DECREE

No. 408

of 6th December 2016

on management system requirements

The State Office for Nuclear Safety sets, according to § 236 of Act No. 263/2016 Coll., the Atomic Act, to implement § 24(7), § 29(7), and § 30(9):

§ 1

Subject matter

This decree incorporates the relevant Euratom legislation[1)] and regulates

a) requirements for the management system implementation, maintenance and improvement,
b) the content of management system documentation and how it is kept,
c) rules for conducting and managing of the processes and activities,
d) rules for conducting and managing of the special processes,
e) management system planning and the scope and method of its documentation,
f) procedures for implementing changes to the management system,
g) rules for assessing the efficiency of the management system, including the processes and activities and changes thereto,
h) non-conformity management procedures,
i) how the appropriate qualifications of personnel conducting processes and activities are ensured,
j) the scope of and method for ensuring permanent development and regular evaluation of the safety culture and
k) content requirements for the management system programme.

§ 2

Definitions

For the purposes of this implementing decree, the following definitions apply:

a) process guarantor - an employee who ensures the implementation and performance of a process affecting nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and security (hereinafter "process") and fulfilment of legislative requirements for this process,

---

1) Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.
Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.
Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.
Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

b) verification - a check that processes and activities and their inputs and outputs are conform with requirements concerning their properties stipulated in the management system documentation,
c) process role - an employee's expected behaviour and actions within the scope of a process that are intended to achieve reliable performance of assigned activities in accordance with the individual's goals pursuant to § 29(1) of the Atomic Act (hereinafter the 'person implementing the management system'),
d) review - an assessment of the suitability, adequacy and efficacy of processes and activities and their inputs and outputs from the perspective of nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
e) process efficacy indicator - data that provides the process guarantor with information on the efficacy of a process and of the activities it comprises, from the perspective of ensuring and increasing nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
f) validation - a check whether processes and activities and their inputs and outputs are conform with their intended use stipulated in the management system documentation.

§ 3

Requirements for management system implementation, maintenance and improvement

(1) The management system must be introduced, maintained, and improved so that

a) the objective whose intent is to ensure and increase nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security (hereinafter the 'management system objective') is achieved in an effective manner and
b) all the requirements that may serve to ensure and increase nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security (hereinafter the 'integrated requirement') are met.

(2) During the decision-making process the person implementing the management system must primarily ensure that the management system objectives are achieved.

(3) The management system processes and activities must be introduced so as to ensure the management system objectives are achieved and the integrated requirements are met.

(4) The management system processes and activities must be performed in a planned and systematic manner.

(5) Within a management system

a) conditions must be created for the maintenance, improvement, and evaluation of the management system, including changes thereto,
b) measures must be introduced to ensure and increase nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
c) measures must be implemented to ensure that the activities performed by the person implementing the management system comply with legislative requirements,
d) the integrated requirements must be met in mutual accordance to permanently ensure nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,

e) the integrated requirements must be linked to permanently ensure nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
f) the management method and the individual management levels must be stipulated within the scope of the organizational structure,
g) the ability to manage employees to ensure and increase nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security (hereinafter 'management ability') of an employee delegated to manage or with managerial abilities (hereinafter a 'manager') must be developed and maintained and
h) management ability must be developed and maintained at all levels of management so that it can be effectively applied in achieving the objectives of the management system and developing and evaluating safety culture.

Process and activity scope, performance, and management

§ 4

(1) A process guarantor must be designated for each process. The process roles must be stipulated for each process.

(2) Processes and activities must

a) be performed and managed in accordance with
   1. the intended use of their outputs and
   2. the requirements stipulated in the management system documentation, including the requirements for the scope of quality assurance of their outputs and acceptability criteria for these outputs,
b) have related processes and activities stipulated as well as a mutual interface with related processes and activities to permanently ensure nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security; the interface between processes and activities must include
   1. material or non-material processes and activity inputs and outputs,
   2. the information that is shared during the performance of related processes and activities and
   3. mutual relationships between the persons performing and managing related processes and activities,
c) be systematically monitored to verify their ability to achieve the stipulated objective of the management system,
d) be documented pursuant to § 14(b) points 4 and 5 and § 14(c) and
e) be performed under the following conditions:
   1. the documentation applicable to processes and activities must be available to every person participating in the processes and activities for their entire duration,
   2. the processes and activities must be subjected to ongoing checks to verify their correct performance and the quality of their outputs at a given moment,
   3. suitable equipment must be used and appropriate work conditions and environment must be ensured,
   4. the relationships between the persons performing and managing processes and the activities must be configured to achieve the objectives of the management system and to meet the integrated requirements,
   5. an employee must be qualified to perform his or her process role and must know the requirements for the processes and activities to which the process role pertains and

6. the equipment used for processes and activities must be kept in a condition that ensures permanent conformance of process and activity outputs with the requirements placed on them.

(3) If a checkpoint is stipulated in the process and activity documentation, the processes and activities cannot continue without the approval of a specified employee. The approval for continued performance of processes and activities may be granted only if the results pass the check performed within the scope of the checkpoint. The approval of continued performance of processes and activities must be recorded.

§ 5

(1) Processes and activities and their inputs and outputs must be reviewed, verified, and validated prior to their first use.

(2) Acceptability criteria must be stipulated for review, verification, and validation of processes and activities.

(3) Process review, verification, and validation must be performed by the process guarantor or a delegated employee with the same qualifications as the guarantor.

(4) For a special process, requirements must be stipulated that correspond to the nature of the special process, for

a) the qualifications of employees that manage, perform, and evaluate it,
b) the procedure used to perform the process and
c) the equipment and a suitable work environment and the conditions for its performance.

(5) The meeting of requirements pursuant to (4)(a) and (b) must be checked by validation prior to the performance of a special process.

(6) Only the equipment whose condition and suitability for the performance of the special process has been checked may be used to perform it.

§ 6

Management system planning and the scope and method of its documentation

(1) During the planning process in the management system

a) a plan to achieve the objectives of the management system and to implement the safety policy pursuant to § 14(a) (hereinafter the 'management system plan') must be created and followed,
b) the management system plan must be known to every worker performing activities to ensure nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
c) the quality of the management system plan must be continuously improved to prevent a decline in nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security,
d) the implementation of the management system plan and the efficacy of its quality improvement must be regularly evaluated from the perspective of its compliance with the planned results and
e) effective measures must be implemented to eliminate non-conformance in the management system plan.

(2) The management system plan must comply with safety policy pursuant to § 14(a).

§ 7

Procedures for implementing changes to the management system

(1) The changes to the management system must be planned. The management system amendment plan must be performed to prevent a decline in nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security.

(2) A proposed change to the management system must be justified and must be evaluated from the perspective of the purpose of the change to the management system and its future influence on nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security.

(3) The efficacy of a change to the management system must be continuously monitored and then subjected to independent evaluation pursuant to § 10(1).

(4) When making changes to the management system, the following must be documented:

a) the proposed change to the management system,
b) the decision on the change to the management system,
c) the manner in which the change to the management system will be prepared,
d) the implementation of the change to the management system,
e) the manner in which the change to the management system will be evaluated, and the evaluation,
f) the schedule for implementing the change to the management system.

(5) Once the change to the management system has been made, its true effect on nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security must be evaluated.

(6) A change to the system is also defined as a change to processes and activities in the management system.

Rules for assessing the efficiency of the management system, including processes and activities and changes thereto

§ 8

(1) Through the assessment of the management system, processes and activities and changes thereto, it must be determined whether these are

a) suitable and adequate to achieve the objectives of the management system; and
b) capable of achieving the planned result.

(2) The efficacy of the management system and of processes, activities, and changes thereto must be assessed to continuously search for ways to improve the management system, including processes and activities and changes thereto.

(3) A process efficacy indicator must be specified and used to assess the process efficacy.

(4) The process efficacy indicator must be regularly evaluated by the process guarantor from the perspective of its ability to provide information on process efficacy.

(5) The management system efficacy assessment must take place internally and via an independent evaluation.

§ 9

(1) The evaluation itself must be performed regularly for each process by the process guarantor by comparing the process outputs with the requirements placed on the process by the management system documentation for

a) the verification of process suitability, adequacy, and efficacy,
b) the identification or prevention of non-conformity that prevents the achievement of the objectives of the management system; and
c) finding and adopting a measure to eliminate the non-conformity pursuant to (b), a corrective measure leading to the prevention of repeated occurrence of non-conformity, or a preventive measure to prevent it.

(2) The internal evaluation must be planned. The internal evaluation plan must stipulate

a) the manner in which the internal evaluation shall be implemented,
b) the frequency of internal evaluation; and
c) the focus of the internal evaluation in the planned period.

(3) The process guarantor performing the internal evaluation must

a) set the objective and scope of the internal evaluation,
b) set the process efficacy indicator according to which the efficacy of the process or activity is to be assessed,
c) draw up an internal evaluation performance programme,
d) compare the process under evaluation and its activities with the set objective and the process efficacy indicator; and
e) based on the results of the internal evaluation, propose
    1. a measure to eliminate the non-conformity, if identified,
    2. a corrective measure leading to the prevention of repeated occurrence of non-conformity; and
    3. a preventive measure to prevent non-conformity, including a proposal to improve process efficacy.

§ 10

(1) The independent evaluation must evaluate a change of the management system and in the processes and activities, and must be performed

a) using a suitable method for evaluating the ability of the management system to achieve its objectives,
b) at regular intervals and
c) by a qualified employee who does not participate in the planning, management, and the performance of the processes and activities that are under evaluation.

(2) The result of the independent evaluation must

a) be formulated in a clear manner and in accordance with its intended use for management system improvement,
b) contain information facilitating its review and
c) make it possible to implement
    1. measures to eliminate non-conformity, if identified; and
    2. a preventive measure to prevent non-conformity.

§ 11

Non-conformity management procedures

(1) Within the scope of non-conformity management, during non-conformity detection

a) the employee charged with ensuring non-conformity correction must immediately be informed that one has occurred,
b) the symptoms of non-conformity must be identified immediately after it has been found,
c) non-conformity must be documented as soon as it has been found,
d) a procedure must be implemented to handle the processes and activities and their inputs and outputs and sources that the non-conformity concerns, including a plan to eliminate non-conformity,
e) requirements must be stipulated to prevent unsuitable handling of processes and activities and their inputs, outputs, or sources that the non-conformity concerns and
f) the resulting and possible impact on nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security must be evaluated.

(2) Within the scope of non-conformity management, during non-conformity correction

a) the seriousness of non-conformity must be evaluated,
b) a root cause analysis of non-conformity must be performed,
c) a measure to eliminate non-conformity must be specified and implemented,
d) the measure implemented to eliminate non-conformity must be monitored and assessed from the perspective of its performance status and its efficacy,
e) the need for a corrective measure that would prevent the repeated occurrence of non-conformity must be evaluated,
f) a corrective measure that would prevent the repeated occurrence of non-conformity that is commensurate to its consequences must be specified and implemented and
g) the corrective measure implemented to eliminate non-conformity must be monitored and assessed from the perspective of its performance status and its efficacy.

(3) Within the scope of non-conformity management, in the interest of preventing non-conformity and its repeated occurrence

a) a non-conformity that could occur (hereinafter a 'potential non-conformity') and its possible causes must be searched for,
b) the need for a preventive measure to prevent the occurrence of a potential non-conformity must be evaluated,
c) a preventive measure commensurate to the possible cause of a potential non-conformity must be implemented; internal operating experience and the operating experience of another person, if available, must be used to stipulate the preventive measure and
d) the preventive measure must be monitored and evaluated from the perspective of its implementation status and its efficacy.

§ 12

How appropriate qualifications of personnel conducting processes and activities are ensured

(1) In order to ensure the qualification of the employee performing processes and activities in the management system it is necessary that

a) the qualification requirements are stipulated, including years of professional experience corresponding to the type and significance of the process and activity the employee performs,
b) a system for theoretical preparation of personnel conducting processes and activities must be used,
c) a system for practical training of personnel conducting processes and activities must be used and
d) the efficacy of the system for theoretical preparation and practical training of personnel conducting processes and activities must be evaluated.

(2) Requirements pursuant to (1) must be met in a manner that ensures the employee performing processes and activities is capable of performing the process and activity and is informed of the influence the process and activity has on ensuring and increasing nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security.

(3) The qualifications of an employee performing processes and activities must be independently verified prior to the first commencement of the process and activity, and subsequently on a regular basis.

(4) The qualifications of an employee performing processes and activities must be continuously maintained in order to ensure the requirements for processes and activities are met and that they are effective.

§ 13

Development and evaluation of the safety culture

(1) In order to continuously develop a safety culture in the management system of the subject implementing the management system:

a) it is necessary to ensure that the main principles of a safety culture for managers and for employees performing processes and activities are understandable and that they are well acquainted with them,
b) the subject implementing the management system must ensure that a manager shall search for information regarding the achievement of the management system objectives and share it with other employees of the subject implementing the management system,
c) the subject implementing the management system must create conditions for informing the manager on how to achieve the objectives of the management system through the employees of this subject,
d) it is necessary to ensure that an employee of the subject implementing the management system is prepared to perform the activity necessary to achieve the objectives of the management system,
e) the employee of the subject implementing the management system must be guided by the manager to search for opportunities for improving the management system and processes and activities, and conditions for this search must be created and
f) the adequacy, suitability, and efficacy of sources must be assessed in a commensurate manner pursuant to § 8 to 10.

(2) The subject implementing the management system must ensure that the manager contributes to constant improvement and development of the safety culture and performs his or her own regular evaluation of the safety culture according to the process role he or she has.

(3) Regular evaluations of the safety culture must take place at least once a year and the result of the safety culture evaluation and measures adopted must be documented.

(4) Every employee of the subject implementing the management system and its suppliers of products or services must be informed of the result of the safety culture evaluation.

Management system documentation

§ 14

The management system documentation must include:

a) a safety policy containing a description of
   1. the objective of the management system,
   2. the objective leading to ensuring and improving the quality of management of processes and activities and their results,
   3. the measures to meet the objective pursuant to points 1 and 2 and its monitoring,
b) a description of the management system containing a description of
   1. the organisational structure of the subject implementing the management system,
   2. the rights and responsibilities of personnel who plan, manage, perform, and evaluate processes and activities and their mutual relationships, communication methods, and decision-making methods at every level of management,
   3. the method of communication between the subject implementing the management system and a product or service supplier, another subject that participates in ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security, and with the Office;
   4. processes and activities, their results and their mutual effects, based on the safety policy pursuant to a) and containing information on their preparation, review, verification and validation, performance, evaluation, and improvement, and recording of data applicable to processes and activities and their results; and
   5. managing records pursuant to (c),
c) records
   1. of the manner in which a process or activity is performed,
   2. of the achieved results upon fulfilment of requirements for the management system and results of processes and activities and
   3. fulfilment of the requirements for other management system documentation;
d) requirements for the processes and activities performed by a product or service supplier and
e) other documentation of the subject implementing a management system that is used to manage processes and activities, especially contracts, programmes, lists of selected equipment, limits and conditions, safety reports, and internal regulations.

§ 15

(1) The management system documentation must be

a) drawn up so that the procedure it describes
   1. facilitates the achievement of the management system objective and
   2. leads to the fulfilment of integrated requirements,
b) reviewed pursuant to § 5 prior to its implementation,
c) approved by a designated employee; a change to management system documentation must be approved by the employee who approved the management system

documentation, and if this is not possible, it must be approved by an employee with the same process role,

d) comprehensible, legible, complete, clearly and easily identifiable and traceable,
e) securely stored and archived for the period stipulated in the management system documentation,
f) regularly assessed to its entire extent during three consecutive years from the perspective of
   1. fulfilment of requirements for the processes and activities it describes and
   2. the efficacy of processes and activities and
g) maintained in accordance with the assessment results pursuant to (f).

(2) The safety policy pursuant to § 14(a) must be

a) notified to all employees at all management levels and to the product or service suppliers so that the requirements it contains are always met to the extent corresponding to the activity being performed,
b) monitored continuously from the perspective of fulfilment of the objective of system management and
c) assessed annually by the subject implementing the management system from the perspective of the adequacy and efficacy of its implementation.

(3) The safety policy pursuant to § 14(a) must stipulate a requirement for the systematic improvement of nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security through

a) identification and assessment of new information applicable to nuclear safety,
b) safety assessments and
c) timely implementation of measures to increase nuclear safety.

§ 16

The management system programme must contain

a) the subject, place of performance, and scope of the activity being authorised,
b) except for a Category III workplace, the identification information of the direct supplier of a product or service being utilised by the subject implementing the management system to a similar extent as information pursuant to (a),
c) a list of processes and activities to which the management system programme applies, with respect to the type of activity being authorised and identifying the process that shall be outsourced,
d) the identification of the employee who must ensure the coordination and maintenance of the management system and compliance of the management system with the requirements of this decree and a description of the rights and responsibilities of this employee,
e) information on the management system including a description of
   1. the rights, responsibilities, and mutual relationships of employees who plan, manage, verify, and assess processes and activities,
   2. mutual relationships and organisation of departments participating in planning, management, performance, review, verification, and validation of processes and activities,
   3. the communication method for internal communication and communication with a product or service supplier and with the Office,

4. how the requirements in this decree applicable to the activity being authorised are fulfilled, including clear identification of documentation pursuant to which these requirements are fulfilled,
5. how the efficacy of the management system and of processes and activities is assessed, including a description of the principles by which the independence of management system assessment, internal assessment, and recording of assessment results is ensured,
6. how the ability of a product or service supplier to deliver the required product or service is verified, including how the product or service quality is ensured, and to fulfil requirements applicable to ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, handling radiological emergencies, and security and
7. except for a Category III workplace, the scope and manner in which the requirements of this decree shall be applied to the management system of a product or service supplier, including how the efficacy of the management system is assessed and how outsourced processes and activities are assessed, and

f) description of how and how often the management system programme is updated.

§ 17

The management system while performing or arranging activities within the scope of exposure situations

While performing or arranging activities within the scope of exposure situations in Category III workplaces, the management system must meet the requirements of § 3 to 5, § 7 to 12, § 14(b) to (e), § 15(1), and § 16.

§ 18

Notification

This Decree has been 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.

Chairperson:
Ing. Dana Drábová, Ph.D., v. r.