Decree of the
Nuclear Regulatory Authority of the Slovak Republic
No. 431/2011 Coll. as amended by Decree No. 104/2016 Coll., Decree No. 154/2022 Coll. and Decree No. 204/2025 Coll.
on a quality management system (consolidated version)

The Nuclear Regulatory Authority of the Slovak Republic (herein referred to as the "Authority"), pursuant to Section 25 (6) of the Atomic Act No. 541/2004 Coll. on peaceful use of nuclear energy (the Atomic Act) and on the amendments and supplements to certain Acts, as amended by Act No. 350/2011 Coll. (hereinafter referred to as the "Act"), lays down as follows

Section 1
Subject of the Decree

The decree lays down the details of requirements for the scope, content, hierarchy, structure and review of quality management system of the applicant for an authorisation and the authorisation holder, as well as details of requirements for the scope, content, hierarchy and structure of its documentation, details of requirements for nuclear installation quality assurance, details of requirements for classified equipment quality assurance of and details on the scope of their approval.

Section 2
Definition of some terms

(1) Quality management system documentation is a set of documents, records and information, regardless of the medium on which they are situated, that define basic requirements, specifies responsibilities, procedures and criteria to achieve the required quality of processes, and record the quality level achieved and provide evidence on performed activities.

(2) Independent assessment of a quality management system is an activity carried out through audits or supervised activities to determine the extent to which the requirements have been met, to evaluate the effectiveness of the management system and to identify opportunities for improvement. Independent assessment shall be conducted by the applicant for an authorisation, or the authorisation holder, the supervisory body, or by independent external person accredited in line with principles in specific procedure[1]) in the area of quality management systems.[2])

(3) Qualification is confirmation, that classified equipment are capable of meeting functional requirements from nuclear safety point of view during their designed operating lifetime, considering the influence of service conditions during their use, while service conditions shall include expected changes in operation with regard to their ageing, wearing out, and impact of events.

(4) A graded approach is the gradation of requirements for processes, activities, quality management system documentation, for nuclear installation quality assurance, for the quality of nuclear installation, for classified equipment quality assurance, for the quality of classified equipment, for the handling of nuclear materials, of radioactive waste, of spent nuclear fuel, for employees and for resources according to

a) their importance and complexity of each activity and its products,
b) possible consequences and level of risk associated with individual activities and products,
c) possible consequences if given activity is carried out incorrectly or a product fails,

(5) Management review[3]) is regular and systematic assessment of a quality management system to identify its suitability, adequacy, efficiency, effectiveness and implementation of corrective actions in terms of the authorisation holder's policies and goals.

(6) A process approach is the systematic identification and management of processes used by the applicant for an authorisation or the authorisation holder, and the identification of interactions between these processes.

(7) Management of quality management system documentation is a process that requires all jobs of the applicant for an authorisation or the authorisation holder to have valid and legible editions of the necessary documentation , for quality management system documentation to meet content and form requirements, for employees and suppliers of the applicant for an authorisation or the authorisation holder are demonstrably familiar with the documentation and to prevent the use of invalid or outdated documents.

(8) Self-assessment[3]) is the regular and systematic review of processes and their results by the applicant for an authorisation or the authorisation holder and their comparison with the requirements of a quality management system. Self-assessment is performed at each management level of the applicant for an authorisation or the authorisation holder with aim to assure continuous improvement.

(9) Specific inspection[4]) there are tests performed on manufacturers' premises in accordance with the relevant product specifications on products to be delivered, or on samples taken from these products, to find out whether products match characteristics specified in quality requirements or in technical documentation for the relevant classified equipment.

(10) Continuous improvement of a quality management system is the process of improving measurable indicators based on the quality policy and quality objectives of the applicant for an authorisation or the authorisation holder based on achieved results, data analysis, preventive and corrective measures and review by top management.

(11) The Type-test is the verification of the ability of classified equipment of a given type to meet specified requirements by putting a representative piece or several pieces of this type of equipment to an appropriate set of physical conditions, chemical conditions, environmental conditions and operating or accident conditions.

(12) Quality assurance[3]) is a part of a quality management system focused on providing confidence that quality requirements shall be met. In the area of nuclear energy utilization, quality assurance is directly influence to ensure nuclear safety.

(13) A commercial-grade item is a structure, system, component or part thereof, designed and manufactured in accordance with international industry standards or norms, and primarily intended for use outside a nuclear installation.

(14) Acceptance of a commercial-grade item is a process that involves identifying the critical characteristics of the structure, system, component or part thereof, and verifying them using acceptance methods for its use as selected equipment in a nuclear installation. The acceptance of a commercial-grade item ensures compliance with the relevant design, material and workmanship characteristics of the commercial-grade item with the aim of ensuring that the commercial-grade item fulfils the required function important to nuclear safety.

(15) Counterfeit, fraudulent and suspicious items are structures, systems, components or parts thereof that differ in composition, configuration, certification or any other characteristics from the original product, but are presented as original. Counterfeit, fraudulent and suspicious items also include items that are suspected of not conforming to their declared characteristics.

(16) A type replacement is a change to selected equipment or part thereof, the quality management system documentation of which can be applied repeatedly to selected equipment that is subject to the same or lower quality requirements. A type replacement may be the replacement of the original element on selected equipment with an equivalent element
a) manufactured and qualified in accordance with the standards and specifics applied in the nuclear industry, while meeting the quality requirements for selected equipment laid down in § 6 and § 8,
b) of a commercial-grade item laid down in § 6 and § 8.

(17) The analysis of the suitability of a commercial-grade item is an assessment of the suitability of the replacement of selected equipment or part thereof with an equivalent commercial-grade item. The suitability analysis referred to in the first sentence shall be documented.

Section 3
Quality management system

(1) The quality management system of the applicant for an authorisation or the authorisation holder shall be established, implemented, maintained and continually improved.

(2) The quality management system shall be based on
a) an implementing and applying a quality management system based on the process management of the applicant for an authorisation and the authorisation holder,
b) systematic, objective and regular assessment of the quality management system and its continuous improvement based on achieved results,
c) an active approach by all employees of the applicant for an authorisation or the authorisation holder, and their comprehension and adoption of management's commitments, policies and goals,
d) awareness of all employees of the applicant for an authorisation or the authorisation holder about the quality management system, and their support, cooperation and active participation,
e) an active approach of the applicant for an authorisation or the authorisation holder to informing the public and other interested parties of his conduct and an open dialogue between them.

(3) The quality management system of the applicant for an authorisation or the authorisation holder shall include a description of his management system, quality policy, quality objectives and management's commitment, organisational structure, the responsibilities and authority of employees at all levels of management, quality management system processes, their description and, interactions, measuring, analysis and improvement, quality management system documentation and resources for quality assurance including human resources.

(4) In his quality management system, the applicant for an authorisation or the authorisation holder shall identify a member of top management who is responsible for ensuring the effectiveness of the quality management system, and must specify his/her responsibilities and authorities in managing the quality management system.

(5) The applicant for an authorisation or the authorisation holder as part of his quality management system shall implement regular review and assessment of his own quality management system effectiveness[4]) by management, including assessment from the nuclear safety aspects based on measurable quality objectives specified in accordance with quality policy, in order to achieve continuous improvement of the quality management system. This review must be documented.

(6) The applicant for an authorisation or the authorisation holder shall continuously implement

into the practice results coming from the regular review and assessment of his quality management system.

(7) The applicant for an authorisation or the authorisation holder shall apply quality management system requirements in a grading manner and at all levels of the quality management system in accordance with the current condition of nuclear installation in order to enhance safety culture and allocate the necessary resources.

(8) The applicant for an authorisation or the authorisation holder shall implement within the quality management system as follows
a) a process approach with emphasis on processes that can influence the safety of nuclear installation,
b) the measurable indicators or process performance indicators, and safety culture assessment,
c) the regular assessment of process development trends.

(9) The applicant for an authorisation or the authorisation holder shall specify in his quality management system documentation the responsibilities and competencies of his employees at all levels of management, with an emphasis on positions with a direct impact on nuclear safety and with an impact on nuclear safety.

(10) The applicant for an authorisation or the authorisation holder shall have a documented and clearly justified organizational structure.

(11) The applicant for an authorisation or the authorisation holder shall systematically analyse, document, and provide the required number of his employees with the necessary professional competency and authorities necessary for ensuring nuclear safety and quality management.

(12) Quality management system requirements for the applicant for an authorisation or the authorisation holder are listed in Annex No. 1.

Section 4
Quality management system documentation

(1) Quality management system documentation of the applicant for an authorisation or the authorisation holder shall describe in particular:
a) an internal management system with regard to quality assurance,
b) the implementation of policy focused on quality, safety and professional employee´s training of employees,
c) a monitoring of compliance with nuclear safety.

(2) Quality management system documentation shall contain
a) the quality policy and quality objectives,
b) the safety policy and safety objectives,
c) a quality manual,
d) an organizational structure and its description,
e) documented procedures, programmes, manuals and records,
f) the nuclear installation quality assurance requirements,
g) the nuclear installation quality requirements,
h) the categorization of classified equipment into safety classes or a list of classified equipment,
i) the classified equipment of quality assurance requirements,
j) the classified equipment of quality requirements.

(3) Quality management system documentation of the applicant for an authorisation pursuant to Section 5 (3) (a) to (d), (f) and (g) of the Act shall contain documentation pursuant to Paragraph 2 (a) to (h).

(4) Quality management system documentation of the authorisation holder pursuant to Section 5 (3) (a) to (d), (f) and (g) of the Act shall contain documentation pursuant to Paragraph 2 (a) to (g), and if classified equipment is part of the nuclear installation, also documentation pursuant to Paragraph 2 (h) to (j).

(5) Quality management system documentation of the applicant for an authorisation or the authorisation holder pursuant to Section 5 (3) (e) of the Act shall contain documentation pursuant to Paragraph 2 (a) to (g).

(6) Documentation of the quality management system of the applicant for an authorisation or the authorisation holder pursuant to Section 5 (3) (j) of the Act shall contain documentation pursuant to Paragraph 2 (a), (c) and (e), and if classified equipment is used for transport, also documentation pursuant to Paragraph 2 (h) to (j).

(7) Documentation of the quality management system of the applicant for an authorisation or the authorisation holder pursuant to Section 5 (3) (k) of the Act shall contain documentation pursuant to Paragraph 2 (a) to (e).

(8) Requirements for quality management system documentation of the applicant for an authorisation or the authorisation holder are listed in Annex No. 2.

(9) The applicant for an authorisation or the authorisation holder shall draw up and maintain a quality manual that describes his quality management system in relation to its processes which take place therein. Requirements for the content of the quality manual are listed in Part C of Annex No. 2.

(10) Except for the obligation listed in Section 10 (1) (b) of the Act, the applicant for an authorisation or the authorisation holder shall also comply with requirements set out in the subsequent valid documentation of the quality management system.

(11) The authorisation holder shall regularly review and update quality management system documentation according to the actual state of the quality management system of the applicant for an authorisation or the authorisation holder, and the condition of nuclear installation. A review of whether quality management system documentation is up-to-date must take place at least once per 3 years. If this review results requires to update documentation not approved or assessed by the Authority, the authorisation holder shall revise it within three months from the time review.

(12) All activities that have impact on quality of nuclear installation or the quality of classified equipment take place pursuant to quality management system documentation approved before these activities are carried out.

(13) The scope of quality management system documentation approved by the Authority pursuant to Section 4 (2) (a) (2) of the Act is laid down in Annex No. 3.

(14) Quality management system documentation of the applicant for an authorisation or the authorisation holder pursuant to Section 5 (3) (o) of the Act shall contain documentation pursuant to Paragraph 2 (a), (c) and (d).

Section 5

Quality assurance requirements for nuclear installation

(1) Quality assurance requirements for nuclear installation shall be contained in quality assurance programmes for a specific nuclear installation or group of nuclear installations.

(2) Quality assurance programmes for nuclear installation shall be divided into:
a) the reference quality assurance programme for nuclear installation (herein referred to as the "reference programme") that details fundamental requirements for quality assurance during all stages of the existence of a nuclear installation,
b) the stage quality assurance programme for nuclear installation (herein referred to as the "stage programme") that details fundamental requirements for quality assurance for a particular stage of the existence of nuclear installation.

(3) The stages of existence of a nuclear installation for purposes of Paragraph 2 shall be split for:
a) design,
b) construction,
c) commissioning,
d) operation,
e) an individual stage of decommissioning,
f) closure of repository.

(4) Requirements for the content of the reference programme and stage programme are listed in Annex No. 4.

(5) The reference programme shall be valid from approval until the exemption of the nuclear installation from the Act. The stage programmes shall be valid from their approval until the end of the stage of existence of the nuclear installation for which they were developed.

(6) Nuclear installation quality assurance programmes must be regularly updated in all stages of its existence in accordance with the actual conditions and stage of its existence. Updates must take place at least by the date of complex and systematic assessment of nuclear safety pursuant to Section 23 (2) (e) and (f) of the Act. Updated quality assurance programmes must be submitted to the Authority for re-approval in accordance with requirements of Section 9.

Section 6
Quality assurance requirements for classified equipment

(1) Quality assurance requirements for classified equipment are lain down in quality plans of classified equipment (hereinafter referred to as the "quality plans") that:
a) set up quality assurance principles for classified equipment specified in quality assurance programmes for nuclear installation,
b) are valid from their approval until the end of the lifetime of classified equipment for which they were drawn up,
c) are drawn up for each classified equipment categorised into safety class I, II and III,
d) can be drawn up as aggregate quality plans for classified equipment of the same kind, design and dimensions categorised into safety class I,
e) can be drawn up as aggregate quality plans for classified equipment of the same kind and type/dimension categorised into safety class II,
f) can be drawn up as aggregate quality plans for classified equipment of the same kind categorised into safety class III,
g) are drawn up independently for each system of I&C including its software that involves sensors, signal transmission and processing equipment and equipment for outputs to actuators,

h) in cases of aggregate quality plans, are drawn up only for classified equipment categorised into the same safety class.

(2) Quality plans shall be drawn up in two phases:
a) prior to the selection of a supplier of the classified equipment (herein referred to as the "quality plan for the first phase"),
b) prior to the start of manufacturing of the classified equipment and, in the case of piping, prior to the start of its installation (herein referred to as the "quality plan for the second phase").

(3) Quality plans shall not be drawn up for classified equipment categorised into the safety class IV. For classified equipment categorised into the safety class IV, analyses of their possible impact on classified equipment of higher safety classes shall be performed (herein referred to as the "impact analyses").

(4) The applicant for an authorisation or the authorisation holder shall be responsible for the drawing up of quality plans and impact analyses.

(5) The applicant for an authorisation or the authorisation holder shall submit quality plans for the first phase to the Authority for approval prior to selecting the supplier of classified equipment of safety classes I to III.

(6) The applicant for an authorisation or the authorisation holder shall submit quality plans for the second phase to the Authority for approval prior to the start of manufacture of classified equipment of safety classes I to III.

(7) The applicant for an authorisation or the authorisation holder shall submit documentation pursuant to Paragraphs 6 and 7 to the Authority for approval as one paper copy as well as in electronic form on portable medium.

(8) Quality assurance requirements for type replacements on the same types of equipment but on different systems or installation locations may be drawn up as aggregate quality plans, provided that the quality assurance requirements comprehensively and unambiguously cover the given type replacement of the selected equipment for each installation position of that type replacement.
(9) The quality assurance requirements for a commercial-grade item and the acceptance process for a commercial-grade item pursuant to § 8(21) shall be provided in the quality plan for selected equipment classified in safety class III, and in the impact analyses for selected equipment classified in safety class IV.

(10) Requirements for the contents of quality plans and for impact analyses are listed in Annex No. 5.

Section 7
Quality requirements for nuclear installations

(1) The scope of submitted requirements for the quality of nuclear installations are listed in Annex No. 6.

(2) The achieved level of quality of a nuclear installation, its changes and development in relation to nuclear safety are described in a systematic complex nuclear safety assessment report pursuant to Section 23 (2) (e) of the Act.

(3) The scope of submitted requirements for the quality of nuclear installations listed in Annex No. 6 shall be drawn up on the current state of understanding and knowledge in relation to the planned nuclear installation at the time of submission of the documentation

Section 8
Quality requirements for classified equipment

(1) Quality requirements for classified equipment shall contain:
a) calculations and calculation results to prove the resistance of classified equipment to seismic activity and environmental influences during all test, operation and accident conditions considered in their design,
b) categorisation into the safety class,
c) quality requirements for classified equipment listed in Annex No. 7.

(2) Quality requirements for classified equipment categorised into the class I, II and III shall be submitted by the applicant for an authorisation or the authorisation holder to the Authority for approval prior to the start of manufacture of the classified equipment, in the case of piping prior to the start of their installation, as one paper copy and at the same time in electronic form on a portable medium.

(3) Classified equipment shall be qualified for their required functionality and presumed effects of the environment for conditions considered in their design, including seismic resistance, during their commissioning, operation, decommissioning, a repository closure, and during accidents. The qualification method shall correspond to the safety class of the classified equipment.

(4) For selected equipment classified in safety classes I and II, except for control and management systems, structural units, pressure vessels, and piping routes, including their static supports and hangers, the type-examination method pursuant to the relevant technical standards7or other equivalent technical specifications with comparable or more stringent requirements shall be used as a priority for the qualification of selected equipment, taking feasibility into account. In justified cases, other methods may also be used for the qualification of the selected equipment referred to in the first sentence, in accordance with paragraph (11).

(5) For I&C systems classified as classified equipment categorised into the safety class II the following methods can be used for their qualification, which is mandatory on the basis of possible feasibility, the indicate method will be used
a) the type-test,
b) the operating experience,
c) the deterministic analysis.

(6) For I&C systems classified as classified equipment categorised into the safety class III the following methods can be used for their qualification
a) the type-test,
b) an operating experience,
c) an analysis,
d) a combination of methods listed in letters a) to c).

(7) For I&C systems classified as classified equipment categorised into the safety class IV that can have impact on equipment listed in Paragraphs 5 and 6, qualification shall take place in accordance with Paragraph 6.

(8) For the I&C systems classified as classified equipment categorised into the safety class IV that cannot have impact equipment listed in Paragraphs 5 and 6, qualification at the level of commercial industrial standards shall be accepted.

(9) For classified equipment such as civil structures, large pressure vessels and pipe lines including static supports and hangers, categorised into the safety class I and II, qualification shall be performed by using calculation analysis.

(10) For classified equipment such as other pressure vessels including their static supports and hangers, categorised into the safety class I and II, qualification shall be performed by using calculation analysis and type-test.

(11) For classified equipment categorised into the safety class III and IV, except I&C systems, the following qualification methods can be used
a) the type-test,
b) an operating experience,
c) an analysis,
d) the calculation analysis,
e) a combination of methods listed in Letters a) to d).

(12) The quality and material characteristics of metallurgical products and welding filler material used to make a classified equipment categorised into the safety class I and II shall be proven with material certificate (inspection document) issued based on a specific inspection with test results listing, in which an authorized inspector independent of the manufacturer's production division and an authorized inspector of the client or an inspector appointed in official regulations confirms, that the supplied products meet requirements for the respective classified equipment approved by the Authority in quality requirements of classify equipment. The manufacturer of the classified equipment may incorporate into the material certificate of test results performed during a specific inspection on raw materials that he had used, provided that he has used a process enabling reverse traceability, and can submit the relevant certificate.

(13) The quality and material characteristics of metallurgical products and welding filler material used to make a classified equipment categorised into the safety class III shall be proven with a material certificate (inspection document) issued based on a specific inspection with the test results listing, in which an authorized inspector independent of the manufacturer's production division confirms, that the supplied products meet requirements for the respective classified equipment approved by the Authority in quality requirements of classified equipment. The manufacturer of the classified equipment may incorporate into the material certificate of tests results performed during a specific inspection on raw materials that he has used, provided that, he has used a process enabling reverse traceability, and can submit the relevant certificate (document).

(14) The quality and characteristics of metallurgical products and welding filler material used to make a classified equipment categorised into the safety class IV shall be proven with a material certificate issued based on a specific inspection with test results listing, in which an authorized inspector independent of the manufacturer's production division confirms that the supplied products meet requirements in technical documentation for the respective classified equipment. The manufacturer of the classified equipment may incorporate into the material certificate of tests results performed during a specific inspection on raw materials that he has used, provided that, he has used a process enabling reverse traceability, and can submit the relevant certificate (document).

(15) The meeting of quality requirements for classified equipment shall be documented in accompanying technical documentation.

(16) Accompanying technical documentation requirements are listed in Annex No. 8.

(17) The applicant for an authorisation or the authorisation holder shall check conformity of classified equipment with quality requirements for classified equipment and accompanying technical documentation when they are delivered to the construction site, and shall make a record of this.

(18) The applicant for an authorisation or the authorisation holder shall check conformity of classified equipment with quality requirements for classified equipment, accompanying technical documentation and quality plans, and conformity of accompanying technical documentation with Annex No. 8, once installation of classified equipment into integrated systems or parts thereof has been completed (herein referred to as the "post-installation tests"), and shall make a record of this.

(19) Pursuant to Section 10 (1) (f) of the Act, the authorisation holder shall notify the Authority of the date post-installation tests at least ten days in advance.

(20) Commercial-grade items may be used only for selected equipment and parts thereof classified in safety classes III and IV. The use of a commercial-grade item for equipment classified in safety class II is subject to individual assessment by the Authority.

(21) In the case of acceptance of a commercial-grade item as selected equipment, the following shall be ensured and documented

a) compliance with the critical design, material and workmanship characteristics of the commercial-grade item or part thereof, which, following successful verification, shall ensure that the commercial-grade item fulfils the required function important to nuclear safety,

b) manufacturer verification in the management of achieving the critical characteristics referred to in point (a), inspections at production control points, or analyses of historical record to demonstrate compliance of the commercial-grade item with requirements,

c) verification of the acceptability of the commercial-grade item after delivery through inspections, tests, or analyses carried out by qualified personnel; a third party independent of the manufacturer or supplier of the commercial-grade item, with proven experience with selected equipment, may also be engaged to perform the tests and analyses.

(22) Commercial-grade items shall be subject to the requirements of paragraphs (15) to (19) to a reasonable extent.

(23) Once the acceptance of a commercial-grade item has been successfully completed, that item shall be considered selected equipment. The progress and results of the acceptance of a commercial-grade item pursuant to paragraph (21) shall be documented in the accompanying technical documentation of the selected equipment.

(24) The permit holder's quality management system shall ensure the implementation of an internationally recognised system for the acceptance of commercial-grade items, which shall include an analysis of the suitability of the commercial-grade item. A third party with proven experience with selected equipment may also be engaged in the process of verifying and evaluating the suitability of the replacement and in preparing the suitability analysis of the commercial-grade item.

(25) The permit holder's quality management system shall contain a process for the early identification of counterfeit, fraudulent and suspicious items.

(26) The quality requirements for selected equipment applicable to type replacements on selected equipment shall be met and documented. In the case of recurring type replacements on the same types of equipment, but on different systems or at different installation locations, the permit holder may submit a single application for approval to the Authority, together with the quality assurance requirements for the selected equipment. The application referred to in the second sentence shall contain a comprehensive scope of requirements for each considered installation position of the selected equipment at which the type replacement of the selected equipment is planned to be implemented.

(27) For a type replacement on selected equipment, the documentation of the type replacement of the selected equipment and an update of the quality requirements for the selected equipment, pursuant to Annex 7 and the requirements for accompanying technical documentation of selected equipment under Annex 8, shall be recorded and documented. The documentation referred to in the first sentence shall be prepared for each installation position of the selected equipment at which the type replacement of the selected equipment is implemented.

(28) If a commercial-grade item is used by the permit holder as a type replacement for selected equipment, the permit holder shall also assess and document the suitability of the replacement pursuant to paragraphs (21) to (24).

(29) The type replacement of selected equipment shall be assigned an installation position, as designated by the permit holder, who shall ensure the necessary evaluation, documentation record-keeping, and the entire change management process.'

Section 9
Change management in quality management system

(1) Changes pursuant to Section 2 (w) of the Act must be justified in advance, carefully planned, and assessed following their implementation.

(2) Changes pursuant to Section 2 (w) and (x) of the Act shall be performed in accordance with principles and requirements applicable for the original installation or documentation. The weaver's application towards to original design requirements or implementation of new requirements must be justified and relevant analyses must be performed to document their acceptability.

(3) At the same time with a change pursuant to Section 2 (w), the applicant for an authorisation or the authorisation holder shall submit

a) an analysis of the causes of the proposed change, with justification of the goal of the change,
b) an impact assessment of the change on nuclear safety,
c) proposed measures to eliminate possible negative effects of a new installation on existing equipment during its installation, inspection, tests, maintenance and operation,
d) proposed measures to eliminate possible negative effects of the change, including its inclusion in quality management system documentation or professional employee´ s training,
e) a list of the quality management system documentation that the change shall affect, and changed quality management system documentation if it is subject to Authority approval, or if the Authority evaluation or if the Authority requires to take look at it,
f) a safety assessment for the proposed change performed by an independent person through risk analysis,
g) an evaluation of the proposed change by the author of the original design, or another qualified person with proven experience.

(4) At the same time with a change pursuant to Section 2 (x) of the Act, the applicant for an authorisation or the authorisation holder shall submit:
a) an impact assessment of the change on nuclear safety,
b) an analysis of the causes of the proposed change, with justification of the goal of the change,
c) proposed measures to eliminate possible negative effects of the change, including its inclusion in quality management system documentation or professional employee´s training if needed,
d) a list of the quality management system documentation that the change shall affect, and changed quality management system documentation if it is subject to Authority approval, or if the Authority requires to take look at it.

(5) The applicant for an authorisation or the authorisation holder shall submit change documentation to the Authority for approval or notification pursuant to Section 2 (w) and (x) of the Act as one paper copy and at the same time in electronic form signed by a certified electronic signature on a portable medium.

(6) After the change has been implemented, the applicant for an authorisation or the authorisation holder shall assess the effectiveness of the change implementation, including its benefits or negative effects, within the timeframe specified by him.

Section 10
Transition provisions

Regarding nuclear installations that were under construction as of the day, when this decree became effective, requirements for quality assurance of classified equipment pursuant to Section 6 and requirements for quality of classified equipment pursuant to Section 8 will be governed by the existing decree until 31 December 2014.

Section 11
Repealing provisions

Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 56/2006 Coll., laying down details on requirements for quality system documentation of an authorisation holder as well as details on quality requirements for nuclear installation, details on requirements for quality of classified equipment, and details on the scope of their approval, shall be repealed.

Section 12

(1) This Decree was adopted in accordance with a legally binding act of the European Union in the field of technical regulations.[5])

(2) The provisions of this Decree, effective from 1 January 2026, were adopted in accordance with a legally binding act of the European Union in the field of technical regulations.[5])

Section 13
Entry into force

The decree shall enter into the force on 1 January 2026.

Marta Žiaková, m. p.

QUALITY MANAGEMENT SYSTEM REQUIREMENTS

The quality management system of the applicant for an authorisation or the authorisation holder shall include

a) a quality assurance, a process-oriented approach, a graded approach and quality management system documentation pursuant to the requirements of this decree, so that the quality management system allows specified goals and the required level of nuclear safety and radiation protection to be achieved in an efficient and effective manner,
b) a description of the management system in terms of quality assurance, including goals, strategies, plans and objectives so that management of its effect on nuclear safety is achieved,
c) a documented quality policy that contains;
   1. a written commitment by top management in priority to achieve, maintain and continuously develop a high level of nuclear safety and radiation protection,
   2. a written commitment by all levels of management to establish, implement, assess and continuously improve the quality management system,
d) a documented safety policy including requirements for meeting and monitoring of safety targets,
e) an implementation of a quality policy including safety policy in practice, and notifying all employees in such a manner that it is properly understood and applied,
f) the measurable targets in accordance with the quality policy and assessment of how these targets have been met,
g) an using of a graded approach in specifying requirements for quality assurance and quality requirements,
h) a quality manual and its regular review,
i) a regular review and assessment of the quality policy, safety policy, professional training policy and all their parts, including the safety policy and quality targets, where this assessment must take place at specified intervals and more frequently than the regular comprehensive and systematic nuclear safety assessment pursuant to Section 23 (2) (e) and (f) of the Act,
j) a regular review and assessment of the quality management system by management based on audits, process measurements, preventive measures, corrective measures and feedback, including an assessment of the quality management system from the perspective of nuclear safety,
k) a regular independent assessment of the quality management system and its processes by an organizational unit independent of the assessed areas or an independent external subject, which must have proper authority and competence to perform this assessment,
l) a self-assessment of activities, work and processes by management or employees responsible for them,
m) a continuous implementation of results of assessments performed pursuant to Paragraphs 5 to 11,
n) the management change pursuant to Section 2 (v) or (w) of the Act, including specification of requirements for this process, its recording, separation into temporary and permanent, identification, review, prioritization, specification of influences and risks, confirmation of suitability, post-implementation assessment, for interim changes to technical equipment or classified equipment, as well as their list, current status, validity date, records according to which they were approved or permitted, and labelling of the respective installation itself and its actuating elements,
o) a professional training policy expressing top management's commitment in priority to ensure the required number of professionally competent employees and specially-professionally competent employees pursuant to Section 24 (2) and (3) of the Act and pursuant to special legislation,[6])

p) an employee responsibilities and competencies determination, their functional responsibilities and commissions including a description of the organizational structure containing a description of the specific job position impact on nuclear safety pursuant to special legislation,[6]) including responsibility for quality assurance and quality management system management,
q) the requirements for human resources, for procedures during hiring, selection and assignation of work positions with direct impact on nuclear safety and with an impact on nuclear safety, qualification and maintenance of employee skills with an emphasis on the ability to ensure a high level of safety culture, and for records of results of the employee´s professional training,
r) the requirements for assurance and availability of financial, material, technical and human resources, employee equipment, work premises, work and technological equipment, nuclear safety, physical protection, emergency preparedness, transport, communication, hardware and software,
s) his identified and appropriately documented processes and their interaction, including processes performed by external persons,
t) the process requirements including criteria and methods for their monitoring and measurement, continuous improvement, ensuring availability of resources and information, and implementation of necessary corrective measures,
u) the requirements related to processes that include, planning, design, verification, implementation, manufacture, operations, providing services, inspections, tests, maintenance and repairs, including requirements for emergency preparedness, physical protection, nuclear and radiation safety, safety culture, design changes and modifications, classified equipment and classified equipment quality plans,
v) an emergency preparedness including requirements to find out the possibilities of the accidents and emergency situations, emergency preparedness procedures and requirements for the regular practice of these procedures,
w) the management of his documentations and his changes, including management of external documents and rules for familiarizing employees with this documentation,
x) the management and storage of records created during his processes as well as the manner they are demonstrated to the Authority,
y) an assessment and selection criteria of suppliers including keeping records on suppliers,
z) the requirements for the procurement and purchase of goods and services including requirements for incoming inspection of purchased products,
aa) the requirements for quality management systems of suppliers of goods and services that have or could have an impact on the nuclear safety of nuclear installation, including requirements for the manner and scope of quality management systems verification of the suppliers',
ab) an observance and familiarization of suppliers with quality policy including the safety policy, so that it is properly understood and applied by suppliers and their employees,
ac) the checks of suppliers and check of activities performed by suppliers, including facilitation of control audits of suppliers and participation of the Authority's inspectors in these audits,
ad) the requirements for the employee’s qualifications performing inspections and tests of specified civil structures, equipment, goods, services and processes, their independence, and requirements for the standards of these inspections and tests,
ae) the requirements for contracts and contractual conditions with suppliers, including requirements pursuant to Letters g), j), p), q), y) to ad), including an assignment of specific employees in the organizational structure responsible for meeting responsibilities listed in these points,
af) a monitoring and measurement of goods or services including requirements for the scope of inspections and equipment used for monitoring and measurement,
ag) an equipment management of measurement and monitoring[7]), including record keeping, regular calibration and maintenance, protection and storage,

ah) the requirements for the identification and traceability of goods and services, for the labelling of technology and equipment, for records on design changes, inspections, tests and welds,
ai) the requirements for the protection of goods during transport, packaging, storage, storage conditions and record keeping for these activities,
aj) the audits of the quality management system including plans, programmes and audit records,
ak) a system of managing and determining causes of non-conformities or inconsistent products,
al) a corrective and preventive activities including keeping records of non-conformities, on corrective and preventive measures, results and acceptability criteria of corrective measures taken,
am) a continuous improvement and increased effectiveness of his processes based on input from self-assessment processes, independent assessment, management review, monitoring and measurement, with emphasis on nuclear safety, radiation protection and safety culture, including plans for providing suitable resources for these activities,
an) an assurance of sufficient internal communication among various levels of management and organizational structure, including managing communication with external subjects and supervisory bodies,
ao) an identification of mandatory requirements and requirements of supervisory bodies for equipment, goods and services, processes or activities, and ensuring conformity with these requirements,
ap) an ensuring and maintaining a suitable level of safety culture,
aq) an ensuring and maintaining a suitable level of nuclear safety, emergency preparedness, physical protection and employee´s professional training,
ar) a utilization and application of operating experience, international safety standards, new research and development findings, their systematic analysis and continuously improving operating activities.
as) the requirements for computer and network systems safety assurance and the requirements coupled with handling documentation pursuant to the Section 3 (14) and (15) of the Act.

REQUIREMENTS FOR QUALITY MANAGEMENT SYSTEM DOCUMENTATION

A. Quality management documentation shall be as follow:

a) an elaborated and documented:
   1. to the range of necessary to meet requirements of all generally binding legal documents, including a list of applicable documentation,
   2. to the range and in details that correspond to the importance and complexity of activities, methods used, skills and professional training who perform these activities,
b) managed according to specified rules and procedures, including
   1. an external documentation used and documentation elaborated by other persons,
   2. a determination of responsibilities for its elaboration, assessment, approval, recording, distribution, storage, changes and cancellation,
c) categorized and protected with respect to its content, form and mutual relationships,
d) regularly reviewed from the perspective of its currency and suitability,
e) approved by authorized employees,
f) easily identifiable, current, comprehensible, legible and easily available at its place of use,
g) marked with and issue or expiry date,
h) cancelled according to specified rules if its contents do not correspond to the current state of affairs, and replaced by updated and approved documentation,
i) labelled and protected from the possible use of out-dated or invalid documentation, including measures for withdrawing such documentation from use,
j) stored for a specified time and according to specified rules[8]), including invalid documentation.

B. Quality management system records shall be

a) managed and documented according to specified procedures, including assignation of responsibilities and rules regarding their production, categorization, labelling, filling in, verification, record keeping, protection, storage and storage periods,
b) specified in quality management system documentation,
c) drawn up to at least to the range that facilitates:
   1. proof of safe operation of nuclear equipment,
   2. proof of maintenance, repairs or modification of classified equipment,
   3. specification of the causes of operating incidents or failures of classified equipment,
   4. proof of who performed an activity, when, and with what result,
   5. effective planning, management and implementation of activities and processes,
d) decidedly legible, complete and easy to identify,
e) labelled with the name, date and signature of their author,
f) stored, recorded and maintained in a manner that makes them easily accessible and protected towards damage, deterioration or loss,
g) stored for at least 10 years after a nuclear installation operation has terminated, for records that are important from the perspective of nuclear safety and the condition of classified equipment.

C. The quality manual shall

a) contain the scope of the quality management system,
b) contain the quality policy and the objectives of the quality management system, or references to documents where they are specified,
c) specify and briefly describe identified processes in the quality management system,
d) contain a description of the sequence of and interaction of processes included in the quality management system,

e) specify requirements, sources, criteria and methods needed to ensure the correct management, occurrence and monitoring of quality management system processes, including assignation of authorities and responsibilities,
f) specify documented quality management system procedures in relation to quality management system processes.

SCOPE OF APPROVED QUALITY MANAGEMENT SYSTEM DOCUMENTATION

(1) Quality manual or manual describing the quality management of the applicant for an authorisation or the authorisation holder.
(2) Quality assurance reference programmes.
(3) Stage quality assurance programmes.
(4) Quality plans.
(5) Pre-service inspection programmes of classified equipment.
(6) In-service inspection programmes of classified equipment.

REQUIREMENTS FOR NUCLEAR INSTALLATION QUALITY ASSURANCE PROGRAMMES

I. The reference programme shall contain

a) a brief description of the nuclear installation,
b) a summary and sequence of activities determining the quality of a nuclear installation during all stages of its existence,
c) the specification of the structure and sequence of stage programmes, assignation of responsibility for their preparation and updates, specification of requirements that need to be detailed within them,
d) an assignation of responsibility for quality assurance in individual stages of a nuclear installation's existence and conditions for assuming this responsibility,
e) a principles of quality management system documentation and record and their transfer between individual phases including their independent verification, specification of requirements for review, updates and operative management of the reference programme,
f) the requirements for quality assurance, for organizational and technical provisions for activities and processes important for assuring quality of the nuclear installation during design, procurement, engineering, production, import, construction, commissioning, operation, maintenance, inspection and decommissioning phases applied during nuclear installation quality assurance,
g) principles of graded approach to quality assurance of classified equipment according to their categorization into the safety classes and importance of nuclear safety during design, procurement, engineering, production, import, construction, commissioning, operation, maintenance, inspection and decommissioning phases,
h) the metrology requirements,
i) a list of generally binding legal documents and basic technical standard documents that will be used during the design the nuclear installation,
j) an information important from the perspective of nuclear safety, requirements for the scope of research, studies, analyses and calculations, functional requirements and reliability requirements, requirements for environmental conditions, requirements of the Authority, of regulations and Slovak technical standards or other similar technical specifications with comparable or more stringent requirements, and requirements for securing their verification,
k) the description of siting planning and coordination,
l) the proposed principles of classified equipment' categorized into the safety classes,
m) the requirements for location selection, the manner of selection of a protective zone with justification of its size, accordance of activities during siting with requirements pursuant to letters a) to i), and verification of methodologies used to assess the selection of the location.

II. The stage programme shall include

a) a brief description of the nuclear installation,
b) a summary and sequence of activities determining the quality of a nuclear installation during the respective stage,
c) the requirements for processes and activities that determine the quality of the nuclear installation and nuclear safety in the respective stage, including activities performed by contractors,
d) the requirements for management and storage documentation and quality management system records, including their transfer between subsequent stages,
e) the requirements for regular review, update and management of the relevant stage programme,
f) the requirements for an identification and marking system for nuclear installation, equipment, systems, components and civil constructions,

g) the principles for categorization of classified equipment into the safety classes and requirements for the creation of a list of classified equipment categorized into safety classes,
h) the requirements for a process for managing changes and modifications on nuclear installation in a respective stage, including evidencing the condition of the nuclear installation during hand over and take over for the next stage,
i) the requirements on processes and procedures of assessment and approval of ad hoc changes of technical documentation of classified equipment in the stages of construction and commissioning of nuclear installation to the operation,
j) the requirements for processes and assessment procedures for non-standard situations, abnormal or accident operation of the nuclear installation, including seismic events and other extreme external hazards,
k) a definition of competencies, responsibilities and requirements for the qualification of employees performing activities and processes important from the perspective of nuclear safety and nuclear installation quality assurance in the respective stage,
l) the requirements for research, studies, analyses and calculations in the respective stage of the nuclear installation,
m) the requirements for reliability and functionality of a nuclear installation and its most important systems and components in the respective stage,
n) the general requirements for qualification, verification and validation procedures of classify equipment,
o) he requirements for the qualification of non-destructive test methods for components of classified equipment,
p) the requirements for nuclear installation operating and work environment conditions including physical, social, psychological and environmental factors,
q) the meeting requirements of the Authority, generally binding legal documents, special legislation and Slovak technical standards or other similar technical specifications with comparable or more stringent requirements, and requirements for their verification,
r) a summary of generally binding legal documents and technical standards documentation used during a respective stage of a nuclear installation,
s) the requirements for documentation of the suitability of metallurgical semi products and welding filler material,
t) the general requirements for documenting accordance of supplied classified equipment and their components with their Authority-approved specifications,
u) the relationship with the safety guidelines issued by the Authority,
v) the requirements for ensuring the checking of activities performed that determine the quality of a nuclear installation in the respective stage, including activities performed by suppliers and the manner of verification of these activities,
w) the requirements for verification, preventive and corrective activities for the documentation of accordance with requirements pursuant to Letters a) to u), including a list of methodologies used.

REQUIREMENTS FOR CLASSIFIED EQUIPMENT QUALITY PLANS

I. The quality plan for the first phase contains

a) a list of the classified equipment to which it applies,
b) an identification information of the classified equipment, if known in the first phase,
c) a categorization of the classified equipment into the safety class,
d) the general technical conditions for classified equipment, especially parameters, data and requirements that the classified equipment shall meet during its operation,
e) a summary of the properties of the classified equipment with an impact on nuclear safety, including the safety function that it performs and the safety class in which it is categorised,[9])
f) a specified scope of qualification; for I&C systems, including electromagnetic compatibility requirements,
g) the requirements for ageing management of the classified equipment,
h) a general summary and sequence of activities that determine the quality of the classified equipment during the first phase,
i) the organizational and technical support for activities and processes important for classified equipment quality assurance during the first phase, including allocation of competencies, responsibilities and requirements for professional competency of employees performing these activities,
j) the general requirements for processes, procurement, design, manufacture, storage, transport, installation, commissioning, and operation of the classified equipment,
k) the general principles of management documentation and records of quality management system and related to the classified equipment,
l) the confirmation of conformity with requirements of the Act and generally binding legal documents issued upon its basis.

II. The quality plan for the second phase contains

a) a list of the classified equipment to which it applies,
b) an identification information of the classified equipment,
c) a categorization of the classified equipment into the safety class,
d) the general technical conditions for classified equipment, especially parameters, data and requirements that the classified equipment shall meet during its operation,
e) a summary of the properties of the classified equipment with an impact on nuclear safety, including the safety function that it performs and the safety class in which it is categorised[9]),
f) a summary and sequence of activities that determine the quality of the classified equipment during all phases of its existence, including requirements for internal audits and processes for design, manufacture, storage, transport, erection, commissioning, operation, maintenance, monitoring and measurement,
g) an organizational and technical support for activities and processes important for quality assurance of the classified equipment during all phases of its existence pursuant to Letter f,
h) an allocation of competencies, responsibilities and requirements for the qualifications of employees performing activities and processes pursuant to Letter f,
i) the requirements for technical manufacturing procedures, and the manner of and scope of inspection of pre-construction, construction and assembly operations,
j) the requirements for technical operating and maintenance procedures, including requirements for the manner and scope of pre-service and in-service inspections,
k) the requirements for identification of materials, parts and components according to predetermined principles, including partially manufactured subsystems and semi-products, auxiliary and filler material and spare parts and materials that are preserved during production operations, storage, transport, preparation for assembly, assembly works, commissioning and operation,

l) principles of control of quality management system documentation and records related to the classified equipment, including the obligation to keep identification records and related quality management system documentation during the entire time of existence of the classified equipment,
m) the suitability analysis of metallurgical semi-products and welding filler material, including the application of technical standards or other similar technical specifications with comparable or more stringent requirements, or requirements of other relevant documents,
n) the manner of certification of conformity of supplied classified equipment and their components with their Authority approved specifications,
o) the relationship with the safety guidelines issued by the Authority and other similar technical standards documentation with a similar focus,
p) a qualification, verification and validation methods and procedures for the classified equipment,
q) for a classified equipment categorised into the safety classes I and II, requirements for keeping records on design verification and confirmation of the validity the design,
r) a confirmation of conformity with the requirements of the Act and subsequent implementing legislation,
s) a set of quality assurance requirements for a commercial-grade item.

III. Requirements for the impact analysis

A. The impact analysis shall contain:
a) the name of equipment and its design number,
b) the location and a summary of equipment features, especially:
   1. the technical parameters,
   2. the functional requirements,
   3. the technical properties,
   4. a usability during normal and abnormal operation, and during accident states,
   5. the description of function which is fulfilled.
c) the specification of affected safety class I to III equipment,
d) the specification of how the analysis is to be performed, for example by calculation or expert assessment,
e) the definition of the scope of possible events,
f) the specification of interactions of equipment categorised into a different safety classes,
g) an assessment of impact on nuclear safety,
h) a set of quality assurance requirements for a commercial-grade item.

B. Set of possible events for selection pursuant to Part A letter (e):
a) the single failure,
b) the common-cause failure,
c) a propagation of failures from equipment categorised into a safety class IV to equipment safety class I to III,
d) an interference during loss of stability or destruction on classified equipment categorised into a safety class I to III,
e) the effect of flow of media or liquids from damaged classified equipment of safety class IV,
f) the loss of integrity,
g) the leakage,
h) the loss of stability,
i) the false actuation,
j) the loss of electrical power,
k) an effect of short-circuits,
l) the loss of coolant,
m) the loss of control media,
n) the loss of control commands or signals,

o) the hardware or software fault,
p) the seismic event,
q) the impact of internal and external events including resultant vibrations and tremors,
r) external hazards,
s) the impact of activity,
t) the impact of neutron flux,
u) a material fatigue,
v) an ageing,
w) the fire,
x) an incorrect operating staff procedure.

NUCLEAR INSTALLATION QUALITY REQUIREMENTS

Nuclear installation quality requirements shall contain

a) the general design aspects and safety objectives,
b) the categorization of initiating events,
c) the manner of defence in depth application,
d) an implementation of physical barriers,
e) the concept of accident prevention,
f) the concept of accident consequence mitigation,
g) the quantitative safety targets, including
   1. the radiation targets,
   2. the probabilistic safety targets,
   3. the probabilistic safety criteria and their relation to internationally accepted requirements,
   4. the probabilistic safety assessment methodology,
h) the deterministic analyses used, details of their methods and limits of use,
i) the manner of ensuring verification and validation of software tools and calculation methods for safety analyses,
j) the quantification of design basis events,
k) a seismic resistance,
l) a solution of events in the design extension conditions and severe accidents, including rules for their evaluation,
m) the description of the severe accident consequences,
n) an analysis of internal and external hazards,
o) the quantification of acceptable risk parameters,
p) the specification of safety functions,
q) the measures to achieve reliability of safety functions,
r) the requirements for equipment qualification,
s) the level of fire protection,
t) the relation to the human factor,
u) the level of main, emergency and accident management operation assurance,
v) the measures ensuring control room inhabitability during accidents,
w) acceptance criteria for maintaining the integrity of barriers to
   1. the normal operation,
   2. the anticipated operational events,
   3. the design basis events,
   4. the events in design extension conditions without serious nuclear fuel damage,
   5. the severe accidents,
   6. the non-power operating modes,
x) the categorization of I&C systems using a graded approach and requirements for their functionality and reliability in all operational states,
y) the manner of ensuring verification and validation of software and hardware tools for I&C systems based on the computer technology,
z) the scope of the post-accident monitoring system and quantification of its technical parameters, reliability and functionality in all operational states,
aa) the scope of qualification of post-accident monitoring system components,
ab) the scope of important the safety parameters display system,
ac) the monitoring scope of critical safety functions,
ad) the provision of power supply system and its reliability,
ae) the power output and its reliability,
af) the provision of diagnostic systems,
ag) the quantification of containment system parameters,

ah) the lifetime parameters of nuclear installation equipment.

CLASSIFIED EQUIPMENT QUALITY REQUIREMENTS

Quality requirements for classified equipment shall include

a) the design inputs specific to the respective classified equipment with a description of changes compared to the basic design,
b) the categorization of the classified equipment into a safety class and safety function,
c) the designation of the prescribed quality and condition of metallurgical semi-products and auxiliary materials with specification of the scope of technical delivery conditions for their specified qualitative level and the manner how to document,
d) the requirements for resistance to external hazards,
e) the dimensions, wall thicknesses and data needed for their design,
f) the location, type, dimensions and coefficient factors for welds and their classification,
g) the test media, test types and their acceptance criteria,
h) the results of calculations made according to technical standards or other similar technical specifications with comparable or more stringent requirements, technical conditions, or according state of arts and technical knowledge, specified in the stage programme,
i) the calculations or calculation results and important technical information on safety equipment parameters, focusing on its type, size, load capacity, location, safeguards, protection, and selectivity,
j) the technological manufacturing procedures and construction procedures, a proposal for their verification, and repair procedures,
k) the assembly instructions and technological assembly procedures,
l) the technical conditions for manufacturing, construction, assembly and repairs, which must contain
    1. the manner, type and scope of heat-treatment equipment, or parts of classified machinery equipment of safety class I and II,
    2. an initial, process and output production inspection and post-assembly inspection, as well as their results acceptance criteria,
    3. the information on the planned useful life component,
    4. the information on the reliability component,
    5. the information on the earthquake resistance components,
m) the technical procedures for welding work done on existing classified equipment of safety class I and II, which shall be assessed by an individual authorized for the area of welding, heat treatment, physical metallurgy, testing of properties and the non-destructive inspections of materials and welded joints of classified equipment,
n) the technological welding procedures, which must be drawn up in accordance with a technical standard or other similar technical specifications with comparable or more stringent requirements, and which must specify the welder's qualifications,
o) an equipment to be constructed in a way that a sudden breach cannot take place during all test and operational states and states considered in design,
p) a programme for visual inspections, checks and functional tests, repairs and maintenance,
q) the sizing of equipment and their power sources, positioning of fixtures, the design, number and position of work media level indicators in equipment, limit value signalling for liquid levels, pressures and temperatures, sizing, location and types of safeguards and measuring instruments and access to them, a signalling system for normal operation and failure conditions, a system for the control and blocking of relevant equipment, setting of limits for temperature, pressure and liquid level values and safety and control equipment,
r) the physical separation of individual safety systems, internal electrical AC/DC circuits, resistance to the effects of short circuits, electrical protection settings and their selective activation,

s) the requirements for laying of concrete and checking its quality, for concrete reinforcements, penetrations, doors, hatches, closures, surface treatment of building constructions and electrical installation,

(t) analysis of the suitability of the commercial-grade item,

(u) requirements for acceptance of a commercial-grade item, depending on the type of the commercial-grade item and its classification in a safety class, using a combination of the following methods

1. verification of evidence of the required quality and characteristics of the item,
2. testing and inspection,
3. verification of the manufacturer's quality assurance system during production.

REQUIREMENTS FOR ACCOMPANYING TECHNICAL DOCUMENTATION FOR CLASSIFIED EQUIPMENT

A. Accompanying technical documentation for classified equipment shall contain

a) certificates and quality inspection reports for materials used, focusing on basic materials, metallurgical semi-products, auxiliary materials for equipment and parts thereof, fittings, safety equipment, connection tools, cables, devices, penetrations, concrete,
b) the test reports, entries and other test and inspection records and their assessment,
c) equipment qualification documents,
d) the certification of the quality and completeness of consignment, installation or construction supported by reports on the results of prescribed tests performed during and after installation, and any other documents on the as-built condition of the installation,
e) the drawings with as-built discrepancies marked up,
f) the in-service inspection programmes,
g) the maintenance and repair instructions,
h) the operation manuals and safe use,
i) reports, documents and records of tests and inspections, and evaluation of the acceptance of the commercial-grade item.

B. Accompanying technical documentation for classified mechanical equipment having the nature of a pressure vessel shall also contain

a) the records of any updates to strength calculations and their results,
b) information on heat treatment,
c) the lists of welders who performed welding work stating the type and validity of certificates,
d) the lists of employees who performed non-destructive inspections stating the type and validity of their authorisations,
e) the protocols on inspection quality welding joints,
f) an information on defect repairs during manufacture,
g) the records on registered indications for classified equipment of safety class I and II,
h) the records on discrepancies from quality management system documentation during manufacture and assessment of changes in properties compared to original design.

C. Accompanying technical documentation for individual integral circuits, branches and systems of classified equipment having the nature of piping systems and rotating machinery must also include

a) the records of any updates to strength calculations and their results,
b) the lists of welders who performed welding work stating the type and validity of certificates,
c) the lists of employees who performed non-destructive inspection stating the type and validity of their authorizations,
d) the inspection records and confirmation of internal cleanliness of the equipment,
e) the records of weld joint quality inspection,
f) the records of leak tightness and strength tests,
g) an information on defect repairs during assembly.

D. Accompanying technical documentation for individual integral circuits, branches and systems of classified electrical equipment focusing on power supply and protection of emergency systems and reactor after cooling systems must also contain

a) the device certificates or conformity certificates pursuant to special legislation,[10])
b) the internal connections,
c) the individual and functional test logs,
d) an expert inspection and test report,

e) the electrical protection configuration logs,
f) the software/hardware verification and validation logs and confirmation of reliability.

E. Accompanying technical documentation for building equipment focusing on hermetic areas and equipment ensuring its tightness and strength under design conditions also contains

a) the records of any updates to strength calculations and their results,
b) the concrete quality protocols supported by results of destructive testing,
c) the list of welders who performed welding work during assembly works, stating the type and validity of certificates,
d) the list of employees who performed non-destructive tests, stating the type and validity of their authorisations,
e) the protocols of weld joint quality inspection,
f) an inspection records and confirmation of internal cleanliness of the premises,
g) the protocols of leak and strength tests of hermetic areas,
h) the protocols on a measurement of angles and flex of floors, walls and ceilings.

Accompanying technical documentation pursuant to Letters a) to g) is prepared for individual premises and rooms of civil structures.

1) The European Parliament Ordinance and the Council (EC) No. 765/2008 of 9 July 2008 laying out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Official Journal of EU L218 of 13 August 2008).
2) E. g. STN EN ISO/IEC 17021Conformity assessment. The requirements for state bodies carried out audit and certification of management system. Part 1:Requirements (ISO/IEC 17021-1) (01 5257).
3) E. g. STN EN ISO 9000 Quality management systems. Principles and vocabulary (ISO 9000) (01 0300).
4) E.g. STN EN ISO 10204 Metal products. Types of control documents (42 0009).
5) 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 (codification) (OJ L 241, 17.9.2015).
6) Decree of Nuclear Regulatory Authority of the Slovak Republic No. 52/2006 Coll. on professional qualification.
7) E.g. STN EN ISO 9001 Quality Management Systems. Requirements (ISO 9001) (01 0320).
8) E.g. Act No. 395/2002 Coll. on Archives and Registries and on Amendment of Certain Acts as amended, Regulation of the Ministry of Internal Affairs of the Slovak Republic No. 628/2002 Coll., by which certain provisions of the act on archives and registries and on amendments of certain acts are executed, as amended.
9) Annex 1 to the Decree of Nuclear Regulatory Authority of the Slovak Republic No. 430/2011 Coll. on nuclear safety requirements.
10) E.g. Act No. 56/2018 Coll. on product conformity assessment, making available on the market and amending certain acts as amended by the Act No. 259/2021 Coll.