

### Clause on selected impacts

<b>1. Basic information</b>	
<b>Name of the document</b>	
Draft Decree of the Nuclear Regulatory Authority of the Slovak Republic No .../2025 amending Decree of the Nuclear Regulatory Authority of the Slovak Republic No 431/2011 on a quality management system, as amended	
<b>Submitter (and co-submitter)</b>	
Nuclear Regulatory Authority of the Slovak Republic	
<b>Nature of the submitted document</b>	<input type="checkbox"/> Document of a non-legislative nature <input checked="" type="checkbox"/> Document of a legislative nature <input type="checkbox"/> Transposition/implementation of EU law
<i>In case of transposition/implementation, please provide a list of transposed/implemented legislation: not applicable</i>	
<b>Start and end dates of the preliminary consultation exercise</b>	11 December 2024
<b>Expected date of submission for the consultation exercise</b>	11 December 2024 – 7 January 2025
<b>Expected start and end dates of final assessment**</b>	
<b>Expected date of submission to a session of the Government of the Slovak Republic*</b>	

  

<b>2. Definition of the issue</b>	
There is no relevant legislation at present that allows the use of commercial-grade items in the nuclear sector. This amendment will eliminate this legal vacuum.	
<b>3. Objectives and the desired outcome</b>	
The adoption of this legislation will establish a procedure for the verification of commercial-grade items and allow for their use in a nuclear installation. The aim is to allow greater flexibility in securing/procuring selected equipment in the event that the original supplier no longer exists or no longer manufactures the original selected equipment for any reason.	
<b>4. Stakeholders</b>	
Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004 on the peaceful use of nuclear energy (the Atomic Act) and on amendments to certain acts, as amended.	
<b>5. Alternative solutions</b>	

No alternative solutions were considered.

If no amendment is adopted, commercial-grade items will not be permitted for use in nuclear installations.

## 6. Implementing legislation

*Is implementing legislation expected to be adopted/amended?* ☐ Yes ☒ No

## 7. Transposition/implementation of EU law

*not applicable*

☒ No

☐ Yes

## 8. Expediency review

The criterion for verifying the correctness of the adopted legislation is its implementation and the frequency of use of commercial-grade items in the nuclear sector.

Deadline: given that changes of this magnitude to nuclear installations will not occur frequently, the expediency review will be conducted one year after the Decree comes into effect.

## 9. Selected impacts of the document

<b>Impacts on the general government budget</b> of which impacts covered by the budget, in case of identified negative impact	<input type="checkbox"/> Positive	<input checked="" type="checkbox"/> None	<input type="checkbox"/> Negative
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Partial
<b>included impacts on the budgets of municipalities and higher territorial units</b> of which impacts covered by the budget, in case of identified negative impact	<input type="checkbox"/> Positive	<input checked="" type="checkbox"/> None	<input type="checkbox"/> Negative
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Partial
Impact on the long-term sustainability of public finances for selected measures ***	<input type="checkbox"/> Yes		<input type="checkbox"/> No
<b>Impacts on the limit of public expenditure</b>	<input type="checkbox"/> Positive	<input checked="" type="checkbox"/> None	<input type="checkbox"/> Negative
<b>Impacts on the business environment</b> of which impacts on SMEs  Bureaucracy and cost reduction	<input checked="" type="checkbox"/> Positive	<input type="checkbox"/> None	<input checked="" type="checkbox"/> Negative
	<input type="checkbox"/> Positive	<input type="checkbox"/> None	<input type="checkbox"/> Negative
	<input checked="" type="checkbox"/> Yes		<input type="checkbox"/> No

mechanism is applied:			
<b>Social impacts</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>
<b>Environmental impacts</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>
The document is assessed under Act No 24/2006 on environmental impact assessment and on amendments to certain acts, as amended	<input type="checkbox"/> Yes		<input type="checkbox"/> No
<b>Impacts related to the information society</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>
<b>Impacts on public administration services for the citizen, of which impacts of public administration services on the citizen</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>
<b>impacts on service processes in public administration</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>
<b>Impacts on marriage, parenthood and families</b>	<input type="checkbox"/> <b>Positive</b>	<input checked="" type="checkbox"/> <b>None</b>	<input type="checkbox"/> <b>Negative</b>

## 10. Notes

PI/2024/232 was published in Slov-lex on 25 September 2024.

Consultations with businesses took place from 25 September 2024 to 18 October 2024. Comments were sent by Slovenské elektrárne, a.s. and Jadrová energetická spoločnosť Slovenska, a.s.

The proposed legislation was published on the website of the Nuclear Regulatory Authority from 25 September 2024 to 25 October 2024 in order to enable the public to participate in the draft document. Seven comments were received from unidentified members of the public.

A hybrid-format meeting was held on 19 November 2024 to discuss the comments from this process, with representatives of the Ministry of Economy of the Slovak Republic also participating.

### Table with comments from businesses and the public

Com ment numb er	Text of the comment/commenting party	Evaluation
	Comments from SE, a.s.	
1.	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 (hereinafter referred to as a 'commercial-grade item').	no
2.	§ 2(14)	Not accepted, only the term 'commercial-grade item' will be retained, the term

	Acceptance of a commercial-grade item is a process that involves identifying and verifying its important characteristics in order to approve its use as selected equipment in a nuclear installation. The acceptance of a commercial-grade item will ensure compliance with the important design, material and workmanship characteristics of the commercial-grade item or part thereof, providing sufficient assurance that the commercial-grade item will be capable of performing the required function important to nuclear safety.	'critical' will be used due to the safety standards. SE, a.s. are OK with this solution
3.	<p>§ 2(16) An equivalent change in selected equipment is a change in the structure, system, component or part thereof (hereinafter referred to as 'SKK'), the quality management system documentation of which can be applied repeatedly to selected equipment that is subject to the same or lower quality requirements. An equivalent change may be a change to the original SKK and an element in the selected equipment implemented using the following procedure:</p> <ul style="list-style-type: none"> <li>a) type replacement, manufactured and qualified in accordance with the standards and specifics applied in the nuclear industry, while meeting the quality requirements for selected equipment specified in this Decree,</li> <li>b) use of a commercial-grade item, as specified by this Decree.</li> </ul>	Not accepted SE, a.s. are OK with this solution
4.	<p>§ 2(17) The analysis of the suitability of a type replacement or a commercial-grade item is an assessment of the suitability of an equivalent change to selected equipment or part thereof.</p>	Not accepted An additional statement will be added specifying be
5.	<p>§ 6(9) The requirements for the process of acceptance for a commercial-grade item pursuant to § 8(21) shall be provided in the quality plan for selected equipment classified in safety classes II and III, and in the impact analyses for selected equipment classified in safety class IV.'.</p>	Not accepted This is linked to control and management system use for safety class II is not substantiated, graduated approach, not ruled out in the future Evaluation: by exemption only individual assessment
6.	<p>§ 8(20) The use of a commercial-grade item is permitted for selected equipment and parts thereof classified in safety classes II, III, and IV.</p>	Same as above ČA Point 6 resolved differently, with an additional exemption,

		SE agrees with the solution
7.	<p>§ 8(21)</p> <p>(21) In the process of acceptance of a commercial-grade item as selected equipment, the permit holder shall ensure and document</p> <p>a) compliance with the important design, material and workmanship characteristics of the commercial-grade item or part thereof, which are demonstrably documented in such a way that the commercial-grade item will be capable of performing the function required by the project and important to nuclear safety,</p> <p>b) the performance of manufacturer verification in the management of achieving the important characteristics referred to in point (a), or inspections at production control points, or analyses of historical record to demonstrate compliance of the commercial-grade item with project requirements,</p> <p>c) verification of the acceptability of the commercial-grade item after delivery through inspections, tests, or analyses carried out by qualified personnel; the tests and analyses may also be performed by a third party independent of the manufacturer or supplier of the commercial equipment, provided that they have demonstrable experience.</p>	<p>a – no</p> <p>b – no, we do not want to narrow it to project requirements</p> <p>c – acceptable</p>
8.	<p>§ 8(24)</p> <p>Within its quality management system, the permit holder 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 demonstrable experience with the relevant systems or equipment in which the commercial-grade item is to be used may also be engaged in the process of acceptance review and evaluation of the suitability of the commercial-grade item replacement.</p>	<p>Not accepted</p> <p>SE agrees with the solution</p>
9.	<p>§ 8(25)</p> <p>A permit holder shall ensure a process for the early identification of counterfeit, fraudulent and suspicious items within its quality management system.</p>	yes

10.	<p>§ 8(26)</p> <p>For type replacements and accepted commercial-grade items on selected equipment, the permit holder shall ensure and document the quality requirements for the selected equipment. In the case of recurring type replacements or, where applicable, accepted commercial-grade items on the same types of SKK, but on different systems or at different installation locations, the permit holder shall:</p> <ul style="list-style-type: none"> <li>a) submit to the Authority a single application for approval of a project for the type replacement or accepted commercial-grade items, together with the quality assurance requirements for the selected equipment, in accordance with § 2(w) of the Atomic Act. The submission of the application shall be subject to the inclusion of a comprehensive scope of quality requirements covering the most demanding conditions and requirements from the considered installation positions of the selected equipment at which the equivalent change of the selected equipment is planned to be implemented,</li> <li>b) submit a list of approved equivalent changes applied at specific positions of repeated installation to the Authority once a year.</li> </ul>	Not accepted
11.	<p>§ 8(27)</p> <p>For an equivalent change to selected equipment, documentation shall be recorded and documented to the following extent:</p> <ul style="list-style-type: none"> <li>a) updates to the quality requirements for selected equipment according to Annex 7, as part of the prepared equivalent change project,</li> <li>b) the implementing and accompanying technical documentation of the selected equipment in accordance with Annex 8 for each installation position of the selected equipment at which the equivalent change has been implemented.</li> </ul>	Not accepted SE agrees

12.	§ 8(28) (28) If a commercial-grade item is used for selected equipment, the permit holder shall additionally conduct and document an assessment of the suitability of this replacement pursuant to paragraphs (21) to (24).	Not accepted, we have modified the text SE agrees
13.	§ 8(29) For a type replacement or a commercial-grade item of selected equipment, an installation position shall be assigned as designated by the permit holder, who shall ensure the necessary evaluation, documentation record-keeping, and the entire change management process.’.	Not accepted SE agrees
14.	1. In Annex 7, the following point (t) is added:  ‘t) the evaluation of an equivalent change shall include requirements for acceptance using the method of  1. verification of evidence of the required quality and characteristics of the item 2. testing and inspection 3. verification of the manufacturer’s quality management system at the time of production 4. a combination of the methods referred to in points 1 to 3, depending on the type of equivalent change and its classification in a safety class.’.	The text has been formulated differently  The permit holder shall test each lot
15.	Transitional provisions The requirements relating to commercial-grade items laid down in § 6 point (9), § 8 points (20) to (25) and (28), Annex 5, Part II, points (s) and (h), Annex 7, point (t), and Annex 8, part A(i) may also be governed by the existing legislation until 1 August 2027.	Not accepted, no transitional provisions will be included
16.	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 shall be used as a priority for their qualification and, where justified, other methods referred to in point (11)	Accepted, but formulated in a slightly different way

	may also be used, in accordance with the relevant standards and taking into account the feasibility of the type-examination.	
	JAVYS, a.s. – no comments	
	Comments from JESS, a.s.	
17.	<p>§ 8(21)(c) ...the tests and analyses may also be performed by a third party independent of the manufacturer or supplier of the commercial equipment, provided that they have demonstrable experience</p> <p>Comments: It is not clearly specified how ‘demonstrable experience’ is to be demonstrated, documented, or verified. It should be defined in some way, either through practical experience or supplier contracts from previous projects...</p>	We will define demonstrable experience in a safety standard
18.	<p>§ 8(24) A third party with demonstrable experience with the relevant systems or equipment in which the commercial-grade item is to be used may also be engaged in the process of verifying and evaluating the suitability of the replacement and the preparation of the suitability analysis of the commercial grade-item.</p> <p>Comments: It is not clearly specified how ‘demonstrable experience’ is to be demonstrated, documented, or verified. It should be defined in some way, either through practical experience or supplier contracts from previous projects...</p>	We will define demonstrable experience in a safety standard
19.	<p>§ 9(1)(g) assessment of the proposed change by the person who prepared the original project, or by another qualified person ‘with demonstrable experience in the field’</p> <p>Comments: It is not clearly specified how ‘demonstrable experience’ is to be demonstrated, documented, or verified. It should be defined in some way, either through practical experience or supplier contracts from previous projects...</p>	We will define demonstrable experience in a safety standard. Justification must be provided or through a contract.
20.	General question – is it possible to apply a ‘commercial-grade item’ and other related provisions to all nuclear installations, i.e. including those already in project stage?	No, this constitutes a project change and is the responsibility of the designer
21.	Will the new terminology also be reflected in	yes



	safety standard BN1/2022?	
	VUJE	
20	<p>DECREE of the Nuclear Regulatory Authority of the Slovak Republic of XX/2025 amending Decree of the Nuclear Regulatory Authority of the Slovak Republic No 431/2011 on a quality management system, as amended</p> <p>3. In § 8, the following paragraphs (20) to (29) are added:          ‘(20) The use of a commercial-grade item is only permitted for selected equipment and parts thereof classified in safety classes III and IV.’</p> <p>Equipment classified in safety classes I and II typically also contains certain commercial-grade items, e.g. in control and management system equipment (distribution boards classified in safety classes I and II) – terminal blocks, switches, circuit breakers, DIN rails, door contacts, relays, transducers, thermostats, etc. This statement should be properly clarified or its meaning should be explained, as even safety class I and II equipment cannot function without certain commercial-grade items.</p>	Formulated in a different way
	Public 1	
22.	In Annex 1, add the following point (au): Identification of appropriate methods for verifying the compliance of the basic and auxiliary materials used with the quality requirements for selected equipment.	No, this is addressed at other levels of documentation. The essence of the proposed wording is covered by the existing provision of Annex 7, point (c) and Annex 4, part I points (f) and (j) of Decree No 431/2011
	Public 2 – Mýto pod Ďumbierom	
23.	In § 4, paragraph (11) reads as follows: The permit holder shall ensure that the documented quality management system procedures are in line with the current state of the relevant processes and regularly carry out a documented review of the up-to-date status of the quality management system’s procedural documentation at least once every three years.	No, this is addressed at other levels of documentation. The essence of the proposed wording is covered by the existing provisions of § 4 (11) of Decree No 431/2011, the only difference is that the existing provisions are worded in more general terms.
	Public 3 – Detva	
24.	In Annex 1, the following point (at) is added: at) the designation of the permit holder’s statutory representative responsible for the quality management system at specific nuclear installations, who acts on behalf of the management, is entrusted with the authority and necessary resources to coordinate, prepare,	No, this is addressed at other levels of documentation The essence of the proposed wording is covered by the existing provisions of § 3(4) of Decree No 431/2011; in addition, the proposed wording ‘... is independent of priorities other than nuclear

	implement, apply, maintain and operationally manage the quality management system, is independent of priorities other than nuclear safety, and has the authority to: 1. review the quality management system and identify issues related to quality assurance and quality improvement, 2. initiate and recommend corrective actions to eliminate the causes of non-conformities, 3. verify the implementation and effectiveness of these corrective actions, 4. suspend activities if their continuation could endanger nuclear safety.	safety...' is unclear (it may have multiple interpretations) and therefore cannot be used in the Decree
	Public 4	
25.	In Annex 3, point 4 is amended as follows: Quality plan for selected equipment in safety classes I and II.	No, this is addressed at other levels of documentation The proposed modification of the wording is not acceptable; under § 6 of Decree No 431/2011, quality plans are to be prepared for selected equipment classified in safety classes I, II, and III – not only for those in safety classes I and II
	Public 5	
26.	Add the following point (aw) in Annex 1: Ensuring the traceability of equipment and software back to the relevant design documentation, quality requirements, and accompanying technical documentation.	No, this is addressed at other levels of documentation. The essence of the proposed wording is covered by the existing provisions in Annex 1, point (ah)
	Public 6	
27.	In § 4(1), the following point (b) is added: b) the implementation of a policy focused on quality, nuclear safety, safety culture, and staff training.	No, this is addressed at other levels of documentation. The essence of the proposed text 'safety culture' is covered by the provisions of § 3(8)(b); Annex 1, point (q) of Decree No 431/2011; the obligations of the permit holder relating to safety culture are also laid down in § 23(c) of the Atomic A
	Public 7	
28.	The following point (av) is added in Annex 1: The requirement to record all activities that have an impact on the quality of selected equipment in the relevant construction and commissioning logbooks.	No, this is addressed at other levels of documentation. The essence of the proposed wording is covered by the provisions of Annex 4 Requirements for the specifications programme and the phase programme for nuclear installation quality as

<b>11. Contact details of the author</b> <i>JUDr. Gabriela Špačková,</i> <a href="mailto:Gabriela.spackova@ujd.gov.sk">Gabriela.spackova@ujd.gov.sk</a> 02/ 58 221 212
<b>12. Sources</b> The professional guarantors of the preparation of this analysis are the Division of Nuclear Installations Control, the Division of Systems, Components and Civil Structures, and the Division of Safety Analysis and Technical Support of the Nuclear Regulatory Authority of the Slovak Republic; the legislative and technical aspects are ensured by the Authority's Division of Legislation and Legal Affairs.  The clause on impacts on the business environment was prepared in cooperation with Slovenské elektrárne, a.s., which will be most affected by the adopted legislation.
<b>13. Opinion of the Commission on the assessment of selected impacts from the preliminary consultation exercise No .....</b> (if carried out pursuant to point 8.1 of the Uniform Methodology)
<input checked="" type="checkbox"/> <b>Agree</b> <input type="checkbox"/> <b>Agree with a proposal for completion</b> <input type="checkbox"/> <b>Disagree</b> Please provide comments from the Commission's opinion in Part II, together with your assessment:  <b>Opinion of the Secretariat of the Permanent Working Commission of the Legislative Council of the Government of the Slovak Republic on the assessment of selected impacts at the Ministry of Economy</b> I wish to inform you that, pursuant to point 8.1. of the Uniform Methodology for the Assessment of Selected Impacts: 'All documents of a legislative or non-legislative nature in which the submitter has identified at least one of the selected impacts (impacts on the general government budget, impacts on the business environment, social impacts, environmental impacts, impacts related to the information society, impacts on public administration services for the citizen, and impacts on marriage, parenthood and families) are to be submitted for the preliminary consultation exercise.' As you have not identified any of the impacts in this case, the document may be submitted directly to the interdepartmental consultation exercise. Naturally, a comment may be raised during the interdepartmental consultation exercise suggesting that one of the impacts be marked. In such a case, the document will have to be submitted for final assessment. However, please consider this information as a description of a potential scenario.
<b>14. Opinion of the Commission on the assessment of selected impacts from final assessment No 018/2025</b> (if carried out pursuant to point 9.1 of the Uniform Methodology)
<input checked="" type="checkbox"/> <b>Agree</b> <input type="checkbox"/> <b>Agree with a proposal for completion</b> <input type="checkbox"/> <b>Disagree</b> Please provide comments from the Commission's opinion in Part II, together with your assessment:

Regarding the clause on selected impacts

The Commission recommends that the submitter mark the 'Bureaucracy and cost reduction mechanism' as 'yes' in the clause on selected impacts in Part 9. Selected impacts of the document.

Grounds: The 'Bureaucracy and cost reduction mechanism' applies if the submitter has identified an impact on the business environment in the 'Clause on selected impacts', and this impact relates to business environment costs pursuant to point 6.4 of the Uniform Methodology for the Assessment of Selected Impacts.

Opinion of the Nuclear Regulatory Authority of the Slovak Republic: the clause on selected impacts has been adapted in accordance with the Opinion of the Commission of the Legislative Council of the Government of the Slovak Republic on the assessment of selected impacts.

## Analysis of impacts on the business environment

**Name of the document:** Draft Decree of the Nuclear Regulatory Authority of the Slovak Republic No .../2025 amending Decree of the Nuclear Regulatory Authority of the Slovak Republic No 431/2011 on a quality management system, as amended

**Submitter:** Nuclear Regulatory Authority of the Slovak Republic

### 3.1 Regulatory costs

#### 3.1.1 Summary table of regulatory costs

Table 1: Changes in costs (per year) for the business environment (BE), evaluation of the bureaucracy and cost reduction mechanism, gold-plating costs<sup>1</sup> for the business environment:

TYPE OF COSTS	Cost increase in EUR for the BE	Cost reduction in EUR for the BE
<i>A. Taxes, levies, duties, and charges aimed at reducing negative externalities</i>	0	0
<i>B. Other charges</i>	0	0
<i>C. Penalties and fines</i>	0	0
<i>D. Indirect financial costs</i>	74,500	1,800,000
<i>E. Administrative costs</i>	209,786	36,518
<i>Total = A+B+C+D+E</i>	284,286	1,836,518

Harmonisation of EU law	Cost increase in EUR for the BE	Cost reduction in EUR for the BE
<i>F. Full harmonisation of EU law</i> (excluding taxes, levies, duties, and charges aimed at reducing negative externalities)	0	0
<i>G. Gold-plating</i>	0	0

CALCULATION OF THE 1in2out RULE:	IN	OUT
<i>H. Costs excluding exceptions = B+D+E-F</i>	284,286	1,836,518

<sup>1</sup> The definition of gold-plating is given in point 4 of Part III of the Uniform Methodology.

### 3.1.2 Calculation of the impacts of individual regulations on changes in costs for businesses

Table 2: Calculation of the impacts of individual regulations (replace with the same table after completing the Cost Calculator):

Se q. no.	Clear and concise description of the regulation (the reason for increasing/reducing costs for the BE and the reason for maintaining costs for the BE that constitute gold-plating)	Number of the legislation (act, decree, etc.)	Localisation (§, paragraph, Article,...)	Origin of regulation: SK/EU complete harmonisation/ Gold-plating	Effective date of regulation	Category of stakeholders	Total number of stakeholders	Impact per business in EUR	Impact on stakeholder category in EUR	Type of impact In (increases costs)/ Out (reduces costs) /No change
1	Aggregation of the preparation of quality plans and quality requirements for the same types of equipment	Decree 431/2011	§ 6(8)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	13,147	13,147	Out (reduces costs)
2	Abolition of the approval by the Nuclear Regulatory Authority of the Slovak Republic of individual type replacements to be implemented in projects.	Decree 431/2011	§ 6(8)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	18,990	18,990	Out (reduces costs)
3	Introduction of the acceptance process for the use of commercial-grade items in the group of selected equipment classified in safety class II	Decree 431/2011	§ 8(20)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	27,754	27,754	In (increases costs)
4	Identification, verification, and validation of the critical characteristics of the intended use of a commercial-grade item	Decree 431/2011	§ 8(21a)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	128,545	128,545	In (increases costs)
5	Auditing of the processes of manufacturers of commercial-grade items intended for use in selected equipment	Decree 431/2011	§ 8(21b)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	72,000	72,000	In (increases costs)
6	Verification of the quality of approved commercial-grade items through independent analyses, tests, and examinations	Decree 431/2011	§ 8(21c)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	12,660	12,660	In (increases costs)
7	Documentation of the use of a commercial-grade item and the update of the accompanying technical documentation for selected equipment	Decree 431/2011	§ 8(23)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	2,921	2,921	In (increases costs)
8	Preparation and implementation of procedural documentation within the quality management system, introduction	Decree 431/2011	§ 8(24)	SK	1.1.2026	Holders of a permit under § 5(3)(a) to (d) of Act No 541/2004	1	4,326	4,326	In (increases costs)

	of commercial-grade item acceptance, along with the setup of the organisational structure and training									
9	Through aggregation, reduction in the number of applications to be prepared due to reuse of commercial-grade items	Decree 431/2011	§ 8(26)	SK		1	1,802,921	1,802,921	Out (reduces costs)	
	Through aggregation, reduction in the number of applications for the approval of project and legislative documentation by the Nuclear Regulatory Authority due to reuse of commercial-grade items	Decree 431/2011	§ 8(26)	SK	1.1.2026	1	1,461	1,461	Out (reduces costs)	
10										
11	Procedural recording of type replacement documentation for each position where a commercial-grade item is used	Decree 431/2011	§ 8(27)	SK	1.1.2026	1	12,660	12,660	In (increases costs)	
12	Documentation and evaluation of the management process for each type replacement and use of a commercial-grade item	Decree 431/2011	§ 8(29)	SK	1.1.2026	1	3,798	3,798	In (increases costs)	
13	Identification, and verification of early identification, of counterfeit, fraudulent and suspicious procured items by tests and examinations	Decree 431/2011	§ 8(25)	SK	1.1.2026	1	18,990	18,990	In (increases costs)	

NOTE: All identified impacts on the business environment listed in rows 1 to 13 concern only a single business and no impacts (negative or positive) have been identified for other businesses (JAVYS, a.s., VÚJE, a.s., JESS, a.s., or others) affected by this draft legislative document.

### **3.1.3 Additional information on how the impacts of individual regulations on cost changes have been calculated**

**Row no 1** *Aggregation of the preparation of quality plans and quality requirements for the same types of equipment.*

Reduction in administrative costs: The aggregation of quality plans and quality requirements for the same types of equipment, along with the abolition of the approval of individual implementation projects for the use of commercial-grade items by the Nuclear Regulatory Authority, reduces the administrative burden both for the relevant business and for the approving authority, the Nuclear Regulatory Authority of the Slovak Republic.

Expert estimate of the reduction in administrative burden resulting from the positive impact of the application of the regulation, inputs:

- in the context of preparing quality plans and quality requirements and aggregating them within a single business for a single type replacement case, this represents a time saving of 45 hours for two employees, i.e. a total of 5,400 minutes, with a frequency of once per month per business.
- calculator input: 5,400 minutes x 12 (frequency) x hourly rate in the national economy.

**Row no 2** *Abolition of the approval by the Nuclear Regulatory Authority of the Slovak Republic of individual type replacements to be implemented in projects.*

Reduction in administrative costs: The abolition of the approval of individual implementation projects for the use of a commercial-grade item by the Nuclear Regulatory Authority reduces the administrative burden on the approving authority, the Nuclear Regulatory Authority of the Slovak Republic.

Expert estimate of the reduction in administrative burden resulting from the positive impact of the application of the regulation, inputs:

- in the context of the abolition of the approval of type replacement implementation projects for a single type replacement case, the time saving is 1,800 minutes, with a frequency of once per week per business.
- calculator input: 1,800 minutes x 52 (frequency) x hourly rate in the national economy.

**Row no 3** *Introduction of the acceptance process for the use of commercial-grade items in the group of selected equipment classified in safety class II.*

Increase in administrative costs: In the context of the introduction of the acceptance process for the use of commercial-grade items in the group of selected equipment classified in safety class II, which goes beyond the scope applicable to selected equipment in safety classes III and IV.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- identification of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 80 hours for two employees, i.e. a total of 9,600 minutes, with a frequency of three times per year per business.



- verification of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 180 hours for two employees, i.e. a total of 21,600 minutes, with a frequency of three times per year per business.
- validation of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 120 hours for two employees, i.e. a total of 14,400 minutes, with a frequency of three times per year per business.
- calculator input:  $(9,600 \times 3 \text{ (frequency)} \times \text{hourly rate in the national economy}) + (21,600 \times 3 \text{ (frequency)} \times \text{hourly rate in the national economy}) + (14,400 \times 3 \text{ (frequency)} \times \text{hourly rate in the national economy})$ .

**Row no 4** *Identification, verification, and validation of the critical characteristics of the intended use of a commercial-grade item in selected equipment classified in safety classes III and IV.*

Increase in administrative costs: In the context of the identification, verification, and validation of the critical characteristics of the commercial-grade item intended for use in selected equipment.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- identification of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 40 hours for two employees, i.e. a total of 4,800 minutes, with a frequency of once per month per business.
- verification of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 120 hours for two employees, i.e. a total of 28,800 minutes, with a frequency of once per month per business.
- validation of the critical characteristics of a type replacement using a commercial-grade item represents a time requirement of 80 hours for two employees, i.e. a total of 19,200 minutes, with a frequency of once per month per business.
- calculator input:  $(4,800 \times 12 \text{ (frequency)} \times \text{hourly rate in the national economy}) + (28,800 \times 12 \text{ (frequency)} \times \text{hourly rate in the national economy}) + (19,200 \times 12 \text{ (frequency)} \times \text{hourly rate in the national economy})$ .

**Row no 5** *Auditing of the processes of manufacturers of commercial-grade items intended for use in selected equipment.*

Increase in indirect financial costs– Conducting audits of manufacturers of primarily foreign commercial-grade items intended for use in selected equipment

Expert estimate of the increase in indirect financial costs resulting from the negative impact of the application of the regulation, inputs:

- auditing of a European manufacturer of a commercial-grade item by two internal auditors over a period of four days per commercial-grade item, with estimated costs (flight, accommodation, per diem and subsistence, and other expenses) of EUR 6,000, with a periodicity of four times per year, i.e. approximately EUR 24,000.
- auditing of an overseas or Asian manufacturer of a commercial-grade item by two internal auditors over a period of 6 days per commercial-grade item, with estimated

costs (flight, accommodation, per diem and subsistence, and other costs) of EUR 12,000, with a periodicity of four times per year, i.e. approximately EUR 48,000.

- indirect financial cost calculator input: EUR 24,000 + EUR 48,000

**Row no 6** *Verification of the quality of approved commercial-grade items through independent analyses, tests, and examinations.*

Increase in administrative costs: In the context of the acceptance process for a commercial-grade item, provision of independent expert analyses, tests and examinations confirming the success of the process.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- preparation of independent analyses on the basis of an external contract, with a high degree of obligation and with a periodicity of once per month
- preparation of independent examinations and tests on the basis of an external contract, with a high degree of obligation and with a periodicity of once per month.
- preparation of independent tests on the basis of an external contract, with a high degree of obligation and with a periodicity of once per month.
- calculator input: automatic calculation in column (X,Y,AA).

**Row no 7** *Documentation of the acceptance process and the update of the accompanying technical documentation for the commercial-grade item used as selected equipment*

Increase in administrative costs: In the context of the progress and results of the acceptance process for the selected commercial-grade item within a type replacement, preparation of the accompanying technical documentation (ATD) of the type replacement as selected equipment.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- documenting and evidencing the quality requirements for selected equipment and ATD, and the procedural registration of a single type replacement by a commercial-grade item within the quality management system cycle of the business, represents a time requirement of 10 hours for two employees, i.e. a total of 1,200 minutes, with a frequency of once per month per business.
- calculator input: 1,200 minutes x 12 (frequency) x hourly rate in the national economy.

**Line no 8** *Preparation and implementation of procedural documentation within the quality management system, introduction of commercial-grade item acceptance, along with the setup of the organisational structure and training*

Increase in administrative costs: Processing and approval of the procedural documentation for implementing the use of a commercial-grade item in the business's quality management system

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- the processing and approval of new procedural documentation for implementing the use of a commercial-grade item represents a time requirement of 300 hours for two employees, i.e. a total of 600 hours, occurring once per business.
- calculator input: 36,000 minutes x 0.25 (frequency) x hourly rate in the national economy.

Increase in indirect financial costs– Training of a designated group of employees procedurally affected by the implementation of a commercial-grade item in the context of a type replacement.

Expert estimate of the increase in indirect financial costs resulting from the negative impact of the application of the regulation, inputs:

- training on the full cycle of the commercial-grade item implementation process covers a total of 120 employees per business, with an average training duration of 9 hours, in groups of 10 employees trained in the business's internal premises, which, at a lecturer rate of EUR 60 per hour, represents a financial cost of approximately EUR 6,500 in total + overheads of EUR 3,500 in total.
- indirect cost calculator input: EUR 6,500 + EUR 3,500

**Row no 9** *Through aggregation, reduction in the number of applications to be prepared due to reuse of commercial-grade items.*

Reduction of indirect financial costs– due to the application of the regulation and the implementation of an accepted commercial-grade item as a project element in a group of selected equipment, the financial costs are significantly reduced by avoiding the need to upgrade the equipment as a whole, in particular in the electrical equipment, measurement and regulation equipment, and radiation and chemical monitoring equipment systems in a nuclear power plant.

Expert estimate of financial cost savings resulting from the positive impact of the application of the regulation, inputs:

- the average cost for the design, manufacture, supply, and installation of a full set of new equipment – consistently across four identical nuclear units in threefold nuclear power plant design redundancy – as well as the power supply control panel and relay automation for selected equipment in safety class III, is approximately EUR 600,000 pre business.
- the need arises three times per year in total, across four nuclear units, for similar equipment replacements, which represents a positive impact amounting to an expert estimate of approximately EUR 1,800,000 for the affected business.
- calculator input: (cost EUR 50,000 x 3 redundancies x 4 units) x 3 (per year)

Reduction in administrative costs: In the case of repeated planned use of an accepted commercial-grade item as a type replacement on different systems forming part of selected equipment, the aggregation of the preparation of technical and legislative documentation (quality plans, quality requirements) will reduce the administrative burden on the business.

Expert estimate of the reduction in administrative burden resulting from the positive impact of the application of the regulation, inputs:

- in the context of the preparation of the technical and legislative documentation by a single business for a single type replacement case, the time requirement is 37.5 hours for two employees, i.e. a total of 4,500 minutes, with a reduction in frequency from once per month to four times per year per business.
- calculator input: 4,500 minutes x 4 (frequency) x hourly rate in the national economy

**Row no 10** *Through aggregation, reduction in the number of applications for the approval of project and legislative documentation by the Nuclear Regulatory Authority due to reuse of commercial-grade items.*

Reduction in administrative costs: In the case of repeated planned use of an accepted commercial-grade item as a type replacement on different systems forming part of selected equipment, aggregation will reduce the administrative burden on the approving authority, the Nuclear Regulatory Authority of the Slovak Republic.

Expert estimate of the reduction in administrative burden resulting from the positive impact of the application of the regulation, inputs:

- in the context of the assessment and approval of technical and legislative documentation by the Nuclear Regulatory Authority, the time requirement per single type replacement case is 1,800 minutes, and the frequency will be reduced from once per month to four times per year per business.
- calculator input: 1,800 minutes x 4 (frequency) x hourly rate in the national economy.

**Row no 11** *Procedural recording and updating of the quality requirements for the selected equipment and the requirements for the ATD for each position using a commercial-grade item in a type replacement.*

Increase in administrative costs: After each implementation of a type replacement using an accepted commercial-grade item, the administrative costs will increase compared to the status quo due to the scope of the acceptance documentation and the documentation of quality and ATD requirements at the stage of documenting and recording such a type replacement for each position at which the type replacement has been implemented.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- documenting and evidencing the quality requirements for selected equipment and ATD, and the procedural registration of a single type replacement position using a commercial-grade item within the quality management system cycle of the business, represents an additional time requirement of 10 hours for two employees, i.e. a total of 1,200 minutes, with a frequency of once per week per business.
- calculator input: 1,200 minutes x 52 (frequency) x hourly rate in the national economy.

**Row no 12** *Documentation and evaluation of the management process for each type replacement and use of a commercial-grade item*

Increase in administrative costs: after each implementation of a type replacement using an accepted commercial-grade item, administrative costs will increase compared to the status quo due to the requirements for documentation and evaluation of such a type replacement.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- the documentation and evaluation of a single type replacement position using a commercial-grade item represents an additional time requirement of 3 hours for two employees, i.e. a total of 360 minutes, with a frequency of once per week per business.
- calculator input: 360 minutes x 52 (frequency) x hourly rate in the national economy.

**Row no 13** *Early identification and verification through tests and examinations of supplied counterfeit, fraudulent and suspicious items.*

Increase in administrative costs: Due to the identification of counterfeit, fraudulent or suspicious items in a selected representative sample within the supply of an identical lot of items, additional quality verification results in increased administrative costs compared to the status quo.

Expert estimate of the increase in administrative burden resulting from the negative impact of the application of the regulation, inputs:

- the implementation of identification and quality verification of a representative sample within the supply of an identical lot of items represents an additional time requirement of 7.5 hours for four employees, i.e. a total of 1,800 minutes, with a frequency of once per week per business.
- calculator input: 1,800 minutes x 52 (frequency) x hourly rate in the national economy.

### **3.1.4 Justification for gold-plating under point 4 of Part III of the Uniform Methodology and other additional information<sup>2</sup>**

*Please provide the required information separately for each identified case of gold-plating (separately for each regulation evaluated as involving gold-plating).*

*Please provide justification for gold-plating in terms of its unquestionable necessity. Support the justification with a thorough assessment of benefits and costs. Please indicate the alternative solutions considered.*

*Please also provide specific information relating to the gold-plating category under the Uniform Methodology, in particular: to which entities it is proposed to extend the scope of the Directive and why; which requirements are being increased and for which entities beyond the minimum requirements of the Directive; which less stringent derogation or modification available under the Directive were not used and why; why stricter sanctioning regimes are*

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<sup>2</sup> Information is provided only if the current regulatory proposal transposes an EU directive and gold-plating has been identified in the correlation table, or if it implements an EU regulation and involves gold-plating. Information is also provided (if the proposal is not a transposition of an EU directive or implementation of an EU regulation) where the present proposal removes gold-plating originating from the earlier retention of existing legislation (existing national requirements).

*proposed; why earlier transposition is proposed; and why existing stricter national requirements are being retained.*

*The use of gold-plating in the transposition or implementation of EU legislation is, in principle, undesirable, as this may lead to a reduction in the competitiveness of domestic enterprises compared to those from countries where legislation is less stringent. The use of gold-plating by the submitter is therefore permissible only in exceptional cases that are duly justified and explained in the analysis of the impacts on the business environment in terms of necessity, social importance, and costs, and that have been consulted with the affected businesses and assessed by the Commission.*

### **3.2 Evaluation of consultations with businesses prior to the preliminary consultation exercise**

The legislation under preparation was drawn up by an internal working group of the Nuclear Regulatory Authority of the Slovak Republic, which was involved and participated in all consultations with the affected businesses and in other meetings held in the context of the legislative process for adopting the amendment of Decree No 431/2011. The proposed legislation also responds to all substantive comments raised during the interdepartmental consultation exercise, as well as to the relevant general comments.

Consultations with the business environment on the document in question were held, and a meeting was convened for this purpose on 19 November 2024.

The interdepartmental consultation exercise took place from 11 December 2024 to 7 January 2025. The comments received on the document included, inter alia, substantive comments, namely from the Ministry of the Economy (the Department for the Improvement of the Business Environment and the Secretariat of the Permanent Working Commission of the Legislative Council of the Government of the Slovak Republic on the assessment of selected impacts at the Ministry of the Economy).

Subsequently, a meeting with the business community was held on 10 February 2025.

As regards the justification for not including JAVYS, a.s. in the calculations of the impacts of the various regulations on changes in business costs, it should be noted that JAVYS, a.s. operates seven nuclear installations, two of which (NPP RÚ RAO and NPP IS RAO) do not include any selected equipment. Two other nuclear installations (NPP A1 and NPP V1) are in the decommissioning phase, which implies that the use of commercial-grade items will only be possible in the remaining three nuclear installations (NPP MSVP, NPP TSÚ RAO and NPP FS KRAO). Each of these three nuclear installations operates with different technologies; therefore, the aggregation of activities leading to the approval of commercial-grade items will be minimal, and the option of type replacement will be used only in isolated cases. Only selected equipment in safety classes III and IV is installed at the nuclear installations of JAVYS, a.s. When comparing the number of selected equipment items at JAVYS, a.s. with those at SE, a.s., and the corresponding number of activities required for the application of commercial-grade items, while also taking into account the sporadic use of this option in the nuclear installations of JAVYS, a.s., the impact on reduced or increased business costs is negligible in comparison to the costs of SE, a.s.; therefore, it is not considered in the present analysis of impacts on the business environment.

When applying item no 13 'Identification, and verification of early identification, of counterfeit, fraudulent and suspicious procured items by tests and examinations', which is to be applied to all selected equipment, simple multiplication by a factor of two cannot be used either, as JAVYS, a.s. does not procure selected equipment in large lots, but typically purchases only a few items at a time. For this reason, the time requirement of 7.5 hours for four employees, with a frequency of once per week, is highly overestimated. I would estimate it at a maximum of 7.5 hours for two employees once per month.

### 3.3 Impacts on competitiveness and productivity

*Are market barriers created or changed?* **NO**

*Will some enterprises or products be treated differently from others in a comparable situation (special regimes for micro and SMEs)?* **NO**

*Does the change in regulation affect cross-border investments (inflow/outflow of foreign investment, or the performance of Slovak companies in foreign markets)?* **NO**

*Will it affect the availability of basic resources (financial, workforce, raw materials, mechanisms, energy, etc.)?* **NO**

*Does the change in regulation affect innovation, science and research?* **YES**

Seeking solutions to the obsolescence (unavailability) of equipment or parts thereof through commercial-grade items encourages innovation in technical solutions.

*If gold-plating has been identified, does it contribute to reducing competitiveness and productivity? In what way?* **NO**

*How does the change in regulation contribute to Slovakia's objective of achieving the best business environment among its neighbouring EU countries?*

The implementation of commercial-grade items, components and elements manufactured to commercial industry standards in selected equipment under the Atomic Act, following a successful acceptance process, will enable the safe and reliable operation of the business' nuclear units, with the aim of:

- ensuring emission-free electricity generation from a nuclear installation.
- being competitive on the international market for electricity generation and supply

#### **Competitiveness:**

*On the basis of the above replies, please tick and describe the document's impact on competitiveness:*

☒ increased   ☐ no change   ☐ reduced

#### **Productivity:**

*What is the impact of the document on the ratio between enterprises' production and their costs?*

*On the basis of the above reply, please tick and describe the document's impact on productivity:*

☒ increased   ☐ no change   ☐ reduced

### 3.4 Other impacts on the business environment

No other impacts of the draft Decree have been identified.