assessment or by involving the supplier.

### **SECTION TWO SELF- ASSESSMENT**

125. Senior management and the heads of all units within the organisation shall on a regular basis carry out self-assessment to evaluate performance of the corresponding units, adequacy of resources, safety culture, other safety-critical aspects of activities and need for improvement actions. The results of such self-assessment shall be documented.

126. In a manner prescribed in the organisation's management system documentation, the management shall inform the representative of the management about the self-assessment results, safety condition, difficulties identified, their main causes and improvement possibilities.

127. The self-assessment results shall be relied upon for improvement of safety culture and security culture.

128. The self-assessment procedure shall be defined in the organisation's management system documentation.

### **SECTION THREE AUDITS**

129. The management's representative or individuals assigned by such a representative to conduct audits shall not evaluate the work of their own or that of their direct superior.

130. The organisation shall ensure that the audits of its processes are carried out on periodic basis in order:

130.1. to determine whether the processes are effective and comply with the requirements applicable to the organisation's licensed activities, including its operational strategy, long-term plans and objectives;

130.2. to assess the organisation's safety culture and security culture;

130.3. to determine the possibilities of improvement of the management system.

131. At time intervals set in the management system documentation, the organisation shall approve and implement the audit programmes that are elaborated in view of the process status, relevance, prior audit results and improvement actions identified.

132. The audit programme of the organisation's management system shall be elaborated in a way the audits of compliance with the requirements established for corresponding process are conducted at least every three years.

133. The audit criteria, scope, time intervals, order of execution, requirements in terms of audit planning and execution, documentation and submission of audit results shall be specified in the organisation's management system documentation.

134. The audit engagement leaders and other auditors assigned shall be competent in the areas of the established requirements and the process audited.

135. The requirements set for the competence of individuals conducting audits shall be specified in the organisation's management system documentation. The organisation shall ensure that overall competence of the audit team is adequate for achievement of audit goals.

136. Based on the audit results and other information obtained in course of audit, the organisation shall determine and implement the relevant improvement actions. Prior to their implementation, the selected improvement actions shall be approved by the auditor or the audit engagement leader who has identified the respective weakness or improvement possibility.

### **SECTION FOUR MANAGEMENT SYSTEM REVIEW**

*Section title amendment:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

137. Senior management shall address safety issues, analyse performance of the organisation's processes and elaborate or update long-term plans and objectives for the nearest upcoming year for the organisation taken as a whole and its units taken individually, in view of the requirements of the interested parties and data on compliance with the Requirements.

138. Senior management shall:

138.1. approve the criteria for monitoring effectiveness and efficiency of the management system and processes and for assessment of their compliance with the requirements applicable to the organisation's licensed activities, requirements for planning of activities, supervision over policy and objective implementation;

138.2. analyse the results of monitoring effectiveness and efficiency of the management system and processes and assessment of their compliance with the requirements applicable to the licensed activities, including policy implementation and appropriateness, at least once per year at the time of the management system review;

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

138.3. elaborate the management system improvement objectives in view of the results of the management system and take the necessary improvement actions, communicate to the organisation's employees the decisions made that may have impact on safety, including the reasons for such decisions.

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

139. The meetings of the management system review shall be documented in the minutes.

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

140. The management system review shall cover analysis and consideration of data on:

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

140.1. results of audits and inspections carried out by the VATESI and non-conformities identified;

140.2. appropriateness of the management system application, policies, objectives and plans and the results of their implementation, process execution results and their compliance with the requirements applicable to the organisation's licensed activities;

140.3. organisational changes, the NF modifications and improvement actions;

140.4. implementation of decisions passed in relation to assurance of safety;

140.5. results of assessment of safety culture and security culture, effectiveness of measures specified in the plan on implementation of safety culture and security culture development measures, as referred to in paragraph 30, and other data on trends in the area of safety culture and security culture;

140.6. adequacy of resources for the fulfilment of requirements applicable to the organisation's licensed activities;

140.7. activities of the suppliers;

140.8. amendments to legal acts relating to the process;

140.9. practice of other organisations engaged in the activities of the same or similar nature;

140.10. other information on factors that may have impact on assurance of safety.

141. The management system review documentation shall be handled in accordance with the requirements set by the organisation.

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

## **SECTION FIVE**

### **NON-CONFORMITY MANAGEMENT AND IMPROVEMENT ACTIONS**

142. The organisation shall ensure that the products and processes, which are found to be non-conforming with the requirements applicable to the organisation's licensed activities, shall be identified and, in view of their impact on safety, such non-conformities shall be managed in one of the following ways:

142.1. actions are taken to eliminate the non-conformity identified;

142.2. actions are taken to prevent from their inappropriate use, including product destruction.

143. The organisation shall ensure that the causes of non-conformities are identified, and that measures are taken to eliminate them and prevent from occurrence of new and re-occurrence of old non-conformities. The preventive actions shall be taken to find out the causes of potential non-conformities and to eliminate them. The preventive actions shall be compatible with the degree of relevance of the potential issue.

144. The non-conformity management procedure shall be documented.

145. The organisation's management system documentation shall specify the requirements for:

145.1. implementation of corrective measures;

145.2. analysis of existing or potential non-conformities and identification of their causes;

145.3. elaboration of preventive and corrective actions and planning of their implementation;

145.4. alignment of the organisation's objectives with the improvement actions identified;

145.5. implementation of the improvement actions, supervision of implementation status and assessment of results;

145.6. communication of improvement actions to the management's representative, owners of processes affected by such actions, and relevant interested parties;

145.7. records on the need for improvement, improvement actions and their results.

146. The organisation, which operates under the licence specified in subparagraphs 1-5 of paragraph 1 of Article 22 of the legal act referred to in subparagraph 4.2. herein, shall develop, document and implement a system for accounting and management of non-conformities and non-compliances identified by the organisation, its suppliers and other interested parties, including the VATESI.

147. The organisation shall ensure that operating experience, development of safety standards and guidelines published by international organisations and scientific research results, which are used when addressing safety issues, shall be analysed on a systematic basis based on the graded approach. The organisation shall define the procedure for analysis of the aforementioned information. Such information and/or results of its analysis shall be relied upon while improving safety of the licensed activities, including the processes, management system, safety culture and security culture of the organisation.

148. The organisation shall monitor implementation of the improvement actions and assess their effectiveness.

149. The organisation's plans on implementation of improvement actions and other measures shall provide for adequate resources necessary to implement the improvement actions.

## **CHAPTER IX FINAL PROVISIONS**

### **SECTION ONE**

#### **SUBMISSION OF MANAGEMENT SYSTEM DOCUMENTATION TO THE VATESI**

150. Decisions regarding approval of the organisation's documents referred to in paragraph 41 and regarding approval of the procedure for classification, planning, implementation, communication, supervision and assessment of the organisational structure changes referred to in paragraph 118 and changes planned therein, which are submitted for agreement with the VATESI, shall be passed by the head of the VATESI within 30 calendar days from the date of receipt of the respective document. Decisions on disapproval of draft documents shall be passed if the documents are found to be not in conformity with the requirements applicable to the organisation's licensed activities.

151. The following information and copies of the approved management system documentation shall be made available by the organisation to the VATESI:

151.1. annual audit programmes of the management system (internal audits and audits of the suppliers) – annually by the 1st of March;

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

151.2. copies of internal audit reports and reports on audit of the suppliers together with the corrective measures (in case of identification of non-conformities) – within 20 calendar days after the approval of internal audit reports and reports on audit of the suppliers together with the corrective measures (in case of identification of non-conformities);

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

151.3. changes in the list of suppliers referred to in paragraph 108 herein – annually by the 1st of March;

151.4. data on non-conformities identified by the suppliers or organisation in relation to the specific procurement or data on non-compliances identified with the requirements of technical normative documentation on nuclear safety, the causes of such non-conformities and non-compliances, and the results of elimination of non-conformities or non-compliances and their causes – annually by the 1st of March;

151.5. information specified in paragraph 28 herein, reports on monitoring, assessment of safety culture and security culture and surveys of employees to assess safety culture and security culture, as referred to in paragraph 36 herein – within 20 calendar days after their approval;

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

151.6. plan on implementation of safety culture and security culture development measures referred to in paragraph 30 herein, specifying in detail implementation of measures indicated in the description of development of safety culture and security culture – annually by the 1st of March;

151.7. documents specified in paragraphs 123 and 139 herein – within 20 calendar days after their approval;

*Paragraph amendments:*

No. [22.3-15](#), dated 30 January 2017, published on the Register of Legal Acts on 31 January 2017, ID code 2017-01726

151.8. copies of other documents agreed with the VATESI and approved and registered in accordance with the procedure set in the organisation's management system documentation.

152. All documents to be submitted to the VATESI shall be drafted in accordance with the provisions of the Requirements, and their authenticity shall be ensured in line with the procedure set forth in the organisation's management system documentation.

153. Amendments to the documents to be submitted for agreement with the VATESI and referred to in paragraphs 41 and 118 shall be accompanied with electronic version of the documents to be submitted together with marked amendments thereto.

154. The organisation shall submit the documents referred to in subparagraphs 151.1, 151.2, 151.5, 151.7 and 151.8 to the VATESI not later than within ten working days after the date of registration of these documents. In case the documents referred to in subparagraph 15.2

provide for corrective measures, the deadline for submission shall be not later within ten working days after the date of establishment of corrective measures.

155. Upon the VATESI's request, the organisation shall submit any other management system documentation or safety-related documents of the organisation.

156. In case the documents are submitted in electronic format, the authenticity of such documents shall be confirmed by a safe electronic signature via safe electronic signature app and certified by a valid qualified certificate.

157. The digital copies of documents submitted to the VATESI shall contain scanned pages certifying their authenticity, as well as the document originator's agreement and approval marks.

158. The digital copies of documents submitted to the VATESI shall be formed in a way that:

158.1. the VATESI is able to recognise the format of the submitted digital documents, review and process them with the help of available IT tools;

158.2. enables search by text, in case the relevant documents contain text information;

158.3. the contents of documents is linked to the corresponding chapters, sections and subsections of the document through references.

## **SECTION TWO LIABILITY**

159. In the event of failure to comply with the Requirements herein, the persons shall be held liable in accordance with the procedure laid down in the legal acts of the Republic of Lithuania.

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