Explanatory memorandum

Draft Decree amending Decree No 408/2016 on management system requirements

I. General section

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

The justification for the proposed amendments to Decree No 408/2016 on management system requirements is based on the deficiencies noted in the description of the current legal situation below. The deficiencies of the Decree were identified particularly during its eight years of application and are linked to findings from international recommendations and good practice. In addition, it can generally be stated that minor deficiencies in the original text of the Decree, caused by incorrect formulations, are also being corrected. The proposed legislation and amendments to the existing text of the Decree can be broadly summarised into the following categories:

Correction of evident deficiencies revealed through the gradual application of the Decree over the course of previous years. This mainly concerns minor modifications to the text, corrections of certain incorrect formulations, and the removal of certain redundant requirements or requirements that were formulated imprecisely.

The second main category of amendments concerns developments in international recommendations, in particular those of the International Atomic Energy Agency, where gaps in implementation of these international recommendations have been or are being identified. These relate, in particular, to the role and tasks of senior management, the management of non-conformities, and the implementation of changes to the management system.

Another category of amendments relates to shifts in international practice, where it has been found that quality assurance of processes and activities and their outputs, i.e. items such as selected equipment and components of nuclear installations, has in recent years suffered from certain shortcomings, not only in the Czech Republic but also globally, and that so-called fraudulent items have been detected. Fraudulent items are a very serious problem in the nuclear field, as they can lead to quality degradation and, consequently, to impacts on safety assurance, i.e. nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management, and security.

In line with international developments, the Decree is also being amended in relation to planned new sources and their construction. New sources will, to a large extent, employ technologies not yet implemented in practice, or building on existing nuclear installation projects,

but incorporating a number of new developments. To this end, it is both desirable and necessary to amend the Decree so that the processes and activities related to, and the preparations for, the construction of nuclear installations are carried out to an adequate standard of quality. In this context, a new requirement – or rather expectation – may be mentioned that, during the construction of nuclear installations, there must be uniform comprehensibility of documentation for the activity subject to a permit and for the management system, a uniform communication platform, or a common language comprehensible to all entities involved. This plays a special role in the construction process itself, as it can be assumed that many foreign entities will be involved.

A separate chapter concerns the set of requirements for 'safety culture', which have not only undergone numerous changes in the international context, but where practice has also shown that the existing legislation is wholly inadequate and does not ensure the proper and necessary level of safety culture, which may have a fundamental impact on safety itself. In this context, it is necessary to undertake a complete and comprehensive revision of the provisions of § 13, which sets out more detailed requirements for safety culture. The requirement to implement and maintain safety culture is, of course, set out in Act No 263/2016, the Atomic Act, and is already a well-established requirement in the Czech legal system.

Last but not least, an important area undergoing amendments is the documentation for activities subject to a permit, and the management system documentation. Practice has shown that the existing legislation unfortunately gives rise to certain ambiguities as to what this documentation should look like, how it should be formulated, what it should contain, and how it should be approached, especially in cases where the entity implementing the management system is also the holder of a permit for one of the activities involving the use of nuclear energy. In this respect, certain duplications and redundancies are being eliminated, thereby reducing the burden on the addressees of these requirements.

It can be stated that the proposed changes, although formally affecting a substantial part of the Decree, do not impose any new burden on the addressees. A major change, appearing at the very beginning of the Decree, concerns the fact that the Decree now adopts a new philosophy as to the very objective of the management system, so that it is integrated and all-encompassing with respect to all potential aspects that may affect the assurance of safety. This introduces a new – or rather modified – legislative shorthand in place of 'management system objective'. The new Decree refers to the 'safety objective of the management system', thereby distinguishing it from other objectives of the entity implementing the management system that that entity may pursue and that may likewise affect the assurance of safety (e.g. economic objectives). This change is reflected throughout the text of the Decree in numerous places, and similarly some other modifications are reflected in several other provisions, so formally speaking, the amendment is relatively extensive; nevertheless, in terms of substance and its impact on practice, it is not particularly significant and does not introduce any substantial new requirements. Conversely, a number of requirements in the existing legislation are being relaxed, simplified, and clarified so that it is unambiguously comprehensible, easier to apply, and does not give rise to doubts in practice.

2. Assessment of the existing legal situation

Decree No 408/2016 is implementing legislation to Act No 263/2016, the Atomic Act. The purpose of the Decree is to set out the details of the implementation and maintenance of a management system, the main objective of which is to ensure an adequate standard of quality for processes and activities carried out by permit holders and other critical entities in the field of the

peaceful use of nuclear energy and ionising radiation, so as to always ensure full nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management, security, and the non-proliferation of nuclear weapons. The existing Decree lays down details of the requirements of the Atomic Act, in particular those under § 29 and § 30 concerning the management system and requirements for the implementation of processes and activities, as well as those under § 24 and in the annexes to the Act concerning the documentation for activities subject to a permit, which is a prerequisite for granting permits for activities in the nuclear field, especially the siting, construction, commissioning and operation of nuclear installations. For these activities and permits, documentation is required under the Annex to the Atomic Act; in particular in relation to the management system, this concerns the so-called management system programme, which describes the management system of the entity concerned and the manner of implementing and managing processes and activities, as well as relations with suppliers and the configuration of processes and activities vis-à-vis suppliers.
The provisions of § 29 and § 30 of the Atomic Act impose specific obligations on the entities concerned, in particular as regards the effective implementation and management of processes and activities, the provision of resources for those processes and activities, including human resources, and the mutual integration of all processes, activities and their resources so as to ensure safety, understood as the entirety of all six components. The Act also lays down requirements for the management of any non-conformities that may arise, for the implementation of changes in a process or in the management system, and for the maintenance of management system documentation. In § 30 there is then a set of requirements for suppliers and the management of suppliers and their processes and activities, including requirements for contracts to be concluded between entities implementing the management system and their suppliers. Finally, a very important category is safety culture, which is an essential prerequisite for ensuring nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management and security.
The existing Decree No 408/2016 details these statutory requirements in a series of provisions that primarily address management systems and the requirements for them in general terms. Furthermore, it addresses the assessment of management systems, the implementation of changes to management systems, the management of non-conformities, and, separately, safety culture. Part of the Decree is dedicated to the requirements for management system documentation, including the aforementioned management system programmes. The existing Decree, in effect since 2017, has exhibited certain deficiencies over the course of its application; these consist not only in the fact that the current wording has proved partly inaccurate and partly insufficient in practice, but, in particular, in the fact that it has already become obsolete in light of international requirements and recommendations, notably those of the International Atomic Energy Agency. The International Atomic Energy Agency issues a series of recommendations that are binding on its Member States, and these recommendations must be implemented by those States in their legal systems. As regards management systems, these recommendations concern, in particular, leadership, safety culture and management systems. In the meantime, a number of developments have appeared in these recommendations that are not reflected in the existing Decree and need to be addressed. Another important aspect in which the Decree has become obsolete is the practical implementation of certain processes and activities, in particular the processes for component procurement, design and purchasing. In recent years there have been significant developments in this respect, particularly in efforts to prevent ‘fraudulent items’. Another aspect that has seen a significant shift is safety culture, where international recommendations and international good practice have been significantly improved and systematised and new requirements have been

placed on it. International experience shows that without a proper safety culture, technology cannot function reliably. People's attitudes and understanding, the understanding of common objectives, and ensuring that employees are properly managed, supervised and motivated – and that they act proactively – are of paramount importance in the nuclear field.

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

The draft legislation complies with the constitutional order and other components of the legal system of the Czech Republic and is based on the principles for drafting implementing legislation, with full respect for statutory reservation.

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

From the perspective of European Union law, it should be noted that the Decree partly contains transposing provisions, reflecting the general requirements contained in
1. Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations;
2. Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste;
3. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.
These Directives contain a very general requirement to have in place a management system, a quality system or a quality assurance system, and the Decree responds by setting out more detailed criteria and characteristics for what these systems should look like. In this respect, the existing Decree does not exhibit any deficiencies in relation to European legislation. The proposed amendments will affect the existing transposition, but not negatively; rather, they serve to deepen and enhance the existing legislative framework, and thus the transposition, precisely because the requirement contained in the EU Directives is very general.

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

The proposed legislation complies with international treaties binding on the Czech Republic that concern nuclear safety, radiation protection, radioactive waste management and the non-proliferation of nuclear weapons.

6. Assessment of whether the draft legislation contains provisions which, by their nature, would constitute a technical regulation under the legislation governing technical product requirements

The draft amends certain provisions that, by their nature, could constitute technical regulations. These are provisions relating to the prevention of so-called fraudulent items, i.e. products supplied contrary to technical requirements while being presented as compliant. Provisions preventing such practices could be considered as related to technical product requirementss. However, these are not direct technical requirements; rather, there is a general requirement to

comply with such requirements. Since the Decree being amended was previously notified as a technical regulation, its amendment is likewise regarded as such.

7. Information on fulfilment of the notification obligation under this legislation (in relation to provisions that are/are not included and that would, by their nature, constitute a technical regulation under the legislation governing technical product requirements)

The draft legislation has been duly notified in the required manner.

8. Information on consultation of the draft legislation with the European Central Bank and the outcome of that consultation, where applicable

The draft is not subject to consultation.

9. Expected economic and financial impact of the draft legislation on the State budget and other public budgets

Given its nature, the draft legislation does not have a negative economic or financial impact on the State budget or other public budgets.

10. Expected impact of the draft legislation on the rights and obligations of natural and legal persons

The draft Decree does not affect the rights and obligations of natural and legal persons.

11. Expected impact of the draft legislation on the business environment of the Czech Republic

The draft does not relate to the business environment as such. It affects both businesses and individuals not engaged in business activities. In terms of the potential burden on businesses, it should be noted that the draft does not introduce new obligations – it merely clarifies the existing provisions in this regard and, where appropriate, reformulates them to make them more comprehensible and unambiguous. In several cases, e.g. requirements for management system documentation, details of certain requirements are being removed, potentially reducing the burden.

12. Expected social impact of the draft legislation, including the impact on specific groups of the population, in particular socially disadvantaged persons, persons with disabilities and ethnic minorities

The draft does not govern this issue and is completely neutral in this regard.

13. Expected impact of the draft legislation on equality between men and women, where the draft legislation governs or affects the status of natural persons

The draft does not govern this issue and is completely neutral in this regard.

14. Expected environmental impact of the draft legislation

The draft Decree will have no impact on the environment. Its purpose is to regulate processes and activities in connection with activities involving the use of nuclear energy and ionising radiation. There may be a very remote and indirect marginal impact on the environment; however, given the nature of the requirements – which are aimed at enhancing safety in these activities – it will always be positive.

15. Expected impact of the draft legislation on the protection of children's rights

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

16. Expected impact of the draft legislation on the security or defence of the State

The draft Decree will not have an impact on the security or defence of the State.

17. Expected impact of the draft legislation in relation to the protection of privacy and personal data

The draft legislation does not concern the protection of personal data, therefore, compliance with Act No 110/2019 on the processing of personal data, or 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), is not being assessed. The draft Decree does not increase the amount of personal data processed or change the manner in which they are handled.

18. Assessment of whether the draft legislation constitutes State aid

The draft legislation does not constitute State aid.

19. Assessment of corruption risks associated with the draft legislation

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

20. Justification for a possible proposal for the Chamber of Deputies to give its consent to the draft legislation at first reading (if proposed)

Not proposed.

21. Justification for any proposal that the proposed legislation should come into effect earlier than the beginning of the fifteenth day following the date of its promulgation (if proposed)

The effective date of the amendment to Decree No 408/2016 is set for 1 February 2026. It was necessary to set the effective date in this way, as the Decree is subject to technical notification, which involves a three-month notification period during which the draft legislation should not be published. Since work on the draft Decree was completed during September, the notification period will not expire until around the turn of 2025 and 2026. At the same time, however, it would be inappropriate to set the effective date to 1 July 2026 since the addressees of the obligations under this Decree are already working intensively on preparing documentation for permitting new nuclear installations in the Czech Republic and a postponement of almost another

six months would lead to delays or necessitate creating documentation that would subsequently have to be changed again. The proposed effective date thus respects § 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).

22. Justification for derogations in the procedure for discussing draft legislation (if proposed and different from previous ones) (if proposed, may be covered by previous chapters)

Not proposed.

II. Special section

Re Article I (Decree amending Decree No 408/2016 on management system requirements)

Re § 2(a)

Clarification of the text of the definition to ensure correct understanding of 'process guarantor'. The process guarantor is not by definition required to perform the process in every case; rather, their primary responsibility is to ensure its implementation, monitoring and improvement. That is why it has been proposed to amend the text; this has no impact on current activities and merely makes the interpretation of the term clearer and less ambiguous. The revised definition is fully consistent with § 4(1), (2)(e)(5), § 13(2) and § 15(1)(c).

Re § 2(c)

Clarification of the definition to ensure correct understanding of 'process role' as a process characteristic. A process role is assigned to entities that perform a particular activity within the process. However, nowadays a robot or AI can also have a process role; accordingly, the term 'employee' is deleted in the text as too restrictive.

Re § 2(f)

Formal amendment related to the addition of a new point.

Re § 2(g)

The amendment adds a new definition of senior management to reflect the intention that the rights and obligations of the entity referred to in § 29(1) of the Atomic Act (implementing a management system) must ensure that the natural persons constituting senior management are responsible for (ensure) the activities described in § 3(6) of the Decree. For practical purposes, it is necessary to state unambiguously that these obligations – and their fulfilment – must be carried out by members of senior management bodies. It is necessary to eliminate any possibility that the internal structure and division of responsibilities are unclear and thus could adversely affect the assurance of safety.

Re § 3(1)(a)

Due to the revision of § 29(3)(j) of the Atomic Act – which clarifies the obligation to integrate all requirements that may serve to ensure and enhance, or may adversely affect, the standard of

nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management, and security, so that they are fulfilled in a mutually consistent manner – an amendment is proposed to add the term ‘safety’ to ‘objective of the management system’ to clarify that primary importance is placed on the safety objective of the management system, rather than on other possible objectives, and that all requirements that may serve to ensure that objective are fulfilled. In practice, it is common that the management systems of addressees of Decree No 408/2016 are more complex and cover matters beyond ensuring safety in the use of nuclear energy or ionising radiation. In such cases, the management system has multiple objectives with differing priorities, e.g. economic, production, or development objectives. The proposed amendment clarifies that the requirements of this Decree relate primarily to the (nuclear) safety objective.
For the sake of clarity in the interpretation and use of terms within the Decree, it is proposed to use the legislative shorthand: (hereinafter the ‘safety objective of the management system’). To reflect this, other provisions of the Decree are also amended accordingly wherever ‘objective of the management system’ is mentioned.

Re § 3(2)

The change in the text is partly based on an addition to § 3(1)(a) introducing the new legislative shorthand ‘safety objective of the management system’; this is also reflected in other parts of the Decree that refer to the ‘objective of the management system’.
However, the proposed change is for the most part based on the amendment to § 29(3)(j) of the Atomic Act, which reads: ‘The entity referred to in paragraph (1) is obliged to integrate all requirements that may serve to ensure and enhance, or may adversely affect, the standard of nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiological emergency management, and security, so that they are fulfilled in a mutually consistent manner.’
The Act now places significant emphasis on the element of integration of all aspects and considerations that may affect safety – these must be taken into account when implementing the management system and pursuing its objective, namely the assurance of safety (in the broader sense). Based on the Act, the amendment to the Decree elaborates the obligation to ensure that pursuing any other objectives of the management system (e.g. financial profit) does not adversely affect the fulfilment of the safety objective, which has priority.

Re § 3(3)

The amendment introduces a change in wording, whereby the term ‘ensure’ is replaced with ‘support’. Processes and activities, by their nature, do not ensure the achievement of the safety objective; rather, their introduction and implementation support its achievement. The amendment is proposed accordingly.
In addition, the expression ‘safety objective’ is used in a new way, based on the amendment to § 3(1)(a), which introduces the new legislative shorthand ‘safety objective of the management system’.

Re § 3(5)(e)

The proposal to replace the text under subparagraph (e) is based on the fact that it overlaps in meaning with subparagraph (d) and, in part, with § 3(1)(c) and § 3(3) of the Decree. The removal of the existing text does not affect the regulated rights and obligations.
The new text is formulated on the basis of the existing wording of § 29(4), under which the entity implementing the management system is obliged to ensure the management of non-conformities within the management system. The details are set out in the existing § 11 of the Decree.

However, the use of fraudulent, counterfeit, and suspect items is a specific type of non-conformity, as it must be prevented, and the set of preventive measures extends more broadly into other areas and processes of the management system (design and development, purchasing, inspection, international cooperation, etc.). The incidence of fraudulent or counterfeit items has been increasing significantly in recent years and has been among the causes of major delays and cost overruns in projects for the construction of new nuclear sources abroad. Since the use of fraudulent or counterfeit items may pose a significant safety risk, the issue is currently at the forefront of the attention of organisations such as WENRA, the IAEA and the OECD NEA. The Decree therefore now elaborates on this matter in greater detail within the general requirements for the management system, thereby assigning a higher normative priority to this requirement.

Re § 3(5)(f)

The methods of management and their respective individual levels cannot be confined to the organisational structure (line management), but must also encompass other forms of management (process, project, etc.). For this reason, the phrase ‘within the organisational structure’ is limiting and prevents correct application of the requirement; therefore, it needs to be deleted from the Decree.

Re § 3(5)(g)

Formal amendment related to the addition of a new point.

Re § 3(5)(h)

The change is made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

Re § 3(5)(i)

The existing legislation does not contain a requirement for risk management to be linked to the achievement of the safety objective of the management system. In view of the risk management requirements laid down in the international recommendations of the IAEA and WENRA (see reference below), it is appropriate to address the missing requirement in the proposed text of the amended legislation and to implement it in practice through the proposed risk management process. The purpose of this process is to prevent unexpected events with adverse effects and to avoid their adverse impacts. Its aim is to limit their likelihood and thereby reduce the extent of their impact on the safety objective of the management system. The level of assessment by risk analysis should have appropriate quality and scope, in particular when decisions depend on the safety significance of the risk concerned.
The requirements to supplement risk management are based on the recommendations under IAEA No. SSR-2/2 (Rev. 1) – Requirement 8: Performance of safety related activities, points 4.25 and 4.32, the recommendations under IAEA No. GSR-Part 2 Requirement 1, point 2.2(d) and Requirement 12, point 5.2(a), and WENRA Issue C, point 3.9.

Re § 3(5)(j)

In order for processes and activities that ensure and maintain safety to function properly, it is essential to establish and maintain a uniform means of communication that is comprehensible to all personnel involved. This requirement has traditionally been considered an obvious part of all existing management systems of operators of regulated installations in the Czech Republic, mainly because the range of participating nationalities speaking different languages was limited. Based on current nuclear projects in the Czech Republic and worldwide, it can be seen that many nationalities speaking different languages are working on them concurrently, and the general

comprehensibility of communication can no longer be taken for granted. It is therefore necessary to emphasise this element in the Decree as well. The Decree does not prescribe a specific method or language of communication; however, it presupposes that it will be one that is commonly used and understandable, since only in this way can the safety objective of the management system be fulfilled.

Re § 3(6)

The Czech Republic has committed itself to implement the requirements of WENRA Safety Reference Levels for Existing Reactors in national legislation. In the current version of this document, most requirements are generally directed at the 'licensee' (in Decree No 408/2016, this corresponds to the 'person referred to in § 29(1) of the Atomic Act' or the 'entity implementing the management system'). However, some of the requirements are so critical that responsibility for their fulfilment lies directly with 'senior management' (namely Issues C1.2, C2.2, C2.3 – C2.6, and C5.1).

The responsibilities of senior management are defined in a similar scope in IAEA GSR Part 2 Leadership and Management for Safety (2016) – namely Requirements 2, 3, 4, 9, and 14.

The current wording of the Decree does not take this into account (a small part of the requirements is addressed to 'a person...', while the rest are framed vaguely, e.g. 'shall be', 'must be'), which in practice causes problems with fulfilling these requirements, as they are not understood and applied in a targeted manner. In fact, many of the requirements of the Atomic Act, as detailed in the Decree, are specific and require direct intervention by members of the management of the entity implementing the management system. Otherwise, such requirements would not be implemented effectively and safety could be compromised. Practice shows that the entities implementing management systems have a natural tendency to transfer certain responsibilities to lower levels of the organisational structure, which can adversely affect activities that potentially involve risks. For this reason, it is proposed to implement this approach, i.e. to prioritise the most important requirements for the management system, together with the introduction of the term 'vrcholové vedení', which most closely corresponds to the term 'senior management' under international requirements.

Re § 3(7)

The new provision clarifies the requirement of the Atomic Act concerning the implementation of the management system from the perspective of timing. It aims to ensure that the entity referred to in § 29(1) of the Atomic Act implements a management system already at the time when its preparatory activities may have an impact on future safety. At the same time, the new provision imposes an obligation to document the management system introduced in this way in the form of a management system programme, since this document (in accordance with the requirements of the Decree that follow) constitutes a comprehensive basis for the successful implementation of the management system and, at the same time, proof of its implementation for regulatory purposes. This clarification has been introduced in view of the negative experience where, in particular for changes subject to a permit under § 9(1)(f) (formerly (h)) of the Atomic Act, the applicant prepared the management system programme for the relevant activity only shortly before submitting the application to the State Office for Nuclear Safety (SÚJB), and the processes and activities during preparation for the change were not carried out in accordance with the implemented and documented management system (or the system was not implemented until after SÚJB issued the permit to carry out the change). The aim of this legislative amendment is to

eliminate ambiguity as to the point in time when the obligation arises to implement and document the management system for activities subject to a permit.

Re § 4(2)(a), point 2

The text is clarified in order to eliminate erroneous (frequent in practice) interpretations according to which processes and activities should be carried out in accordance with the documentation regardless of whether it is correct. In practice, the existing provision has also led to situations where the entity implementing the management system sought to carry out processes and activities correctly and in line with their objectives, but failed to comply with its documentation, as that documentation was out of date. Paradoxically, this resulted in two offences. The added reference makes it clear that processes and activities must be carried out in line with documentation that complies with the requirements of the Decree, thereby eliminating conflicting interpretations of the provision.

Re § 4(2)(c)

The change is made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

In addition, the archaic term ‘soustavně’ [constantly] is replaced with the term ‘regularly’. This is a clarification to provide a clearer and more unambiguous interpretation of the obligation to regularly monitor processes and activities in order to verify their capability to achieve the safety objective of the management system. The term ‘constantly’ led to the misinterpretation that processes and activities need to be monitored 24 hours a day, which was not intended even under the current legislation. The term ‘regularly’ gives the addressee of the Decree discretion to set, within their management system, the interval and frequency of regular monitoring of the system, applying a graded approach according to the complexity of the processes and activities, so that, as a priority, the safety objective of the management system is achieved.

Re § 4(2)(e), point 4

The change is made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

Re § 4(2)(e), point 5

Formal amendment related to the addition of a new point.

Re § 4(2)(e), point 6

Formal amendment related to the addition of a new point.

Re § 4(2)(e), point 7

The new provision aims to eliminate a practical shortcoming whereby processes and activities performed by a supplier are managed and evaluated, in terms of quality, by other suppliers. Their relationship with the entity implementing the management system is, however, less direct; they lack the necessary engagement and sense of responsibility for the supervision performed, and the quality of supplier processes and activities managed in this way has proved inadequate. Ensuring management and evaluation by the entity’s own employees – who are positively motivated and more actively engaged – yields positive results in practice.

Re § 4(3)

The current wording of the Decree does not reflect situations where, for example, the result of an inspection does not fully meet the specified criteria, yet the inspected product is approved for use

with a ‘deviation’. A similar situation may arise in the inspection of a process when non-compliance with, for example, a specified efficiency criterion is found (i.e. the inspection result is not positive), yet the process may continue. Hence, the requirement as originally formulated cannot be complied with in full. The Decree needs to be modified so that it does not impose a requirement that is impossible to fulfil in practice.

Re § 5(1)

The proposed amendment constitutes a relaxation of the requirements applicable to processes and activities. Not all processes and activities require validation before their first use. For example, the purchasing process. Validation is rightly required for special processes and is explicitly set out in § 5(5) of the Decree. Hence, in the first three paragraphs, the redundant requirement is corrected (deleted).

Re § 5(2)

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Re § 6(1)(a)

The current wording of the Decree is based on the assumption that the management system plan is developed and implemented by the entity implementing the management system. In practice, however, there may be cases where that entity does not develop the plan itself but adopts or selects it from existing plans. In order to express this fact more precisely, the formulation is adjusted and the term ‘designated’ is used. In addition, it is somewhat tautological to require that the plan be implemented during planning.
The change is also made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

Re § 6(1)(b)

Planning, as a strategic activity, is the task of employees in leadership roles who manage processes and activities. For the successful implementation of the management system, it is sufficient that these leaders are familiar with the plan. Requiring every employee to be familiar with it, as under the current wording of the Decree, appears unduly burdensome.

Re § 6(1)(c)

The current requirement for continuous improvement of the plan’s quality is difficult to implement and evaluate in practice, or, rather is not entirely realistic. It is possible to improve quality according to the given conditions; above all, however, it is necessary to continually assess whether the plan is suitable for the needs and up to date. In this sense, it is necessary to modify the requirement under the Decree and align it with realistic possibilities.

Re § 6(1)(d)

This point of the amendment responds to the change made under the preceding subparagraph and to the deletion of the requirement to improve the plan's quality. For the purposes of quality assurance and the management system, assessment of the plan's effectiveness will be sufficient.

Re § 6(1)(e)

Procedures for eliminating non-conformities in the management system and in processes and activities, including planning, are addressed by other provisions of the Decree. In this part of the text, it seems more appropriate to require the adoption of measures to achieve the plan's results if the assessment under subparagraph (d) shows that it is not sufficiently effective. This element was not previously covered by the Decree, which led in practice to deficiencies in the implementation of plans.

Re § 7(7)

The provision introduces a new exemption, consistent with the new philosophy concerning the safety objective of the management system. The provisions of § 7 set out the rights and obligations concerning the implementation of changes to the management system in general; this new provision allows an exception where a change to the management system does not affect safety. In such a case, the change is non-significant and need not be regulated.

Re § 8(1)(a)

The change is made in connection with the newly introduced (modified) legislative shorthand 'safety objective of the management system'.

Re § 9(1)(b)

The change is made in connection with the newly introduced (modified) legislative shorthand 'safety objective of the management system'.

Re § 10(1)

The current wording of the Decree limited independent evaluation to cases of changes to the management system – if no change occurred, independent evaluation was not carried out. However, this devalued the overall assessment of the management system in practice, as entities implementing the management system limited themselves to self-assessment when taking a comprehensive view of the system. This can be – and in practice often is – biased and does not deliver the necessary results. Furthermore, such a limitation was inconsistent with § 8 of the Decree, which provides for independent evaluation for 'assessing the effectiveness of the management system' in general. The new wording remedies these deficiencies and, at the same time, better implements IAEA No. SSR-2/2 (Rev. 1), points 4.34 and 4.36.

Re § 10(1)(a)

The change is made in connection with the newly introduced (modified) legislative shorthand 'safety objective of the management system'.

Re § 10(1)(c)

The amendment is proposed due to the absence of a regulatory framework requiring the entity referred to in § 29(1) of the Atomic Act to create conditions for the employee performing an independent evaluation so that they have sufficient powers to carry it out – for example, the right of access and the right to report to senior management without fear of pressure within project or line management, as well as access to the information, data and equipment necessary for

independent evaluation. In practice, situations often arise where such an employee is exposed to attempts to influence them and lacks the tools to support their independence and fulfil their role adequately. This addition is intended to remedy these deficiencies. These powers must be set out in the management system documentation in such a way that interpretation is unambiguous, clear and complete.

Re § 11(1)(e)

Formal amendment related to the addition of a new point.

Re § 11(1)(f)

Formal amendment related to the addition of a new point.

Re § 11(1)(g)

Fraudulent, counterfeit and suspect items are among the most serious quality-assurance problems in the nuclear field today and are widely discussed and addressed internationally. In practice, their detection represents one of the most significant non-conformities in the management system, as it results from a chain of failures in processes, activities and their configuration (component ordering and manufacture, takeover inspection, assembly, testing, etc.). They are typically a symptom of longer-term problems in the management system that are not easily detectable by the mechanisms of the entity implementing the management system. It is therefore essential that, in such cases, the relevant information be received by the State, or the regulator, so that it can intervene and apply its own control and corrective mechanisms. Hence, an essential part of the management system (resolution of non-conformities) is then the provision of information to the supervisory authority, as it is equipped with sufficiently effective instruments – including international – to address cases involving such items, including the involvement of law enforcement authorities. A supplement to the non-conformity resolution mechanism is introduced to enable such provision of information.

Re § 11(3)

The text of paragraph (3) has been moved to § 3 and merged with the obligation to manage risks, as together they constitute a general obligation to prevent risks, including potential non-conformities. Conversely, § 10 addresses procedures for managing non-conformities that have already occurred and are therefore not a risk but a consequence of one. This shift is a logical outcome and a more systematic legal solution to the problem where the primary objective of general requirements is to prevent non-conformities, and only when a non-conformity occurs should the obligations for the management of non-conformities be followed.

Re § 12(1)(a)

As mentioned above, the issue of uniformly comprehensible communication is currently becoming critical in the internationally diverse environment of nuclear technologies. Thus, the prerequisite for the proper functioning of the personnel of the entity implementing the management system is not only their professional qualifications, but also their ability to understand documentation, instructions and colleagues during joint activities. Deficiencies in this regard could seriously compromise safety. Communication and language skills are therefore newly introduced as a required attribute for employees.

Re § 13

The replacement of the entire text of § 13 in the amended Decree is justified by two main factors. The first is the implementation of international practice in relation to safety culture (hereinafter

'SC'), especially in connection with the requirements set out in IAEA No. GSR Part 2. Experience from communication in international working groups and from our own regulatory practice shows that our legislative concept of rights and obligations concerning the ability to regulate the approach of entities implementing management systems to SC is very vague or even inadequate. A review of GSR Part 2 and a comparison of the requirements contained in it with the current content of Decree No 408/2016 identified numerous SC areas that are not included in the Decree and are significantly lacking in the regulatory process in the Czech Republic. Since amending the current § 13 of Decree No 408/2016 would result in numerous non-cohesive changes, the submitter chose to fully rewrite § 13 so that it contains coherent SC requirements arising from international practice, evaluated as essential and necessary to implement in our legal system in the most compact and comprehensible form possible.
SC requirements are introduced for all entities implementing the management system, but a graded approach is used as regards the expected degree of fulfilment. Typically, for holders of a permit to operate a nuclear installation under § 9(1)(d) (formerly (e)), fulfilment is absolutely essential in a full, non-graded approach; by contrast, for manufacturers of selected equipment in safety class 3, whose sole safety function is protection against the release of radioactive substances into the environment (for illustration – selected equipment ensuring only decontaminable room surfaces), application of the requirements is expected using a graded approach according to the complexity of the processes and activities related to the peaceful use of nuclear energy. The second essential area for the amendment is the SÚJB's own practice in the regulatory process regarding the relationship of permit holders to their SC. Weak and unhealthy SC has been assessed as the root cause of all major nuclear incidents (namely Chernobyl and Fukushima; in the case of Three Mile Island, only human and organisational factors were mentioned, but these form part of SC as a functional whole). Over the past 13 years, the 'nuclear community' has focused its attention on SC, which is valued as a comprehensive model for working with operational experience data in relation to safety areas. The existing legislative options for regulating permit holders' approach to SC have been markedly limited. With the broadened § 13, benefits are expected in the form of broader tools for regulating SC assessment requirements (both internal and external independent), as well as requirements for the conduct and decision-making approach of senior management. SC would also become a valuable source of data on permit holders' safety attitude and conduct. At present, the safety culture of permit holders is perceived as a marginal matter and, from the perspective of the public interest in ensuring nuclear safety, it is misunderstood and inadequately addressed. For these reasons, an amended version of the entire § 13 has been proposed.

Re § 14(a), point 1

The change is made in connection with the newly introduced (modified) legislative shorthand 'safety objective of the management system'.

Re § 14(a), point 2

The amendment clarifies the text in line with the new philosophy of the 'safety objective of the management system'. The safety policy is a document of a general and strategic nature which, by definition, deals with overarching objectives rather than specific processes and activities. The existing wording was confusing in this regard.

Re § 14(a), point 3

Here, too, the change is made to more accurately reflect the nature of the safety policy as a strategic document. Measures to achieve the objectives are part of those objectives and do not need to be emphasised in the text of the Decree.

Re § 14(b)

\The addition refines the description of the requirements for management system documentation, which includes a description of the management system. In practice, there were instances of duplication, where this description was included both in the document under § 14 of the Decree and, for some entities, in the management system programme. The amendment corrects this duplication and reduces the burden on those that have a management system programme. For such entities, this description is already contained in that programme, and creating a secondary document in this respect is undesirable.

Re § 14(b), point 4

The text needs to be adapted to reflect the new approach, under which ‘validation’ is required only for special processes. Hence, the phrase ‘if required’ is inserted after the word ‘validation’ (which, in the e-Legislativa system, results in complete replacement of the text).

Re § 14(b), point 5

Re § 14(e)

The amendment limits the scope of the documentation concerned to that which serves to achieve the safety objective of the management system. This adjustment corresponds to the newly introduced legislative shorthand and, at the same time, emphasises that other documentation does not belong in this category, which was not clear in practice.

The second addition further specifies the scope of other documentation or, where applicable, adds certain essential cases of such documentation. In practice, addressees were often unable to identify the relevant documentation, and some deliberately avoided classifying certain document types in this group (in order to avoid the associated obligations). Paradoxically, this problem also affected the most important documents governing the implementation of the activity, which form part of the documentation for activities subject to a permit and are assessed by SÚJB. The amendment thus puts this list beyond doubt.

Re § 15(1)(a), point 1

The change is made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

Re § 15(1)(c)

The deletion of the text does not alter the meaning of the provision. The documentation must still be approved by the designated employee. It is then up to the entity how to arrange substitutability of designated employees, and it is not necessary to specify this in the Decree, as this is a general management principle.

Re § 15(1)(d)

The proposal stems from the practical application of the provision. Surprisingly, in practice, the provision did not lead to the creation of documentation that is user-friendly, systematic, and logically structured. Very often, documents were mutually inconsistent and lacked relevant content interfaces and interconnections. There was also no requirement for the documentation to be unambiguous, so it tended to be internally inconsistent and ambiguous. These deficiencies

were then reflected in the quality of the processes and activities performed and consequently compromised safety.

Re § 15(1)(f)
The addition of the exception is in line with the clarification provided in § 6. This exception is introduced because evaluating planning in the management system over a period of three consecutive years does not make sense, as planning is an ongoing process and this requirement cannot be properly applied to it. The proposed text merely makes the exception explicit, so as to avoid multiple interpretations and to ensure that the requirements are mutually consistent and interconnected.

Re § 15(1)(g)
The addition of the exception is in line with the clarification provided in § 6. This exception is introduced because evaluating planning in the management system over a period of three consecutive years does not make sense, as planning is an ongoing process and this requirement cannot be properly applied to it. The proposed text merely makes the exception explicit, so as to avoid multiple interpretations and to ensure that the requirements are mutually consistent and interconnected.

Re § 15(2)(b)
The change is being made in connection with the newly introduced (modified) legislative shorthand ‘safety objective of the management system’.

Re § 15(3)(a)
This requirement, as follows from the provisions of § 29 of the Act implemented by this Decree, must relate not only to nuclear safety but to all six components of ‘safety’ in the broader sense. These components are interlinked and share the same purpose – to protect the public from the adverse effects of nuclear energy and ionising radiation. Hence, in order to implement the Act correctly, the list must be supplemented to include the missing elements.

Re § 15(3)(c)
This requirement, as follows from the provisions of § 29 of the Act implemented by this Decree, must relate not only to nuclear safety but to all six components of ‘safety’ in the broader sense. These components are interlinked and share the same purpose – to protect the public from the adverse effects of nuclear energy and ionising radiation. Hence, in order to implement the Act correctly, the list must be supplemented to include the missing elements.

Re § 16(e), point 2
The text needs to be adapted to reflect the new approach, under which ‘validation’ is required only for special processes. Hence, the phrase ‘if required’ is inserted after the word ‘validation’.

Re § 16(e), point 6
Clarification of the text in order to ensure its correct application and interpretation.

Re Article II (Final provisions)
The Decree was notified as a technical regulation, as it sets out, to a small extent, details of requirements that concern technical requirements for products and their free movement. Namely, this concerns the prevention of so-called ‘fraudulent items’ (products).

Re Article III (Effective date)

The effective date of the amendment to Decree No 408/2016 is set for 1 February 2026. It was necessary to set the effective date in this way, as the Decree is subject to technical notification, which involves a three-month notification period during which the draft legislation should not be published. Since work on the draft Decree was completed during September, the notification period will not expire until around the turn of 2025 and 2026. At the same time, however, it would be inappropriate to set the effective date to 1 July 2026 since the addressees of the obligations under this Decree are already working intensively on preparing documentation for permitting new nuclear installations in the Czech Republic and a postponement of almost another six months would lead to delays or necessitate creating documentation that would subsequently have to be changed again. The proposed effective date thus respects § 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).