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**DECREE  
of ...****amending Decree No 408/2016 on management  
system requirements**

Pursuant to § 236 of Act No 263/2016, the Atomic Act, the State Office for Nuclear Safety lays down the following for the implementation of § 24(7), § 29(7) and § 30(9):

**Article I**

Decree No 408/2016 on management system requirements is amended as follows:

1. In § 2(a), the word ‘monitoring’ is inserted after the words ‘implementation of’.
2. In § (2)(a), the word ‘performance’ is replaced by the word ‘improvement’.
3. In § (2)(c), the word ‘employee’ is deleted.
4. In § (2)(f), the full stop at the end is replaced by a semicolon.
5. The following § 2(g) is added:

‘g) senior management means natural persons who have the power to make key decisions about the policy, resources and direction of the entity implementing the management system.’.

6. In § 3(1)(a), the word ‘safety,’ is inserted after the words ‘achievement of’.
7. In § 3(1)(a), the words ‘of the management system’ are inserted after the word ‘objectives’.
8. In § 3(1)(a), the word ‘objective’ is replaced by the words ‘safety objective’.
9. In § 3(2), the words ‘the safety objective of the management system in such a way that the achievement of other objectives of the management system and requirements for processes and activities does not adversely affect the achievement of the safety objective’ are inserted after the word ‘achieving’.
10. In § 3(3), the first sentence is replaced by the words ‘Processes and activities in the management system must be implemented in such a way as to achieve the safety objective of the management system and the fulfilment of integrated requirements.’.
11. In § 3(5)(e), the words ‘integrated requirements linked together so’ are replaced by ‘measures in place to prevent and avoid the use of fraudulent’.

12. In § 3(5)(e), the words 'so that nuclear safety, radiation protection, technical safety, radiation monitoring, radiation emergency management' are replaced by 'counterfeit'.
13. In § 3(5)(e), the words 'security are permanently ensured' are replaced by the words 'suspect items'.
14. In § 3(5)(f), the words 'within the organisational structure' are deleted.
15. In § 3(5)(g), the word 'and' is replaced by a semicolon.
16. In § 3(5)(h), the word 'safety' is inserted after the word 'achieving'.
17. In § 3(5)(h), the full stop at the end is replaced by a semicolon.
18. The following § 3(5)(i) is added:

'(i) implementation of risk management to achieve the safety objective of the management system; risk management must include, as part of the prevention of non-compliance,

1. finding potential non-conformity (hereinafter 'potential non-conformity') and its possible causes;
2. evaluating the need for a preventive measure to prevent the occurrence of potential non-compliance;
3. implementing a preventive measure proportionate to the possible cause of the potential non-conformity; own operational experience and, where available, the operational experience of another person must be used to stipulate the preventive measure; and
4. monitoring and evaluation of the preventive measure in terms of its implementation status and its effectiveness and'.

19. The following § 3(5)(j) is added:

'(j) specification of a uniform method of communication and the language that ensures it.'

20. The following § 3(6) is added:

'(6) Members of senior management must ensure that:

- a) a security policy has been established and its safety objective of the management system has been fulfilled;
- b) the objectives of the management system aimed at fulfilling the safety objective of the management system, the management system plans and the tasks of the entity implementing the management system are in accordance with the safety policy and their impact on nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and security is taken into account and managed in such a way that nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and security are not compromised by other priorities;

- c) the adequacy and effectiveness of the management system are monitored and evaluated; and
- d) regular self-assessments and independent evaluations are carried out concerning
  - 1. the performance of activities in relation to the safety objective of the management system carried out by a member of senior management;
  - 2. management capabilities in the fields of nuclear safety, radiation protection, technical safety, radiation situation monitoring, extraordinary radiation event management and security, including safety culture and basic attitudes and behaviours.’.

21. The following § 3(7) is added:

‘(7) The management system must be established and documented prior to the commencement of activity related to the utilisation of nuclear energy from the time when the processes and activities may affect the future achievement of the safety objective of the management system. In such a case, the management system programme is part of the management system documentation.’.

22. In § 4(2)(a)(2), the words ', which complies with § 15(1)' are inserted after the word 'management'.

23. In § 4(2)(c), the word 'continually' is replaced by the word 'regularly'.

24. In § 4(2)(c), the word 'safety' is inserted after the word 'stipulated'.

25. In § 4(2)(e)(4), the word 'safety' is inserted after the word 'achieved'.

26. In § 4(2)(e)(5), the word 'and' is deleted.

27. In § 4(2)(e)(6), the full stop at the end is replaced by the word 'and'.

28. The following § 4(2)(e)(7) is added:

‘7. for the management and evaluation of processes and activities carried out by a contractor, an appropriate number of own staff of the entity implementing the management system must be ensured.’.

29. In § 4(3), the second sentence is deleted.

30. in § 5(1) the comma is replaced by the word 'and'.

31. In § 5(1), the words 'and validation' are deleted.

32. in § 5(2) the comma is replaced by the word 'and'.

33. In § 5(2), the words 'and validation' are deleted.

34. in § 5(3) the comma is replaced by the word 'and'.

35. In § 5(3), the words 'and validation' are deleted.

36. In § 6(1)(a), the words 'established and fulfilled' are replaced by the word 'designated'.

37. In § 6(1)(a), the word 'safety' is inserted after the word 'achieving'.

38. In § 6(1)(b), the word 'every' is replaced by the word 'managerial'.

39. In § 6(1)(b), the words 'carrying out activities to ensure and improve nuclear safety, radiation protection, technical safety, radiation monitoring, radiation emergency management and security' are deleted.

40. In § 6(1)(c), the words 'the management system plan' are inserted at the beginning.
41. In § 6(1)(c), the words 'the quality of the management system plan must be improved' are replaced by ' must be assessed from the perspective of accuracy and timeliness and kept up to date'.
42. In § 6(1)(d), the word 'its' is inserted after the word 'and'.
43. In § 6(1)(d), the words 'increasing its quality' are deleted.
44. In § 6(1)(e), the words 'elimination of non-compliance in' are replaced by the words 'achievement of results'.
45. In § 6(1)(e), the words 'pursuant to subparagraph (d)' are added at the end of the text.
46. The following § 7(7) is added:

‘(7) Where a change in the management system does not affect nuclear safety, radiation protection, technical safety, radiation monitoring, extraordinary radiation event management or security, the requirements of paragraphs 2 to 5 shall not apply.’.

47. In § 8(1)(a), the word 'safety' is inserted after the word 'achieving'.
48. In § 9(1)(b), the word 'safety' is inserted after the word 'achieving'.
49. In the introductory part of § 10(1), the words 'change in the system' are replaced by the word 'system'.
50. In the introductory part of § 10(1), the words ', including processes' are inserted after the word 'management'.
51. In the introductory part of § 10(1), the words 'change in processes and activities' are replaced by 'activities,'.
52. In § 10(1)(a), the word 'safety' is inserted after the word 'achieve'.
53. In § 10(1)(c), the words 'with the appropriate powers to implement it' are inserted after the word 'employee'.
54. In § 11(1)(e), the word 'and' is deleted.
55. In § 11(1)(f), the full stop at the end is replaced with the word 'and'.
56. The following § 11(1)(g) is added:

'g) in the event of the discovery of a fraudulent, counterfeit or suspect item, inform the Office without delay.'

57. § 11(3) is deleted.
58. In § 12(1)(a), the words 'stipulate the qualification requirements, including the length of professional experience, appropriate to the type and significance of the process and activity carried out by the worker' are replaced by the words 'stipulate the qualification requirements, including the duration of professional experience, and the language and communication skills requirements appropriate to the type and significance of the process and activity carried out by the employee;'.
59. § 13 reads as follows:

## **Development and evaluation of a safety culture**

- (1) To continuously develop a culture of safety in the management system of the entity implementing the management system,
- a) clarity and awareness of the main principles of the safety culture for members of management and those carrying out processes and activities must be ensured;
  - b) managers must ensure information on the achievement of the safety objective of the management system is sought and shared with other employees of the entity implementing the management system;
  - c) conditions must be created for informing managers of how the safety objective of the management system is achieved by the entity implementing the management system via that entity's employees;
  - d) it must be effectively ensured that the activities of managers lead to the development of a safety culture entirely commensurate with the intent of the entity implementing the management system, including for employees, managers and the organisation, in particular to
    - 1. support the reporting of problems related to nuclear safety, radiation protection, technical safety, radiation monitoring and radiation emergency management;
    - 2. the development of a questioning attitude; and
    - 3. correction of activities or conditions that may adversely affect nuclear safety, radiation protection, technical safety, radiation monitoring and radiation emergency management;
  - e) ensuring the readiness of the entity implementing the management system to undertake the activities necessary to achieve the safety objective of the management system, using its competence, which the entity implementing the management system must maintain from its internal resources, including
    - 1. competence for guidance on nuclear safety, radiation protection, technical safety, radiation situation monitoring and radiological emergency management at all management levels;
    - 2. competence to promote and maintain a strong safety culture; and
    - 3. expertise to understand the technical, human and organisational aspects or activities for ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring and radiological emergency management;
  - f) employees of the entity implementing the management system must be encouraged by managerd to seek opportunities to improve the management system and processes and activities and create the conditions for doing so;
  - g) the management system must be used in a manner conducive to achieving the safety objective of the management system and to improving the level of nuclear safety, radiation protection, technical safety, radiation monitoring, radiation incident management and to developing a safety culture by ensuring

that nuclear safety, radiation protection, technical safety, radiation monitoring and radiation incident management

1. are taken into account in all decision-making, and
2. are not compromised by the decisions taken;

- h) the adequacy, suitability and effectiveness of the resources must be assessed proportionately pursuant to § 8 to 10; and
  - i) knowledge and information within the organisation must be managed as a resource.
- (2) The entity implementing the management system must ensure that managers contribute to the continuous development of a safety culture in that
- a) all employees of the entity implementing the management system contribute to the development of a safety culture;
  - b) their behaviour and conduct promote and encourage trust, cooperation, consultation and communication;
  - c) they apply measures to promote an enquiry and learning approach at all levels and avoid complacency, inattention and deliberate inaction in areas related to nuclear safety, radiation protection, technical safety, radiation monitoring and radiation emergency management;
  - d) they use a systematic approach in which interactions between technical, human and organisational factors are taken into account; and
  - e) they carry out regular self-assessments of the safety culture according to their procedural role.
- (3) The entity implementing the management system must ensure that regular assessment of the safety culture is
- a) carried out at least once a year at all levels of management and for all positions in the organisational structure;
  - b) carried out at least once a year in the form of self-assessments by managers in the field of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and safety culture, with the use of management and safety culture experts; and
  - c) documented, including the conclusions of the assessment and the measures taken to develop a safety culture.
- (4) The result of the safety culture assessment must be communicated to each employee of the entity implementing the management system and its supplier of the product or service.
- (5) The entity implementing the management system must ensure that, on the basis of the conclusions of the safety culture assessment, measures are taken to promote and maintain the safety culture, in particular to improve leadership for nuclear safety, radiation protection, technical safety, radiation monitoring and radiation incident management and to promote a learning approach.’.

60. In the introductory part of § 14(a), the words ‘description’ is deleted.
61. In § 14(a)(1), the words ‘description of security’ are inserted at the beginning.
62. In § 14(a)(1), the semicolon at the end is replaced by the word ‘; and’.
63. In § 14(a)(2), the words ‘objectives of the manager’ are replaced by the words ‘overall plans and intentions of the entity implementing the management system in relation’.
64. In § 14(a)(2), the words ‘quality assurance and improvement’ are replaced by the words ‘the safety objective of the system’.
65. In § 14(a)(2), the words ‘processes and activities and their outputs and’ are replaced by a semicolon.
66. § 14(a)(3) is deleted.
67. In the introductory part of § 14(b), the words ‘a description of the management system containing a description’ are replaced by ‘a document containing a description of the management system, which is the management system programme, if the entity implementing the management system pursuant to § 24(1)(a) of the Atomic Energy Act is required to have it, to the extent’.
68. In § 14(b)(4), the words ‘processes and activities, their outputs and their interactions based on the security policy pursuant to point (a) and containing information on their preparation, review, verification and validation, implementation, evaluation and improvement, and recording of data related to processes and activities and their outputs and’ are replaced by the words ‘processes and activities, their outputs and their interactions based on the security policy pursuant to point (a) and containing information on their preparation, review, verification and validation, if required, implementation, evaluation and improvement, and recording of data related to processes and activities and their outputs and’.
69. In § 14(e), the comma is replaced by ‘when achieving the safety objective of the management system; these documents are’.
70. In § 14(e), the word ‘, plans’ is inserted after the word ‘programmes’.
71. In § 14(e), the words ‘selected equipment’ are deleted.
72. In § 14(e), the words ‘limits and conditions, safety reports’ are replaced by the words ‘documentation for the permitted activity’.
73. In § 15(1)(a)(1), the word ‘security’ is inserted after the words ‘achievement of’.
74. In § 15(1)(c), the words ‘; the change to the management system documentation must be approved by the employee who approved the management system documentation and, if this is not possible, by an employee with the same procedural role’ are deleted.
75. In § 15(1)(d), the words ‘structured from the general to the specific,’ are added at the beginning.
76. In § 15(1)(d), the words ‘and interlinked’ are inserted after the word ‘legible’.
77. In § 15(1)(d), the words ‘and unambiguous’ are inserted after the word ‘complete’.
78. In § 15(1)(d), the words ‘and easily’ are deleted.
79. In the introductory part of § 15(1)(f), the words ‘with the exception of documentation relating to planning in the management system’ are inserted at the beginning.
80. In § 15(1)(g), the words ‘with the exception of documentation relating to planning in the management system’ are inserted at the beginning.
81. In § 15(2)(b), the word ‘safety’ is inserted after the words ‘fulfilment of’.

82. In § 15(3)(a), the words ‘radiation protection, technical safety, radiation monitoring, radiation emergency management and security;’ are added at the end.
83. In § 15(3)(c), the words ‘, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and security’ are added at the end of the text.
84. In § 16(e)(2), the words ‘, if required,’ are inserted after the word ‘validation’.
85. In § 16(e)(6), the words ‘his abilities’ are inserted after the word ‘and’.
- CELEX 32014L0087, 32011L0070, 32009L0071, 32013L0059*

## Article II

### **Final provisions**

1. This Decree was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, as amended.

## Article III

### **Effective date**

This Decree comes into effect on 1 February 2026.