Explanatory memorandum to the draft amendment to Decree No 422/2016 on radiation protection and security of radionuclide sources

I. GENERAL SECTION

Regulatory impact assessment (RIA)

In accordance with the approved Plan for the Preparation of Decrees by Central Government Authorities for 2024, the draft was not subject to a regulatory impact assessment and no final RIA report was prepared.

a) Explanation of the necessity of the proposed legislation and justification of its main principles

The State Office for Nuclear Safety (hereinafter 'SÚJB') is submitting a draft decree amending Decree No 422/2016 on radiation protection and security of radionuclide sources (hereinafter 'Decree No 422/2016'). Decree No 422/2016 implements Act No 263/2016, the Atomic Act (hereinafter the 'Atomic Act'). The SÚJB is authorised to issue Decree No 422/2016 under the provisions of § 236 of the Atomic Act.

The draft Decree is being submitted in accordance with the Plan for the Preparation of Decrees for 2024, while, based on the approved Plan for the Preparation of Decrees by Central Government Authorities for 2024 indicating the obligation to prepare a Regulatory Impact Assessment (RIA), the RIA is not being prepared for the draft Decree.

The main objectives of the amendment are adaptation to findings from practical experience, especially in the field of the use of ionising radiation, e.g. by modifying certain requirements for testing sources of ionising radiation and the patient protection regime in the event of radiological incidents; the implementation of international recommendations, e.g. in relation to ensuring security, especially in connection with the results of international evaluation missions (with regard to 'security culture'); reflection of new requirements from other legislation of the Czech Republic (e.g. digitalisation); more consistent transposition of European regulations and remedying shortcomings in the legal regulation (revealed through practical application).

The draft Decree reflects changes to the statutory provisions introduced by Act No 83/2025 in the field of radiation protection and the security of radionuclide sources regulated by the Atomic Act. These changes mainly consist of:

- reflecting statutory provisions which have not been transposed in detail or the amended legal provisions introduced by the amendment to the Atomic Act (e.g. new provisions on radiological incidents or the obligation to notify applications for authorisation of clinical trials with radiopharmaceuticals);
- adjustment to the calculation of derived limits for radiation workers;
- partial modifications to the categorisation of sources of ionising radiation;
- modification of the regulation of acceptance tests, long-term stability tests and operational stability tests;

- modifications to some of the rules for keeping records on sources of ionising radiation by the licence holder and the registrant;
- in connection with the statutory authorisation, specification of the number of workplaces at which the supervising person performs systematic supervision that is considered excessive;
- regulating the entry of persons into controlled and monitored zones;
- partial adaptations to the radiation protection programme and other documentation for the licensed activity and documentation for the registered activity;
- adjustment of the job description of the person ensuring the registrant's radiation protection;
- adjustment of the regulation of personal monitoring of radiation workers and the area surrounding the workplace;
- regulation of requirements for sources of ionising radiation used in medical exposure and for workplaces with sources of ionising radiation intended for medical exposure;
- new provisions on the SÚJB notification concerning the submission of applications for authorisation of clinical trials with radiopharmaceuticals;
- new provisions on the detailed rules for regulating radiological incidents;
- clarification of certain rules concerning natural sources of ionising radiation and regarding existing exposure situations;
- the regulation of the consumption and distribution of locally produced or unprotected food in areas affected by a radiological accident, and the distribution and marketing of products situated in areas affected by a radiological accident;
- introduction of details concerning security culture for radionuclide sources;
- modifications to annexes – in particular those concerning conversion factors for recalculating activity concentration, radiological incidents, the content of documentation, and registration forms.

The draft Decree, although quite extensive in length, is rather of a non-exhaustive and legislative-technical nature, building on the experience gained in the application of this Decree in the context of the SÚJB's monitoring activities in the field of technical and organisational measures to limit the exposure of individuals and to protect the environment from the effects of ionising radiation; it does not envisage any increase in the administrative or financial burden compared with the current situation, nor any other negative impacts.

b) Assessment of compliance of the draft legislation with the Act it is to implement, including compliance with the statutory authorisation to issue the legislation

The SÚJB is authorised to issue Decree No 422/2016 under the provisions of § 236 of the Atomic Act. The amended provisions of Decree No 422/2016 are provisions that implement § 9(2)(c) and (j), § 17(3), § 24(7), § 25(2)(a) to (d), § 60(4), § 61(6), § 63(6), § 66(6), § 67(4), § 68(2)(a) to (i) and (k), § 69(2), § 70(2)(b) and (c), § 71(2), § 72(5), § 73(3), § 74(4), § 75(5)(a), § 76(6), § 77(2), § 78(3), § 81(3), § 83(7), § 85(5), § 86(3), § 87(5), § 88(6), § 89(2), § 93(5), § 95(6), § 96(3), § 98(4), § 99(5), § 100(3), § 101(4), § 104(9), § 159a(5a) and § 164(2) of the Atomic Act.

The draft legislation fully respects the legislation which it is proposed to implement and is fully consistent with the above-mentioned authorisations.

The purpose of a substantial part of the provisions of the Atomic Act, specifically Part Two, Title II, is to ensure the necessary level of protection of the population and the environment from the adverse effects of ionising radiation. Accordingly, the Atomic Act sets out requirements to establish a system of administrative, organisational, technical and other instruments for protection against ionising radiation, i.e. radiation protection. It takes into account three types of exposure situations where ionising radiation may occur – planned, where it is used or affected intentionally; emergency, resulting from accidents, and existing, resulting from the previous two or existing independently of human activity. For each of these situations, different radiation protection instruments must be chosen by the nature of the case. For example, in a planned exposure situation, dose limits can be set and their observance continuously monitored and supervised, whereas for the other two situations, it is necessary to apply less categorical regulatory instruments, as they cannot always be freely influenced.

At the same time, the Atomic Act governs the security obligations of persons handling radionuclide sources, i.e. their protection against misuse in activities involving security risks, e.g. sabotage, terrorist acts, theft, etc. As a result of these malicious acts, radionuclide sources may cause undesirable exposure of the population or the environment to ionising radiation, which must be prevented by a set of regulatory instruments that are characteristically different from the radiation protection system. These security instruments are by their nature akin to security systems, control of access to hazardous or valuable material and prevention of misuse of this material or remedy of such misuse.

The proposed Decree reflects these fundamental premises of the statutory regulation and follows the above-mentioned principles, which were further strengthened and streamlined by Act No 83/2025. It lays down detailed requirements for individual exposure situations and for the methods and aspects of the use of, and protection from, ionising radiation, e.g. requirement for the equipment of workplaces and sources of ionising radiation or for testing sources, as well as the parameters and starting points used to apply the obligations set out by the Atomic Act (e.g. dose limits, categorisation of sources of ionising radiation and workplaces using them, or categorisation of radiation workers). In the field of security, it lays down details of the elements of the security system for radionuclide sources so as to prevent the misuse of, or damage to, radionuclide sources by unauthorised personnel. This system is further strengthened by the concept of ‘security culture’. The Decree thus constitutes a

necessary complement to the provisions of the Atomic Act, because without the specific technical details laid down in the Decree many concepts of radiation protection and security established by the Act could not be applied.

The structure of the Decree respects the logic of the statutory authorisations and, given the considerable length of the text, it also makes use of references to the provisions implemented under the headings of paragraphs, groups of paragraphs or larger systematic units for easier navigation. In view of the number and nature of the changes described above, the existing Decree has not undergone a full revision; instead, only the present draft amendment to the Decree is proposed, containing all the above-mentioned modifications arising from the amendment to the Act, recommendations of international evaluations, and practical application.

The effective date of the amendment to Decree No 422/2016 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. 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 intensive work is currently already underway on the part of the addressees of the obligations under this Decree to prepare documentation and adapt their internal conditions to the amendment to the Atomic Act, which would then have to be amended again. The proposed date of entry into effect thus complies with 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).

c) Assessment of compliance of the draft legislation with European Union legislation, European Union case law and the general principles of European Union law

At the Euratom level, the framework is laid down in particular in Articles 31 and 32 (which also constitute the legal basis for Council Directive 2013/59/Euratom) and Articles 35 and 36 of the consolidated version of the Treaty establishing the European Atomic Energy Community, the consolidated version of 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, and Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. These are framework directives primarily transposed into the Czech legal order by the Atomic Act.

Proceedings No 2020/2365 were initiated against the Czech Republic in relation to Directive 2013/59/Euratom. The correctness of the Czech transposition was successfully demonstrated to the European Commission, nevertheless, this gave us an indication of which provisions the Commission considers potentially problematic. The European Commission has conducted several studies concerning national legislation in the area covered by Directive 2013/59/Euratom, such as the ‘Review of Current Off-site Nuclear

Emergency Preparedness and Response Arrangements in EU Member States and Neighbouring Countries', 'Proposal for guidelines for the transposition and implementation of the provisions of Directive 2013/59/Euratom on EP&R', 'Study on good practices in implementing the requirements on public information in the event of an emergency, under the Euratom Basic Safety Standards Directive and Nuclear Safety Directive', 'Implementation of Council Directive 2013/59/Euratom requirements for medical equipment with respect to monitoring and control of patient's radiation exposures'. These activities (questionnaires, seminars and presentations of study findings) made it possible to gain experience with the transposition of the Directive in other Euratom Member States. The above-mentioned findings and practical experience gained in the application of the Atomic Act have led to the proposed amendments to the provisions of the Atomic Act transposing Directive 2013/59/Euratom into the legal order of the Czech Republic. Examples include the new provisions of § 1(2)(d) – exclusion of cosmic radiation affecting members of the public or workers from the scope of the Atomic Act, § 2(3)(k) – addition of a definition of spacecraft, § 2(3)(c)(3) of the Atomic Act – explicit inclusion of medical exposure in the context of biomedical research within medical exposures, § 87 of the Atomic Act – inclusion of a potential radiological incident in the text of the provisions, etc.

The Czech Republic held informal discussions with the European Commission in 2020 in order to ensure the correct implementation of Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. In this case, too, all the uncertainties raised were satisfactorily explained to the European Commission. In response to questions from the Commission and based on the experience gained, the scope of application of the Atomic Act was clarified with regard to mineral water (§ 1(2)(a) of the Atomic Act) and the obligation to monitor tritium levels in drinking water was added to § 100 of the Atomic Act.

In line with the above, Decree No 422/2016, as well as the submitted amendment to this Decree, builds on the Atomic Act and implements and further specifies the requirements and obligations laid down therein. The provisions in both Decree No 422/2016 and in the submitted amendment are consistent with the Atomic Act as well as with Council Directive 2013/59/Euratom.

Furthermore, this issue is also addressed by Commission Recommendation 2000/473/Euratom on the application of Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole, and Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation.

d) Assessment of the existing provisions and justification of the need to amend them

The existing Decree No 422/2016 on radiation protection and security of radionuclide sources came into effect on 1 January 2017 and has not been amended to date. This Decree governs the details of ensuring radiation protection in exposure situations and the method of securing radionuclide sources, including radionuclide sources in security categories 1 to 3.

The main objective of the amendment to Decree No 422/2016 is to respond to the amendment to the Atomic Act, which, in the field of radiation protection, consists primarily of minor (but rather numerous) modifications to the procedures for ensuring radiation protection. This must be ensured across a wide range of activities associated with sources of ionising radiation. In particular, these include activities involving sources of ionising radiation in industrial activities, medical use (treatment and diagnostics) and mineral extraction.

The new legislation introduces changes in the areas covered by the amendment to the Atomic Act (Act No 83/2025), which are summarised under point (a) of this Explanatory Memorandum. If this Decree were not amended, a dual-track arrangement would arise between the Atomic Act and its implementing regulation, which is undesirable, inconsistent, and confusing for the addressees of obligations under the Atomic Act.

In view of the number and nature of the changes described above, the existing Decree has not undergone a full revision; instead, only the present draft amendment to the Decree is proposed, containing all the above-mentioned modifications arising from the amendment to the Act, recommendations of international evaluations, and practical application.

The draft Decree builds on experience gained by the SÚJB in applying the Decree in its monitoring activities and in the context of international expert missions (International Atomic Energy Agency's IPPAS security mission in 2021 and IRRS safety mission in 2023), and on suggestions from the addressees of obligations in radiation protection and the security of radionuclide sources, as well as from other public authorities involved in this system.

e) Expected economic and financial impacts of the proposed legislation on the state budget, other public budgets and the business environment in the Czech Republic

The draft legislation will not have an impact on the state budget or on other public budgets. Nor will the legislation have a negative economic and financial impact on economic operators, including small and medium-sized enterprises. The legislation merely refines, supplements and clarifies existing obligations and, in several places, will lead to more efficient processes and cost savings for the addressees of the individual obligations.

No new costs for public authorities are expected to arise in connection with the adoption of the submitted Decree.

f) Assessment as to whether the draft Decree constitutes state aid

The draft Decree does not constitute state aid.

g) Assessment of impact 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. The amendment to the Decree consists solely in specifying the details of the obligations already laid down in the amended Atomic Act.

h) Assessment of social impacts, including impacts on specific groups of the population, in particular socially disadvantaged persons, persons with disabilities and national minorities, impacts on the protection of children's rights and environmental impacts

The draft Decree is not expected to have any negative social impact, including impacts on specific groups of the population, in particular socially disadvantaged persons, persons with disabilities and national minorities, as the entire legislation is without relevance in this respect. Neither will the proposed legislation have negative impacts on the environment. Conversely, the streamlining of regulation in the field of radiation protection has indirect implications in terms of strengthening regulation of environmental protection, since the definition of radiation protection implies that it serves to limit the exposure of individuals and to protect the environment from the effects of ionising radiation.

i) Assessment of the current situation and impacts of the proposed policy in relation to the prohibition of discrimination and in relation to gender equality

The draft legislation does not contain any provisions that would have an impact on the issue of discrimination, nor does it envisage any impact on gender equality.

j) Assessment of the impacts of the proposed policy in relation to the protection of privacy and personal data

The draft legislation does not entail any new processing of personal data nor does it change the existing processing of personal data. It does not regulate any obligations or rights of data subjects.

k) Assessment of corruption risks

There are no corruption risks associated with the draft legislation. It contains details on the obligations laid down in the Atomic Act concerning entities involved in monitoring the radiation situation in the Czech Republic.

l) Assessment of impact on state security or defence

The draft legislation does not envisage any negative impacts on national security or defence. Conversely, the present draft Decree will contribute to strengthening the security of the State, as its aim is to streamline certain partial processes in ensuring radiation protection and, in particular, to lay down detailed provisions to ensure security culture for radionuclide sources.

m) Assessment of the impact on families, in particular with regard to the fulfilment of the functions of a family, the number of dependent members, the possible presence of disabled members, single-parent families, families with three or more children, and other specific life situations, as well as strengthening family integrity and stability, enhancing family harmony, achieving a better work-family balance, and strengthening intergenerational and wider family relationships

The draft Decree is not related to this issue and therefore will not have any impacts on families.

n) Evaluation of territorial impacts, including impacts on territorial self-governing units

The draft legislation has no territorial implications. The draft does not affect the independent or delegated competence of territorial self-governing units.

o) Assessment of the compliance of the proposed policy with the principles of digitally-friendly legislation, including an assessment of the risk of exclusion or restriction of access to certain services for specific groups of persons as a result of the digitalisation of their provision (digital exclusion)

The draft legislation is not in conflict with the principles of digitally-friendly legislation.

II. SPECIAL SECTION

Re introductory provision

A legislative-technical amendment in view of the recent amendment to the Atomic Act, which introduced certain new authorisations or modified the numbering of some sections of the Atomic Act.

§ 2(q)

The definition of conversion factors is being refined to clarify certain interpretative issues and is consistent with both national and international practice (in particular with the recommendations of the ICRP – International Commission on Radiological Protection). Conversion factors are further set out in detail in Annex 3 to the Decree.

§ 2(x)

The term ‘useless radiation’ is being deleted, as it is no longer used to the same extent following the amendment to the Decree, and this definition appears to be redundant.

§ 5(1)

In this provision, the registrant is added among the entities obliged to assess compliance with the limits for pupils and students. The obligation to comply with the dose limits under § 63 of the Atomic Act applies to both licence holders and registrants. However, they have so far been absent from this provision developing § 63 of the Atomic Act.

§ 6

The proposed modifications are related to the change in conversion factors in Annex 3 and to the newly added conversion factors for determining the radon inhalation dose in Annex 30.

§ 8(5)

The text of this provision described the requirements for the document Radiation Protection Optimisation Procedures [Postupy optimalizace radiační ochrany], which is part of the documentation for licensed activities pursuant to § 24 and Annex 1 of the Atomic Act, however, due to an error, its exact title was not included. This was an error in the original text, which is corrected by this amendment. For this reason, the reference is also made more precise, with § 8 now also referring to the provisions governing the documentation for the licensed activity – § 24(7).

§ 10

This provision clarifies a requirement that had given rise to interpretative ambiguities. It is now clarified that the activity exemption levels refer to the total amount of radioactive substances handled in an activity involving radiation.

§ 15

This provision adjusts the categorisation of sources affected by the changes to licensed and registered activities under the amendment to the Atomic Act to continue ensuring adequate protection under the graded approach for activities involving the sources.

§ 18

This provision clarifies a requirement that had given rise to interpretative ambiguities. For security purposes, this is to be understood as a workplace where several radionuclide sources are located simultaneously.

§ 19

This provision adjusts the categorisation of workplaces affected by the changes to licensed and registered activities under the amendment to the Atomic Act to continue ensuring adequate protection under the graded approach for activities involving the workplaces.

§ 21(2)(d)

Given the significant rise in the use of artificial intelligence tools, the SÚJB recognises the need to be informed about their use in licensed and registered activities in order to assess the potential risks associated with this technology in relation to radiation protection.

§ 26 to § 32, § 43(3)(l), § 63(e), (i)

The changes in the provisions relating to the testing of sources respond to the relevant changes introduced by the amendment to the Atomic Act. These changes are being implemented in the Decree and, due to the many changes to these provisions, entirely new sections are being inserted. The changes concerning acceptance tests, long-term stability tests and operational stability tests are further reflected and supplemented in Annexes 10 et seq. Under § 30a(1)(i), it is stipulated that the person conducting the test assesses the suitability of the source and the workplace for carrying out the test. It is therefore an expert assessment of whether the test can be carried out in full and under safe conditions. However, in practice, there have repeatedly been situations in which the operator of

the source required the test to be carried out under circumstances where it was not possible to ensure that the test was carried out in full and properly, or where doing so would pose an increased risk (for example due to the absence of structural radiation shielding elements). Therefore, the proposed amendment explicitly confirms the authority of persons carrying out the tests to assess the conditions on site and, if the necessary requirements are not met, to refuse to carry out the test until the prerequisites for the safe performance of the activity, in particular the protection of personnel carrying out the test, are ensured.

§ 30a

The amendment introduces an entirely new section which elaborates in greater detail on the activities of persons managing and performing assessments of the properties of a source of ionising radiation. This is in response to the new obligation under § 69(1)(i) of the Atomic Act to appoint persons to manage and carry out the assessment of the characteristics of the source of ionising radiation when assessing its properties through testing.

§ 33(3)

The deleted text was incorrect in the existing legislation and gave the impression that it concerned other individuals, whereas under the definition of medical exposure these persons are already covered by the phrase ‘natural persons who undergo medical or non-medical exposure in the controlled zone’.

§ 33(5)

This provision clarifies a requirement that had given rise to interpretative ambiguities and proved to be impracticable. Data on personal doses must be recorded separately – not the personal doses themselves.

§ 33(7)

In view of the large amount of data reported to the SÚJB under the relevant provisions, it is necessary to process these data automatically. To this end, it is necessary to specify the appropriate format in which the data are to be transmitted (this format may change with technological developments or data security requirements) – the SÚJB specifies the format to be used (e.g. *.csv file). It is further clarified that the data are transmitted by the relevant licence holder, who processes them and has established the appropriate procedures and methodologies for this purpose.

§ 38(3) and (4)

The existing provision did not make it clear whether this obligation applied only to the licence holder or registrant using the source, or also to the licence holder performing the test. This is now clarified by the amended text.

§ 39

A missing reference to § 25 of the Atomic Act is being corrected and, at the same time, an additional provision is being introduced to enable the monitoring of all products that are of interest or subject to regulation by the SÚJB.

§ 43(4) and (5)

These new paragraphs implement a new requirement of the Atomic Act – to set a limit on the number of licence holders and ionising radiation sources for which the supervising person performs continuous supervision. If a person were to act as a supervising person for more than the specified number of holders and sources, it would not be possible to ensure that they perform this activity properly, which could compromise radiation protection. These figures are based on the regulatory practice of the SÚJB, which considers them to be sufficiently non-restrictive while not compromising the radiation protection system at the relevant workplaces.

Paragraph (5) implements the requirement under Article 83(3) of Directive 2013/59/EURATOM – the regulation of the activities of a medical physics expert.

§ 46(7) and (8)

The existing wording caused interpretative ambiguities related to activities that need to be performed in the controlled zone by persons other than category A radiation workers and that do not constitute activities (tasks) for which the controlled zone has been established (which may be performed only by category A workers). This includes e.g. periodic inspections of electrical installations. Furthermore, the authority of an SÚJB inspector to enter, and the purpose entitling the inspector to enter the controlled zone independently, are specified in order to prevent abuse and minimise inspectors' entries into controlled zones.

§ 47 and § 49(3)(b)

The current wording of both provisions contained substantive errors, in that they presumed that these obligations applied to all persons entering the monitored or controlled zone. However, these obligations were de facto unenforceable for persons who are to undergo medical or non-medical exposure in these zones. Compliance would make it impossible to perform the task for which the persons enter the controlled zone and these persons are therefore now exempt from these requirements.

§ 48

The text of these provisions described the documentation requirements for the licensed activity consisting in the delineation of the controlled zone. However, the nomenclature is clarified so that, in accordance with the Atomic Act, it explicitly concerns documentation for the delineation of the controlled zone when carrying out a licensed activity. This was an error in the original text, which is corrected by this amendment. For this reason, the reference is also made more precise, with § 48 now also referring to the provisions governing the documentation for the licensed activity – § 24(7).

§ 50(5) and (7)

This provision has been reworded to make it clear who is responsible for fulfilling the obligation under the Atomic Act and how this obligation is to be fulfilled. In connection with this, § 50(7)(b) is also deleted.

§ 52

The documentation requirements for the licensed activity are specified in relation to the performance of servicing operations on sources and their installations. These activities have not been significantly regulated to date, although they often directly affect radiation protection during everyday use. The new provisions will give SÚJB greater control over these processes and enable it to monitor whether these operations lead to any deterioration in the safety of the sources.

§ 53(1)

These provisions are being modified to implement part of the requirement under Article 27(1)(a) of Directive 2013/59/EURATOM – this requirement is mostly implemented by § 9 and § 10 of the Atomic Act, however, it could previously occur that a licence holder was generally authorised to use sources of ionising radiation without an explicit indication of whether they could be used for medical, non-medical or veterinary exposure. Under the new arrangement, licence holders have to indicate these facts in the documentation for the licensed activity, which is binding under § 24 of the Act (it must be followed when performing the licensed activity), so that it is clear whether a given person may use the sources for these purposes within the scope of their activity or not. Annex 19 to the Decree does not specify the content of all remaining documentation for the licensed activity, but only certain selected parts.

§ 54(1)(i)

This provision introduces changes that implement the modifications to radiological incidents introduced by the amendment to the Atomic Act in § 69.

§ 54(1)(j)

This provision introduces changes that implement the modifications to diagnostic reference levels introduced by the amendment to the Atomic Act in § 69.

§ 63

It is added that this section concerns only a registered activity under § 10 of the Atomic Act for the use of a source of ionising radiation. This is because the provisions of § 10 also require registration for other activities under the Atomic Act which are not the target of these provisions.

The existing formulation of point (f) was imprecise – it assumed that the person ensuring the registrant's radiation protection is responsible for compliance with the requirements of Annex 20 to the Decree and it did not use the correct formulations; as a result, it was unclear what this person actually ensures for the registrant. The formulation now uses the title of Annex 20, thereby clarifying the relationship between these provisions.

§ 65

The provisions of § 65 are amended so that they now lay down only the content of the documentation for the registered activity for the use of a source of ionising radiation. In the registration process, all required information is provided in the registration form, which is set out in Annex 21 below. The items of the documentation referred to in § 65 therefore apply only to specific cases of the registrations listed here. In the case of paragraph (2), a distinction is made between two specific cases of use where 'special' justification is required (this is also in line with Directive 2013/59/EURATOM).

§ 66

The added content of the monitoring programme (documentation for the licensed activity) is related to the requirements laid down by metrological legislation, which assumes that, in the case of measuring instruments used in the field of ionising radiation, their classification is decided by the Office for Standards, Metrology and Testing in agreement with the State Office for Nuclear Safety. The State Office for Nuclear Safety thus has the opportunity to present its opinion on the list during the documentation assessment process.

§ 67

The proposed amendments are related to the change in conversion factors in Annex 3.

§ 68(2) and (3)

In light of practical experience, where a rigidly legislated level value meant that the actual needs and practices of a particular workplace were not reflected, paragraph (2)(a) is deleted, leaving only point (b), which ensures that all values are monitored so that trends occurring at the workplace can be evaluated, while, at the same time, the wording in paragraph (3) contains a definition on the basis of which licence holders are to decide at what value to set the investigation level – namely, so that it serves to distinguish deviations from normal operation.

§ 70(2)

The provisions under this paragraph have been supplemented in view of the amendment to § 78(1)(f) of the Atomic Act, which lays down the obligation to equip a category A radiation worker with personal dosimeters in the event of exposure to external radiation and to ensure their evaluation; and, in the case of a category A radiation worker working underground where mining or mining-like activities are carried out, also with a personal dosimeter for measuring exposure to radon decay products and from the intake of mixtures of long-lived alpha-emitting radionuclides.

§ 70(5)

This provision is being clarified in view of the practical possibilities and availability of personal dosimeters for measuring certain types of radiation.

§ 70(6)

The existing wording contained internal inconsistencies that led to ambiguity as to under what circumstances a second dosimeter should be assigned. The new wording clarifies this.

§ 73(2)(a)

The provision introduces a grammatical amendment to improve the clarity of the existing text.

§ 74

The amendments relate to the introduction of the obligation to monitor tritium content in water – an obligation introduced by the amendment to the Atomic Act in § 100(1)(a). Until now, the monitoring has mainly been carried out on the basis of water management legislation. The amendments to § 74 reflect existing practice.

§ 75 to § 78

These requirements for sources and workplaces where medical radiation exposure is administered are inherently relatively dynamic and must respond to technological developments in healthcare. Over the past 9 years, there have been significant technological advances in radiology, which have led to situations where some properties of sources of ionising radiation that were previously considered suitable for medical exposure now cause, for example, intolerable levels of patient exposure. Therefore, these requirements have been revised so that they continue to prevent effectively the operation of sources with characteristics that are now unacceptable, or that are used in inadequately equipped workplaces. Due to numerous changes, entirely new sections are being proposed.

§ 79 and Annex 22

The amendments to the Act concerning diagnostic reference levels no longer require their implementation in the Decree, therefore, the relevant provisions have been deleted from the Decree. The now-vacant § 79 is instead used to implement a new provision of the Act concerning clinical trials with radiopharmaceuticals, newly regulated in § 85(4) of the Atomic Act. The provisions of § 79 of the Decree thus lay down the content of the notification of the submission of an application for authorisation of a clinical trial with radiopharmaceuticals. This amendment replaces the existing provision in § 18 of Act No 378/2008 on pharmaceuticals and on amendments to certain related acts (the Act on Pharmaceuticals), which requires the opinion of the State Office for Nuclear Safety as part of an application for authorisation of a clinical trial under the Act on Pharmaceuticals. In light of the change in the procedure for submitting applications for authorisation of clinical trials and the introduction of a pan-European regime, a situation has arisen where the obligation to submit the SÚJB‘s opinion on the application could impede the application process and, as a result, remove the Czech Republic from the list of countries where clinical trials are conducted, thereby limiting patients’ access to state-of-the-art care. On the basis of an agreement with the State Institute for Drug Control, which authorises clinical trials, the obligation to submit the SÚJB’s opinion under the Act on Pharmaceuticals has been deleted and replaced by the sponsor’s obligation under the Atomic Act to notify the submission of the application. This notification will be accompanied by information

relevant from the point of view of radiation protection, as further specified in § 79 and Annex 22 to the Decree.

This amendment will ensure that the clinical trial authorisation procedure will not be constrained by the prior acquisition of the SÚJB's opinion, while at the same time the SÚJB will have information about the planned clinical trial and will be able to verify in advance whether the workplace where the trial will be conducted holds the relevant authorisations and meets all conditions, so that radiation protection of patients or personnel is not compromised. Notification at the time of submission of the application will also align the timing of the individual processes to prevent a situation where the State Institute for Drug Control authorises a clinical trial without all the requirements arising from nuclear legislation having been met.

§ 80, § 81 and Annex 23

Comprehensive amendments to the Act concerning radiological incidents (covered by § 87) also necessitate changes to the Decree – these provisions now reflect the new regulation in the field of radiological incidents and focus in detail on the categorisation of these incidents and on the procedure to be followed in the event of a radiological incident or a potential radiological incident, including the provision of information and record-keeping thereof. Certain provisions have been explicitly moved to the Atomic Act and are therefore deleted from the Decree; for example, § 81(1) has now been incorporated into § 87(2) of the Atomic Act.

§ 83

§ 83 introduces minor terminological changes resulting from the changes in the regulation of diagnostic reference levels in the Act and the introduction of the term 'radiological equipment' in Act No 373/2011.

§ 87

The amendment clarifies the list of workplaces with potentially increased irradiation from natural radiation sources, for example by specifying that the activity in question is mining carried out exclusively underground, where there is a hazard associated with the content of a natural radionuclide in the material.

§ 88

The amendment specifies the procedure for assessing the situation at workplaces with potentially increased exposure from natural radiation sources – i.e. workplaces handling materials with an increased content of a natural radionuclide. The changes are based on the SÚJB's monitoring practice and mainly consist in modifications to the rules for optimising and determining personal doses. These provisions are further elaborated in Annex 30 to this Decree, which sets out dose conversion factors for determining the effective dose.

§ 89

Amendment related to the renumbering of sections following the amendment to the Atomic Act and to the obligation to send the required data via the Electronic Submission Portal, which is the responsibility of the licence holder under § 9(2)(h)(2) of the Atomic Act.

§ 90

The provisions governing optimisation of radiation protection at workplaces with potentially increased exposure from natural radiation sources have been supplemented to better reflect the possibilities of optimising radiation protection at such workplaces on the basis of practical knowledge – it will always be necessary to prepare an optimisation analysis, which must contain alternative solutions and, based on this analysis, the most suitable measures to reduce exposure to natural radiation sources must be selected and applied.

§ 91

The modifications to the measurement and assessment of radionuclide content in a radioactive substance released from a workplace with potentially increased exposure from a natural radiation source provide administrative relief for obliged persons, who are no longer required to carry out measurements annually unless the conditions set out here apply; at the same time, a provision is introduced concerning the obligation to submit the required data via the Electronic Submission Portal.

§ 93 and Annex 30

This provision specifies the procedure for assessing the situation at workplaces with potentially increased exposure to radon, in particular with regard to optimisation of radiation protection at these workplaces, and refers to the new Annex 30, which sets out dose conversion factors for determining the effective dose to a worker and is terminologically consistent with other legislation, in particular mining legislation.

§ 94

A modification related to the obligation to submit the required data via the Electronic Submission Portal.

§ 95

These provisions have been revised to better reflect the possibilities for optimising radiation protection at workplaces with potentially increased exposure to radon based on practical experience from SÚJB's monitoring activities.

§ 98 and § 99

The amendments relate to the introduction of the obligation to monitor tritium content in water, as provided for by the amended Atomic Act in § 100(1)(a). Until now, the monitoring has mainly been carried out on the basis of water management legislation. The amendments lay down the rules and applicable values in accordance with the statutory authorisation. These provisions no longer apply

only to natural radionuclides in water; accordingly, terminological changes are introduced in the heading and texts of these sections.

§ 100

The modifications entail administrative relief for obliged entities, which are no longer required to report the mandatory data annually, but only in the event of a change in the data where it is genuinely necessary to inform SÚJB of such a fact. The addition of the site ID number for e-submissions [IČPE] is for the purpose of information-sharing with the Ministry of Agriculture, which maintains the register. The number is assigned in accordance with Decree No 428/2001, implementing Act No 274/2001, on water supply and sewerage systems for public use.

§ 101

An additional option for optimising radionuclide content in water is introduced – namely, by mixing water from multiple sources.

§ 102

This provision is modified with regard to the practical possibilities for the relevant determinations. The incorrectly stated thorium isotope is replaced with thorium-232.

§ 103

The modifications entail administrative relief for obliged entities, which are no longer required to report the mandatory data annually, but only in the event of a change in the data where it is genuinely necessary to inform SÚJB of such a fact.

§ 104

The existing wording has created interpretative ambiguities in the case of continuous releases of radionuclides. It was unclear over what period the average activity concentration was to be calculated. The new wording defines that, in such cases, averaging is performed over one day.

§ 105

Minor adjustments to the formulation to bring the text into line with the terminology used in mining legislation.

§ 107

The additions reflect, in particular, findings from the ‘Zóna’ exercise. The provisions specify or supplement subsequent protective measures that would need to be taken in the event of a radiological accident. These consist in prohibiting the consumption and distribution of locally produced or unprotected foodstuffs in areas affected by the radiological accident for the period necessary to establish specific conditions for their consumption and distribution in the given emergency situation, and prohibiting the distribution and marketing of products situated in areas affected by the radiological accident for the period necessary to establish specific conditions for their

distribution and marketing in the given emergency situation. This means that these are justified urgent measures in emergency exposure situations pursuant to § 104 of the Atomic Act.

§ 114a

An entirely new provision that reflects the new concept of security culture introduced by the amendment to the Atomic Act in § 159a. 'Security culture' refers to a set of characteristics, attitudes and behaviours of individuals and institutions that ensure the maintenance, promotion and strengthening of security, and, as such, it also applies to the security of radionuclide sources. In accordance with the requirements of the amended Act, more detailed requirements are added here for implementing security culture for radionuclide sources, which the relevant licence holder must ensure in the course of activities involving those sources.

Annex 2

There was a formatting error in the existing version which completely changed the mathematical meaning of the formula in the table giving the Q (quality) factors. The formula is now rendered correctly – number -2.2 is not a superscript but a value to be subtracted from the preceding part of the formula. The new formulation is in line with the ICRP's international recommendations.

Annex 3

The Annex sets out numerical values for conversion factors used to convert the activity of radionuclides received into the dose received. This extensive Annex has been completely revised due to multiple changes in various parts of the tables. However, the changes, which do not alter the fundamentals of the regulation and do not introduce anything entirely new, are based mainly on changes in the ICRP's recommendations and international best practice.

Annexes 10, 11, 12, 19(1)

The changes to the provisions concerning tests of sources respond to the relevant amendments to the Atomic Act – these amendments are being implemented in the Decree.

Annexes 13, 20, 21

Changes in registered and licensed activities in the Atomic Act lead directly to changes in the activities of registrants – operational stability tests, radiation protection arrangements, and the registration forms themselves. These changes, which have already been implemented by other amending provisions of this Decree, are also reflected in these Annexes, which are referenced in the text of the Decree. Annex 21 sets out new modernised templates for the submission of applications for registration and for confirmations thereof for all cases of registration in the field of radiation protection pursuant to § 10 of the Atomic Act. The information specified in the template is necessary for the SÚJB to be able to assess the registered activity and carry out the registration.

Annex 25

Based on the latest research and available data, several municipalities where a higher incidence of radon can be expected have been added to the table. Due to the large number of changes, an entirely new table is being inserted.

Re Article II (Final provisions)

Re Article II

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)

Re Article III

The effective date of the amendment to Decree No 422/2016 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. 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 intensive work is currently already underway on the part of the addressees of the obligations under this Decree to prepare documentation and adapt their internal conditions to the amendment to the Atomic Act, which would then have to be amended again. The proposed date of entry into effect thus complies with 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).

A deferred effective date is proposed for § 76 and 77. By definition, § 76 and § 77 contain dynamically evolving provisions because they express the minimum technical characteristics of sources of ionising radiation used for medical exposure. These represent a certain minimum standard that naturally keeps shifting with technical progress; technical development in radiology is very dynamic and some properties of sources that were standard a few years ago are now unacceptable because they lead to unjustifiably high exposures or unacceptably low image quality. Some technologies are even effectively disappearing, which gives rise to situations where their continued use would result in a significantly lower quality of medical services than when those technologies were used in the past. One example is film imaging in radiology – due to the massive development of digitalisation in radiology and the photography industry in general, film imaging has become a fringe technique. The sharp decline in demand has led to a significant deterioration in the quality of currently manufactured film, processing chemicals and processing machines. Therefore, it is no longer advisable to use this technology in radiology, as it would result in significantly poorer quality than only a few years ago.

On the other hand, the newly introduced ban on the use of some of these sources constitutes a relatively significant interference with the normal operation of health service providers. These sources cannot always be replaced quickly and easily, therefore, similarly to 2016 when the original wording of the Decree was adopted, SÚJB proposes to defer the effective date of selected provisions of § 76 and § 77. This involves introducing requirements for sources that were not previously imposed at all, or only on certain sources. At the same time, the SÚJB register of sources shows that

a significant percentage of these sources do not meet these requirements and are still in operation. Deferring the effective date will allow providers to prepare and complete the necessary tenders for the procurement of new sources. The deferred effective date is divided into two groups – from 1 January 2028 for sources that are clearly technologically obsolete, whose continued use could lead to a significant deterioration in the quality of care provided. And from 1 January 2030 for sources in which the effect is markedly less pronounced and the natural replacement cycle of medical devices can be allowed to run its course.