

(Draft)

DECREE
of the Nuclear Regulatory Authority of the Slovak Republic
of 2025,
amending Decree of the Nuclear Regulatory Authority of the Slovak Republic
No 431/2011 on a quality management system,
as amended

Pursuant to § 25(6) of Act No 541/2004 on the peaceful use of nuclear energy (the Atomic Act) and on amendments to certain acts, as amended, the Nuclear Regulatory Authority of the Slovak Republic lays down the following:

Article I

Decree of the Nuclear Regulatory Authority of the Slovak Republic No 431/2011 on a quality management system, as amended by Decree No 104/2016 and Decree No 154/2022, is amended as follows:

1. In § 2, the following paragraphs (13) to (17) are added:

‘(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.’.

2. In § 6, the following new paragraphs (8) and (9) are inserted after paragraph (7):

‘(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.’.

Paragraph (8) is renumbered as paragraph (10).

3. In § 8, paragraph (4) reads as follows:

‘(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 standards⁷ or 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).’.

4. In § 8, the following paragraphs (20) to (29) are added:

‘(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.'

5. In § 9(3)(g), the following words are added at the end:

'with proven experience'.

6. § 12 reads as follows:

'§ 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⁾'.

Footnote 5 reads as follows:

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).'

7. In Annex 5, Part II, the following point (s) is added:
'(s) a set of quality assurance requirements for a commercial-grade item.'

8. In Annex 5, Part III, point A, the following point (h) is added:
'(h) a set of quality assurance requirements for a commercial-grade item.'

9. At the end of Annex 7, point (b), the following words are added:
'and safety function'.

10. In Annex 7, the following points (t) and (u) are added:
'(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.'

11. In Annex 8, point A, the following point (i) is added:
'(i) reports, documents and records of tests and inspections, and evaluation of the acceptance of the commercial-grade item.'

Article II

This Decree shall come into effect on 1 January 2026.