

Explanatory memorandum

Draft Decree amending Decree No 358/2016 on requirements for assurance of quality and technical safety and assessment and verification of conformity of selected equipment

I. General part

1. Description of the content of the draft legislation, stating the reasons for its submission and a summary of the basic principles and the most important changes it introduces compared to the current legislation.

The need to adapt Decree No 358/2016 C on requirements for assurance of quality and technical safety and assessment and verification of conformity of selected equipment to current practice, and especially to the new developments that will be brought about by the deployment of new nuclear sources, leads the amendment to focus on the following areas:

1. Formally and substantively, there is a distinction between the processes of 'repair' and 'maintenance', which, especially in the operation of the selected equipment, was not always sharply and clearly delineated in practice. Therefore, the Decree introduces new definitions in this regard.

2. In connection with the amendment of Act No 263/2016, the Atomic Act by Act No 83/2025, the concept of 'part of selected equipment' is fully implemented in implementing legislation. The amendment to the Atomic Act also added the concept of parts to a number of obligations in which it previously did not explicitly appear. Following the amendment, the Decree does the same throughout, and this brings the greatest number of amendments to the text of the Decree itself.

3. The next step is to add measures to prevent counterfeit or fraudulent items. This is equipment for which compliance with technical requirements was not adequately assessed, inadequate tests were carried out with varying degrees of planning or intent, inadequate documents were produced, and this equipment was subsequently delivered and deployed in the operation of the nuclear installation as full-fledged and fully legally compliant selected equipment. These fraudulent items must be prevented in practice, as their deployment not only leads to fraudulent behaviour that has the characteristics of a criminal offence, but in particular may endanger nuclear safety, as such equipment does not have the required characteristics and may fail and endanger the operation of the nuclear installation. To this end, several new provisions are added to the Decree, taking into account the new international trend in the prevention of fraudulent or counterfeit items.

4. There are also some changes in the area of conformity assessment procedures, where

a. some procedures are newly applied to less serious safety classes of selected equipment or parts thereof, as the original procedures for these selected equipment were too demanding and burdensome, thus reducing the burden, including the administrative burden;

b. the operator of the nuclear installation, and thus of the selected equipment, is accepted as an entity carrying out conformity assessment for its own needs. This concept was introduced by the aforementioned amendment to the Atomic Act, and the Decree further elaborates and specifies which specific conformity assessment procedures are to be used and to which specific classes of selected equipment they may be applied.

5. There is a substantial change in the Decree as regards the requirement of correct conformity assessment or the demonstration that the entity carrying out the conformity assessment, whether an authorised or accredited entity or the manufacturer, importer or operator, must ensure or meet certain requirements in order to provide proof and achieve that conformity assessment will be performed with the appropriate quality, with the required expertise, with equipment of sufficient quality and to the proper extent. This is achieved by establishing new framework requirements for entities performing conformity assessment laid down as a prerequisite for accreditation, which is newly required for entities assessing conformity. These are also prerequisites that are newly assessed and required when issuing a binding opinion of the State Office for Nuclear Safety (SONS) for the authorisation of specific persons for conformity assessment.

6. Another area of change affects in particular the annexes to the Decree, namely in specific areas of technical requirements, where individual requirements are specified, as well as in specific conformity assessment procedures, in which new conformity assessment procedures are introduced in part, e.g. for the assessment of the conformity of parts of selected equipment by the operator. At the same time, certain changes are being made to existing conformity assessment procedures as required by practice.

Last but not least, we can mention the transitional period for conformity assessment entities obtaining accreditation. This has hitherto not been required in this manner and to this extent, so there is a transitional period of one and a half years from the effective date of the Decree. This period can be considered sufficiently long to allow the persons assessing conformity to obtain all the necessities, and at the same time it takes into account the capacity of the Czech Institute for Accreditation so as not to overload it. Moreover, in the nuclear field, these authorised entities or conformity assessment entities number in the single digits, but their specialisation and area of competence is very technically demanding, which is also reflected in the accreditation process.

2. Assessment of the existing legal situation

Decree No 358/2016 is the implementing legislation for § 57, 58 and 59 of the Atomic Act in particular. In these provisions, the Atomic Act regulates the field of technical safety, i.e. requirements for selected equipment that has a particularly significant impact on ensuring nuclear safety because it contributes to the performance of safety functions. This selected equipment is of crucial importance in nuclear installations, because its proper functioning and the proper fulfilment of the required characteristics contribute to ensuring nuclear safety. The Decree lays down not only the technical requirements for certain types of this selected equipment, but in particular, in connection with the Atomic Act, it regulates the way in which the conformity of this equipment with the technical requirements imposed on it is assessed during the design, production, assembly and commissioning of this selected equipment.

This conformity assessment is carried out by accredited entities, authorised entities or, where applicable, the manufacturer or importer of this selected equipment. The Decree lays down both

the scope and methods of conformity assessment depending on the safety classes in which the selected equipment classified. Last but not least, the Decree regulates technical safety and conformity testing, which means that in a situation in which selected equipment is already being used in the operation of a nuclear installation, its permanent conformity with technical requirements must be continually assessed. In terms of type, the Decree is a technical regulation as defined by the relevant EU legislation and as such has already been notified and successfully passed the notification procedure in 2016.

Since its entry into effect, which builds on the historical predecessors of this decree that already regulated technical safety in the past, there has been a gradual discovery of various needs for improvement of the legislation, its streamlining or supplementation, especially in relation to practical experience and the needs determined by various cases related to deficiencies and defects of selected equipment, whether these were deficiencies during the testing of this selected equipment, verification of its safety, or conformity assessment. Based on this practical experience, it is currently necessary to supplement the Decree in several respects. Further to the amendment to the Atomic Act No 83/2025, some concepts are being broadened, some requirements are being relaxed in the case of parts of selected equipment, and a number of new possibilities related to the involvement of the operator of the selected equipment in conformity assessment procedures are also being introduced.

The current legal situation is mostly satisfactory, but the amendment is mainly required by the need to adapt the legislation to upcoming new projects in the field of nuclear energy, which are introducing a number of new procedures, previously unused, along with new technologies, including other approaches to selected equipment. The current legal situation is therefore satisfactory, but it is necessary, including with regard to future needs, to amend the current decree so that it is applicable in the coming years and contributes to ensuring technical safety and thus to nuclear safety.

3. Evaluation of the compliance of the draft legislation with the constitutional order and other components of the legal order of the Czech Republic.

The draft legislation is in line with the constitutional order and other components of the legal system of the Czech Republic and is based on the principles for the formulation of implementing legislation, with full respect for the reservation of the Act.

4. Evaluation of the compliance of the draft legislation with the obligations arising for the Czech Republic from its membership of the European Union.

Neither the Decree nor its original version directly affects EU or EURATOM law.

5. Assessment of compliance of the proposed legislation with international treaties binding on the Czech Republic.

The proposed legislation is in accordance with international treaties by which the Czech Republic is bound relating to nuclear safety, radiation protection, handling of radioactive waste and non-proliferation of nuclear weapons.

6. Expected economic and financial impact of the draft legislation on the state budget and other public budgets.

Given its nature, the draft legislation has no negative economic or financial impact on the state budget or other public budgets.

7. Justification for a possible proposal for the Chamber of Deputies to give its consent to the draft legislation at first reading.

Not relevant.

8. Explanation of any proposal that the proposed legislation come into effect on a date other than 1 January or 1 July of the calendar year.

The effective date of the amendment to Decree No 358/2016 is stipulated as 1 February 2026. This effective date is necessary because the Decree is subject to technical notification, where there is a three-month notification period during which the given draft legislation should not be published. Due to the completion of work on the draft decree during September, the notification period would not expire until sometime in late 2025 or early 2026. At the same time, however, it would be inappropriate to postpone its entry into effect until 1 July 2026, because there is already intensive work being conducted on the part of the addressees of the obligations under this Regulation to prepare documentation for the authorisation of new nuclear installations in the Czech Republic at present, so postponement for almost another half of a year would lead to a delay in work or the need to create documentation that would subsequently have to be changed again. The proposed date of entry into effect thus respects the provisions of § 9(3) and (5) of Act No 222/2016 on the Collection of Laws and International Treaties and on the creation of legislation promulgated in the Collection of Laws and International Treaties, as well as the effective date of the amendment to the Atomic Act (Act No 83/2025).

9. Justification of the individual provisions of the draft legislation; the justification shall include an explanation of their purpose and necessity, a description of the legal rules contained therein and of the rights and obligations arising therefrom.

See the specific part of this explanatory memorandum.

10. Evaluation of whether the draft legislation contains a provision which by its nature would constitute a technical regulation under the legislation governing technical requirements for products and information on compliance with the notification obligation under this legislation.

The amendment concerns a provision which, by its nature, could constitute a technical regulation. The amended decree sets out the procedures for ensuring compliance with the technical requirements listed in the annexes, as well as the conformity assessment procedures that are a prerequisite for putting a product (selected nuclear equipment) into service. Most of these provisions are affected by the amendment, including the requirements listed in the annexes. As a technical regulation, the amendment has been notified to the EC and EU Member States.

11. Information on the consultation of the draft legislation with the European Central Bank and the outcome of the consultation if the draft legislation is subject to such consultation.

Not relevant.

12. Expected impact of the draft legislation, in particular.

12.1. Impact on the rights and obligations of natural persons and corporate entities.

The draft Decree does not have any impact on the rights and obligations of natural persons and corporate entities.

12.2. Impact on the business environment of the Czech Republic.

The proposal does not relate to the business environment. It affects both businesses and non-businesses. In terms of the potential burden on businesses, it should be noted that the proposal does not introduce new obligations, but only refines or reformulates the existing regulation in this respect in the direction of greater comprehensibility and clarity. On the contrary, in several cases, e.g. requirements on conformity assessment methods, the details of some requirements are omitted and the burden is potentially reduced.

12.3. Assessment of whether the draft legislation constitutes State aid.

The proposal does not regulate this area and is completely neutral in this respect.

12.4. Social impact, including impact on specific groups of the population, in particular the socially vulnerable, persons with disabilities and national minorities.

The proposal does not regulate this area and is completely neutral in this respect.

12.5. Expected impact of the draft legislation on equality between men and women, if the draft legislation regulates or affects the status of natural persons.

The proposal does not regulate this area and is completely neutral in this respect.

12.6. Environmental impact.

The draft decree will not have an impact on the environment. Its purpose is to regulate the requirements for selected equipment and the assessment and verification of compliance with them for activities in the field of the utilisation of nuclear energy and ionising radiation. The environmental impact may be very marginal and indirect, but always positive given the nature of the requirements aimed at enhancing safety in these activities.

12.7. Impact on the protection of children's rights.

The draft decree will not affect the protection of children's rights.

12.8. Impacts on national security or defence.

The proposal does not regulate this area and is completely neutral in this respect.

12.9. Impacts relating to the protection of privacy and personal data.

The proposed legislation does not concern the protection of personal data and therefore compliance with Act No 110/2019 on the processing of personal data, as well as with Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), and hence is not assessed. The draft decree does not increase the amount of personal data processed or alter the way they are handled.

13. Assessment of corruption risks of the draft legislation.

The draft legislation contains no provisions that would pose corruption risks. The details of the obligations laid down by law are formulated independently, objectively and without the potential to confer any advantages.

14. Justification for any proposed derogation in the procedure for discussing the draft legislation.

Not relevant.

15. Information under the Lobbying Regulation Act

There were no lobbying activities during the preparation of the draft after the Act on the Regulation of Lobbying entered into effect.

II. Special part

Re Article I (Amendment to the Decree on requirements for assurance of quality and technical safety and assessment and verification of conformity of selected equipment)

Re the introductory sentence

The introductory sentence of the Decree, more precisely the reference to the provisions of the Atomic Act being implemented, is modified in accordance with the amendment of the Atomic Act through Act No 83/2025, which has resulted in a change in the numbering of the relevant paragraphs.

Re § 1(j)

The amendment adds a new final provision to the enumeration, therefore the enumeration in the previous points of the enumeration is also formally modified.

Re § 1(k)

The amendment adds a new final provision to the enumeration, therefore the enumeration in the previous points of the enumeration is also formally modified.

Re § 1(l)

The amendment adds a new final provision to the list, relating to the amendment to the Atomic Act No 83/2025, which added new requirements and a related enabling provision. The amended Decree shall newly restate the basis for issuing a binding opinion of SONS on the implementation of the authorisation of the nuclear conformity assessment body.

Re § 2(c)

§ 16(7) lays down the obligations for carrying out the final assessment of selected equipment after repair or re-installation after repair and after modification. It is therefore necessary to define the concept of 'repair of selected equipment' and to distinguish it from the concept of 'maintenance of selected equipment', since a final assessment is not required after the

maintenance of selected equipment has been carried out. The absence of definitions could lead to confusion between the two concepts and the associated requirements in practice, as the boundary between them is sometimes blurred (in the interest of maintenance, repairs are often necessary). Act No 250/2021 on occupational safety in connection with the operation of dedicated equipment and amending related acts also uses these terms, so it is necessary to legislate their definitions for the purposes of this Decree.

Re § 2(d)

§ 16(7) lays down the obligations for carrying out the final assessment of selected equipment after repair or re-installation after repair and after modification. It is therefore necessary to define the concept of ‘repair of selected equipment’ and to distinguish it from the concept of ‘maintenance of selected equipment’, since a final assessment is not required after the maintenance of selected equipment has been carried out. The absence of definitions could lead to confusion between the two concepts and the associated requirements in practice, as the boundary between them is sometimes blurred (in the interest of maintenance, repairs are often necessary).

Act No 250/2021 on occupational safety in connection with the operation of dedicated equipment and amending related acts also uses these terms, so it is necessary to legislate their definitions for the purposes of this Decree.

Re § 4(4)(b)

The amendment modifies the text in connection with Decree No 21/2017 on ensuring the nuclear safety of a nuclear installation. The existing text of the decree described the process of ‘monitoring and evaluation of viability’ in an imprecise, descriptive manner, while the Atomic Act and Decree No 21/2017 speak of ‘managed ageing’ in this context.

Re: § 4(4)(e)

The change is being made to ensure that parts of selected equipment are already defined at the design stage of the selected equipment, so that it is possible to identify the relevant conformity assessment procedures pursuant to § 15(2) or to define other conformity assessment procedures as defined by § 12(6) of the Decree. The previously mentioned ‘acceptability criteria for quality assurance’ are already covered by the previous subparagraphs.

Re: § 5(1)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 5(2)(d)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 5(2)(g)

Given the nature of the production of the selected equipment newly set out in § 12(3)(e) of the Decree, the requirement is unnecessarily burdensome. In order to reduce this burden, a derogation is introduced in the Decree for selected equipment that is fuel element cladding and the fuel assembly structure.

Re: § 5(3)(b)

Linguistic clarification of enumeration. In practice, manufacturing documentation tends to be different from installation documentation, while the current text gave the impression that it was intended to cover both types of activities (and that others are not covered by the requirement).

Re § 6

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 6(1)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re § 6(1)(a)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 6(2)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 6(2)(b)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 6(2)(d)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 7(1)(f)

Correction of a typographical error in the Decree.

Re: § 7(1)(g)

The amendment adds a new final provision to the enumeration, therefore the enumeration is also formally modified in the previous points of the enumeration.

Re: § 7(1)(h)

The amendment adds a new final provision to the enumeration, therefore the enumeration is also formally modified in the previous points of the enumeration.

Re: § 7(1)(i)

For the process of operating selected equipment in particular, in which various types of changes to selected equipment may occur, it is necessary to specify the requirement for conformity assessment of the change to the selected equipment depending on its scope. Changes in the design of the selected equipment are generally so severe that they affect the extent and manner of compliance with the technical requirements of the selected equipment and potentially also

technical safety. In this case, the conformity assessment is an authoritative procedure to verify that the design change has been implemented with sufficient quality and with respect to the legal requirements for the selected equipment.

Re: § 7(2)

In view of the nature of the selected equipment newly set out in § 12(3)(e) of the Decree, the requirements of Paragraph 1 would be unnecessarily burdensome or even infeasible. In order to reduce this burden and to maintain the applicability of legislation, an exception is inserted in the implementing decree for selected equipment that is fuel element cladding and the fuel assembly structure.

Re § 8(1)(c)

The reference to these categories of pressure equipment is removed because of the requirement to apply the managed ageing process as defined by § 49(1) of the Atomic Act and Decree No 21/2017, which applies to all selected equipment. The existing text is thus misleading, as it limits the components of this process to only certain categories of selected equipment.

Re: § 8(1)(d)

The reference to these categories of pressure equipment is removed because of the requirement to apply the managed ageing process as defined by § 49(1) of the Atomic Act and Decree No 21/2017, which applies to all selected equipment. The existing text is thus misleading, as it limits the components of this process to only certain categories of selected equipment.

Re: § 11(1)

Addition of the text following the modification of the paragraph made in § 7(1)(i) of the Decree.

Re § 12(3)(c)

The amendment adds a new final provision to the enumeration, therefore the enumeration is also formally modified in the previous points of the enumeration.

Re: § 12(3)(d)

The amendment adds a new final provision to the enumeration, therefore the enumeration is also formally modified in the previous points of the enumeration.

Re: § 12(3)(e)

Added due to the current lack of a legislative requirement for the scope and method of conformity assessment of this selected equipment. Although the fuel element cladding and the fuel assembly structure are key selected equipment for ensuring nuclear safety and performing basic safety functions, this equipment has not up to now been included among equipment for which an authoritative assessment of conformity with the technical requirements is required. In practice, this created the undesirable situation that the components making up the essence of the nuclear installation were not assessed and not subjected to qualitative oversight. This could have undesirable safety implications, especially for new types of fuel and nuclear installations.

Re: § 12(4)

Modification in the interest of greater clarity of the text. Its interpretation has so far caused considerable problems in practice.

Re: § 12(6)

The purpose of the proposed change to the test is to prevent the use of separately designed parts of selected equipment, because the requirements for a part of selected equipment must logically be based on the design of the selected equipment itself so that the individual parts form a consistent whole and are compatible. It is also necessary to clarify the use of separately manufactured parts of selected equipment or parts installed after manufacture, for which the draft does not require conformity assessment according to the amended Decree, so that they cannot be used on selected safety class 1 equipment, which the current regulation allows in the case of the group of selected equipment referred to in § 12(3)(a) of the Decree. The acceptance of this procedure for safety class 1 poses a significant risk to nuclear safety.

The end of the introductory part and the new subparagraphs add the specific scope of the conformity assessment by the operator of selected equipment and the conditions under which the operator of selected equipment may carry out a conformity assessment pursuant to § 58(2)(d) of the Atomic Act. Here, the Decree responds to the new possibility of conformity assessment by the operator itself, which was introduced by Amendment No 83/2025. A restrictive scope of the selected equipment concerned and a new conformity assessment procedure, further detailed in the Annex to the Decree, are deliberately chosen.

Re § 12(6)(a)

The end of the introductory part and the new subparagraphs add the specific scope of the conformity assessment by the operator of selected equipment and the conditions under which the operator of selected equipment may carry out a conformity assessment pursuant to § 58(2)(d) of the Atomic Act. Here, the Decree responds to the new possibility of conformity assessment by the operator itself, which was introduced by Amendment No 83/2025. A restrictive scope of the selected equipment concerned and a new conformity assessment procedure, further detailed in the Annex to the Decree, are deliberately chosen.

Re: § 12(6)(b)

The end of the introductory part and the new subparagraphs add the specific scope of the conformity assessment by the operator of selected equipment and the conditions under which the operator of selected equipment may carry out a conformity assessment pursuant to § 58(2)(d) of the Atomic Act. Here, the Decree responds to the new possibility of conformity assessment by the operator itself, which was introduced by Amendment No 83/2025. A restrictive scope of the selected equipment concerned and a new conformity assessment procedure, further detailed in the Annex to the Decree, are deliberately chosen.

Re: § 12(8)

Textual modification in connection with the amendment of the Atomic Act, which introduces the possibility of conformity assessment by a broader range of entities. The provision is therefore generalised.

Re: § 12(9)

Ensuring that the way in which the conformity assessment of separately supplied safety equipment is carried out takes into account the way in which the conformity assessment of the selected equipment it protects is carried out. This way, the appropriate quality of the equipment and its compatibility with the selected equipment will be ensured.

Re: § 12(10)

In line with the amendment to the Atomic Energy Act, the new Paragraph 10 harmonises the approach to the different conformity assessment procedures by the different types of entities carrying out conformity assessments. By using internationally recognised (also Czech) technical requirements for the competence and independence of entities performing conformity assessment, a similar level of quality of assessment and, as a result, an adequate level of safety will be achieved. The text of the paragraph refers to specific parts and annexes of the Decree that are inseparable from these aspects and must be affected by the required level of quality in the interest of ensuring safety.

Re: § 12(11)

The new Paragraph 11 adds the requirements for an adequate level of quality in the conformity assessment referred to in Paragraph 10. Quality must not only be ensured de facto, but it is necessary for it to be officially assessed and approved that this is indeed the case. This role can be adequately ensured only by accreditation, carried out by an official accreditation body. This way, the protection of the public interest will not only be formal, but also fulfilled in practical terms.

Re: § 12(12)

The new Paragraph 12 follows up on the new authorisation in the Atomic Act and stipulates what is a condition for a positive binding opinion for granting authorisation in the nuclear field. In particular, SONS will take into account the conditions for conformity assessment, as newly set out in Paragraphs 10 and 11, and the body applying for authorisation must fulfil them, as this is the only way to ensure the required level of subsequent conformity assessment.

Re: § 13(1)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 13(2)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 13(3)

The change in the text of the Decree (addition of the word ‘part’ of selected equipment) is made in connection with the amendment of the Atomic Act by Act No 83/2025, which expanded the concept of quality assurance and conformity assessment to include parts of selected equipment.

Re: § 14(2)(b)

The amendment to the text responds to the extension of the scope of entities carrying out conformity assessment, which was already carried out by the amendment to the Atomic Act through Act No 83/2025. Instead of adding ‘operator’ to the list, a simpler way of generalising it is chosen.

Re: § 15(2)

The changes in § 15(2) seek to graduate the requirements for individual conformity assessment procedures for parts of selected equipment in accordance with the categories of selected equipment concerned. Current practice shows that some procedures are excessively demanding, especially for selected devices or parts thereof classified in safety class 3.

The novelty of conformity assessment by the operator of the selected equipment is also taken into account. In this situation, the Decree lays down a specific procedure, also in the annex to the Decree, in such a way as not to discredit the principle of independence of conformity assessment and to ensure that it is of adequate quality.

Re: § 16(2)

Clarification of the scope of compliance verification, which in the current regulation is insufficiently related only to the performance of activities according to the documentation for the operation of the nuclear installation approved by SONS (operational control programme). In practice, compliance checks must also be carried out under the preventive maintenance programme (and are already being carried out). At the same time, this amendment also achieves compliance with Decree No 21/2017, which approaches the problem in a similar way.

Re: § 16(6)

Necessary amendments to the text related to the amendment of § 15(2) of the Decree.

Re Annexes 1 to 4 and 6 to 8

The amendments to the annexes to the Decree respond, on the one hand, to the changes made to the Decree itself and, on the other hand, to experience with its application. Requirements related to specific processes have been generalised, e.g. requirements previously related to welding are now generally listed as special processes or permanent joints; this also entails requirements for the qualification of procedures or certification of personnel – e.g. opening these requirements towards other certification schemes with regard to new sources.

There are also more formal adaptations in the annexes in order to take into account the consistent implementation of ‘parts of selected equipment’ in the text of the Decree. From a legislative technical point of view, in some cases the entire text of the annex is replaced, because the implementation of partial amendments in the form of individual amendment points would make the amendment unclear.

Re Article II (Transitional provisions)**Article II(1)**

The Decree lays down a 18-month transitional period for obtaining accreditation for the needs of arranging expertise and other conformity assessment requirements. This period seems sufficient (following consultations with the persons concerned and the Czech Institute for Accreditation (ČIA), as the official accreditation authority) to meet all the necessary formal requirements, while at the same time allowing sufficient time for ČIA to carry out the preparation and the whole process. It takes into account its existing capacity and the fact that the addressees of this obligation number in the single digits. At the same time, there is no disproportionate delay in compliance with this requirement over time, which could have negative effects on safety.

Re Article II(2)

In the interests of legal certainty and in line with the usual legislative procedures, the principle of completing a conformity assessment initiated under existing legislation is explicitly enshrined. Such a procedure will make it easier for authorised entities as well as entities requesting an assessment to plan their activities effectively while maintaining the necessary level of security.

Re Article III (Common provisions)

The Decree was notified as a technical regulation as it lays down the details of the requirements which affect the technical requirements for products and their free movement.

Re Article IV (Effective date)

The effective date of the amendment to Decree No 358/2016 is stipulated as 1 February 2026. This effective date is necessary because the Decree is subject to technical notification, where there is a three-month notification period during which the given draft legislation should not be published. Due to the completion of work on the draft decree during September, the notification period would not expire until sometime in late 2025 or early 2026. At the same time, however, it would be inappropriate to postpone its entry into effect until 1 July 2026, because there is already intensive work being conducted on the part of the addressees of the obligations under this Regulation to prepare documentation for the authorisation of new nuclear installations in the Czech Republic at present, so postponement for almost another half of a year would lead to a delay in work or the need to create documentation that would subsequently have to be changed again. The proposed date of entry into effect thus respects the provisions of § 9(3) and (5) of Act No 222/2016 on the Collection of Laws and International Treaties and on the creation of legislation promulgated in the Collection of Laws and International Treaties, as well as the effective date of the amendment to the Atomic Act (Act No 83/2025).